**Personnel Reliability Plan**

INSTRUCTIONS: This document may be used as a template to be completed and customized by students or other users to ensure that it applies to their site-specific requirements.

* **Black text** is a generic text that will likely be appropriate for inclusion. However, the student(s)/user(s) may change this text as needed.
* **Red text** is guidance text and **must** be replaced with institution-specific information.

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4. **General Management**
   1. **Purpose**

The purpose of the Personnel Reliability Plan (PRP) is to provide standards and guidelines pertaining to the personnel reliability of all (enter your organization and/or facility name here)personnel, including those with access to biological areas, hazardous biological agents and toxins, as well as other hazardous and or valuable material at (enter your organization and/or facility name here).

The PRP is one of the methods used to ensure everyone who is authorized access to sensitive materials, and everyone authorized to escort and/or supervise personnel with access to sensitive materials, including the Responsible and Certifying Official(s)/Committees, meets the highest standards of integrity, trust, and personal reliability.

The PRP provides a system for early identification of factors that could make an employee potentially vulnerable to exploitation by an external entity, compromising the employee and resulting in that individual becoming an insider threat to (enter your organization and/or facility name here).

The (enter your organization and/or facility name here) PRP recognizes the need for individual support for employees that addresses human reliability and behavioral safety, including:

* Adherence to procedures
* Communication, consultation, and feedback
* Conflict management and resolution
* Empowerment, including the authority to stop work if potentially unsafe or unsecured conditions, are identified
* Avoidance of “blame culture,” including the willingness to report accidents, incidents or unsafe working conditions/behaviors, and protection of workers who do so
* Respect for individual privacy and dignity

Determination of integrity and reliability shall be accomplished, in part, through the initial and continuing evaluation of individuals assigned duties associated with Biological Select Agent or Toxins (BSAT)/Especially Dangerous Pathogens (EDP)/Valuable Biological Materials (VBM). The continuing evaluations will ensure these individuals do not pose a risk to public health and safety or national security.

This PRP implements the rules from and integrates with the Biorisk Management (BRM), safety, security, and biosecurity policies, plans, and standard operating procedures (SOPs) of (enter your organization and/or facility name here) as applicable.

* 1. **Acronyms**

| **Terms** | **Definitions** |
| --- | --- |
| ARO | Alternate Responsible Official |
| BSO | Biological Safety Officer |
| BSAT | Biological Select Agents and Toxins |
| BRM | Biorisk Management |
| BSL | Biosafety Level |
| BSL-1 | Biosafety Level 1 |
| BSL-2 | Biosafety Level 2 |
| BSL-3 | Biosafety Level 3 |
| BSL-4 | Biosafety Level 4 |
| CDC | U.S. Centers for Disease Control and Prevention |
| CEN | Comité Europé De Normalisation |
| CWA | CEN Workshop Agreement |
| DOD | U.S. Department of Defense |
| DSM | Diagnostic and Statistical Manual of Mental Disorders |
| DTRA | U.S. Defense Threat Reduction Agency |
| GMO | Genetically Modified Organisms |
| HCR-20 | Historical Clinical Risk Management-20 |
| IBC | Institutional Biosafety Committee |
| IR-46 | Islamic Radicalization |
| ISO | International Organization for Standardization |
| MLG | Multi-level Guidelines |
| NCAVC | National Center for the Analysis of Violent Crime |
| PPE | Personal Protective Equipment |
| PRP | Personnel Reliability Program |
| PSI | Personnel Security Investigation |
| RO | Responsible Official |
| SOP | Standard Operating Procedure |
| SPJ | Structured Professional Judgment |
| TRAP-18 | Terrorist Radicalization Assessment Protocol |
| VBM | Valuable Biological Materials |
| WAVR-21 | Workplace Assessment of Violence Risk |
| WHO | World Health Organization |

* 1. **Terms and Definitions**

The following terms are important to understand and apply in the (enter your organization and/or facility name here) personnel reliability program. All (enter your organization and/or facility name here) staff members are encouraged to carefully read and contemplate how the terms below apply to create a culture of security and safety inside all laboratories and throughout (enter your organization and/or facility name here) facilities.

At the end of each definition, in parenthesis, is the location in the appendix for the guidance document for which the term and definition are derived, if applicable.

