Proper Management of Incident Reporting in Biological Research Labs

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Overview

- Definitions
- Steps in an Incident Investigation
  - Notification
  - Exposure Determination
  - Root Cause Analysis
  - Corrective Actions
  - Record Keeping
- Case Studies

Definitions

- **Incident** – an individual occurrence or event (spill, release, injury, exposure, near-miss, facility)
- **Near Miss** – an incident that, under different circumstances, could have resulted in an exposure, spill, release, or personal injury
- **Exposure** – physical contact with an agent (release, break in PPE, mishandling, unknown infectious agent present)
- **Infection** – invasion and multiplication of microorganisms in body tissue due to an exposure (symptomatic, asymptomatic)

Incident Reporting Structure

- **Primary personnel involved** – persons directly involved in incident (laboratory personnel, facility personnel, custodial staff, managers, supervisors)
- **Responsible Personnel** – those with roles and responsibilities in incident management (supervisor, security, police, safety officers, lab managers)
- **Ability to contact Responsible Personnel**– quick and reliable way for all personnel to contact those necessary when an incident occurs
- **Incident Commander (IC)** – designated person responsible for managing responses to incidents (usually involving aspects of life and health)

Incident Management

- **Notification**
  - **Electronic notification**
    - Who receives the notification?
    - Different notification structure for different types of incidents (injury, near-miss)
    - Who responds?
    - Is it an active emergency?
  - **Negative implications for notification**
    - Rewards for incident free time?
    - Consequences for cause of incident?
    - Retaliation for reporting incident
    - Re-assurance from management that reporting will not result in punishment

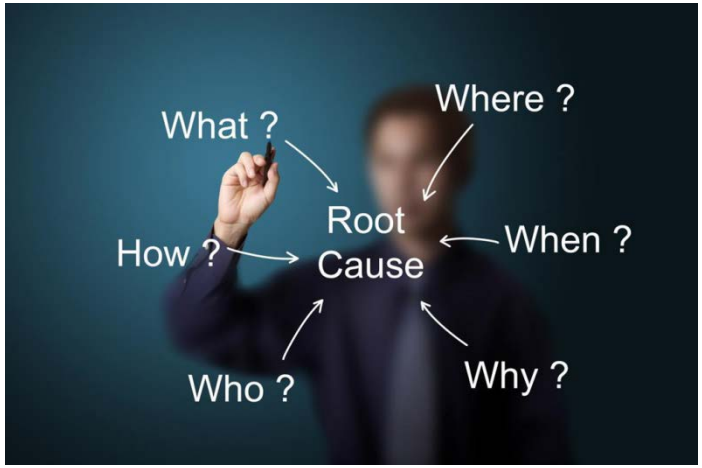
Exposure Determination

- How do you determine probability of exposure to staff?
  - USAMRIID Occ Health Manual
  - Set guidelines for determination
    - Exposure route?, Transmissibility of agent? Break in PPE?, Break in protocol?, Break in skin?, Symptomatic?
  - Discuss between Staff, Health Care Staff, Safety Personnel
  - Directly related to treatment strategies

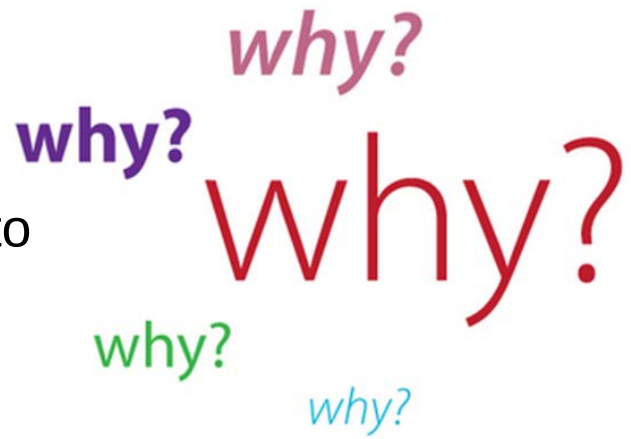
Root Cause Analysis

- Determine **WHY** the incident occurred
- Develop methods to **PREVENT** recurrence

- Root Cause Analysis
  - In depth analysis of cause of incident
  - Multiple variables that account for incident
  - Who, what, when, where, why, how



Root Cause Analysis



- 5 Why Analysis
  - Analysis of asking **WHY** at multiple levels to determine a root cause
  - Centrifuge failure – release of agent

1. Why did the centrifuge fail? (unbalanced)
2. Why didn't the safety cups contain the spill? (O-rings not effective)
3. Why weren't the O-rings effective? (no preventative maintenance)
4. Why isn't there a preventative maintenance program?

