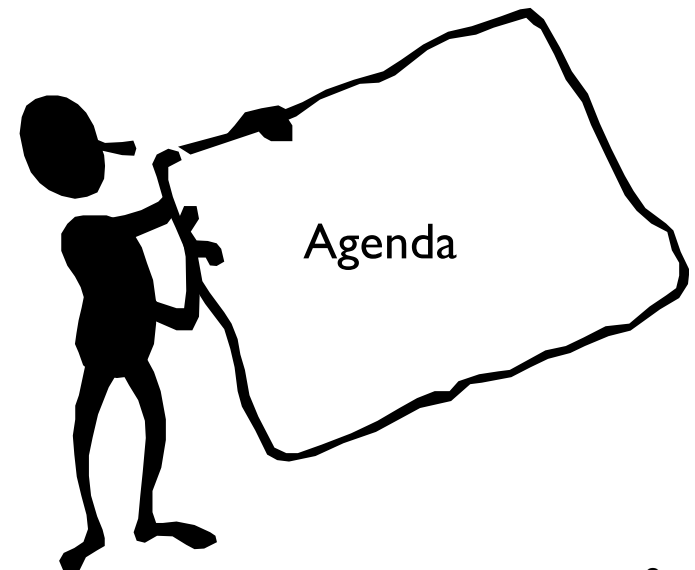


Agenda

- ▶ Formaldehyde Hazards and Regulations
- ▶ Case study background
- ▶ Exposure Assessments Conducted
- ▶ Next Steps - Ventilation Design
- ▶ Ventilation Re-Design
- ▶ Surrogate Monitoring
- ▶ Conclusion
- ▶ Lessons Learned



Formaldehyde

Formaldehyde Hazards

- ▶ Toxic (inhalation, dermal)
- ▶ Corrosive to the eyes
- ▶ Skin/respiratory irritant and sensitizer
- ▶ Carcinogen



Formaldehyde Uses

- ▶ Component of Formalin (preserving biological samples/tissue fixation)
- ▶ Commonly used in histology & pathology labs
- ▶ Used in embalming solutions

Cal/OSHA Formaldehyde Standard

- ▶ **Cal/OSHA Regulated Carcinogen**
- ▶ **Employer Requirements:**
 - Monitor formaldehyde levels.
 - Implement ventilation and work practice controls.
 - Provide personal protective equipment (PPE).
 - Establish medical surveillance programs.
 - Train employees on hazards and safety.

These OELs are established to minimize health effects of formaldehyde exposure.

Cal/OSHA Action Level (ppm)	Cal/OSHA PEL (ppm)	ACGIH TLV (ppm)	Cal/OSHA STEL (ppm)	ACGIH STEL (ppm)
0.5	0.75	0.1	2	0.3

Applicability of Formaldehyde Standard

- ▶ Substance-specific standards (e.g., regulated carcinogens) superseded by the Lab Standard in Research
- ▶ Exceptions include:
 - Limiting exposure to the OEL/AL,
 - where skin and eye contact is prohibited,
 - medical surveillance requirements,
 - Article 110 reporting, and
 - **Section 5217 shall apply to anatomy, histology and pathology laboratories.**

Background at University Medical School

- ▶ Embalming lab run by two personnel for 40+ years. Prior exposure assessment did not indicate exposure concern (less than the AL).
- ▶ New staff joined, triggering new exposure assessment interest.
- ▶ Jan. 2022 - first air monitoring session with new staff.



Donor Program

- ▶ The School of Medicine manages a donor/gift/willed body program.
- ▶ Donors can be used for:
 - Fresh/frozen for research
 - Embalmed for research or teaching
 - Long term storage may be needed
- ▶ Donors are screened upon arrival:
 - Hep B/C., HIV
 - Weight - < 230 lbs
- ▶ Embalming completed within 3 days of receipt of serology
 - IH gets at most 3-4 days notice for scheduling air monitoring

Embalming 101

- ▶ Body cleaned, clothes removed, and body placed on embalming table
- ▶ Cannula inserted in femoral artery and carotid artery
- ▶ Small hole drilled in skull, 60-120 cc embalming fluid injected into brain
- ▶ Embalming fluids fed into body from embalming machine through cannula
- ▶ Injections into digits with syringe
- ▶ Excess fluids from process collected from drain hole in table into carboy
- ▶ Post-embalming, clean and wrap body for storage
- ▶ Store on a large rack
- ▶ Typically 1.5-2.5 hours per body. Up to 3 bodies per day, rarely seen.

