

U.S. Department of Homeland Security | Science and Technology Directorate

Scientific, Technical, and Engineering Support (STENS) for the Plum Island Animal Disease Center (PIADC) Decontamination and Closure

Plum Island Closure and Support (PICS) Program
Welcome and Introductory Remarks



Science and
Technology

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DHS STAD

June 29, 2022

Agenda

Welcome and Introductions

Expectations

Presentations

- PIADC Science & Biorisk Mgmt
- PICS Program & STENS Overview
- Biocontainment Virtual Pre-Tour

Biosafety Training

Lunch

Tour of Biocontainment and Reading Room

Biocompound Tour

Closing Remarks



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Scientific, Technical, and Engineering Support (STENS) for the Plum Island Animal Disease Center (PIADC) Decontamination and Closure

Plum Island Closure and Support (PICS) Program
PIADC Background: Scientific Programs and Biorisk Management



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Technology

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June 29, 2022

Overview

- Plum Island Background
- PIADC Mission
- PIADC Scientific Program Summary
- Key Scientific Infrastructure
- PIADC Pathogen Inventory
- PIADC Biorisk Management
Regulatory Framework and Adopted
Standards
- PIADC Biorisk Management: Key
Concepts
- PIADC Operational Material and
Space Decontamination Practices



Plum Island Background

- 840-acre island
- 8 miles from CT and 1.5 miles from NY
- 1897 Plum Island established as part of the coastal defense infrastructure; construction of Fort Terry commenced that same year
- 1952 selected to be home of a national laboratory for Foot-and-Mouth Disease (FMD) research
- 1954 research operations commenced under United States Department of Agriculture (USDA) ownership first in Building 257 and followed by Building 101 in 1956
- Ownership transferred to DHS from USDA as part of Homeland Security Act (2003)



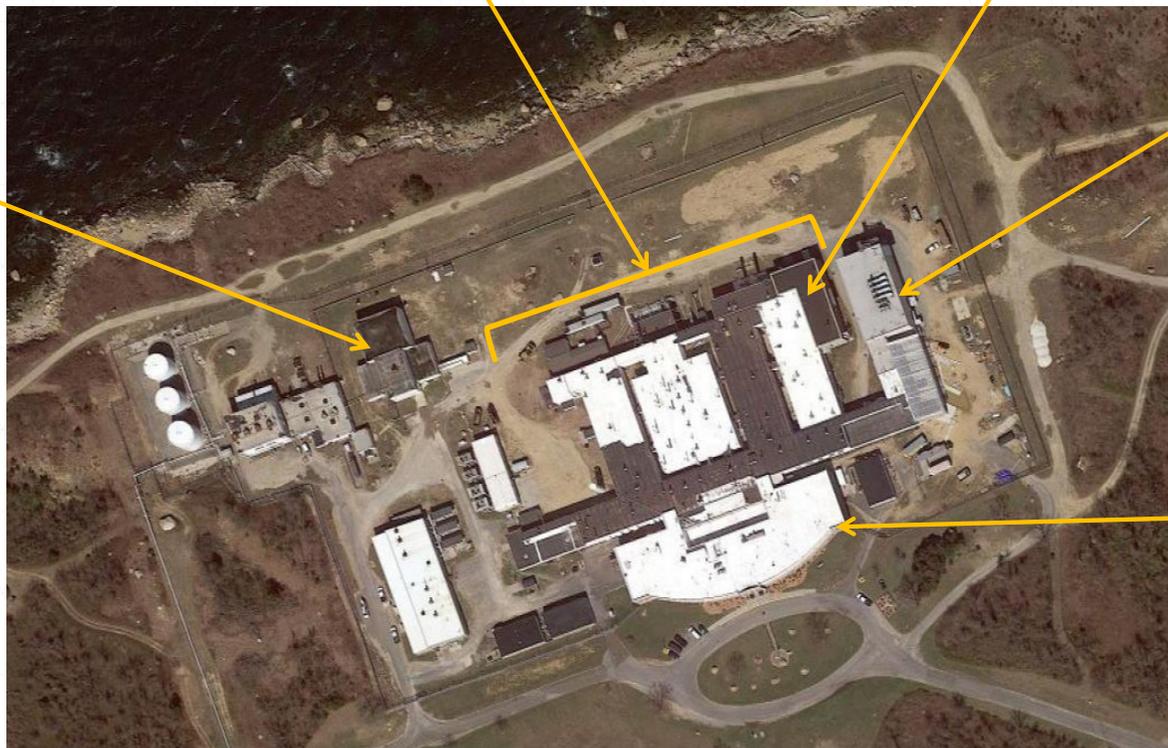
PIADC Biocompound – Aerial View

Biocontainment Labs &
Animal Areas (Bldg. 101)

