



Results of Class II A2 and Class II B2 Bio-Safety Cabinet Sampling Study

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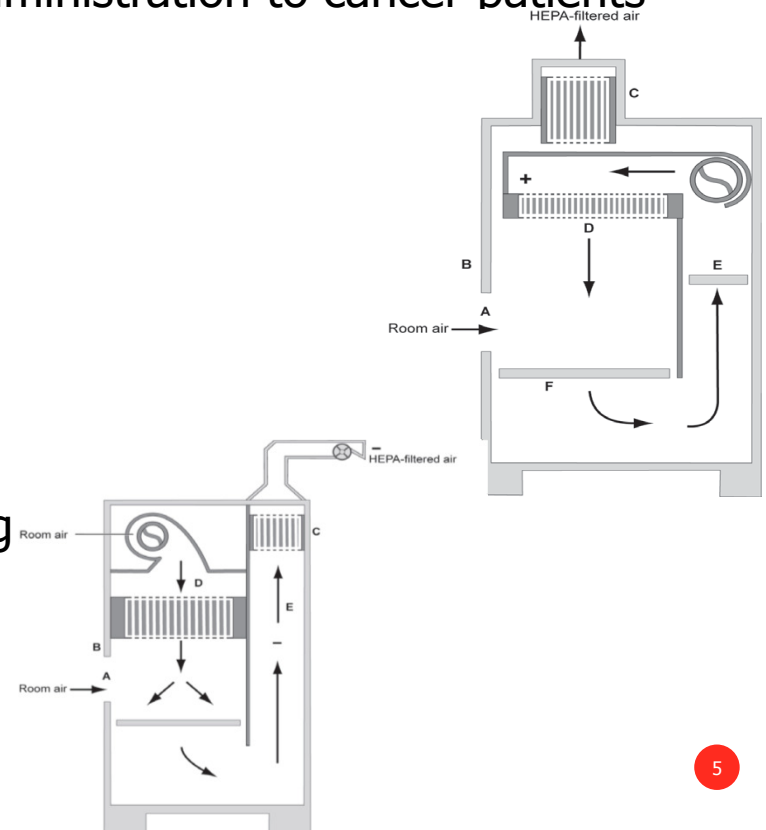
The Dilemma

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Biological Safety Cabinets (BSC)

Many healthcare facilities in WA use Class II BSC for compounding of chemotherapy (antineoplastic) drugs prior to administration to cancer patients

1. Recirculating Class II Type A2 ventilated cabinets exhaust ~30% airflow to the exterior and recirculate the balance back into the BSC
2. Class II Type B2 ventilated cabinets exhaust 100% of all air to the exterior of the building



The Question and Dilemma

Do recirculating Class II A2 ventilated cabinets offer the same or similar worker protection as Class II B2 ventilated cabinets during chemo drug compounding activities or a spill (particularly for volatile fractions)?

- Few peer-reviewed studies evaluating this topic and no comprehensive data, particularly for volatile fractions of chemotherapy drugs
- No known validated air-sampling test protocols for volatile fractions of chemotherapy drugs

