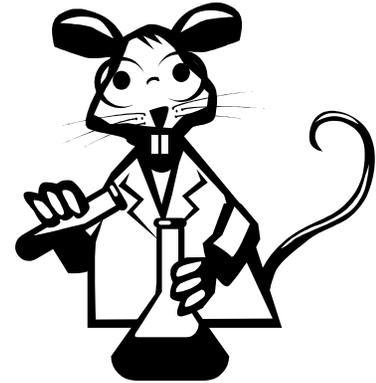


# Disaster Recovery & Business Continuity – Related, but NOT the Same!

Teri Stokes, Ph.D., Director  
GXP International

# BCP Definitions

- **Business Continuity Plan:** An ongoing process supported by senior management and funded to insure that the necessary steps are taken to identify the impact of potential losses, maintain viable recovery strategies and recovery plans, and ensure continuity of services through *personnel training, plan testing, and maintenance.*

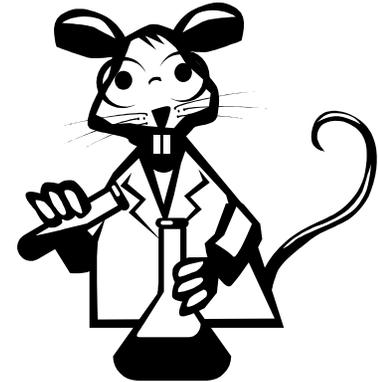


***NFPA 1600 Standard on Disaster/Emergency Management and Business Continuity Programs, 2004 Edition***

# BCP Definitions

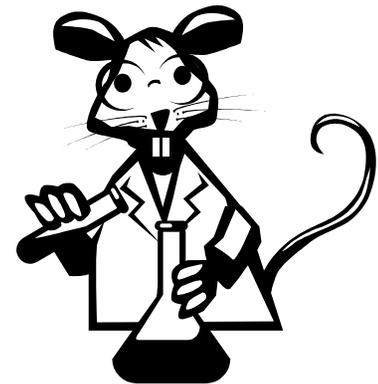
- **Disaster** - An occurrence or imminent threat to the organization of widespread or severe damage, injury, or loss of life or property resulting from natural or human causes.
- **Emergency** – An occurrence that is beyond the normal response resources of the organization and would require outside resources and assistance for recovery.

*NFPA 1600 Standard on Disaster/Emergency Management and Business Continuity Programs, 2004 Edition*



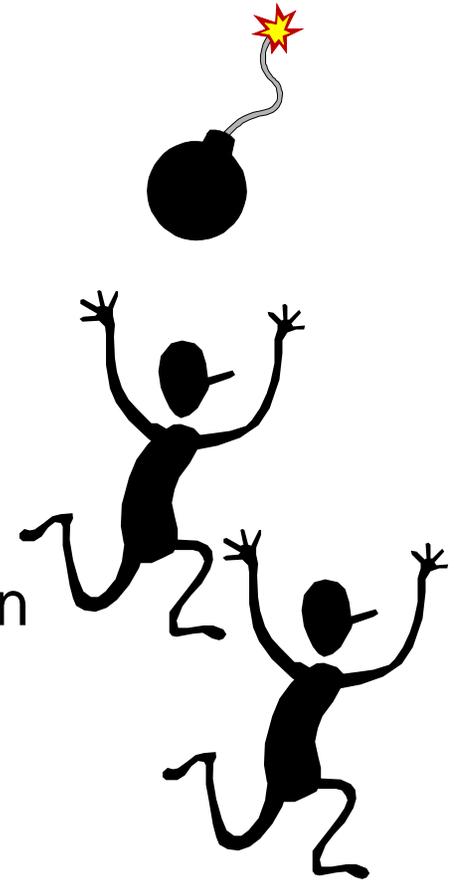
# BCP First Points to Consider

- BCP takes longer than expected to install.
- BCP can be modeled after and integrated into other types of GXP/validation planning and testing for IT and laboratory facilities including the animal vivarium.
- BCP never ends!!

