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**COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON**

WESTERN WASHINGTON ONCOLOGY, P.S.,

Appellant,

v.

WASHINGTON STATE DEPARTMENT OF LABOR AND
INDUSTRIES,

Respondent.

BRIEF OF RESPONDENT

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I. INTRODUCTION

The Department of Labor and Industries (Department) cited Western Washington Oncology, P.S. (WW Oncology) for violating the worker safety regulations under the Washington Industrial Safety and Health Act (WISHA). The citation was based on the fact that WW Oncology did not require nurses and technicians working with chemotherapy drugs to wear appropriate personal protective equipment – impermeable gowns – to adequately protect them from the serious hazard of toxic drugs coming into contact with their skin.

WW Oncology appealed to the Board of Industrial Insurance Appeals (Board). In a proposed decision issued after a hearing, an Industrial Appeals Judge (IAJ) affirmed the violation now before this Court. WW Oncology then petitioned the three-member Board for review, but the Board denied the petition, thereby adopting the IAJ's proposed decision as the final order of the Board. WW Oncology appealed the Board's decision to superior court, which affirmed the Board's decision. WW Oncology now appeals to this Court.

The Department's WISHA safety regulations require employers to identify, provide, and ensure that workers use appropriate and necessary personal protective equipment. What personal protective equipment is required under the regulations is determined by what a "reasonable person" in the affected industry would have required. The record in this case amply demonstrates that a reasonable person in the chemotherapy industry would provide his or her employees with impermeable gowns to

protect them from the hazards of the toxic chemicals with which they work, and would have ensured that the employees wore those gowns. Because WW Oncology failed to enforce the use of impermeable gowns, this Court should affirm the decisions below.

II. COUNTERSTATEMENT OF THE ISSUES

- 1. Does substantial evidence support the Board's finding that chemotherapy drugs can have adverse effects on the surface of the skin, and serious systemic effects if absorbed by the skin?**
- 2. Does substantial evidence support the Board's determination that impermeable gowns are necessary personal protective equipment for workers in the chemotherapy industry, where the National Institute of Occupational Safety and Health; the federal Occupational Safety and Health Authority; and the Oncology Nursing Society all recommend the use of such protection for workers exposed to chemotherapy drugs, and where WW Oncology had actual knowledge of these industry recommendations?**
- 3. Does substantial evidence support the Board's finding that WW Oncology failed to enforce the use of adequate personal protective equipment for nurses and technicians mixing or administering chemotherapy?**
- 4. The WISHA Core Personal Protective Equipment Rules, WAC 296-800-160 through 16070, require employers to ensure that workers use adequate personal protective equipment. Do the Board's findings of fact support its conclusion of law that WW Oncology violated these standards by failing to require its workers handling toxic chemotherapy drugs to wear impervious gowns as recommended by the National Institute for Occupational Safety and Health (NIOSH), the Oncology Nursing Society, the *Occupational Safety***

and Health Act (OSHA) Technical Manual and other national consensus authorities?

- 5. Did the Board correctly determine that the testimony of the Department's Certified Industrial Hygienist about recent research in her field satisfied the *Frye*¹ standard and was admissible under ER 702?**

III. COUNTERSTATEMENT OF THE CASE

A. Overview Of The Facts

Nurses and admixture technicians at the three WW Oncology chemotherapy clinics work with and are exposed to toxic chemicals every day. Nurses or technicians *mixing* chemotherapy are exposed to *undiluted* toxic chemicals for six to eight hours a day.² Nurses *administering* chemotherapy to cancer patients are exposed to *diluted mixtures* of toxic chemicals during their entire work week.³ The effects of exposure to cytotoxic or antineoplastic⁴ drugs are well known, and can be cumulative.⁵ Chemotherapy drugs which come in contact with the skin may cause rash, itching, irritation and skin damage. If the drugs are on the skin long enough to be absorbed, they may cause adverse systemic effects, including leukemia, miscarriages, and birth defects.⁶ Nurses working in the three WW Oncology clinics have had cytotoxic drugs spilled on them in large

¹ See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

² Certified Appeals Board Record (CABR), Transcript (Tr.), 11/14/07, Batchelor-Hancock at 128.

³ CABR, Tr., 11/14/07.

⁴ Antineoplastic and cytotoxic are used interchangeably in the record to describe chemotherapy drugs. However, antineoplastic means suppressing the growth of neoplasms and cytotoxic means toxic to cells. *Webster's II New Riverside University Dictionary*, 1988; CABR, Tr., 11/14/07, Cunningham at 41.

⁵ CABR, Tr., 11/14/07, Hilkemeier at 168.

⁶ CABR, Tr., 11/14/07, Cunningham at 44.

enough amounts that the drugs soaked through their clothing to the skin. In some instances, the drugs remained on the skin long enough to penetrate.⁷

In September 2004, the National Institute for Occupational Safety and Health (NIOSH) issued an alert to bring to the attention of health care workers and their employers the most recent research on the hazards of cytotoxic drugs, and to recommend engineering controls and protective equipment for handling such drugs.⁸ NIOSH recommended that nurses and technicians handling cytotoxic drugs wear disposable gowns made of polyethylene-coated polypropylene, with closed fronts, long sleeves and elastic or knit closed cuffs for all activities associated with drug administration – opening the outer bag, assembling the delivery system, delivering the drug to the patient, and disposing of all equipment used to administer drugs.⁹

Melody Edgington, the chief executive officer for WW Oncology, received a copy of the NIOSH Alert - when it was first published - from Carol Hulse, WW Oncology's nurse manager, who attended the NIOSH conference in October 2004.¹⁰ Since the date of the NIOSH Alert, professional publications such as the *Guidelines of the Oncology Nursing Society*, the *Journal of Oncology Pharmacy Practice*, and the *OSHA Technical Manual* consider splash-resistant gowns with polyethylene or

⁷ CABR, Tr., 11/14/07, Lindley at 144.

⁸ CABR, NIOSH Alert, Exhibit (Ex.) 13; Tr., 11/14/07, Cunningham at 57-59.

⁹ CABR, NIOSH Alert, Ex. 13, at 13-14; Tr., 11/14/07, Cunningham at 57-59.

¹⁰ CABR, Carol Hulse Deposition (Hulse Dep.) 9/27/07, at 20.

vinyl coatings essential personal protection equipment for nurses and technicians handling chemotherapy drugs.¹¹

Under the WISHA's Core Personal Protective Rules (WAC 296-800-160 through -16070), employers must identify potential hazards in the workplace, select appropriate personal protective equipment (PPE) to protect employees from the hazards, train the employees to use the PPE, and require the employees to use necessary PPE on the job. Nevertheless, when the WISHA inspection began, one year and nine months after the 2004 NIOSH Alert, WW Oncology did not require the use of impermeable gowns for nurses or technicians working with cytotoxic chemicals.¹² Indeed, the management of WW Oncology permitted nurses and technicians to wear whatever they pleased when they mixed or administered chemotherapy, including scrubs, a white lab coat, or a porous yellow gown, none of which provided an adequate barrier against the extremely toxic chemicals with which they routinely worked.¹³

B. Employees Sometimes Spilled Or Sprayed Toxic Drugs On Themselves Resulting in Contact With Their Skin

Approximately a week before WISHA Industrial Hygienist Margaret Cunningham interviewed the WW Oncology employees at the Centralia Clinic, an IV clamp became disconnected and a mixture containing the cytotoxic drug Taxol was spilled and/or sprayed on the

¹¹ CABR, Tr., 11/14/07, Cunningham at 57-59.

¹² CABR, Tr., 11/14/07, Cunningham at 64.

¹³ CABR, Tr. 11/14/07, Guilford-Elenes at 90, 92; Tr., 11/14/07, Batchelor-Hancock at 131; Tr., 11/14/07, Lindley at 141; Tr., 12/3/07, Ishler at 52.

patient's blanket and on Marsha Justus, the nurse who was trying to assist the patient.¹⁴ Ms. Justus was wearing the Graham Medical gown 242, a yellow gown through which the drug passed, reaching her skin. Ms. Justus described the incident as follows:

A. (Justus) When I was out doing patient care an IV clamp had become disconnected and as I was attempting to turn it off, it had come in contact with my skin.