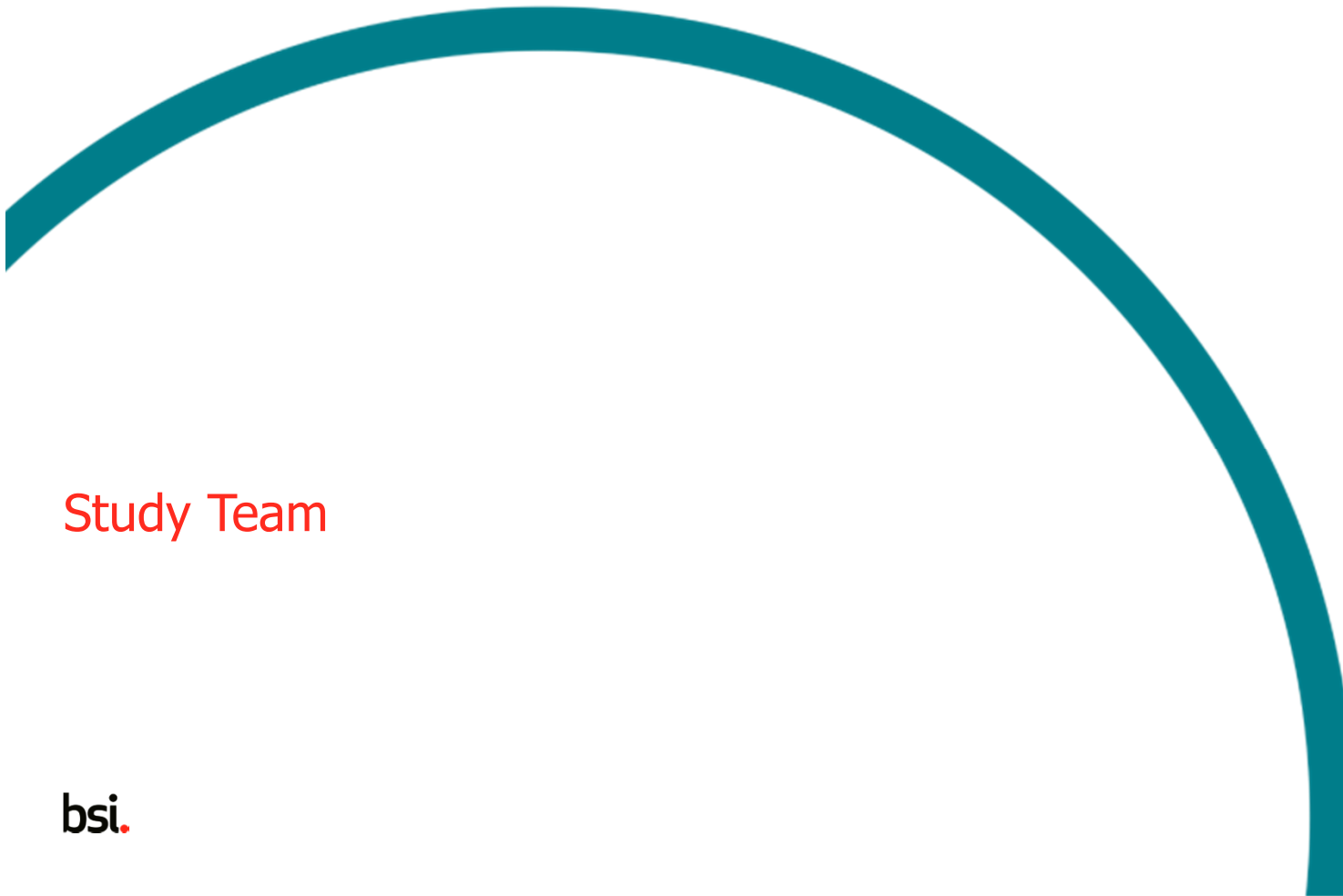


Study Purpose and Objective

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Study Purpose and Objective

- Study Purpose: to assist the WA State L&I with determining whether Class II A2 BSC together with administrative controls used by many healthcare facilities in WA for compounding are effective at controlling workplace exposures or require change or modification
- Study Objective: obtain representative air sampling data to evaluate the relative effectiveness of Class II A2 BSC as compared with Class II B2 BSC at controlling workplace exposures to select chemotherapy agents and/or a suitable surrogate compound
- Study Impact: Provide the WA State L&I with preliminary baseline data for review for future decision-making regarding compliance with applicable regulations
- Study Impact: Assist healthcare organizations with future decision-making on use/effectiveness of Class II A2 BSC vs. Class II B2 BSC for their own facilities



Study Team

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Key Study Personnel and Primary Responsibilities

- John Stebbins (WA L&I): Review and approval of study design and final report
- Jeff Rochon (WSPA): Study advocate, recruitment of healthcare partner facilities
- Alex Truchot (KP): Study advocate, study design and planning, review/comment of methods, final report
- Xavier Alcaraz (BSI): Principal investigator, study design, data analyses, reporting
- Michael Peterson (BSI): On-site assessments, data management, reporting
- Russel Snyders (BSI): Study coordination, study oversight and management, reporting quality review
- Nick Filipp (BSI): Reporting quality review, technical resource

Study Phases

- Phase 1: Assess the airborne concentrations of two chemotherapy drugs (particulate and aerosol fractions) in the breathing zones of personnel and the ambient air in rooms and/or areas of compounding during typical compounding activities and during a simulated spill condition in Class II A2 BSC for the purpose of comparing the results of similar air sampling performed in Class II B2 BSC
- Phase 2: Assess the airborne concentrations of a suitable surrogate chemical compound (vapor fraction) to evaluate simulated incidental and worst-case spill conditions involving chemotherapy drugs in Class II A2 BSC for the purpose of comparing the results of similar air sampling performed in Class II B2 BSC

Participating Healthcare Facilities

The facilities evaluated were located in larger hospitals or medical centers in the greater Seattle-Tacoma area

