The Role of the Occupational Health Professional in Supporting Biological Personnel Reliability Programs

The Competent Medical Authority and the Personnel Reliability Program

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• The views expressed in this presentation are those of the author and do not necessarily reflect the official policy of the Department of Defense, Department of Army, U.S. Army Medical Department, or the U.S. government.

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Given a candidate or an enrolled worker in a biological personnel reliability program (PRP), working with Tier 1 select agents and toxins, perform the duties of the competent medical authority (CMA) in conducting a hazard-specific medical surveillance exam, and assessing the reliability and suitability of the candidate or employee for enrollment or retention in the biological PRP.
WHAT ARE THE SELECT AGENTS?
(Biological Select Agents and Toxins – BSAT)

• The Centers for Disease Control and Prevention (CDC) regulates the possession, use, and transfer of biological select agents and toxins (BSAT) that have the potential to pose a severe threat to public health, and the Animal and Plant Health Inspection Service (APHIS) regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant product.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002
• **Antiterrorism and Effective Death Penalty Act of 1996**, (Section 511 of Public Law 104 132)

• **Additional Requirements for Facilities Transferring or Receiving Select Agents** (Title 42 CFR Part 72 & App. A), April 15, 1997 (Department of Health & Human Services (DHHS))

• **Possession, Use, and Transfer of Select Agents and Toxins**; Final Rule, March 18, 2005 (DHHS)

• **Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins**; Final Rule, March 18, 2005 (USDA)
• Biosafety in Microbiological and Biomedical Laboratories [5th ed., February, 2007]

• Occupational Health Program Guidance Document for Working with Tier 1 Select Agents and Toxins [CDC, 1 October 2012]


• Biosafety REFERENCE MANUAL [AIHA Publications – 2nd ed., 1995]

**BIOSAFETY LEVELS**

**BSL - 1**
- Defined organisms
- Not known to cause disease in healthy adults
- Examples: *Lactobacillus*, Baculovirus

**BSL - 2**
- Moderate-risk agents present in the community
- Disease of varying severity
- Examples: *Salmonella*, Hepatitis, Herpes simplex

**BSL - 3**
- Indigenous or exotic agents, aerosol transmission
- Serious and potentially lethal infection
- Examples: *Brucella*, Rift Valley Fever virus, VEE

**BSL - 4**
- Dangerous or exotic, high-risk agents
- Life threatening disease
- Examples: Ebola, Marburg, Lassa, Machupo viruses

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**POTENTIAL HAZARD**

- **LOWEST**
  - Basic Laboratories

- **CONTAINMENT LABORATORIES**

- **HIGHEST**
Standard and Special Practices, Safety Equipment and Facilities*

- Limited access (double - door change room or airlock)
- Exhaust air fan interlocked with supply air fan
- HEPA - filtered room exhaust air**
- Directional airflow
- Protective laboratory clothing

*Plus criteria listed for BSL - 2

**When working with certain Arboviruses
Biosafety Level 4

- Standard and Special Practices, Safety Equipment and Facilities
- Locked door access
- Treatment of sewage
- Sterilization of all items leaving the area
- An airlock
- Individual room supply and exhaust air
- Emergency power source
- Back-up filtration units (two HEPA filters in series)
- Back-up exhaust fans
Inside a BSL-4 Laboratory

CDC photos
The Biological PRP is part of a total quality management program, involving multiple stakeholders from different organizations, that has built-in control measures to ensure that bio-containment work conducted with Tier 1 Select Agents and Toxins is performed in a safe and secure manner, with personnel who are highly reliable.
• Purpose - ensure worker reliability / suitability / safety

• Considers health, attitude, behavior, performance of its enrollees - they are held to a higher standard

• Enrollment is a privilege, not a right

• It is a highly visible and inspected program

• All occupational health encounters are screened for potentially disqualifying information that may impact the reliability / suitability of enrollees
Key Stakeholders in the PRP

• Competent Medical Authority (CMA)
  – Makes reliability / suitability assessments and recommendations

• Certifying Official (CO)
  – Makes reliability / suitability decisions

• Reviewing Official (RO)
  – Reviews decisions of CO; upholds or overrules
• Physician, physician assistant or nurse practitioner (military, civilian or contractor)

• Trained as a competent medical authority

• Awarded clinical privileges for independent practice, or if not privileged then supervised by a trained CMA who is privileged to practice independently
  – Appointed in writing by the medical treatment facility commander or contracting officer’s representative (COR)
CMA Tasks