Q. Could you describe that in more detail?

A. Well, the patient had a bunch of blankets on their lap. As I was searching for the clamp to turn the chemo off, it was spraying. It had – I had noticed that it was kind of - at first, it was just sitting on the yellow gown and then it started to kind of seep into it.

Q. You were wearing the yellow gown at the time?

A. Uh-huh, yes.

Q. Did you actually get some on your skin?

A. Yes.¹⁵

It was 15 minutes before Ms. Justus was able to clean the chemotherapy off her skin.

This was not the first time Ms. Justus had been sprayed with antineoplastic drugs while administering chemotherapy. On a prior occasion, she was assisting a patient in the bathroom and the IV tubing came apart, spraying some of the cytotoxic drug mixture on her.¹⁶ On other occasions, a faulty syringe or a cheap stopper would spray *undiluted* cytotoxic drugs onto her gloved hands while she was mixing them, and on

¹⁴ CABR, Tr., 12/3/07, Justus at 34-35.

¹⁵ CABR, Tr., 12/3/07, Justus at 34-35.

¹⁶ CABR, Tr., 12/3/07, Justus at 38.

one such occasion, the liquid got above her gloves and reached the unprotected skin on her wrist.¹⁷

Similar incidents took place in all three WW Oncology clinics. In fact, four of the six nurses who testified at the hearing described incidents in which chemotherapy drugs were spilled, splashed or sprayed on them. And all four of them testified that on at least one occasion the drugs penetrated to their skin.¹⁸ Cytotoxic drugs in the potent *undiluted* form reached the skin of two nurses, Marsha Justus (see above) and Robert Hilkemeier.¹⁹

Robert Hilkemeier had drops of *undiluted* cytotoxic agents leak from a stopper or a syringe, fall on his gown, and penetrate to the skin when he was mixing chemotherapy.²⁰ Drops would leak from the syringe almost daily, and penetrated to his skin several times a year. He also had cytotoxic chemicals spilled on him while administering chemotherapy to patients. On one occasion, the clamp on a bag of Cytoxan failed, and the drug leaked down his pants and scrubs.

A. (Hilkemeier) To my recollection it was a bag of Cytoxan prepared in the hood by a coworker and set on

¹⁷ CABR, Tr., 12/3/07, Justus at 39-40.

¹⁸ Although some of these incidents took place two or three years before the WISHA inspection, the testimony shows that despite engineering controls, such as the Biosafety Cabinets in which chemotherapy was mixed, and the care taken by the nurses, accidental spills of cytotoxic drugs did occur at WW Oncology. The employer did not present any evidence that conditions had changed or procedures changed in the ensuing years to lessen the probability of such incidents, many of which were attributable to clamp failures and similar equipment malfunctions.

¹⁹ When the antineoplastic drugs were being mixed in the Biosafety Cabinets, they were undiluted. When they were being administered to patients, they were usually diluted with a saline solution. CABR, Tr. 11/14/07, Cunningham at 65, 108, 109.

²⁰ CABR, Tr., 11/14/07, Hilkemeier at 169-170.

a designated area for us to double-check the dose prior to administering it. As I picked up the bag, I did not realize that the clamp had broken and failed. And as I picked up the bag, on the way to carry it to the patient, the chemotherapy was unbeknownst to me leaking all down my pants and scrubs as well as gown.²¹

The Cytocan saturated his lab coat and streamed down his leg. Because WW Oncology had no shower facilities, he had to wait until he got home after work to take a shower.

Lori Lindley had a similar experience when a bag of Taxol spilled on her because a plug fell out of it. As she described it, she was soaked. Her hair was wet; the whole back of her shirt was saturated.²²

A. (Lindley) The plug - the line that - the plug that goes in the bag fell out. And I was right there at the patient and I just wore it. I mean, it douched me. My hair was wet. My clothes were wet.

...

A. The whole back of my shirt was saturated. And I freaked out.²³

She could not shower and change until she got home, about two hours later.

Another incident took place in September 2005, 11 months before the WISHA inspection. A 500cc bag of Oxaliplatin splashed on Leah Guilford-Elenes's shoulder, pants and shoes, penetrating to her skin.²⁴ Again, there was no place in the clinic to shower and change.²⁵

²¹ CABR, Tr., 11/14/07, Hilkemeier at 171-172.

²² CABR, Tr., 11/14/07, Lindley at 143-144.

²³ CABR, Tr., 11/14/07, Lindley at 143-145.

²⁴ CABR, Tr., 11/14/07, Guilford-Elenes at 93-94.

A. (Guilford-Elenes) A patient was standing up with their hand on the IV pull and inadvertently had the tubing in his hand. He went to stand up and popped the line out of the bag of chemotherapy. And I was coming over to help him at that time, and the bag came undone from the tubing, so an open hole hanging upside down splashed on me.²⁶

The bag of chemotherapy was Oxaliplatin, and it reached her skin. She put a sheet in her car and drove home to shower and change.

The toxic effects of chemotherapy drugs can be cumulative,²⁷ thus admixture technicians who mix the undiluted drugs for up to eight hours a day,²⁸ and nurses who often administer the drugs to cancer patients up to nine and one-half hours a day,²⁹ are exposed to the cumulative effect of small exposures.

Other testimony from nurses confirms the hazardous nature of the cytotoxic drugs with which they routinely worked.³⁰ For example, Robert Hilkemeier learned when studying to become a certified oncology nurse that exposure to the drugs he mixed and administered “could cause secondary malignancies and a lot of potential unknown and unforeseeable medical issues, heart problems, liver problems, bladder problems.”³¹

²⁵ CABR, Tr., 11/14/07, Guilford-Elenes at 93-94.

²⁶ CABR, Tr., 11/14/07, Guilford-Elenes at 93-94.

²⁷ CABR, Tr., 11/14/07, Hilkemeier at 168.

²⁸ CABR, Tr., 11/14/07, Batchelor-Hancock at 128.

²⁹ CABR, Tr., 12/3/07, Justus at 31; Tr., 12/3/07, Ishler at 51.

³⁰ One nurse, Shanna Ishler, stopped working with chemotherapy altogether because she wanted to have children. “I stopped chemo because I wanted to do something different and because I am trying to have children and a lot of textbooks and whatnot they don’t recommend that you hang chemo at all even in a hospital setting if you are trying to have children.” CABR, Tr. 12/3/07, Ishler at 52.

³¹ CABR, Tr., 11/14/07, Hilkemeier at 177.

Adriamycin, a primary drug for breast cancer and lymphomas, was used frequently at the WW Oncology clinics.³² Adriamycin was also one of the more dangerous drugs. Lori Lindley was always nervous when she used Adriamycin. “Adriamycin was the one that scared me the most That was sort of a red flag for me. And I was extremely careful with that one.”³³

C. WW Oncology Did Not Require Its Staff To Wear Protective Gowns; Workers Wore Whatever They Pleased Most Of The Time

Despite the risk that a malfunctioning IV line or syringe could bring cytotoxic drugs into contact with an employee’s skin, WW Oncology did not require that nurses or admixture technicians wear protective gowns with polyethylene or vinyl coatings when mixing the undiluted drugs or administering chemotherapy.³⁴ At the time of the WISHA inspection (August 2006), nurses in all three clinics were *administering* chemotherapy wearing only cotton scrubs, a white cotton lab coat, or, rarely, the yellow Graham gown 242 which is not impervious to liquid.³⁵ When *mixing* cytotoxic drugs, only the nurses or technicians in the Aberdeen clinic wore splash-resistant gowns (blue in color) and they did so, not because the employer required it, but because one of the nurses had been taught to wear such a gown when she mixed chemotherapy at

³² CABR, Tr., 11/14/07, Lindley at 160-161.

³³ CABR, Tr., 11/14/07, Lindley at 162.

³⁴ CABR, Tr., 11/14/07, Guilford-Elenes at 94; Tr., 11/14/07, Hilke-meier at 175.

³⁵ Samples of the white cotton lab coat (Ex. 3), the yellow Graham gown 242 (Ex. 15), and the blue splash-resistant gown (Ex. 2) were entered into evidence.

