LESSONS LEARNED: CDC YEAR THREE
THE "NEW" SELECT AGENT INSPECTION

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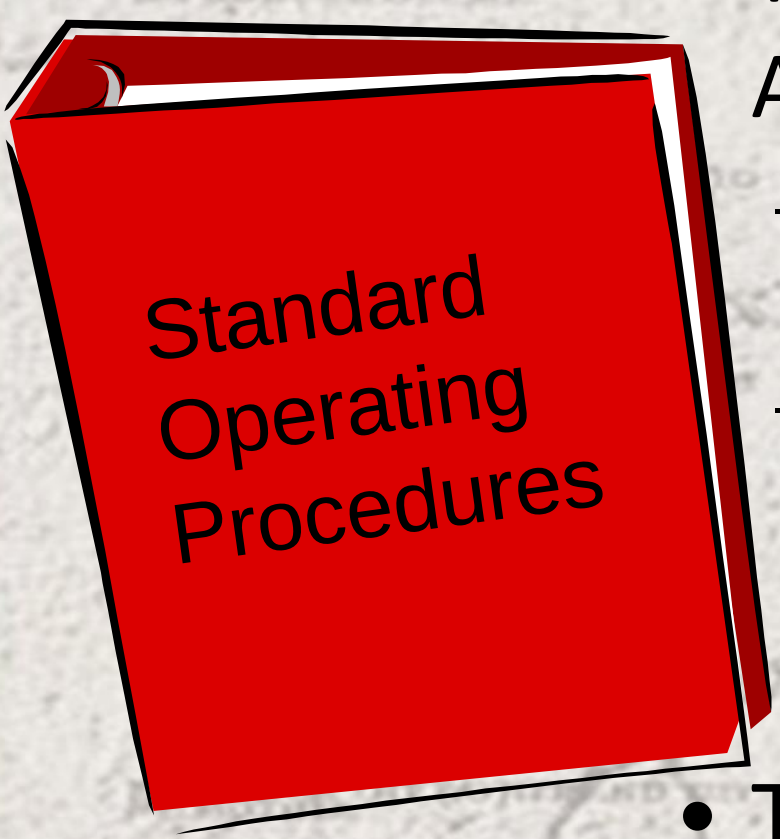
ASU ARIZONA STATE UNIVERSITY

10 Commandments of the "New" CDC Inspection

Commandment #I:

- Thou Shalt Not Assume Thy Researchers Know Anything About Biosafety
  - Have Detailed SOPs:
    - "don't put your head in the BSC"
  - Extensive Training



Commandment #II:

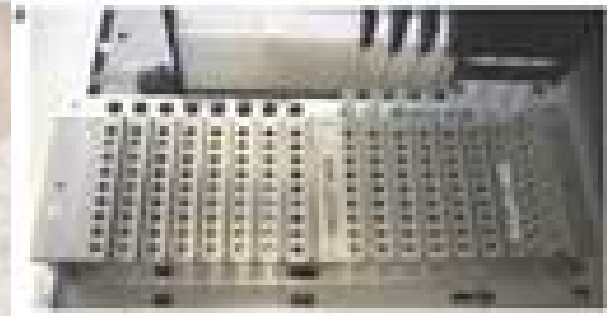
- Thou Shall Not Steal

-SOPs from another institution

Commandment #III: Know Thy Vials

- Impressed that our researcher knew # of vials.
- Inventory – using their form

Commandment #IV:



- Thou shall have an even better Medical Surveillance Program
- Health Hazard Assessment
- Serum Banking Program
- "…The individual that received the exposure or potential exposure will be given a medical consultation and advised of available treatments."

ASU Arizona State University

Arizona State University
Department of Environmental Health & Safety

Health Hazards Assessment
For Laboratories using Select Agents & Toxins

PRINCIPAL INVESTIGATOR:		Phone No:	
Department:		Fax No:	
Building, Room, Mail Code:		Email:	

Please fully complete each section. It may be helpful to refer to the Population and Health Branch of the Canadian's Government MSDS website, http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/index.html.

1. Agent Identification

Name (genus/species):

Type of Agent (check all that apply)

Bacterium: ☐
Prion: ☐
Fungus: ☐
Rickettsia: ☐
Parasite: ☐
Toxin derived from living organism: ☐
Virus: ☐
Recombinant DNA: ☐

For recombinant DNA, the following questions must be answered:

1) Does the inserted gene encode a known toxin or a relatively uncharacterized toxin?

   No: ☐ Yes: ☐ If yes explain:

2) Does the modification have the potential to alter the host range or cell tropism of the virus?

