



University of Pittsburgh

Evolution of a Team-Run BSL-3 Facility Maintenance Program

Lesley Homer
University of Pittsburgh
Regional Biocontainment Laboratory
Biosafety Officer

Daniel J. Fisher
University Of Pittsburgh
Assistant Vice Chancellor
Research Operations





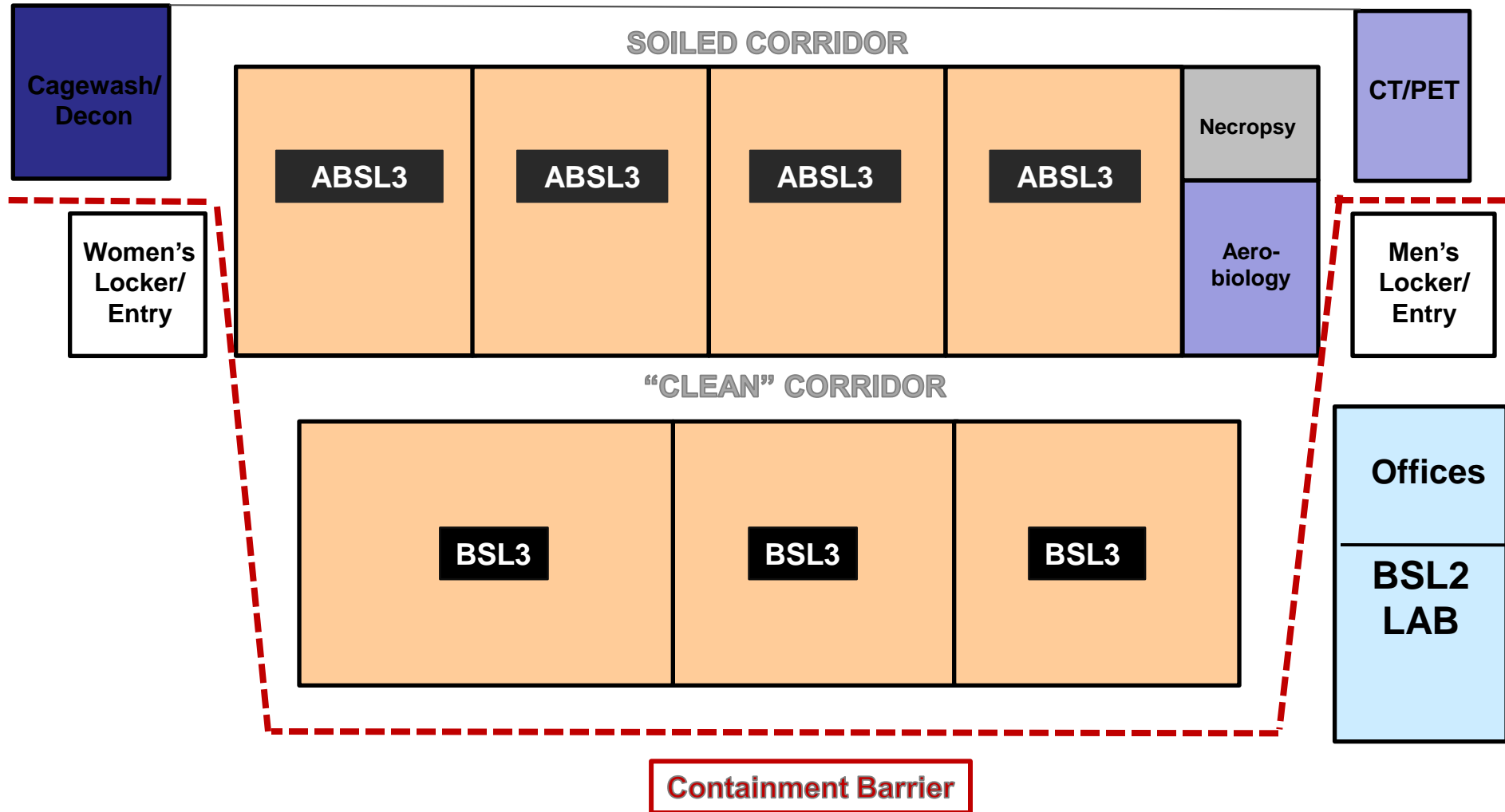
University of Pittsburgh Regional Biocontainment Laboratory

- 33,000 sq. ft. Multi user Multi Pathogen Facility
 - 3 – BSL3 Laboratory Suites
 - 4 – ABSL3 Laboratory Suites
 - Imaging Suite
 - Necropsy Suite
 - Aerosol Challenge Suite





Regional Biocontainment Lab





1st Year Timeline of Occupancy and Operation

April 2008

Commissioning completed uninfected primates delivered

May 2008

Started BSL₃ work with Tuberculosis

June 2008

DSAT/CDC and APHIS inspections for use of Select Agents

November 2008

Received approval to store and use Select Agents

March 2009

Completed first few transfers of Select Agents into facility

April 2009

Began work with Select agents; most suites hot

August 2009

Initiated annual re-verification program



Why is Annual Re-Verification Needed?