* + 1. **Access** **-** The freedom or ability to obtain and/or make use of BSAT/EDP/VBM by any individual. (3.1.1.8)
    2. **Accident -** Unintended event giving rise to harm. (3.1.1.3)
    3. **Accountability -** Accountability ensures that VBM (see definition below) are controlled and traced as intended by formally associating the specified materials with the individuals who provide oversight and are held responsible for them. (3.1.1.2)
    4. **Affective/Impromptu Violence -** This is an act of spontaneous violence often sparked by situational or contextual triggers. (3.1.1.10)
    5. **Alcohol Abuse -** The use of alcohol to the extent that it has an adverse effect on the user’s health, behavior, family, community, or leads to unacceptable behavior as evidenced by one or more acts of alcohol-related misconduct and/or the illegal use of alcohol. Alcohol abuse may include a diagnosis of alcohol dependence. (3.1.1.8)
    6. **Alcohol Dependence and/or Alcoholism -** Psychological and/or physiological reliance on alcohol; alcoholism is defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association, the most current version. (3.1.1.8)
    7. **Alcohol-related Incident -** Any substandard behavior or performance in which alcohol consumption by the individual is a contributing factor as determined by law enforcement with consultation from the Competent Medical Authority (e.g., intoxicated driving, domestic disturbances, assault, disorderly conduct, personal injury, failure to submit to testing, or voluntary consumption of alcohol by an individual previously diagnosed as alcohol dependent, underage drinking). (3.1.1.8)
    8. **Alternate Responsible Official (ARO) -** The person with authority and responsibility to ensure requirements are met in the absence of the responsible office. (3.1.1.8)
    9. **Audit** **-** Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. (3.1.1.1)
       1. Note 1 to entry: An audit can be an internal audit (first-party) or an external audit (a second- or third-party) and a combined audit (combining two or more disciplines). (3.1.1.1)
       2. Note 2 to entry: An internal audit is conducted by the organization’s employees or by an external party on the organization’s behalf. (3.1.1.1)
       3. Note 3 to entry: “Audit evidence” and “audit criteria” are defined in International Organization for Standardization (ISO) 19011:2018. (3.1.1.1)
    10. **Bioethics -** The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications in genetic engineering and drug research. (3.1.1.2)
    11. **Biohazard -** Potential source of harm caused by biological materials. (3.1.1.1)
    12. **Biological Agent -** Any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replicating or transferring genetic material that may be able to provoke infection, allergy, toxicity, or other adverse effects in humans, animals, or plants. (3.1.1.1)
        1. Examples include bacteria, fungi, viruses, viroids, and endo and ectoparasites. (3.1.1.1)
        2. Note 1 to entry: The definition of biological agents covers commonly used terms, such as pathogens, quarantine microorganisms, microorganisms of dual-use potential. (3.1.1.1)
        3. Note 2 to entry: For the purpose of this ISO 35001, prions are regarded as biological agents. (3.1.1.1)
        4. Note 3 to entry: The term “engineered” includes biological agents that are synthetically derived. (3.1.1.1)
    13. **Biological Materials -** Any material comprised of, containing, or that may contain biological agents and/or their harmful products, such as toxins and allergens. (3.1.1.1)
        1. Note 1 to entry: Biological materials may be blood, secretions, or tissues of human or animal origin. Other biological materials include organic debris material from nature, culture, or preservation media, and/or cell cultures from human, animal, and plants. (3.1.1.1)
        2. Note 2 to entry: Animals and plants or parts thereof handled in relevant laboratories containing biological agents or toxins or biological agent vectors, such as arthropods, nematodes, and mites, are considered biological materials. (3.1.1.1)
    14. **Biological Restricted Area -** An area where access to BSAT/EDP/VBM 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 degrees of access to BSAT/EDP/VBM or other relevant matter contained in the area. (3.1.1.8)
    15. **Biological Select Agents and Toxins (BSAT)** **-** Biological agents and toxins that present a high bioterrorism risk to national security and have the greatest potential for an adverse public health impact with mass casualties of humans and/or animals or that pose a severe threat to plant health or to plant products. (3.1.1.8)
    16. **Biorisk -** Effect of uncertainty expressed by the combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” (as defined in ISO Guide 73) of occurrence, where biological material is the source of harm. (3.1.1.1)
        1. Note 1 to entry: The harm can result from unintentional exposure, accidental release, or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release. (3.1.1.1)
    17. **Biorisk Assessment -** The process to identify acceptable and unacceptable risks [embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion, or intentional release)] and their potential consequences. (3.1.1.2)
    18. **Biorisk Control -** Actions to implement BRM decisions. (3.1.1.3)
        1. Note 1 to entry: Biorisk control may involve monitoring, re-evaluation, and compliance with decisions. (3.1.1.3)
    19. **Biorisk Management (BRM) -** Coordinated activities to direct and control an organization with regard to biorisk. (3.1.1.1)
    20. **Biorisk Management Advisor -** An individual who has expertise in the biohazards encountered in the organization and is competent to advise top management and staff on biorisk management issues. (3.1.1.3)
        1. Note 1 to entry: The role of a biorisk management advisor may be differently named depending on national guidelines and institutional traditions (e.g., biosafety officer, biosecurity officer, biorisk manager, or biorisk management officer). (3.1.1.3)
    21. **Biorisk Management Committee** **-** Institutional committee of individuals competent in biorisk control and other representatives as appropriate. (3.1.1.3)
    22. **Biorisk Management System -** Management system or part of a management system used to establish BRM policies, objectives, and processes to achieve those objectives. (3.1.1.1)
        1. Note 1 to entry: A BRM system addresses the control of biorisk(s). (3.1.1.1)
    23. **Biosafety -** Practices and controls that reduce the risk of unintentional exposure or release of biological materials. (3.1.1.1)
    24. **Biosafety Level (BSL) -** Specific combinations of work practices, safety equipment, and facilities designed to minimize the exposure of workers and the environment to infectious agents. There are four BSLs. (3.1.1.8)
        1. **BSL Level 1 (BSL-1) -** Practices, safety equipment, and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories and for other laboratories. Work is done with defined and characterized strains of viable microorganisms *not known to consistently cause diseases in healthy adult humans.* (3.1.1.8)
        2. **BSL Level 2 (BSL-2) -** Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories. Work is done with the broad spectrum of indigenous *moderate-risk agents that are present in the community and associated with human diseases of varying severity.* (3.1.1.8)
        3. **BSL Level 3 (BSL-3) -** Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities. Work is done with *indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.* (3.1.1.8)
        4. **BSL Level 4 (BSL-4)** **-** Practices, safety equipment, and facility design and construction are applicable for work with *dangerous and exotic agents that pose a high individual risk of life-threatening disease*, which *may be transmitted via the aerosol route and for which there is no available vaccine or therapy.* (3.1.1.8)
    25. **Biosecurity -** Practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials. (3.1.1.1)
        1. Note 1 to entry: In the context of ISO 35001, biosecurity does not include all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of non-indigenous species and pathogens. (3.1.1.1)
    26. **Calibration -** Correlation of the performance of equipment (e.g., readings of an instrument) to a standard. (3.1.1.3)
    27. **Certification -** Systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance. (3.1.1.3)
    28. **Certifying Official(s)/Committee** **-** The person (or committee of people) in an organization responsible for certifying personnel for access to BSAT/EDP/VBM and Biological Restricted Areas. (3.1.1.8)
    29. **Code of Conduct, Code of Ethics, Code of Practice -** Non-legislated guidelines that one or more organizations and individuals voluntarily agree to abide by or set out the standard of conduct or behavior with respect to a particular activity. (3.1.1.2)
    30. **Community -** People outside the workplace are potentially affected by the activities of the facility. (3.1.1.3)
    31. **Competence** - Ability to apply knowledge and skills to achieve intended results. (3.1.1.3)
    32. **Concerning behaviors** **-** Any behavior that suggests the person may intend to commit violence or other harmful behavior. (3.1.1.9)
    33. **Conformity** **-** Fulfilment of a requirement. (3.1.1.1)
    34. **Containment -** System for confining microorganisms or organisms or other entities within a defined space. (3.1.1.3)
    35. **Continuing Evaluation -** The Certifying Official’s/Certifying Committee’s ongoing process by which PRP-certified individuals are observed for compliance with reliability standards and consider duty performance, physical and psychological fitness, and on- and off-duty behavior and reliability on a continuing basis. (3.1.1.8)
    36. **Continual Improvement -** Recurring activity to enhance performance. (3.1.1.1)
    37. **Control -** Control is the combination of engineered and procedural measures that ensure VBM (see definition below) is only used as intended. (3.1.1.2)
    38. **Corrective Action** **-** Action to eliminate the cause of nonconformity and to prevent a recurrence. (3.1.1.1)
    39. **Decontamination** **-** Procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects. (3.1.1.1)
    40. **Disinfection -** Process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms. (3.1.1.3)
    41. **Disqualification -** Any action that is taken based on the receipt of disqualifying information to terminate the BPRP certification of an individual in training or being considered for assignment to duties involving access to BSAT/EDP/VBM. (3.1.1.8)
    42. **Documented Information -** Information required to be controlled and maintained by an organization and the medium on which it is contained. (3.1.1.1)
        1. Note 1 to entry: Documented information can be in any format and media and from any source. (3.1.1.1)
        2. Note 2 to entry: Documented information can refer to:
           1. Information on the BRM system, including related processes. (3.1.1.1)
           2. Information that is created in order for the organization to operate (documentation). (3.1.1.1)
           3. Evidence of results achieved (records). (3.1.1.1)
    43. **Drug/Substance Abuse -** The wrongful use, possession, distribution, or introduction of a controlled substance, prescription medication, over-the-counter medication, or intoxicating substance (other than alcohol) onto the organization. For the purpose of this Instruction, wrongful is defined as without legal justification or excuse and includes use contrary to the directions of the manufacturer or prescribing healthcare provider and use of any intoxicating substance not intended for human ingestion. (3.1.1.8)
    44. **Drug/Substance Dependence -** Psychological and/or physiological reliance on a chemical or pharmacological agent as such reliance is defined by the DSM of the American Psychiatric Association, most current version. The term does not include the continuing prescribed use of pharmaceuticals as part of the medical management of a chronic disease or medical condition. (3.1.1.1)
    45. **Dual-Use** **-** Initially used to refer to certain materials, information, and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer to military and civilian purposes and to harmful misuse and peaceful activities. (3.1.1.2)
    46. **Effectiveness -** Extent to which planned activities are realized and planned results achieved. (3.1.1.1)
    47. **Environment -** Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships. (3.1.1.1)
        1. Note 1 to entry: Surroundings can extend from within an organization to the local, regional, and global system. (3.1.1.1)
        2. Note 2 to entry: Surroundings can be described in terms of biodiversity, ecosystems, climate, or other characteristics. (3.1.1.1)
    48. **Especially Dangerous Pathogen -** Those pathogens on the United States Select Agents List or 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. (3.1.1.1)
    49. **Event -** Occurrence of a particular set of circumstances. (3.1.1.3)
    50. **Facility -** Operational unit and associated buildings and equipment used to manage biological materials. (3.1.1.1)
        1. Note 1 to entry: This includes the laboratory, and the supporting infrastructure, equipment, and services, including ancillary rooms, such as airlocks, changing rooms, sterilizing rooms, and storage rooms. (3.1.1.1)
        2. Note 2 to entry: This document applies to other facility types that fall outside the laboratory definition (e.g., vivaria, aquaria, and greenhouses) but engage in relevant activities. (3.1.1.1)
    51. **Genetically Modified Organisms (GMO) -** Organisms whose genetic material has been altered using techniques generally known as "recombinant DNA technology." Recombinant DNA technology is the ability to combine DNA molecules from different sources into one molecule in a test tube. GMOs are often not reproducible in nature, and the term generally does not cover organisms whose genetic composition has been altered by conventional cross-breeding or by "mutagenesis" breeding, as these methods predate the discovery (1973) of recombinant DNA techniques. (3.1.1.2)
    52. **Good Microbiological Techniques -** Working methods applied to eliminate or minimize exposure to biological agents via aerosols, splashes, and accidental inoculation. (3.1.1.3)
    53. **Harm -** Adverse effect on the health of people, animals, or plants, the environment, or property. (3.1.1.1)
    54. **Hazard -** Source or situation with a potential for causing harm. (3.1.1.1)