   No: ☐ Yes: ☐ If yes explain:

3) Does the modification have the potential to increase the replication capacity of the virus?

   No: ☐ Yes: ☐ If yes explain:

4) Does the inserted gene encode a known oncogene?

   No: ☐ Yes: ☐ If yes explain:

5) Does the inserted gene have the potential for altering the cell cycle?

   No: ☐ Yes: ☐ If yes explain:

6) What is the probability of generating replication-competent viruses?

   No: ☐ Yes: ☐ If yes explain:

Commandment #V:

- Obey your application
  - Prepare as if you are in full operation!!!
  - Signs
  - Drills
  - Training

Commandment #VI:

- Respect thy PAPR

Commandment #VII:

- Thou shall not drip outside of “primary” containment
- Select Agent and Toxin Theft, Loss and Release Information Document
- http://www.selectagents.gov/resources/CDC-APHIS_Theft_Loss_Release_Information_Document.pdf
- READ IT, KNOW IT, LIVE IT

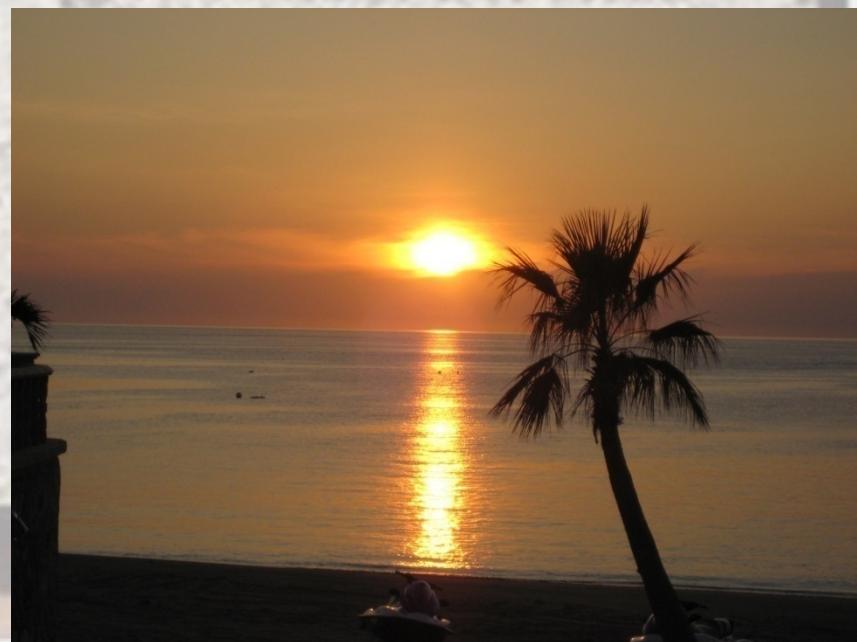
Commandment #VIII:

- Respect Available Resources
- Checklists – National Select Agent Registry
- BSL3 Inspection Video

Commandment #IX:

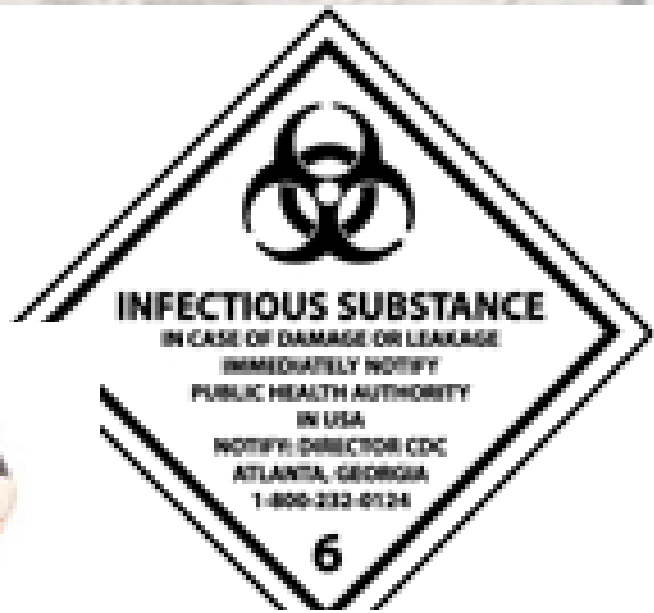
- Honor the past,

  but look to the future



Commandment #X

- Continued Guidance from CDC –shipping



I – Detailed SOPs

II – Steal SOPs

III – Inventory

IV – Medical Surveillance

V – Prepare as if you are in full operation

VI – PAPR/PPE

VII – Report Drips

VIII – CDC Resources

IX – Future

X – Guidance

Thanks!

Questions?

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