Effluent Decontamination Systems (EDS): Annual Verification and General Maintenance

September 21, 2023

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

USDA

Effluent Decontamination Systems (EDS)

An **effluent decontamination system** (**EDS**) is a device, or suite of devices, designed to decontaminate or sterilize biologically active or biohazardous materials in fluid and liquid waste material.

- Common methods of EDS decontamination:
  - Heat
  - Chemical Treatment
- Common operating:
  - Batch
  - Continuous Flow

A/BSL3 Verification Policy Statement
(Release Date: November 20, 2014)

1. The means of detecting air flow (tell-tale, magnehelic or digital gauge, Baulin-Tube®, etc.) has been confirmed to accurately reflect observed air flow. It is recommended, but not required, that digital or magnehelic gauges be calibrated annually.
2. Inward directional airflow has been confirmed by observation for the laboratory.
3. **Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly.**
4. If a Building Automation System (BAS) has the capacity to monitor and record performance measurements e.g., differential pressures, the entity is encouraged to capture and store data from potential failure events, drills, etc. This information may provide verification of system performance. In addition, any programmed BAS alarms should be verified for proper functioning.
5. All alarms (fire, air flow, security, etc.) have been checked and are functioning according to established specifications.
6. Laboratory HVAC HEPA filters, if present, have been certified annually.
7. Exhaust fan motors have been checked and routine maintenance conducted.
8. The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present.
9. All biological safety cabinets have been certified annually.
10. Seals on centrifuges, Class III cabinets, gloves on Class III cabinets, etc. have been checked and replaced if required.
11. Drench showers, eye wash stations, and hands-free sinks have been confirmed to be operating properly.

A/BSL4 Verification Policy Statement

(Release Date: February 9, 2023)

Section 3(A). Confirmation that decontamination systems are operating as designed: effluent, tissue, and autoclave decontamination systems

I. Annual **verification of system operational components** to ensure **biologically validated** set point parameters are maintained (e.g., volumetric, pressure, temperature components);

II. Biological **validation** is performed at least annually or more often, if required by institutional policy and/or risk assessment.

III. **Annual certification testing** of associated high-efficiency particulate air (HEPA) filters, if applicable (e.g., operating vent, pressure relief vent, chamber effluent/vent);

IV. Certification of laboratory HVAC, plumbing vent line, and decontamination system filters by appropriate means and appropriate acceptance criteria to ensure integrity (e.g., HEPA, PTFE).

V. **Verify appropriate filter media is selected** and maintained annually (e.g., HEPA, polytetrafluoroethylene [PTFE]); and

VI. **Implementation of a risk-based preventative maintenance** for other equipment that is critical to containment components, but is not specifically included above (e.g., cook tanks, etc.);

Verification of System Components: Value of the Preventative Maintenance Cycle (1 of 2)

Verification of system components usually includes testing and calibration of all gauges, transmitters and alarms such as:

- Pressure
- Temperature
- Level switches and alarms (load cell, radar, etc.)
- These system components are generally designed to include redundancy for each monitoring point.
- Recalibration should be assessed for each paired data point and allow for monitoring for set point drift outside of their tolerance.

Verification of System Components: Value of the Preventative Maintenance Cycle (2 of 2)

The verification process should also include:

- Exercising valves.

- Visual inspection of valves, piping, and tanks for leaks and defects.
  - Consider impact of frequent decontamination of system sub-components prior to a maintenance activity. For example, bleach versus MicroChem on gasketed unions.

- Building Automation System (BAS)/Human-Machine Interface (HMI) screens display/record proper parameter values.

EDS Batch Cycle Data. What trends do you see and what should that suggest regarding a maintenance event? (1 of 2)

Typical batch data record:

1. Batch cycle data presented must match **validated** parameters included in Standard Operating Procedures and other operational documents.
2. Consistent review of data will reveal any deviations from tolerance and should trigger the need for maintenance.