    55. **Hazard Identification -** Process of recognizing that a hazard exists and defining its characteristics. (3.1.1.3)
    56. **Incident -** Occurrence arising out of, or in the course of, work that could or does result in harm. (3.1.1.1)
        1. Note 1 to entry: An incident where harm occurs is referred to by some as an “accident.”. (3.1.1.1)
        2. Note 2 to entry: Although there can be one or more nonconformities related to an incident, an incident can also occur where there is no nonconformity. (3.1.1.1)
    57. **Information Security -** Preservation of confidentiality, integrity, and availability of information. (3.1.1.1)
        1. Note 1 to entry: Information security also includes preserving authenticity, accountability, non-repudiation, and reliability where necessary. (3.1.1.1)
        2. Note 2 to entry: The purpose of information security is the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction (3.1.1.1)
    58. **Insider Threat -** An individual or group with authorized access to BSAT/EDP/VBM as part of their job who has the potential to misuse BSAT/EDP/VBM. (3.1.1.6)
    59. **Inspection -** Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing, or gauging. (3.1.1.1)
    60. **Institutional Biosafety Committee (IBC) -** A committee that meets the requirements for membership specified in Section IV-B-2 of the “*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),*” **and** that reviews, approves, and overseas projects in accordance with the responsibilities defined in IV-B-2 of the “*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).”* An IBC’s responsibilities need not be restricted to recombinant or synthetic nucleic acid molecule research. (3.1.1.5)
    61. **Interested Party Stakeholder -** Person or organization that can affect, be affected by, or perceive themselves as affected by a decision or activity. (3.1.1.1)
    62. **Inventory -** Itemized record of stored supplies of biological agents or VBMs. (3.1.1.3)
    63. **Laboratory** **-** Room or clearly defined area within a facility designated for work on biological materials. (3.1.1.1)
    64. **Management system -** Set of interrelated or interacting elements of an organization to establish policies, objectives, and processes to achieve those objectives. (3.1.1.1)
        1. Note 1 to entry: A management system can address a single discipline or several disciplines. (3.1.1.1)
        2. Note 2 to entry: The system elements include the organization’s structure, roles, responsibilities, planning, and operation. (3.1.1.1)
        3. Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations. (3.1.1.1)
    65. **Measurement** **-** Process to determine a value. (3.1.1.1)
    66. **Microorganism -** Microbiological entity, cellular or non-cellular, capable of replicating or transferring genetic material including viruses, viroids, animal and plant cells in culture. (3.1.1.3)
    67. **Misuse -** The misuse of VBM (see definition below) describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties, and conventions. (3.1.1.2)
    68. **Monitoring** **-** Determining the status of a system, a process, or an activity. (3.1.1.1)
        1. Note 1 to entry: Determining the status may require a need to check, supervise, or critically observe. (3.1.1.1)
        2. Note 2 to entry: Examples of monitoring processes include checking, supervising, and critically observing. (3.1.1.1)
    69. **Nonconformity -** Non-fulfilment of a requirement. (3.1.1.1)
    70. **Objective -** Result to be achieved. (3.1.1.1)
        1. Note 1 to entry: An objective can be strategic, tactical, or operational. (3.1.1.1)
        2. Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and apply at different levels (e.g., strategic, organization-wide, project, product, and process). (3.1.1.1)
        3. Note 3 to entry: An objective can be expressed in other ways (e.g., as an intended outcome, a purpose, an operational criterion), or by the use of different words with similar meaning (e.g., aim, goal, or target). (3.1.1.1)
        4. Note 4 to entry: In the context of BRM systems, objectives are set by the organization, consistent with the organization’s policy, to achieve specific results. (3.1.1.1)
    71. **Organization -** A person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives. (3.1.1.1)
    72. **Outsource** (verb) **-** An arrangement where an external organization performs part of an organization's function or process. (3.1.1.1)
        1. Note 1 to entry: An external organization is outside the management system’s scope, although the outsourced function or process is within scope. (3.1.1.1)
    73. **Permanent Decertification -** Determination by Certifying Official(s)/Committee that an individual is no longer capable of meeting the PRP’s personal reliability standards. (3.1.1.8)
    74. **Personal Protective Equipment (PPE) -** Material used to prevent exposure to or contamination of a person by biological materials. (3.1.1.1)
        1. Examples include gowns, coats, gloves, respirators, and safety glasses. (3.1.1.1)
    75. **Personnel Reliability Program (PRP)** **-** Also referred to as a “*Suitability Assessment Program,*” is a program designed to reduce the risk of an insider threat (3.1.1.6) and to ensure everyone who is authorized access to sensitive materials, or everyone authorized to escort and/or supervise personnel with access to sensitive materials, meet the highest standards of integrity, trust, and personal reliability. (3.1.1.7)
    76. **Potentially Disqualifying Information -** Any information that cast doubt about an individual’s ability or reliability to perform their duties. This information may include, but is not limited to, an individual’s physical, mental, emotional status, conduct, or character, on- and off-duty. (3.1.1.8)
    77. **Procedure -** Specified way to carry out an activity or a process. (3.1.1.3)
    78. **Physical security -** Combination of physical measures to reduce the risk of unauthorized access, safeguard assets and people, and protect from a potential security incident. (3.1.1.1)
        1. Note 1 to entry: The term **asset** in this context refers to items or information of value, including biological materials, equipment, laboratory, facility, resources, and undocumented and documented information. (3.1.1.1)
        2. Note 2 to entry: Security incident includes but is not limited to the damage, loss, and theft of biological materials, equipment, or information. (3.1.1.1)
    79. **Policy -** Intentions and direction of an organization as formally expressed by its top management. (3.1.1.1)
    80. **Process -** Measurable result. (3.1.1.1)
        1. Note 1 to entry: Performance can relate either to quantitative or qualitative findings. (3.1.1.1)
        2. Note 2 to entry: Performance can relate to the management of activities, processes, products (including services), systems, or organizations. (3.1.1.1)
    81. **Record -** Document stating results achieved or providing evidence of activities performed. (3.1.1.3)
    82. **Reliability -** Property of consistent intended behavior and results. (3.1.1.1)
    83. **Requirement -** Need or expectation that is stated, generally implied, or obligatory. (3.1.1.1)
    84. **Responsible Official (RO) -** An individual who has authority and responsibility to ensure requirements are met. (3.1.1.8)
    85. **Restricted Person -** A person restricted from access to BSAT, EDP, or VBM for one or more disqualifying factors as defined by the organization’s PRP. (3.1.1.8)
    86. **Risk -** Effect of uncertainty. (3.1.1.1)
        1. Note 1 to entry: An effect is a deviation from the expected — positive or negative. (3.1.1.1)
        2. Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (3.1.1.1)
        3. Note 3 to entry: Risk is often characterized by reference to potential “events” (as defined in ISO Guide 73) and “consequences” (as defined in ISO Guide 73), or a combination of these. (3.1.1.1)
        4. Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” (as defined in ISO Guide 73) of occurrence. (3.1.1.1)
    87. **Risk Assessment -** Process of evaluating the risk(s) arising from a hazard(s), considering the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable. (3.1.1.3)
    88. **Safety -** Freedom from unacceptable risk. (3.1.1.3)
    89. **Standard Operating Procedure (SOP) -** Set of written instructions that document a routine or repetitive activity followed by an organization. (3.1.1.3)
    90. **Source -** Anitem or activity having a potential for a consequence. (3.1.1.3)
    91. **Suspension -** To immediately remove an individual from duties requiring PRP certification due to unfavorable personal reliability information or situations causing a need for additional investigation without starting a decertification action. When suspended, an individual is still considered reliable under the PRP but is not authorized to perform duties requiring PRP certification. (3.1.1.8)
    92. **Targeted Violence -** Violent incidents involving an identifiable subject (perpetrator) who possesses the intent to cause harm to an identifiable target. (3.1.1.10)
    93. **Temporary Decertification -** Anaction taken by the Certifying Official(s)/Committee to remove an individual from duties requiring PRP certification temporarily. Temporary decertification shall occur immediately upon receipt of information that is, or appears to be, a reason for decertification from the PRP. (3.1.1.8)
    94. **Threat -** Potential cause of an incident, which may harm individuals, assets, systems, organizations, or the environment. (3.1.1.1)
        1. Note 1 to entry: In the context of biosecurity, the term threat refers to an individual or group of people who have the motive, means, and opportunity to cause harm intentionally. (3.1.1.1)
        2. Note 2 to entry: in the context of workplace violence, the term threat is used to refer to any verbal or physical conduct that conveys an intent or is reasonably perceived to convey an intent to cause physical harm or to place someone in fear of physical harm. (3.1.1.4)
    95. **Threat Assessment -** A fact-based method of assessment/investigation that focuses on an individual's patterns of thinking and behavior to determine whether, and to what extent, he or she is moving toward an attack on an identifiable target (3.1.1.4)
        1. Note 1 to entry: In the context of workplace violence prevention, “Threat Assessment” is a systematic, fact-based method of investigation and examination that blends the collection and analysis of multiple sources of information with published research and practitioner experience, focusing on an individual’s pattern of thinking and behavior to determine whether, and to what extent, a person of concern is moving toward and attack. (3.1.1.9)
    96. **Threat Management -** Managing a subject’s behavior through interventions and strategies designed to disrupt or prevent an act of targeted violence. (3.1.1.9)
    97. **Transfer of VBM -** Legal and/or administrative policies and procedures relating to the oversight and approval process for the transfer of custody and/or ownership of VBM (see definition below) between countries, entities (e.g., organizations, institutions, facilities), or individuals. (3.1.1.2)
    98. **Transport of VBM -** Procedures and practices to correctly categorize, package, document, and safely and securely transport VBM (see definition below) from one place to another, following applicable national and/or international regulations. (3.1.1.2)
    99. **Top Management -** Person or group of people who directs and controls an organization at the highest level. (3.1.1.1)
        1. Note 1 to entry: Top management can delegate authority and provide resources within the organization. (3.1.1.1)
        2. Note 2 to entry: If the scope of the BRM system covers only part of an organization, then top management refers to those who direct and control that part of the organization. (3.1.1.1)
    100. **Toxin -** Substance produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. (3.1.1.1)
         1. Note 1 to entry: This definition includes substances and materials, natural or as a result of biotechnology, that may contain toxins (see also biohazard), any poisonous substance, or any poisonous isomer, homologue, or derivative of such a substance. (3.1.1.1)
    101. **Typology of Workplace Violence Type 1 -** Violent acts by criminals who have no other connection with the workplace but enter to commit robbery or another crime. (3.1.1.11)
    102. **Typology of Workplace Violence Type 2 -** Violence directed at employees by customers, clients, patients, students, inmates, or others for whom an organization provides services. (3.1.1.11)
    103. **Typology of Workplace Violence Type 3 -** Violence against coworkers, supervisors, or managers by a present or former employee. (3.1.1.11)
    104. **Typology of Workplace Violence Type 4 -** Violence committed in the workplace by someone who doesn't work there but has a personal relationship with an employee—an abusive spouse or domestic partner. (3.1.1.11)
    105. **Validation -** Establishment of the performance characteristics of a method and provision of objective evidence that the performance requirements for a specified intended use are fulfilled. (3.1.1.1)
    106. **Valuable Biological Materials (VBM) -** 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, GMOs, cell components, genetic elements, and extraterrestrial samples. (3.1.1.2)
    107. **Verification -** Demonstration that a validated method functions in the user’s hands according to the method’s specifications determined in the validation study and is fit for purpose. (3.1.1.1)
         1. Note 1 to entry: Verification can also be applied to non-validated standardized reference methods (ISO 16140-1:2016, 2.59). (3.1.1.1)
    108. **Violence risk assessment -** A continuous investigative and analytical process of evaluating an individual’s probability of committing an act of violence based on personal and situational variables by an individual qualified (through training, experience, or education) to make risk determinations and recommendations for the response, management, and mitigation of that risk. (3.1.1.4)
    109. **Vulnerability assessment -** An evaluation (assessment) to determine the vulnerability of an installation, unit, exercise, port, ship, residence, facility, or another site to attack from the full range of threats to the security of personnel and resources. Identifies areas of improvement to withstand, mitigate, or deter acts of violence or terrorism. (3.1.1.8)
    110. **Worker -** Person performing work or work-related activities under the control of the organization. (3.1.1.1)

