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BUILDING PARTNERSHIPS FOR A SAFER WORKPLACE

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Keys to a Successful VPP IH Program

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VPP
Voluntary Protection Programs
An OSHA Cooperative Program

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Food for Thought

- Do you have a formal IH program?
- What IH goals do you have for 2019?
- How do you account for exposures when starting a new project?
- Is your program thriving?

OSHA VPP Site-Based Participation Evaluation Report

Section I: Management Leadership & Employee Involvement	Yes or No		Interview	Observation	Doc Review
A. Written Safety & Health Management System					
A1. Are all the elements (such as Management Leadership and Employee Involvement, Worksite Analysis, Hazard Prevention and Control, and Safety and Health Training) and sub-elements of a basic safety and health management system part of a signed, written document? (For Federal Agencies, include 29 CFR 1960.) If not, please explain. ▪					
A2. Have all VPP elements and sub-elements been in place at least 1 year? If not, please identify those elements that have not been in place for at least 1 year. ▪					
A3. Is the written safety and health management system at least minimally effective to address the scope and complexity of worksite hazards? If not, please explain. **MRØ** ▪					

OSHA VPP Site-Based Participation Evaluation Report

Section I: Management Leadership & Employee Involvement
B. Management Commitment & Leadership
B1. Does management overall demonstrate at least minimally effective, visible leadership with respect to the safety and health management system (as per FRN, VOL. 74, NO. 6, 01/09/09 page 936, IV. A.5. a-h)? Provide examples. **MRØ** ▪
B2. How has the site communicated established policies and results-oriented goals and objectives for employee safety to employees? ▪
B3. Do employees understand the goals and objectives for the safety and health management system? ▪

OSHA VPP Site-Based Participation Evaluation Report

A. Baseline Hazard Analysis
A1. Has the site been at least minimally effective at identifying and documenting the common safety and health hazards associated with the site (such as those found in OSHA regulations, building standards, etc., and for which existing controls are well known)? If not, please explain. **MRØ** ▪
A2. What methods are used in the baseline hazard analysis to identify health hazards? (Please include examples of instances when initial screening and full-shift sampling were used. See FRN page 937, B.2.b) ▪
A3. Does the company rely on historical data to evaluate health hazards on the worksite? If so, did the company identify any operations that differed significantly from past experience and conduct additional analysis such as sampling or monitoring to ensure employee protection? If so, please describe. ▪
A4. Does the site have a documented sampling strategy used to identify health hazards and assess employees' exposure (including duration, route, and frequency of exposure), and the number of exposed employees? If not, please explain. **MRØ** ▪
A5. Do sampling, testing, and analysis follow nationally recognized procedures? If not, please explain. ▪
A6. Does the site compare sampling results to the minimum exposure limits or are more restrictive exposure limits (PELs, TLVs, etc.) used? Please explain.

Search for the Key Where to Start Building

- Inventory your exposures
- Make priorities and build a sampling plan
- Consider statistical significance

Evaluate Your Operations

- Best practice is for companies to develop Job Hazard Analysis (JHA)
  - Inventory of exposures should occur when JHAs are developed
- Use chemical inventory required per 1910.1200.
- Look at SDSs and labels

Hellman & Associates JHAs

JOB HAZARD ANALYSIS FORM

Job Title: Oil & Gas Site Assessments **Date:** June 15, 2015

Job Location: Location dependent on project and client

Step	Hazard	Cause	Preventive Measure
1) Walking onto site	Auto-pedestrian accident	Heavy equipment or oil hauler operator not seeing you.	• Yield to all traffic. • Make eye contact with operators of equipment and receive an acknowledgement.
	Asphyxiation	Various gases on site.	• Wear calibrated 4 gas monitor on site. • Stand upwind of operating equipment, wells and tanks. • Stay away from normal operating vents and from areas where employees may be actively venting tanks or opening hatches. • Watch gas monitor when approaching site. • Visually inspect site from distance for leaks before approaching.
	Hand Injury	Sharp edge or pinch point.	• Be conscious of hand placement. • Watch for unprotected equipment. • Wear appropriate gloves.

Hellman & Associates JHAs

JOB HAZARD ANALYSIS FORM

Job Title: Industrial Hygiene Assessment **Date:** March 7, 2016

Job Location: Not Applicable

Step	Hazard	Cause	Preventive Measure
1) Anticipation of hazardous conditions at site where assessment will be performed.	Unknown.	Unknown.	Call site before assessment and inquire about specific job hazards. Are there air contaminant hazards, chemical hazards, physical hazards, or biological hazards? Gather information about site safety by reading company safety rules or watching site safety video.
2.) Identify site activity and PPE needs.	Employee health hazards.	Not being fully prepared.	Ask site contact for a list of PPE their employees are required to wear and an explanation of the activity you will be monitoring. Additionally, ask what engineering controls, administrative controls, and PPE are currently being utilized at their site. Inspect all PPE and equipment and ensure that it is working properly and meets all ANSI standards before heading to job site.
3.) Recognition of specific hazards associated with industrial hygiene assessment.	Air contaminants.	Inhalation of particulate, gas, or vapor contaminants.	Utilize best judgment to determine if additional PPE is needed (document the PPE assessment on the Certification of PPE Hazard Assessment form). Conduct H&A employee monitoring while during the assessment in order to determine H&A employee exposure (documented on Project Management Checklist).

Hellman & Associates Project Checklist

Company:		**Project Manager/Consultant:**	
Project:		**Project Date**	

☐	1. Review proposal. Make sure that scope and allotted hours to complete the project are understood.
☐	2. Schedule project kickoff meeting.
☐	3. Contact client representative to schedule work. Identify potential hazards and company requirements for conducting onsite work. (Note: Check box format is Yes/No.)

(Y/N) Hazard Identification:	(Y/N) PPE Required:	(Y/N) Other:
☐/☐ Driving[1]	☐/☐ Hearing Protection	☐/☐ H&A staff IH monitoring required?
☐/☐ Loud noise (if ≥ 95 dBA)[2]	☐/☐ Safety Glasses/Goggles	☐/☐ New JHA needed?
☐/☐ Chemical[1]	☐/☐ Safety Shoes	☐/☐ PPE assessment?
☐/☐ Electrical[1]	☐/☐ Gloves[2]	☐/☐ Sampling plan?
☐/☐ Heat stress[1]	☐/☐ Hard Hat	☐/☐ Camera use ok?
☐/☐ Cold stress[1]	☐/☐ Respirator[2]	☐/☐ Escort required?
☐/☐ Elevated work/Ladder Use	☐/☐ Fall Protection[2]	☐/☐ Non-disclosure agreement?
☐/☐ Vehicle traffic	☐/☐ Safety Vest	☐/☐ Contractor support?
		☐/☐ Training documentation needed?

[1]JHA required if any of these Hazard Identification boxes are checked. Others may be required based on project scope.
[2]PPE Assessment required if any of these PPE Required boxes are checked.

JHA's To Be Reviewed			
☐ Asbestos Building Inspection	☐ Electrical Testing	☐ Ladder Use	☐ PIT Training
☐ Construction Inspection	☐ General Industry Inspection	☐ Machine Guarding	
☐ Driving	☐ IH Assessment	☐ Mold Assessment	

Required IH Monitoring			
☐ None	☐ Ammonia (NH_3)	☐ Carbon Dioxide (CO_2)	☐ Hydrogen Sulfide (H_2S)
☐ Other (List):			

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Feed Production Facility

Food & Beverage Industry

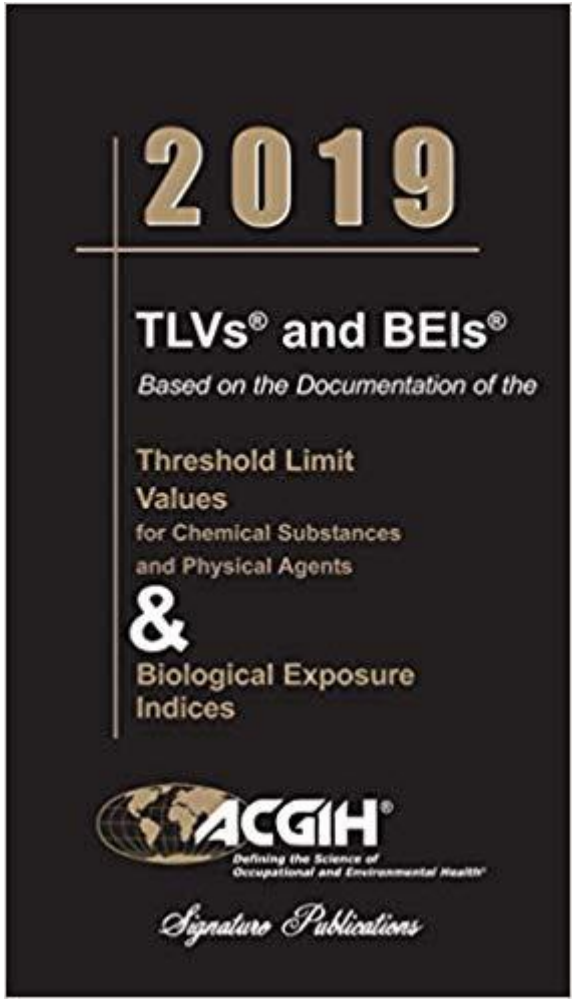
Looking Further at Exposures

- Do chemicals have occupational exposure limits?
- Which chemicals have the lowest exposure limits?
- Do chemicals have IH sampling methods?
- Which chemicals are used the most frequently and in the largest quantity?
- Have you sampled those chemicals in previous years?
- How confident are you in the data?

