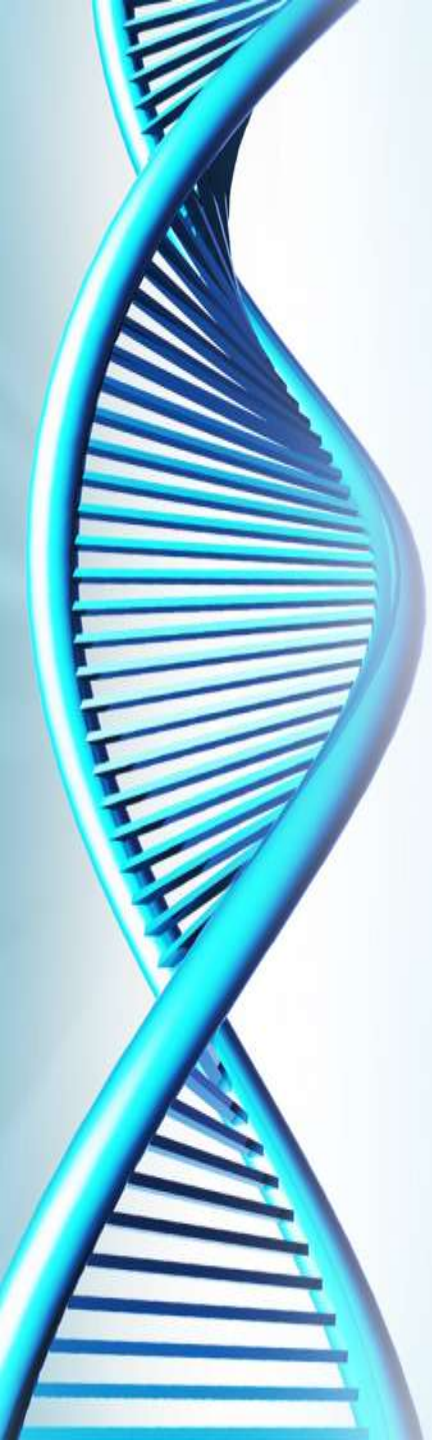




# Incident Reporting: Lessons (Re)Learned

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# **NIH PBBP**

## **NIH Program on Biosecurity and Biosafety Policy**

**The biosecurity and biosafety responsibilities  
formerly carried out by the NIH Office of  
Biotechnology Activities (OBA) are now being  
conducted by the NIH PBBP**



# Incident Reporting Requirements under the *NIH Guidelines*

- Under the *NIH Guidelines* "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days
- Certain types of accidents must be immediately reported to NIH:
  - Spills or accidents in BL2 laboratories resulting in an overt exposure
  - Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure



# Importance of Incident Reporting

- Keeps institutions aware of and accountable for safety-related problems
- Provides NIH PBBP an opportunity to educate institutions about optimal responses to safety events
- Allows NIH PBBP to identify patterns of safety problems at particular institutions, possibly pointing to a need for
  - Broad-based training
  - Interventions in particular laboratories



# Importance of Incident Reporting

- **Allows NIH PBBP to identify patterns of safety problems nationwide which may need broader educational outreach**
  - **Issues with particular practices**
  - **Safety challenges with particular agents**
  - **Points of emphasis in NIH PBBP educational programs**
  - **Areas where the *NIH Guidelines* may need clarification or amendment**

# Incident Reporting FAQs



## *Frequently Asked Questions for Labs Conducting Recombinant or Synthetic Nucleic Acid Research*

### Reporting of Incidents Related to Research Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids to the National Institutes of Health (NIH) Program on Biosecurity and Biosafety Policy (PBBP)

#### **1. What kinds of incidents involving research subject to the NIH Guidelines must be reported to the NIH PBBP?**

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to NIH, within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BSL2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

#### **2. How serious must a problem be to warrant reporting to NIH PBBP?**

Any spill or accident involving recombinant or synthetic nucleic acid molecule research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to NIH PBBP. These kinds of events might include skin punctures with needles containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to NIH PBBP.

Minor spills of low-risk agents not involving a breach of containment that was properly cleaned and decontaminated generally do not need to be reported. NIH PBBP should be consulted if the Institutional Biosafety Committee (IBC), investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting. NIH PBBP can assist in making this determination.

#### **3. Who is responsible for reporting incidents involving research subject to the NIH Guidelines to NIH PBBP?**

Under the NIH Guidelines incident reporting is articulated as a responsibility of the Institution, IBC, Biological Safety Officer, and Principal Investigator. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient.

#### **4. What information should incident reports include?**

Incident reports should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to preclude its recurrence. An