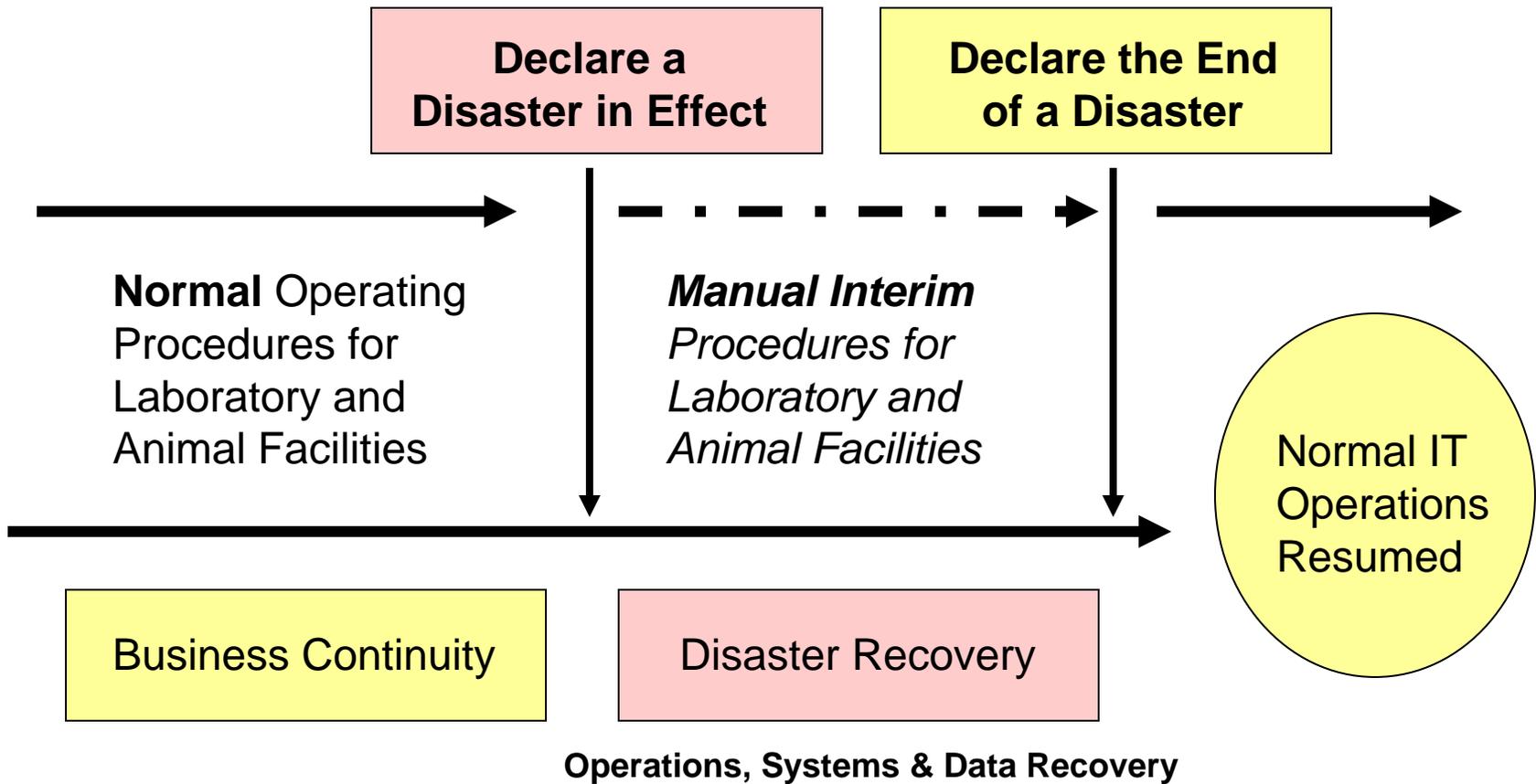


# BC Program vs. BC Plan

- A Business Continuity Program is the organizational approach to develop, test, and maintain a Business Continuity Plan.
- Without an ongoing BC Program, the BC Plan is just paper and can even be dangerous if it gives outdated information at a time of great need.
- A good BC Program integrates the BC Plan with ongoing GXP validation and Quality Assurances activities.