Data Points & TLVs / BEIs

TABLE Z-1. - LIMITS FOR AIR CONTAMINANTS

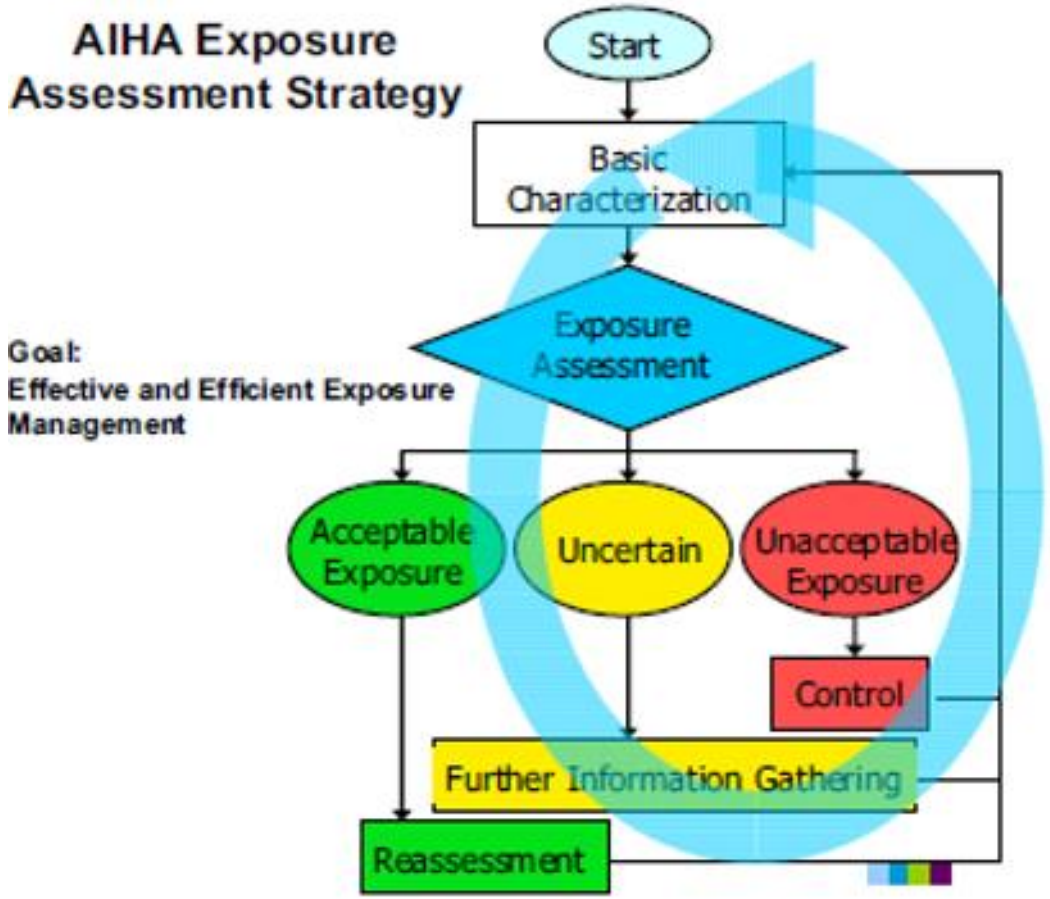
Substance	CAS No. (c)	ppm (a)(1)	mg/m(3) (b)(1)	Skin designation
Acetaldehyde	75-07-0	200	360	
Acetic acid	64-19-7	10	25	
Acetic anhydride	108-24-7	5	20	
Acetone	67-64-1	1000	2400	
Acetonitrile	75-05-8	40	70	
2-Acetylaminofluorene; see 1910.1014	53-96-3			
Acetylene dichloride; see 1,2-Dichloroethylene.				
Acetylene tetrabromide	79-27-6	1	14	
Acrolein	107-02-8	0.1	0.25	
Acrylamide	79-06-1	.....	0.3	X
Acrylonitrile; see 1910.1045	107-13-1			
Aldrin	309-00-2	.....	0.25	X
Allyl alcohol	107-18-6	2	5	X



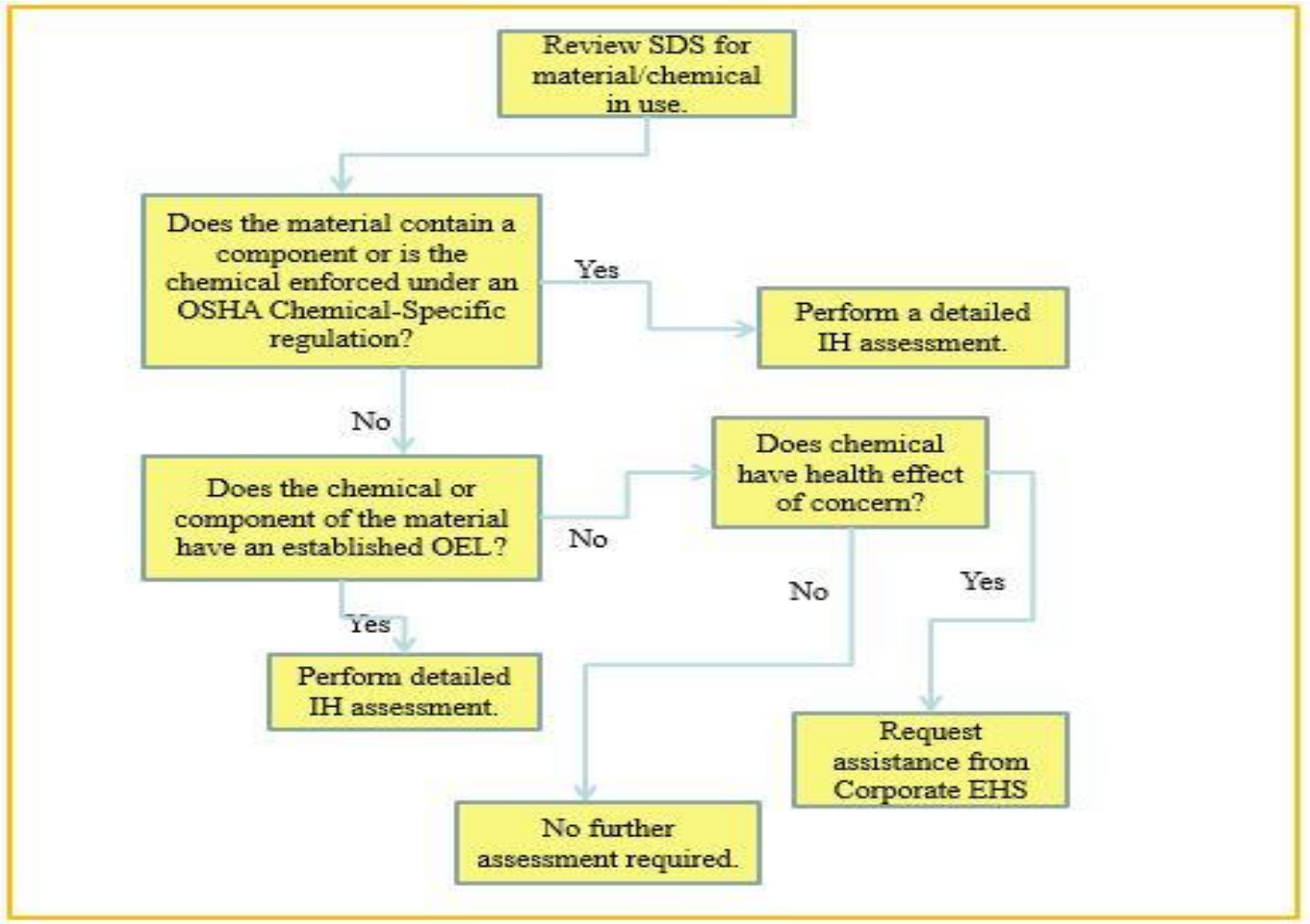
Regulations & Exposures

SUBSTANCE / CAS#	FEE PER SAMPLE	ADDITIONAL COMPATIBLE ANALYTE	METHOD + NOTES	ANALYTICAL TECHNIQUE	COLLECTION MEDIUM	ORDER NUMBER	MEDIA SHELF LIFE	VOL. / TIME / AREA / MASS	SAMPLING RATE	LOQ
Acetonitrile [2] 75-05-8	$52.00	U $28.00	mod. NIOSH 1606; GC/FID Refrigerate samples after collection. Interferences: samples containing greater than 15% methanol or other alcohols	GC/FID	Charcoal	226-01/ 226-09	5 yrs./ 5 yrs.	1-25 L	0.01-0.2 LPM	10 ug
Allyl alcohol [2] 107-18-6	$52.00	U $28.00	mod. NIOSH 1402; GC/FID BADGE Interferences: high humidity	GC/FID	PM	3M 3500/ 3M 3520	18 mos./ 18 mos.	8 hrs.		6 ug
Allyl alcohol [2] 107-18-6	$52.00	U $28.00	mod. NIOSH 1402; GC/FID BADGE Manufacturer recommends returning samples to the laboratory within 14 days of the sampling event. Interferences: high humidity	GC/FID	PM	N566/ N521	mfg. exp. date/ mfg. exp. date	15 min. - 12 hrs.		6 ug
Benzyl alcohol [2] 100-51-6	$52.00	U $28.00	mod. NIOSH 1401; GC/FID	GC/FID	Charcoal	226-01/ 226-09	5 yrs./ 5 yrs.	2-10 L	0.01-0.2 LPM	10 ug
Benzyl alcohol [2] 100-51-6	$52.00	U $28.00	mod. NIOSH 1401; GC/FID BADGE	GC/FID	PM	3M 3500/ 3M 3520	18 mos./ 18 mos.			20 ug

AIHA Exposure Assessment Strategy Diagram

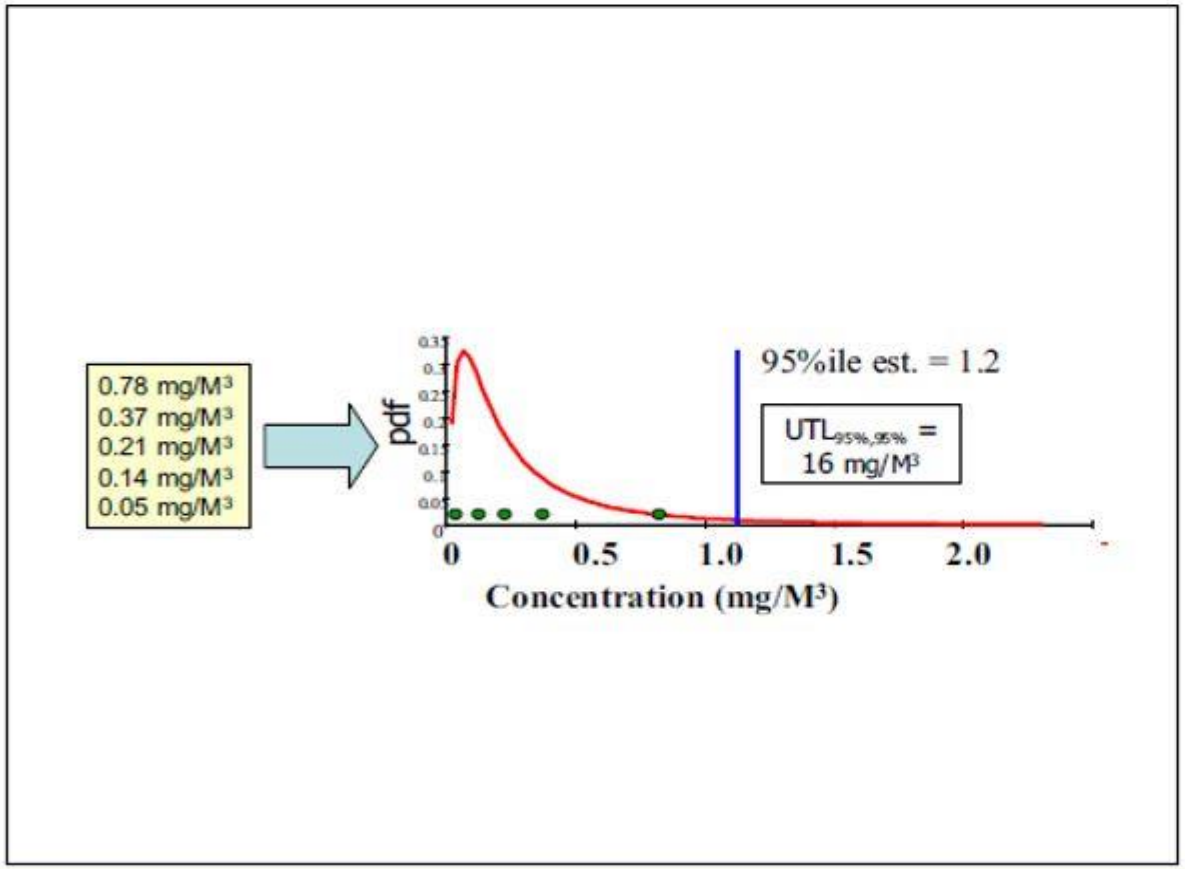


Chemical Assessment Flow Chart



Monitoring and Statistical Analysis

Monitoring and Statistical Analysis



For Agent "X" the Occupational Exposure Limit (OEL) is 1 milligram / meter-cubed (mg/m^3)

Have we sampled enough?