Solution: implement maintenance program

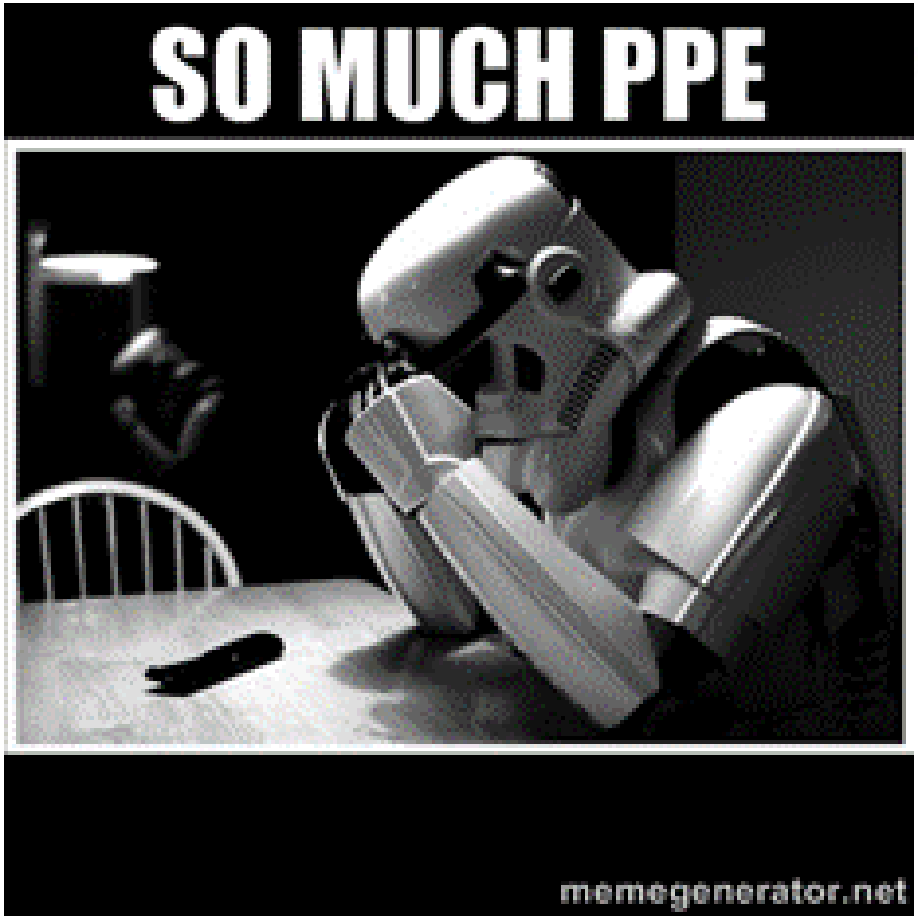
Common Questions?

- What happened?
  - Get an accurate account of
  - rDNA, antibiotic resistance
- Animal information
- Health consult?
- What SOPs were involved?
  - If yes, did the assessment recognize the risks involved in incident?
  - If no, conduct the assessment with the incident in mind

How can we prevent this from occurring in the future?

Questions can vary dependent upon nature of incident

Corrective Actions



- Control effectiveness
- Solution should be…..
  - Sustainable
  - Applicable to all involved
  - Designed so it does not negatively effect research
  - Designed to not limit dexterity
  - Incorporated into future training appropriately

Notifications

Do you know who to notify, and when?
Who should perform the notifications?

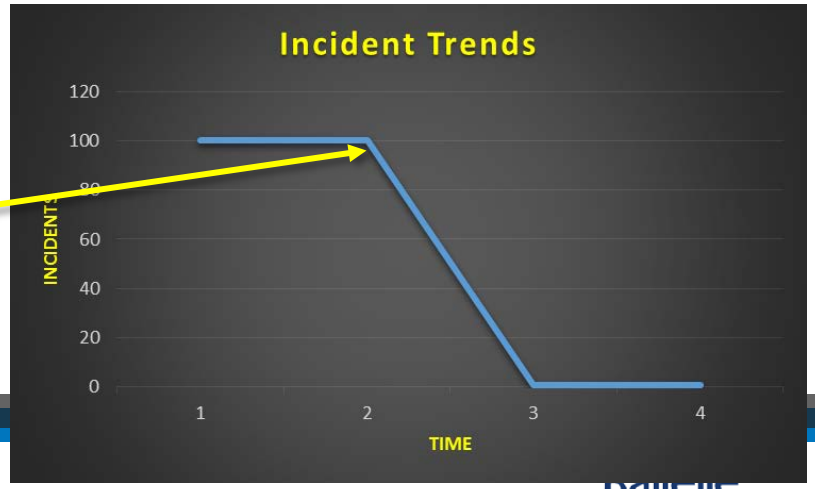
- OSHA 300 - Injuries
- NIH - rDNA
- CDC – Select Agent
- Waste management – State, local authorities
- Internal Organizational Management Chain