- Provides a time for staff, support personnel, and vendors to perform required routine, repair, and preventative maintenance
 - Verification of engineering controls
 - Verification of room integrity
 - Annual inspection of scientific/clinical equipment
 - Update and review standard operating procedures



1st Year Re-Verification Program

- RBL Management Team
 - Associate Director
 - Biosafety Officer
 - Operations Manager
 - Laboratory Manager
 - Vet & Vet Supervisor
 - Aerosol Director
- Management Team will provide oversight of re-verification program
- Start with laboratory suites
- Relocate investigators to other suites to support continuous research





1st Year Re-Verification Program

- Disinfect & clear each suite with no PPE required
- Conduct re-verification tasks
- Return PI to home suite and reopen
- Repeat for lab suites
- Repeat for animal suites
- Complete re-verification in **one year**





Relocation and Disinfection

Tasks:

- Relocation of PI supplies/equipment
- Surface disinfection of suite
- Vaporized hydrogen peroxide disinfection of all labs
- Clearance of suite

Personnel Required:

- Lab Manager, BSO, laboratory technicians, veterinary technicians, Operations Manager, facilities staff

Timeline: 90 labor hours





Re-Verification Tasks: Engineering Controls

Tasks:

- Calibration of Environmental Controls, Sensors and Alarms
 - Temperature, humidity, differential pressure sensors
- Verification of Isolation Controls
 - Bubble tight dampers
 - Control Valves

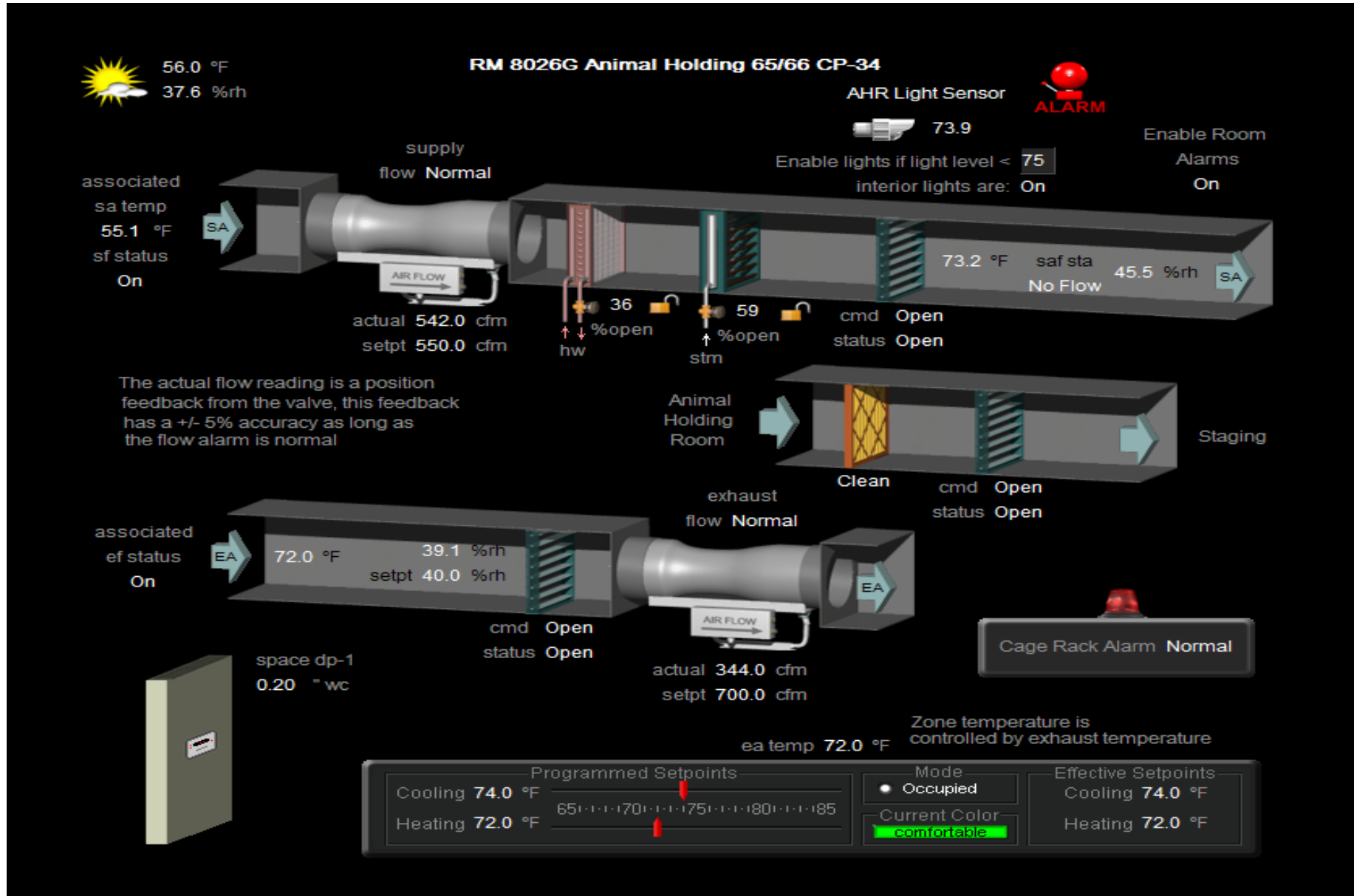
Personnel required:

- Facilities Engineers

Timeline:

- 24 labor hours







Re-Verification Tasks: Suite/Facility

Tasks:

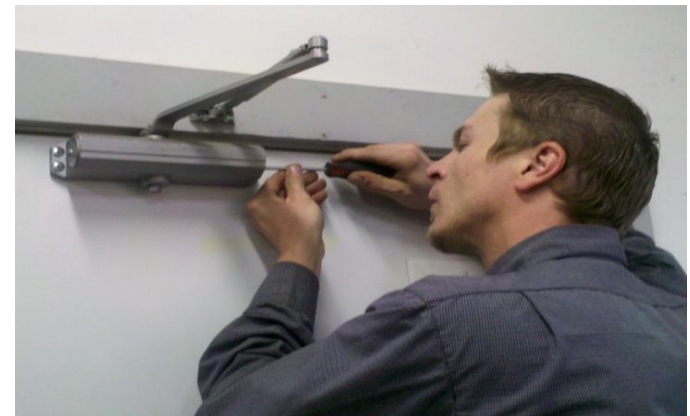
- Re-lamping of all fixtures
- Door closure adjustments
- Room level filter changes (animal suites)
- Safety shower testing
- General repairs to the facility
- Lab equipment maintenance

Personnel required:

- Facilities Engineers & lab techs

Timeline:

- 24 labor hours



Re-Verification Tasks: Exhaust HEPAs

Tasks:

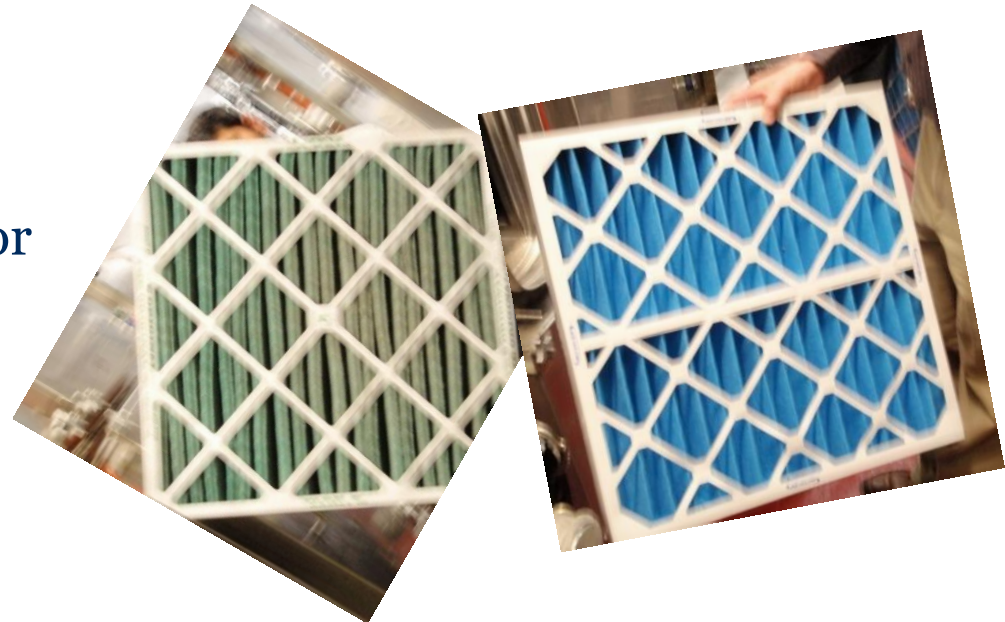
- Validated VHP decontamination of pre-filters and HEPA filters
- Changing of pre-filters and trace filters
- Recertification of HEPA filters

Personnel required:

- BSO, Facilities Engineers & vendor

Timeline:

- 24 labor hours



Re-Verification Tasks: Room Integrity Testing

Tasks:

- Verification of directional air flow source
- Use commissioning data as baseline
- Perform relative tightness test
 - Seal all known sources of air (i.e. around door)
 - Draw room down to a $-.2''$ w.c.
 - Measure and record the make-up air
 - Repeat test at operating pressure $-.05''$ w.c.