Batch Data Report

Batch:		2935
Reactor:		A
Batch Start:	10/5/2022	3:13:29 PM
Batch End:	10/5/2022	6:04:08 PM
Pass/Fail Status:		Pass

Elapsed Time:

Integrity Time (minutes):	20
Fill Time (minutes):	230
Warm Up Time (minutes):	73
Sterilizing Time (minutes):	60
Drain Time (minutes):	38

Cycle Data:

Total Effluent (gallons):	1033.1
ECM Water Total (gallons):	1436.3
Drain Total (gallons):	2469.5

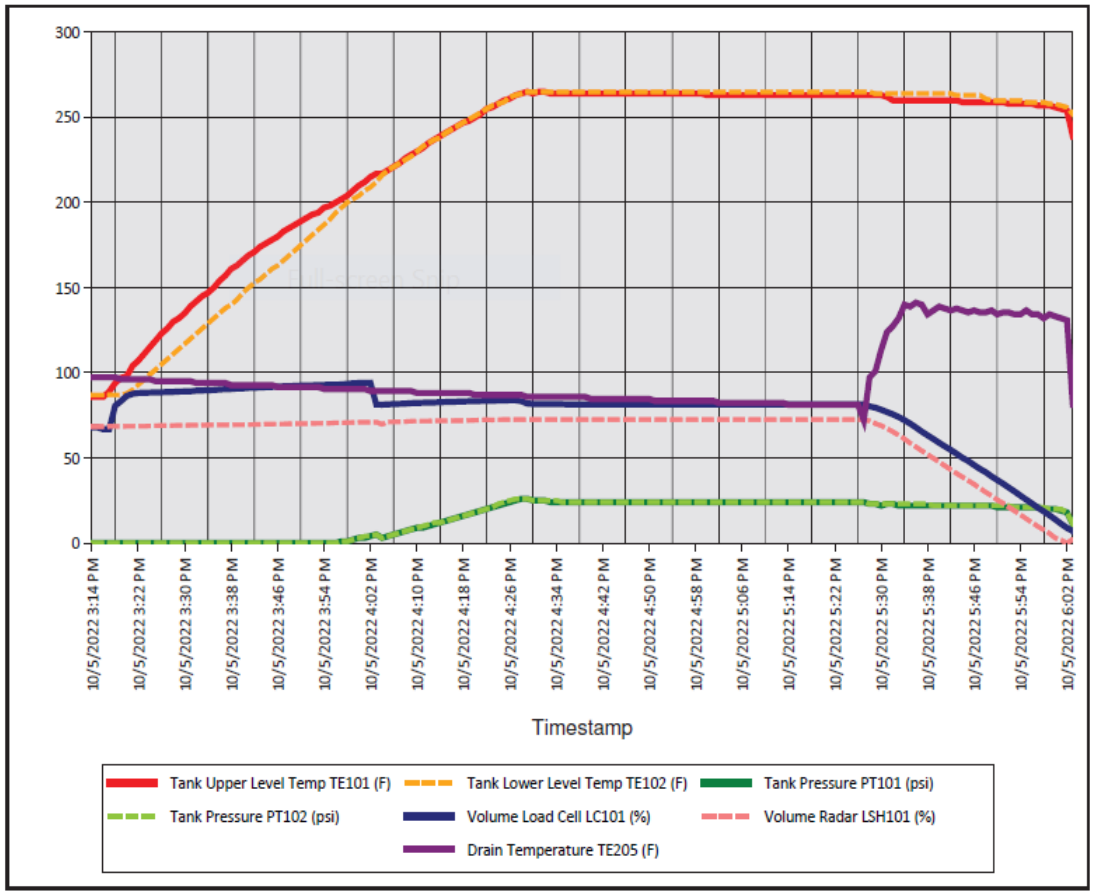
OP Setpoints:

Level (gallons):	950
Temperature (F):	260
Time (minutes):	61

Sterilization Phase Data:

Start Time:	10/5/2022	4:25:41 PM
End Time:	10/5/2022	5:25:58 PM
Start Pressure (psi):		23.9
End Pressure (psi):		23.6
Start Temperature (F):		259.9
End Temperature (F):		262.9
Max Temp. (F):		265
Min Temp. (F):		259.9
Warm Up Start Temp (F):		86

Comment:



EDS Batch Cycle Data. What trends do you see and what should that suggest regarding a maintenance event? (2 of 2)

Batch data reviews and changes in operational function:

1. Look for data drift between the paired redundant monitoring points
2. Look for delayed drain times, heat up times, etc.
3. Investigate root cause(s)