- Reviews medical records and “self-reports” for potentially disqualifying information (PDI); transmits PDI to CO, with recommendations for action
- Monitors medical and dental care given to PRP workers by providers outside the occupational health clinic
- Conducts hazard-specific medical surveillance exams
- Conducts mental health reliability screening and substance use disorder screening evaluations
- Conducts medical review officer functions
- Conducts post-exposure / potential exposure evaluations
• Responsible for day to day implementation
  – Appointed by Commander / Director
  – May or may not be employee’s supervisor
  – May also be contracting officer’s representative
• Makes individual reliability decisions
• Liaison with Competent Medical Authority (CMA)
• The Facility Director who has overall responsibility for the execution of the PRP program;

• May delegate the function of certifying official to others who work for him or her;

• Serves as the appellant authority, in situations where employees wish to appeal or dispute the decision of a certifying official
PRP Elements

• Identification of positions - RO
• Initial interview with candidate - CO
• Candidate interviews with personnel, security, medical
• Certification of reliability - CO
• Enrollment / Assignment to position – CO
• Continuing evaluation of enrollee - All stakeholders
Reliability - Qualifying Factors

• Mental alertness
• Mental and emotional stability
• Trustworthiness
• Physically competent / able
• Dependability / flexibility
• Free from unstable medical conditions
• Good social adjustment
• Sound judgment under stress
• Positive attitude
Potentially Disqualifying Information

• PDI is any information regarding, but not limited to, a person’s physical, mental, emotional status, conduct or character - on duty or off duty - which may cast doubt upon the individual’s suitability or reliability to perform biological PRP duties

• All PDI uncovered is reportable by the CMA to the CO, whether or not the CMA feels that a medical restriction, suspension or disqualification is required
• Current diagnosis of drug / substance abuse or alcohol dependence, as determined by CMA
• Drug / substance abuse within five years previous to the initial PRP interview
• Trafficking in illegal / controlled drugs within the past 15 years
• Cultivating, processing or manufacturing of illegal or controlled drugs within the past 15 years
• Drug / substance abuse while in PRP, either admitted or as result of verified positive drug test
• Inability to safely wear required personal protective equipment

NOTE: DSM-5 now refers to mild, moderate or severe Substance Use Disorders, rather than to alcohol or substance abuse or dependence
Potentially Disqualifying Factors

- Alcohol related incidents, or alcohol abuse
- Drug / substance abuse (> 5 years, < 15 years prior to initial PRP interview)
- Inappropriate attitude, conduct or behavior
- Any medical condition, medication usage or medical treatment which results in:
  - Altered level of consciousness
  - Impaired judgment or concentration
  - Inability to perform physical requirements
  - Attempted or threatened suicide
- Attempt to conceal or willfully neglect to report PDI
  - e.g., purposely misleading CMA concerning alcohol consumption, past DUls, use of illicit substances, etc.
The primary responsibility of the CMA is to identify to the Certifying Official any PDI that may reflect on an individual’s suitability for assignment to a BPRP position, and to provide a recommendation to the Certifying Official as to whether the PDI will preclude the individual from performing BPRP duties.
• CMA will evaluate locally available medical records
  – Includes existing occupational health, substance abuse, behavioral health, family advocacy, immunization clinic, sub-specialty clinics

• CMA will conduct a face to face interview and medical examination

• Request for outside records may be requested
  – The CMA is the arbiter of credibility and sufficiency of medical information received

• Identify medically necessary limitations / accommodations

• Make recommendation to CO regarding PRP duty
Before transmitting any PDI to the CO, the CMA must ensure that the PRP candidate has executed a HIPAA-compliant release of PHI.

This form should include the names of all CMAs and/or organizations authorized to release PHI, as well as all current COs and ROs to whom the PHI may be released.

Each time a CMA, CO, or RO changes, a new HIPAA compliant release form should be executed to keep this authorization current.
• Typically part of any medical examination

• Partially subjective compared to physical evaluation

• Key Concerns: anxiety, depression, substance abuse, attitude towards requirement for timely self-disclosure

• Key principles:
  – Reliance on externally consensus - validated tools (questionnaires, etc.)
  – Low threshold for BH specialist consultation
• Medical Record entry
  – Complete (all conditions, medications and PDI)
  – Includes rationale as to why something is or is not PDI
• Written Communication to CO
  – Clearly defines what the PDI is, its impact on safe performance of duty, and any impacts, in layman’s terminology
• Recommendation must be one of 5 options:
  – No Restrictions; Medical Restriction; Suspension; Disqualification; Awaiting Further Information
Continuing Evaluation (Medical)

- Multiple sources of information
  - Worker
  - Co-workers
  - Supervisors
  - Medical personnel
- Conditions, treatments, medications or stressors affecting reliability
- Medical recommendation; CO decision
Medication Classes

- Class I - Over the counter meds
- Class II - Anything not identified in Class I or III
- Class III - Narcotics, sedatives, tranquilizers, insulin, diabetes medications that can cause hypoglycemia
Topics of Frequent Concern