Embalming Hazards

- ▶ **Chemical (formaldehyde, phenol)**
- ▶ Biological (ATD, BBP)
 - Sharps
- ▶ Ergonomics
 - Heavy and awkward lifts
 - Awkward posture
 - RSI from finger force (injections and cutting clothes)
- ▶ Physical hazards
 - 55-gallon drum using a 2-point lift

Embalming Solutions

- ▶ Two solutions varying ratios depending on needs
- ▶ About 3-6 gallons total
- ▶ Proprietary solutions unique to each institution
 - Typically a minimum of 3-4% formaldehyde to prevent mold growth

Solution 1:

~3% Formaldehyde. Other hazardous ingredients 45-55% IPA

Solution 2:

~3% Formaldehyde, 15% phenol, Other hazardous ingredients 45-55% IPA

Formaldehyde Exposure Sources

- ▶ **Body**
 - Injection
 - Excess fluid leakage
 - Squirting out
- ▶ **Fluid transfers**
 - From 55-gallon drums to bucket
 - Bucket to embalming machine
 - Filling syringe from bucket
 - Pouring waste bucket to 55-gallon drum



Existing Exposure Controls



- ▶ Ventilation
 - 12 ACH general exhaust ventilation
- ▶ Work practices
 - Capping and closing the drums
- ▶ PPE
 - Safety glasses
 - Disposable PE gown
 - Disposable nitrile gloves
 - Safety shoes
 - Scrubs

Initial Air Monitoring Observations

- ▶ EE hand pumped solutions from 55-gallon drums to bucket
- ▶ Poured from bucket to embalming machine
- ▶ Waste bucket hanging from drain hole, no lid
- ▶ Poured waste bucket into a funnel to the 55-gallon drum
- ▶ EE's breathing zone was in the pumping/pouring zone due to stature
- ▶ Only one body embalmed



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Initial Air Monitoring Results

Sample Location	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)	Cal/OSHA PEL / AL (ppm)	ACGIH TLV (ppm)
Area - Above sink near gurney	0.94	0.29	0.75	0.1
EE – embalming task	2.5	0.79	0.75 / 0.5	0.1

Initial Air Monitoring Results

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Area - Above sink near gurney	0.94	0.29	0.75	0.1
EE – embalming task	2.5	0.79	0.75 / 0.5	0.1
EE – pumping Embalming Sol'n 1 to fill embalming machine	2.0	N/A	2 (STEL)	0.3 (STEL)
EE – pumping Embalming Sol'n 2 to fill embalming machine	1.6	N/A	2 (STEL)	0.3 (STEL)
EE – pumping Embalming Sol'n 1 to fill embalming machine	2.4	N/A	2 (STEL)	0.3 (STEL)
EE – pouring waste solution into waste drum	6.4	N/A	2 (STEL)	0.3 (STEL)

Pouring Waste Solution into a Drum

- ▶ Step with highest exposure:
 - 16-min. Sample: 6.4 ppm
 - Cal/OSHA STEL: 2 ppm
 - ACGIH STEL: 0.3 ppm



Recommendations from Initial Air Monitoring

- ❑ Continued monitoring
- ❑ Engineering controls
 - ❑ Peristaltic/Electric pump
 - ❑ Local exhaust ventilation / downdraft table
 - ❑ Collect waste directly into waste carboy; no consolidation
- ❑ Administrative Controls
 - ❑ Training
 - ❑ Covers open & waste bucket
 - ❑ Signage
 - ❑ Turn off embalming machine between tasks
- ❑ PPE
 - ❑ Respirators
 - ❑ Improved skin protection - gown and gloves
 - ❑ Improved splash protection - goggles and face shield

Air Monitoring Reassessment - Round 2 (March 2023)

- ▶ 14 months later, a new personnel
- ▶ Improvements implemented to date:
 - ☑ Continued monitoring
 - ☐ Engineering controls
 - ☑ Peristaltic/Electric pump
 - ☐ Local exhaust ventilation / downdraft table
 - ☑ Collect waste directly into waste carboy; no consolidation
 - ☐ Administrative Controls
 - ☑ Training
 - ☑ Covers open & waste bucket
 - ☑ Signage
 - ☑ Turn off embalming machine between tasks
 - ☐ PPE
 - ☑ Respirators
 - ☐ Improved skin protection - gown and gloves
 - ☐ Improved splash protection - goggles and face shield

(Check box from Flat Icon by Juicy Fish)

Air Monitoring Reassessment - Round 2 (March 2023)

- ▶ 14 months later, a new personnel
- ▶ Observations:
 - Spraying may occur during injections
 - Eyewash/safety shower not tested in 3 months*
 - Still wearing PE gown
 - Manual pumping solution 2



Air Monitoring Reassessment - Round 2 (March 2023)

- ▶ 14 months later, a new personnel
- ▶ Observations:
 - Spraying may occur during injections
 - Eyewash/safety shower not tested in 3 months*
 - Still wearing PE gown
 - Manual pumping solution 2
 - Pouring solutions into embalming machine



Air Monitoring Reassessment - Round 2 (March 2023)

Sample Location	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)	Cal/OSHA PEL / AL (ppm)	ACGIH TLV (ppm)
Area - Above sink near gurney	1.0	0.36	0.75 / 0.5	0.1
EE – embalming task	1.4	0.51	0.75 / 0.5	0.1
EE – pumping Embalming Sol'n 1 to fill embalming machine (electric pump)	0.25	N/A	2 (STEL)	0.3 (STEL)
EE – pumping Embalming Sol'n 2 to fill embalming machine (manual)	1.4	N/A	2 (STEL)	0.3 (STEL)
EE – moving waste containers	0.84	N/A	2 (STEL)	0.3 (STEL)