Source (AIHCE, 2010):

PDC 705:
PROFESSIONAL JUDGMENT IN EXPOSURE ASSESSMENT DECISION-MAKING

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Sheryl Milz, PhD, CIH

Search for the Key: Where to Start Building

- Inventory your exposures.
- Make priorities and build a sampling plan.
- Consider statistical significance.

Hellman & Associates – The Basic Plan

- Set an annual goal to conduct monitoring on client sites when available.
- Review goals at each safety committee and staff meeting.
- Wear PPE to match client current requirements (as a minimum).
- Complete reports for individual exposure in addition to client's official IH report.

H&A Safety Goals

	Goal: 100% Project Management Checklist Completion												2016
		January	February	March	April	May	June	July	August	September	October	November	December	Total
41	AssuredCompliance	100.0%	100.0%	100.0%										100.0%
42	Other Projects	100.0%	100.0%	66.7%										88.9%

	Goal: Maintain VPP Star												
		January	February	March	April	May	June	July	August	September	October	November	December
47	Annual Report Submittal (due Feb 15)		X										
48	Additional H&A SGE						X						
49	SGE VPP Site Assessment			X									

	Goal: Management System Improvements												2016
		January	February	March	April	May	June	July	August	September	October	November	December	Total
54	Improvements Made				1									1

	Goal: Staff IH Monitoring Events												2016
		January	February	March	April	May	June	July	August	September	October	November	December	Total
59	IH Monitoring				1									1

Oil & Gas Monitoring

Oil & Gas Monitoring

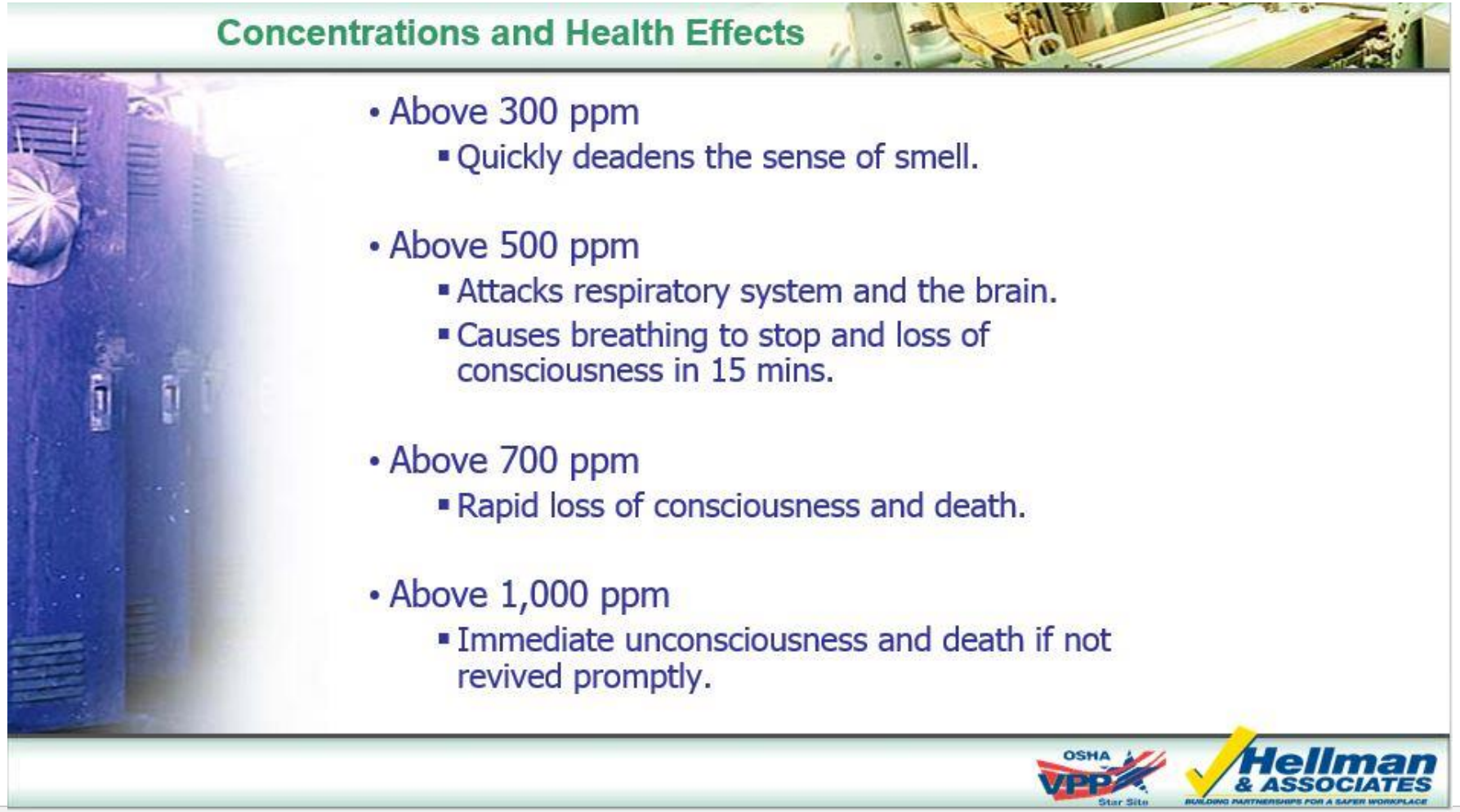
Concentrations and Health Effects

- 0.032 – 0.02 ppm
  - Start to smell the gas.
- At or above 10 ppm
  - Toxic to personnel – wear respiratory protection.
- OSHA PEL (29 CFR 1910.1000, Z-2 Table)
  - 20 ppm Ceiling.
  - 50 ppm Peak - 10 mins. once only if no other measurable exposure occurs.
- At 100 ppm
  - Considered Immediately Dangerous to Life and Health (IDLH),

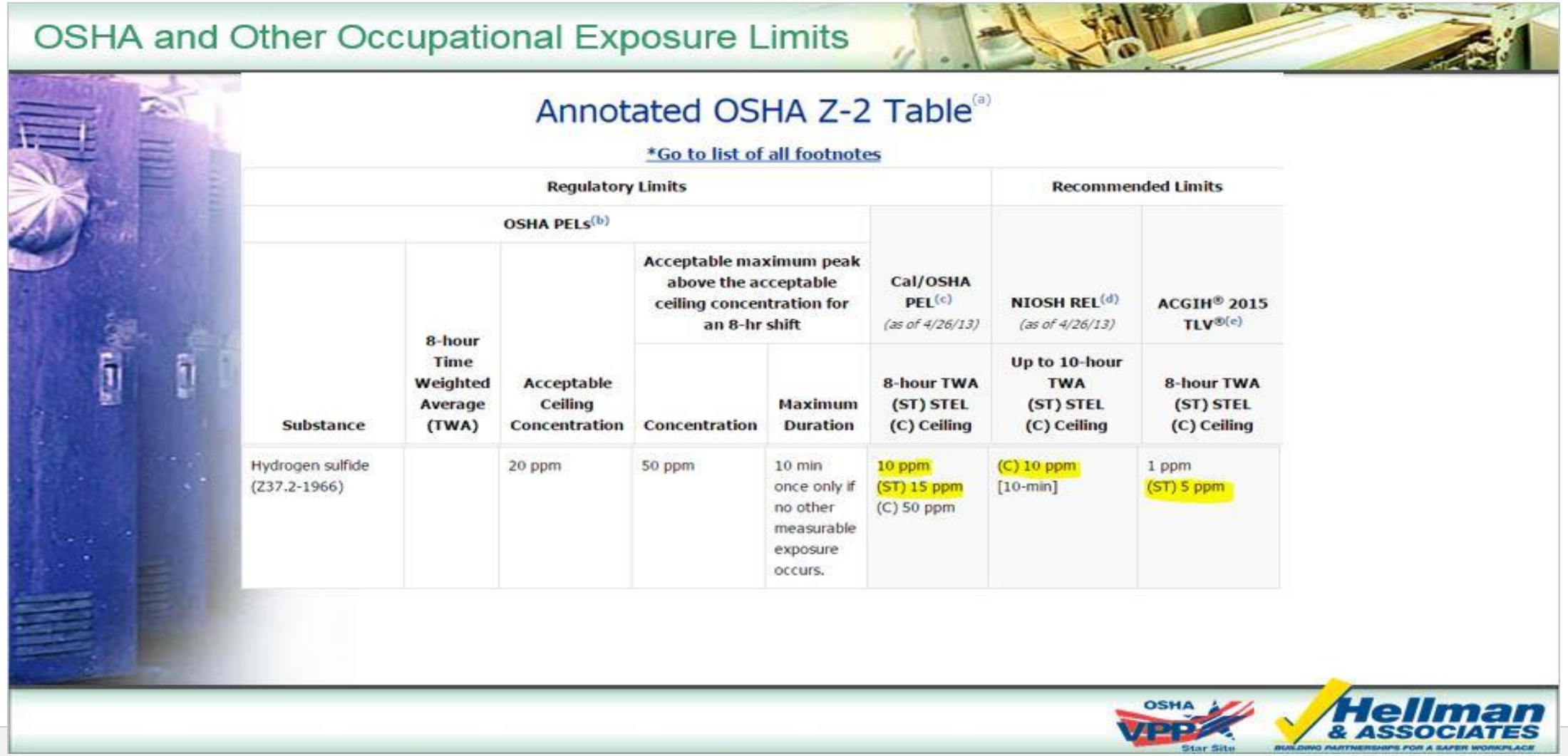
Health effects of H_2S exposure

- High concentrations can cause:
  - Shock, convulsions, inability to breathe, extremely rapid unconsciousness, coma, and death.
- Effects can occur within a few breaths, and possibly or even a single breath.