# Incident Reporting Template

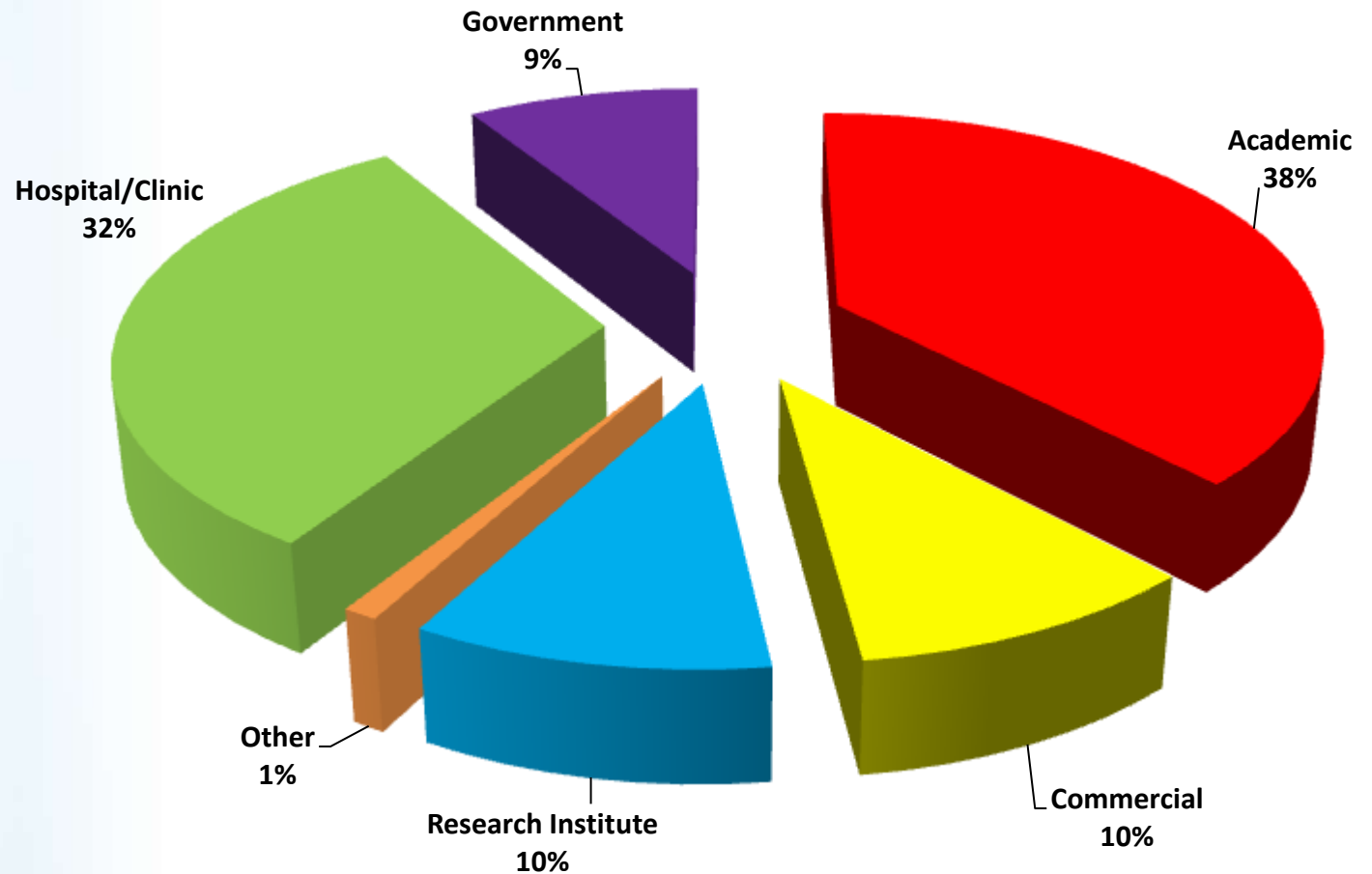


**Template for Reporting Incidents Related to Research Subject to the  
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids  
to the National Institutes of Health (NIH)  
Program on Biosecurity and Biosafety Policy (PBBP)**

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports  
NIH Program on Biosecurity and Biosafety Policy  
6705 Rockledge Drive, Suite 750  
Bethesda, Maryland 20892-7985  
(For all non-USPS deliveries use Zip Code 20817)  
Telephone 301-496-9838  
Fax 301-496-9839  
E-mail: [PBBP@od.nih.gov](mailto:PBBP@od.nih.gov)