**Workplace -** Any physical location in which work-related activities are performed under the control of the organization (3.1.1.3)

* 1. **Roles and Responsibilities**
     1. **All personnel at (enter your organization and/or facility name here):**
        1. It is the responsibility of all facility personnel to ensure that BSAT/EDP and VBM are protected from theft, loss, or release.
        2. All personnel working in areas containing sensitive materials or information will be aware of this plan and understand that their actions contribute to the safeguarding of BSAT/EDP and VBM.
        3. Personnel are required to wear all appropriate PPE.
        4. Personnel are required to understand all safety requirements related to BSAT/EDP and/or VBM found in the laboratories in which they use or enter.
        5. Personnel are required to attend biological safety and security training designated for entry to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, and specific training for their laboratory, as applicable.
        6. Personnel who may be involved in escorting visitors and guests around BSAT/EDP and VBM use and storage areas will attend training on the escorts’ duties and responsibilities, which covers security and safety requirements.
        7. Personnel at (enter your organization and/or facility name here) are expected to notify management, RO, and any other designated personnel of any events or incidents that impact the policy defined in this plan.
        8. It is the responsibility of all members of (enter your organization and/or facility name here) to report intimidating, threatening, or concerning behavior.
     2. **Top Management, Supervisors, Laboratory Managers, Biorisk Management Advisor, Biosafety Officer, Biosecurity Officer, Biorisk Manager, Biorisk Management Officer:**
        1. Supervisors and Laboratory Managers are responsible for ensuring staff can identify intruders and control access to all personnel using or entering the applicable suites. They will keep training records and ensure that their staff members have sufficient time to attend required escort duty training. They will make requests through the Director for guests and visitors and ensure the Biorisk Management Advisor has the approved list of visitor and guest names for the required security and safety training.
        2. The Biorisk Management Advisor, if different than the Biological Safety Officer (BSO), shall coordinate with the BSO to maintain a daily list of visitors, clearance for biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas. The Biorisk Management Advisor will provide this daily list to the security team at (enter your organization and/or facility name here) and coordinate all access permissions for employees with approval from the Director of (enter your organization and/or facility name here) and BSO.
        3. It is the responsibility of the Certifying Official(s)/Committee, RO(s), Biorisk Management Advisor, Biorisk Manager, Biorisk Management Officer, BSO, and Biosecurity Officer to ensure personnel requiring access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas have completed all the procedures and have complied with all the requirements described in this plan and all other associated documents.
        4. The Certifying Official(s)/Committee is responsible for implementing, administering, and managing the PRP and supporting the RO(s), Biorisk Management Advisor, Biorisk Manager, Biorisk Management Officer, BSO, and Biosecurity Officer.
        5. The Biorisk Management Advisor will monitor the biological restricted areas, BSL-2, BSL-3, and BSL-4 containment area training and orientation program. The Biorisk Management Advisor (or that personnel the Biorisk Management Advisor delegates responsibility) will oversee the guest and visitor tours into containment during general biological restricted areas, BSL-2, BSL-3, and BSL-4 containment area operations. The Biorisk Management Advisor or other designated qualified individual will escort visitors and guests into the biological restricted areas, BSL-2, BSL-3, and BSL-4 containment laboratories.
        6. The requirements set forth in this PRP will be observed and enforced by the management of (enter your organization and/or facility name here) including the Director, Deputy Director, Biorisk Management Advisor, Heads of Departments, and staff with supervisory responsibilities over other members of staff, and the biological safety staff.
        7. Senior management (Director, Deputy Director, Heads of Department, Biorisk Management Advisor) and the BSO/Assistant BSO will work together to ensure that all staff members and visitors receive appropriate training about the risks and hazards in the workplace and that all individuals are provided appropriate PPE to mitigate these risks.
        8. Senior management (Director, Deputy Director, Heads of Department, Biorisk Management Advisor) and the BSO/Assistant BSO shall work together to create all applicable SOPs from this PRP.
     3. (**Enter your organization’s highest authority position such as Director/President/Chancellor**), (**enter your organization and/or facility name here**):
        1. Serve as Director, Safety
        2. Serve as Director, Biological Safety
        3. Serve as Director, Security
        4. Serve as Director, (Insert role as needed)
        5. Possesses primary responsibility to ensure all staff gain and maintain compliance with (**enter your organization and/or facility name here**) security and biological security processes and requirements.
        6. Ensures that sufficient resources are allocated to support activities within biological restricted areas, BSL-2, BSL-3, and BSL-4 containment laboratories.
        7. Approve qualified individuals, visitors, and guests for entry to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment laboratories.
        8. Establish the minimum-security standards for safeguarding BSAT/EDP and VBM.
        9. Establish a PRP for individuals with access to BSAT/EDP and VBM.
        10. Ensures that personal reliability measures are determined based upon a risk assessment process.
        11. Establish and maintain a secure database and inventory of all BSAT/EDP and VBM for certified activities at (**enter your organization and/or facility name here**).
        12. Ensures that personnel reliability measures for (**enter your organization and/or facility name here**) are based on local and national areas of concern for the types of agents and type of work being conducted at (**enter your organization and/or facility name here**).
        13. Ensure that the ROs and Alternate ROs are designated to fulfill program requirements, as well as other necessary and designated personnel.
        14. Ensure compliance with this PRP to include planning and programming fiscal and personnel resources necessary to implement the plan.
        15. Possesses primary responsibility to ensure that adequate resources are provided for the maintenance and continuous improvement of Biological Safety and Security at (**enter your organization and/or facility name here**).
        16. Possesses primary responsibility to ensure that facilities at (**enter your organization and/or facility name here)** are designed, constructed, maintained, and decommissioned, considering security, biological safety, and biological security requirements.
        17. Ensures that all policies, plans, manuals, and SOPs necessary to fulfill this document’s requirements are created, communicated, implemented, and enforced.
        18. Ensures that all personnel reliability measures taken are lawful and ethical.