Oil & Gas Monitoring



Other Occupational Exposure Limits



OSHA and Other Occupational Exposure Limits

Annotated OSHA Z-2 Table[a]

*Go to list of all footnotes

Regulatory Limits						Recommended Limits	
OSHA PELs[b]					Cal/OSHA PEL[c] (as of 4/26/13)	NIOSH REL[d] (as of 4/26/13)	ACGIH® 2015 TLV®[e]
Substance	8-hour Time Weighted Average (TWA)	Acceptable Ceiling Concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift: Concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift: Maximum Duration	8-hour TWA (ST) STEL (C) Ceiling	Up to 10-hour TWA (ST) STEL (C) Ceiling	8-hour TWA (ST) STEL (C) Ceiling
Hydrogen sulfide (Z37.2-1966)		20 ppm	50 ppm	10 min once only if no other measurable exposure occurs.	10 ppm (ST) 15 ppm (C) 50 ppm	(C) 10 ppm [10-min]	1 ppm (ST) 5 ppm

OSHA VPP Star Site

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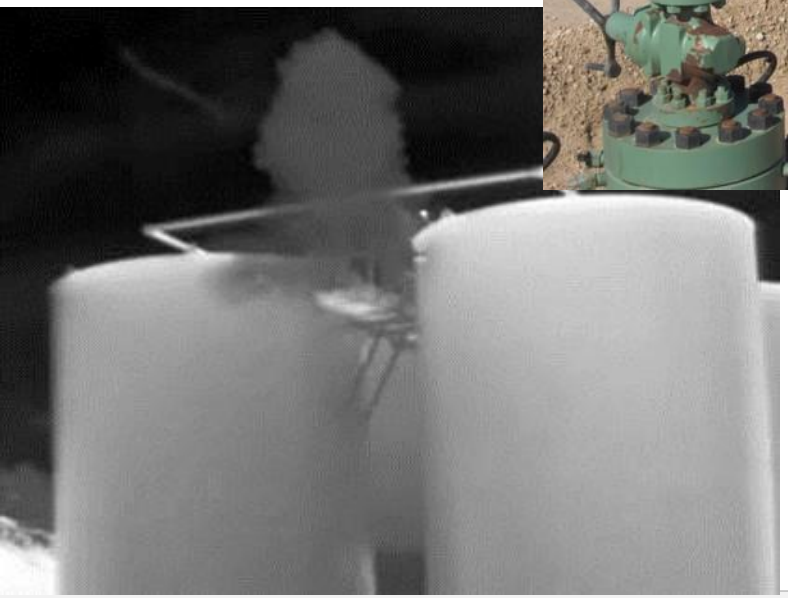
Oil & Gas Monitoring



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Exposure Monitoring Summary Form

EXPOSURE MONITORING SUMMARY FORM

Company: Whiting Petroleum Date: 8/18/2015

Project: H2S Sampling

Principal Project Manager: Craig Snyder

This form is to be used to document H&A employee exposure to health hazards including but not limited to noise and air contaminants. Should engineering or administrative controls not be applicable, the appropriate PPE or other control measures should be selected for the hazard. With regard to PPE, a determination should be made that the PPE selected was appropriate for the hazard (e.g., NRR for hearing protection, protection factor for respiratory protection, etc.).

Hazard Description:
Opening petroleum tank hatches under pressure. 100% LEL, Oxygen deficient atmospheres, H2S, benzene and other high levels of hydrocarbon gasses are expected above IDLH levels.

PPE Selected (include specifications such as NRR, protection factor, etc.):
H&A employees wore self-contained breathing apparatus (SCBA), hard hats, safety toe boots, gloves and flame resistant clothing.

Type of Monitoring Performed:
Eight hour time weighted average (TWA) and short term exposure limits (STEL) airborne contaminant sampling at the operator's breathing zone was conducted using passive organic vapor badges. Four gas monitors were worn to evaluate other exposures including hydrogen sulfide, carbon monoxide and oxygen deficiency.

Monitoring Results (attach or provide link to any documentation):
Lab results attached.

Airborne Contaminant Occupational Exposure Limits (OEL)

Contaminant (CAS #)	OSHA PEL		ACGIH TLV	
	8-Hour TWA	STEL	8-Hour TWA	STEL
Benzene	1ppm	5ppm	0.5ppm	2.5ppm
H2S	NE	20ppm (ceiling)	1ppm	5ppm
CO	50	NE	25	NE
Oxygen	NA	Minimum 19.5	NA	NA

EXPOSURE MONITORING SUMMARY FORM

Company: Hospira Boulder, Inc. Date: 7/21/2015

Project: PA-10 7-TES BAC III Packaging

Principal Project Manager: Craig Snyder

This form is to be used to document H&A employee exposure to health hazards including but not limited to noise and air contaminants. Should engineering or administrative controls not be applicable, the appropriate PPE or other control measures should be selected for the hazard. With regard to PPE, a determination should be made that the PPE selected was appropriate for the hazard (e.g., NRR for hearing protection, protection factor for respiratory protection, etc.).

Hazard Description:

Manufacturing Technicians in PA-10 were packaging an intermediate to the active pharmaceutical ingredient (API) Paclitaxel. Hospira recently made changes to the dryer unit FL-3400 where 7-TES BAC III is packaged from. Technicians now use a glove bag and ILC Dover Continuous Liner to contain the product when packaging. As an intermediate to Paclitaxel, 7-TES BAC III shares similar toxicological properties with Paclitaxel but is not as biologically available as the final product. Paclitaxel induces microtubule formation and stabilization of microtubules, thereby disrupting normal cell division in the G2 and M phases of the cell cycle. Paclitaxel is used for the primary treatment of advanced ovarian cancer with Cisplatin or Carboplatin.

PPE Selected (include specifications such as NRR, protection factor, etc.):

Bullard powered air purifying respirator (PAPR) and RT series loose fitting hood with combination organic vapor/particulate cartridges with an assigned protection factor of 1000, Tyvek suit with double booties with inner booties taped to suit, Tyvek sleevelets, and double form-fitting nitrile gloves with inner gloves tapes to sleeves.

Type of Monitoring Performed:

Task specific personal air monitoring was performed during the final packaging of 7-TES BAC III. This task lasted just over 2-hours (136 minutes). Personal air monitoring was completed on 25 mm, 1.0 micron PTFE filters at a flow rate of approximately 2 liters per minute (lpm). All samples were analyzed by Bureau Veritas using method BV-2013-25528.

Monitoring Results (attach or provide link to any documentation):

Sample Number	Sampler Location	Duration (min.)	Reported Concentration	TWA
822	Personal breathing zone, outside respiratory protection	136	<0.132	<0.037

Were Engineering or Administrative Controls put in place and, if yes, were they adequate and appropriate for the project?

Engineering controls in place during the time of monitoring include a flexible containment glove bag connected to local exhaust ventilation and HEPA filters. The product was packaged using the ILC Dover continuous liner, to maintain product containment until in a final package. No administrative controls were in place at the time of the event.

Was the level of PPE selected appropriate for the project? Yes / No. If No, describe any corrective actions taken to upgrade the PPE level:

Yes, both the total concentration result and the TWA result were both well below the Hospira EEL of 10 µg/m³.

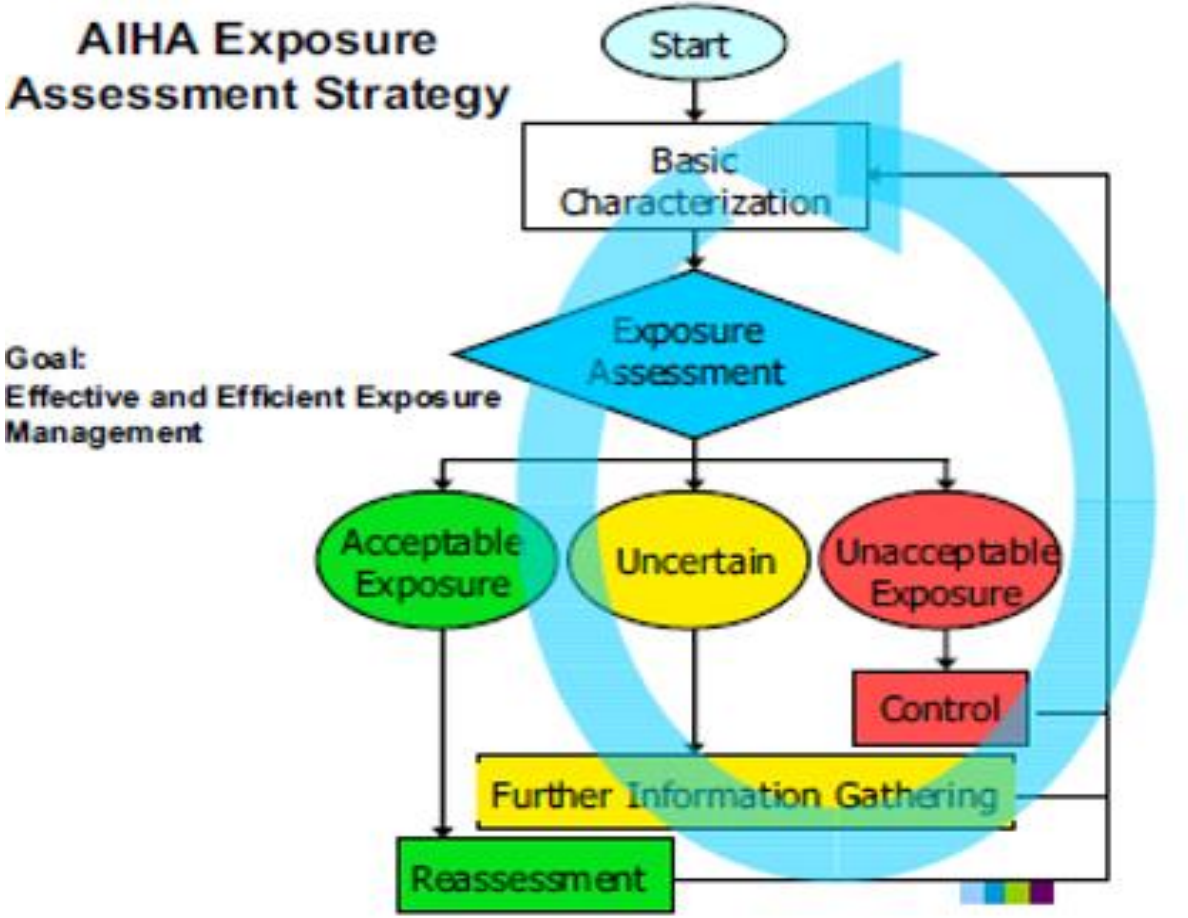
Building on the Basics – The Advanced Approach

