Safety and Health Investment Projects
FINAL REPORT REQUIREMENTS

The purpose of the final report of your SHIP project is to:

1. Evaluate and document the achievements, challenges, and shortcomings of the project for the constructive benefit of others interested in learning from SHIP projects; and
2. Provide the Division of Occupational Safety and Health with information that shows:
   a. The outcomes specified in the project application were met; and
   b. The grant was used for the purpose(s) for which it was approved and in accordance with relevant WAC rules and any special conditions or requirements; and
   c. The outputs of the project have been disseminated as specified in the application.

The report format has four sections:

1. Cover Sheet
2. Narrative Report (part I)
3. Financial Information (part II)
4. Attachments (part III)

Please provide complete and detailed information in the final report. If you have questions, please call your SHIP grant manager.

REMINDER!!: All products produced, whether by the grantee or a subcontractor to the grantee, as a result of a SHIP grant are in the public domain and can not be copyrighted, patented, claimed as trade secrets, or otherwise restricted in any way.

SAFETY AND HEALTH INVESTMENT PROJECTS
FINAL REPORT

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

Assigned SHIP grant #2016ZA00328

July 14, 2016 to August 15, 2017

Project Manager
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Washington State Pharmacy Association/ /Kaiser Permanente Washington/ MultiCare Health System/ CHI Franciscan Health/BSI EHS Services and Solutions

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Washingotn State Pharmacy Association is solely responsible for the content of and views expressed in this report and related materials unless they have been formally endorsed by the Washington State Department of Labor and Industries.

PART I

Narrative Report

Abstract:

Present a short overview of the nature and scope of the project and major findings (less than half a page).

This study involved performing airborne sampling over two separate phases to compare the ventilation effectiveness of representative Class II A2 BSC with Class II B2 BSC. The study phases were as follows:

- **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 worst-case 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 potential, 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

To accomplish this, the study design focused on collecting airborne samples in the breathing zones of personnel and/or ambient air in rooms and/or areas of compounding during typical compounding activities or during simulated spill conditions in each BSC.

The Phase 1 air sampling results of assessing the particulate and aerosol fractions of Cyclophosphamide and 5-Fluorouracil during representative compounding activities and simulated spill events in Class II A2 BSC vs. Class II B2 BSC across all study sites were below the respective occupational exposure limits which suggests that current exposure control methods appear to be similarly effective during compounding work activities.

The Phase 2 air sampling data suggest that there is no notable difference in the effectiveness of controlling volatile fractions of propylene glycol 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. However, the air sampling data also suggest that during minor and/or large spills, there is a potential for airborne exposure risk to volatile fractions of chemotherapy drugs inside the ventilated cabinets for both the Class II A2 BSC and Class II B2 BSC.

Purpose of Project:

Describe what the project was intended to accomplish.

The objective of this cohort study was to obtain representative air sampling data to evaluate the relative effectiveness of Class II A2 Biosafety Cabinets (BSC) as compared with Class II B2 BSC at controlling workplace exposures to select chemotherapy agents and/or a suitable surrogate compound.

The purpose of this study was to assist the Washington State Department of Labor & Industries with determining whether the use of Class II A2 BSC together with administrative controls used by many healthcare facilities in Washington State for compounding tasks are effective at controlling worker exposures or if current controls require change/modification.

Statement and Evidence of the Results:

Provide a clear statement of the results of the project include major findings and outcomes and provide evidence of how well the results met or fulfilled the intended objectives of the project.

The Phase 1 air sampling results assessing the particulate and aerosol fractions of Cyclophosphamide and 5-Fluorouracil during representative compounding activities and simulated spill events in Class II A2 BSC vs. Class II B2 BSC across all study sites were below the respective occupational exposure limits which suggests that current exposure control methods appear to be similarly effective during compounding work activities.

The Phase 2 air sampling data suggest that there is no notable difference in the effectiveness of controlling volatile fractions of propylene glycol 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.