1. **Personnel Reliability Program**
   1. **Requirements**
      1. The following requirements apply to all personnel.
      2. Individuals identified by the Certifying Official(s)/Committee as having a legitimate need to access biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM shall be screened for suitability and reliability. They shall be emotionally and mentally stable and trustworthy, physically competent, and adequately trained to perform the assigned duties. They shall complete a current and favorable personnel security investigation, with periodic reinvestigations according to regulations. Personnel will pass a urinalysis test for illegal drug/substance use before certification for access to BSAT/EDP and/or VBM. They will also be subject to random urinalysis tests.
      3. Certifying Official(s)/Committees will ensure personnel have had a final adjudication of appropriate security clearances and personnel security investigations before any access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM, regardless if personnel are supervised and/or escorted.
      4. When the Certifying Official(s)/Committee has information that could negatively affect an individual’s job performance or reliability, the individual shall be decertified. Temporary decertification can be considered unless facts warrant permanent decertification. When temporarily decertified, the individual may not perform duties requiring PRP certification. Within 15 workdays of the temporary decertification, the Certifying Official(s)/Committee shall provide the individual in writing the reason(s) for temporary decertification. Individuals temporarily decertified will remain under continuous evaluation for PRP purposes until permanently decertified or recertified into the PRP.
      5. Certifying Official(s)/Committee can take suspension action on an individual should negative information become known; however, additional review and/or investigation is warranted before final adjudication. Although a recommendation to suspend an individual from applicable duties may come from many sources, the Certifying Official(s)/Committee must evaluate the individual’s situation and circumstances to determine whether the suspension is appropriate.
      6. The Biorisk Management Advisor, Biorisk Manager, Biorisk Management Officer, BSO, Biosecurity Officer, ROs, Alternate ROs, and all senior management at (**enter your organization and/or facility name here)** must meet the requirements of the PRP certification.
      7. Individuals with duties requiring PRP certification shall be evaluated on a continuing basis using this plan’s criteria.
      8. Personnel currently employed in positions requiring PRP certification shall submit the required documents within 60 days of the effective date of this plan if not already accomplished. ROs can approve that personnel remain in their current positions during the certification process unless negative information affecting their certification status is known.
      9. After the effective date of this plan, personnel who require access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and VBM under the requirements of the PRP shall not assume duties until successful adjudication of the appropriate background investigation and approval is received. However, if a RO determines that a person’s expertise is critical to the performance of an official mission at **(enter your organization and/or facility name here)**, a waiver may be requested, in writing, from the Director **(enter your organization and/or facility name here).**
      10. Individuals certified and enrolled in the PRP at **(enter your organization and/or facility name here)** must be periodically recertified every **(enter the period here. [e.g., one year, two years, three years])**
      11. Right of Appeal. Any personnel or member of staff that has been decertified has the right to appeal to the management of the organization. The person must be provided with the reasons for their decertification so that they may properly appeal their decertification. See section 2.7 for the detailed appeals process.
   2. **General Reliability Standards**
      1. The area the RO shall have the final ruling for determining an individual’s eligibility for access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, including BSAT/EDP and/or VBM. He or she shall consider all established policies, procedures, and relevant facts to make the final judgment before signing and submitting the certification statement to obtain approval for an individual to access those areas.
      2. The Certifying Official(s)/Committee shall certify an individual’s eligibility for access to BSAT/EDP and/or VBM based on factors including a favorable personnel security investigation, an evaluation of the individual’s physical and mental capability, appropriate personnel, and medical records, and a personal interview. The eligible individual will sign an agreement affirming his or her responsibility to abide by the requirements for maintaining PRP certification. Once a determination regarding an individual’s certification for access to BSAT/EDP or VBM is made, the Certifying Official(s)/Committee grant them unescorted access to the requested specified restricted area(s) and notify (**enter your organization and/or facility name here)** security of the approval for access. The Biorisk Management Advisor will add the individual to a “Restricted Access Authorization List,” documenting the position, identifiers, date of authorization, and biological restricted areas, BSL-2, BSL-3, and BSL-4 containment area(s) they are approved to access.
      3. The PRP requirements for escorts and supervisors covered under the PRP shall be incorporated into all contracts or similar arrangements involving the custody, the security provided for, possession, use, or on-site/off-site transport of the governed materials for any purpose.
      4. **(Enter any additional general reliability standards here)**
   3. **Qualifying Standards**
      1. The following qualifying standards represent the reliability standards expected of all individuals assigned duties requiring PRP certification.
         1. Emotionally and mentally stable, trustworthy, physically competent, and adequately trained to perform the assigned duties.
         2. Dependability in accepting and executing PRP responsibilities.
         3. Flexibility and adaptability in adjusting to a restrictive and demanding work environment with BSAT/EDP and/or VBM that must be strictly controlled and secured.
         4. Personnel Security Investigation (PSI). The investigative requirements in the investigatory process that shall be favorably adjudicated before access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM is granted.
         5. Successful medical evaluation.
            1. The Certifying Official(s)/Committee must be confident that the individual being certified is physically and mentally competent, alert and dependable, and are not a threat for compromising the PRP program and/or mission of (**enter your organization and/or facility name here)**. To that end, the Occupational Health (or other medical) provider to (**enter your organization and/or facility name here)** must provide the Certifying Official(s)/Committee an evaluation of the individual’s physical competence and mental stability to perform duties requiring PRP certification. The primary 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 judgment.
            2. Health records shall reflect the assignment of an individual to a position requiring PRP certification to ensure the proper treatment, review, and reporting of potentially disqualifying information to the Certifying Official(s)/Committee. All potentially disqualifying medical information shall be documented in the individual’s health records and transmitted to the appropriate Certifying Official(s)/Committee. A record must be made to show evidence of the record transmission to the Certifying Official(s)/Committee.
         6. The Biorisk Management Advisor, in coordination with the BSO and Certifying Official(s)/Committee, shall conduct a personal interview with each PRP candidate. Any relevant and potentially disqualifying information will be solicited and, if appropriate, discussed during the interview. Information considered on background investigations (e.g., financial issues) should be included.
         7. The Certifying Official(s)/Committee shall obtain evidence of demonstrated professional or technical proficiency, as appropriate. Evidence shall be obtained through previous employment and/or academic records and appropriate interviews of former supervisors and/or academic instructors.
         8. All candidates for PRP positions shall be tested for drug/substance abuse before being certified into the PRP. Positions requiring PRP certification shall be designated for random testing. Results of the drug/substance abuse test shall be submitted to the Certifying Official(s)/Committee. Positive test results will result in disqualification or permanent decertification, as appropriate, for the PRP.
         9. **(Enter any additional qualifying standards here).**
   4. **Disqualifying Standards**
      1. Alcohol-related incidents, abuse, or dependence will be evaluated according to the following guidance. In evaluating these traits or conduct, Certifying Official(s)/Committees shall ensure an individual's reliability and assignment to a PRP position is consistent with (**enter your organization and/or facility name here)** and national security interests:
         1. Individuals being considered for certification in the PRP with any alcohol-related incidents during the previous five (5) years or any diagnosis of alcohol abuse or alcohol dependence will be referred to the Occupational Health (or other medical) provider for evaluation. If the provider determines that the individual abuses alcohol or is alcohol dependent, procedures in this section will be followed, as appropriate. In all other circumstances, the Certifying Official(s)/Committee will review and consider the Occupational Health (or other medical) provider evaluation as part of the certification process.
         2. Individuals currently certified in the PRP who are involved in an alcohol-related incident shall be, at a minimum, suspended immediately from duties requiring PRP certification pending an evaluation. The Biorisk Management Advisor shall investigate the circumstances of the incident and request a medical evaluation. The investigation and medical evaluation results will be provided to the Certifying Official(s)/Committee.
         3. If the Occupational Health (or other medical) provider determines that the individual is currently abusing alcohol or is alcohol dependent, procedures in this section will be followed as appropriate. In all other circumstances, the Certifying Official(s)/Committee will assess the individual's reliability based on the investigation and the medical evaluation and determine if the individual should be decertified or reinstated and returned to duties requiring PRP certification.
         4. Individuals diagnosed as abusing alcohol but who are not alcohol dependent, shall at a minimum, be suspended pending completion of rehabilitation program or treatment regimen prescribed by the Occupational Health (or other medical) provider. Before the individual is reinstated and returned to duties requiring PRP certification (or before the individual is certified), the Certifying Official(s)/Committee will assess if the individual has displayed positive changes in personal reliability and lifestyle and if the individual has a favorable medical prognosis from the Occupational Health (or other medical) provider. Failure to satisfactorily meet these requirements shall result in disqualification or decertification.
         5. Individuals diagnosed as "alcohol dependent" shall be disqualified or decertified from the PRP.
         6. Individuals disqualified or decertified for alcohol dependency may be reconsidered for PRP duties after meeting all the following conditions:
            1. The individual has successfully completed an initial intensive rehabilitation program and is released for duties requiring PRP certification by the Occupational Health (or other medical) provider.
            2. The individual has completed a one-year strict compliance with an aftercare program.
            3. The individual has received a favorable prognosis by the Occupational Health (or other medical) provider, and a psychological evaluation is completed.
            4. The Certifying Official(s)/Committee has considered the value of the individual's continued presence in the PRP versus the risk from potential future alcohol-related incidents. The Certifying Official(s)/Committee must document that they have full trust and confidence in the individual's reliability.
      2. Drug/substance abuse will be evaluated according to the following guidance. In evaluating these traits or conduct, Certifying Official(s)/Committees shall ensure an individual's reliability and that assignment to a PRP position is consistent with **(enter your organization and/or facility name here)** and national security interests.
         1. Individuals in the following circumstances will be decertified or disqualified from the PRP.
            1. Individuals who had abused drugs/substances in the five (5) years before the initial PRP interview.