Personnel required:

- Facilities Engineers

Timeline: 10 labor hours



Re-Verification Tasks: Equipment Certification

Tasks:

- Biosafety cabinet certification
- Supply-side HEPA filter certification
- Animal caging certification
- Transfer cart certification
- Requires escort at all times

Personnel required:

- Engineers, lab/vet techs, & vendor

Timeline: 20 labor hours





Re-Verification Tasks: Completion

Tasks:

- Inventory and restock drugs
- PAPR cleaning
- Restock PPE/garb in entrance/exit rooms
- Restock exposure kits
- Update all signage
- Return PI to suite and reopen suite

Personnel required:

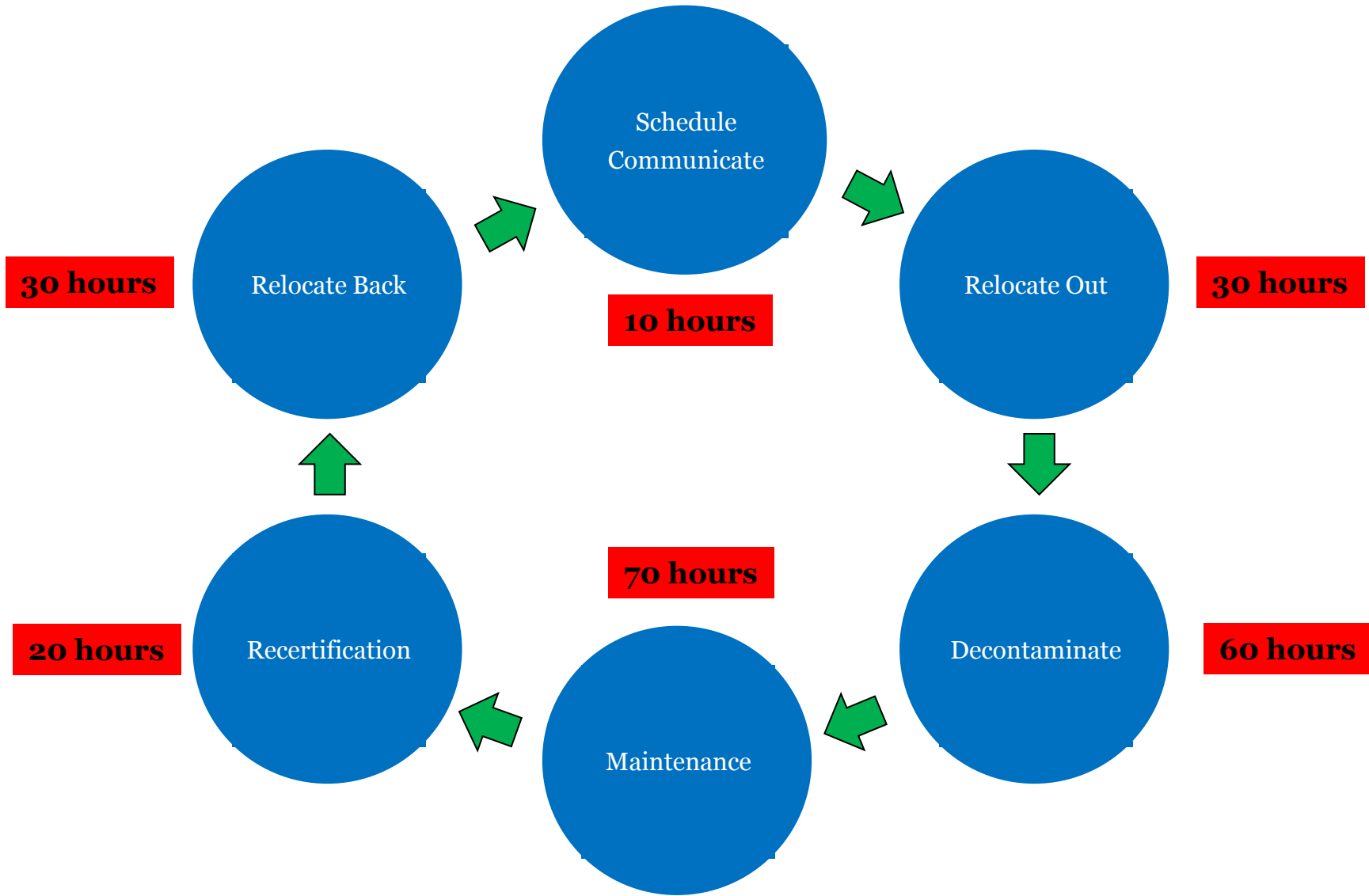
- RBL BSO, Lab Manager, lab & vet techs

Timeline: 40 labor hours





Re-Verification Year 1: Milestones & Timelines





Re-Verification Year 1: Lessons Learned

- Met the timeline
- Validated VHP process for all labs/rooms/suites
- Performed preventative maintenance and calibration
 - Allowed time for unexpected and necessary repairs to the facility
- Developed documentation and tools
 - SOPs and checklists
 - Tracker for HEPA filter certification
- Relocating PIs is extremely labor-intensive
- Relocating PIs is disruptive to ongoing work



Goals for Re-Verification Year 2

- Lab suites:
 - Leave PIs in place with no relocation
 - Leave lab suites hot & perform re-verification quickly
- Animal suites:
 - Leave PIs in place when possible; relocate only when needed
 - Fully decontaminate and clear animal suites more efficiently
- Schedule multiple building engineers if needed
- Complete each suite re-verification in 1-2 weeks
- Conduct rolling exhaust HEPA filter certification
- Complete all Year 2 ABSL3/BSL3 re-verifications in one year