- CHI Franciscan Health, Highline Cancer Center Pharmacy, Burien, WA
- CHI Franciscan Health, St. Joseph Medical Center, Tacoma, WA
- Group Health (Kaiser), Bellevue Medical Center, Bellevue, WA
- Group Health (Kaiser), Capitol Hill Campus, Seattle, WA
- MultiCare Health System, Tacoma General Hospital, Tacoma, WA



Phase 1 Methods



Selection of Chemotherapy Drugs and BSC

Several common chemotherapy drugs were considered for incorporation into the study including the following:

- 5-Fluorouracil (5-FU) - selected
- Cyclophosphamide (CP) - selected
- Ifosfamide
- Methotrexate

6 BSC were selected for inclusion in Phases 1 and 2

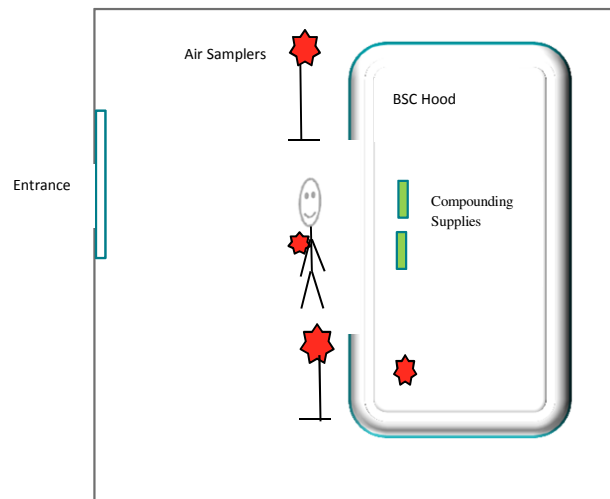
- 3 Class II A2 BSC
- 3 Class II B2 BSC

Study Conditions – Compounding

- Cyclophosphamide and 5-Fluorouracil chemotherapy solutions were individually prepared/compounded in each cabinet, in series
- Duration of compounding tasks for each agent ranged from 75 - 92 minutes including preparation and clean-up time
- Air sampling was conducted during the entire duration of compounding and continued at least 30 minutes after the completion of compounding
- Discarded PPE and compounding task-related materials (consumables) were left inside the cabinet to assess the cabinet's ventilation effectiveness and not variations in PPE or waste materials handling techniques

Study Conditions - Compounding

- Typical compounding room and the personal and air sample locations (red) during compounding

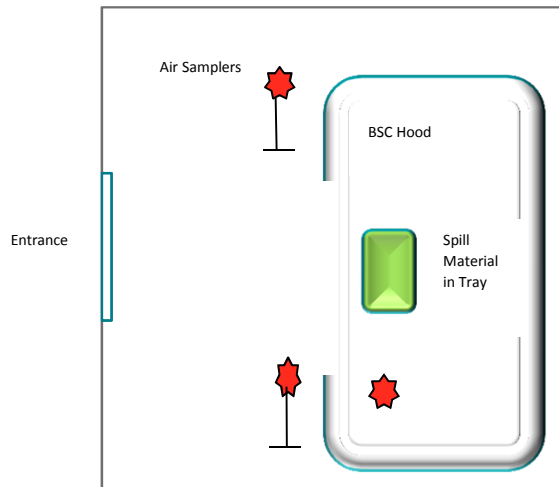


Study Conditions – Simulated Spill Condition

- Cyclophosphamide and 5-Fluorouracil were used to simulate a worst-case spill condition in each BSC
- The max volume used for compounding (~250 ml) for each were both poured into a single containment tray (18"x18"x4") inside each cabinet with the sash position maintained at working height
- Air sampling for both compounds was conducted simultaneously for at least 30 minutes
- Discarded PPE and other consumables were left inside the cabinet during the test
- Spilled materials were cleaned using DSS ChemoSorb pads
- Air sampling continued for an additional 30 minutes following spill clean-up activities

Study Conditions - Simulated Spill Condition

- Typical compounding room and the area air sample locations (red) during a simulated spill scenario