OSHA 300+
Injury Compliance Reporting

Trend Analysis

- Positive impacts on Safety are difficult to prove
  - Record incidents over time
  - Record application of corrective actions
  - Correlate safety improvements with rate of incidents
  - Tracking of Near Miss Reporting trends (you want to see good communication… a high number is not a bad thing).
  - Demonstrates effectiveness of Biosafety Program and staff engagement

Corrective actions applied

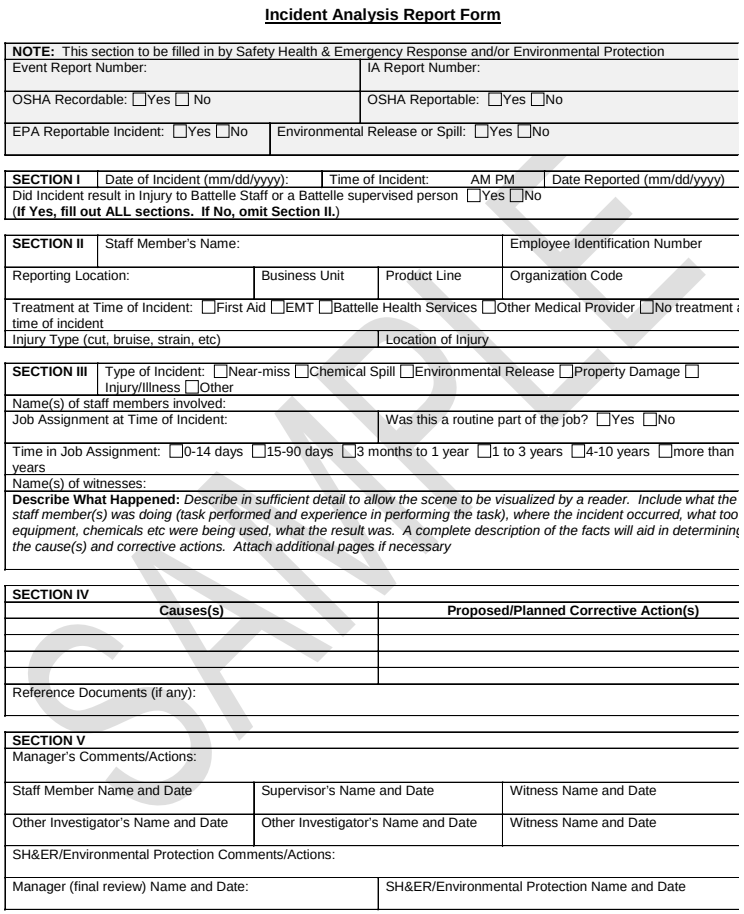


Incident Notification System

- Online notification system
- Any employee can use system for incidents (near misses, emergencies)
- Information sent to managers, supervisors, safety personnel
- Safety can follow-up with incident investigation

Incident Investigation

- Safety personnel conduct investigation for each incident
  - Detailed description of incident
  - Root cause analysis
  - Corrective actions
  - Contact information
  - Central Database
  - Quarterly safety reports
- Trends based on data