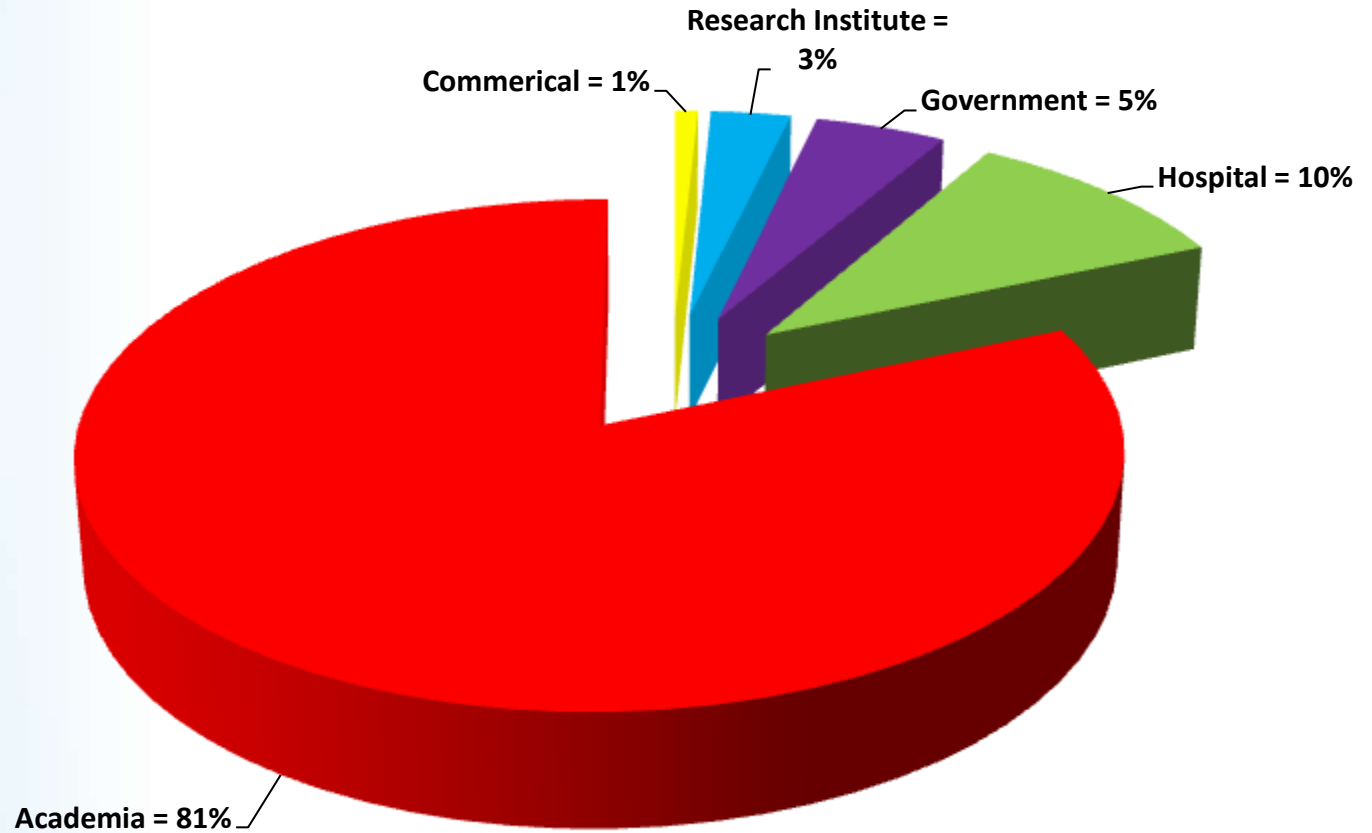
# IBCs Registered with NIH PBBP (October 2014)