Recommendations from Round 2 Assessment

- ❑ Continue monitoring
- ❑ Engineering controls
 - ❑ Electric pump for solution 2
 - ❑ Ventilation - install LEV near gurney or ventilated table
- ❑ Administrative Controls
 - ❑ Update embalming room procedures SOP to reflect current practices
- ❑ PPE
 - ❑ Wear chemical safety goggles and face shield or a full face respirator during tasks with splash hazard
 - ❑ Improved skin protection - gown and gloves

Air Monitoring Reassessment - Round 3 (Oct. 2023)

- ▶ New staff
- ▶ Electric pump for both solutions
- ▶ New embalming machine (first use)
- ▶ Observations:
 - EE wore prescription eyeglasses and ½-face APR
 - Wore disposable PE gown

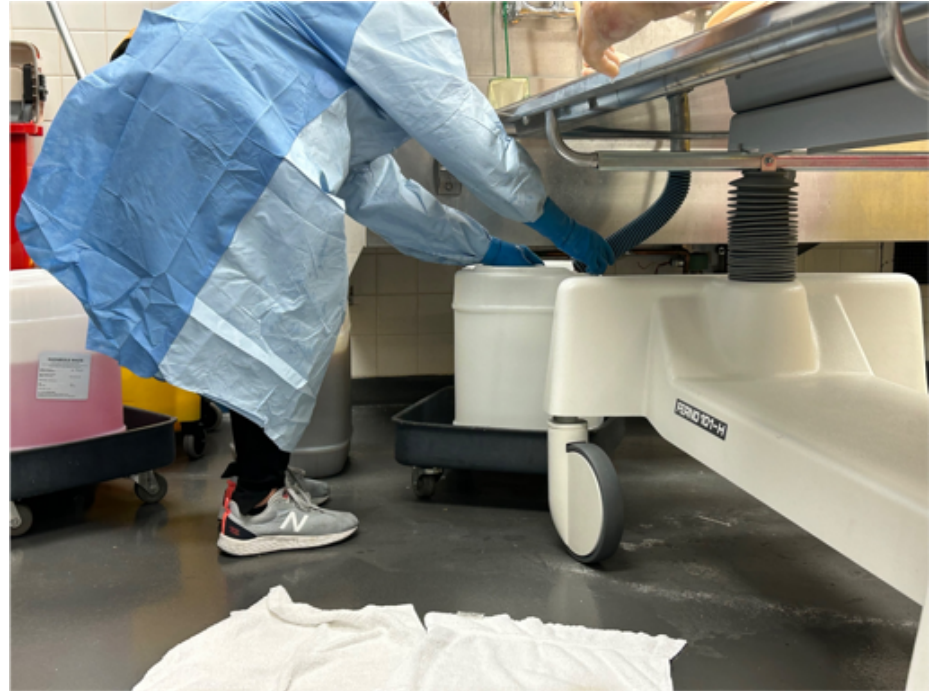


Round 3 Improvements

No more pouring!



Waste solution transfer - no pouring of waste solutions



Round 3 Monitoring Results

Sample Location	Sample Duration (minutes)	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)	Cal/OSHA PEL (ppm)	Cal/OSHA Action Level (ppm)	ACGIH TLV (ppm)
Area – Above sink	174	0.24	0.087	0.75	0.5	0.1
EE –embalming task	173	0.38	0.14	0.75	0.5	0.1
EE – pumping Sol’n 1 to fill embalming machine	15	0.16	N/A	2 (STEL)	0.5	0.3 (STEL)
EE – pumping Sol’n 2 and 1 to fill embalming machine	15	0.27	N/A	2 (STEL)	0.5	0.3 (STEL)
EE – pumping Sol’n 2 to fill embalming machine	15	0.24	N/A	2 (STEL)	0.5	0.3 (STEL)
EE – change out waste carboy under gurney	16	0.37	N/A	2 (STEL)	0.5	0.3 (STEL)

Improvements in Exposure Results

Sample Location	January 2022		March 2023		October 2023	
	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)	Task Result (ppm)	Calculated 8-Hr TWA Result (ppm)
Area - Above sink	0.94	0.29	1.0	0.36	0.24	0.087
EE –embalming task	2.5	0.79	1.4	0.51	0.38	0.14
EE –fill embalming machine with Sol'n 1 (manual pump in 2022, electric pump in 2023)	2.0 and 2.4	N/A	0.25	N/A	0.16, and 0.27	N/A
EE –fill embalming machine with Sol'n 2 (manual pump in 2022 and Mar. 2023, electric pump in Oct. 2023)	1.6	N/A	1.4	N/A	0.27 and 0.24	N/A
EE – managing waste (pouring into drums in 2022, moving waste containers in 2023)	6.4	N/A	0.84	N/A	0.37	N/A

Cal/OSHA AL (ppm)	Cal/OSHA PEL (ppm)	ACGIH TLV (ppm)	Cal/OSHA STEL (ppm)	ACGIH STEL (ppm)
0.5	0.75	0.1	2	0.3

Recommendations from Round 3 Assessment

- ▶ Ventilation
 - LEV
- ▶ Continue monitoring
- ▶ Update SOP
- ▶ PPE
 - Wear prescription safety goggles + face shield / full face APR with prescription spectacle kit
 - Improve gown material (no polyethylene)