North Animal Wing

Old Wastewater
Thermal
Decontamination
Plant (Bldg. 102)

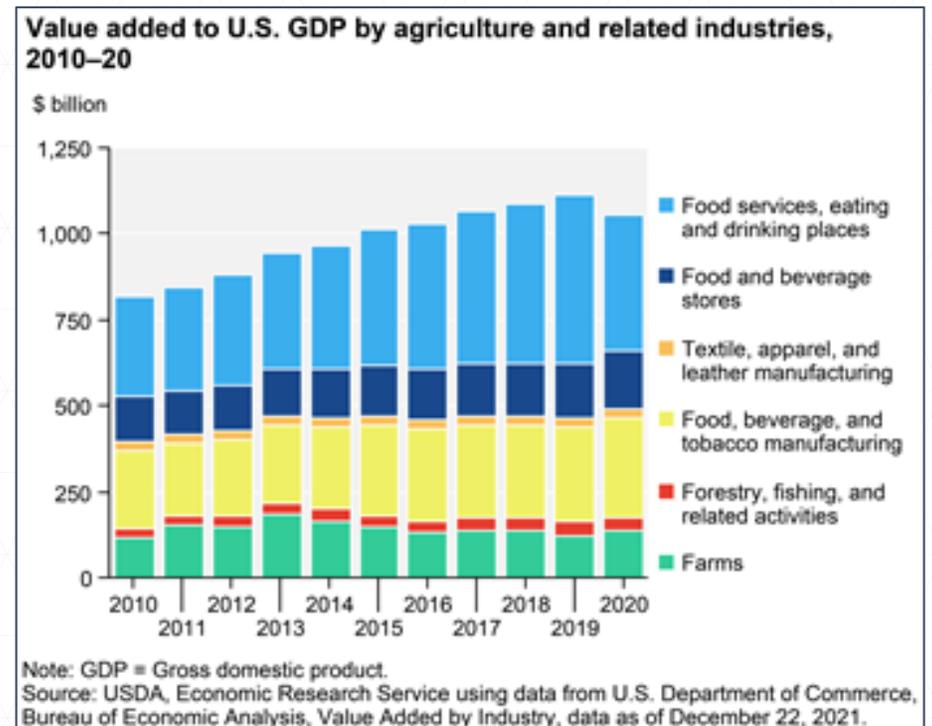
Replacement
Wastewater Thermal
Decontamination
Plant (Bldg. 111)



Administrative
Building
(Bldg. 100)

PIADC Mission

- Programmatic Mission – To defend the nation’s agricultural infrastructure against the intentional, accidental, or naturally occurring introduction of a Transboundary Animal Disease (TAD) – *Food and Agriculture is a critical infrastructure sector (PPD-21)*.
- By statute, PIADC is the only facility in the nation that can conduct diagnostics, training, and research using live FMDV (21USC113a).
- PIADC is the only BSL-3 laboratory and BSL-3Ag vivarium federal test bed facility for research, development, test, and evaluation on commercially available and candidate countermeasures for FMD and other TAD.



PIADC Scientific Program Summary

- The DHS S&T Office of National Laboratories (ONL) Science Program - generates actionable data and veterinary medical countermeasures
- The Foreign Animal Disease Research Unit (FADRU), Agricultural Research Service (ARS), USDA – conducts basic and translational research
- The Foreign Animal Disease Diagnostic Laboratory (FADDL), Animal and Plant Health Inspection Service (APHIS), USDA – conducts diagnostics and training, manages vaccine stockpile

PIADC's mission to be transferred to the National Bio and Agro-Defense Facility in Manhattan, Kansas.