Total = 883

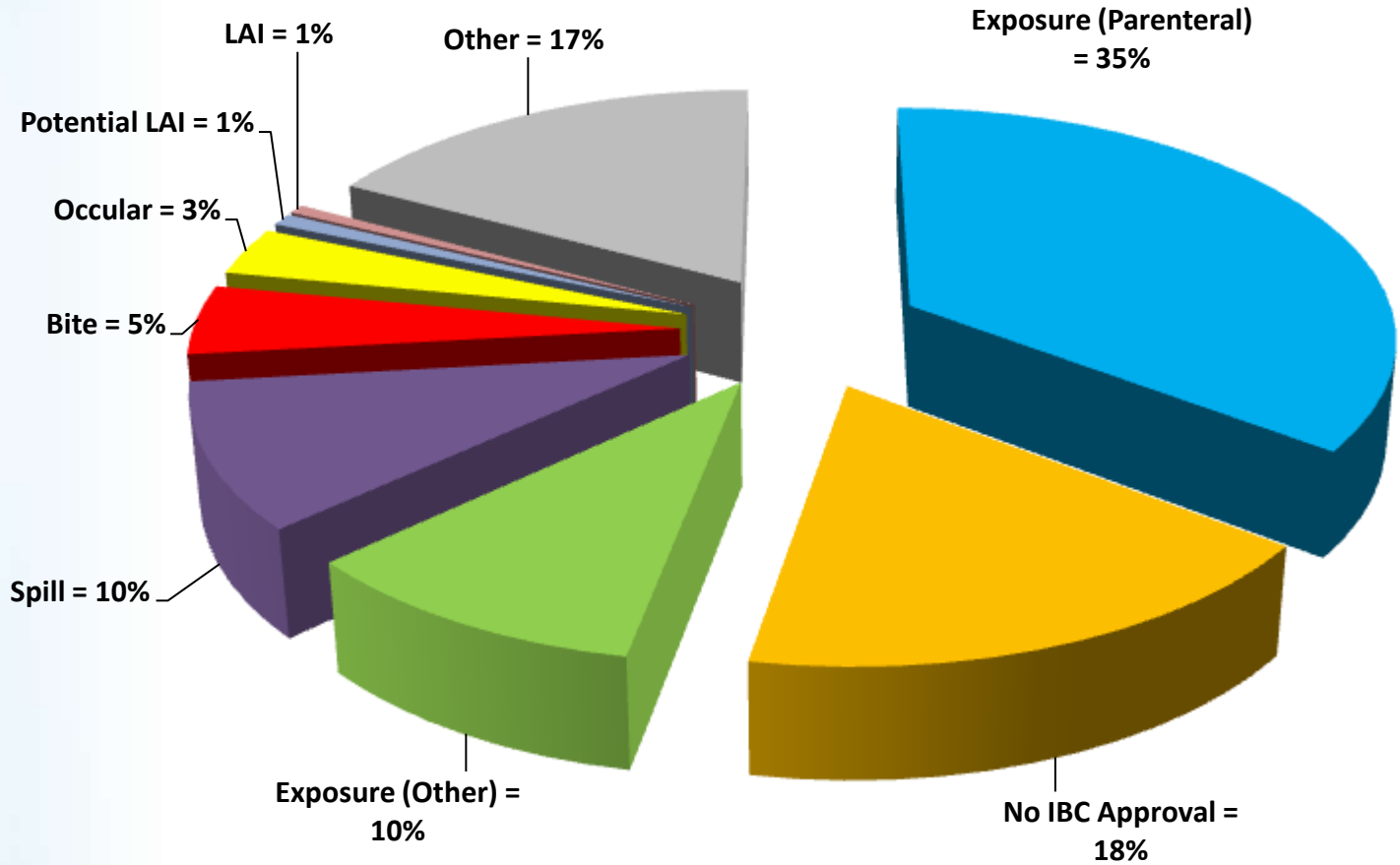


# Incident Reports by Institutional Type (2010 – 2014\*)



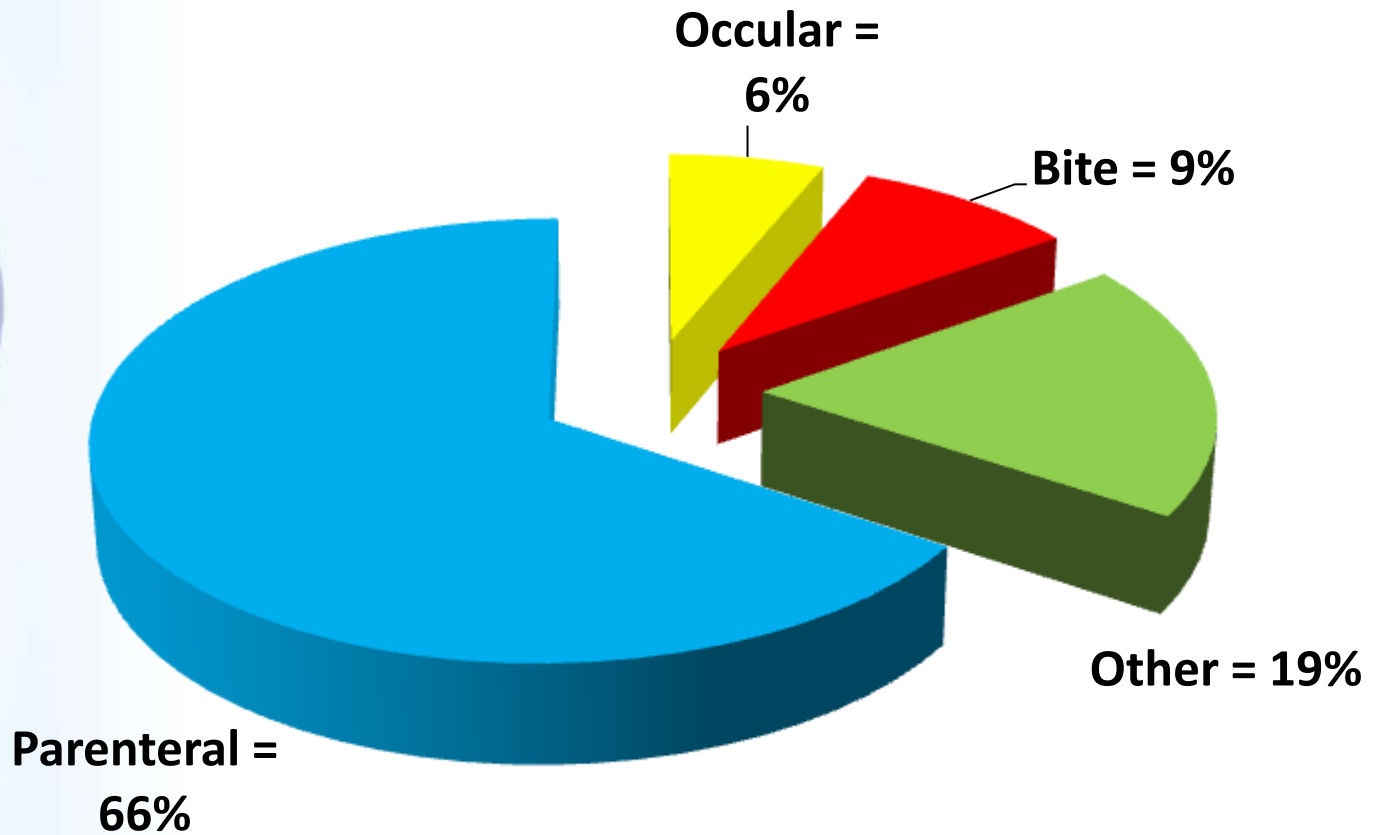
\*Through July 2014

# Reported Incidents by Type (2010 – 2013)

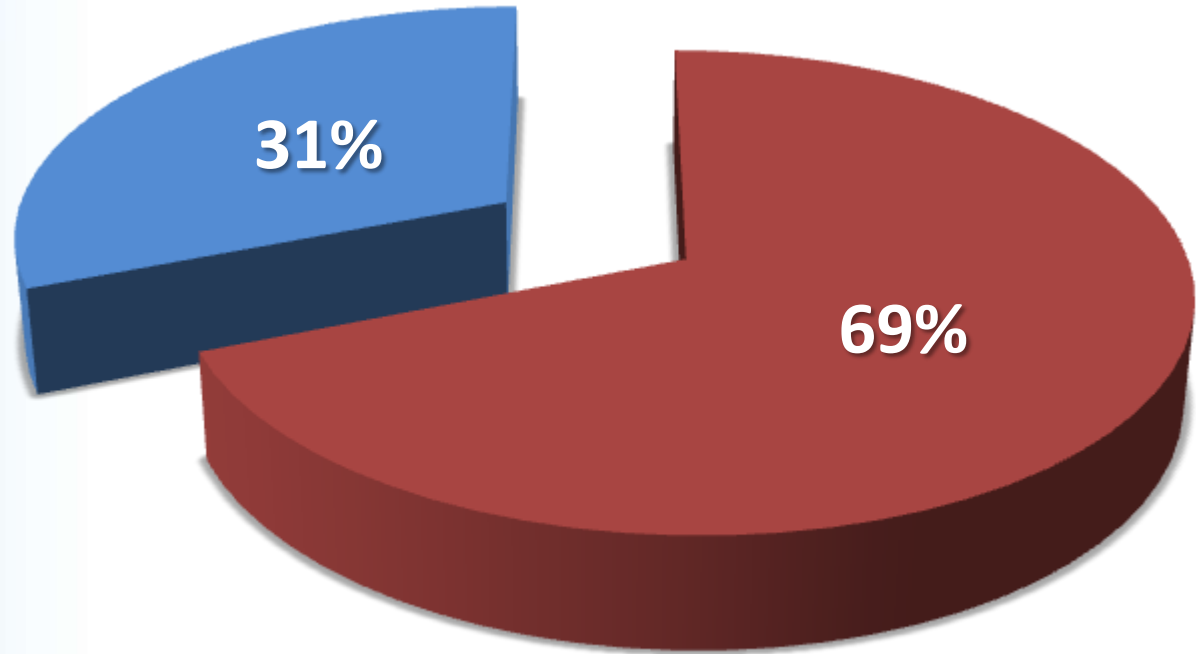