            2. Individuals who have ever illegally trafficked in illegal or controlled drugs/substances.
            3. Individuals who have abused drugs/substances while enrolled and/or certified in any PRP.
         2. The Occupational Health (or other medical) provider will evaluate and make recommendations regarding individuals not disqualified or decertified who have abused drugs more than five (5) years before the initial PRP screening or have isolated episodes of abuse of prescribed drug within 15 years of the initial PRP screening.
         3. The Certifying Official(s)/Committee will consider the Occupational Health (or other medical) provider’s recommendations and evaluate the individual’s reliability and adjudicate the individual’s qualifications based on the Occupational Health (or other medical) provider evaluation, consideration of circumstances pertaining to the drug abuse (e.g., frequency of drug abuse, age of the individual at the time of abuse), and any extenuating or mitigating circumstances (e.g., successful completion of a drug rehabilitation program).
         4. It is not the intent of these requirements to automatically disqualify or decertify any individual from the PRP who, in an effort to self-medicate, inadvertently or deliberately exceeds the recommended safe dosage of over-the-counter substances or who abuses/uses his or her own prescribed medications. If the Certifying Official(s)/Committee suspects or the individual admits to such improper usage, the individual must be suspended from duties requiring PRP certification and the Occupational Health (or other medical) provider consulted. If, after the provider’s evaluation, the Certifying Official(s)/Committee concludes drug/substance abuse has occurred, the Certifying Official(s)/Committee must disqualify or decertify the individual.
      3. Any individual suspected of attempting and/or threatening suicide shall be suspended from PRP duties pending the results of an Occupational Health (or other medical) provider consultation and a mental health assessment/evaluation. Any suicide attempt and/or threat may be grounds for disqualification or decertification.
      4. Leaving a job (including part-time/second jobs) under unfavorable circumstances may be grounds for disqualification or decertification.
      5. Being charged with or convicted of any criminal offense may be grounds for disqualification or decertification.
      6. Being a fugitive from justice may be grounds for disqualification or decertification.
      7. Significant financial problems such as filing for bankruptcy, garnishment of wages, property repossession, a lien against the property for failure to pay taxes or debts, unpaid court judgments, debt delinquency greater than 90 days may be grounds for disqualification or decertification.
      8. Being a party to any public record court action may be grounds for disqualification or decertification.
      9. Designation by the national government governing (**enter your organization and/or facility name here)** as a member of, acting on behalf of, or operating under the control of a terrorist organization or committing acts of terrorism may be grounds for disqualification or decertification**.**
         1. **Notification to** (**enter your organization and/or facility name here) by the national government that an individual is under investigation under that government’s terrorism legislation may be grounds for temporary decertification.**
      10. All potentially disqualifying information on individuals assigned to a position requiring PRP certification must be sent to the appropriate Certifying Official(s)/Committee for further review. The Certifying Official(s)/Committee shall evaluate this information to determine if the individual’s reliability is affected and take appropriate action.
      11. **(Enter any additional disqualifying standards here)**
   5. **PRP Certification - Adjudication**
      * 1. If the Certifying Official(s)/Committee's review of the PRP candidate's job or duty history reveals 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 removed from access. 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). Consideration may be given to:
        2. The nature of the event and whether the individual’s demonstrated behavior increases the risk in the facility or laboratory.
        3. The assessed individual’s circumstances at the time of an event.
        4. The time that has passed since the event of concern.
        5. The total number of events causing concern.
        6. The Certifying Official(s)/Committee may utilize security personnel and legal counsel to evaluate criminal conviction and arrest records when determining suitability under this plan.
        7. If the Certifying Official(s)/Committee determines that an individual has activity associated with them that meets the disqualifying standards under this PRP, they shall be designated a “Restricted Person.”
        8. A Restricted Person is ineligible for duties requiring PRP certification.
   6. **Continuing Evaluation**
      1. Certifying Official(s)/Committees must observe the behavior and performance of individuals certified under the PRP on a frequent and consistent basis and are responsible for ensuring that all individuals assigned to PRP positions meet all of the requirements of the continuous evaluation process.
      2. Individuals assigned to duties requiring PRP certification are responsible for monitoring themselves as well as others performing PRP duties. Failure to discharge these responsibilities may cast doubt on an individual’s reliability. Individuals shall advise the Biorisk Management Advisor, their supervisors, or area the RO of any factors that could have an adverse impact on their performance, reliability, or security while performing duties requiring PRP certification. This information will be provided to the Certifying Official(s)/Committee.
      3. Information that would be identified during the next periodic reinvestigation should be reported to the Certifying Official(s)/Committee as soon as possible, and not just during the reinvestigation process. Information that should be reported may include:
         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.
         16. Individuals assigned to duties requiring PRP certification should be self-aware of stressors and possess the ability to recognize stress in others assigned to duties requiring PRP certification. Stressors place real or perceived demands and pressures on individuals. Stressors can be physical or psychological and manifest from individual, sociological, and organizational factors. A person's behavior may be recognizable warning signs that a person is under mounting or accelerating stressors.
         17. The following are some examples of reportable stressors (note: this is not an exhaustive checklist as people may perceive demands and pressures differently and react differently).
             1. Mental health
             2. Financial strain
             3. Significant financial problems
             4. Job-related
             5. Conflicts with friends/peers
             6. Marital problems
             7. Abuse of illicit drugs/alcohol
             8. Other (e.g., caregiving responsibilities)
             9. Conflict at school
             10. Physical injury
             11. Conflict with parents
             12. Conflict with other family members
             13. Sexual stress/frustration
             14. Criminal problems
             15. Civil problems
             16. Death of friend/relative
         18. Concerning behaviors are observable behaviors exhibited by a person. These may be associated with the stressors detailed above.
         19. The following are examples of reportable concerning behaviors (note: this is not an exhaustive checklist as people may react differently to perceive demands and pressures).
             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. 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
         20. **(Enter any additional reportable information here)**
      4. Certifying Official(s)/Committees shall ensure actions of disqualification and/or decertification and any steps relating to recertification are accurately documented and recorded in the affected individual’s personnel record.
      5. The Certifying Official(s)/Committee will establish an anonymous reporting program (“Whistleblower Program”) and ensure all **(enter your organization and/or facility name here)** personnel are aware of the program so that all personnel can provide information that would affect the PRP certification of any PRP certified or proposed PRP certified individual.
      6. **(enter your organization and/or facility name here)** shall ensure the confidentiality of the reporting process and the information collected.
      7. **(enter your organization and/or facility name here)** shall establish policies and procedures to ensure that no individual is subject to reprisal for reporting an induvial under the stipulations of this plan.
      8. **(enter your organization and/or facility name here)** may utilize existing resources (e.g., human resources, security, occupational health) in providing recommendations to the Certifying Official(s)/Committee concerning access decisions in response to reported information.
      9. **(Enter any additional continuing evaluation rules/regs here).**
   7. **Continuing Evaluation – Adjudication**
      1. Just as with initial certification adjudication (see 2.5), If the Certifying Official(s)/Committee's review of the PRP member during continuing evaluation reveals 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 removed from access.
      2. 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). Consideration may be given to the following risk mitigators:
         1. Positive information about the person, including work performance and/or education since the derogatory event(s).
         2. The interpretation of the derogatory event(s) by supervisors at the time.
         3. How the individual being assessed interprets the derogatory event(s) during his or her interview.
         4. The context and timing of the concerning behavior are also important to note. Individuals assigned to duties requiring PRP certification should also consider.
         5. The nature of the event and whether the individual’s demonstrated behavior increases the risk in the facility or laboratory.
         6. The assessed individual's circumstances at the time of an event.
         7. The time that has passed since the event of concern.
         8. The total number of events causing concern along with frequency and severity.
         9. The assessed individual’s circumstances at the time of an event.
         10. Presence of a supportive family or support group.
         11. Presence of healthy social supports.
         12. Positive coping mechanisms.
         13. Access and receptiveness to assistance.
      3. The Certifying Official(s)/Committee may utilize security personnel and legal counsel to evaluate criminal conviction and arrest records when determining suitability under this plan.
      4. If the Certifying Official(s)/Committee determines that an individual has activity associated with them that meets the disqualifying standards under this PRP, they shall be designated a “Restricted Person.”
      5. A Restricted Person is ineligible for duties requiring PRP certification.
   8. **Termination of Access**
      1. Termination of access privileges to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM shall occur when an individual:
         1. Is no longer employed by **(enter your organization and/or facility name here).**
         2. Has job duties that no longer require access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM.
         3. Voluntarily requests to have access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM removed (“Opt-Out”).
         4. Is found unsuitable for access to biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and/or VBM based upon the rules and regulations stipulated in this document and **(enter your organization and/or facility name here)’s** Certifying Official(s)/Committee assessment of suitability.
      2. Temporary termination of access can be considered unless facts warrant permanent termination of access. When temporarily terminating access, the individual may not perform duties requiring PRP certification. Within 15 workdays of the temporary termination of access, the Certifying Official(s)/Committee shall provide the individual in writing the reason(s) for temporary termination of access. Individuals with access temporarily terminated will remain under continuous evaluation for PRP purposes until their access is permanently terminated or they are recertified into the PRP and their access restored.
   9. **Appeals to Decertification**
      1. If any personnel have been decertified as being able to access biological restricted areas, BSL-2, BSL-3, and BSL-4 containment areas, BSAT/EDP, and VBM, the decertified individual has a right to appeal to their management.
      2. The appeal process is as follows:
         1. The personnel having been decertified must write a letter within 14 days of having been notified of decertification. They must write a letter to their organization’s Head of Department, Certifying Official(s)/Committee, Deputy Director, and Director stating that they wish to appeal the decertification.