Providence St. Peter Hospital.³⁶ Nurses and technicians in the Centralia and Lacey clinics wore either the inadequate yellow Graham 242 gown, or a white cotton lab coat when *mixing* cytotoxic drugs.

In fact, WW Oncology did not *require* the use of gowns as personal protective equipment at all.³⁷ Although two of the nurses testified that Carol Hulse, a former head nurse, suggested that they “protect their arms” by wearing a white lab coat³⁸ or the yellow Graham Medical gown 242 when mixing chemotherapy, it was a suggestion, not a mandatory directive, and neither the cotton lab coat nor the yellow gown was impervious to liquid spills.

No one in authority at WW Oncology disciplined nurses or technicians who wore only cotton scrubs or lab coats when working with chemotherapy. Leah Guilford-Elenes, who had been working at WW Oncology for eight years, testified that management had never required nurses to wear protective gowns when administering chemotherapy.³⁹ Shanna Isler’s testimony was similar: as far as she knew, supervisors at WW Oncology had never insisted that nurses wear protective gowns when administering chemotherapy.⁴⁰ When Christine Batchelor-Hancock was asked if she had ever heard any supervisor from WW Oncology require nurses administering

³⁶ CABR, Tr., 11/14/07, Batchelor-Hancock at 129.

³⁷ CABR, Tr., 11/14/07, Guilford-Elenes at 90, 92; Tr., 11/14/07, Batchelor-Hancock at 131; Tr., 11/14/07, Lindley at 141; Tr., 12/3/07, Isler at 52.

³⁸ CABR, Tr. 11/14/07, Hilkemeier at 173-174.

³⁹ CABR, Tr., 11/14/07, Guilford-Elenes at 90, 93.

⁴⁰ CABR, Tr., 12/3/07, Isler at 52.

chemotherapy to wear an impervious gown, she answered, “no.”⁴¹ As a result, nurses and technicians wore whatever they pleased, even when they were handling the most dangerous chemotherapy drugs.

D. Cytotoxic Drugs Can Have Adverse Effects On The Surface Of The Skin, And Serious Systemic Effects When Absorbed By The Skin

Margaret Cunningham, a registered nurse, Certified Industrial Hygienist, and the Department’s expert witness, testified that:

Antineoplastic drugs are toxic and have adverse effects when absorbed by the skin. The purpose of chemotherapy drugs is to kill cells. That’s the entire purpose. That’s the reason it is given to cancer patients with tumors, to kill the cells.⁴²

...

The effects of chemotherapy coming in contact with the outside of the skin can cause irritation, cause rash, cause itching, can cause damage to the skin. Those chemotherapy drugs that are either absorbed through the skin, inhaled via vapor, or because they’re on hands and get into the mouth, in other words, get inside the body in some way, cause systemic effects. Those identified in the literature include leukemia, birth defects, premature miscarriage, and are considered to be very serious hazards.⁴³

In forming her opinion, Ms. Cunningham relied, *inter alia*, upon research done by numerous authorities, including the September 2004 alert on the hazards of handling antineoplastic drugs published by the NIOSH, a

⁴¹ CABR, Tr., 11/14/07, Batchelor-Hancock at 132.

⁴² CABR, Tr., 11/14/07, Cunningham at 41.

⁴³ CABR, Tr., 11/14/07, Cunningham at 44-45.

branch of the Centers for Disease Control;⁴⁴ the *Occupational Safety and Health Act (OSHA) Technical Manual*, which gives guidance on the interpretation of OSHA codes; guidelines published by the Oncology Nursing Society, a professional organization dedicated to the science of nursing care for cancer patients; the *Journal of Oncology Pharmacy Practice*; the *American Society for Health System Pharmacists Guidelines on Handling Hazardous Drugs*; and the chemical manufacturers' Material Safety Data Sheets for many of the chemicals used by WW Oncology.⁴⁵

These authorities uniformly recommend the use of a disposable gown that would provide an adequate barrier between the nurse or technician and the antineoplastic drugs they were working with.⁴⁶ The only gowns recommended by these authorities are gowns with polyethylene or vinyl coatings which prevented penetration of the antineoplastic agents.⁴⁷ For example, the document from the Oncology Nursing Society reads:

Gowns that provide adequate protection from hazardous drugs are disposable, made of a lint-free, low-permeability fabric. They should have a solid front (back closure) and knit or elastic cuffs. Laboratory coats and other cloth fabrics absorb fluids, so they provide an inadequate barrier to hazardous drugs and are not recommended.

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⁴⁴CABR, Tr., 11/14/07, Cunningham at 46. As noted above, WW Oncology received a copy of this report shortly after it was published.

⁴⁵ CABR, Tr., 11/14/07, Cunningham at 45-63.

⁴⁶ CABR, Tr., 11/14/07, Cunningham at 58.

⁴⁷ CABR, Tr., 11/14/07, Cunningham at 59.

In a study of gowns, the permeability of six commercially available protective gowns was evaluated by splash testing them with 15 antineoplastic agents. Gowns with polyethylene or vinyl coatings provided adequate splash protection and prevented penetration of the antineoplastic agents.

...

Gowns always should be worn during chemotherapy preparation and while administering intravenous (IV) chemotherapy. Gowns also should be used during the administration of hazardous drugs by any other route, especially if splashing is possible. This represents a change in practice for many nurses but is necessary to provide adequate protection against exposure to hazardous drugs.⁴⁸

Similarly, the manufacturers' Material Safety Data Sheet (MSDS) for Taxol, one of the chemotherapy drugs, states: "Wear protective lab coat. If the potential exists for significant dermal contact, wear impervious disposable coveralls with closed front, long sleeves and elastic cuffs and boots to protect from dust, splashes or sprays."⁴⁹ The MSDS sheet for Carboplatin, another of the chemotherapy drugs, under the heading "special clothing", reads, "Wear *impervious* disposable coveralls with closed front, long sleeves and elastic cuffs" (emphasis added).⁵⁰

⁴⁸ CABR, Tr., 11/14/07, Cunningham at 113, 120.

⁴⁹ CABR, Tr., 11/14/07, Cunningham at 60.

⁵⁰ CABR, Tr., 11/14/07, Cunningham at 61; Ex. 4.

E. Within A Month After The NIOSH Alert Was Published, WW Oncology Received A Copy

In 2004, Carol Hulse, the Nurse Manager for WW Oncology, learned of the NIOSH Alert when she attended a NIOSH conference in San Antonio, Texas.

Q. And after you read the NIOSH Alert, did you talk to your immediate supervisor, Melody Edgington, about it?

A. (Hulse) Yes, I did.

Q. And what date was that, do you know?

A. Just shortly after I came back from it, so in October.

Q. In the fall of 2004?

A. Mn-hmm. Yes.

Q. Okay. Did you actually give her a copy of the NIOSH Alert?

A. Yes, I did.⁵¹

Even before the NIOSH alert was published, WW Oncology knew that its laboratory pharmacy technicians needed to wear an impervious gown when mixing hazardous chemicals. In its Chemical Hygiene Plan dated 2003, WW Oncology required laboratory employees to wear an impermeable apron “in areas where chemical splashes are common.”⁵² Margaret Cunningham testified that because mixing chemicals in the laboratory is so similar to mixing antineoplastic drugs in the clinics, WW Oncology should have extended the requirement to wear impermeable gowns contained in its Chemical Hygiene Plan to *all*

⁵¹ CABR, Hulse Dep., 9/27/07 at 20.

