

Implementing the New Tier 1 Regulations at Kansas State University's Biosecurity Research Institute

ABSTRACT

The Biosecurity Research Institute (BRI) at Kansas State University in Manhattan KS currently has an active select agent program that includes with a number of the select agents that were placed on the new Tier 1 select agent list. The BRI already has in place a security program and an occupational medicine program but both programs had to be expanded to become compliant with the new regulations. The one program that was not already in place at the BRI was the personnel suitability program. This program had to be created from the ground up.

OBJECTIVES

- Implementing the new Tier 1 select agent regulations for the security program.
- Implementing the new Tier 1 select agent regulations for the occupational medicine program.
- Implementing the new Tier 1 select agent regulations for the suitability program.

SECURITY PROGRAM

The BRI already has in place a robust security program, and all select agent work at K-State is done only in the BRI, so a majorit Tier 1 requirements for the security program were already being met. There were 4 requirements that we had to address in o either enhancing what we already had in place or implementing new policies and procedures. These 4 areas were; the triple requirement, the intrusion detection system (IDS), the response time, and the annual insider threat awareness training. Listed main requirements for each area we had to improve upon and some examples of how it can be done.

TRIPLE BARRIER

- Must identify the 3 barriers on your registration and discuss them in your security plan
- Each security barrier must add to the delay in reaching the Tier 1 select agents and toxins
- Examples would include fences, locked doors, and locked freezers.
- A "trained" person is a barrier when physically present - A "trained" person is someone who is trained to identify and respond to suspicious activities. Persons who receive inside suspicious person training or similar training along with response procedures are considered "trained personnel"
- One barrier must be monitored under all conditions - Examples of monitoring would be the IDS, video cameras, or tamper-evident tape on containers - Ideally the very first barrier is what is monitored
- The final security barrier must limit access to Tier 1 select agents and toxins to only personnel approved for access by the H or administrator (i.e. SRA approved personnel)
- Examples would include a locked lab door or a locked freezer

INTRUSION DETECTION SYSTEM (IDS)

- All areas that reasonably afford access to Tier 1 select agents and toxins must have an IDS active unless physically occupied
- IDS consists of a sensor device that triggers an alarm when a security breach occurs and notifies a response force who can response for stop the threat
- Examples of an IDS are door alarms, glass break sensors, and motion detection systems
- Personnel monitoring the IDS must be able to evaluate and interpret the alarm and alert the security response force or law - Examples of who monitors the IDS are the entity's own security force or local law enforcement
- If the monitoring of the IDS is contracted and law enforcement respond, then law enforcement needs to understand the importance of responding to the alarms despite the potential for false alarms
- Law enforcement needs to understand that IDS alarms are not typical property crime and understand the consequence of theft of a select agent or toxin

RESPONSE TIME

- ♦ 15 MINUTES = The time the response force is notified to the time the response force arrives
- Response force is a force capable of interrupting a threat
- Examples of a response force are local law enforcement or university police Two Options to meet the requirement
- Determine that the response time for the response force is 15 minutes or less
- Calculate delay time provided by security barriers and compare to the expected response time of the response force
- If local law enforcement is the response force make sure they know the alarm triggered by the IDS is not a typical property alarm

ANNUAL INSIDER THREAT AWARENESS TRAINING

- Training should include:
- How to identify and remove suspicious persons
- How to identify and react to suspicious persons
- Escort procedures
- Security Policies
- How to respond to alarms
- How to respond to security breaches
- Who outsider threat groups are

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OCCUPATIONAL MEDICINE PROGRAM

The BRI occupational medicine program has already been established and is provided for all persons working in the BRI working with materials requiring participation. Additions were made to the occupational medicine program to meet the new Tier 1 requirements. These additional items were: 1) a thorough physical exam by the health service provider required for anyone with access to Tier 1 select agents or toxins, 2) a Tier 1 occupational medical risk assessment form, and 3) a Tier 1 agent specific post exposure plan. The flow charts below show the occupational medicine program process with the addition of the new Tier 1 requirements.