PRI

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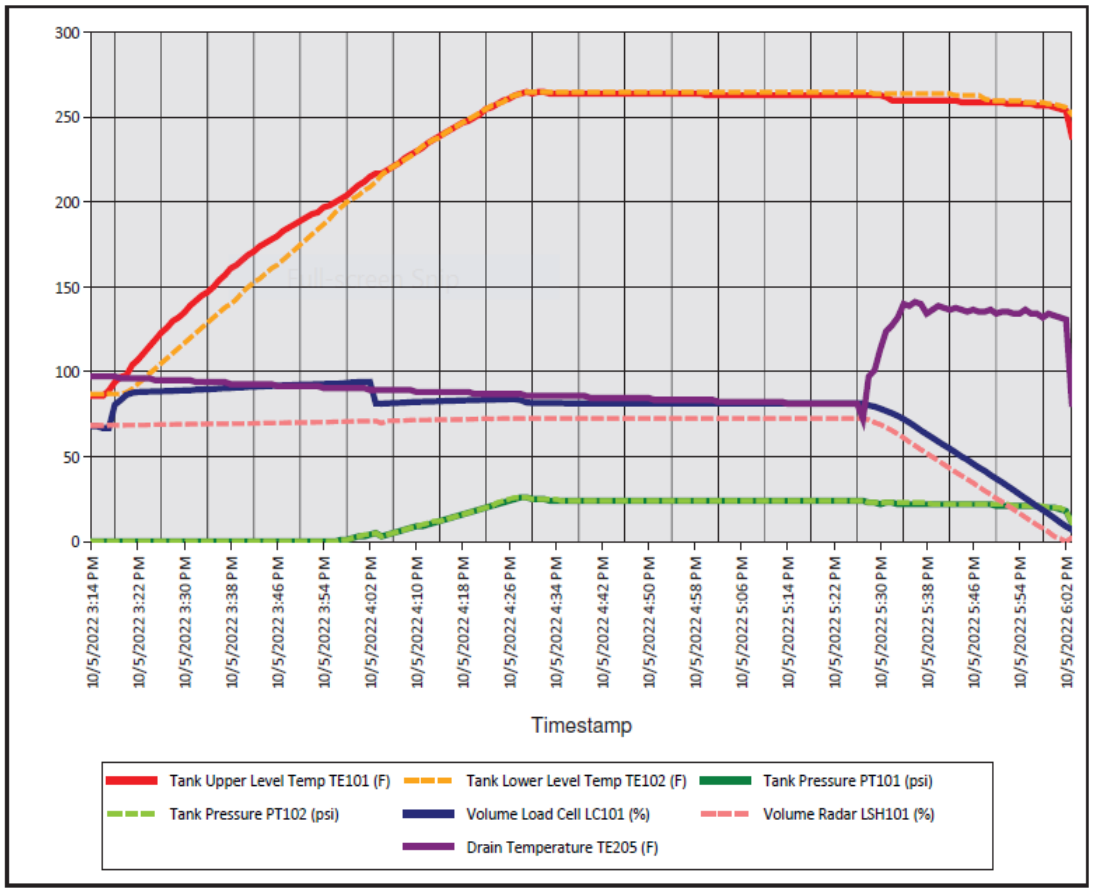


Annual Filter Verification

System Biocontainment Filters:

- Where and why?
  - Operating and emergency vents
  - Found on EDS design at both BSL3 and BSL4
- BSL4 containment design requires two in-line series vent filters
  - If polymeric membrane filters are used, a single dual-membrane filter generally meets the requirement for two in-series filters
- Test methods:
  - Water Intrusion Testing (WIT)
  - Poly Alpha Olefin (PAO) or equivalent challenge

Water Intrusion Testing (WIT)

- Pros:
  - Widely accepted
  - Manufacturer recommended
  - Tested *in situ*

- Cons
  - Requires specialized equipment
  - Requires specialized training
  - Equipment may become contaminated

Poly Alpha Olefin (PAO) Challenge Test

- Pros:
  - Does not require specialized equipment
  - Does not require specialized training
  - May be more suitable for unique filter orientation
- Cons
  - Challenge agent is a hydrocarbon oil
    - Effect on a hydrophobic membrane is not known (i.e., fouling, filter performance issues)
  - Appropriate definition of acceptance criteria
    - Bioburden correlation studies are limited
  - Not recommended by most PTFE (Teflon™) filter manufacturers