⁵² CABR, Tr., 12/3/07, Cunningham at 10; Ex. 5. Dr. Gordon, one of the owners of WW Oncology, argued that the Chemical Hygiene Plan was adopted because laboratory technicians are exposed to biological hazards from contaminated blood and urine. CABR, Tr. 12/3/07, Dr. Gordon at 66. However, the Chemical Hygiene Plan requires an impermeable apron only for areas where “chemical splashes are common,” not for exposure to blood-borne pathogens.

employees exposed to hazardous chemicals – including those administering the toxic chemotherapy treatments that were WW Oncology’s business.⁵³

By 2006, some nurses began hearing through secondary sources, such as the Oncology Nursing Society or through WISHA training, that impervious gowns should be worn while mixing or administering chemotherapy. After Leah Guilford-Elenes and a co-worker attended a safe handling class through the Oncology Nursing Society, they both started wearing the splash-resistant blue gown when administering chemotherapy in the Aberdeen clinic, but, at that time, they were the only nurses wearing them; others still wore only the permeable white lab coat.⁵⁴

F. At The Hearing, The Department Demonstrated That Liquid Immediately Penetrated The Yellow Graham Gown 242 Worn by Some of WW Oncology’s Nurses

The yellow Graham Medical gown 242 which was worn by the nurses in the Centralia clinic when mixing chemotherapy is not adequate protection against liquids.⁵⁵ Margaret Cunningham, the Department’s expert, demonstrated this by testing the yellow gown during the hearing. She held a dropper of saline solution about eight inches from the surface of the yellow gown and let several drops fall on the material. The saline solution penetrated the material immediately, leaving drops on the scrub underneath.⁵⁶ The demonstration and a similar demonstration done with

⁵³ CABR, Tr., 12/3/07, Cunningham at 22-23.

⁵⁴ CABR, Tr., 11/14/07, Guilford-Elenes at 91-92.

⁵⁵ CABR, Tr., 11/14/07, Cunningham at 75.

⁵⁶ CABR, Tr., 11/14/07, Cunningham at 78-80.

Dr. Gordon, one of the owners of WW Oncology present, refuted Dr. Gordon's claim that when he tested the yellow gown, water bounced off.⁵⁷

G. The WISHA Citation

The Department cited WW Oncology for three serious safety violations of the Washington Administrative Code (WAC). The Department later vacated Violations 1-1 and 1-2, and amended Violation 1-3. As amended, the remaining violation read:

Violation 1, Item 3 --- Type of Violation: Serious
Washington Administrative Code (WAC) violated:
296-800-16040.

The employer did not enforce the use of necessary personal protective equipment (PPE), in that Western Washington Oncology did not ensure that employees mixing or working with chemotherapy complied with safety rules and WISHA regulations by wearing a gown that adequately protected them against liquid aerosols and splashes. Employees in some clinics wore Gown 242 by Graham Medical, which is inadequate protection for contact with liquid chemicals such as chemotherapy.

H. Board Review Of The Citation

WW Oncology appealed the WISHA citation to the Board. After the hearing, the Board's Industrial Appeals Judge (IAJ) issued a Proposed Decision and Order.⁵⁸ In the proposed order, the IAJ found that:

Exposure to antineoplastic drugs (chemotherapy) can be toxic and terminal to healthy cells as well as cancer cells.

⁵⁷ CABR, Tr. 12/3/07, Gordon at 72.

⁵⁸ CABR at 41-52 (Proposed Decision and Order).

Accordingly, exposure outside the skin can cause irritation, rash, itching, and damage to the skin. Absorption through the skin and/or inhalation can cause systemic effects such as leukemia, birth defects, and premature miscarriage.⁵⁹

The IAJ also determined that medical standards had evolved since 2002, and that the blue impermeable gown was now essential PPE for workers exposed to chemotherapy.

However, it is the responsibility of WWO to remain cognizant of changes in medical practices and by the date of Ms. Cunningham's inspection, the blue impermeable gowns were known to provide more complete protection during exposure to chemotherapy.

Although the yellow low-permeable gowns may have satisfied the prior medical standard, WWO failed to modify its accident prevention program to upgrade PPE. The regulations require nothing less than this constant vigilance and mandate hazard assessment. Such reviews are continual in their nature; five year intervals are simply not adequate, particularly for occupations related to the daily contact with chemotherapy.⁶⁰

The IAJ concluded that WW Oncology had failed to ensure the wearing of adequate protective clothing:

As of August 24, 2006, WWO failed to comply with the requirements of WAC 296-800-16040 and did not require employees to wear gowns that adequately protected them from antineoplastic drugs during the course of mixing and/or administering chemotherapy to cancer patients.⁶¹

⁵⁹ CABR at 51 (Proposed Decision and Order, Finding of Fact No. 3). A copy of the Proposed Decision and Order is attached hereto as Appendix A.

⁶⁰ CABR at 49 (Proposed Decision and Order).

⁶¹ CABR at 51 (Proposed Decision and Order, Finding of Fact No. 6).

Consequently, the IAJ affirmed the serious violation of WAC 296-800-16040 with which WW Oncology had been cited. WW Oncology filed a Petition for Review with the Board.⁶² The Board denied review, making the Proposed Decision and Order the final Decision and Order of the Board.⁶³

I. Superior Court Review Of The Board's Decision

WW Oncology then sought judicial review in the Superior Court of Thurston County. The Superior Court affirmed the Board's decision.⁶⁴ This appeal followed.

IV. ARGUMENT

A. Standard Of Review

Judicial review of the Board's decision is governed by RCW 49.17.150. Under this standard, the Board's Findings of Fact must be affirmed if they are supported by substantial evidence. "The findings of the board or [its Industrial Appeals Judge] where the board has denied a petition or petitions for review with respect to questions of fact, *if supported by substantial evidence on the record considered as a whole, shall be conclusive.*" RCW 49.17.150(1) (emphasis added).

Substantial evidence is evidence in sufficient quantum to persuade a fair-minded person that a finding is true. *Martinez Melgoza v. Dep't of Labor & Indus.*, 125 Wn. App. 843, 847, 848, 106 P.3d 776 (2005), review

⁶² CABR at 3-19 (Employer's Petition for Review).

⁶³ CABR at 1 (Order Denying Petition for Review)

⁶⁴ Clerk's Papers, Sub No. 20, Order Affirming Decision, dated 1/16/09.

denied, 155 Wn.2d 1015, 124 P.3d 304 (2005). In determining whether substantial evidence exists, the Court must take the “record in the light most favorable to the party who prevailed [before the fact-finding tribunal],” and must not “rebalance the competing [evidence] and inferences.” *Harrison Memorial Hosp. v. Gagnon*, 110 Wn. App. 475, 485, 40 P.3d 1221 (2002).

The Board’s conclusions are reviewed in the context of its Findings of Fact. More specifically, the conclusions must be affirmed if they are supported by the findings. *See Inland Foundry Co. Inc. v. Dep’t of Labor & Indus.*, 106 Wn. App. 333, 336, 24 P.3d 424 (2001); *Washington Cedar & Supply Co, Inc. v. Dep’t of Labor & Indus.*, 119 Wn. App. 906, 911, 83 P.3d 1012 (2003); *Dep’t of Labor & Indus. v. Kaiser Aluminum & Chemical Corp.*, 111 Wn. App. 771, 773, 48 P.3d 324 (2002).

Legal issues, including whether expert testimony meets the *Frye* standard, are reviewed de novo. *Washington Cedar & Supply Co., Inc.*, 119 Wn. App. at 912. The Board’s ruling under ER 702 is reviewed for abuse of discretion. *State v. Cheatam*, 150 Wn.2d 626, 645, 81 P.3d 830 (2003).

B. WISHA Must Be Liberally Construed To Protect Workers And Department Interpretations Of Its Safety Regulations Are Entitled To Deference

The purpose of WISHA is to provide safe and healthful working conditions for every man and woman working in the state of Washington.

RCW 49.17.010. The Act must be liberally construed to carry out this purpose. *Inland Foundry Co., Inc.*, 106 Wn. App. at 333. Any safety standard adopted under Chapter 49.17, RCW is interpreted to further this purpose. *Stute v. P.B.M.C.*, 114 Wn.2d 454, 464, 788 P.2d 545 (1990).

Washington courts give deference to an agency's interpretation of its own properly promulgated regulations, "absent a compelling indication" that the agency's regulatory interpretation conflicts with legislative intent or is in excess of the agency's authority. *Silverstreak, Inc. v. Dep't of Labor & Indus.*, 159 Wn.2d 868, 884, 154 P.3d 891 (2007) (citations omitted). Substantial deference is granted by the Washington courts to the Department's interpretation of WISHA and the regulations promulgated under it. *Lee Cook Trucking & Logging v. Dep't of Labor & Indus.*, 109 Wn. App. 471, 477, 36 P.3d 558 (2001). Thus the Department's interpretation of WISHA and the Department's regulations are of considerable importance in construing them.

