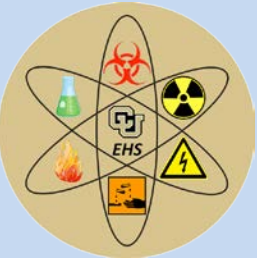


Facing New Challenges in Implementing a TIER 1 Select Agent Program

Denise A. Donnelly, CHMM
Assistant Biosafety Officer, ARO
Environmental Health & Safety

2013 ABSA



University of Colorado Denver | Anschutz Medical Campus
Office of Regulatory Compliance
Environmental Health and Safety

University of Colorado Denver | Anschutz Medical Campus

- Medical research campus
- Approx. \$400 million in research funding
- Research includes use of RG1-3 agents, SAT, and Human Gene Transfer trials

SA Program Overview







- Registered by CDC-DSAT
- Two Tier 1 SA micro-organisms

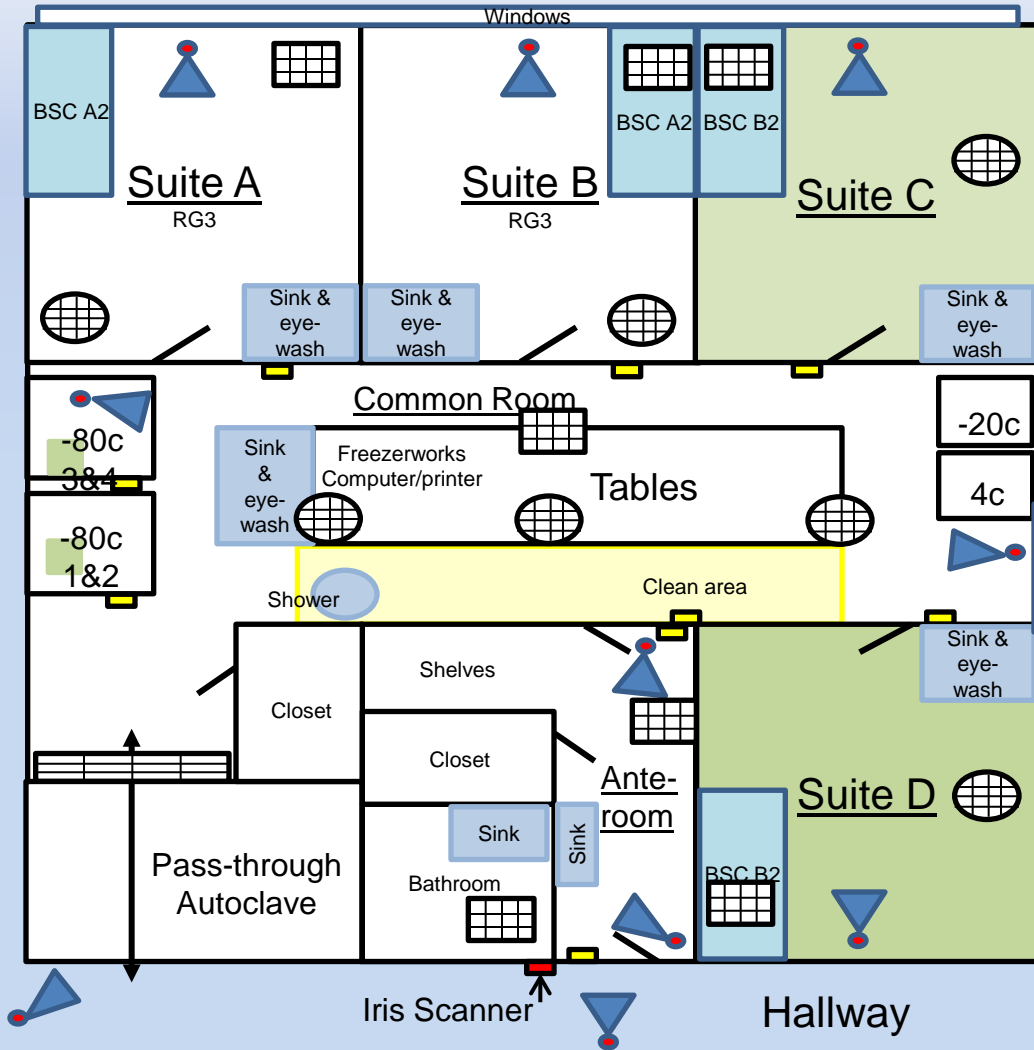
SRA-Cleared Personnel

- Currently a total of 20 SRA-cleared personnel
 - RO and 5 AROs
 - 10 laboratorians
 - 4 security personnel