S&T



Key Science Infrastructure

- BSL-2 and BSL-3 Laboratories
- Necropsy (BSL-3Ag)
- Vivarium/animal care spaces (BSL-3Ag/ABSL-3)



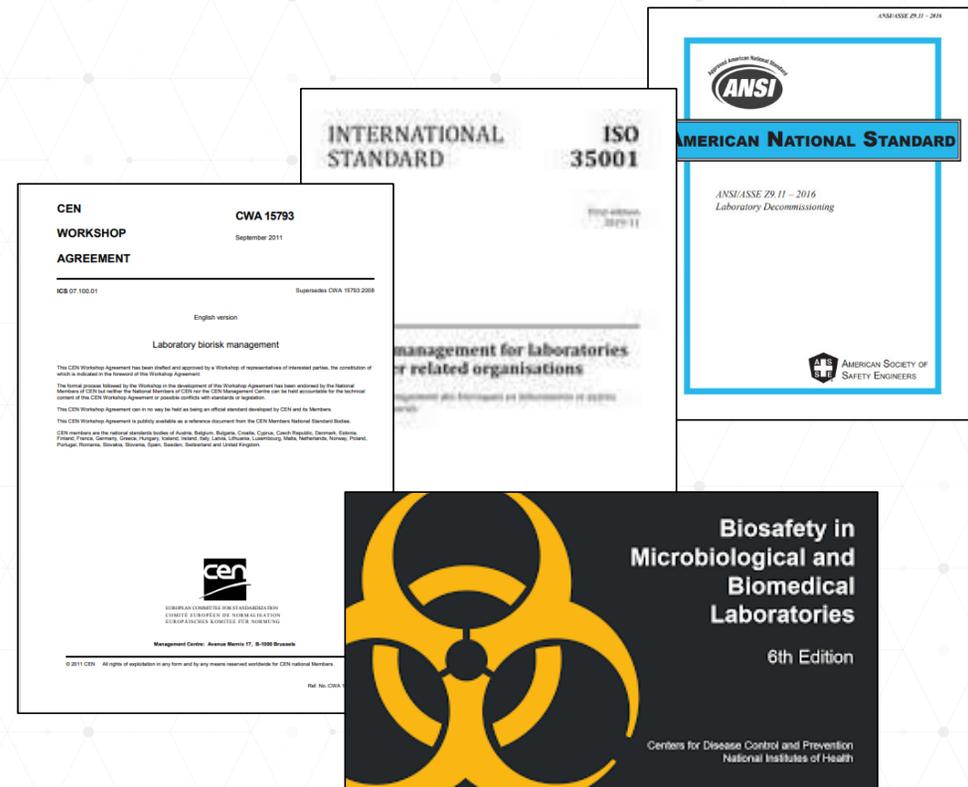
PIADC Biorisk Management Regulatory Framework and Adopted Standards

Regulatory Requirements

- 9 CFR § 121. Possession, Use and Transfer of Select Agents and Toxins
- 21USC § 113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases
- USDA Select Agent Registration
 - Heavily uses the Biosafety in Microbiological and Biomedical Laboratories (BMBL) for regulatory enforcement
- New York State Regulatory Requirements
 - 6 CRR-NY 201-8.3 New York State Air Resources
 - 6 NYCRR Part 360 – Solid waste management

Other voluntarily adopted sources/standards

- CEN Workshop Agreement CWA 15793: Laboratory Biorisk Management
- ISO 35001:2019 Biorisk management for laboratories and other related organizations
- ANSI/ASSE Z9.11-2016, Laboratory Decommissioning
- ISO9001, Quality Management Systems



PIADC Biorisk Management: Key Concepts

- Risk Group/BSL requirements – infrastructure requirements and personal practices
- Pathogen-specific risk analyses
- Hierarchy of Controls (occupational hazard reduction)
- Facility design features, i.e., “box within a box” – *unique facility design with machine space surrounding large biocontained area (labs, animal rooms, hallways, etc.)*
- Movement control – personnel (showers, movement from clean to dirty, etc.), infectious materials, animals, waste
- Medical Surveillance/Personnel Reliability Program
- Personal Recognizant Quarantine

ZONE 1

All areas and buildings on Plum Island except Bldgs. 101/102

ZONE 2

Mechanical spaces, hallways, lunchrooms (areas of no infectious agent use) in Bldgs. 101/102

ZONE 3

All laboratory areas of Bldgs. 101/102 where infectious agents are manipulated in closed vessels

ZONE 4

All laboratory areas of Bldg. 101/102 where infectious agents are manipulated in animal isolation and necropsy rooms, BSCs, and primary containment devices

PIADC Operational Zones – Zones 2, 3, and 4 have escalating restrictions for entry and controlled movement of personnel and materials.