Year 2: Disinfection & Relocation

- Lab suites:
 - Left PIs in place with no relocation
 - Left lab suites hot-
Only basic surface disinfection
- Animal suites:
 - Only relocated PIs from 2 suites
 - Fully decontaminated all suites in
<1 week



Re-Verification Tasks Year 2

Tasks:

- Calibration of environmental controls, sensors and alarms
- Suite tasks such as re-lamping & door closure adjustments
- Room integrity testing
- Lab equipment maintenance
- Certification of all HEPAs/BSCs

Personnel required:

- MULTIPLE Facilities Engineers & lab techs

Timeline:

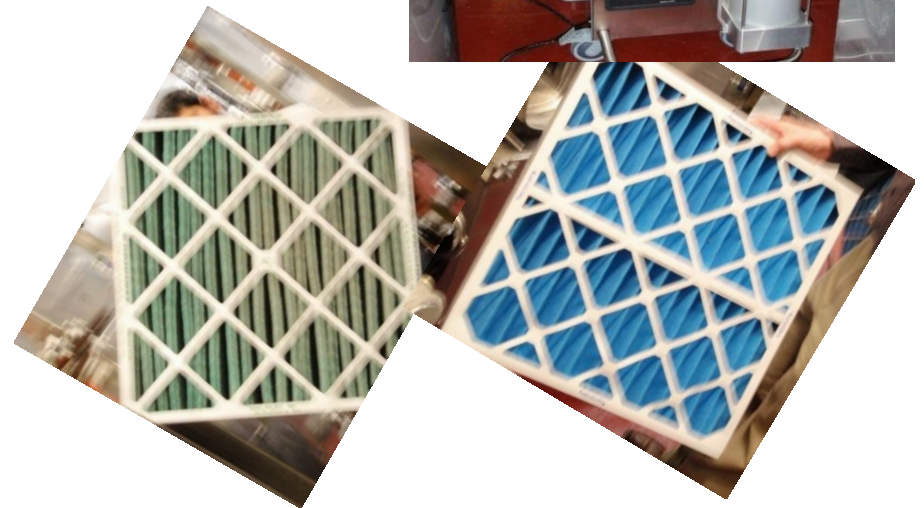
- 70 + 20 labor hours (all in same week)





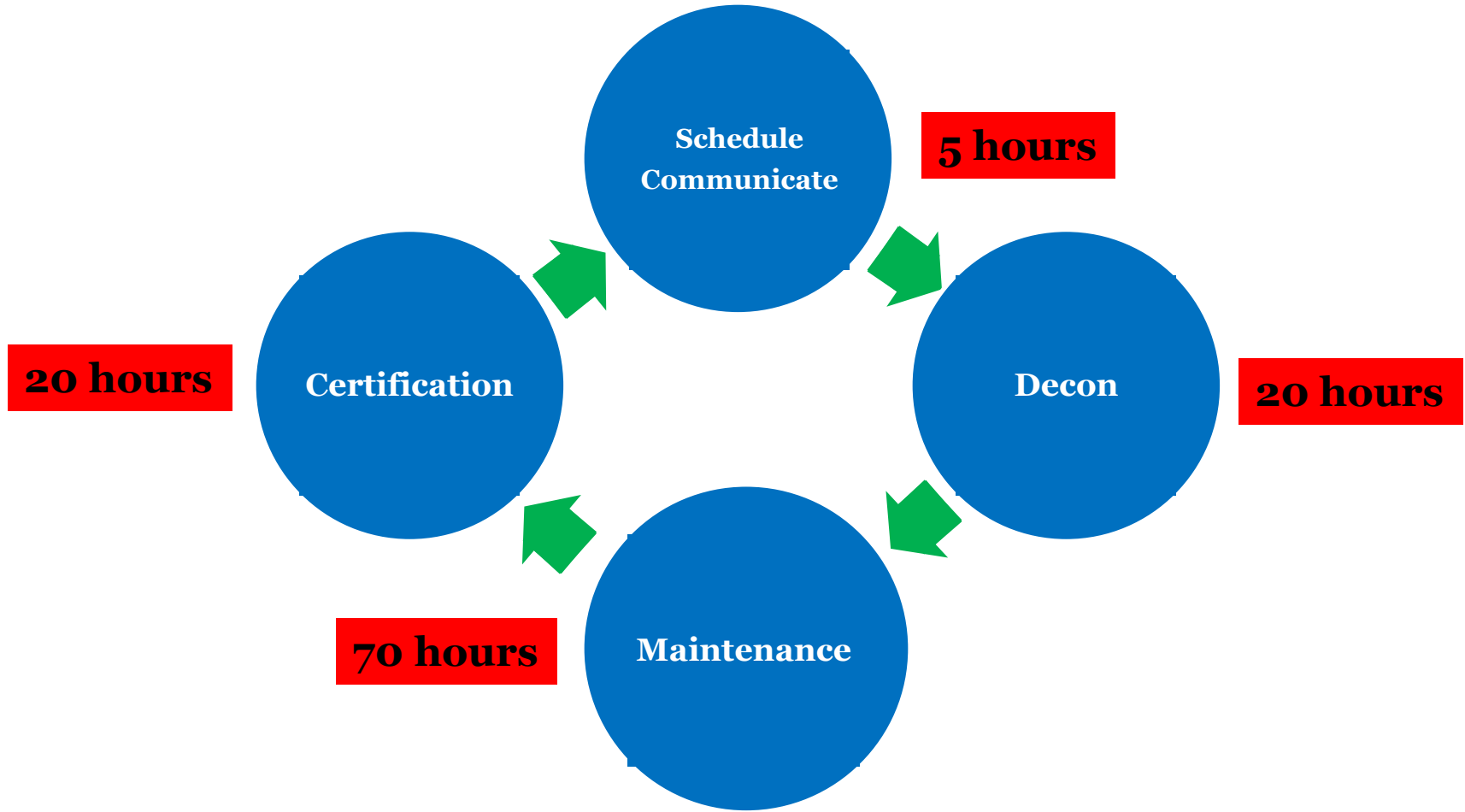
Re-Verification Year 2: Exhaust HEPA Filter Maintenance

