

DESIGN, COMMISSIONING, AND VALIDATION OF EFFLUENT DECONTAMINATION SYSTEMS (EDS) FOR CL3 AND CL4 LABORATORIES



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Outline

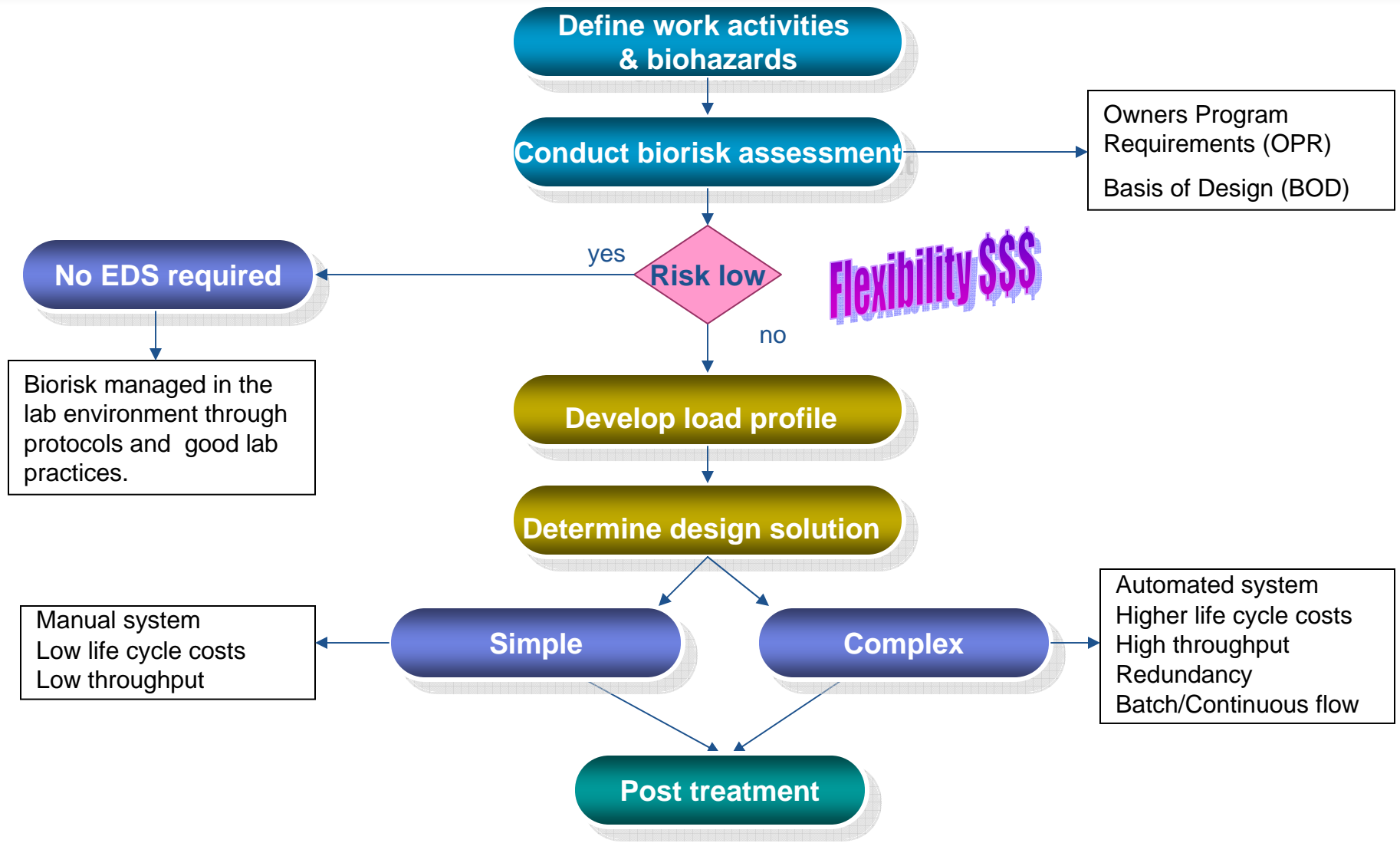
1. Design

2. Testing

3. Verification

4. Case Studies

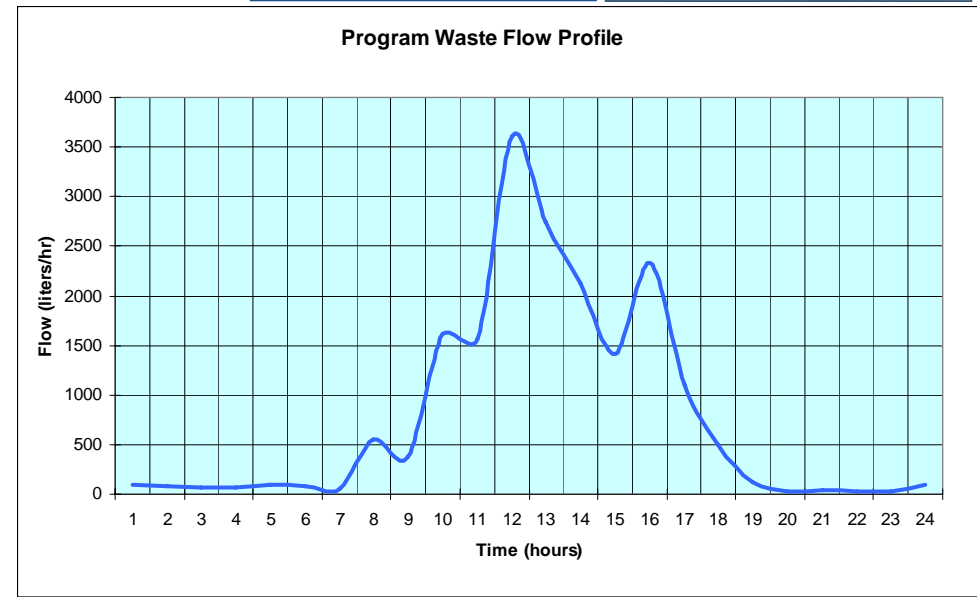
Planning and Design





Develop Load Profile

- Generate the right profile! Consider:
 - How many personnel?
 - Usage cycle vs Treatment cycle
 - Protocols (showers/washdowns)
 - Program type
- Sources:
 - Sinks
 - Floor Drains
 - Toilets
 - Autoclaves
 - Showers
 - Animal spaces
- Unforeseen Loads
 - Fire Protection System load
 - Valve leakage
 - Human error





Design Considerations

- What is the expected biowaste flow?
 - Chemicals; Solids
 - Material of construction
- What central services are available?
- Treatment Parameters (adjustable):
 - Time, temperature, chemical
- Process Type
 - Batch vs Continuous flow
 - Thermal vs Chemical; or thermal-chemical hybrid
- Maintainability
 - Off the shelf technology
 - Decontamination (piping, vessel)
 - Vendor support

Steel	Cost Factor
carbon	1
316L	2.5
2205	5.5
Al 6XN	6





Design Considerations

- System Options

- Heating Method
- Cooling Methods
- Heat Recovery
- Collection Tanks
- Reactor size 100 gal to 8000 gal
- Vent Filter
- Blend Tanks
- Environmental Monitoring
- Method of Biological Verification

- Waste Piping Distribution

- What is the decontamination chemical?
- What temperatures will we see?
- What is the routing of the waste pipe?
- Materials
- Options





Design Considerations

Batch Systems

- High Through put
- Can handle some solids
- Process options
- Adjustable treatment parameters
- Document proof of process (Batch Report)
- Dry well for spore testing kill cycle
- Proven and Robust System
- Life Cycle costs \$\$\$



Continuous Flow Systems

- Low/Medium Throughput
- 20 Gallon a day (sink unit) or larger (depending of flows)
- Continuous Operation
- No Solids
- Smaller Footprint, no external tanks
- Life Cycle costs \$\$