Sampling Details for 5-FU and CP

- Baseline area sample (outside of the BSC) was collected for ~30 minutes prior to the chemotherapy testing to determine background levels in the compounding room
- Personal sampler were attached to the compounding technician/employee's breathing zone (lapel)
- Area samples placed on tri-pods within room at approximate breathing zone level
- Due to the relative small size of compounding rooms, the area samples were generally placed on opposite sides of the BSC
- Source samples were placed inside the BSC adjacent to the compounding materials/activities
- 2 field blank samples and 2 laboratory blanks were submitted per each sample lot
- Lab analysis of samples using a Bureau Veritas internally-developed and validated sampling method by Liquid Chromatography/Mass Spectroscopy (LC/MS)
- Approx. 10 samples (including field blanks) were collected for each of the six BSC
- A total of 48 air samples (plus 14 field/lab QC blanks) were collected

Ventilation Assessments on each BSC

- Particle Capture and Filtration Test
 - Smoke released and measured with calibrated TSI P-Trak Ultrafine Particle Counter Model 8525 (diameter range of 20 nm to 1,000 nm, and resolution of 10 p/cc)
 - Measurements collected at the HEPA supply inside the Class II A2 BSC
 - Minimal or no measured particle release through the HEPA-filtered air supply was an expected result
- Ventilation Performance Test
 - Velometer used to test face velocity (target = 100 fpm) with the cabinet sashes adjusted to their proper working positions
- The facility HVAC in each compounding room was allowed to operate according to each facility's standard operating mode



Phase 2 Methods



Driver for Phase 2

- Phase 1 air sampling data were representative for powder, particulate and aerosol forms of 5-FU and Cyclophosphamide; however, they were not representative for their volatile fractions
- No known validated methods for the capture of volatile fractions of 5-FU and CP
- BSI proposed use of a surrogate compound with semi-volatile properties for air sampling under realistic and worst-case simulated spill conditions within Class II A2 BSC for comparison with Class II B2 BSC
- All sampling events for Phase 2 were similarly performed at the same medical centers, in the same rooms, and for the same BSC selected for Phase 1 of the study

Surrogate Sampling Chemical

BSI proposed the use of propylene glycol (PG) as the surrogate chemical for several reasons:

- Low vapor pressure
 - VP of PG at room temp is approx 1,000x higher than CP, 5-FU, and several other chemo agents = greater safety factor for use of PG as a surrogate
- Miscible in water
- Low toxicity
- Validated air sampling method for the volatile fraction
- Readily available
- NIOSH considered PG as one of several potential surrogate compounds for evaluating the effectiveness of CSTD

Study Conditions – Simulated Minor Spill Condition

PG used to simulate minor (incidental) spill or leakage of a chemo agent in solution that could occur during compounding in a BSC using a closed system transfer device (CSTD)

- Small quantity of propylene glycol (5 ml) was dispensed onto an absorbent wipe using a 5 – 10 ml syringe and placed inside a single containment tray (18"x18"x4") inside BSC with sash position maintained at working height
- Air sampling for PG was conducted for at least 30 minutes under this condition
- Discarded PPE and other consumables were left inside the cabinet during the test

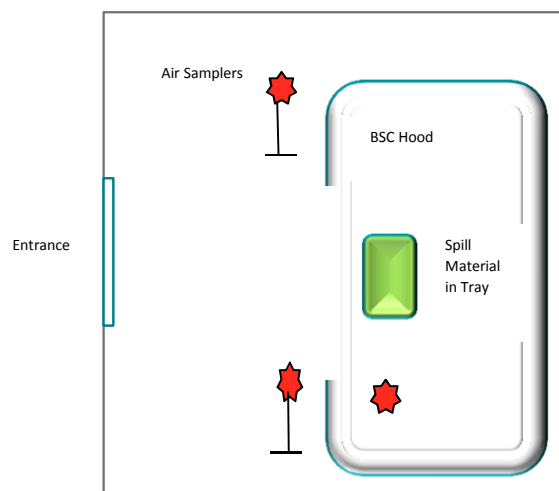
Study Conditions – Simulated Large Spill Condition

Propylene glycol was used to simulate a worst-case spill condition in each BSC

- The max volume used for compounding (~250 ml) was poured into a single containment tray (18"x18"x4") inside of the cabinet with the cabinet sash position maintained at working height
- Air sampling was conducted for at least 30 minutes under this condition
- The spilled materials were cleaned using DSS ChemoSorb pads
- Air sampling continued for an additional 30 minutes following spill clean-up activities

Study Conditions - Simulated Spill Conditions

- Typical compounding room and the area air sample locations (red) during a simulated spill scenario – Minor and Large



