

# Update: NIH Sterile and Non-Sterile Processing Facilities

2<sup>nd</sup> Meeting of the NIH Clinical Center Research Hospital Board

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Lawrence A. Tabak, DDS, PhD  
Principal Deputy Director, NIH



# Inspection and Assessment of Facilities

- Following PDS event, an in-depth inspection of all sterile and non-sterile processing facilities occurred
- Engaged Working Buildings, Clinical IQ, and IPS Integrated Project Services
- Many activities are ongoing, but all facilities are in control
- New Office of Research Support and Compliance (ORSC) has been established within the Office of Intramural Research (Michael Gottesman, MD, Deputy Director for Intramural Research)
  - Led by Andy Griffith, MD, PhD; Bruce Burnett, PhD; and Val Bonham, JD
  - Responsible for ongoing monitoring of these facilities and related activities

# Intravenous Admixture Unit (IVAU)

- **Role:** Supply sterile pharmaceuticals by prescription
- **Status:**
  - Operating under a moderate level of control
  - Construction and process improvements complete
  - Constructing an interim-IVAU (I-IVAU) in former PDS space
  - Once I-IVAU is operational, current IVAU will be closed for renovation (~2 yrs)
  - After renovations, IVAU operations will be returned to renovated facility and I-IVAU space will be used for additional cell processing



# Department of Transfusion Medicine (DTM)

- **Role:** Supply infusible materials for cell-based therapies including engineered immune cells and gene therapies
- **Status:**
  - Operating under minimum physical control with robust administrative controls currently
  - July 2016 unannounced FDA inspection – no formal findings
  - Constructing a new facility (2J) and then will renovate current facility (3T)



# Positron Emission Tomography (PET) Facilities

- **Role:** Produces sterile PET radiopharmaceuticals for human scanning studies
- **Status:**
  - **CC Facility:** Monitoring continues and most physical concerns have been resolved
  - **NIMH Facility:** Consolidating manufacturing activities with the CC PET Department



# Nuclear Medicine Department Radiopharmacy

- **Role:** Provides only commercially available nuclear medicine radiopharmaceutical products purchased from local sources
- **Status:**
  - Has not manufactured product directly
  - Construction to enable sterile manufacturing



# NCI Surgery Branch Cell Processing Laboratory (Located in CRC 3 West)

- **Role:** Investigational cell and gene therapy products
- **Status:**
  - Construction/renovations to remediate the space, as well as administrative efforts (e.g., SOPs, equipment)
  - Reopened with restricted manufacturing with moderate facility control



# NCI Surgery Branch Cell Processing Laboratory (Expansion Space in Building 53)

- **Role:** Same role as CRC 3 West; this project improves capacity
- **Status:**
  - Building 53, an unused facility on the Bethesda campus, will house a cGMP facility constructed with prefabricated modular components
  - Project will significantly increase the volume of cell processing
  - Working Buildings will develop Basis of Design, attend Type C Meeting, provide design and construction surveillance, and provide facility qualification support



# NCI Surgery Branch Vector Production Laboratory and Thoracic Epigenetics Laboratory

## ■ Role:

- **Surgery Branch Vector Production (SBVP) Lab:** Produced vectors for use in manufacture of engineered cells
- **Thoracic Epigenetics (TE) Lab:** Produced experimental cancer vaccines

## ■ Status:

- **SBVP Lab:** Concerns about physical plant and layout; Trailer 1 purchased to enable work to continue
- **TE Lab:** Irresolvable space layout deficiencies; Trailer 2 designed to enable work to continue, plus the work of 2 other researchers



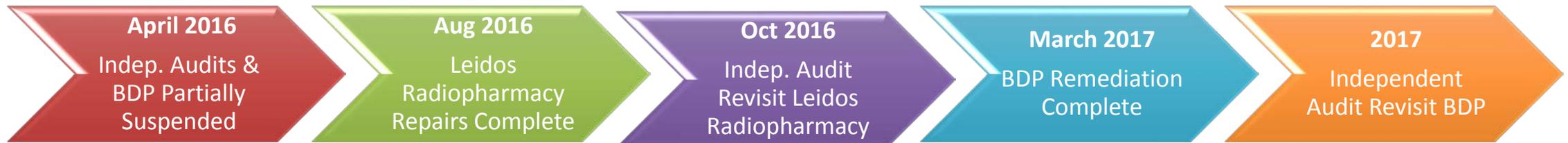
# NCI Biopharmaceutical Development Program (BDP) and Leidos Radiopharmacy

## ■ Role:

- **BDP:** Produces monoclonal antibodies, recombinant proteins, immunotoxins, oncolytic viruses, and vaccines
- **Leidos Radiopharmacy:** Prepares radiopharmaceuticals (short-lived PET agents)

## ■ Status:

- **BDP:** Remediation ongoing and production continuing
- **Leidos Radiopharmacy:** Operating at a high level of control; minimal remediation



# NIAID Vaccine Stock Manufacturing

- **Role:**

- Manufactures viral seed stock drug substance that is then sent to Charles River Labs for additional processing, purification, and release

- **Status:**

- Administrative controls changed to allow for continued operation until renovations could be completed



# NIAID Vaccine Research Center (VRC) Vaccine Pilot Plant and Malaria Vaccine Laboratory

## ■ Role:

- **VRC Vaccine Pilot Plant:** Produces vaccines, monoclonal antibodies, and placebo products
- **Malaria Vaccine Laboratory:** Being considered to produce malaria vaccine

## ■ Status:

- **VRC Vaccine Pilot Plant:** Operating at an exceptionally high level of control
  - No remedial actions were recommended or undertaken
- **Malaria Vaccine Laboratory:** Consultation with CDC
  - Cancelled on-campus planning
  - Planning to perform this work at off campus location

# Comments/Questions?

[Lawrence.Tabak@nih.gov](mailto:Lawrence.Tabak@nih.gov)