“Other” includes: equipment failure, loss of containment, etc.

# Exposure Incidents by Type (2010 – 2013)



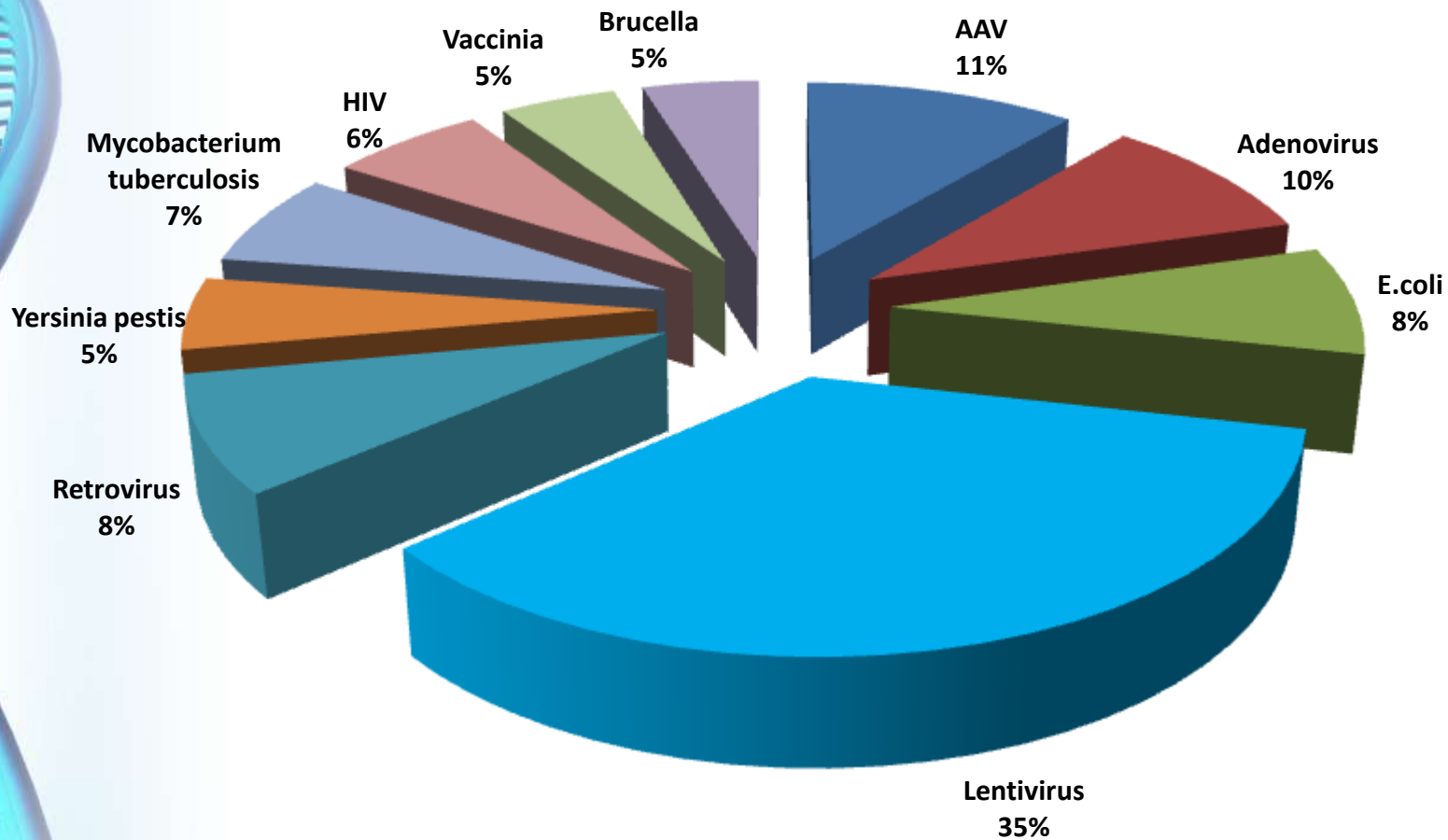
# Institutions Reporting Incidents\* 2010-2012