Sampling Details for PG – Integrated Air Sampling

- Baseline area sample (outside of the BSC) was collected for ~30 minutes prior to the PG sampling to determine background levels in the compounding room
- Area samples placed on tri-pods within the room at approximate breathing zone level
- Due to the relative small size of compounding rooms, the area samples were generally placed on opposite sides of the BSC
- Source samples were placed inside the BSC adjacent to the spill materials
- 2 field blank samples and 2 laboratory blanks were submitted per each sample lot
- Lab analysis by ALS Environmental (Cincinnati, OH) using and NIOSH Method 5523 for glycols by Gas Chromatography/ Flame Ionization Detection (GC/FID)
- Approximately 9 samples (including field blanks) were collected for each of the six BSC
- A total of 48 air samples and 12 field/laboratory quality control blanks were collected

Sampling Details for PG – Direct Read Air Sampling

- Photo-ionization detectors (PIDs) are suitable for monitoring a large variety of organic and some inorganic compounds
- PID was used for direct-read air sampling for PG using a calibrated ppbRae3000 (RAE Systems) photo-ionization detector (PID) equipped with a 10.6eV lamp configuration
- Spot measurements were collected in the same locations as integrated samplers at 5 minute intervals throughout the simulated spill sampling periods
- A baseline (background) measurement was collected prior to initiating each spill event, in between spill events, and following completion of the final spill event
- The final direct-read sampling data was converted using the manufacturer's-provided correction factor for PG (5.5 for ppbRae3000 with 10.6eV lamp)

Ventilation Assessments on each BSC

- Ventilation performance re-tested
- Ventilation Performance Test
 - Velometer used to test face velocity (target = 100 fpm) with the cabinet sashes adjusted to their proper working positions
- The facility HVAC in each compounding room was allowed to operate according to each facility's standard operating mode



Phase 1 Results

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General Observations

- The compounding areas were generally small rooms ($<100\text{ ft}^2$) to medium sized rooms ($100\text{ ft}^2 - 500\text{ ft}^2$)
- The compounding rooms generally had 1 – 2 BSC within the room
 - one site (St. Joseph Medical Center) had 3 BSC in the room
- Compounding was performed by one individual and technicians follow strict methods for preparation of chemotherapy solutions which were very similar across all sites
- All facilities used CSTD for compounding during sampling events which minimizes the risk of spillage or release of chemotherapy compounds
- Duration of compounding activities ranged from 20 - 30 min for each of the two solutions

General Observations – Continued

- Total task time including preparation, compounding, and clean-up ranged from 75 - 92 min per compounding event
- Compounding at each facility reportedly varies from <1 hr/day to >8 hrs/day
- Compounding technicians generally wore disposable coveralls or lab coat, sterile nitrile gloves, hairnet, and patient mask
- CP is in dry-powder form prior to compounding, whereas 5-FU in liquid solution
- 50ml of sodium chloride solution is added to 1 gram of dry form CP, mixed by hand. An aliquot of the solution is extracted and mixed into 250ml saline solution (IV bag). The process was similarly repeated, but using 5 grams of 5-FU pre-prepared in solution.
- No spillage or release was observed during compounding activities at any of the sites

Air Sampling Results for 5-FU and CP during representative compounding activities

- All air sampling results for CP and 5-FU during representative compounding activities in both Class II A2 BSC and Class II B2 BSC were lower than the analytical laboratory's limit of quantitation (1 ng/sample)
- The resulting non-detect exposure values ranged from $<0.00319 \mu\text{g}/\text{m}^3$ to $<0.00549 \mu\text{g}/\text{m}^3$
 - Variation in detection level due to variation in sampling times (i.e., volumes of air collected) for the samples

Air Sampling Results for 5-FU and CP During Representative Compounding Activities in Class II A2 BSC vs. Class II B2 BSC Across All Study Sites

Cabinet Type	Sample Type: Task, Location	Sampling Duration Range (min)	Chemotherapy Agent	Range ($\mu\text{g}/\text{m}^3$)
Class II A2	Area: Compounding, inside cabinet	112 - 120	Cyclophosphamide	ND, <0.00333 - ND, <0.00359
			5-Fluorouracil	ND, <0.00333 - ND, <0.00359
Class II A2	Area: Compounding, outside cabinet	112 - 120	Cyclophosphamide	ND, <0.00336 - ND, <0.00358
			5-Fluorouracil	ND, <0.00336 - ND, <0.00358
Class II A2	Personal: Compounding	85 - 92	Cyclophosphamide	ND, <0.00428 - ND, <0.0048
			5-Fluorouracil	ND, <0.00428 - ND, <0.0048
Class II B2	Area: Compounding, inside cabinet	105 - 120	Cyclophosphamide	ND, <0.00327 - ND, <0.00387
			5-Fluorouracil	ND, <0.00327 - ND, <0.00387
Class II B2	Area: Compounding, outside cabinet	105 - 120	Cyclophosphamide	ND, <0.00319 - ND, <0.00394
			5-Fluorouracil	ND, <0.00319 - ND, <0.00394
Class II B2	Personal: Compounding	75 - 86	Cyclophosphamide	ND, <0.00467 - ND, <0.00549
			5-Fluorouracil	ND, <0.00467 - ND, <0.00549