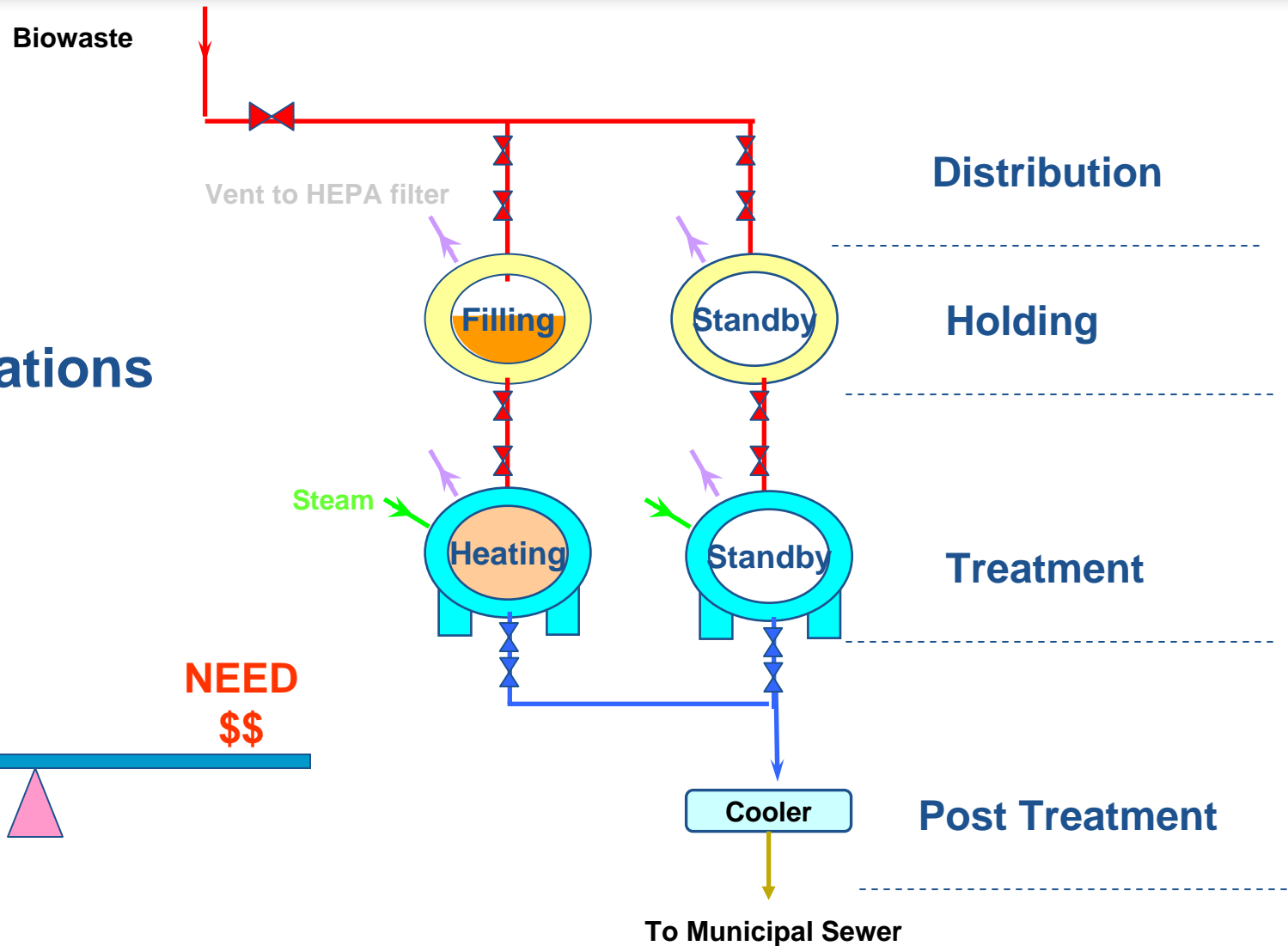


Design Considerations

System Configurations
>100

WANT
\$\$\$\$

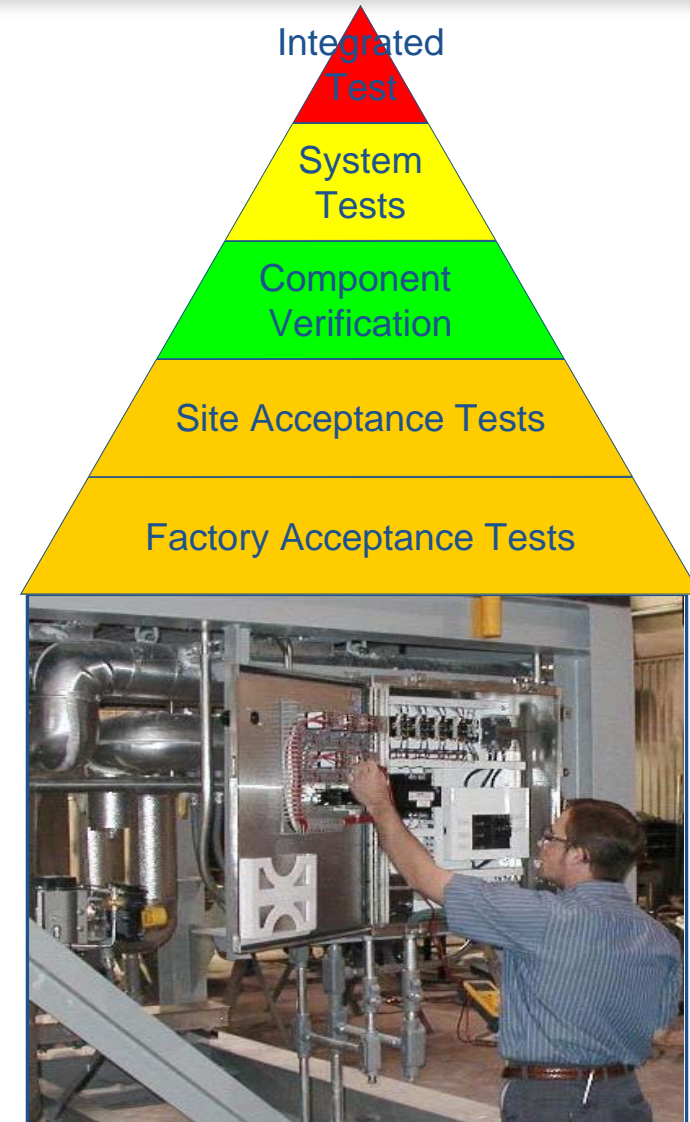
NEED
\$\$





Testing

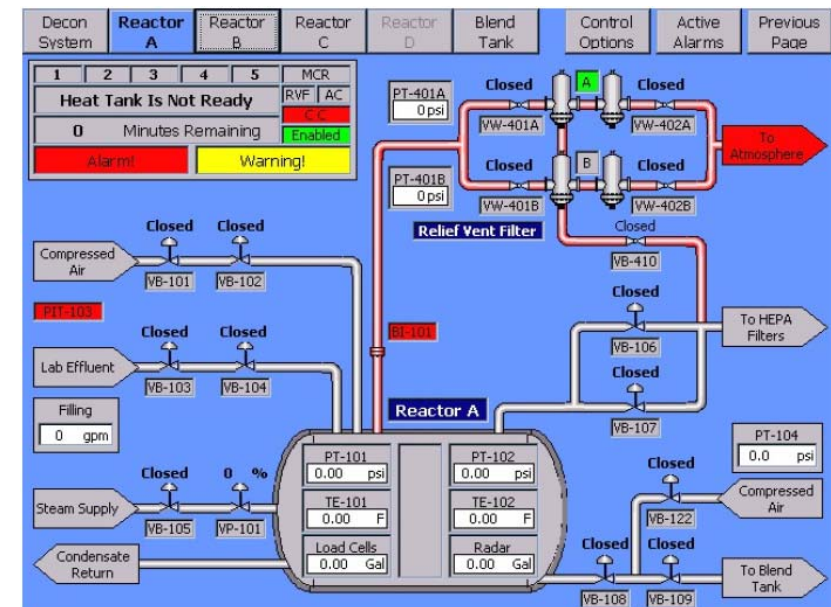