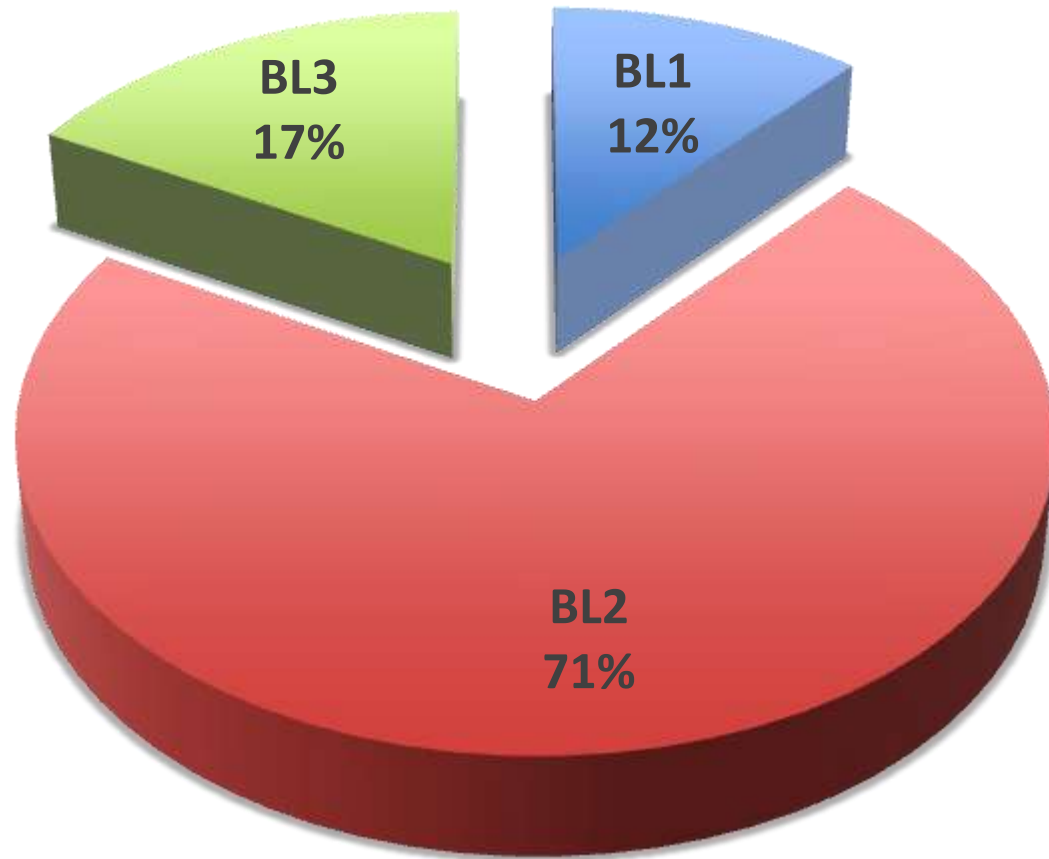
- Institutions that have been site-visited
- Institutions that have NOT been site-visited

\*(Excluding Failure to Obtain IBC Approval)

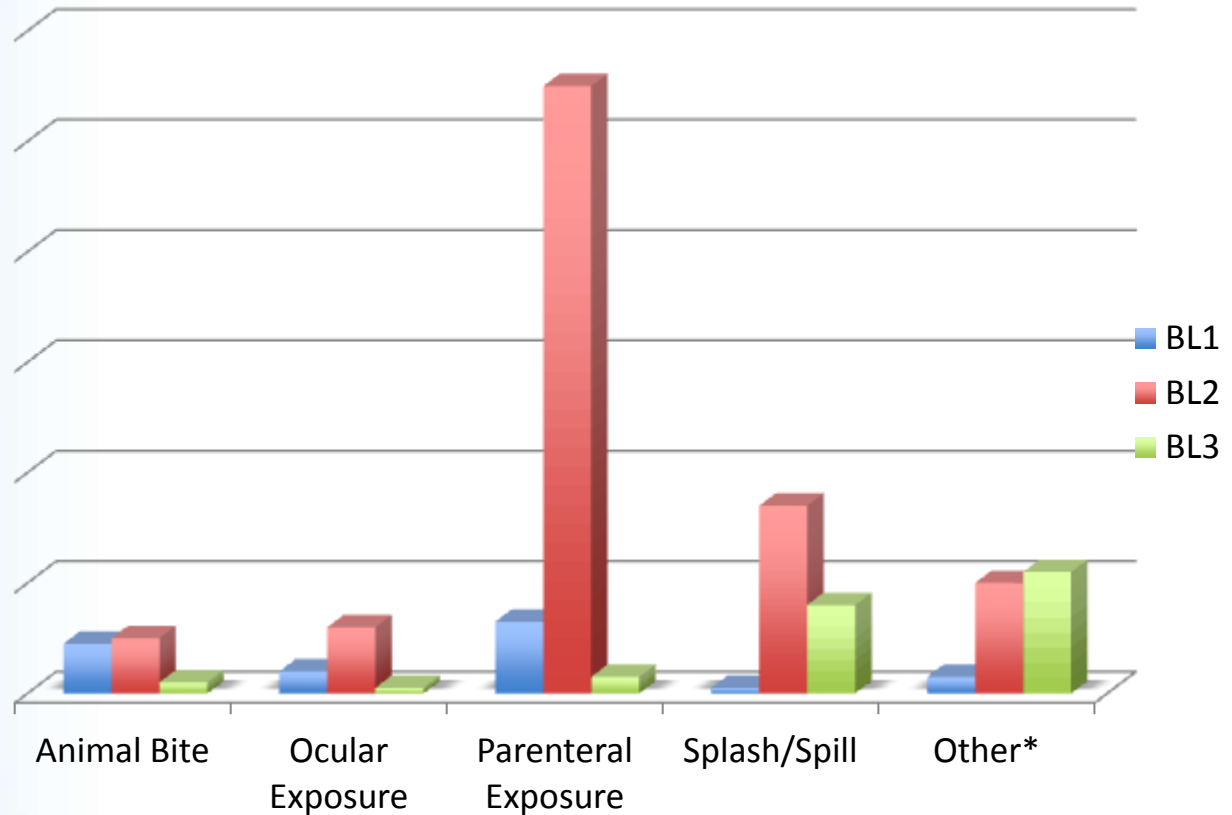
# Top 10 Agents Reported 2010-2013 (60% of Total Exposures Reported)