- Look at developing internal OELs
- Consider exposure banding
- Set goals for number of samples to collect each year
- Repeat monitoring for tasks that require controls (engineering, PPE, etc.)
- Increase number of samples from the minimum needed
- Track and trend results (data analysis)
- Develop similar exposure groups (SEGs)

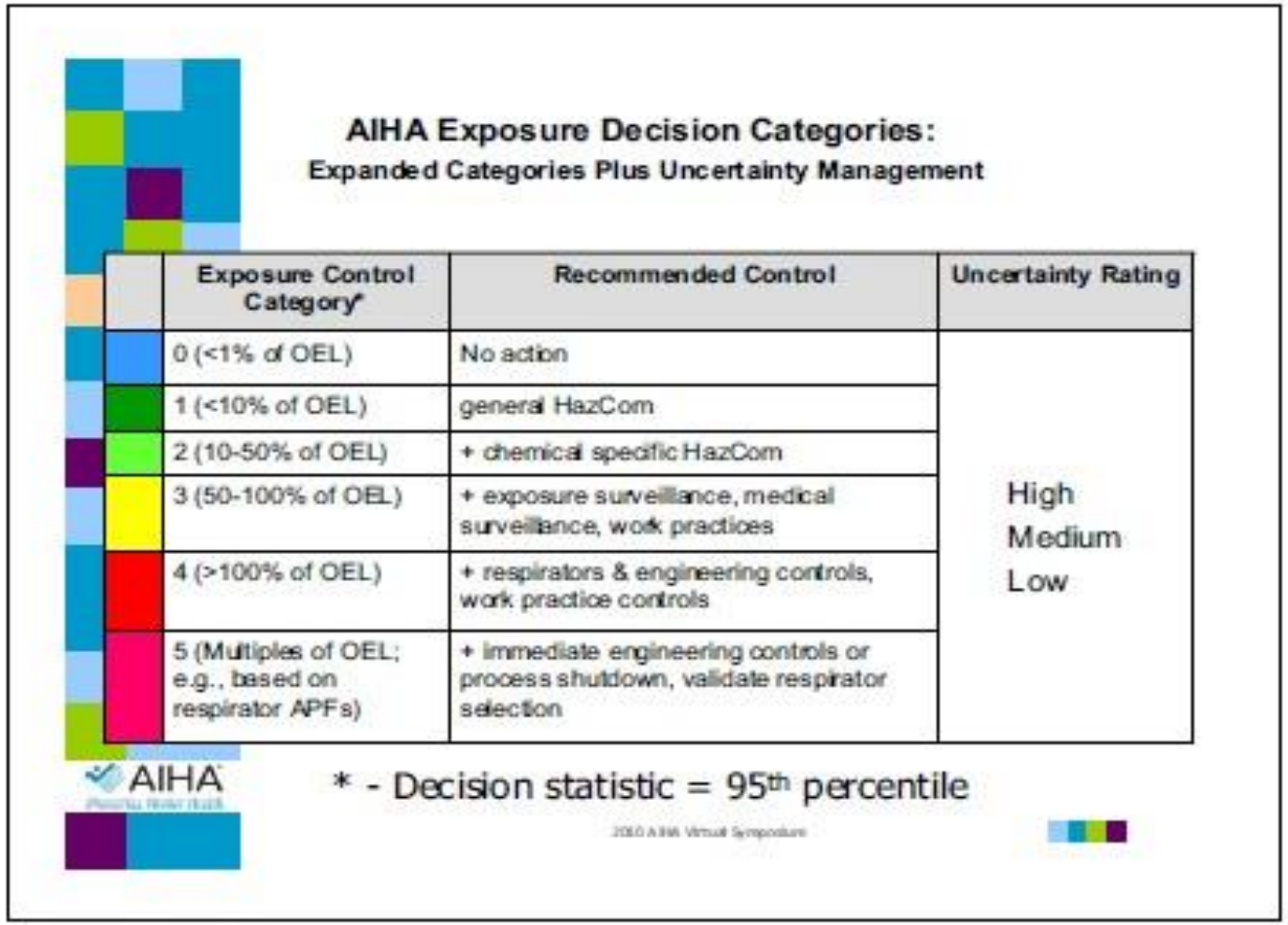
Case Study – Food & Beverage

- Goal: Create a corporate program that would allow sites to easily develop written IH programs that could be recognized as best practice by OSHA VPP
- Consider AIHA model
- Consider statistical significance
- Create documentation for consistency across multiple locations

AIHA Exposure Assessment Strategy



AIHA Exposure Decision Categories



AIHA Exposure Decision Categories:
Expanded Categories Plus Uncertainty Management

	Exposure Control Category*	Recommended Control	Uncertainty Rating
	0 (<1% of OEL)	No action	High Medium Low
	1 (<10% of OEL)	general HazCom	
	2 (10-50% of OEL)	+ chemical specific HazCom	
	3 (50-100% of OEL)	+ exposure surveillance, medical surveillance, work practices	
	4 (>100% of OEL)	+ respirators & engineering controls, work practice controls	
	5 (Multiples of OEL; e.g., based on respirator APFs)	+ immediate engineering controls or process shutdown, validate respirator selection	

AIHA

* - Decision statistic = 95th percentile

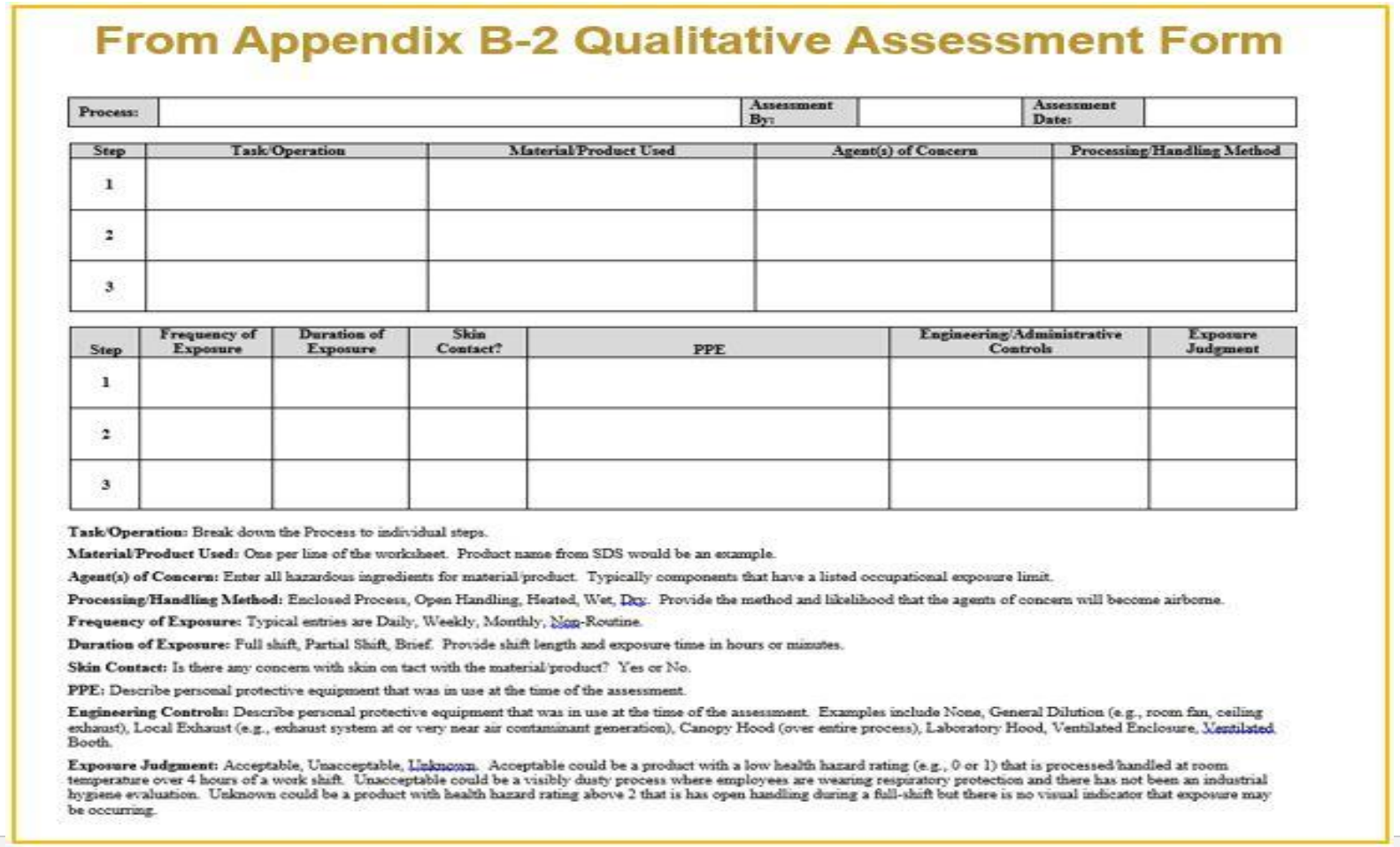
Baseline Assessment

- Qualitative assessment (some diagnostic monitoring may be performed)
- Review of health hazards without regard to use of PPE
  - Process observation
  - SDS review
  - Engineering and work practice review
- Can be a series of assessments over time, does not need to happen all at the same time
- Assessment tool provided
- Outcome is prioritized list of processes/tasks that required a detailed IH assessment and those that are lower in priority
- Allows limited resources to be focused

SEGs and Rule of Thumb

- The “rule-of-thumb” is to collect 6 to 10 personal exposure samples per SEG in order to achieve statistical significance.
- If the sample results are significantly different (i.e., by an order of magnitude) then the SEG should be reviewed to determine if the employees were properly grouped
  - This situation may be the result of differing employee work practices which must be addressed rather than improper grouping
- If the process or task is changed in any way that would impact employee exposure (e.g., ventilation system chance, product substitution) then a new data set would need to be generated

From Appendix B-2 Qualitative Assessment Form



From Appendix B-2 Qualitative Assessment Form

Process:		Assessment By:		Assessment Date:	

Step	Task/Operation	Material/Product Used	Agent(s) of Concern	Processing/Handling Method
1				
2				
3				

Step	Frequency of Exposure	Duration of Exposure	Skin Contact?	PPE	Engineering/Administrative Controls	Exposure Judgment
1						
2						
3						

Task/Operation: Break down the Process to individual steps.

Material/Product Used: One per line of the worksheet. Product name from SDS would be an example.

Agent(s) of Concern: Enter all hazardous ingredients for material/product. Typically components that have a listed occupational exposure limit.

Processing/Handling Method: Enclosed Process, Open Handling, Heated, Wet, Dry. Provide the method and likelihood that the agents of concern will become airborne.

Frequency of Exposure: Typical entries are Daily, Weekly, Monthly, Non-Routine.