When applying a WISHA standard which has a federal counterpart under the Occupational Safety and Health Act (OSHA), Washington courts will consider decisions of the Occupational Safety and Health Review Commission (OSHRC) and the federal courts construing the parallel federal regulation. *Adkins v. Aluminum Company of America*, 110 Wn.2d 128, 147, 750 P.2d 1257 (1988).

C. Under The WISHA Core Rules, Employers Must Require Employees To Use Personal Protective Equipment That Is Adequate To Protect Them From Workplace Hazards

1. The Personal Protective Equipment Rules Are Mandatory

Under the WISHA Core Personal Protective Equipment Rules, employers must identify potential hazards in the workplace, WAC 296-800-16010; select appropriate personal protective equipment (PPE) to protect employees from the hazards, WAC 296-800-16015; train the employees to use the personal protective equipment, WAC 296-800-16025; and require the employees to use necessary personal protective equipment on the job, WAC 296-800-16040.⁶⁵ A hazard is defined in the Core Rules as “any condition, potential or inherent, which can cause injury, death, or occupational disease.” WAC 296-800-370.

To assist employers in selecting appropriate personal protective equipment, WAC 296-800-16015 lists other regulations which have information about personal protective equipment for specific workplaces. The standard references, for example, construction work in Chapter 296-155 WAC, electrical work in Chapter 296-45 WAC, and logging operations in Chapter 296-54 WAC. A note at the end of WAC 296-800-16015 provides further guidance, directing employers to additional resources – an OSHA website (now <http://www.osha.go/SLTC/personalprotectiveequipment.html>), an

⁶⁵ A copy of the WISHA Core Personal Protective Rules is attached to this brief as Appendix B.

800 telephone number, and links to safety and health professional organizations , which are included with the 296-800 WACs (the Core Rules) when they are mailed to employers. The resource links are also found at the Department's website, <http://www.lni.wa.gov>. A copy of the link for contacting NIOSH is attached to this brief as Appendix C.

In addition, WISHA adopts nationally-recognized standards by reference, and requires employers to consult such standards. In the Core Rules, WAC 296-800-360 directs employers to use the safety and health standards from national organizations and federal agencies when directed to by WISHA rules.

2. The Personal Protective Equipment That An Employer Must Provide is Determined Based On What A Reasonable Person In The Affected Industry Would Understand To Be Required

OSHA's personal protective equipment regulations, 29 CFR 1910.132(a) and 1910.132(d)(1)(i), are similar to WISHA's regulations. When determining whether an employer has violated the personal protective equipment regulations, OSHRC examines whether a reasonable person familiar with the industry and the factual circumstances surrounding the allegedly hazardous condition would recognize a hazard warranting the use of personal protective equipment. *E.g., Siemens Energy & Automation, Inc.*, 20 OSHC 2196, 2005 OSHD ¶ 32,880 (2005); *S&H Riggers & Erectors, Inc.*, 7 OSHC 1260, 1979 OSHD ¶ 23,480

(1979), *reversed*, 659 F.2d 1273 (5th Cir. 1981)⁶⁶; *see generally* Mark A. Rothstein, *Occupational Safety and Health Law* (Rothstein), 2009 Edition, § 5.4 (citing cases). The “reasonable person familiar with the industry” standard has been adopted in all but one of the circuits which have considered it. *Id.*

For example, in *Advance Bronze, Inc. v. Dole*, 917 F.2d 944 (6th Cir. 1990), Advance Bronze failed to provide aprons and leggings to employees working with molten metal. The Sixth Circuit held that reasonably prudent employers in the foundry industry would recognize the hazard of molten metal splashes and protect against it by providing aprons and leggings to employees. *See also, e.g., Cape Vineyard Div. v. OSHRC*, 512 F.2d 1148, 1152 (1st Cir. 1975); *American Airlines, Inc. v. Sec’y of Labor*, 578 F.2d 38, 41 (2nd Cir. 1978); *Voegele Company, Inc. v. OSHRC*, 625 F.2d 1075, 1078-1079 (3rd Cir. 1980) (applying reasonable person test to personal protective equipment standard for construction industry); *McLean Trucking Co. v. OSHRC*, 503 F.2d 8, 10-11 (4th Cir. 1974); *Faultless Div., Bliss & Laughlin Indus. v. Sec’y of Labor*, 674 F.2d 1177, 1186-1188 (7th Cir. 1982) (machine guarding standard); *Arkansas-Best Freight System, Inc. v. OSHRC*, 529 F.2d 649, 654-655 (8th Cir. 1976); *Brennan v. Smoke-Craft, Inc.*, 530 F.2d 843, 845-846 (9th Cir. 1976);

⁶⁶ *S&H Riggers* remains the seminal OSHRC case on the “reasonable person” test despite having been reversed on appeal. As set out below, the Fifth Circuit is the only court to have considered this question and not accepted the OSHRC standard; the other circuit courts to have considered the question have explicitly rejected the Fifth Circuit’s interpretation in *S&H Riggers*. *See, e.g., Dep’t of Labor v. OSHRC*, 938 F.2d 1116, 1119 n.4 (10th Cir. 1991).

Dep't of Labor v. OSHRC, 938 F.2d 1116, 1119 (10th Cir. 1991) (eye protection standard); *Century Steel Erectors, Inc. v. Dole*, 888 F.2d 1399, 1404 (D.C. Cir. 1989) (construction industry standard).

The overwhelming majority of authority establishes that the test for a violation of the personal protective equipment standard is whether a reasonable person familiar with the industry would have recognized the hazard and protected against it. The “industry” of chemotherapy exists to treat cancer, *i.e.*, to mix and administer drugs that kill cells. Any person in this industry, reasonable or not, would recognize that these drugs are hazardous and that employees working with them need adequate protection.

As noted, the only circuit to have rejected the “reasonable person” standard is the Fifth. *See B & B Insulation, Inc. v. OSHRC*, 583 F.2d 1364 (5th Cir. 1978) (applying “industry standard” test).⁶⁷ Even the Fifth Circuit, however, will find a violation of the general PPE standard if the cited employer, like WW Oncology here, has *actual* knowledge of both the hazardous condition *and* the necessary personal protective equipment. *Owens-Corning Fiberglass Corp. v. Donovan*, 659 F.2d 1285 (5th Cir. 1981); Rothstein at § 5.4.

Here, WW Oncology *knew* that antineoplastic drugs are hazardous. They required the nurses and technicians mixing the undiluted drugs to use gloves, and biosafety cabinets. After 2004, WW Oncology’s CEO

⁶⁷ No other Circuit has accepted the Fifth Circuit’s reasoning, and the OSHRC has rejected it for decades. *See* Rothstein at § 5.4 nn. 11-14.

knew that the NIOSH Alert recommended impervious gowns for workers mixing or administering chemotherapy. Moreover, WW Oncology was familiar with and had used other professional resources to which they could turn for information on appropriate personal protective equipment. They used the OSHA Technical Manual when they wrote their chemical hygiene plan for laboratory workers.⁶⁸ Their nurses regularly attended classes put on by the Oncology Nursing Society.⁶⁹

3. The National Institute of Occupational Safety And Health (NIOSH), The OSHA Technical Manual, And the Publications of the Oncology Nursing Society Are Preeminent Nationally Recognized Authorities

The publications of three nationally-recognized organizations – NIOSH, OSHA, the Oncology Nursing Society, that were repeatedly referenced during the hearing, are essential resources on the hazards of antineoplastic drugs and the types of personal protective equipment best suited to protect workers from the hazards of these toxins. The first two are familiar to all health and safety professionals and the third is familiar to all health professionals in the field of Oncology. All three are easily accessed and WW Oncology itself was familiar with all three.

The Occupational Safety and Health Act of 1970 created both the National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA). Under OSHA, NIOSH, is authorized to “develop recommendations for health and safety

⁶⁸ CABR, Section 1, purpose, in Ex. 5.

⁶⁹ CABR, Tr. 11/14/07, Guilford-Elenes at 22-23.

standards”, to “develop information on safe levels of exposure to toxic materials and harmful physical agents and substances” and “to conduct research on new safety and health problems.” 29 U.S.C. § 671 (Section 22, Occupational Safety and Health Act of 1970).