Air Monitoring Reassessment - Round 4 (March 2024)

- ▶ No changes to engineering controls or work practices
- ▶ Observations:
 - Spray occurred, left room to change
 - Not wearing faceshield
 - Cartridges expired on half-face APR
- ▶ Results:
 - Below Cal/OSHA but exceed ACGIH OELs

Round 4 Results

Sample Location	Sample Duration (minutes)	Task Result (ppm)	Calculated 8- Hr TWA Result (ppm)	Cal/OSHA PEL (ppm)	Cal/OSHA Action Level (ppm)	ACGIH TLV (ppm) ¹
EE - embalming task	120	0.56	0.36	0.75	0.5	0.1
Area sample – sink near table	120	0.65	0.16	0.75	0.5	0.1
Electric pumping solution 1	15	0.45	N/A	2 (STEL)	0.5	0.3 (STEL)
Electric pumping solution 2	15	0.65	N/A	2 (STEL)	0.5	0.3 (STEL)
Waste container change out	15	0.89	N/A	2 (STEL)	0.5	0.3 (STEL)

Takeaways After Multiple Rounds of Exposure Assessment

- ▶ Only so much can be fixed without engineering controls/ventilation
- ▶ PPE is unreliable
- ▶ Individual practices are more difficult to control
- ▶ All samples were of 1 embalming procedure. If the results were extrapolated to 2-3 procedures in a day, the AL would be exceeded.

Conclusion:

Additional measures are needed, ideally improved ventilation.

Next Steps - Ventilation Design

- ▶ Best design is to locate ventilation close to the source
- ▶ Identified a ventilated embalming table from a reputable manufacturer in the mortuary industry
- ▶ School of Medicine project managers worked with the Embalming Program leadership to acquire and install.



Next Steps - Ventilation Design

- ▶ Best design is to locate ventilation close to the source
- ▶ Identified a ventilated embalming table from a reputable manufacturer in the mortuary industry
- ▶ School of Medicine project managers worked with the Embalming Program leadership to acquire and install.
- ▶ Embalmer “wanted to cry” when she saw the new table
 - Too small for a body!
 - Lots of gurney manipulation to move the body
 - Fluid drained into the ventilation run
- ▶ Went back to the traditional unventilated embalming gurney