PIADC Operational Material and Space Decontamination Practices

- Current approved decontamination practices in *operational* use at PIADC include
 - Chemicals: Paraformaldehyde Fumigation, Virkon-S, Bleach, Sodium hydroxide
 - Steam for thermal decontamination in autoclaves and for liquid effluent treatment
- A key role of the STENS contract services will be to test and validate decontamination and monitoring technologies to optimize their availability to meet PICS program effectiveness and efficiency for *terminal decontamination* objectives



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Plum Island Closure and Support (PICS) Program
PICS Program and STENS Overview



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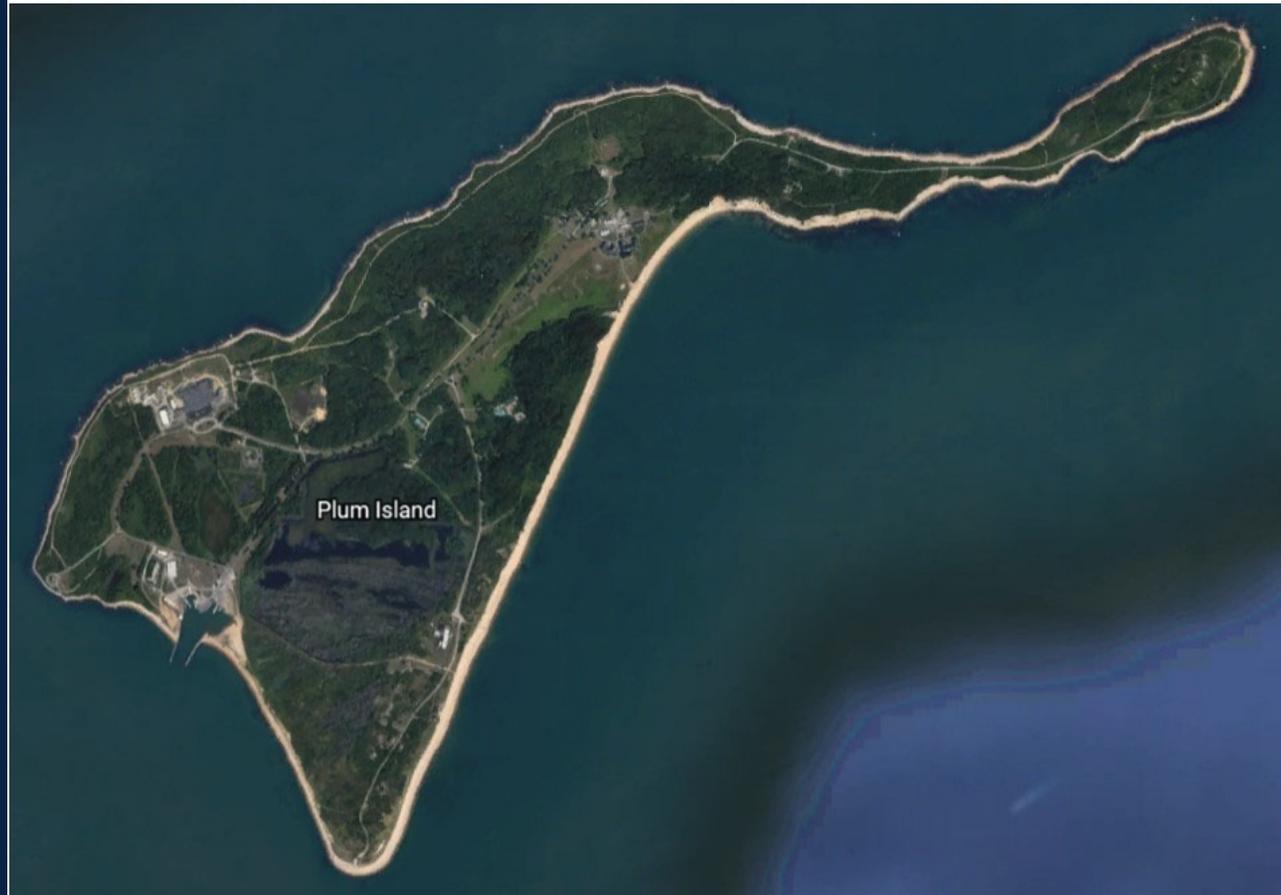
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June 29, 2022

PICS Program Overview

PICS Program Overview

The PICS Program involves the closure and conveyance of the DHS Plum Island asset, including all real and personal property, transportation assets, and the Orient Point facility that support operation of PIADC.