Incident Analysis Report Form

NOTE: This section to be filled in by Safety Health & Emergency Response and/or Environmental Protection			
Event Report Number:		IA Report Number:	
OSHA Recordable: ☐Yes ☐ No		OSHA Reportable: ☐Yes ☐No	
EPA Reportable Incident: ☐Yes ☐No		Environmental Release or Spill: ☐Yes ☐No	
SECTION I	Date of Incident (mm/dd/yyyy):	Time of Incident: AM PM	Date Reported (mm/dd/yyyy)
Did Incident result in Injury to Battelle Staff or a Battelle supervised person ☐Yes ☐No **(If Yes, fill out ALL sections. If No, omit Section II.)**			
SECTION II	Staff Member's Name:		Employee Identification Number
Reporting Location:	Business Unit	Product Line	Organization Code
Treatment at Time of Incident: ☐First Aid ☐EMT ☐Battelle Health Services ☐Other Medical Provider ☐No treatment time of incident			
Injury Type (cut, bruise, strain, etc)		Location of Injury	
SECTION III	Type of Incident: ☐Near-miss ☐Chemical Spill ☐Environmental Release ☐Property Damage ☐ Injury/Illness ☐Other		
Name(s) of staff members involved:			
Job Assignment at Time of Incident:		Was this a routine part of the job? ☐Yes ☐No	
Time in Job Assignment: ☐0-14 days ☐15-90 days ☐3 months to 1 year ☐1 to 3 years ☐4-10 years ☐more than years			
Name(s) of witnesses:			
Describe What Happened: *Describe in sufficient detail to allow the scene to be visualized by a reader. Include what the staff member(s) was doing (task performed and experience in performing the task), where the incident occurred, what too equipment, chemicals etc were being used, what the result was. A complete description of the facts will aid in determinin the cause(s) and corrective actions. Attach additional pages if necessary*			
SECTION IV			
Causes(s)		**Proposed/Planned Corrective Action(s)**	
Reference Documents (if any):			
SECTION V			
Manager's Comments/Actions:			
Staff Member Name and Date	Supervisor's Name and Date		Witness Name and Date
Other Investigator's Name and Date	Other Investigator's Name and Date		Witness Name and Date
SH&ER/Environmental Protection Comments/Actions:			
Manager (final review) Name and Date:		SH&ER/Environmental Protection Name and Date	

Case Studies

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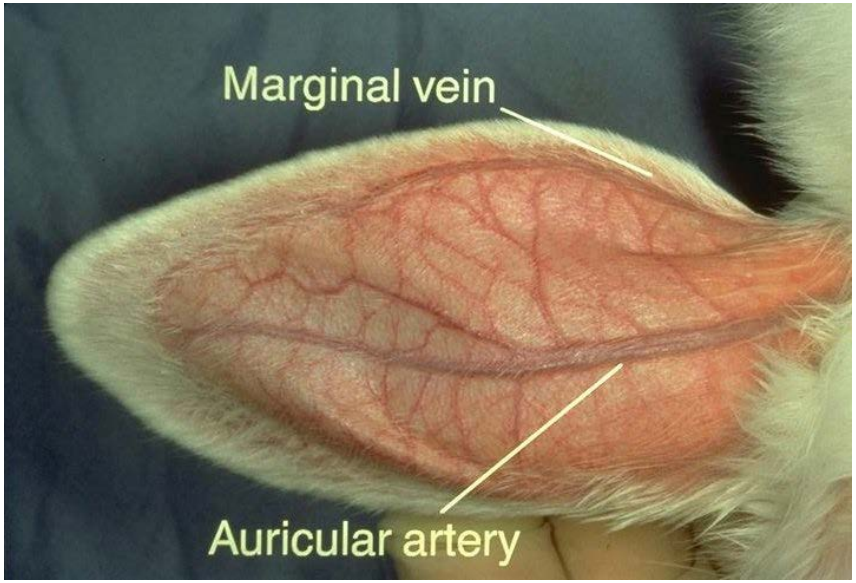
Case Study #1 - Rabbit Blood Draw

- Needlesticks from naïve rabbit blood draws
  - Part of >400 rabbit study (challenged with agent)
- Common aspects
  - Rabbit moved during draw
  - Needlestick to non-dominant hand
  - Acepromazine
  - Physical restraints
  - Improper hand placements



Case Study #1 - Rabbit Blood Draw

- Root Cause
  - Improper hand placement
- Corrective Action
  - Determine proper hand placement
  - Re-train all staff in proper hand placement
  - Demonstrate proficiency
- Outcome
  - **NO** needlesticks during rabbit ear blood draws since re-training