# BCP Example - IT & GLP Facilities



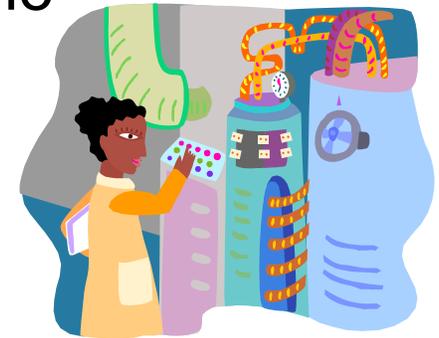
# BCP Goals for IT & Toxicology

- Minimize the impact/loss to analytical lab and animal/vivarium operations from interruption or loss of IT systems and services
- Maintain the trustworthiness of GLP study data pre, mid, and post disaster
- Restore normal operations and recover data from archives post disaster



# Laboratory BC Planning Phase

- Identify an Executive Sponsor - **essential**
- Identify BCP scope & participants
- Examine functional and lab systems within the scope for inter-dependencies
- Define a Way Forward approach to develop and implement the BC Plan



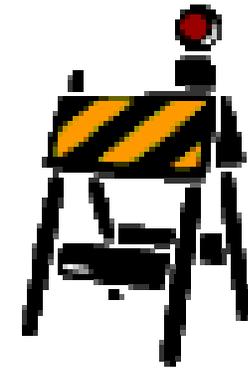
# Impact Assessment Phase

- Baseline internal and external laboratory and vivarium functions that use computerized systems
- Analyze impact on GLP study data and operational costs for system loss
- Develop interim alternative, recovery, and resumption strategies for system loss



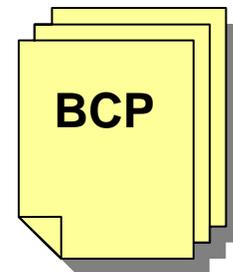
# Impact Assessment Phase

- Identify potential hazards and classify degree of responses for people, animals, GXP study data, and facilities – interim and post the emergency or disaster event
- Plan mitigation of hazards – removal, reduction, segregation, modification, protective equipment, warning systems, redundancy of essential items



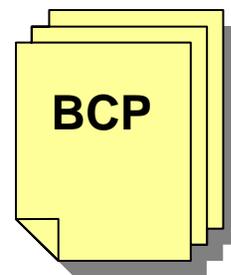
# Develop the BC Plan - Content

- Executive Summary: Interdependencies of BCP with various Disaster Recovery Plans
- Purpose & Scope (Inclusions/Exclusions/Assumptions)
- Definitions & References to related Disaster Recovery Plans
- Lab Continuity Strategy –
  - Disaster declaration process
  - Communications during disaster
  - Lab interim operations & documentation
  - Laboratory recovery actions & documentation



# Develop the BC Plan - Content

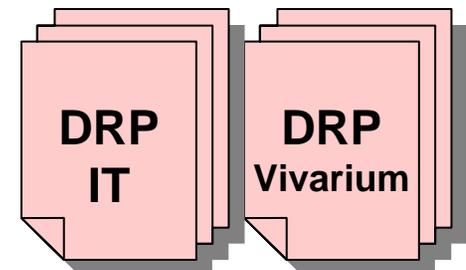
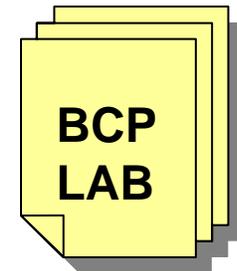
- Lab Resumption Strategy –
  - Disaster over process
  - Close out of interim process
  - Lessons learned documentation
- BC Plan Maintenance Procedure – Review and update process, controlled copies for off site storage by responsible roles
- Document History & Approval Page
- Forms for BC Incident Reporting