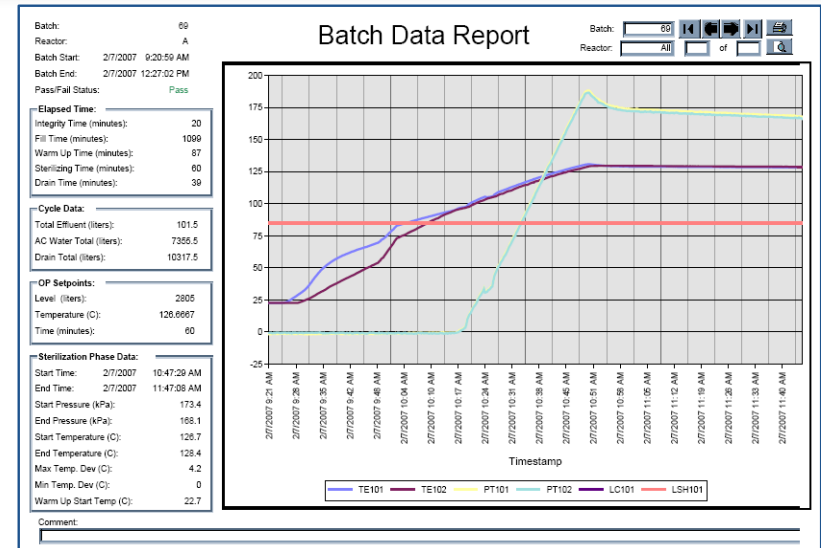
- Factory Acceptance Test
 - Sequence of Operation
- Site Acceptance Tests
 - Start-up
 - Performance verification
- Commissioning
 - Component verification
 - System testing
 - Integrated testing