OCCUPATIONAL MEDICINE PROGRAM ENROLLMENT

		New Individual at t
ity of the new our program by barrier d below are the		Individual is given the Workplace Haz
	out	with the assistance of their supervisor and
		Individual is given the Medical Asse
		and sends completed form to the h
	He	ealth service provider receives the Medical
	If the Individual will have acc	ess to Tier 1 select agents & toxins, an app
	during the appointment t	the completed Tier 1 Risk Assessment form
er threat,	Health services provider co	mpletes the Health Risk Assessment & Rec
	Unconditional Clearance	Conditional Clea
HHS Secretary		
		Follow-up is needed, the i
		be contacted but can still wor
		Follow-up completed, individual
		new Health Risk Assessment & Re
ł		Occupational medicine
respond and		completed individual receives a
v enforcement		

ANNUAL OCCUPATIONAL MEDICINE PROGRAM REASSESSMENT

Indiv	vidual enrolled in the occupational medie	cine program is identified for annual
		↓
	BRI biosafety staff sends the Annual Rea	ssessment form to the individual to
	Individual sends completed Annual Re	eassessment form to the BRI biosafe
If the Individua	I has access to Tier 1 select agents & tox	ins, an appointment is made to mee
provider, during the app	pointment the completed Tier 1 Risk Ass	essment form is reviewed and the ir
Individual indicates no change	e on annual reassessment form	Individual indicates a
No pervious	Medical surveillance	Individual given Healt
medical surveillance	being done, continue	complete and
No follow-up needed	as required	
		Health service provid
		Assessment & Recom
		No change in
		surveillance program
		continue as required
	↓	•
	Annual occupational medicine	e program reassessment completed





The BRI did not have a personnel suitability program in place and had to build it from the ground up to become compliant with the new Tier 1 regulatory requirements. We developed the K-State Tier 1 Suitability Assessment and Monitoring Program (SAMP). The goal of the SAMP is to promote a culture of reliability, safety, and security regarding access to Tier 1 select agents and toxins and to safeguard Tier 1 select agents and toxins from theft, loss, or release. Suitability assessments are intended to look beyond an individual's education and experience and assess whether the individual, as a whole person, possesses attributes that support personal and public safety and the security of Tier 1 select agents and toxins. Through the SAMP, it is a goal of the K-State BRI to assist individuals in identifying issues and help them recognize the importance of receiving assistance prior to problems escalating to a level that may impact the safety and security of Tier 1 select agents and toxins, but these policies are not to be construed as a guarantee or right of a particular accommodation or continued employment.

Throughout the process, honesty and completeness of answers by individuals with access to Tier 1 select agents and toxins is of paramount importance, and an individual who fails to provide complete and honest information will be subject to disciplinary action

INITIAL PROCESS FOR NEW PERSONNEL

Pre-Access **Information For** Meet with CO Background Check (In addition to SRA approval)

Certifying Official

The Responsible Official (RO) or Alternate Responsible Official (ARO) (dependent on who is being evaluated) will act as Certifying Official (CO). COs will consider the advice and recommendations of the Reviewer (REV), in conjunction with review of the completed Pre-Access Information form, any relevant background check status, medical assessments, training records, accident/incident reports, performance evaluations, and peer reports to determine the suitability of an individual to have access to Tier 1 select agents and toxins.

The Reviewer (REV) will be outside the supervisory chain of the individual whose suitability is being evaluated and have experience in human resources. The REV will review the completed Tier 1 Suitability Self-Assessment Questionnaires and meet with the individual. This review and meeting will be completed prior to the individual having access to Tier 1 select agents and toxins and annually thereafter. The REV will also assist with developing and conducting SAMP training and conduct additional activities to promote open communication as deemed necessary by the RO. The REV will turn over all documents obtained to a CO at or about the same time the REV provides the advice and recommendation to a CO.

ONGOING PROCESS FOR PREVIOUSLY APPROVED PERSONNEL

Self Assessment Questionnaire Meet with REV Annual Background Check Every 3 years (In addition to SRA approval)

KANSAS STATE UNIVER R S I T Y

PERSONNEL SUITABILITY PROGRAM