- Protected Health Information
- “Outside” healthcare and records
- Need for in-depth evaluation / testing
- Behavioral health
- Substance use or abuse
- Duration of restriction for medication use
- Dialogue vs. one-way transmission of medical information
CASE STUDY #1 *

• The employee is a 39 year old BPRP veterinary technician who works principally in BSL-3 suites and animal rooms dosing animals, euthanizing animals, and assisting with necropsies. The CO refers her for CMA evaluation due to employee complaints regarding her behavior (swearing, yelling at people, refusing to share equipment, and disrupted BSL-3 experiment conducted by others while animal was anesthetized).

*The situations described are hypothetical and are not attributable to any specific individual or organization*
CASE STUDY #1 (continued)

- Supervisor reports that she has known the employee eight years, she always been a little difficult to work with, but behavior has become more caustic and disruptive recently. When supervisor tried to talk to her last week, she became very “hostile” and supervisor became “worried.”
QUESTION #1

WHAT THINGS WOULD BE MOST RELEVANT TO THE CMA DURING THE INITIAL EVALUATION?

a. Review of systems, list of medications

b. Social history, supervisory assessment of conduct

c. Mental health reliability screening

d. Substance use disorder screening

e. All of the above
WHAT THINGS WOULD BE MOST RELEVANT TO THE CMA DURING THE INITIAL EVALUATION?

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e. All of the above
• ROS, medications
• Social hx (within GINA restrictions)
• Mental health reliability screening
• Substance abuse screening
• Past work history
• Supervisory assessment
• Remarkable for frequent migraines (1-2 per week), heartburn, loss of appetite, severe fatigue, insomnia (4-5 hours sleep per night), anhedonia, diffuse myalgias and arthralgias, increasingly frequent low back pain (6-7 / 10 intensity, non-radiating). 10 lb weight loss over last 6 months.

• Medications include Nexium®, Relpax®, Excedrin Migraine®, Flexeril® (prn), and Percocet® [5 mg/325 mg], 1-2 tablets, 2-3 times per week, usually after work)

• The frequency of her LBP and migraine HAs, and the severity of the insomnia and fatigue, have increased significantly over the past 6 months
Social History

- Product of intact union to now deceased alcoholic father
- Physically and verbally abused as a child
- First husband (now divorced) was an alcoholic, who was also physically and verbally abusive
- No close friends nearby—recent departure of best friend
- Son moved out and took a job 3 months ago out of state
- Horse of 20 years died one year ago - tearful
- Lives on a working farm at home - no help with daily chores
• GAD 7 - 0

• Beck’s Depression Inventory - 11

• Depressed affect, tearful, poor insight into how she is feeling, how others around her perceive her, and how she deals with stress
• 1-2 beers per week; 1-2 beers per occasion

• CAGE: 0/4

• SHORT MAST: 0

• DAST-10: 1

• Was prescribed Percocet® for low back pain; she uses it for neck pain, abdominal pain, and other significant joint pains; has used 30 pills per month, over the last 6 months; a year ago, she was using 30 pills every 2 months; denies THC, amphetamines, benzos, other
• Disruptive conduct in the workplace
• Angry, verbally abusive to other employees
• Uses scatological language in the workplace
• Disrupts experiments during safety sensitive tasks in the laboratory (i.e., IV dosing of animals)
• Misperceptions - suspicious of other employee and supervisor’s conduct toward her
• Unable to take constructive criticism or counseling
QUESTION #2

BASED ON THE FOREGOING, ALL OF THE FOLLOWING ARE TRUE EXCEPT (SELECT 1)

a. This patient most likely has diagnosis of depression, with anger & irritability as a result

b. She does not currently meet mental & emotional stability standards within the BPRP

c. She needs a full psychological evaluation for appropriate treatment and disposition

d. Given that she is not suicidal, medical restriction is most appropriate CMA recommendation
ANSWER TO QUESTION #2

a. This patient most likely has diagnosis of depression, with anger & irritability as a result

b. She does not currently meet mental & emotional stability standards within the BPRP

c. She needs a full psychological evaluation for appropriate treatment and disposition

d. Given that she is not suicidal, medical restriction is most appropriate CMA recommendation
• Report PDI to CO, with recommendation for suspension from PRP duties due mental and emotional instability;

• Refer to behavioral health through EAP for evaluation, cognitive behavioral therapy and medication;

• Continue to follow-up in occupational health at least every 30 days to see response to therapy;

• Recommend the return to BPRP duties, once a psychological assessment documents that depressive disorder is in full remission (no clinical criteria met for the diagnosis for at least 2 months)
QUESTIONS