Air Sampling Results for 5-FU and CP during simulated worst-case spill conditions

- All air sampling results for CP and 5-FU during simulated worst-case spill conditions in both Class II A2 BSC and Class II B2 BSC were lower than the analytical laboratory's limit of quantitation (1 ng/sample)
- The resulting non-detect exposure values ranged from $<0.00629 \mu\text{g}/\text{m}^3$ to $<0.00712 \mu\text{g}/\text{m}^3$

Air Sampling Results for 5-FU and CP During Simulated Spill Conditions in Class II A2 BSC vs. Class II B2 BSC Across All Study Sites

Cabinet Type	Sample Type: Task, Location	Sampling Duration Range (min)	Chemotherapy Agent	Range ($\mu\text{g}/\text{m}^3$)
Class II A2	Area: Spill, outside cabinet	60	Cyclophosphamide	ND, <0.00659 - ND, <0.00689
			5-Fluorouracil	ND, <0.00659 - ND, <0.00689
Class II A2	Area: Spill, inside cabinet	60	Cyclophosphamide	ND, <0.00675 - ND, <0.00707
			5-Fluorouracil	ND, <0.00675 - ND, <0.00707
Class II B2	Area: Spill, outside cabinet	58 - 60	Cyclophosphamide	ND, <0.00629 - ND, <0.00712
			5-Fluorouracil	ND, <0.00629 - ND, <0.00712
Class II B2	Area: Spill, inside cabinet	58 – 60	Cyclophosphamide	ND, <0.00631 - ND, <0.00707
			5-Fluorouracil	ND, <0.00631 - ND, <0.00707

Summary of Recommended Occupational Exposure Limits for Study Compounds

Compound Name	Recommended Occupational Exposure Limit 8-hour TWA	Source
5-Fluorouracil	Occupational Exposure Band 5 = $<1 \mu\text{g}/\text{m}^3$	Pfizer Safety Data Sheet: Fluorouracil Injection Revision date: 19-Jul-2012
Cyclophosphamide	$0.1 \mu\text{g}/\text{m}^3$	Edward V. Sargent, et. al. (2002

Ventilation Assessment

- All BSC cabinets evaluated in the study were of stainless steel construction with an adjustable sash
- The BSC cabinets were equipped with integrated airflow monitoring devices that alarm when they fall below a minimum performance level
- The compounding rooms were designed to maintain a negative air pressure in relation to the adjacent rooms
- All BSC had average face velocity measurements above 100 fpm (with no value single measurement value below 75 fpm) when the sash was at working height (i.e., at indicator arrows)
- Particle testing data indicate that the Class II A2 supply HEPA filters which recirculate air back into the BSC were operating effectively on the dates of our sampling events
- All BSC cabinets were performance-tested and certified by an independent ventilation test contractor within 6 months prior to our sampling events

Comparison of Ventilation Assessment Results of Class II A2 BSC and Class II B2 BSC Across All Study Sites

Facility	Date	Cabinet Type	Phase 1 Face Velocity* (fpm)	Phase 2 Face Velocity* (fpm)	Phase 1 Flow Rate (cfm)	Phase 1 Particle Count - Outside Cabinet/Inside Cabinet (particles/cc)	Certified in Last 6 months?
Group Health – Bellevue	10/24/16	Class II A2	141.4	139	653.0	10 - 18	Yes
						0 - 1	
CHI - Highline	11/2/16	Class II A2	145.0	150	704.8	2,370 – 2,800	Yes
						0	
MultiCare Health	11/8/16	Class II A2	114.3	118.5	499.7	0 - 2	Yes
						0	
Group Health – Capitol Hill	10/27/16	Class II B2	135.4	152	526.6	7 – 18	Yes
						0	
St. Joseph Medical Center	11/3/16	Class II B2	154.1	115	599.5	12 – 34	Yes
						0	
MultiCare Health	11/7/16	Class II B2	130.2	138	291.6	15 – 23	Yes
						0	