Note: 2 of the laboratorians do not conduct SA research but need access to equipment located in the SA space, and 2 laboratorians are not actively engaged in research but still maintain samples in storage

BSL-3 Facility

-  Air Supply
-  Air Exhaust
-  Video Camera
-  Iris Scanner
-  Badge reader
-  Select Agent Areas



BSL-3 Operations Management

- On-going and monthly PM
- Maintain inventory of general supplies
- Routine cleaning and disinfection of core area
- BSC certifications
- Autoclave spore tests
- Visitor and Facility Management escort
- Training
- Alarm response and follow-up during normal business hrs.

New to Regulations

§ 73.3 HHS Select agents and toxins

- Conotoxins
 - alpha conotoxins
 - specific amino acid sequence
- SARS
 - associated coronavirus (SARS-CoV)



DESTRUCTION OF SELECT AGENT

The Select Agent listed in this document has been destroyed in accordance with all requirements set forth by the U.S. Department of Health and Human Services (HHS) per 42 CFR 73.

Entity Registration Number: C20111018-1276

Entity Name: The Regents of the University of Colorado, a body corporate

Entity Address: 1784 Racine Street, Bldg. 401; Rm. 210, Mailstop F484 Aurora, CO 80045

Select Agent to be Destroyed: _____ Quantity Destroyed: _____

Registered PI: _____ Date of Destruction: _____

Date Submitted to CDC Division of Select Agents and Toxins: _____

Destruction Process	Performed By	Witness
Identify and remove Select Agent from freezer; verify physical inventory with FreezerWorks		
Destruction Process – Autoclave with biological and chemical indicators		
Post Destruction Process - Verification of negative biological and chemical indicators		
Remove Select Agent inventory from FreezerWorks		
Dispose of destroyed Select Agent through Biomedical Waste Program		

Narrative and Additional Information

Destruction of Select Agent Performed By: _____

Name, Title

Signature Date

Witness for Destruction of Select Agent: _____

Name, Title

Signature Date

Responsible Official: _____

Name, Title

Signature Date

New to Regulations

§ 73.9 (a)(5) Responsible Official

- Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the SA regulations and be able to respond in a timely manner to onsite incidents involving SA and Toxins in accordance with the entity's incident response plan,

New to Regulations

§ 73.11 Biosafety

- Existing Occupational Health program
- Established *Criteria of Fitness for Duty*
- Further defining medical evaluation

New to Regulations

§ 73.11 Security - Personnel Suitability & Reliability

New program to meet new federal requirements, but many components were already in place.

Pre-access Program

1. FBI/CJIS investigation
2. Local investigation
3. Interviews
4. Work and personal history
5. Initial training
6. Assurance statement
7. Occupational Health

On-Going Program

1. Local background check
2. Peer and self-reporting mechanisms
3. Annual training
4. Annual exercise
5. Performance evaluation
6. Occupational Health

Both of these programs are multi-departmental involving EHS, UPD, HR, Legal, Academic Dept's, etc.

New to Regulations

§ 73.14 Incident Response

- 15 minute response time

New to Regulations

§ 73.16 (l)(1) Transfers

- *Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins.*



Reset Form

Submit by E-mail

Select Agent Toxin Transfer Exempt Quantity Request

This tracking document must have Responsible Official (RO) or Alternate Responsible Official (ARO) approval BEFORE transferring Select Agent Toxin in exempt quantity from one entity to another.

Requestor: Complete **Section 1** and transmit form to transferring lab.

Transferor: Complete **Section 2** and transmit form using the Submit by E-mail button for RO/ARO review and approval.

RO/ARO: RO/ARO assigns an EHS tracking number and indicates approval of transfer with signature in **Section 3**.

RO/ARO returns form to transferor to initiate toxin transfer.

Transferor: Complete **Section 4** and transmit form to both Requestor and use the Submit by E-mail button for RO/ARO.

Requestor: Complete **Section 5** when transfer is complete and transmit form using the Submit by E-mail button.