* + - 1. Within seven (7) business days of receipt of the letter, the organization must provide the decertified personnel with the reason why they have been decertified, and the evidence used to determine the reasons for decertification.
      2. Within 30 days, the decertified personnel should provide in writing to their Head of Department, Certifying Official(s)/Committee, Deputy Director and Director evidence to disprove the evidence used to determine decertification or information and evidence that identifies extenuating circumstances, or that the issue that caused the decertification has been satisfactorily dealt with and would not require the member of staff to be decertified.
      3. Within 30 days, the Director, in coordination with the Certifying Official(s)/Committee, must make an adjudication and decide whether the decertification will remain in place or be withdrawn, or if an intermediate position needs to be maintained such as additional training be provided, additional monitoring be put in place for the staff member to either be recertified or to be able to gain recertification within a defined time period.
    1. **(Enter any additional appeals to decertification rules/regs here).**
  1. **Training**
     1. All personnel governed by the **(enter your organization and/or facility name here)** PRP must undergo initial and periodic training on the requirements and procedures in this document as well as any other documents associated with this document.
     2. **(enter your organization and/or facility name here)** must conduct annual insider threat awareness briefings to all PRP personnel on how to identify and report suspicious behaviors.
        1. The annual insider threat awareness training may be coordinated with other required training, encompassing biosafety, security, incident response, and job-specific duties, in order to conserve resources and time.
        2. The primary focus of the annual insider threat awareness training is to promote insider threat awareness and inform individuals with access approval to the **(enter your organization and/or facility name here)** PRP of the policies and procedures contained in the **(enter your organization and/or facility name here)** PRP. The training could include:
           1. Insider threat awareness
           2. Behaviors of concern
           3. **(enter your organization and/or facility name here)** pre-access suitability policies (e.g., qualifying and disqualifying standards)
           4. Self and peer reporting procedures
           5. Statutory prohibitors (Disqualifying standards)
        3. Should the (enter your organization and/or facility name here) choose to use a violence risk assessment tool such as the Historical Clinical Risk Management-20 (HCR-20) or another protocol as part of its threat assessment process, specialized training in such a tool shall be acquired for prospective users.
     3. Training must be documented, identifying the participant, date of completion, and an evaluation of the participant’s successful completion and understanding of the training.