*At working sash height/arrow



Phase 2 Results

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Sampling Results for PG during Simulated Minor Spill Conditions

- The majority of air sampling results for PG during simulated incidental (minor) spill conditions outside of both Class II A2 BSC and Class II B2 BSC did not exceed the analytical laboratory's limit of quantitation
- One of the integrated air samples collected outside of a Class II A2 BSC at Group Health Bellevue Medical Center resulted in a detection of PG at 0.10 ppm
- One of the two field blanks collected at Group Health Capitol Hill contained a detectable level of PG
- Two air samples collected inside of two separate Class II A2 BSC resulted in detections of PG ranging from 0.014 ppm to 0.017 ppm.
- Similarly, one integrated air sample collected inside of a Class II B2 BSC resulted in detection of PG at 0.051 ppm

Results for Propylene Glycol During Simulated Incidental Spillage in Class II A2 BSC vs. Class II B2 BSC Across All Study Sites

Cabinet Type	Sample Type: Task, Location	Sampling Duration (min)	Integrated Air Sampling Results - Range (ppm)	Direct-Read Sampling Results - Range (ppm)
Class II A2	Inside cabinet (right)	30	ND, <0.0052 0.014 0.017	ND
Class II A2	Outside cabinet (left)	30	ND, <0.0052 ND, <0.0052 ND, <0.0053	ND
Class II A2	Outside cabinet (right)	30	ND, <0.0053 ND, <0.0054 0.10	ND
Class II B2	Inside cabinet (right)	30	ND, <0.0054 ND, <0.0056 0.051	ND
Class II B2	Outside cabinet (left)	30	ND, <0.0051 ND, <0.0054 ND, <0.0056	ND
Class II B2	Outside cabinet (right)	30	ND, <0.0052 ND, <0.0054 ND, <0.0055	ND

Sampling Results for PG during Simulated Large Spill Conditions -

- The majority of the integrated air sampling results for PG during worst-case spill conditions outside of both Class II A2 BSC and Class II B2 BSC did not exceed the analytical laboratory's limit of quantitation
- Two integrated air samples collected inside of two separate Class II A2 BSC during the simulated large spill condition resulted in detections of PG ranging from 0.040 ppm to 0.044 ppm
- One integrated air sample collected inside of a Class II B2 BSC during the large spill condition resulted in detection of PG

Sampling Results for PG during Simulated Large Spill Conditions – Continued

- Direct-read PID air sampling measurements outside of a Class II B2 BSC at Multi-Care Health – Tacoma General detected values from non-detect to 3,850 ppb
 - It was observed that cleaning activities were being performed in an adjacent room concurrently with our air sampling. Because the compounding room is under negative pressure, the cleaning solvent used in the adjacent room may have contributed or been the sole source of the direct-read PID measurements.
- All other direct-read PID air sampling results for PG during simulated incidental (minor) and worst-case spill conditions inside and outside of both Class II A2 BSC and Class II B2 BSC did not exceed the instrument's lower level of detection (1 ppb)

Air Sampling Results for Propylene Glycol During Simulated Large Spill Conditions in Class II A2 BSC vs. Class II B2 BSC Across All Study Sites

Cabinet Type	Sample Type: Task, Location	Sampling Duration (min)	Integrated Air Sampling Results - Range (ppm)	Direct-Read Sampling Results - Range (ppm)
Class II A2	Inside cabinet (right)	30	ND, <0.0026 x3 (repeat sampling) 0.04 0.044	ND
Class II A2	Outside cabinet (left)	60	ND, <0.0026 x3 (repeat sampling) ND, <0.0026 ND, <0.0027	ND
Class II A2	Outside cabinet (right)	60	ND, <0.0026 x3 (repeat sampling) ND, <0.0027 ND, <0.0027	ND
Class II B2	Inside cabinet (right)	60	ND, <0.0026 ND, <0.0028 0.0070	ND
Class II B2	Outside cabinet (left)	60	ND, <0.0026 ND, <0.0027 ND, <0.0027	ND
Class II B2	Outside cabinet (right)	60	ND, <0.0026 ND, <0.0027 ND, <0.0028	ND – 0.70 /3.85*



Conclusions – Phase 1

Phase 1 Conclusions

Air sampling results assessing the particulate and aerosol fractions of CP and 5-FU during representative compounding activities and simulated worst-case spill events in Class II A2 BSC vs. Class II B2 BSC:

- Air sampling results across all study sites were below the occupational exposure limits
- Current exposure control methods (e.g., strict compounding protocols and use of certified BSC) appear to be similarly effective for particulates forms of chemo agents
- Strict compounding protocols established at each facility using CSTD for both the liquid form of 5-FU and the powder form of CP also serve to minimize exposure to particulate fractions of the chemo agents
- Risk of exposure to particulate fractions of chemotherapy agents could be higher if powders were incidentally released as a spill inside the hood and/or if the spill extended beyond the confines of the BSC
 - However, these spill conditions reportedly have a low probability and, thus were not assessed as part of study scope



Conclusions – Phase 2

Phase 2 Conclusions

Air sampling results assessing for the vapor fractions of the selected surrogate compound (propylene glycol) during simulated minor and worst-case spill events in Class II A2 BSC vs. Class II B2 BSC

- Almost all air sampling results for PG outside of both BSC types across all sites were non-detect
- No notable difference in effectiveness of control of volatile fractions of PG outside of Class II A2 BSC as compared to Class II B2 BSC
 - This is relevant to healthcare workers such as compounding technicians who work in the compounding rooms
- During minor and/or large spills, there is potential for airborne exposure to volatile fractions of chemotherapy drugs inside **BOTH** BSC types
 - BSC sash would need to be lifted and EE insert their face/breathing zone into BSC
 - Possible scenario: spill requiring extensive cleaning of interior surfaces of BSC

Considerations for Further Study

- Perform additional sampling to include additional sites and repeat sampling
- Perform sampling at small metro facilities and small rural facilities to document potential variations in procedures, equipment, and/or facilities
- Use a semi-volatile surrogate chemical during typical chemotherapy compounding activities to evaluate the effectiveness of exposure control during use of CSTD and other compounding protocols not involving use of a CSTD
- Perform qualitative ventilation assessments to evaluate capture efficiency and/or potential air turbulence conditions at the face of each cabinet. Excess air turbulence and poor capture efficiency at the face of the cabinet can affect exposure potential even when cabinets meet minimum face-velocity performance requirements.
- Further evaluate the relative volatile chemical properties of antineoplastic agents and how they are handled in Class II A2 BSC to screen their potential exposure risk
- Develop a sampling and analytical method to simultaneously monitor the volatile and non-volatile fractions of antineoplastic agents in workplace air



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 - CHI Franciscan Health - Highline Cancer Center Pharmacy
 - CHI Franciscan Health - St. Joseph Medical Center
 - Group Health - Bellevue Medical Center (now known as Kaiser Permanente)
 - Group Health - Capitol Hill Campus (now known as Kaiser Permanente)
 - MultiCare Health System - Tacoma General Hospital
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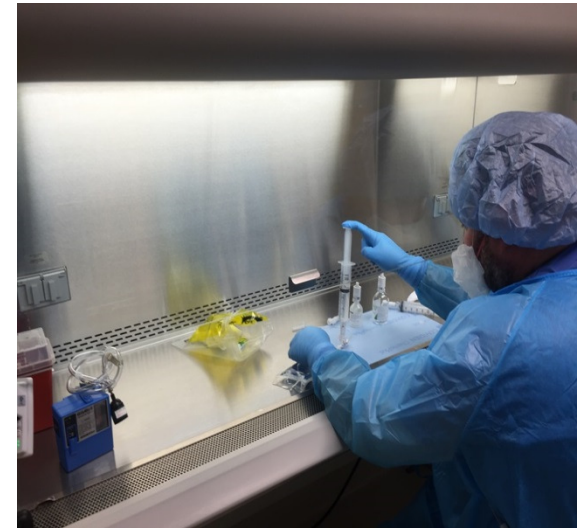


Thank You!

Questions?

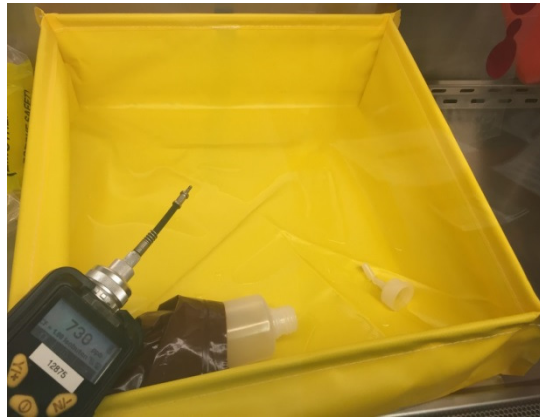


Study Photos



Use of CSTD for compounding during Phase 1

Study Photos



Simulated large spill condition during Phase 2



Integrated airflow monitoring devices on BSC



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