Duration of Exposure: Full shift, Partial Shift, Brief. Provide shift length and exposure time in hours or minutes.

Skin Contact: Is there any concern with skin on tact with the material/product? Yes or No.

PPE: Describe personal protective equipment that was in use at the time of the assessment.

Engineering Controls: Describe personal protective equipment that was in use at the time of the assessment. Examples include None, General Dilution (e.g., room fan, ceiling exhaust), Local Exhaust (e.g., exhaust system at or very near air contaminant generation), Canopy Hood (over entire process), Laboratory Hood, Ventilated Enclosure, Ventilated Booth.

Exposure Judgment: Acceptable, Unacceptable, Unknown. Acceptable could be a product with a low health hazard rating (e.g., 0 or 1) that is processed/handled at room temperature over 4 hours of a work shift. Unacceptable could be a visibly dusty process where employees are wearing respiratory protection and there has not been an industrial hygiene evaluation. Unknown could be a product with health hazard rating above 2 that is has open handling during a full-shift but there is no visual indicator that exposure may be occurring.

Air Contaminant Required Action Summary Table

Air Contaminant Required Action Summary Table

Required Action Category [1/]	Sample Results	Monitoring Frequency [2,3/]	Required Action	Verification Monitoring Frequency [2,4/]
RA4	One or more IH samples > OEL	Until lower RA category achieved	Work practice or engineering improvements	Quarterly
RA3	One or more IH samples > AL, but all < OEL	Semiannually	Work practice or engineering improvements	Quarterly
RA2	One or more IH samples > 10% OEL, but all < AL	Annual	None	3 years
RA1	All IH samples < 10% OEL	Periodic [5/]	None	None

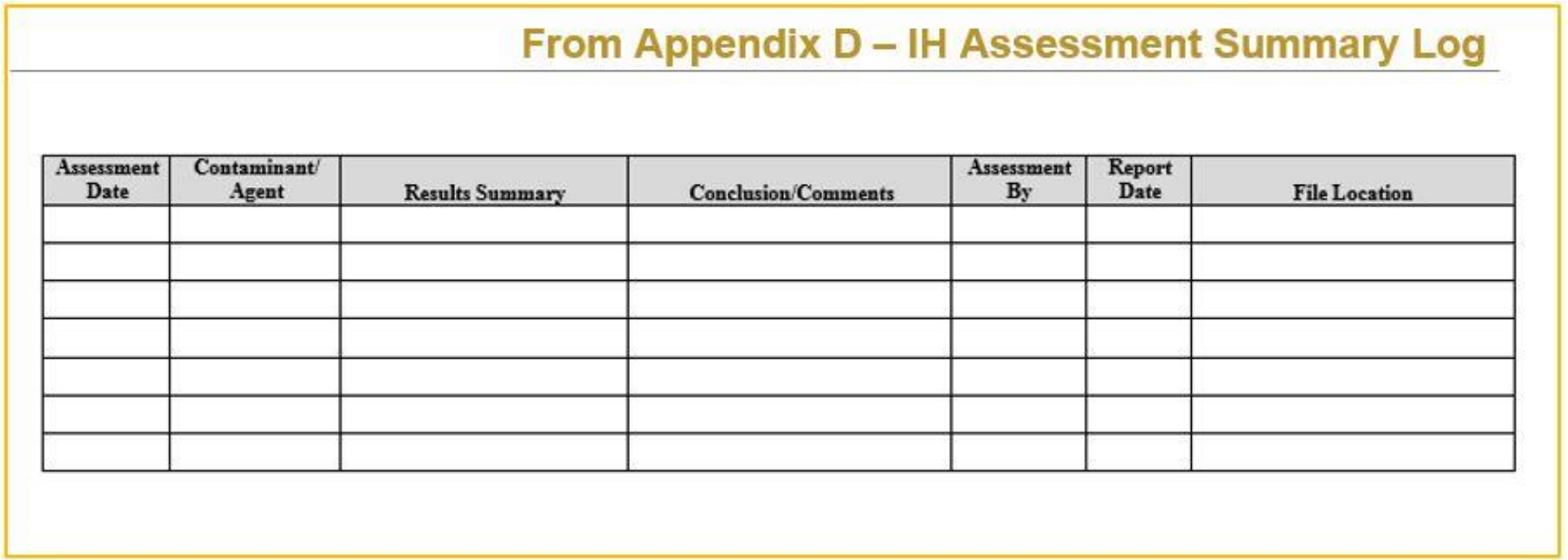
From Appendix C – IH Monitoring Plan

From Appendix C – IH Monitoring Plan

Priority [1]			Agent	Location/Operation	Required Monitoring [2]			Target Date	Completion Date
High	Med	Low			TWA	STEL	Ceiling		
Comment/Notes:									
Comment/Notes:									
Comment/Notes:									
Comment/Notes:									
Comment/Notes:									
Comment/Notes:									
Comment/Notes:									

[1] Priority examples: High priority would include Select: OSHA or Cal/OSHA specifically regulated chemicals, Category 3 or 4 processes/tasks. Medium priority would include Category 2 processes/tasks. Low priority would include Category 1 processes/tasks.
[2] Ceiling samples should be collected similar to STEL samples if direct reading instrumentation is not available.
STEL – Short-term exposure limit
TWA – Time-weighted average

From Appendix D – IH Summary Log



From Appendix D – IH Assessment Summary Log

Assessment Date	Contaminant/ Agent	Results Summary	Conclusion/Comments	Assessment By	Report Date	File Location

From Appendix I – Medical Surveillance Summary

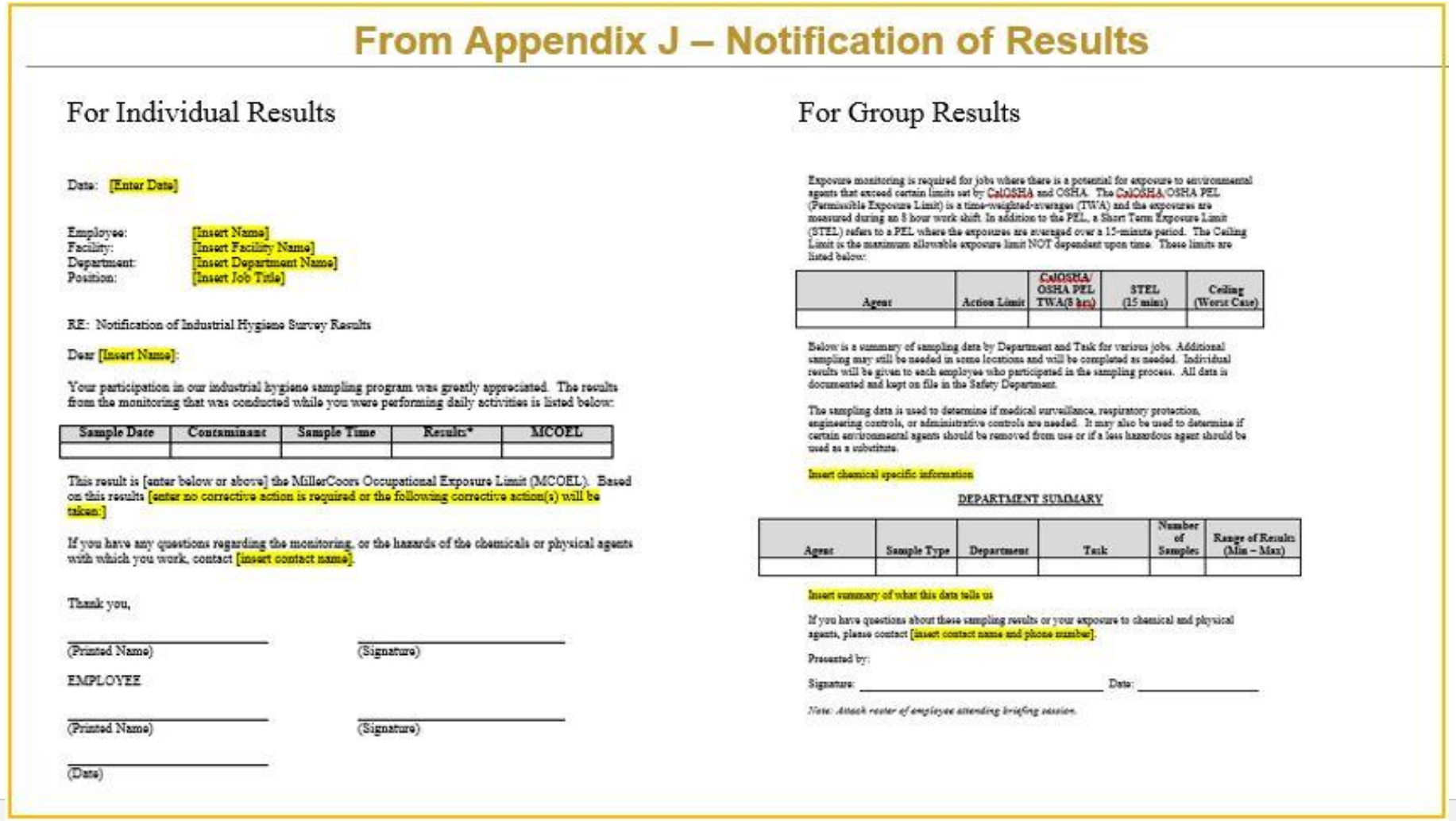
From Appendix I – Medical Surveillance Summary

Job Task/SEG	Department	Exposure To	PPE Type [1]	Medical Surveillance Reasoning [2]

[1] The most common types of PPE that require medical surveillance are respirators and hearing protection. Include specific type of respirator used so that the protection factor can be confirmed. For hearing protection include Noise Reduction Rating (NRR).

[2] Example reasoning would be a Category 4 air contaminant for respiratory protection, for noise an example would be sound level at 95 dBA.

From Appendix J – Notification of Results



From Appendix J – Notification of Results

For Individual Results

Date: [Enter Date]

Employee: [Insert Name]
Facility: [Insert Facility Name]
Department: [Insert Department Name]
Position: [Insert Job Title]

RE: Notification of Industrial Hygiene Survey Results

Dear [Insert Name]:

Your participation in our industrial hygiene sampling program was greatly appreciated. The results from the monitoring that was conducted while you were performing daily activities is listed below:

Sample Date	Contaminant	Sample Time	Results*	MCOEL

This result is [enter below or above] the MillerCoors Occupational Exposure Limit (MCOEL). Based on this results [enter no corrective action is required or the following corrective action(s) will be taken:]

If you have any questions regarding the monitoring, or the hazards of the chemicals or physical agents with which you work, contact [insert contact name].