- Performed separately from suite revalidation for flexibility
- One filter per bank per suite isolated, decontaminated, and recertified
 - Does not impact directional airflow
- Third Party vendor performs certification
- Recertify 6 filters per visit





Re-Verification Year 2:



Total of 100 labor hours for BSL3
Total of 120 labor hours for ABSL3



Year 1 vs. Year 2 Time Requirements

Suite	Total Hours Year 1	Total Hours Year 2	Total duration suite was closed Year 1	Total duration suite was closed Year 2
Lab Suite 1	220	100	8 weeks	1 week
Lab Suite 2	20	100	N/A	1 week
Lab Suite 3	220	100	10 weeks	2 weeks
ABSL 1	220	180	4 weeks	2 weeks
ABSL 2	160	120	5 weeks	2 weeks
ABSL 3	160	120	4 weeks	2 weeks
ABSL 4	220	120	8 weeks	2 weeks
Service Corridor	140	80	4 days	1 week
Aerobiology	30	10	2 days	1 day



Re-Verification Year 2: Lessons Learned

- Leaving PIs in their suites saved time
- Leaving lab suites hot saved time
- Separation of exhaust HEPA filter certification from suite revalidation worked well
 - No impact to suite level ventilation
 - Simplified filter recertification scheduling
- Developed new tool for tracking progress per suite