BCP Incident Report Form Report Query	BCP Incident Site: BIOData HQ, Concord, MA Report Response
When and where did the disaster/emergency event occur?	<b>Date:</b> June 10, 200X <b>Time:</b> 7:00 AM <b>Resolved at</b> 1:30 PM <b>Incident location:</b> BIOData HQ, Concord
Describe disaster/emergency event. What happened? Who was involved? Was there physical injury to personnel or property?	Network Outage: Various personnel lost access to Internet and email. Two switches used to patch in network connections for BIOData personnel failed.
Was this a real incident or a simulated test?	Real event.
How was the event resolved e.g., who took what actions?	Discovered by early arrivals. Reported by Q. Douglas to Network Admin M. Chilton and P. Massey via cell phone. Diagnosis of intermittent failures was difficult. Ultimately replacing the switch and reconfiguring the panels solved the problem.
What was the business impact to the site?	No email, no Internet, and no internal LAN connection for 6 hours of the business day.
What was the business impact for the company as a whole?	Productivity greatly reduced for 6 hours. No development or testing could be performed because couldn't reach servers or repositories. Rest of organization had no calendars, email, etc.
What lessons were learned by the event?	There had been some warning signs that the switch was "flakey."
How could BIOData prevent or mitigate the impact of such an incident in the future?	Given the cost of a switch (\$400-500) and the business impact of a switch failure, it seems wise to keep a "hot" spare switch on site. Automated ping testing could be improved/added against strategic servers and applications.
Was the Site Continuity Checklist followed?	This form was not in use at the time of the event.
What updates need to be made to the Site Continuity Checklist for future events?	To be determined.
Report author's signature and date of Report	<b>Author's Name:</b> Qylan Douglas <b>Signature:</b> _____ <b>Qylan Douglas</b> _____ <b>Date:</b> ___June 17, 200X___

# Manage the BC Plan

- BCP Training Program – All employees
- Test & Review Process – Walk through the BC Plan to test for practical issues arising & amend BC Plan accordingly – Check for DR Plan(s) interdependencies
- Maintain the BC Plan – Integrate periodic checks of BCP with every system validation effort and internal QA audit
- Implement BC Plan when Disaster strikes



# BCP vs. DRP

- The Business Continuity Plan (BCP) tells us what essential resources are needed to continue business operations.
- The Disaster Recovery Plan (DRP) tells us how to bring back those essential resources.



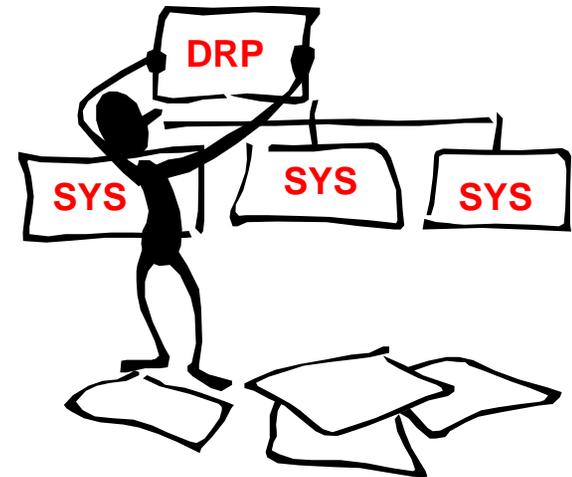
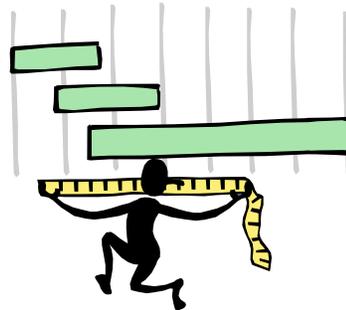
# Goals for IT & Laboratory DRP

- Provide instructions on process to restore critical business services as outlined in the Business Continuity Plan.
- Minimize the impact/loss to animal and analytical lab operations due to interruption or loss of IT systems and services
- Maintain the integrity and trustworthiness of study data/business processing pre, mid, and post disaster
- Restore normal operations and recover data archives post disaster
- Document activities performed during disaster event



# DR Plan Development

- The Disaster Recovery Plan looks to the Business Continuity Plan to provide the list of services to be restored.
- Identify systems that support the services to be restored.
- Define the process for restoration of services



# DR Plan Development

- Three different types of services to restore:
  - IT Processing
  - Analytical Laboratory Processing
  - Animal Facility
- Each type has specific dependencies that need to be addressed