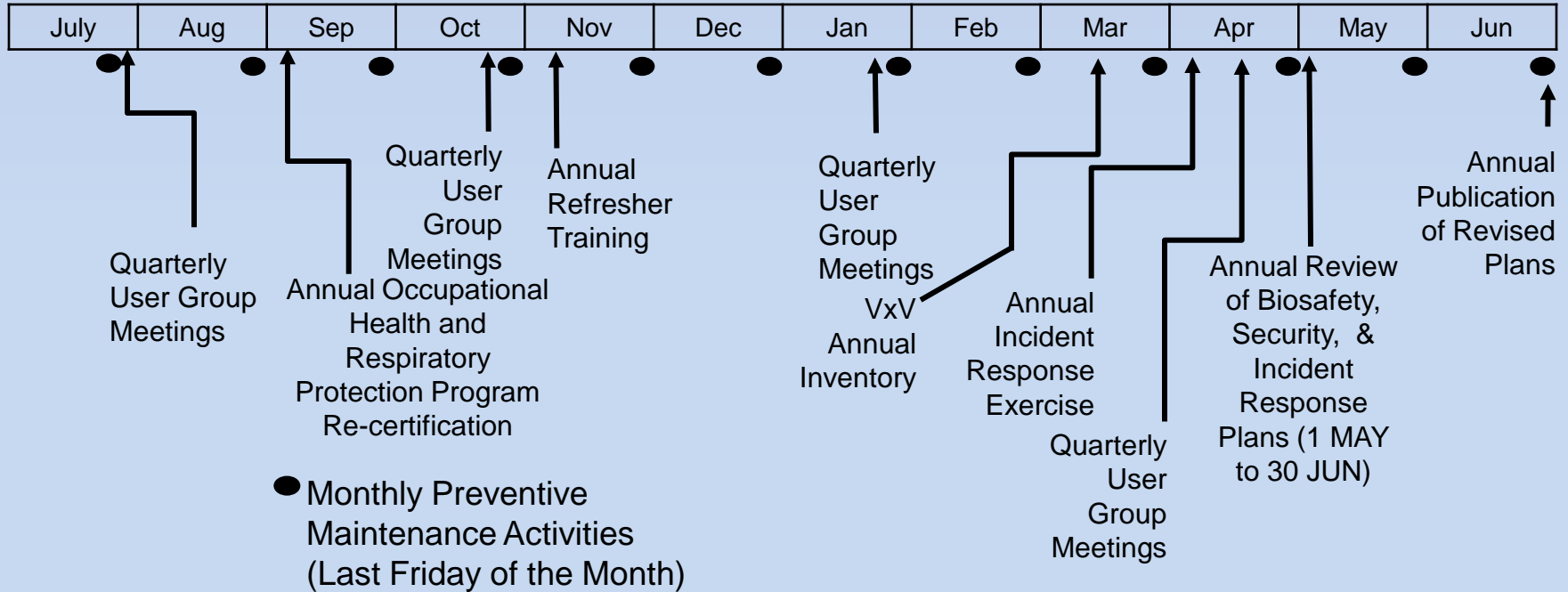
QUESTIONS or ASSISTANCE: Call 303-724-0345 or biosafety.program@ucdenver.edu

SECTION 1 - Requestor	
PI:	Signature: Date:
Building and Laboratory Room Number:	
Select Agent Toxin:	CAS #
Intended Use:	Qty. Requested:
Material: <input type="checkbox"/> Active <input type="checkbox"/> Inactivated, explain how:	
SECTION 2 - Transferor	
PI:	Signature: Date:
Building and Laboratory Room Number:	# Vials: Vol or Wt per vial:
Agent Characteristics:	List Constituents:
SECTION 3 - RO/ARO	
RO/ARO:	Signature Field Date: EHS Tracking #
SECTION 4 - Transferor	
Amnt per ¹⁰ Receptacle:	# of ¹⁰ Receptacles per Container: # of Packages Shipped:
Completed "Shipping Biological Materials" Training Date:	Ship Date: Vendor:
Tracking #(s):	Confirmation of Receipt by Requestor Date:
SECTION 5 - Requestor	
# of Packages Received:	# of Vials Received: Total Qnty Received: Date Received:
Signature:	Date:

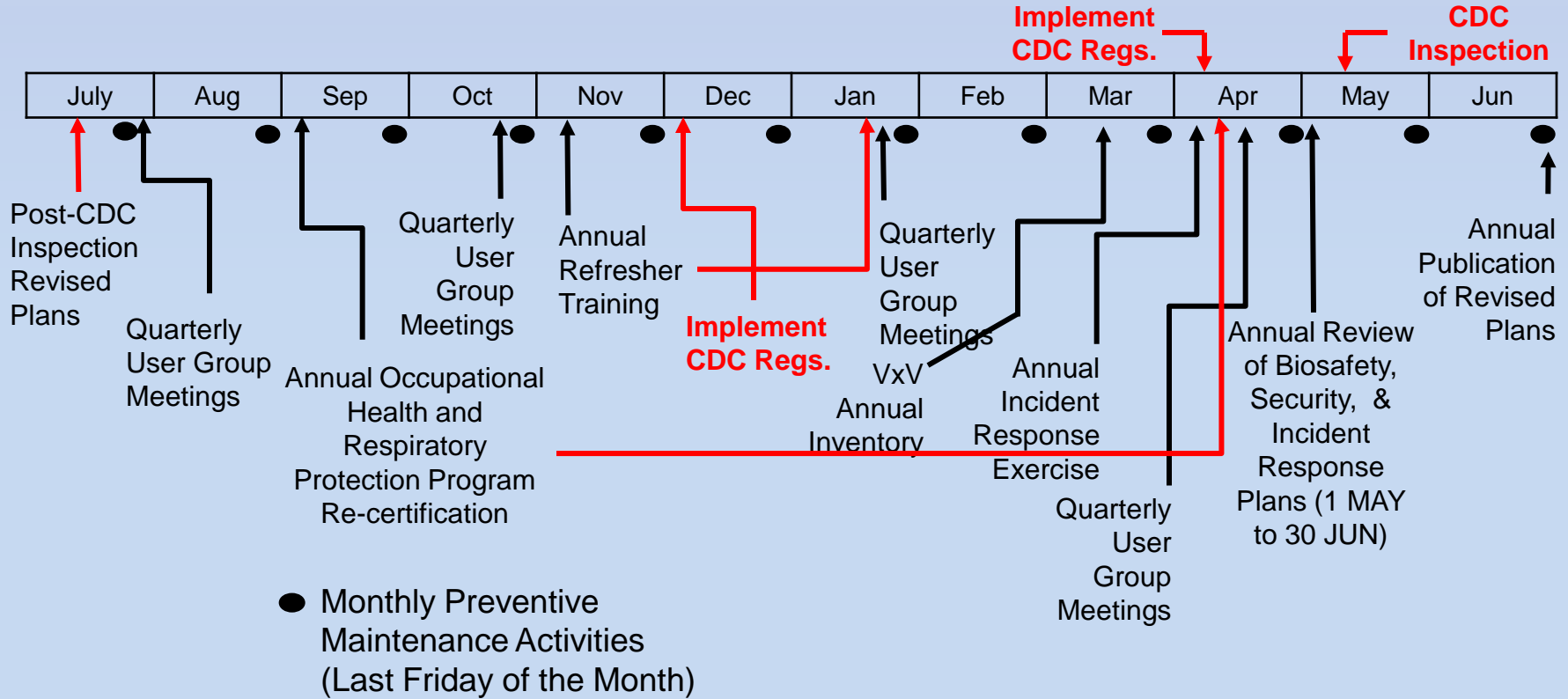
Additional Challenges

- Scheduling / Coordination
 - Quarterly User Group Mtgs.
 - Training
 - Inspections
 - Annual OH
 - Annual Incident Response Exercises
 - Annual Review and Revision of Plans

Select Agent Program Annual Activities



“Revised” Select Agent Program Annual Activities



Conclusion

The National Select Agent program has amended the regulations and provided associated Guidance documents which allow entities the latitude to design and implement a Tier 1 BSAT program that's specific to meeting their stakeholder's needs while maintaining regulatory compliance and safe work environment.

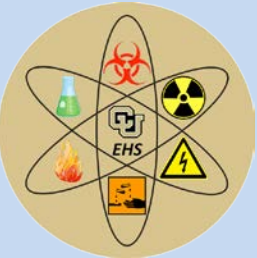
Acknowledgements

*Ethan P. Carter, PhD
Responsible Official*

*Zachary Wilson, MS
Alternate Responsible Official*

*Beth A. Strimpel, RN, MA
Occupational Health Program Manager*

*The Safety, Security, and Compliance of the Select Agent
Program are CU Denver's top priority.*



University of Colorado Denver
Office of Regulatory Compliance
Environmental Health and Safety