# Incidents reported to OBA by Biosafety Level (2010 – 2012)

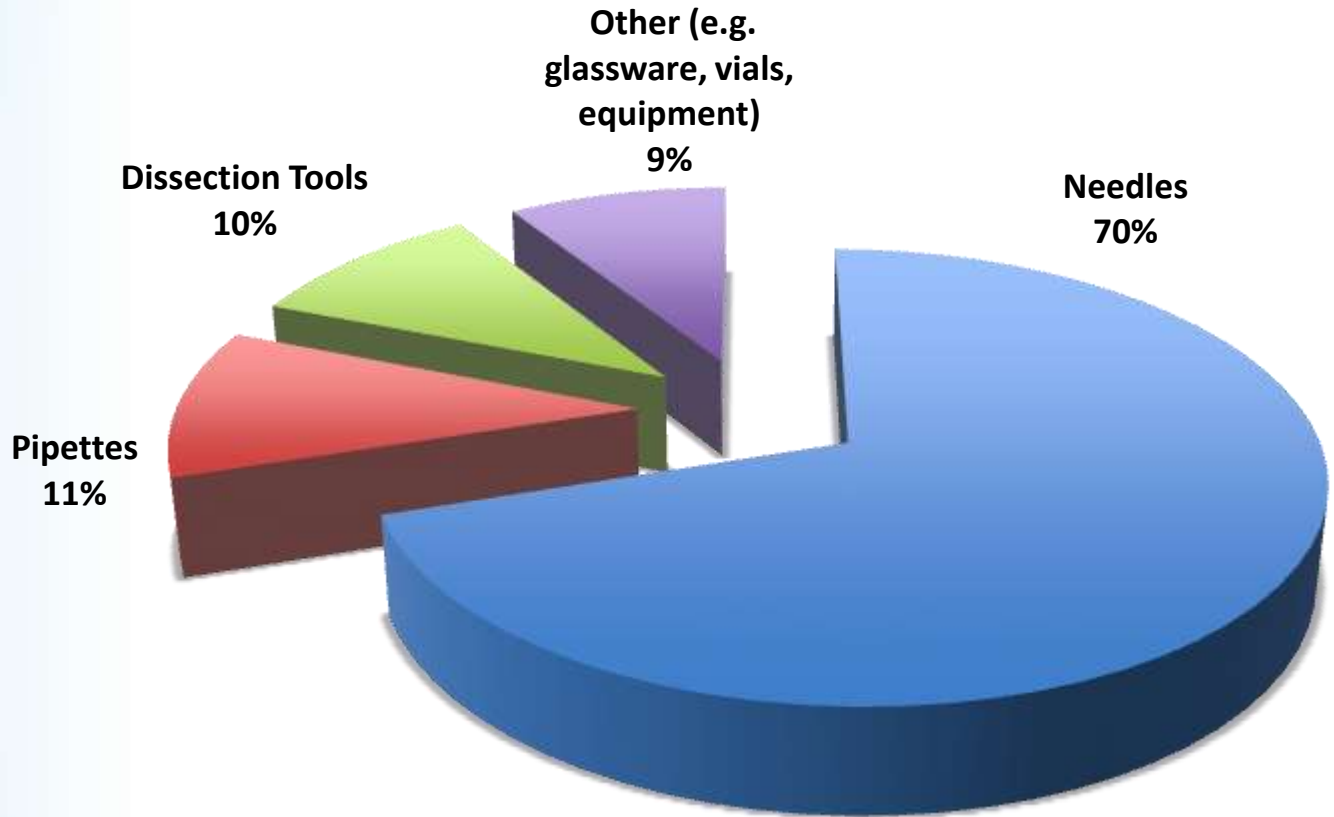


# Incidents Reported to OBA (2010-2012)



\* Includes: equipment failure, containment violation, potential exposure, etc. (excluding failure to obtain IBC approval)