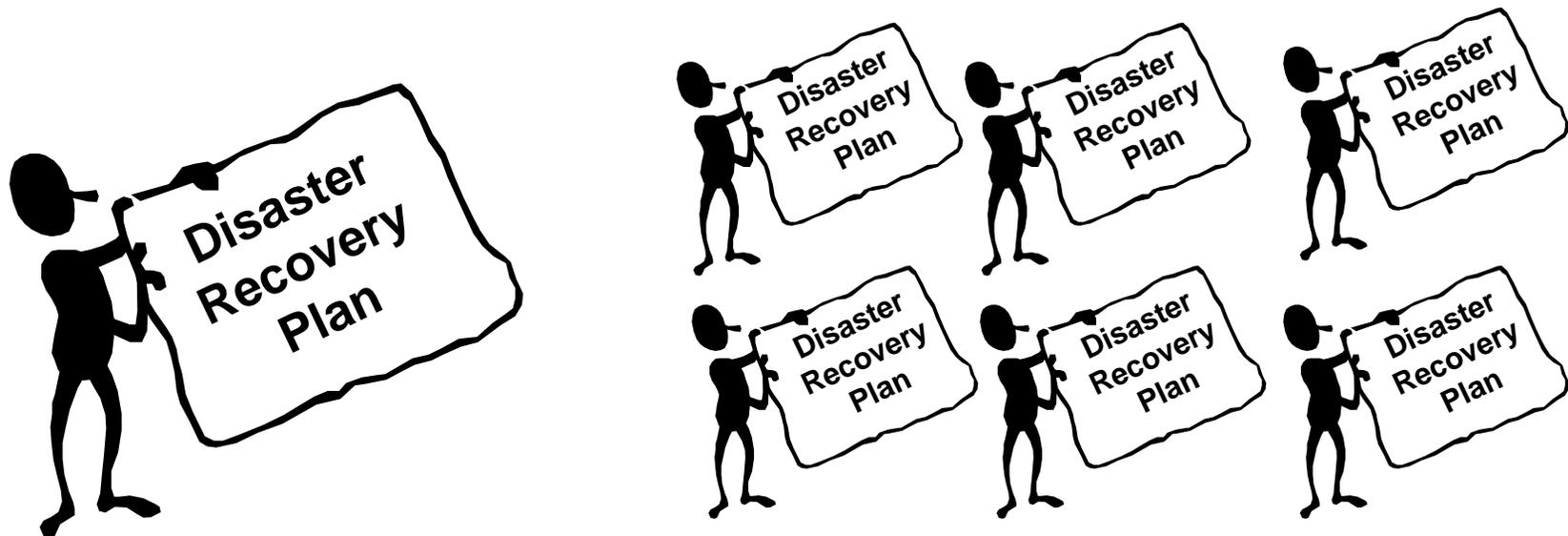


**Note:  
Not to scale**



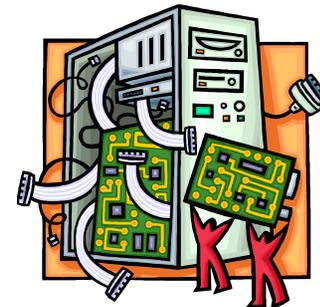
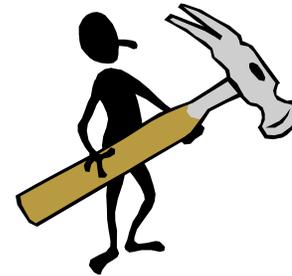
# DR Plan Development - Approach

- You may wish to have one plan with multiple attachments/addendums or separate plans for each service resumption



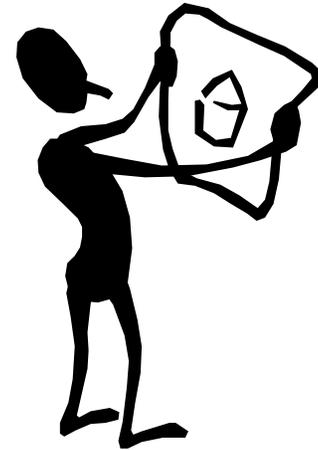
# DR Plan Development - Content

- Executive Summary:  
Interdependencies with BCP and other Disaster Recovery Plans
- Purpose & Scope  
(Inclusions/Exclusions/Assumptions)
- Definitions & References to BCP and other Disaster Recovery Plans
- Resources: Each service to be restored will most likely require specialized skills to perform recovery activities