However, the air sampling data also suggest that during minor and/or large spills, there is a potential for airborne exposure risk to volatile fractions of chemotherapy drugs inside the ventilated cabinets for both Class II A2 BSC and Class II B2 BSC. In order for this exposure risk to be realized, the compounding technicians would need to lift the ventilated cabinet sash and insert their face/breathing zone into the cabinet. This scenario could occur if a spill requires extensive cleaning of the interior surfaces of the cabinet without proper respiratory protection.

Measures to Judge Success:

If relevant, state what measures or procedures were taken to judge whether/ how well the objectives were met and whether the project or some other qualified outside specialist conducted an evaluation.

A sampling strategy/protocol for both Phase 1 and Phase 2 portions of the study design was prepared, submitted for review, and approved by study partners (including John Stebbins of Labor & Industries) prior to proceeding with the study. Upon completion of the field study and assessment of data, a formal, comprehensive study report was submitted to study partners (including Labor & Industries). Comments and edits were review and incorporated into the final study report, where applicable.

Relevant Processes and Lessons Learned:

Specify all relevant processes, impact or other evaluation information which would be useful to others seeking to replicate, implement, or build on previous work

AND

Provide information on lessons learned through the implementation of your project. Include both positive and negative lessons. This may be helpful to other organizations interested in implementing a similar project.

Phase 1 air sampling and laboratory analytical methods were effective for capture of powder, particulate and aerosol forms of 5-Fluorouracil and Cyclophosphamide; however, they were not effective and/or have not been validated for the capture of volatile fractions of 5-Fluorouracil and Cyclophosphamide. Since there are no known validated methods for the capture of volatile fractions of 5-Fluorouracil and Cyclophosphamide, BSI proposed the use of a surrogate compound with semi-volatile properties for air sampling under realistic and worst-case simulated spill conditions within representative Class II A2 BSC as compared with Class II B2 BSC. This surrogate compound air sampling was performed to supplement the existing sampling data for powder, particulate and aerosol forms of 5-Fluorouracil and Cyclophosphamide. Propylene glycol was selected for several reasons including the following:

- Low vapor pressure
- Miscible in water
- Low toxicity
- Validated air sampling method for the volatile fraction
- Readily available

Although the vapor pressure of propylene glycol at room temperature is several orders of magnitude higher (approximately 1,000x) than that of Cyclophosphamide, 5-Fluorouracil, and several other antineoplastic agents, this provided a greater safety factor for use of propylene glycol as a surrogate chemical for sampling. Thus, it is the author's opinion that propylene glycol was a suitable surrogate compound with semi-volatile properties for air sampling to simulate volatile fractions of 5-Fluorouracil and Cyclophosphamide under realistic and worst-case simulated spill conditions within representative Class II A2 BSC and Class II B2 BSC.

The number of integrated air samples collected for each unique spill condition was small, and the number of study sites was limited (three Class II A2 BSC and three Class II B2 BSC). As such, the study sample set did not allow for robust statistical analysis of the data. Furthermore, many of the air sample results were non-detect, which also limited the comparative analysis across BSC types.

Product Dissemination:

Outline of how the products of the project have been shared or made transferrable.

A detailed sampling strategy/protocol for both Phase 1 and Phase 2 portions of the study design was prepared. Upon completion of the field study and assessment of data, a formal, comprehensive study report was prepared.
A manuscript(s) will be adapted from the comprehensive study report and be submitted to a peer-reviewed scholarly journal for consideration for publication.

Feedback:

Provide feedback from participants, trainees, individuals who have used your products/processes, as well as any reports from an independent evaluator on the project.

The formal study report was distributed for review within a small group of study partners; thus it is unlikely that any of the processes used in this study have been replicated. However, comments from this group of study partners were limited and largely in agreement with the results and conclusions.

Project's Promotion of Prevention:

Explain how the results or outcomes of this project promote the prevention of workplace injuries, illnesses, and fatalities?

The study data suggest that Class II A2 BSC together with administrative controls used by many healthcare facilities in Washington State for compounding tasks are effective at controlling worker exposures under normal conditions/operations. However, during minor and/or large spills, there is a potential for airborne exposure risk to volatile fractions of chemotherapy drugs inside the ventilated cabinets for both Class II A2 BSC and Class II B2 BSC if compounding technicians lift the ventilated cabinet sash and insert their face/breathing zone into the cabinet. This scenario could occur if a spill requires extensive cleaning of the interior surfaces of the cabinet without proper respiratory protection.

