

**Primary Containment of Non-Human Primates
in Biosafety Level 4 Laboratories:
Challenges and Best Practices**

**Office of Science Policy
National Institutes of Health**

**March 28, 2014
NIH Campus, Building 31, Conference Room 6C6
Bethesda, MD**

AGENDA

8:00 AM **Welcome and Opening Remarks**

Co-Chairs:

Jacqueline Corrigan-Curay, JD, MD

Office of Biotechnology Activities (OBA)

Office of Science Policy, National Institutes of Health (NIH), Bethesda, MD

Robbin Weyant, PhD, RBP

Division of Select Agents and Toxins (DSAT), Centers for Disease Control and
Prevention (CDC), Atlanta, GA

*Session I: Biosafety Containment Guidance for Housing
Non-Human Primates (NHPs) in BL4 Laboratories and
Animal Welfare Considerations*

8:20 AM ***Principles of Biosafety and the Biosafety in Microbiological and Biomedical
Laboratories (BMBL)***

RADM Deborah E. Wilson, DrPH

Division of Occupational Health and Safety (DOHS), NIH, Bethesda, MD

8:45 AM ***NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic
Acid Molecules***

Jacqueline Corrigan-Curay, JD, MD

8:55 AM **Questions**

9:00 AM ***Non-Human Primates: Animal Welfare Requirements in Research Settings***
John Bradfield, PhD

Association for Assessment and Accreditation of Laboratory Animal Care
(AAALAC), Frederick, MD

9:20 AM **BREAK**

*Session II: Handling NHPs under
Containment Levels BL3 and BL4*

9:30 AM

Panel Discussion

Moderators:

RADM Deborah Wilson, DrPH, CBSP

Richard Henkel, PhD

DSAT, CDC

Panelists:

Paul Meechan, PhD, MPH, RPB, CBSP

Office of Health and Safety, CDC

Penny Holeman, MPH, MA, MS, RBP, CBSP

Lovelace Respiratory Research Institute (LRRI)

Albuquerque, NM

Dee Zimmerman, MA

Environmental Health and Safety, University of Texas Medical Branch (UTMB)

Galveston, TX

Nancy Hoe, PhD, CBSP

DOHS, NIH

Mary Louise Graham, MSc, RM (C.C.M.)

Office of Biosafety and Biocontainment Operations

Public Health Agency of Canada

Ottawa Ontario, Canada

Discussion:

- How is primary containment defined in a BL3 lab *versus* a BL4 suit lab?
 - How are the issues of primary containment for NHPs different for research at BL3 *versus* BL4 laboratories, e.g., if primary containment caging is not used at BL4 but often is used at BL3, what might be the reasons to support this difference?
- What are the standard design elements (e.g. double barrier construction such as doors, airlocks, autoclaves) and engineering standards (e.g. air-flow, pressure differentials, waste treatment) that are required for a high containment facility?
- In practice, NHP can be housed as large or small animals. What safety criteria should be used to determine the most appropriate type of containment? What engineering requirements should be in place for an animal housing room if open cages are to be used?

10:30 AM

BREAK

10:45 AM

What are the key transmission risks for the RG4 viruses being studied?

Gary Kobinger, PhD

National Microbiology Laboratory, Public Health Agency of Canada

*Session III: Current Practices for Research with NHPs under
High Containment (BL4)*

11:00 AM

Round Table

In this session we will briefly review current practices.

Representatives from seven laboratories will provide 5-7 minute presentations that respond to the presentation outline.

Moderators:

Freeda Isaac, DVM

Animal and Plant Health Inspection Service (APHIS)

US Department of Agriculture (USDA)

Riverdale, MD

Robbin Weyant, PhD, RBP

Presentation Outline:

- Describe which species of NHPs your lab works with.
- Describe how NHPs are currently housed in your BL4 laboratory.
- Describe whether housing differs by type of NHP.
- Describe access points to animal rooms.
- Describe how the NHP housing area(s) is/are separated from adjacent areas within the BL4 laboratory.