Case Study #2 – Cage Injuries

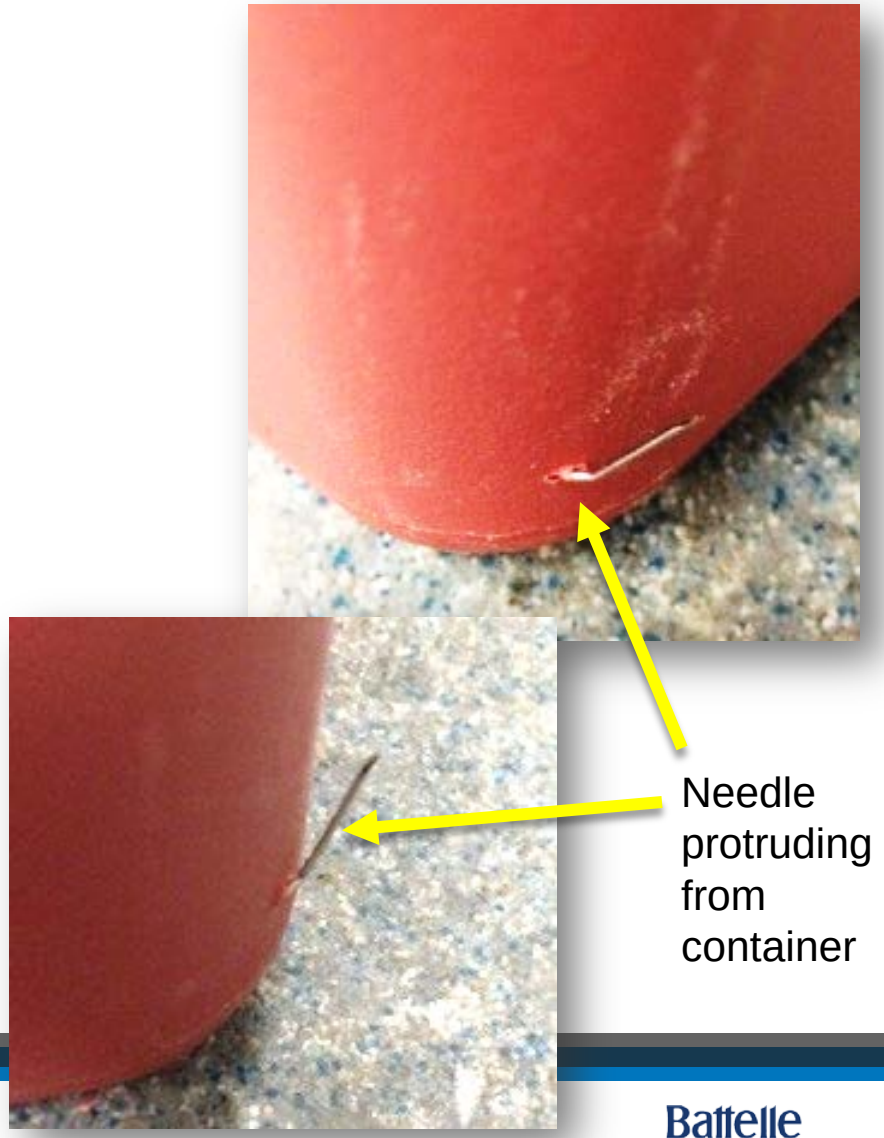
- Cuts and scrapes from sharp areas of animal caging
- Common aspects
  - Unfinished edges and burrs
  - All hand injuries
  - No particular cage handling procedure
    - Cage moving
    - Cage washing
    - Cage cleaning

Case Study #2 – Cage Injuries

- Root Cause
  - No preventative maintenance for sharp edges
- Corrective Action
  - Cages/racks tagged with unique identifier number
  - Faulty equipment placed out of service and repaired
  - Vivo staff inspect for sharp edges and address with emery cloth
  - Database of cage issues tracked
- Outcome
  - **NO** hand injuries from cages recorded since preventative maintenance implemented

Case Study #3 – Faulty Sharps Container

- Needlestick from protruding needle of sharps container
- Aspects
  - Recently autoclaved 8 gallon sharps container
  - Container 1/3 full
  - Processing waste, received needlestick



Case Study #3 – Faulty Sharps Container

- Root Cause
  - Containers were **NOT** recommended for autoclaving
- Corrective action
  - Take out of service
  - Replace with proper containers
- Outcome
  - During investigation, staff member stated this has occurred in the past
  - Never reported due to no injury
  - Near miss reporting could have prevented incident

Conclusions

- Properly maintained incident management system will increase safe work practices
  - Reduce recurrence of incidents
  - Able to see trends in safety (positive, negative)
  - Effective corrective actions are sustainable with trained staff – future incidents will be due to complacency or unforeseen issue
- Ability to share lessons learned from incidents can improve biosafety practices
  - Central database, list-serve
  - All incidents mentioned above were non-reportable, no infections, no agents involved, etc.

“The safety of our staff is our number one priority. I have yet to review an accident or injury that could not have been avoided.”

Dr. Jeffrey Wadsworth, President and Chief Executive Officer

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