NIOSH is the national and world leader in conducting scientific research to prevent work-related illness, injury, disability and death. Its Board of Scientific Counselors is composed of renowned scientists from a variety of fields related to occupational safety and health. <http://www.cdc.gov/niosh/about.html>. Both Industrial Hygienists, who testified at the hearing, recognized that NIOSH is *the* national consensus authority for workplace safety and health.⁷⁰ The NIOSH Alert, which WW Oncology received in 2004, describes the latest research into the toxicity of antineoplastic drugs and recommends that nurses handling such drugs wear an impermeable gown. Ex. 13.

The OSHA Technical Manual, used as a primary reference by federal and state safety and health compliance officers and other safety professionals, contains a comprehensive and authoritative section on exposure to hazardous drugs, including antineoplastic drugs. It can be accessed at http://www.osha.gov/dts/osta/otm/otm_vi_2.html. The manual summarizes the latest research on the hazards of cytotoxic drugs, describes the effects of occupational exposure to such toxins, and recommends specific engineering controls and PPE to protect workers. The manual

⁷⁰ CABR, Tr., 12/3/07, Anderson at 118; Tr., 11/14/07, Cunningham at 45-46.

also references research papers on the subject, and contains a list of drugs which are considered hazardous. See Ex. 17. Both Margaret Cunningham and Anne Anderson, the Department's expert and the employer's expert respectively, testified that Industrial Hygienists rely on the OSHA Technical Manual in their work.⁷¹

As with the 2004 NIOSH Alert, WW Oncology had actual knowledge of the OSHA Technical Manual. In fact, WW Oncology wrote its Chemical Hygiene Plan, which required an impervious apron in areas where chemical splashed are common, specifically to comply with OSHA guidelines. See Section 1, purpose, in Ex. 5.

The third resource, the Oncology Nursing Society, is even more specialized. <http://www.ons.org/about.index.shtml>. As a professional organization of over 37,000 dedicated to excellence in patient care, education, research and administration, its publications are familiar to anyone in Oncology nursing. Anne Anderson, the employer's Industrial Hygienist, used references to Oncology Nursing Society publications in her testimony.⁷² Nurses at WW Oncology attended classes presented by the Oncology Nursing Society, such as the safe handling class that Leah Guilford-Elenes and a co-worker attended where they learned to wear the impervious blue gown.⁷³

⁷¹ CABR, Tr., 11/14/07, Cunningham at 63; Tr., 12/03/07; Anderson at 125.

⁷² CABR, Tr., 12/3/07, Anderson at 121.

⁷³ CABR, Tr., 11/14/07, Guilford-Elenes at 22-23.

D. Substantial Evidence Supports The Board's Finding That Antineoplastic Drugs Can Cause Adverse Effects When Spilled On The Skin, And Serious Systemic Effects When Absorbed Through The Skin

The Board found that:

Exposure to antineoplastic drugs (chemotherapy) can be toxic and terminal to healthy cells as well as cancer cells. Accordingly, exposure outside the skin can cause irritation, rash, itching, and damage to the skin. Absorption through the skin and/or inhalation can cause systemic effects such as leukemia, birth defects, and premature miscarriage.⁷⁴

Substantial evidence supports this finding.

A "hazard" is identified in the Core Rules as "any condition, potential or inherent, which can cause injury, death or occupational disease." WAC 296-800-370. The omnipresent hazard in the WW Oncology clinics is the presence of potent and toxic antineoplastic and cytotoxic drugs, and the potential and reality of these drugs being splattered, spilled and sprayed on the technicians and nurses whose job is to prepare and administer them. As Margaret Cunningham testified, the hazards of chemotherapy drugs are well documented. The drugs are toxic to human cells. They are administered to cancer patients because they kill cancer cells. In the process, they also kill healthy cells,⁷⁵ leading to the well-known side effects of chemotherapy, such as nausea, and hair loss.

⁷⁴ CABR at 51 (Proposed Decision and Order, Finding of Fact No. 3).

⁷⁵ CABR, Tr., 12/3/07, Gordon at 68.

This is common knowledge that WW Oncology cannot and does not dispute.⁷⁶

Research on the hazards of exposure to antineoplastic drugs has accelerated in the past 10 years. In 2003, NIOSH began a study on the effects of antineoplastic drugs on healthcare workers. The proposal is discussed in the Federal Register, 68 FR 32056-01, 2003 WL 212225463 (F.R.)⁷⁷

These drugs possess mutagenic, teratogenic, and carcinogenic properties, cause organ damage, and affect reproductive function. Healthcare workers such as pharmacists and nurses who handle, prepare, and administer these drugs are at increased risk of adverse health effects from these agents, if exposed Since air concentrations of antineoplastic drugs in many of the studies have been low to non-detectable, it appears that the dermal route may be an important consideration for internal absorption.

Numerous studies, including those after the OSHA guidelines were revised in 1995, have demonstrated adverse health effects from healthcare workers' exposure to antineoplastic agents. The most common endpoints have been either markers of exposure, such as metabolites in the urine, or genotoxic markers, such as micronuclei, sister chromatid exchange, and chromosomal aberrations. Female reproductive adverse effects have also been shown to occur with healthcare workers' exposure to

⁷⁶ WW Oncology does question the damage that antineoplastic drugs can cause to its employees' skin, emphasizing that such drugs "are even used to cure skin cancer and are *applied directly to the skin* of patients undergoing treatment." Appellant's Opening Brief at 24 (emphasis in original). The obvious purpose of this treatment is to kill cancerous skin cells, a destructive process that, equally obviously, is damaging to healthy cells.

⁷⁷ Pursuant to 44 U.S.C. § 1507, "[t]he contents of the Federal Register shall be judicially noticed and without prejudice to any other mode of citation, may be cited by volume and page number."

antineoplastic drugs. Not only have spontaneous abortion and miscarriage been reported, but changes in the menstrual cycle have been demonstrated as well. . . . One study estimated that exposure to cyclophosphamide by healthcare workers increases the risk of leukemia cases by 17-100 new cases/million workers/10 years.

The resulting study was published in the 2004 NIOSH Alert, Ex. 13, parts of which were read into the record by both Margaret Cunningham and Anne Anderson. The NIOSH Alert, which WW Oncology received shortly after its publication, discusses the evidence for adverse health effects of antineoplastic drugs in workers, and includes specific case reports. Among the adverse effects discussed are mutagenicity (increased genotoxic effects), developmental and reproductive effects (fetal loss, congenital malformations and low birth weight), and cancer (an increased risk of leukemia). Ex. 13, at 5-10.

In strongly worded recommendations, the NIOSH Alert instructed health care workers and employers to use disposable gowns made of polyethylene-coated polypropylene for all activities associated with antineoplastic drug administration – opening the outer bag, assembling the delivery system, delivering the drug to the patient and disposing of all equipment used to administer drugs. Ex. 13, at 13-14.

Anne Anderson, an Industrial Hygienist and WW Oncology's own expert witness, agreed that industrial hygienists customarily rely on scientific information from NIOSH, the OSHA Technical Manual, and the Material Safety Data Sheets (MSDS) that state and federal law require.⁷⁸

⁷⁸ CABR, Tr., 12/3/2007, Anderson, at 118.

She agreed that employers are required to keep copies of MSDS for the drugs their employees use, required to train their employees on the information in the MSDS, and required to evaluate their workplaces to determine the extent of employee exposure to the drugs.⁷⁹ Consistent with the overwhelming evidence from other sources, Ms. Anderson also agreed that antineoplastic drugs are hazardous, and she recognized that they are carcinogens.⁸⁰

In contrast, Dr. Gordon admitted that he knew nothing about industrial hygiene, he had not read the NIOSH Alert on chemotherapy, he had not read the OSHA Technical Guidelines, and he had not read the MSDS for the drugs he administered at the WW Oncology clinics.⁸¹ He did not even know what an MSDS was.⁸²

Despite Dr. Gordon's ignorance, WW Oncology relies on Dr. Gordon's "opinion" that nurses in the clinics working with chemotherapy drugs were not exposed to a risk. This reliance is particularly surprising given that Dr. Gordon could not cite a *single* scientific or medical source to support his opinion.⁸³ He admitted that he had not read any studies on the hazards of skin exposure to antineoplastic

⁷⁹ CABR, Tr., 12/3/2007, Anderson, at 126, 127. As noted supra 15-16, the MSDSs for the drugs that WW Oncology used directed those working with them to wear protective equipment that would prevent contact with the skin.