Presenters:

Ricardo Carrion, Jr., PhD

Southwest National Primate Research Center

Texas Biomedical Research Institute (Texas Biomed)

San Antonio, TX

Rachel LaCasse, PhD, CMAR, RLATg

Heinz Feldmann, PhD (*by teleconference*)

Rocky Mountain Laboratory (RML)

National Institute of Allergy and Infectious Diseases (NIAID), NIH

Hamilton, MT

Alexander Freiberg, PhD

Robert E. Shope Laboratory, UTMB

Curtis Klages, DVM

Galveston National Laboratory (GNL), UTMB

Gary Kobinger, PhD

Frédéric Jacquot, CEA (MS) (*by teleconference*)
Jean Mérieux Laboratory
Institut national de la santé et de la recherche médicale (INSERM)
Lyon, France

Mark Lever, PhD
Defense Science and Technology Laboratory (DSTL)
Porton Down, United Kingdom

Discussion:
Representatives from other labs will have the opportunity to comment on similarities and differences between what was presented and the practices in their labs.

12:15 PM

LUNCH

<p><i>Session IV: Challenges of Using Primary Containment Housing for NHPs under Containment Level BL4</i></p>
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1:15 PM

Panel Discussion

Moderators:
CAPT Inger Damon, MD, PhD
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), CDC

Marshall Bloom, MD
RML, NIAID, NIH

Panelists:
LTC Neal Woollen, DVM, PhD
US Army Medical Research Institute of Infectious Diseases (USAMRIID)

Curtis Klages, DVM
Galveston National Laboratory (GNL), UTMB

Andreas Kurth, PhD
Robert Koch Institute
Berlin, Germany

Don Gardner, DVM
NIAID, NIH

Nathaniel Powell, DVM, MS
Coordinating Center for Infectious Diseases, CDC

Mark Lever, PhD

Discussion:

- What are the risks of working with primary caging?
 - To the animals?
 - Are the considerations different depending upon the species of the NHP?
 - To the lab workers?
- What are the risks of soft-wall barriers, e.g. biobubbles?
 - To the animals?
 - To the lab workers?
- Animal transport methods in a facility
 - How are animals moved from the holding area to a procedure area
 - How is containment maintained during this procedure
 - What risks are involved in the transport of NHP

Session V: Alternative Strategies to Achieve Primary Containment

2:30 PM

Panel Discussion

Moderators:

Jacqueline Corrigan-Curay, JD, MD

Robbin Weyant, PhD

Panelists:

Peter Jahrling, PhD

NIAID, NIH

Jean Patterson, PhD

Department of Virology and Immunology, Texas Biomed

James LeDuc, PhD

UTMB

J. Patrick Fitch, PhD

National Biodefense Analysis and Countermeasure Center (NBACC)

Frederick, MD

James Levin, DVM, DACLAM

Boston University

Boston, MA

Glenn Marsh, PhD

Commonwealth Scientific and Industrial Research Organisation (CSIRO)

Geelong, Australia

Discussion:

- Is it possible for the room to become the primary containment enclosure and meet the biosafety standards for BL4?
 - Should this be considered for all NHPs or only those of a particular size for which primary containment caging presents unique challenges?
 - What combination of physical barriers, engineering controls, and special practices should be in place to provide containment equivalent to ventilated enclosures or bio-isolators?
 - If the room is the primary containment enclosure, what separation should there be between the animal housing room and other BL4 space?
 - How is this separation achieved?
 - If the room is used as primary containment, what changes need to be made to the emergency response plan in order to respond to a loss of containment?

4:15 PM

BREAK

4:30 PM

Summary of the key points raised and outstanding questions:

- What are the key differences in the current biosafety guidances regarding housing of NHPs at BL4?
- What are the current practices and what are the main challenges?
- What are the alternatives that could meet the objectives of containment for a BL4 laboratory, which include optimizing laboratory worker safety and the safety of the public, as well as animal welfare?
- What are the standard engineering and other requirements that should be in place when alternatives to primary containment caging are being considered?

5:15 PM

ADJOURN