



NSABB Public Consultation on Personnel Reliability

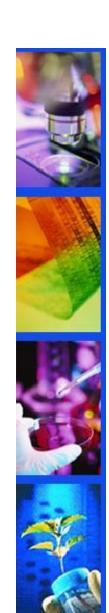


April 2009



Public Consultation: Purpose

- Explore potential impact on the scientific community
 - Investigators
 - Research institutions and organizations
- Topics
 - Concept of personnel reliability and its implementation
 - Personnel reliability measures
 - Optimal characteristics and methods for assessing reliability
 - Potential benefits and consequences of personnel reliability programs



Public Consultation

- April 3, 2009
 - Presentations,
 videocast, podcasts at
 www.biosecurityboard.gov
- ~200 attendees
 - Public
 - □ Private
 - Non-profit



April 2009 Meeting - April 3

Agenda and Webcasts

NSABB - Past Meetings

OFFICE OF SCIENCE POLICY - National Institutes of Health

Office of Biotechnology Activities

News and Events



Public Consultation: Background Presentations

- Extant Personnel Reliability Programs (PRPs)
 - Army
 - DOE
- Select Agent Program: Security Risk Assessment
 - CDC and DOJ/CJIS
- PRP in Academia (planned)
 - UTMB, Galveston National Lab
- NSABB WG on PR: Proposed Optimal Personnel Characteristics



Public Consultation: Organizing Framework

- Optimal Personnel Characteristics
 - No history of scientific or professional misconduct
 - Emotionally stable and capable of sound judgment
 - Positive attitude toward safety and security measures, and standard operating procedures
 - Free of vulnerability to coercion
 - Free of felony convictions
 - No domestic or international terrorist ties



Public Consultation: Panelist expertise

- Select agent and other biomedical research
- Personnel reliability programs
- Biosafety
- Research administration
- Responsible conduct of research
- Psychiatry and psychometric research



Themes and Issues: Operational aspects of PRPs

- Role of the Responsible Official (RO)
 - Qualifications, training, and responsibilities
- Costs of PRPs vary greatly
 - type of institution
 - existing infrastructure



Themes and Issues: *Utility, applicability & effectiveness of PR measures*

- Adequacy of current measures
- Need for additional measures
- Correlation between optimal characteristics and security
- Data supporting effectiveness



Utility, applicability, & effectiveness of PR measures (cont.)

- Personal history
 - Is the past prologue to the future?
 - □ Unreliability ≠ will engage in bioterrorism
 - Past behavior may provide a false sense of security
- Job performance measures may be more effective



Themes and Issues: General lack of support for the two person rule

- Biosafety and biosecurity applications
- Resource-intensive
- Difficult to implement with limited number of staff



Themes and Issues: Reporting to USG when access is restricted

- Need guidance on reporting the restriction of access
 - What to report, to whom, and when?
 - Disclose reasoning and procedures leading to the decision?
- Potential negative effects
 - Individual's career and reputation
 - Privacy and liability issues
 - Culture of trust



Engaged leadership at the local level is critical

- Reliability is best managed locally at the institutional level
- Investigators must be engaged
- Strong working relationships should be fostered
- Training is critical



A balanced approach is needed

- PRP could be a disincentive to remain in or enter select agent research
 - "Culture shock"
 - Recruiting difficulties
- New requirements may stifle innovation
- Must monitor PRP impacts, effectiveness, and unintended consequences
- Proceed with caution



Layers of accountability

- Local or institutional level:
 - Committed institutional and laboratory leadership
 - Peer reporting
 - Training
- Federal level:
 - Effective regulatory programs
 - -performance-based standards
 - -flexibility and discretion in application
 - -local enforcement



Other issues of concern

- Psychological assessments administered by a trained professional
- Privacy
- ADA issues
- Impact of restricting an individual's access
- Compounding compliance burden