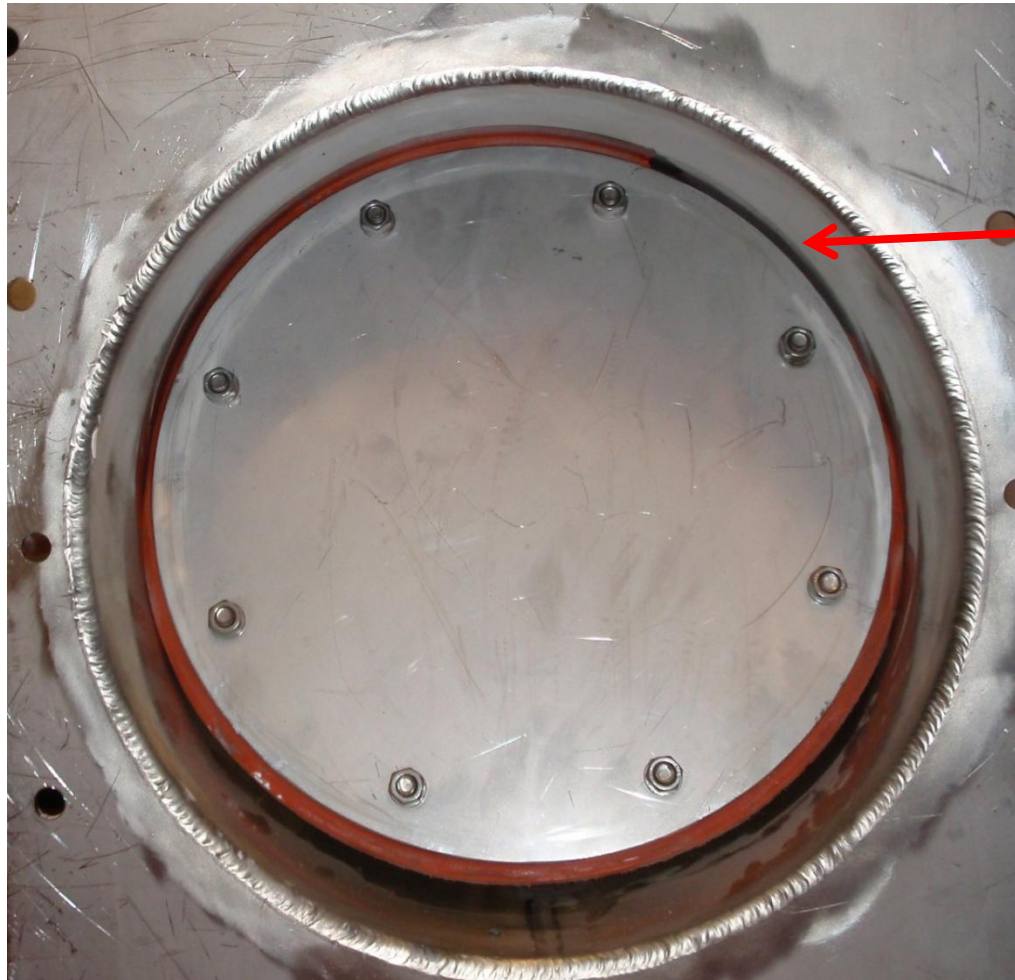


Regulatory Oversight

- Inspected twice since re-verification program began
- Provided re-verification protocols and records to inspectors
- Received positive feedback on program
- In compliance with “SA-Gram” issued 8/5/2011 regarding initial verification and annual re-verification of facility and HVAC