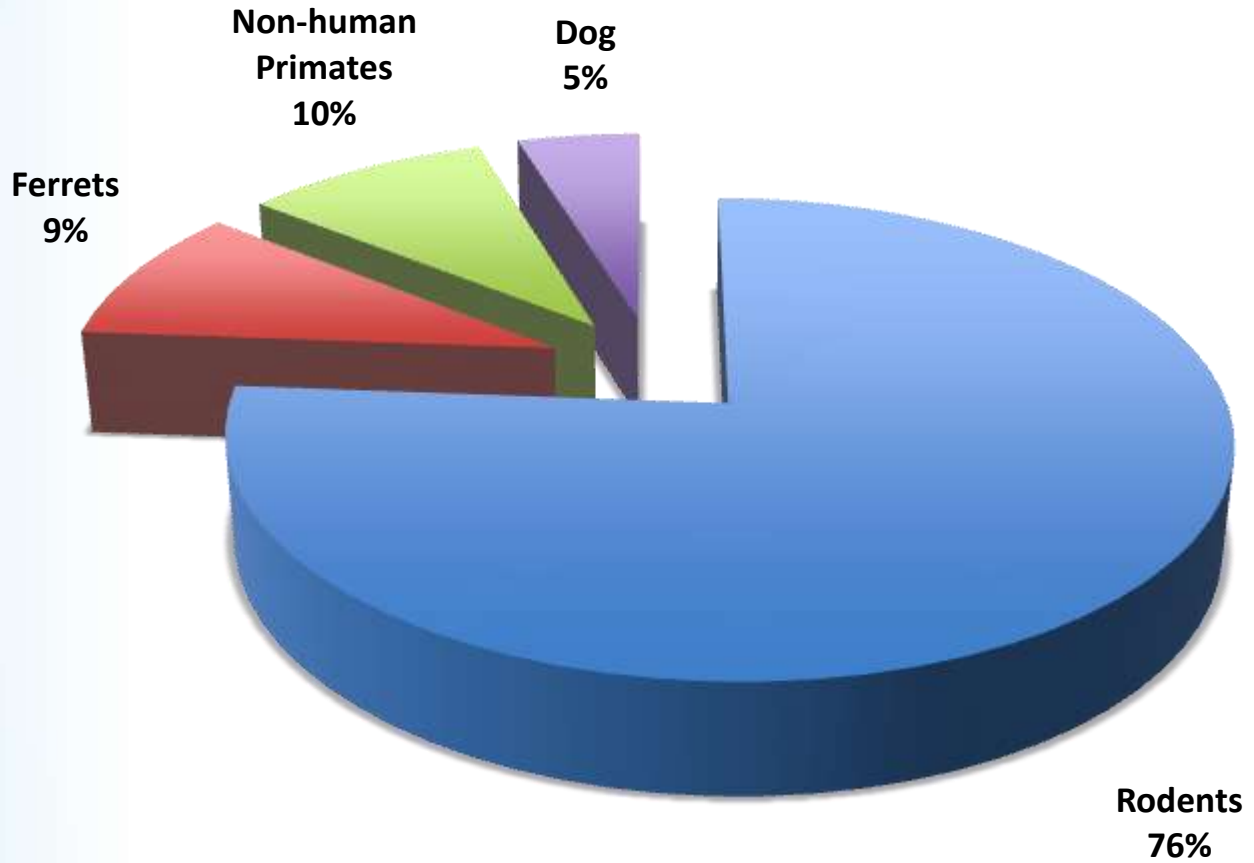
# Parenteral Exposures (2010 – 2012)



**Approximately 30% of parenteral exposures occurred while handling a live animal**



# Animal Bites (2010 - 2012)



***Mustela putorius furo* (Jack 'n' Jill)**





# **We know you know.... But...**

- **Ensure proper PPE use at all times, ESPECIALLY EYEWEAR**
- **Legs and feet should be covered**
- **Ensure proper posting of signage for potential hazards, SOPs, and emergency response procedures**
- **Be constantly aware of all types of experiments being conducted, whether they have been approved, and whether they are being conducted at the appropriate containment level**



# **We know you know ... But ...**

## **Common Sharps Sense – Top 10**

- 1. Conduct frequent training on proper sharps use and disposal.**
- 2. Pay special attention when using sharps, avoid recapping needles**
- 3. Empty sharps disposal containers regularly. Don't compact with hands or try to overstuff when full.**
- 4. Don't place sharps disposal containers next to regular trash cans.**
- 5. Don't "retrieve" items from sharps containers.**
- 6. Ensure animals are properly restrained or anesthetized before attempting an injection.**
- 7. Use plastic rather than glass, or sharps with built in safety features when possible**
- 8. Inspect glassware carefully before use.**
- 9. Tidy up breakages and equipment.**
- 10. Avoid multiple researchers working in close proximity with sharps if possible.**



# We know you know ... But...

- Make sure THEY know
  - Training ...training ... and more training
  - Provide specific examples of what can go/has gone wrong
  - Stress importance of reporting and requirements to do so (and that it's not punitive)

# Contact PBBP

**Program on Biosecurity and Biosafety Policy  
Office of the Director  
National Institutes of Health  
Suite 750  
6705 Rockledge Drive,  
Bethesda, MD 20892-7985**

**Phone (301) 496-9838  
Fax (301) 496-9839**



**[PBBP@od.nih.gov](mailto:PBBP@od.nih.gov)**

# Questions