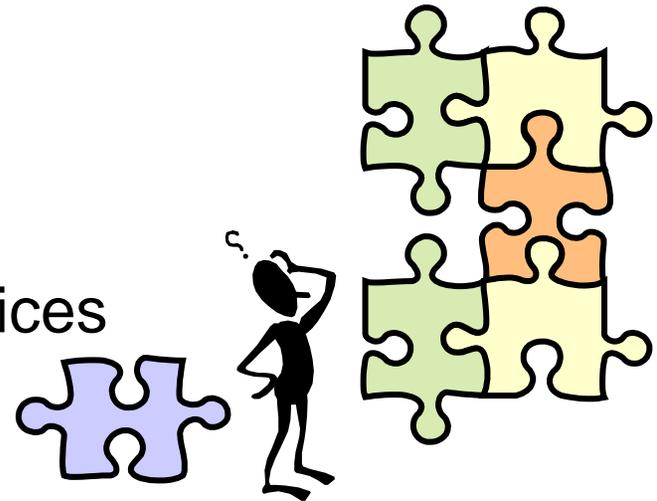
# DR Plan Development - Content

- Resource Availability: Make sure that your resources will be available when needed
- Any specialized information that you would need to be aware of to protect humans, animals or business process during recovery operations



# DR Plan Development IT Services

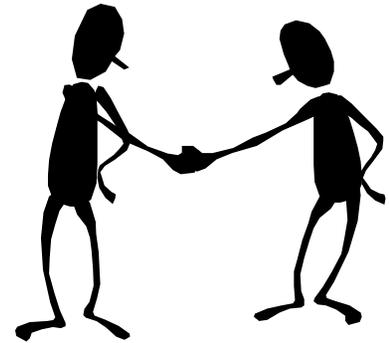
- Identification of computerized equipment that supports GXP services (servers, infrastructure)
- Consideration of external components of the service (telecommunications, external systems)
- Consider the relative cost of different recovery scenarios including cost of running at a reduced capacity and time to recovery



# DR Plan Development

## Analytical Laboratory Processing

- Buy replacement equipment? Equipment Qualification needed?
- Consideration of sister sites for service resumption
- Consideration of reciprocal agreements with other companies for service resumption
- Cross calibration of equipment to eliminate “variance”



# DR Plan Development Animal Facilities

- Protection of Animals and Humans are of major importance
- Consideration of alternate facilities with appropriate controls (environmental, security)
- Consider the relative cost of different recovery scenarios including cost of running at a reduced capacity



# DR Plan Development

## Animal Facilities – Practical Issues

- Appropriate transportation methods and controls



# Plan Development – More Content

- Post-Disaster wrap-up
  - Final analysis of event and records collection
  - Business Continuity Post-Mortem discussion (updates to BCP and DRP)
  - Records for Retention (driven by regulatory and business needs)
  - Where and what to file as records after disaster incident is ended.
  
- Disaster Recovery Plan Maintenance
  - Plan review & update process, controlled copies for off site storage
  
- Document History & Approval Page
  
- Forms for recording DR activities





# Plan Development – More Content

- Additional information – Helpful, but must be kept current!
  - Network Diagrams
    - Diagrams of how systems are interconnected
    - Diagrams of system interdependencies
  - System Inventory Lists
    - Computer systems with serial numbers
    - Lab equipment with firmware revision numbers
    - List of vendors and contacts

# Plan Development - Testing

- The amount of testing is depends on several factors:
  - Impact of testing on the business
  - Cost of testing
  - Risk factor of the recovery plan



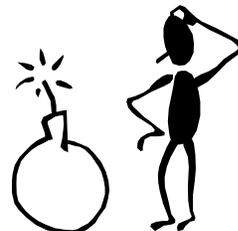
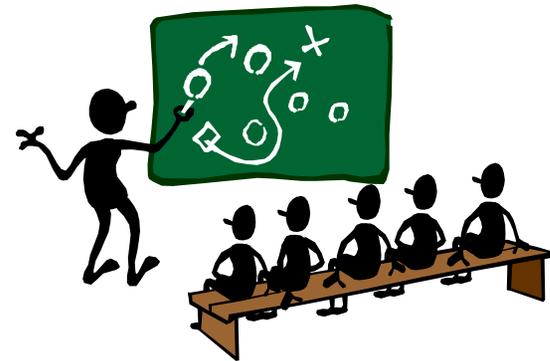
# Plan Development - Testing

- The type of testing will be depend on your environment and the amount of intrusion that you can allow.
- Different services will allow for different testing types
- Testing Types
  - Desktop Walk-through
  - Partial Test
  - Full Test