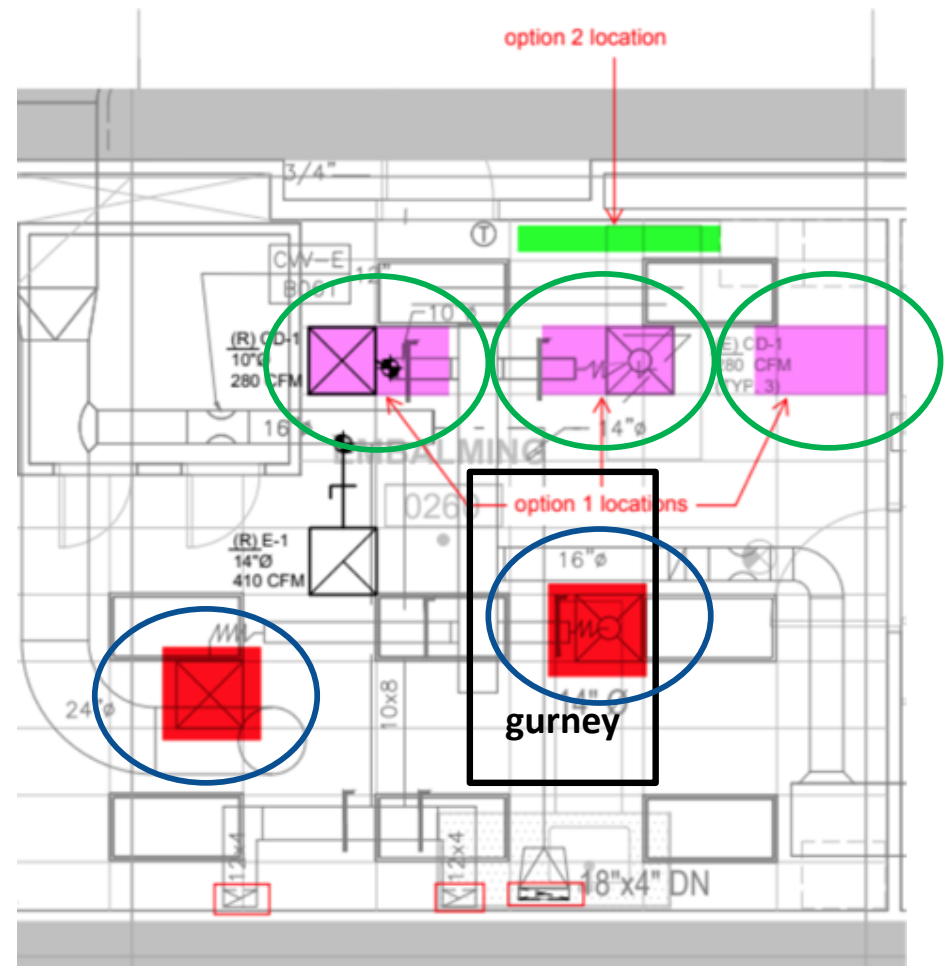


Ventilation Redesign

1. Customize the existing downdraft table
 - a. Rejected by project team - good money after bad
2. Benchmarking
 - a. Worked with a different local university with a similar embalming program, got their IH data, site visit.
 - b. Their air monitoring data was well below Cal/OSHA AL / STEL even for multiple procedures / day
 - c. Similar formaldehyde concentration used.
 - d. Push/pull system of general supply at ceiling and slot hood at foot and a canopy hood over the 55-gallon drum 10 feet from foot of embalming table
3. SOM Project Team brought in HVAC Engineers
 - a. Suggested two push-pull design options

Assessing the Options

- ▶ Close two supply grilles
- ▶ Open supply grilles near head



Testing + Mock-up

- ▶ Option 1: Open the ceiling grille for “soft” air diffusion from the plenum
- ▶ Option 2: Place a box under the ceiling opening that is open to the wall



Option 1



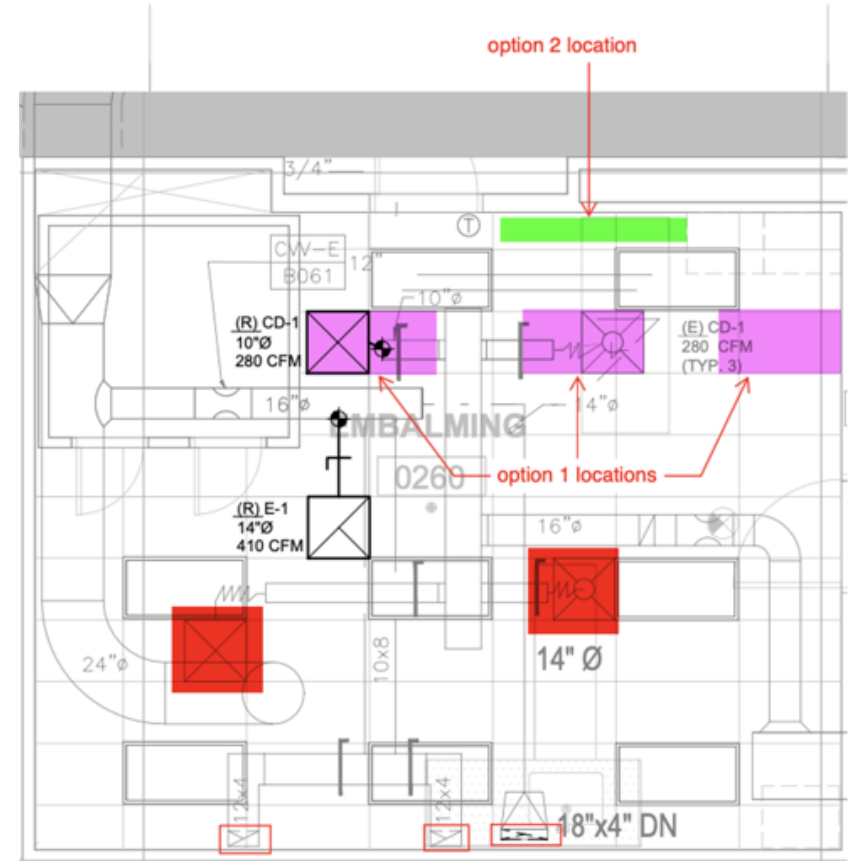
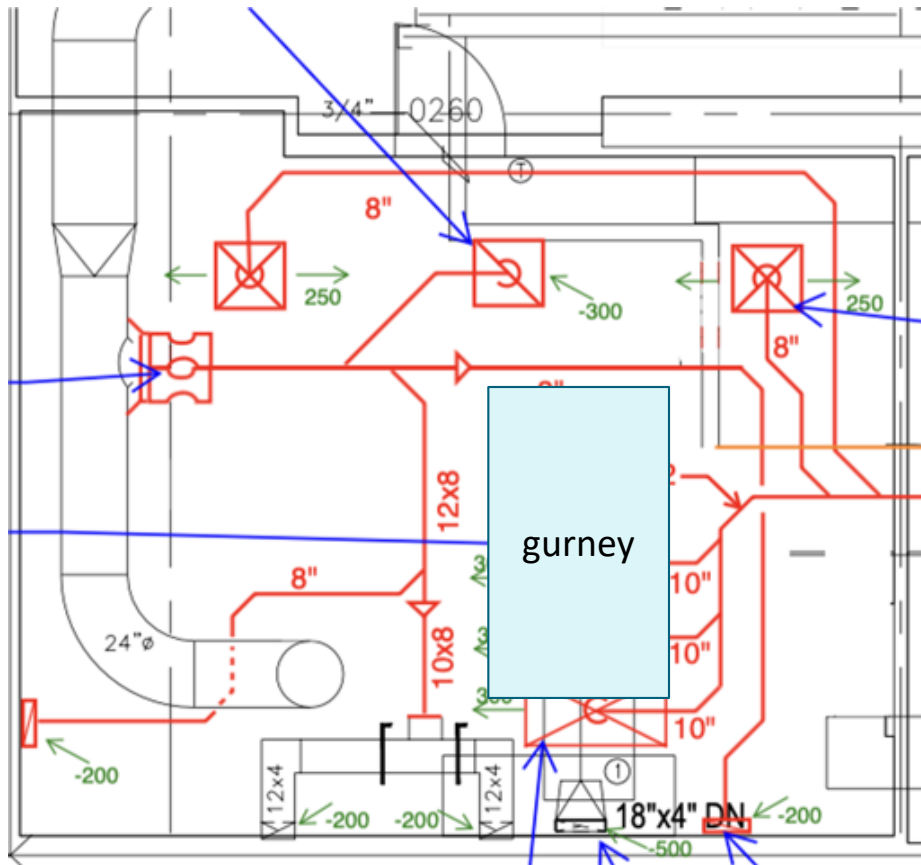
Option 2