⁸⁰ CABR, Tr., 12/3/2007, Anderson at 127.

⁸¹ CABR, Tr., 12/3/2007, Gordon at 68, 70.

⁸² CABR, Tr., 12/3/2007, Gordon at 70. This is a surprising admission from an owner of the WW Oncology clinics, since employers are required under WAC 296-800-17015 to obtain and maintain material safety data sheets (MSDS) for each hazardous chemical used, train employees on the hazards of the chemicals, and preserve the MSDS as exposure records for 30 years. WAC 296-800-18005.

⁸³ CABR, Tr., 12/3/2007, Gordon at 77-78.

drugs, and that his information came entirely from meetings of the American Society of Clinical Oncology which he attended once a year.⁸⁴

Dr. Gordon's uninformed opinion is the *only* evidence in this record that suggests that the chemotherapy drugs to which his employees were exposed were not hazardous. Given the testimony of both expert witnesses as well as the unanimous literature establishing the dangers of working with cytotoxic and antineoplastic drugs, the Board's finding that such drugs created workplace hazards is amply supported by the record.

E. Substantial Evidence Supports The Board's Determination That At Least Since 2004, Splash-Resistant Gowns With Polyethylene Or Vinyl Coatings Have Been Considered Essential Personal Protective Equipment For Nurses And Technicians Handling Antineoplastic Drugs

The 2004 NIOSH Alert changed the practice of Oncology nursing. When the NIOSH Alert was published, professional associations, such as the Oncology Nursing Society adopted new personal protective equipment guidelines, including guidelines on protective gowns for healthcare workers, to meet the growing awareness of the hazards of exposure to antineoplastic drugs.⁸⁵ This change can most clearly be seen by comparing the recommendations of the Oncology Nursing Society before and after September 2004.⁸⁶ After the NIOSH Alert, the Oncology

⁸⁴ CABR, Tr., 12/3/2007, Gordon at 79.

⁸⁵ The PPE recommendations from the Oncology Nursing Society (page 4) were accepted into evidence at the hearing as CABR, Exhibit 16.

⁸⁶ Both Dr. Gordon and WW Oncology's expert, Anne Anderson, referred to publications of the Oncology Nursing Society published *before* the 2004 NIOSH Alert. CABR, Tr., 12/3/07, Gordon at 62; CABR, Tr., Anderson at 113. CABR, Exhibit 16, at 4, the excerpt from the Oncology Nursing Society publication, is dated 2006, *after* the NIOSH Alert.

Nursing Society and other such professional organizations recommended that “Gowns always should be worn during chemotherapy preparation and when administering intravenous (IV) chemotherapy.”⁸⁷ Specifically, the Oncology Nursing Society recommended “Gowns with polyethylene or vinyl coatings [that] provide adequate splash protection and prevent penetration of antineoplastic agents.”⁸⁸ Similar recommendations are contained in the OSHA Technical Manual,⁸⁹ and in the many other authorities relied upon by Margaret Cunningham.⁹⁰

Once WW Oncology had identified antineoplastic drugs as a workplace hazard under WAC 296-800-16010; the company was required to select appropriate personal protective equipment for its employees. This would not have been difficult, because, after 2004, all of the relevant medical authorities recommended impermeable gowns. A reasonably prudent employer familiar with the industry, and the hazard faced by WW Oncology’s nurses and technicians would have recognized the need to use impervious gowns as personal protective equipment.

In fact, WW Oncology did select the appropriate personal protective equipment in its Chemical Hygiene Plan.⁹¹ For its laboratory

⁸⁷ CABR, Ex. 16, at 4.

⁸⁸ CABR, Ex. 16 at 4.

⁸⁷ CABR, Ex. 16 at 17.

⁹⁰ The recommendations of NIOSH, the Oncology Nursing Society, the OSHA Technical Manual, and other such authorities are not mandatory, because these are publications of research or professional associations, not regulatory agencies. WAC 296-800-16015 requires employers to select “appropriate” PPE, and recommendations for such appropriate PPE can be found in current professional publications.

⁹¹ CABR, Ex. 5.

technicians working with other kinds of hazardous chemicals, WW Oncology choose an “impermeable apron.” However, for unknown reasons, the company failed to extend this protection to the nurses and technicians handling antineoplastic drugs in the clinics.

As the Board determined in the Proposed Decision and Order:

[I]t is the responsibility of WWO to remain cognizant of changes in medical practices and by the date of Ms. Cunningham’s inspection, the blue impermeable gowns were known to provide more complete protection during exposure to chemotherapy.

Although the yellow low-permeable gowns may have satisfied the prior medical standard, WWO failed to modify its accident prevention program to upgrade PPE. The regulations require nothing less than this constant vigilance and mandate hazard assessment. Such reviews are continual in their nature; five year intervals are simply not adequate, particularly for occupations related to the daily contact with chemotherapy.⁹²

F. Substantial Evidence Supports The Board’s Finding That WW Oncology Failed To Enforce The Use Of Protective Gowns For Nurses And Technicians Mixing Or Administering Chemotherapy

Finally, under WAC 296-800-16040, WW Oncology was required to ensure that its employees wore necessary personal protective gowns. In Finding of Fact No. 6, the Board stated, “As of August 24, 2006, WWO failed to comply with the requirements of WAC 296-800-16040 and did not require employees to wear gowns that adequately protected them from

⁹² CABR at 49 (Proposed Decision and Order).

antineoplastic drugs during the course of mixing and/or administering chemotherapy to cancer patients.”⁹³

On this subject, the witnesses were unanimous. WW Oncology did not require nurses or technicians to wear impervious protective gowns even when they were mixing the undiluted drug *until after the WISHA inspection*.⁹⁴ In fact, despite NIOSH’s unambiguous recommendations, WW Oncology let the nurses wear anything they pleased, including cotton scrubs, or white lab coats when they were *administering* chemotherapy.⁹⁵

Assuming, for the sake of argument, that the yellow Graham Medical gown 242 was adequate protection, WW Oncology failed to enforce the use of even that gown. Nurses and technicians wore the yellow gown when *mixing* chemotherapy at the Centralia clinic, in part because a former Head Nurse recommended it. But there was no requirement that it be worn. No one was ever disciplined for not using it. Moreover, the yellow Graham Medical gown 242 was *not* adequate protection. As the tests demonstrated at hearing, liquid penetrated the yellow gown immediately. Ms. Justus testified that this is precisely what happened to her while administering chemotherapy.

⁹³ CABR at 51 (Proposed Decision and Order).

⁹⁴ CABR, Tr., 11/14/07, Guilford-Elenes at 94; Hilkemeier at 175.

⁹⁵ CABR, Tr., 11/14/07, Guilford-Elenes at 90, 92; Batchelor-Hancock at 131; Lindley at 141. Although some of the nurses testified that Carol Hulse, a former head nurse, suggested that they wear yellow Graham gown 242 when *mixing* chemotherapy, this was never mandatory. All of the nurses testified that no one in authority at WW Oncology disciplined nurses or technicians who wore only cotton scrubs or lab coats when mixing or administering chemotherapy.

There is overwhelming evidence that nurses administering chemotherapy in all three clinics wore scrub jackets or the white lab coat *at least* half the time - and did so without protest from management. WW Oncology was indifferent to the type of gown worn by nurses both when mixing drugs and when administering chemotherapy. And again, witnesses testified that chemotherapy agents had reached their skin, through and around their gowns and lab coats.

G. The Personal Protective Equipment Rules Are Not Unconstitutionally Vague

WW Oncology's opening brief does not clarify the legal basis for its challenge to the WISHA personal protective equipment standards.⁹⁶ To the extent that WW Oncology is attempting to raise a constitutional vagueness question, it is baseless. In *Inland Foundry*, , the employer contended that several provisions of the Washington Administrative Code were vague and therefore violated due process. 106 Wn. App. at 339.⁹⁷ Commenting that "a regulation does not have to satisfy impossible standards of specificity. It need not provide a person with the ability to predict with 'complete certainty' whether it proscribes a particular course of conduct," the Court of Appeals held that the challenged standards were not unconstitutionally vague. *Inland Foundry* 106 Wn. App. at 339.