PICS Program Overview

Expectations:

- To execute Program activities with the highest transparency, while mitigating risks and meeting Regulatory Entities' expectations for Program execution in accordance with requirements, standards, and best practices - particularly in regard to separation of design/planning, execution, and verification/validation of program elements.
- To meet other stakeholder (political and public) expectations of transparency and independence with respect to planning, execution, and verification/validation of all work.

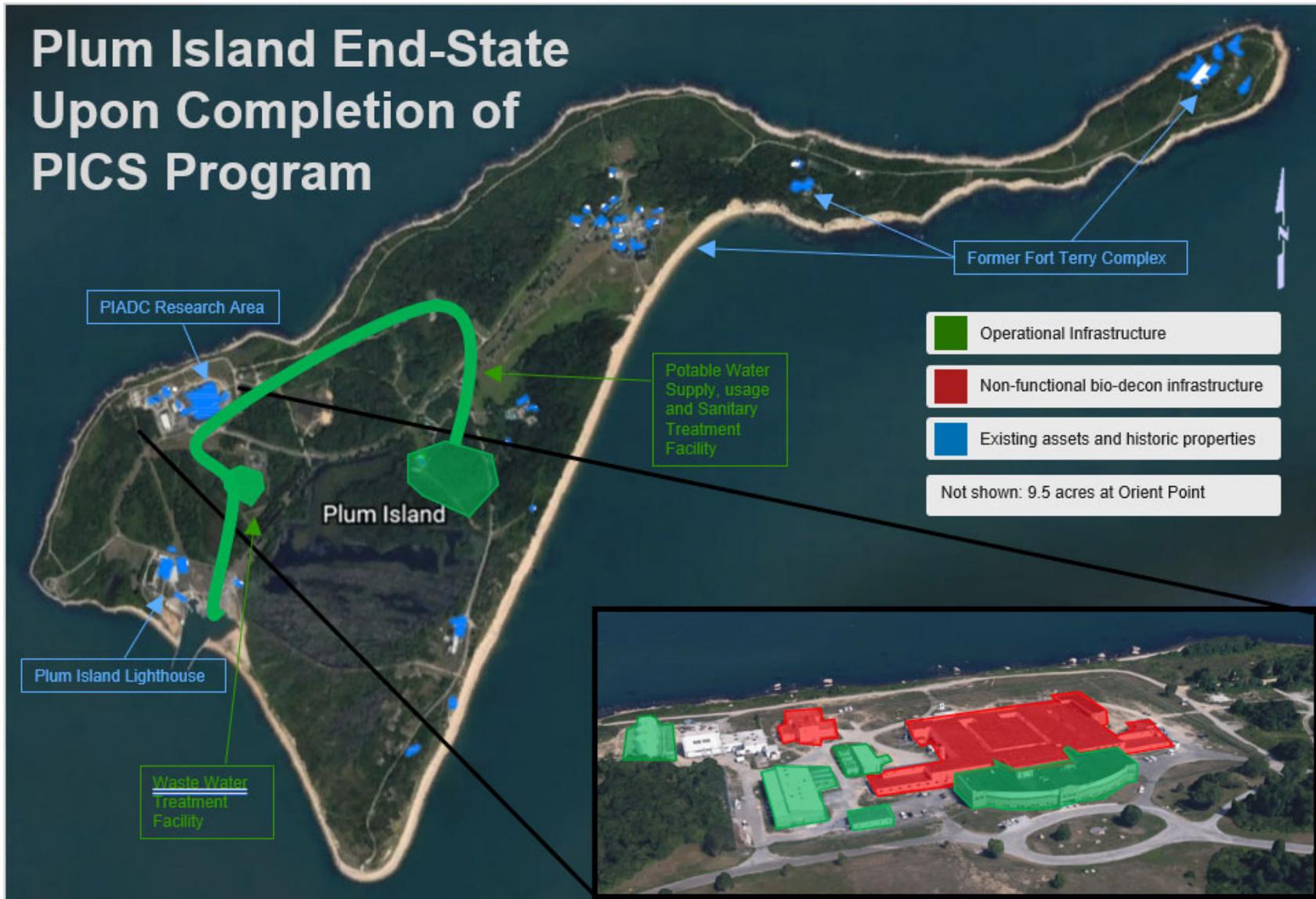
End-state goals:

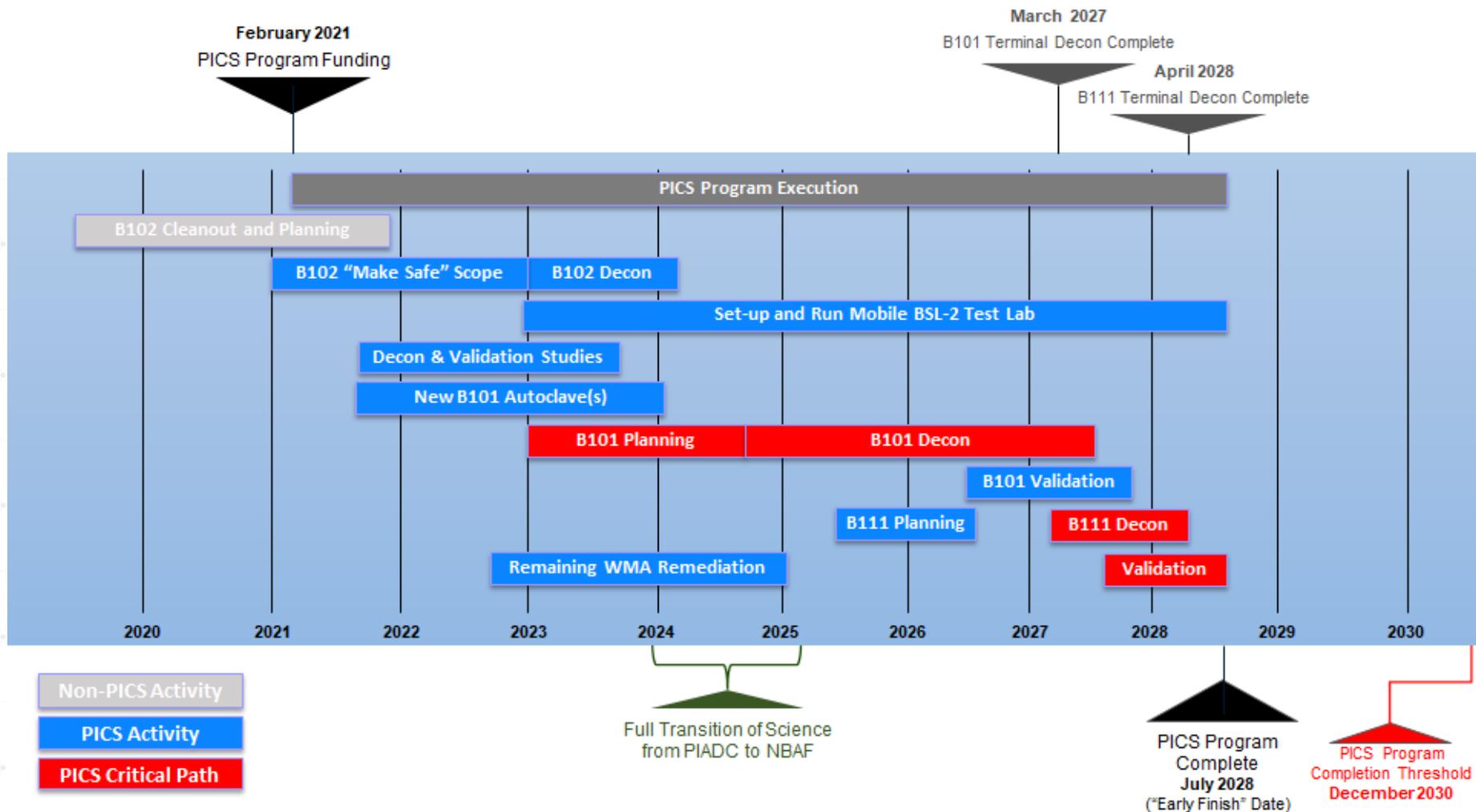
- Minimize PICS Program costs, execution risk, and the period of performance.
- Satisfy all regulatory considerations of Federal Select Agent Program (FSAP) and New York State Department of Environmental Conservation (NYSDEC).
- Preserve operable island assets deemed by GSA to be valuable.