Monitoring Options

- ▶ Embalming procedure
 - Logistically difficult
 - Variability in the procedure, not apples to apples
 - Unnecessary hazard
- ▶ Embalming Solutions only
 - Unnecessary hazard
- ▶ Surrogate
 - Low(er) hazard/toxicity & higher OELs
 - Similar vapor pressure
 - Detectable on real time instrument
 - Cheap, readily accessible



Layout and Re-Design Options



Monitoring IPA concentrations during mock use



PID locations simulate areas where embalmer typically stands while embalming

Simulated use of chemical at gurney and embalming machine



Poured 160-ml IPA on gurney to simulate embalming solution leaking out of body

IPA

Placed open containers of IPA to simulate open containers of embalming solutions: 40-ml on gurney and 120-ml on top of embalming machine

Surrogate Air Monitoring

1. “As-Is”: Measured IPA concentrations with existing ventilation conditions
2. Option 1: Open the ceiling grille for “soft” air diffusion from the plenum
3. Option 2: Place a box under the ceiling opening that is open to the wall

For each condition above, 3 iterations were performed to get 3 sets of data.

Results

PID location	Existing Set-up - IPA concentration	Option #1 - IPA concentration	Option #2 - IPA concentration
	Average (ppm)	Average (ppm)	Average (ppm)
Head	22.6	9.5	9.5
Foot	15.1	17.9	17.1

Note: As-is ventilation allowed general mixing; options 1 & 2 “pushed” air from head to toe of gurney