Uses:

How might the products of your project be used within the target industry at the end of your project?

Is there potential for the product of the project to be used in other industries or with different target audiences?

Study methods used and developed for this study may be used to validate the conclusions of this study and/or perform further assessment to provide additional evaluation. Currently, the National Institute of Occupational Safety and Health (NIOSH) is considering use of various surrogate compounds for similar studies. Propylene glycol is one such proposed surrogate compound.

Organization Profile:

For awarded organizations, to include partners and collaborators, provide a brief description of each organization. Mission, vision, and purpose for each of the organizations who applied (this includes partners and collaborators) for the grant.

The **Washington State Pharmacy Association** exists to advocate on behalf of its members to ensure pharmacy professionals are recognized, engaged, and valued as essential to the healthcare team. The vision of the Washington State Pharmacy Association is to ensure everyone understands and recognizes the importance of the profession of pharmacy. We strive to advance quality and safe health care through supporting member success in providing patient-focused and outcome-oriented pharmacy practice. We are committed to responding to our members' needs by providing quality programs and services while demonstrating visible leadership and innovative thinking.

As the leading provider of EHS and sustainability management and technical consulting services, **BSI EHS Services and Solutions** strives to align our own business practices and principles with the guidance we deliver to our clients. We do this by committing to excellence in environmental performance, and in the health and safety of our employees, customers, and communities. Meeting this commitment is a primary management objective and the individual and collective responsibility of all our employees.

Kaiser Permanente Washington exists to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. We are trusted partners in total health, collaborating with people to help them thrive and creating communities that are among the healthiest in the nation.

MultiCare Health System's mission is partnering for healing and a healthy future. Our vision is that MultiCare will be the Pacific Northwest's highest value system of health.

The mission of **Catholic Health Initiatives** is to nurture the healing ministry of the Church, supported by education and research. Fidelity to the Gospel urges us to emphasize human dignity and social justice as we create healthier communities. We will lead the transformation of healthcare to achieve optimal health and wellbeing for the individuals and communities we serve, especially those who are poor and vulnerable.

Additional Information

Project Type

- ☐ Best Practice
- ☐ Technical Innovation
- ☐ Training and Education Development
- ☐ Event
- ☐ Intervention
- ☒ Research
- ☐ Return to Work
- ☐ Other (Explain):

Target Audience: Hospitals, pharmacies, medical clinics, research institutions, universities

Languages: English

Industry Classification (check industry(s) this project reached directly)

- ☐ 11 Agriculture, Forestry, Fishing and Hunting
- ☐ 21 Mining
- ☐ 22 Utilities
- ☐ 23 Construction
- ☐ 31-33 Manufacturing
- ☐ 42 Wholesale Trade
- ☐ 44-45 Retail Trade
- ☐ 48-49 Transportation and Warehousing
- ☐ 51 Information
- ☐ 52 Finance and Insurance
- ☐ 53 Real Estate and Rental and Leasing
- ☒ 54 Professional, Scientific, and Technical Services
- ☐ 55 Management of Companies and Enterprises
- ☐ 56 Administrative and Support and Waste Management and Remediation Services
- ☐ 61 Educational Services
- ☒ 62 Health Care and Social Assistance
- ☐ 71 Arts, Entertainment, and Recreation
- ☐ 72 Accommodation and Food Services
- ☐ 81 Other Services (except Public Administration)
- ☐ 92 Public Administration

Please provide the following information - - *(information may not apply to all projects)*

# classes/events:	
# hours trained	
# students under 18	
# workers	
# companies represented	
# reached (if awareness activities)	
Total reached	

List, by number above, industries that project products could potentially be applied to.
Unknown

Potential impact (in number of persons or companies) after life of project?
Unknown

Have there been requests for project products from external sources? No
If Yes, please indicate sources of requests:

PART II

Financial Information
Budget Summary

Project Title:	Development of a Testing Protocol for Air Monitoring of Workers Compounding Volatile Chemotherapy in Ventilated Cabinets ad Comparing Protection of Different Types of Ventilated Cabinets		
Project #:	2016ZA00328	**Report Date:**	August 15, 2017
Contact Person:	Jeff Rochon	**Contact #:**	K-3632
Start Date:	August 30, 2016	**Completion Date:**	August 15, 2017

1.	**Total original budget for the project**	$ 131,783
2.	**Total original SHIP Grant Award**	$ 131,783
3.	**Total of SHIP Funds Used**	$ 131,783
4.	**Budget Modifications (= or - if applicable)**	$ 0
5.	**Total In-kind contributions**	$ 12,344
6.	**Total Expenditures (lines 3+4+5)**	$ 144,127

Instructions:

- Complete the Supplemental Schedule (Budget) form first (on the next page).
- The final report must include all expenditures from date of completion of interim report through termination date of grant.
- Indicate period covered by report by specifying the inclusive dates.
- Report and itemize all expenditures during specified reporting period per the attached supplemental schedule.
- Forms must be signed by authorized person (see last page).
- Forward one copy of the report to **Arlene Hallom, SHIP Grant Manager** at **PO Box 44612, Olympia, WA 98504-4612**

PART II *(Continued)*

Financial Information
Supplemental Schedules (Budget)

Project Title:	Development of a Testing Protocol for Air Monitoring of Workers Compounding Volatile Chemotherapy in Ventilated Cabinets ad Comparing Protection of Different Types of Ventilated Cabinets		
Project #:	2016ZA00328	**Report Date:**	August 15, 2017
Contact Person:	Jeff Rochon	**Contact #:**	K-3632
Total Awarded:	$131,783		

ITEMIZED BUDGET: How were SHIP award funds used to achieve the purpose of your project?

	Budgeted for Project	Amount Paid Out	Difference
A. PERSONNEL	$19,400		
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
B. SUBCONTRACTOR	112383	112,383	none
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
C. TRAVEL	none	none	none
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
D. SUPPLIES	none	none	none
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
E. PUBLICATIONS	none	none	none
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
F. OTHER	none	none	none
Explanation for Difference and other relevant information:			

	Budgeted for Project	Amount Paid Out	Difference
TOTAL DIRECT COSTS	$131,783	$131,783	0
	Budgeted for Project	Amount Paid Out	Difference
TOTAL INDIRECT COSTS	none	none	none
	Budgeted for Project	Amount Paid Out	Difference
TOTAL SHIP BUDGET	$131,783	$131,783	none

	Budgeted for Project	Amount Paid Out	Difference

G. IN-KIND	$50,000	$12,344	$37,656
Explanation for Difference and other relevant information: There are several reasons for the Difference. These included: • The amount of time required to orient the Health System Partner Organizations and their staff was less than anticipated. Their professional staff were very receptive and willing to participate. • The testing time was made efficient by the technicians and BSI to minimize overall time. • The testing was scheduled after hours. The costs for decontaminating and disinfecting the BSCs were not included as project costs by the partners. • The rates submitted by the partners appear to be raw salary rates and did not include the indirect costs. • Leadership at each of the Health System Partners was organized and efficient. They provided careful planning and scheduling for the testing.			

I hereby certify that the expenditures listed on this report were made with my approval:

8/15/17 _____ _____

Date Signature of Project Manager

PART III
Attachments:

Provide resources such as written material, training packages, or video/ audio tapes, curriculum information, etc. produced under the grant.

Also include copies of publications, news releases, curriculum, posters, brochures, etc.

The above information should also be provided on a CD or DVD for inclusion in the file.

- DVD: must be in an MP4 format
  Other video files must be provided in uncompressed source files

- Publications:
  PDF of publication should be provided. SHIP also needs the original publishing documents (design documents), .eps, and .psd (if any illustrations/graphics are used)

REMINDER!!: All products produced, whether by the grantee or a subcontractor to the grantee, as a result of a SHIP grant are in the public domain and can not be copyrighted, patented, claimed as trade secrets, or otherwise restricted in any way.