Objectives:

- Decontaminate biological liabilities in accordance with FSAP and NYSDEC requirements using validated decontamination/validation methodologies. (ANSI/ASSE Z9.11 – 2016, EPA DQO Process and RCRA-like process)
- Remediate environmental liabilities in accordance with NYSDEC requirements. (Waste Management Areas)
- Leave key operable infrastructure in operating condition, in a 'lay-up' condition, or decommissioned.
- Complete all other PICS Program Key Performance Parameters as identified in the Program Execution Plan.

Plum Island End-State Upon Completion of PICS Program





STENS Support to PICS Program

The STENS Contractor will provide independent support for terminal decontamination * and validation as well as engineering for major PICS Program workstreams.

* includes oversight for, but not physical execution of, terminal decon

- B257 – Biological Sampling & Analysis
 - B102 – Validation of Decontamination
 - B101 & B111
 - Planning for Terminal Decontamination and Validation **
 - Engineering Planning and Oversight of Required Facility/Utility Modifications
 - Oversight of Execution of Decontamination
 - Validation of Decontamination
- ** Includes scientific support to PIADC for determination of appropriate methods for terminal decontamination and validation

STENS Overview

STENS is Key to the PICS Program's Success

PIADC is the only location in the U.S. where live Foot-and-Mouth Disease virus can be used as part of research. Therefore, terminal decon of the facility is inherently novel.

- Public, regulatory, and legislative scrutiny based on risk of terminal decon failure/incomplete inactivation
- Scientific challenges considering historical pathogen characteristics and use
- Engineering technical challenges for a site-specific solution



STENS will require inherent scientific and engineering knowledge and experience, as well as the ability to collaborate with other parties (federal, state, academic, contractors, etc.).

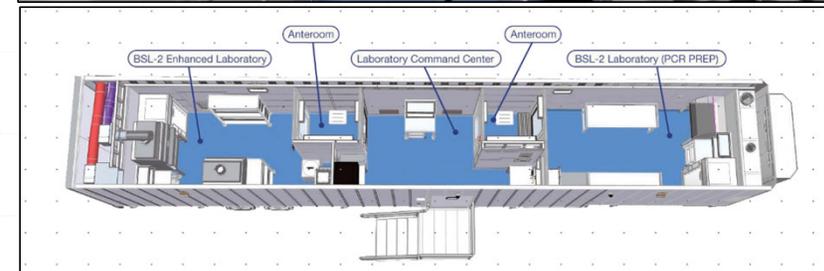
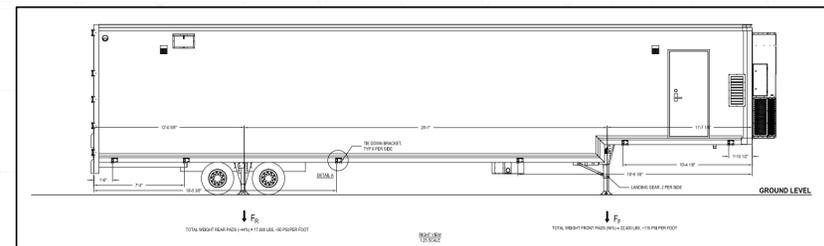
STENS – Summary of Tasks

- Task 1 – Routine Operation of Mobile Laboratory
- Task 2 – Matrixed Support from SMEs w/ Experience in Biological Decontamination at Facility-Scale
- Task 3 – Design and Execute Applied Scientific Activities to Enable Biocontainment Facility Decontamination
- Task 4 – Facility Modification Engineering, Planning, and Implementation
- Task 5 – Subcontract & Manage Independent Third-Party Lab for Biological & Chemical Indicator Verification & Decontamination Sample Analysis