Testing

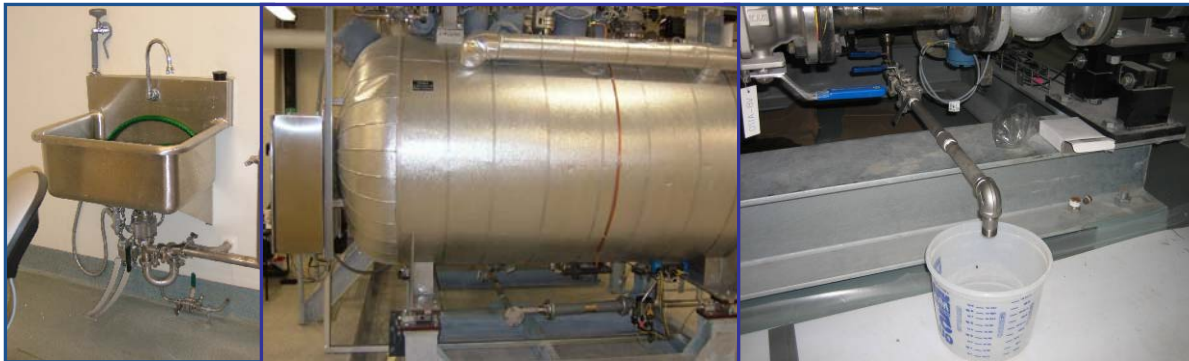
- Normal
 - Establish baselines
 - Quantify loads
 - Shutdown and Isolation
 - Vary operational parameters
 - Generate trends/reports
 - Biological Verification
- Abnormal (Failure)
 - Sensor/valve failures
 - Loss of Power (during sterilize mode)
 - Loss of critical utilities
 - Inability to receive effluent
 - Loss of cooling process
 - Decontamination procedures





Verification

- Biological Challenge
 - Performed by Facility BioSafety Professional
 - Direct vs Indirect
 - 6 log reduction of spore sample
 - Geobacillus Stearothermophilus
 - Bacillus atrophaeus
 - Initial indication after 48 hrs



Direct



Indirect



Case Study (project x)

System configuration;

- EDS installed to support CL3 program (w/select agent).
- Loads consist of sinks and a body shower
- Stainless steel Holding tank (x1) and Cool tank (x1)
- No factory acceptance tests
- Thermal-Chemical process (low temperature)
- Steam coil heating (point source)
- Dual temperature sensors
- Discharge cooled w/domestic water
- Discharge non-gravity flow (pumped)
- Automated control system
- Biological verification (direct and indirect)

















Case Study (project x)