1. **Appendix:** 
   * 1. **Supplemental Guidance Documents.**

**This document is supplemented with guidance from the latest editions of:**

* + - 1. (ISO 35001:2019 - “Biorisk management for laboratories and other related organisations” - November 2019.
      2. World Health Organization (WHO) - “Biorisk management Laboratory biosecurity guidance” - September 2006.
      3. European Committee for Standardization, Comité Europé De Normalisation (CEN) Europäisches Komitee Fűr Normung, Workshop Agreement (CWA) 15793 - “Laboratory biorisk management standard” - February 2008.
      4. ASIS International Standard ASIS WVPI AA-2020 - “Workplace Violence and Active Assailant – Prevention, Intervention, and Response” - May 2020.
      5. National Institutes of Health - “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)” - April 2019.
      6. United States (U.S.) Centers for Disease Control and Prevention (CDC)/Animal and Plant Health Inspection Service (APHIS) - “Suitability Assessment Program Guidance” – March 2017.
      7. U.S. Defense Threat Reduction Agency (DTRA) - “Biological Threat Reduction Program, Biosafety and Security Standards”- November 2009.
      8. U.S. Department of Defense (DoD) – “Minimum Security Standards for Safeguarding Biological Select Agents and Toxins” – April 2006.
      9. Amman, M., Bowlin, M., Buckles, L., Burton, K. C., Brunell, K. F., Gibson, K. A., & Robins, C. J. - U.S. Department of Justice – “Making prevention a reality: Identifying, assessing, and managing the threat of targeted attacks” – 2017.
      10. Frederick S. Calhoun, Stephen W. Weston J.D. – “Concepts and Case Studies in Threat Management” – 2012.
      11. National Center for the Analysis of Violent Crime (NCAVC) – “Workplace Violence: Issues in Response” – 2003.
      12. Borum, R., Fein, R., Vossekuil, B., & Berglund, J. Behavioral Sciences and the Law, 17, 323-337. “Threat assessment: Defining an approach for evaluating risk of targeted violence.” – 1999.
    1. **Violence Risk Assessment Tools**  
       1. As the discipline of threat assessment becomes increasingly standardized and formalized, violence risk assessment tools—particularly so-called actuarial and structured professional judgment (SPJ) protocols—are becoming an important component of workplace violence and threat assessment programs. This section highlights some of the key tools that can be leveraged by institutions and teams for threat assessment uses.
       2. The process for adopting some of the violence risk tools highlighted below involves the following steps. Institutions and individuals planning to utilize such tools should first receive general behavioral threat assessment training and get exposure to tool use. This should be followed by specialized training in specific tools and the establishment of procedures and metrics for tool use. Trained individuals should then begin utilizing tools. Evaluation of tool use should take place within several months to a year of tool use implementation.
       3. The following tools are among the most important to consider in the context of workplace violence and PRP programs:  
          1. HCR-20: The -20 is a violence risk assessment tool that considers twenty historical, clinical, and risk management factors in evaluating violence risk. It is among the most widely used tools globally and in Asia and has been used in a variety of contexts, despite the HCR-20 manual suggesting it should be used primarily in “settings in which there is a high proportion of persons with histories of violence, and a strong suggestion of mental illness or severe personality disorder.” This intended use and the fact that many of the historical and clinical factors would be difficult to evaluate. This creates challenges for use in a PRP context, but it is still a leading tool and has been validated with the Filipino-American community.
          2. WAVR-21: The Workplace Assessment of Violence Risk (WAVR-21) is the most easily applied and useful SPJ tool for evaluating workplace violence. The ideal subject is an employee, and the ideal assessor is anyone who has been trained on the protocol. Most of the 21 risk factors are also behavioral characters that would be observable by the assessor or colleagues. The historical and/or mental health-related data required is minimal compared to other instruments.
          3. TRAP-18: The Terrorist Radicalization Assessment Protocol (TRAP-18) SPJ tool is one of the most prominent frameworks for assessing individuals deemed at risk of radicalization and extremism-related violence, particularly lone actors. The tool can be used by trained non-specialists and is especially useful in settings where extremism-related insider threats may be a concern. Compared to the Extremism Risk Guide (ERG 22+) and the Violent Extremism Risk Assessment (VERA), the intended subject of the tool is not intended to be a previous offender. One disadvantage of the tools is that their so-called distal characteristics and warning behaviors may be difficult to observe in situations involving employees. Furthermore, it is still undergoing validation. One similar tool to consider to the TRAP-18 is Identifying Vulnerable People (IVP).
          4. MLG: The Multi-level Guidelines (MLG) are an SPJ tool consisting of 20 risk factors that can help determine the risk of group-based violence. Specifically, this tool can help understand whether identification with a particular group can increase the risk of violence. MLG is one of the few tools where self-study is possible, but it may be challenging to use for risk assessors without significant experience.
          5. IR-46: Islamic Radicalization (IR-46) is a 46-risk factor SPJ tool that was originally developed by the Dutch National Police. It is specifically intended for use in the evaluation of individuals susceptible to engaging in violence due to a radical Islamic ideology. Though it allows for dynamic assessment and is designed for use on individuals that are not previous offenders, its validity in the international context is thus far not fully determined.