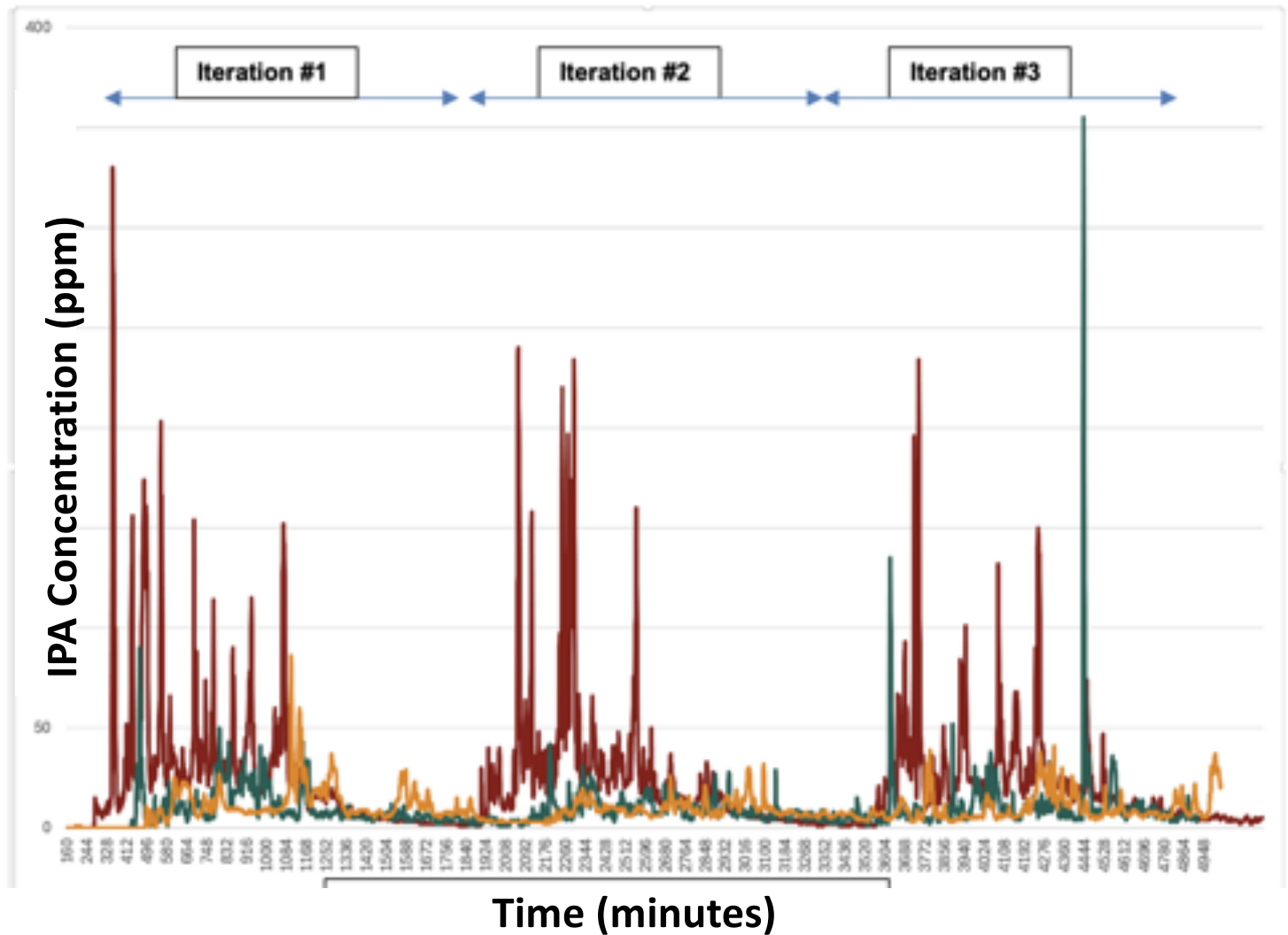
Results

PID location	Existing Set-up - IPA concentration		Option #1 - IPA concentration		Option #2 - IPA concentration	
	Maximum (ppm)	Average (ppm)	Maximum (ppm)	Average (ppm)	Maximum (ppm)	Average (ppm)
Head	330	22.6	355	9.5	86	9.5
Foot	78	15.1	113	17.9	135	17.1

Note: As-is ventilation allowed general mixing; options 1 & 2 “pushed” air from head to toe of gurney