Unexpected Maintenance Findings



Damaged Gasket

- **Bubble
Tight
Damper
Repair**



Unexpected Maintenance Findings



Damaged Supply Side
Hepa Filter



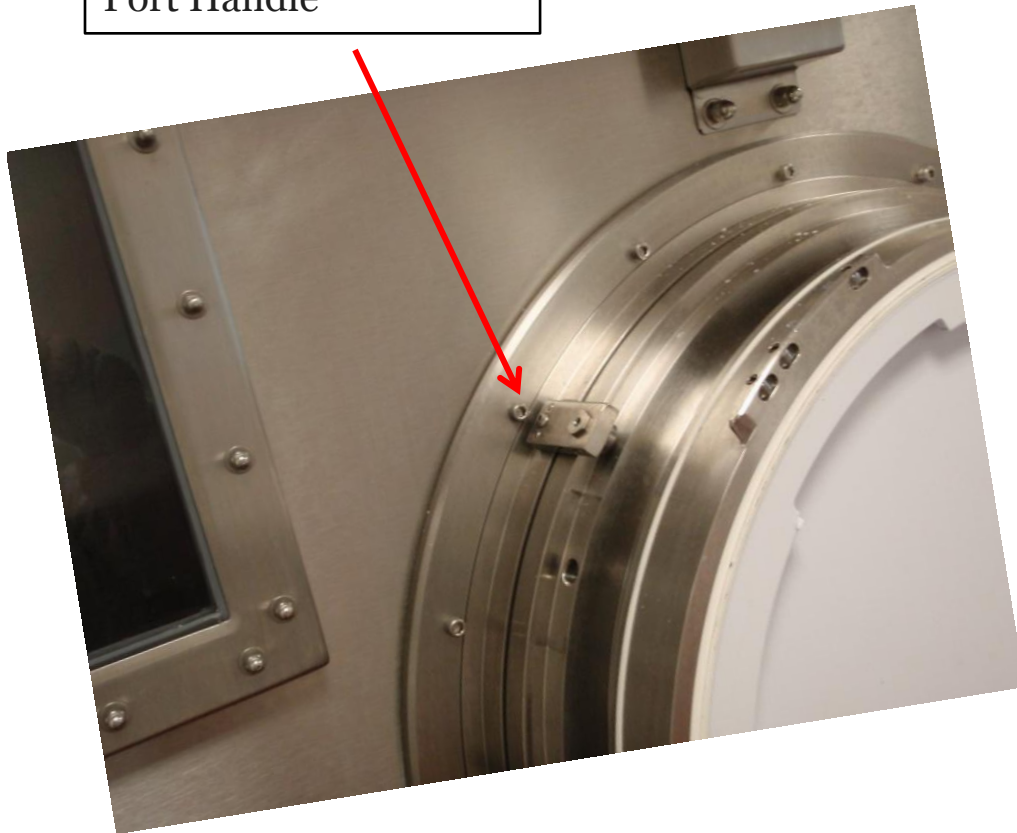
Unexpected Maintenance Findings

Door Seals damaged
by rapid transfer cart
and cagebanks

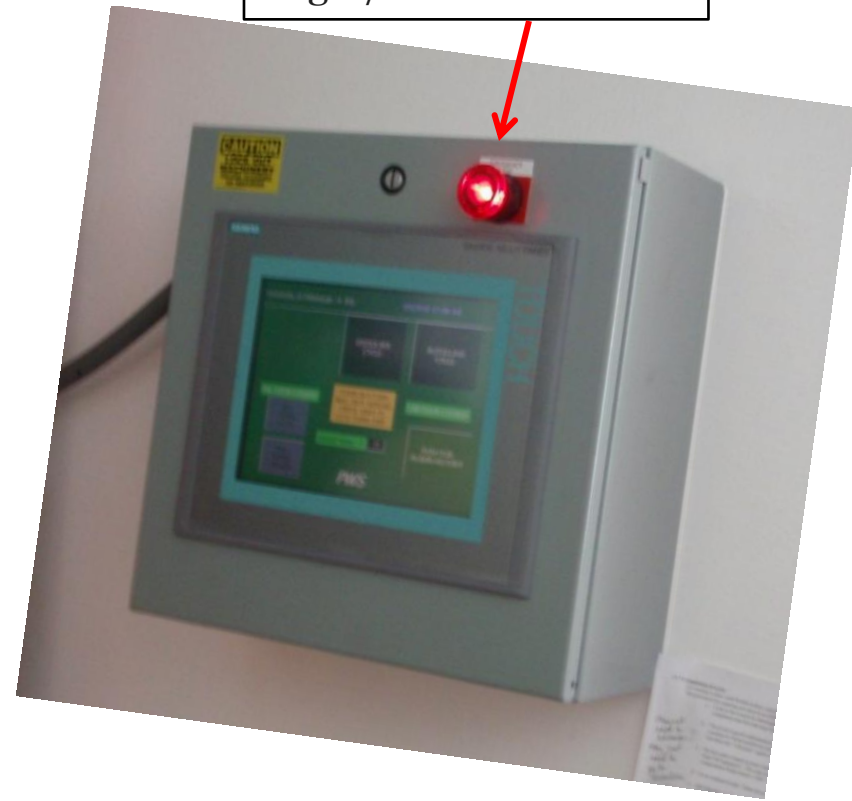


Unexpected Maintenance Findings

Missing Rapid Transfer Port Handle



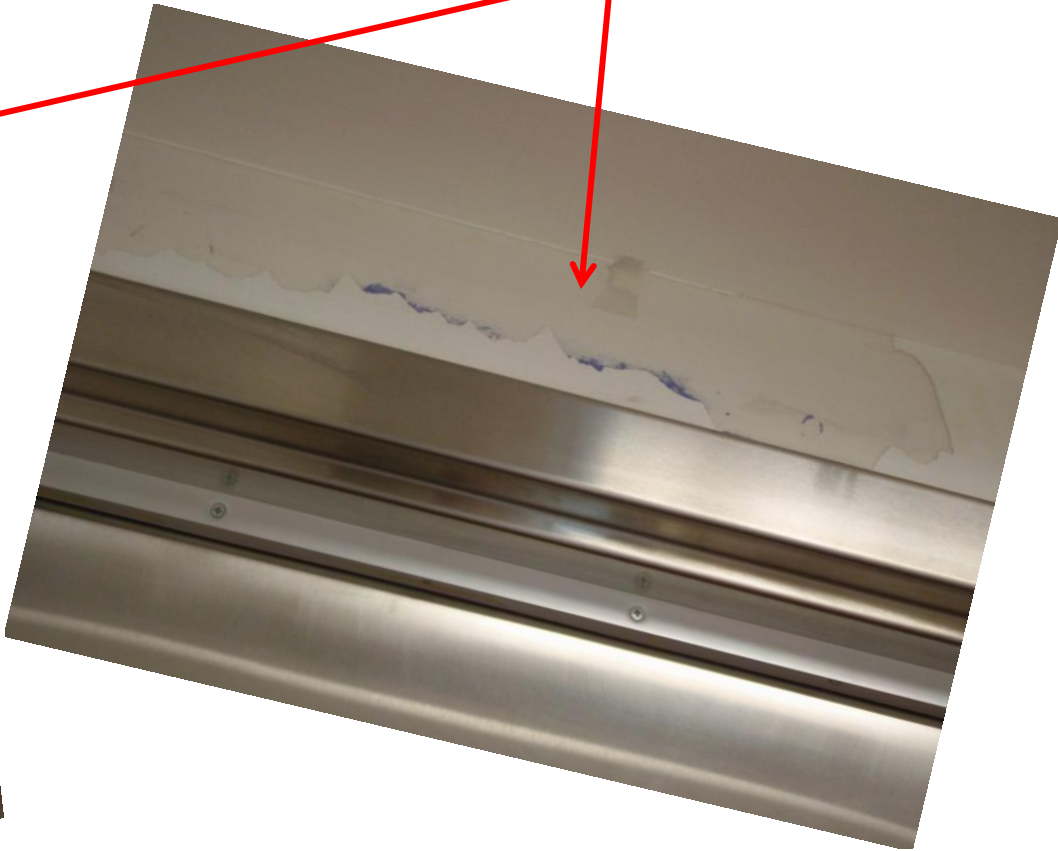
Buttons Knocked Off By Cages/Carts





Unexpected Maintenance Findings

Removal of TNEMEC paint when removing plastic sealant around door frame for decontamination





Goals for Re-Verification Year 3

- Continue Year 2 plan
- Complete each suite in 1-2 weeks
- Continue rolling certification of exhaust HEPA filters
- Complete all Year 3 ABSL3/BSL3 re-verifications in one year