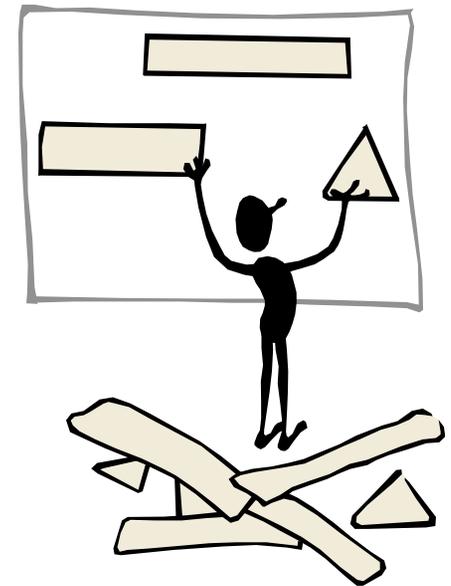
# Plan Implementation and Maintenance

- **DRP Training Program** – All applicable employees (Mix of Technical and Procedural topics.)
- **Maintain the Disaster Recovery Plans**
  - Paper copies at facility and remote
  - Have periodic checks to ensure plans are kept up to date
- **Follow Business Continuity Plan when Disaster strikes**



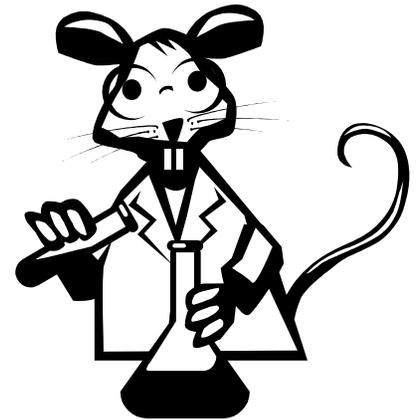
# DRP Final Points to Consider

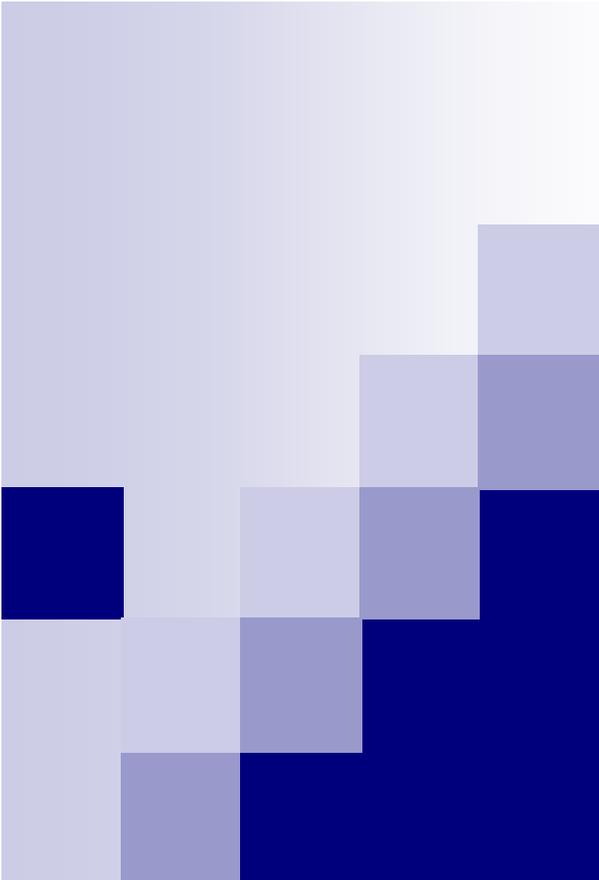
- The purpose of the Disaster Recovery Plan (DRP) is to carry out the Business Continuity Plan (BCP)
- Do not underestimate what it will take to restore services.
- Different types of services could require vastly different strategies.
- The DRP can be highly complex and highly technical
- Disaster Recovery Planning never ends!!



# BCP Final Points to Consider

- BCP takes longer than expected to install.
- BCP can be modeled after and integrated into other types of GXP/validation planning and testing for IT and laboratory facilities including the animal vivarium.
- Business Continuity Planning never ends!!





**Thank You!**  
**Merci! Gracias!**

**Teri Stokes, Ph.D.**  
**[www.GXPInternational.com](http://www.GXPInternational.com)**

Note: Special thanks to Bradley Wong, Allergan, Inc. for  
collaboration with DRP slides.