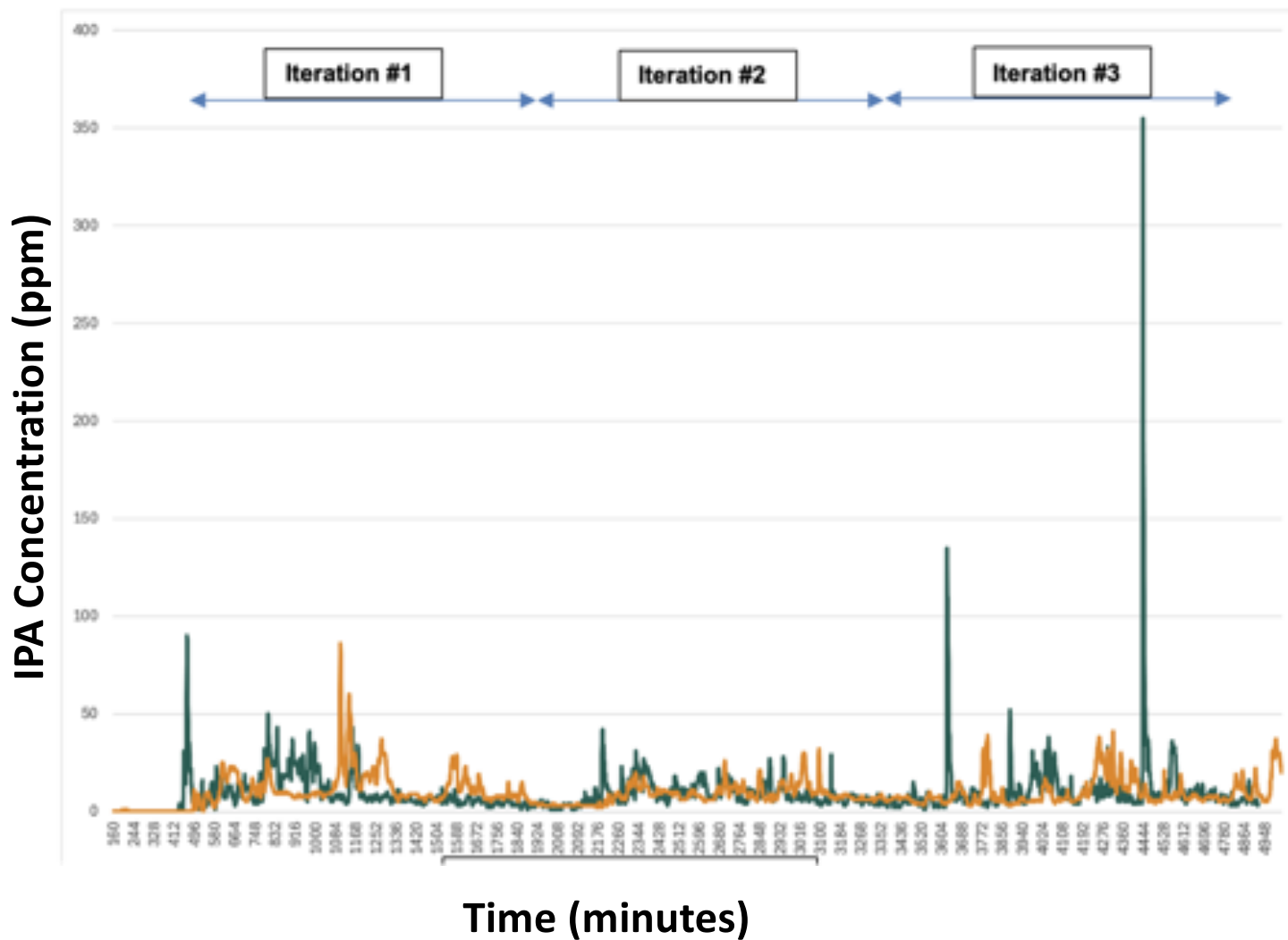
Results: Head of table

- As-is
- Option 1
- Option 2



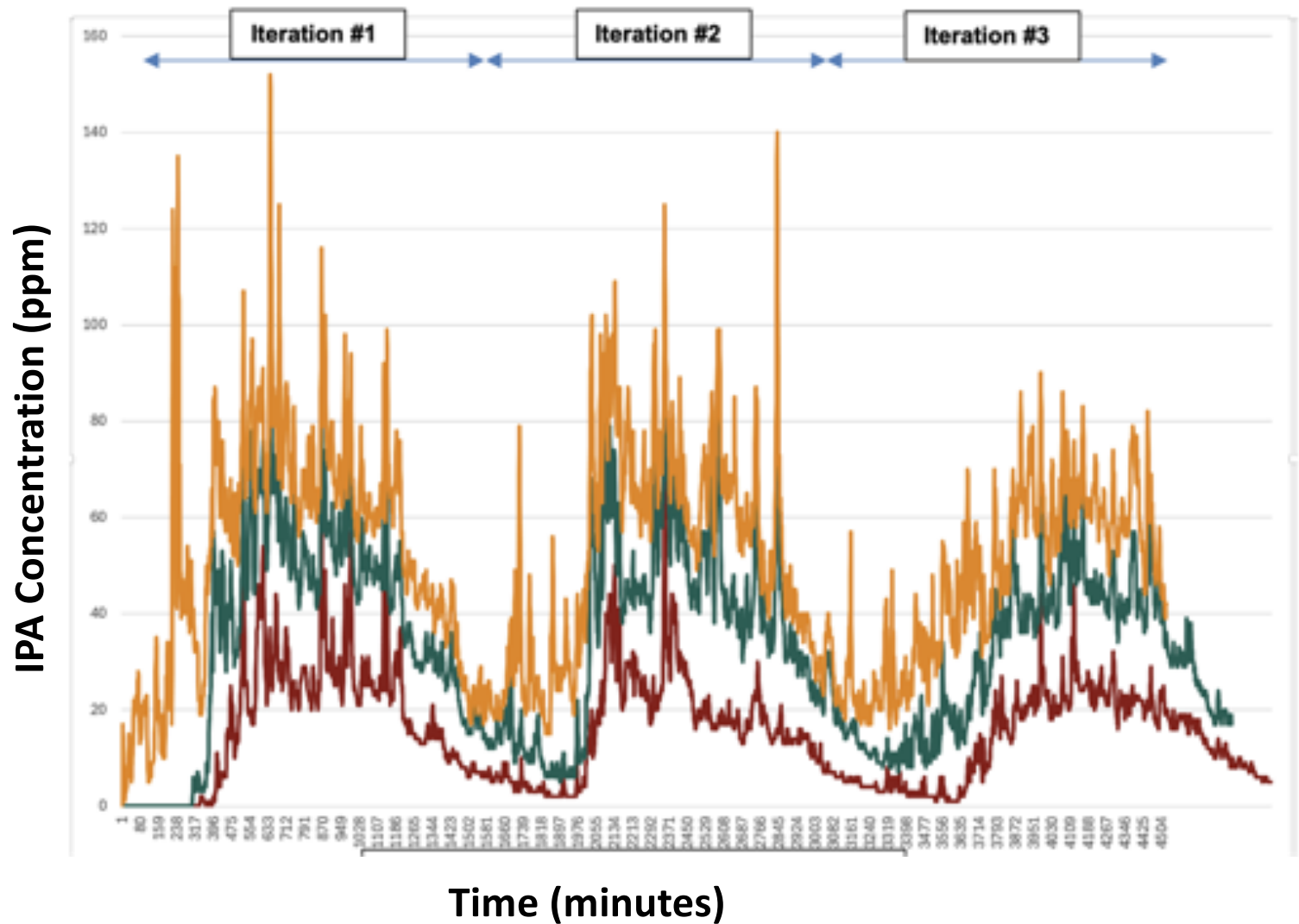
Results: Head of table (Option 1 v. 2)

Option 1
Option 2



Results: Foot of table

- As-is
- Option 1
- Option 2



Lessons Learned

- ▶ Everyone needs to be at the table, especially the line workers
- ▶ Try it before you buy it
- ▶ Walk through the whole process
 - Encourage workers to see products at conferences
- ▶ Surrogate monitoring is highly valuable
 - Consistent and repeatable
 - Configurable to instrumentation needs
 - Can adjust hazard profile
 - Real-world data collection
 - Data-driven decision making prior to capital investment
- ▶ Engineering controls are more effective and consistent than PPE