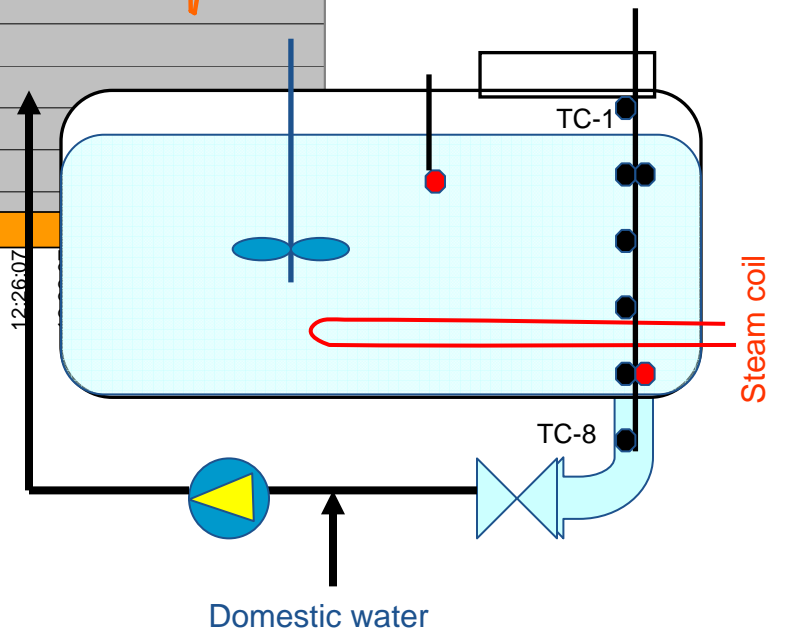
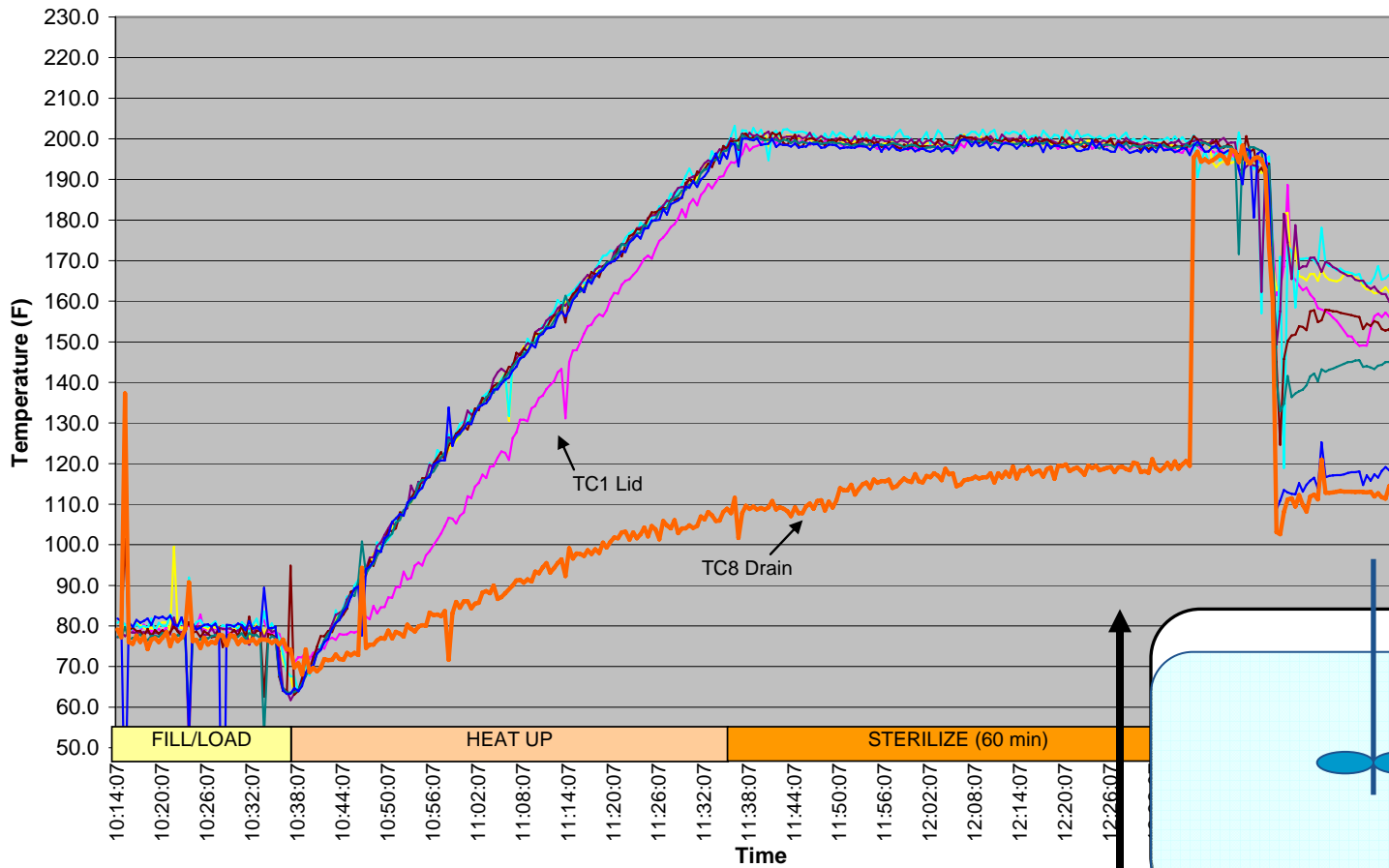
System Test Criteria