Thank you,

_____ _____
(Printed Name) (Signature)

EMPLOYEE

_____ _____
(Printed Name) (Signature)

_____
(Date)

For Group Results

Exposure monitoring is required for jobs where there is a potential for exposure to environmental agents that exceed certain limits set by CalOSHA and OSHA. The CalOSHA/OSHA PEL (Permissible Exposure Limit) is a time-weighted-average (TWA) and the exposures are measured during an 8 hour work shift. In addition to the PEL, a Short Term Exposure Limit (STEL) refers to a PEL where the exposures are averaged over a 15-minute period. The Ceiling Limit is the maximum allowable exposure limit NOT dependent upon time. These limits are listed below:

Agent	Action Limit	CalOSHA/ OSHA PEL TWA(8 hrs)	STEL (15 mins)	Ceiling (Worst Case)

Below is a summary of sampling data by Department and Task for various jobs. Additional sampling may still be needed in some locations and will be completed as needed. Individual results will be given to each employee who participated in the sampling process. All data is documented and kept on file in the Safety Department.

The sampling data is used to determine if medical surveillance, respiratory protection, engineering controls, or administrative controls are needed. It may also be used to determine if certain environmental agents should be removed from use or if a less hazardous agent should be used as a substitute.

Insert chemical specific information

DEPARTMENT SUMMARY

Agent	Sample Type	Department	Task	Number of Samples	Range of Results (Min – Max)

Insert summary of what this data tells us

If you have questions about these sampling results or your exposure to chemical and physical agents, please contact [insert contact name and phone number].

Presented by:

Signature: _____ Date: _____

Note: Attach roster of employee attending briefing session.

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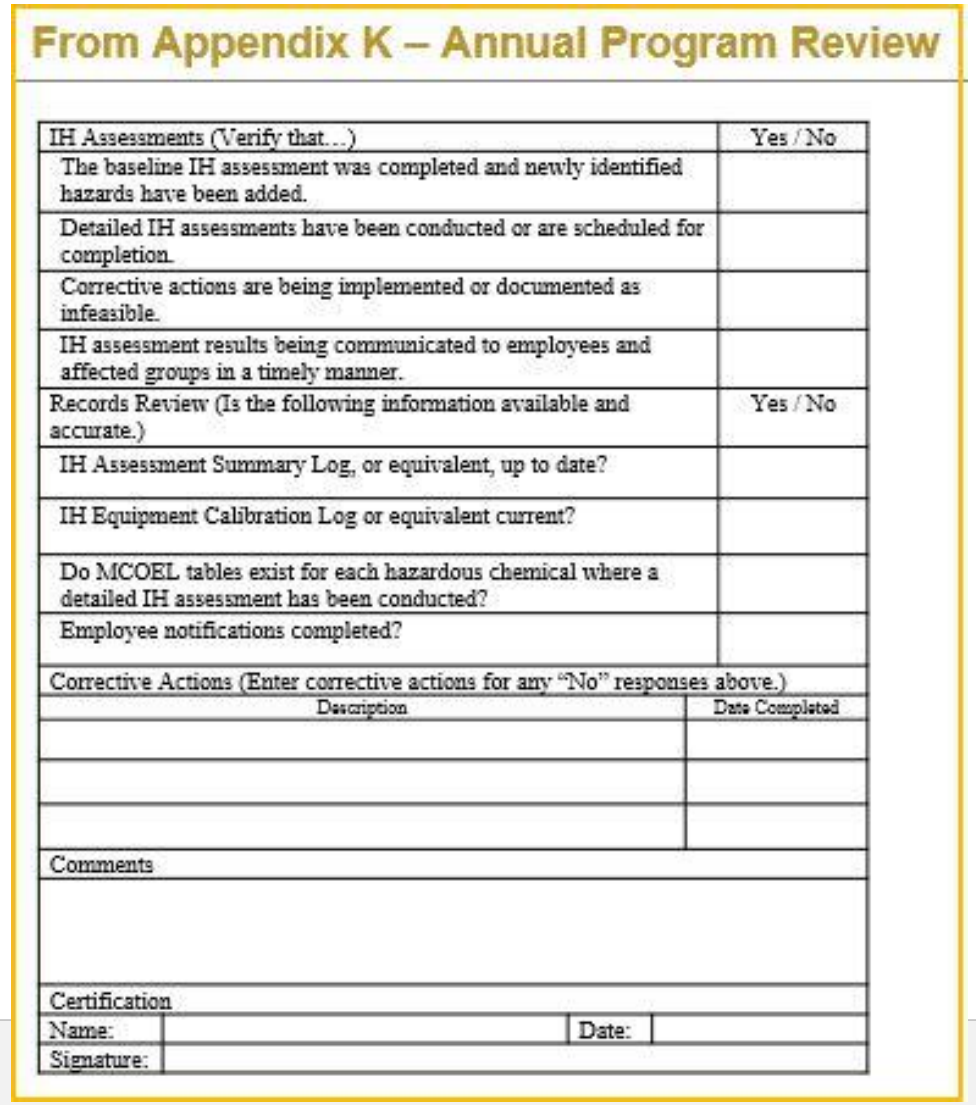
From Appendix K – Annual Program Review



From Appendix K – Annual Program Review

IH Assessments (Verify that…)	Yes / No
The baseline IH assessment was completed and newly identified hazards have been added.	
Detailed IH assessments have been conducted or are scheduled for completion.	
Corrective actions are being implemented or documented as infeasible.	
IH assessment results being communicated to employees and affected groups in a timely manner.	
Records Review (Is the following information available and accurate.)	Yes / No
IH Assessment Summary Log, or equivalent, up to date?	
IH Equipment Calibration Log or equivalent current?	
Do MCOEL tables exist for each hazardous chemical where a detailed IH assessment has been conducted?	
Employee notifications completed?	

Corrective Actions (Enter corrective actions for any "No" responses above.)	
Description	Date Completed

Comments

Certification			
Name:		Date:	
Signature:			

Case Study - Pharmaceutical

- Large focus on relieving respiratory protection upon installation of engineering controls.
- Corporate toxicologists develop exposure limits for finished products and high hazard raw materials.
- Analytical laboratory is given a priority list of methods to develop.
- All APIs with limits and methods are sampled for.
- Individual sites develop annual sampling plans and present to corporate.
- Action limits are set at 50% the OEL.
- Engineering containment levels.

Industrial Hygiene Exposure Assessment and Control Program

3.1 Industrial Hygiene Exposure Assessment and Control Program

3.1.1 Each organization shall establish an Industrial Hygiene exposure assessment and control program to identify, evaluate, and control employee exposures. (Diagram illustrates the program process). The program shall include:

3.1.1.1 Industrial Hygiene risk assessment and exposure monitoring to determine levels of exposure;

3.1.1.2 The selection of controls to reduce employee exposures to acceptable levels;

3.1.1.3 Exposure interpretation/reporting; and records retention.

EEL (micrograms/m^3)	Engineering Containment Level
≤ 1	4
1 - 10	3
$>10 \leq 100$	2
>100	1

The Use of Controls to Reduce Employee Exposures

3.7 The Use of Controls to Reduce Employee Exposures

3.7.1 If results from Industrial Hygiene exposure monitoring suggest that employee exposures are above the Action Level (AL) of the EEL or the EEL-R (independent of the use of PPE):

3.7.1.1 Additional engineering controls, administrative controls, PPE and/or applicable medical surveillance requirements (see section 3.8.1) shall be immediately instituted.

3.7.1.2 Document and track the actions taken to reduce exposures. The Enablon IH module should be used to document the actions taken.

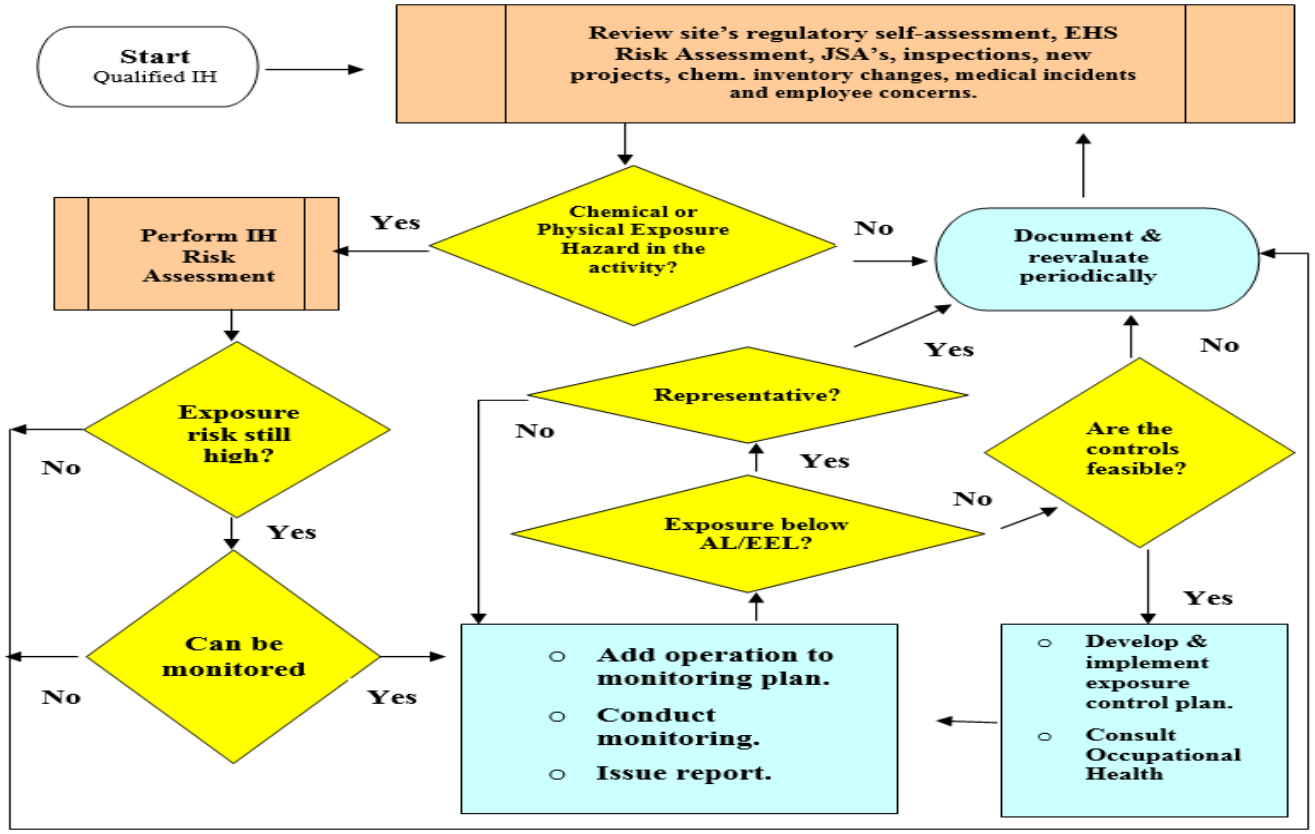
3.7.1.3 Where administrative controls are implemented or engineering controls are added or repaired to control employee exposures, the organization must verify that controls are functioning as intended through additional monitoring.