EDS Batch Cycle Data

Chemical batch data

Operators Batch Report Log

Date: 7-29-19

Batch#	Ejector Tank Levels #1	#2	Treatment Tank #	Fill Start Time	Fill Stop Time	Effluent Volume	Bleach Dose Required	Drain Start Time	Drain Stop Time	Batch Notes
1307	3952	4005	1	1845	1852	946	14 MIN	2106	2116	
1305	4276	4334	2	2006	2013	946	14 MIN	2227	2237	
1398	4534	4577	1	2116	2122	946	14 MIN	2336	2346	
1306	4460	4530	2	2237	2245	946	14 MIN	0057	0107	
1309	4380	4438	1	2346	2354	946	14 MIN	0208	0218	

Biological Validation (1 of 2)

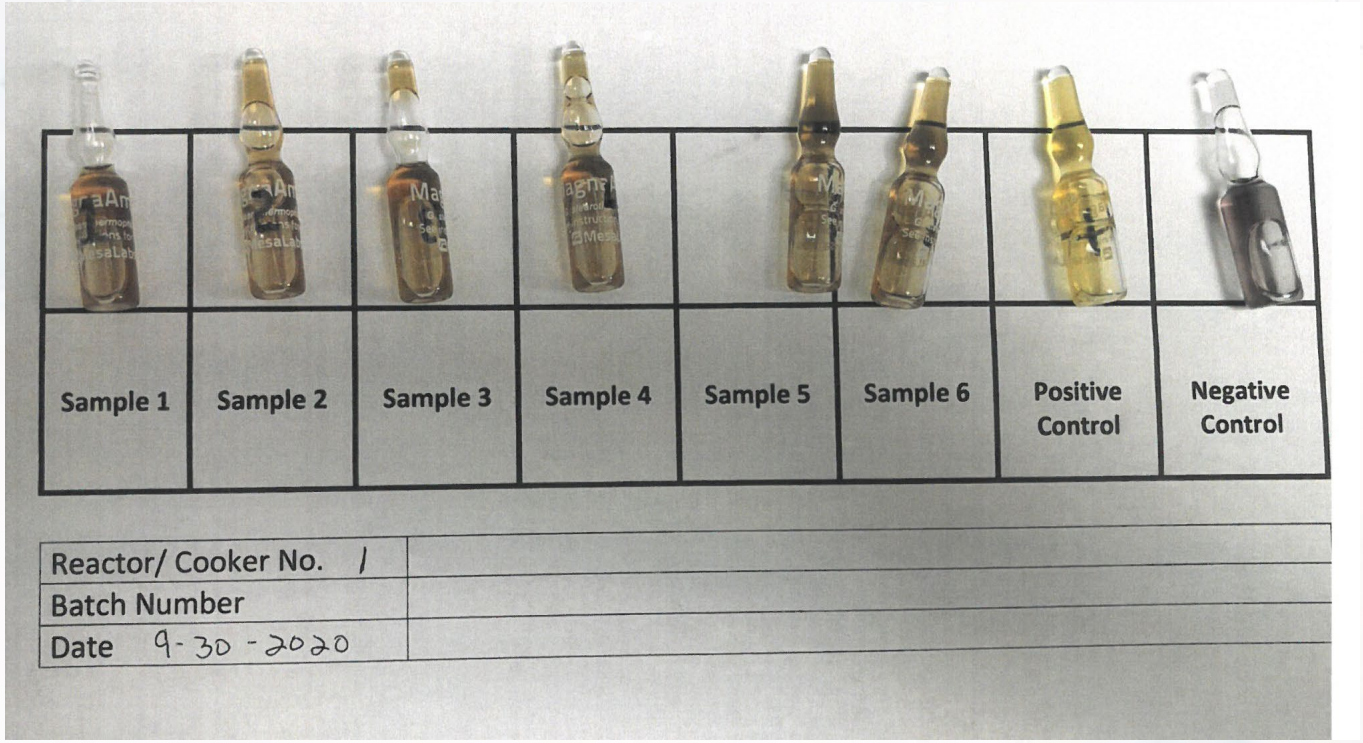
Requirements:

- BSL3: "Decontamination processes are verified on a routine basis." BMBL, BSL3, B.11
  - "Routine" is not clearly defined and should be established via risk assessment.
  - Validation is required if tank operational parameters are changed.
- BSL4: "Biological validation is performed at least annually or more often, if required by institutional policy." BMBL, BSL4, C.15(a).