Test #1

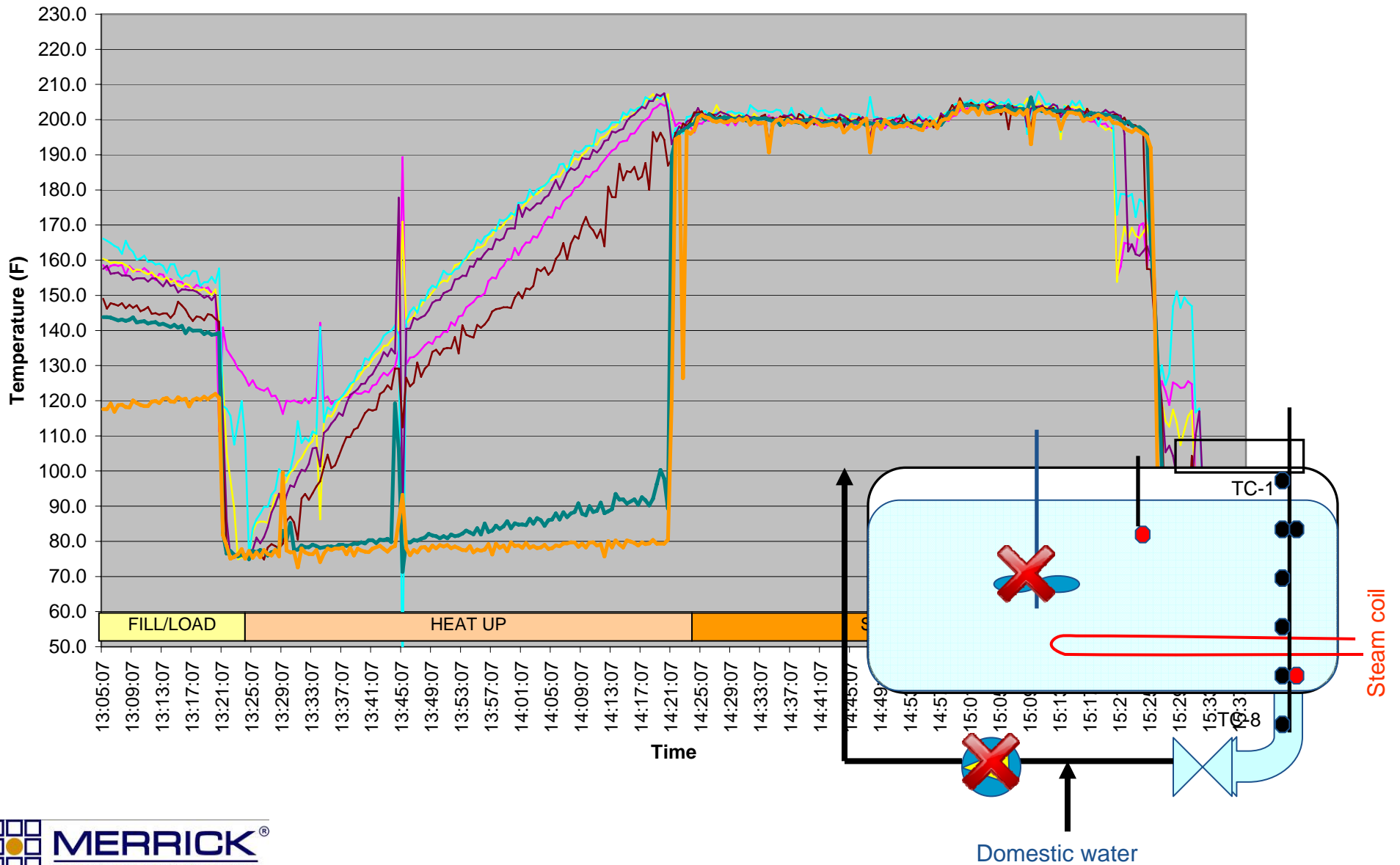
Test #2

System operational parameters achieved under normal operation		
Even heating through out the sterilize cycle (no stratification below setpoint)		
System able to be shutdown and decontaminated for servicing		
Interlocks and fail safes (soft wired and hard wired) in place.		
Sensors and control devices (installed, calibrated, monitored, controlled)		
Abnormal and failure testing of high probability events tested and accounted for		
Information Management strategy implemented and functional (alarm monitoring, batch reporting)		