3.7.1.4 Once controls are in place, a minimum of three (3) additional representative sampling periods shall be obtained to document that the controls have successfully reduced employee exposure.

Industrial Hygiene Program Process

Diagram 1

Hospira Industrial Hygiene Program Process



Exposure Limits

Chemical	CAS #	Exposure Limit 8-hr TWA	NFPA rating (H- F- I	Analytical Method? (yes/no)	Considered for 2015 sampling?
7-TES BAC III	N/A	10 mcg/m³	3-0-0	Yes	Yes
Acetic Acid	64-19-7	10 ppm	3-2-0	Yes	No
Acetone	67-64-1	2,500 ppm	1-3-0	Yes	No
Acetonitrile	75-05-8	20 ppm (skin)	2-3-0	Yes	Yes
Acetyl chloride	75-36-5	2 ppm ceiling as HCl	3-3-3	No	No
Alumina N1	1344-28-1	5 mg/m3 STEL/15 mg/m3	0-0-0	Yes	No
Chlorotriethylsilane	994-30-9	2 ppm ceiling as HCl	3-3-1	No	No
CIP 200	Mixture	1 mg/m³	2-0-1	Yes	No
Dexmedetomidine Tartrate (DEX-T)	176721-04-3	100 ng/m³	NE	Yes	Yes
Diisopropylcarbodiimide (DIC)	693-13-0	100 µg/m³	3-3-1	No	No
Helium	7440-59-7	O_2 < 19.5%	1-0-0	No	No
Heptane	142-82-5	400 ppm	1-3-0	Yes	No
Highly Purified Water	7732-18-5	N/A	N/A	No	No
Irinotecan Hydrochloride	136572-09-3	1 µg/m³	3-0-0	Yes	No
Isobutyl Acetate (IBAc)	110-19-0	150 ppm	1-3-0	Yes	Yes
Isopropyl Alcohol	67-63-0	200 ppm	1-3-0	Yes	No
Isopropylamine	75-31-0	750 ppm	3-4-0	Yes	No
Isopropylamine hydrochloride	15572-56-2	N.E	3-4-0	No	No
Isoproterenol Hydrochloride	51-30-9	N.E.	3-0-0	Yes	Yes
Isoproterenone	121-28-8	N.E	3-3-0	No	No
Isoproterenone hydrochloride	N.E.	N.E.	3-0-0	No	No
Methanesulfonic Acid	75-75-2	N/A	3-0-0	No	No
Methanol	67-56-1	200 ppm	(2-3-0)	Yes	Yes
Methylene Chloride	75-09-2	25 ppm	2-1-0	Yes	Yes
Methylmagnesium chloride in THF	676-58-4	N.E.	3-3-1	No	No
N,N Di-methylformamide (DMF)	68-12-2	10 ppm	2-2-0	Yes	No
n-Heptane	142-82-5	400 ppm	1-3-0	Yes	No

Dex ESTL & Dex SCHH

ESTL:

Drug Classification:	Not a drug
Use:	4-(1-trityl)imidazolyl-2,3-dimethyl phenyl methanol (T2P, CAS 176721-01-0) is the Step 1 isolated intermediate in the dexmedetomidine hydrochloride synthetic process.
Dose:	Not a drug.
Side Effects:	In the workplace, this material is anticipated to be irritating to the skin, eyes, and respiratory tract.
Animal Data:	Not available

Estimated EEL:

8-Hour TWA (mcg/m3):	500
15-Minute TWA (mcg/m3):	N/A
Ceiling (mcg/m3):	N/A
Notation:	N/A
Comment:	N/A
Rationale:	Recommendation to minimize the potential occurrence for ocular and/or respiratory irritation.

SPECIAL CHRONIC HEALTH HAZARD
DETAIL SHEET
FOR
4-(1-TRITYL)IMIDAZOLYL-2,3-DIMETHYL PHENYL METHANOL (T2P)
(Dexmedetomidine Hydrochloride Process, Step 1 isolated intermediate)

CHAP/SCHH Code: C100
R-CHAP Code: 100ADHIK
HMIS Code: 200
OSHA GHS Classification:

Hazard Class	Eye Damage/Irritation	STOT - SE
Hazard Category	2B	3
Symbol	NA	
Signal Word	Warning	Warning
Hazard Statement	Causes eye irritation	May cause respiratory irritation

COMMENTS: 4-(1-trityl)imidazolyl-2,3-dimethyl phenyl methanol (T2P, CAS 176721-01-0) is the Step 1 isolated intermediate in the dexmedetomidine hydrochloride synthetic process.

CYTOTOXIC: [ ] YES [X] NO

Not a cytotoxic compound.

HOSPIRA HORMONE: [ ] YES [X] NO

Not a hormone.

LISTED CARCINOGEN [ ] YES [X] NO

Not a listed carcinogen.

POTENT COMPOUND [ ] YES [X] NO

Not a drug.

REPRODUCTIVE HAZARD [ ] YES [X] NO

None known from occupational exposure.

Field Assessment

Recommendations

The following are specific recommendations to address issues identified through the course of this investigation:

Immediate corrective actions

1. Continue reliance on respiratory protection when performing filter wet cake transfer and packaging operations until alternative measures or engineering controls are identified and validated;
2. Evaluate the effectiveness of Hydrogen Peroxide as a deactivation agent for Paclitaxel in the affected process areas and determine alternative options if necessary;
3. Update cleaning procedure (A-MFC-0001) in order to correct identified inconsistencies including location of sticky mats and terminology.
4. Clean surfaces identified as having a concentration in excess of the 0.1 µg/cm^2 DL for Paclitaxel and replace contaminated consumables that cannot be effectively cleaned; and
5. Replace sticky mats as often as necessary in order to avoid excess migration of Paclitaxel out of PA-5 into other common and process areas;

Long term solutions

1. Identify and implement new containment technologies and equipment by relocating operations to PA-42 so that no open product handling occurs during Paclitaxel manufacturing and final isolation;
2. Complete installation and use of site wide breathing air compressor to minimize reliance on PAPRs which are not optimal for production activities due to non-disposable accessories' decontamination issues for (and between) different highly active pharmaceutical ingredient products.
3. Continue periodic industrial hygiene monitoring to ensure employee protection is maintained for Paclitaxel production operations.

Sample Data & Results

Discharge door glove bag operation

Twist and crimp of ILC Dover

Heal scraping at door opposite dicharge

Sample number	Sample type	Sampler location	Duration (minutes)	Reported concentration (ng/m³)[1]	TWA (ng/m³)
746	Mfg. Tech #1 Personal	Personal breathing zone, outside respiratory protection, employee primarily responsible for assembling 100 g. packages of Isoproterenol and twisting, crimping and cutting final packages.	220	<0.8	<0.38
742	Mfg. Tech #2 Personal	Personal breathing zone, outside respiratory protection, employee primarily responsible for batch record completion and assisting in twisting, crimping and cutting final packages.	218	<0.8	<0.38
723	Area	Placed in anteroom outside PA-6 near exit door.	223	<0.8	<0.39
733	Area	Placed underneath the east side of the glovebox, below weighing and packaging activities.	209	<0.9	<0.38
725	Area	Placed at entrance to south end of walk-in hood; the closest point of the hood to the ILC Dover system.	209	<0.9	<0.37

[1]ng/m³– Nanograms per cubic meter.

[2]TWA – Time-weighted average for 8 hours. Employee exposure limit (EEL) for Isoproterenol is 100 ng/m³ as an 8-hour TWA.

[3]Symbol (<) indicates the sample result was less than the analytical limit of detection (LOD).

Sample Data & Results

Wet cake transfer, windows open

Final break-up, no PAPR use

Packaging, PAPR in use

Sample number	Sample type	Sampler location	Duration (minutes)	Reported concentration (µg/m³)[1]	8-hour TWA[2] (µg/m³)
825	Mfg. Tech #1 - Personal	Personal breathing zone, outside respiratory protection, employee primarily responsible for discharging of material into ILC dover from FL-3400 filter dryer, assisted in twisting, crimping and cutting process.	133	2.47	0.684
833	Mfg. Tech #2 - Personal	Personal breathing zone, outside respiratory protection, employee primarily responsible for heal scraping from hand opening opposite product discharge door, assisted in twisting, crimping and cutting process.	130	1.19	0.322
822	Industrial Hygienist #1 - Personal	Personal breathing zone, outside respiratory protection, responsible for completing industrial hygiene monitoring	136	<0.132	<0.037
827	Area	Placed 6 inches above flexible containment attachment ring to discharge door.	131	0.246	0.067
831	Area	Placed 6 inches above flexible containment attachment ring to hand opening opposite product discharge door.	132	<0.135	<0.037

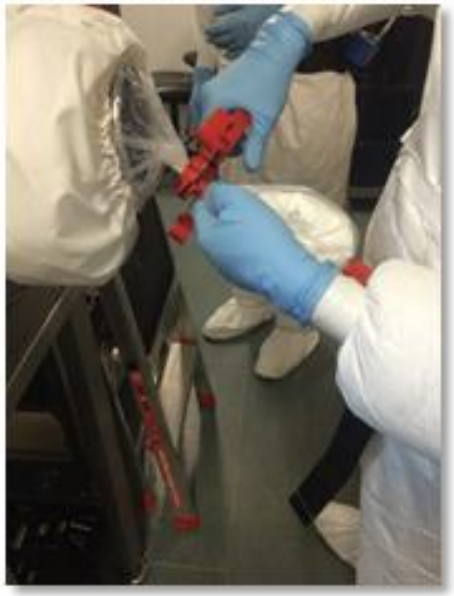
[1]µg/m³– Micrograms per cubic meter.

[2]TWA – Time-weighted average for 8 hours. Employee exposure limit (EEL) for 7-TES BAC III is 10 µg/m³ as an 8-hour TWA.

[3]Symbol (<) indicates the sample result was less than the value reported.

Sample Data & Results

Transferring product from the mixing drum to 100 gram packages



Twisting, crimping and cutting of continuous liner

Removing packaging equipment, tools and waste from antechamber

Access to Resources

D6. Is access to experts (for example, Certified Industrial Hygienists, Certified Safety Professionals, Occupational Nurses, or Engineers), reasonably available, based upon the nature, conditions, complexity, and hazards of the site? If so, under what arrangements and how often are they used?

-

Winston Churchill

"Continuous effort – not strength or intelligence – is the key to unlocking our potential."
- Winston Churchill

You Have the Keys - Now Go Open Greatness

- Ask for help if you need it!
- Remember to consider all hazards at your job site (chemical, noise, radiation, etc.)
- PRIORITIZE – Look at exposure limits, amount used, etc.
- Control hazards – Hierarchy of hazard control
- Gain statistical significance
- Reevaluate – At least ANNUALLY

Thank You!

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