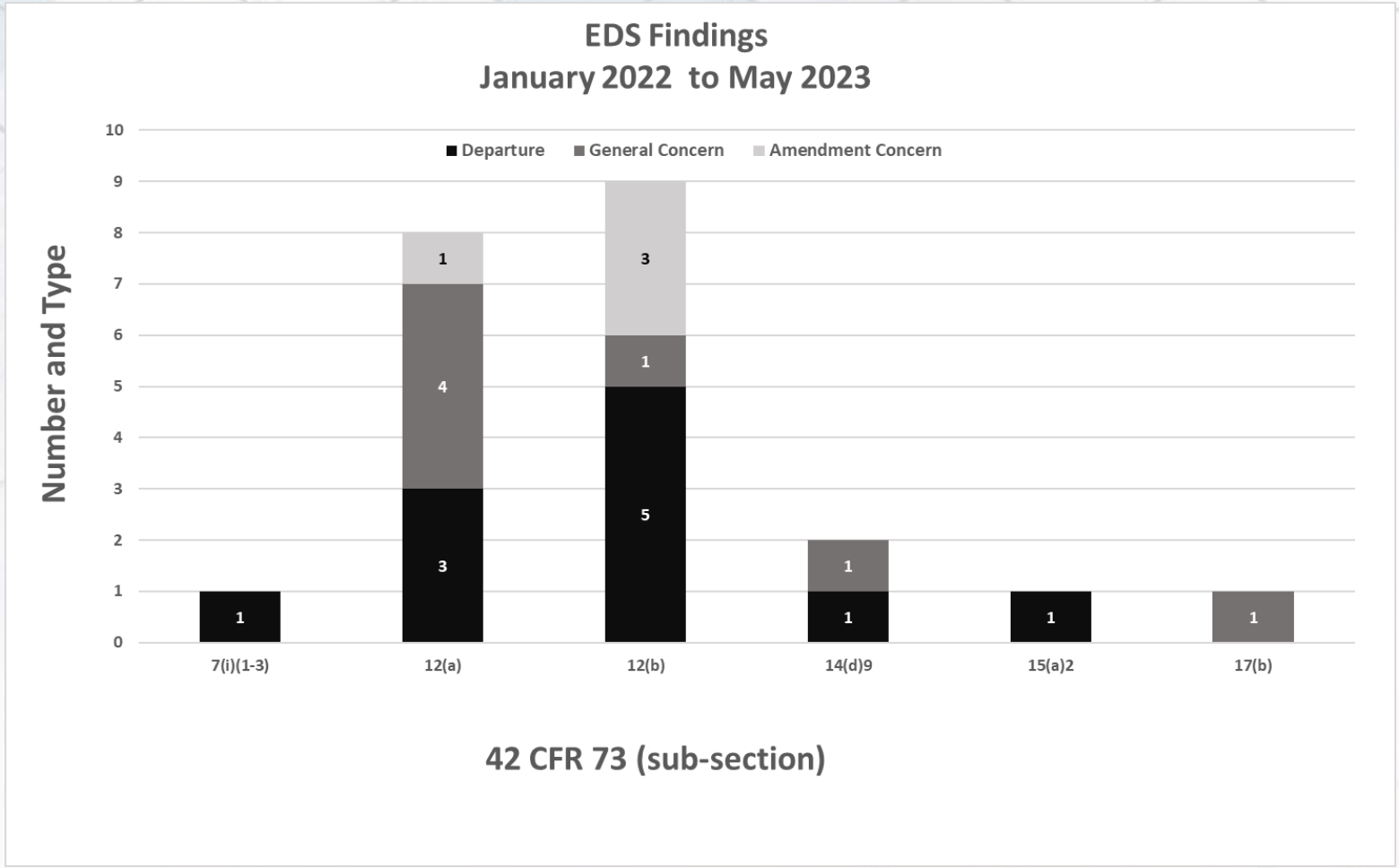
Biological Validation (2 of 2)

Methods:

- Biological indicators (BIs) are the predominant method of EDS validation.



What have we found during recent inspections?



Summary

General Maintenance:

- Operating parameters verified using BI's
- Verify System component tolerances
- Valves and appurtenances
- Filter verification
- Leak detection

Resources

The Federal Select Agent Program www.selectagents.gov:

- https://selectagents.gov/regulations/policy/BSL3ABSL3.htm
- https://selectagents.gov/regulations/policy/BSL4ABSL4.htm

www.selectagents.gov

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