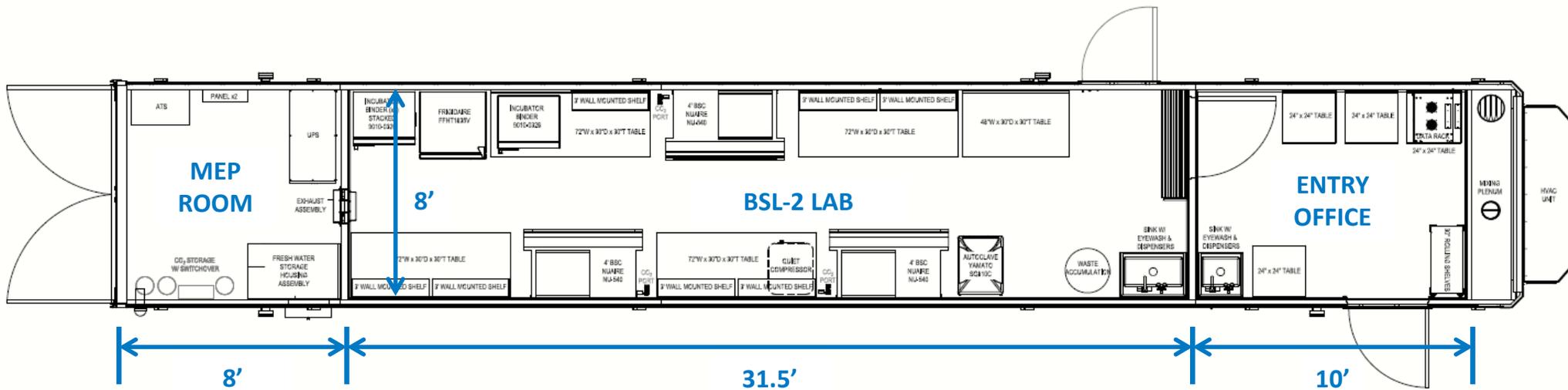
STENS – Overview of Task 1

Routine Operation of the Mobile Laboratory

- Includes aspects of operating the DHS mobile lab for receiving, processing, and reporting on samples.
- The mobile laboratory will support:
 - Sampling and Analysis for B257
 - Decontamination of B102
 - Decontamination of B101/B111
- Primary on-island lab for processing biological and chemical indicators to provide independent verification/validation of decontamination
 - “Independent” from those performing physical decon work



STENS – Overview of Task 1



Note: A certain percentage of samples may need to be sent to an off-island, independent laboratory for confirmatory testing and/or analyses beyond the capability of the on-island mobile laboratory.

STENS – Overview of Task 2

Matrixed Support from Subject Matter Experts (SMEs) with Experience in Biological Decontamination at Facility-Scale

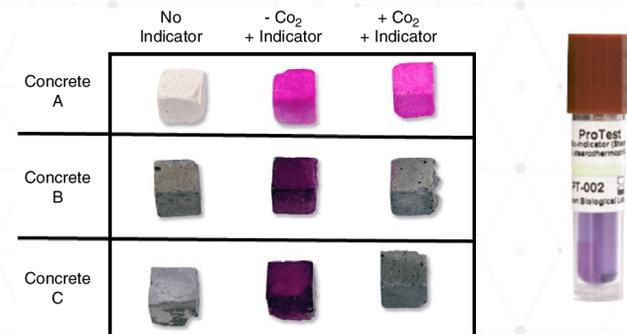
- Provides access to a body of SMEs with a range of expertise/experience in biological decontamination of facility-scale biocontainment laboratories
- Supports development of key components of scientific planning, plans for facility modification, methodologies for validation, interactions with regulatory officials, etc.
- Aligns with Task 3 to execute scientific studies



STENS – Overview of Task 3

Design and Execute Applied Scientific Activities to Enable Biocontainment Facility Decontamination

- Design and facilitate scientific studies to close knowledge gaps (working w/ PIADC personnel)
- Recommend down-select of decon and validation technologies for use in terminal decon for PIADC
- Develop supporting protocols for application at facility-scale, with support from SMEs (Task 2)



Studies will assess decontamination and validation technologies for efficacy specific to the PIADC application.

Provides the foundation of the terminal decontamination plan, but also informs best practices among similar facilities and generates peer-reviewed publications (per foundational science workstream).

STENS – Overview of Task 4

Facility Modification Engineering, Planning, and Implementation

- Provide engineering interface to support implementation of decontamination methods for the facility
- Requires integration between engineering and science to ensure methods developed are appropriately applied and required conditions can be attained in the facility

Planning of facility modifications will require collaboration/coordination with PIADC Ops, BioSafety, etc.

STENS – Overview of Task 5

Subcontract and Manage Independent Third-Party Lab for Biological and Chemical Indicator Verification and Decontamination Sample Analysis

- Off-island, independent laboratory will be required to support:
 - Confirmatory verification/validation of biological and chemical indicators generated in decontamination activities
 - Verification/validation of solids, soils, or solutions generated in decontamination activities (if testing is beyond capability of on-island mobile lab)



Questions

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