Case Study (project x)



Case Study (project x)





Case Study (project y)

System configuration;

- EDS installed to support CL3 program (w/select agent).
- Loads consist of sinks, autoclave, and a chemical shower
- Three cooling tanks and two vertical Cool tanks (1500 gal))
- Thermal process (high temperature)
- Steam jacket heating
- Dual temperature sensors
- Discharge cooled w/domestic water
- Discharge non-gravity flow (pumped)
- Automated control system
- Biological verification (direct)

















Case Study (project y)

System Test Criteria

Test #1

Test #2

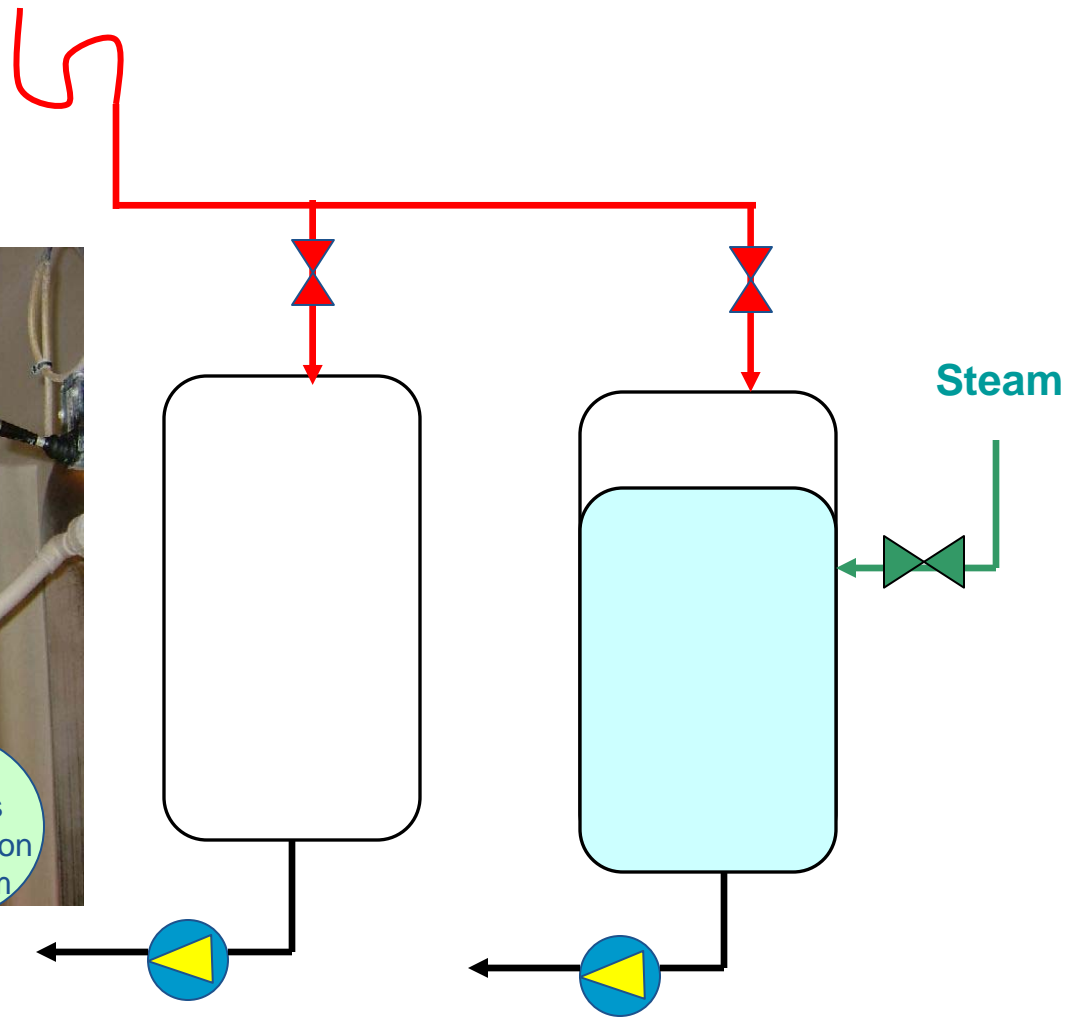
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Case Study (project y)

Lab space



Witness Protection Program





In Closing

1. Design to the project requirements
2. Test, test and more tests
3. Determine the biological verification standards





Thank You.....

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