⁹⁶ See Appellant's Opening Brief (AB) at 1, 16-19.

⁹⁷ Although one of the WACs *Inland Foundry* challenged was a PPE standard previously codified in WAC 296-24-07501, the standard cited was failure to do a hazard assessment for PPE, not for failing to require employees to use necessary PPE on the job, the standard cited here. Nevertheless, the comment of the Court of Appeals is relevant to the issues raised by the PPE standard cited here.

Similarly, OSHA personal protective equipment standards have been upheld under constitutional vagueness scrutiny. In *Ryder Truck Lines, Inc. v. Brennan*, 497 F.2d 230, 233 (5th Cir. 1974), Ryder argued that the OSHA PPE regulations were so vague that an employer could not determine what specific PPE was necessary for its employees. Recognizing that “[t]he regulation appears to have been drafted with as much exactitude as possible in light of the myriad conceivable situations which could arise and which would be capable of causing injury,” the Fifth Circuit upheld the regulation’s constitutionality. *Id.*

H. The Board’s Findings Support Its Conclusion Of Law That WW Oncology Committed A Serious Violation Of WAC 296-800-16040

The Board’s well-supported findings discussed above establish that WW Oncology committed a violation of WAC 296-800-16040 and that the violation was serious. WW Oncology argues that, even if it committed a violation of WAC 296-800-16040, the violation was not serious.

RCW 49.17.180(6) defines a serious violation. It reads as follows:

For the purposes of this section, a serious violation shall be deemed to exist in a work place if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use in such work place, *unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation.*

RCW 49.17.180(6) (emphasis added).

It is not clear from the Appellant's Opening Brief whether WW Oncology is alleging that the Department did not prove employer knowledge of the violation. However, employer knowledge is not in doubt, because WW Oncology's CEO received a copy of the NIOSH Alert the month it was published, and with the exercise of reasonable diligence (reading the NIOSH Alert and reading the subsequent publications of the Oncology Nursing Society) WW Oncology's managers, including Carol Hulse, Nurse Manager, and Melody Edgington, CEO, were or should have been aware of the violation. *See BD Roofing, Inc. v. Dept of Labor & Indus.*, 139 Wn. App. 98, 105-110, 161 P.3d 387 (2007) (explaining the employer-knowledge element of RCW 49.17.180(6)).

WW Oncology does argue that the Department failed to prove that employees were exposed to a serious hazard because no testimony was offered to show (1) the amount (volume) of the cytotoxic drugs spilled or sprayed on nurses or technicians, (2) how much the drugs were diluted with saline solution or water, or (3) the rate of absorption of the drugs into the skin.⁹⁸

WW Oncology's argument is based on false assumptions. First, WW Oncology appears to suggest that the Department and Board assessments of its employees' exposures were based on significant single spills or splashes. In fact, the *amount* of a single exposure is not significant

⁹⁸ *See* AB at 24-26. WW Oncology also asserts that, "more importantly," the Department did not observe any violations that occurred after the first conference with the employer. AB at 26. Abatement after the Department discovers worker safety violations, however, does not provide a defense to a citation. *See generally* Rothstein at § 5.34(5).

because there are no permissible exposure limits for cytotoxic drugs absorbed through the skin, and *any* skin contact is considered a hazard. As Ms. Cunningham testified:

There are not permissible exposure limits or PELs for antineoplastic drugs. First of all, permissible exposure limits apply to airborne inhaled exposures, those inhaled directly to the body. They do not relate to skin contact. There are no permissible exposure limits for skin contact for any chemical that I ever heard of.⁹⁹

Any contact of an antineoplastic drug with the skin is considered a hazard.¹⁰⁰ Moreover, because exposure to cytotoxic drugs is cumulative, nurses and technicians exposed to small amounts in any one incident could have a significant cumulative exposure over the course of a year or over the course of their careers.¹⁰¹

Second, WW Oncology appears to assume that all exposures were to only diluted drugs.¹⁰² They were not – two of the employees who testified, testified that the *undiluted* drugs they were mixing in the bio-safety cabinets reached their skin.¹⁰³ The drugs were eventually diluted “so that the drug will be in solution in an appropriate mixture so it won’t crystallize out before being effectively administered to the patient.”¹⁰⁴ Third, WW Oncology may

⁹⁹ CABR, Tr., 12/3/07, Cunningham at 4.

¹⁰⁰ CABR, Tr. 11/14/07, Cunningham at 118.

¹⁰¹ The studies on which the NIOSH Alert were based, used chemotherapy in amounts and concentrations customarily used to treat cancer patients. CABR, Tr., 11/14/07, Cunningham at 4.

¹⁰² See AB at 3, 6, 25.

¹⁰³ Cytotoxic drugs in the potent *undiluted* form reached the skin of two nurses, Marsha Justus and Robert Hilkemeier. CABR, Tr. 12/3/07, Justus at 39-40; Tr. 11/14/07, Hilkemeier at 169-170.

¹⁰⁴ CABR, Tr. 12/3/2007, Gordon at 59.

be assuming that the studies reported in the NIOSH Alert, and other medical sources cited by Ms. Cunningham, were based on exposure to large doses of undiluted drugs.¹⁰⁵ As Ms. Cunningham testified, however, that is not true.

Q. (Owada): Isn't it true that all of the studies you have read applied to large doses of antineoplastic drugs being given to patients intravenously?

A. (Cunningham): Not that I recall them large doses, no. The typical doses that are given to treat or cure cancer.¹⁰⁶

WW Oncology's objection to the serious designation of the violation also appears to be based on a mistaken view of the law: that a violation is serious only when there is employee exposure to a hazard that has a substantial probability of causing a severe injury or death.¹⁰⁷

The Court of Appeals considered the definition of a serious violation in *Lee Cook Trucking and Logging v. Department of Labor & Industries*, 109 Wn. App. 471, 482, 36 P.3d 558, (2001). At issue in *Lee Cook* was the interpretation of the "substantial probability" language of the statute. The employer Lee Cook asserted that there must be proof of a substantial probability that harm *will* result from the violation. *Id.* The Court of Appeals disagreed, holding that the employer misapprehended the statutory definition of "serious" which does not refer to the possibility of injury, but to the likelihood that injury, if it did occur, would be serious or fatal. *Id.*

Applied here, if a WW Oncology employee is harmed by long-term exposure to cytotoxic drugs, that injury would likely be serious (e.g.,

¹⁰⁵ See AB at 25 (questioning proof of the "amount" of exposure).

¹⁰⁶ CABR, Tr. 12/3/07, Cunningham at 16.

¹⁰⁷ See AB at 24-25.

leukemia, birth defects, miscarriage). Even if the employee was exposed only once to a potent and toxic drug like Adriamycin, if the employee were injured by that exposure, it is likely that the injury would be serious.

I. The Board Did Not Err Under ER 702 Or Under *Frye* In Admitting The Testimony Of The Department's Expert Witness

1. Ms. Cunningham Had Impressive Qualifications As An Industrial Hygienist

Under ER 702, a hearing tribunal's admission of expert testimony is reviewed for abuse of discretion. *State v. Cheatam*, 150 Wn.2d at 645. The trial court abuses its discretion only when its decision is manifestly unreasonable or exercised on untenable grounds or for untenable reasons. *Lewis v. Simpson Timber Company*, 145 Wn. App. 302, 327, 189 P.3d 178 (2008). Margaret Cunningham, a registered nurse and industrial hygienist with impressive training and experience was accepted by the Board as an expert in industrial hygiene. Ms. Cunningham has a Master of Science degree in nursing and she has over 20 years of experience, including experience teaching a course in oncology nursing at Washington University in St. Louis, Missouri. She is also a Certified Industrial Hygienist with eight years experience working for an environmental remediation firm and 12 years experience working for the Department of Labor and Industries.¹⁰⁸

¹⁰⁸ WW Oncology's expert, Anne Anderson, was neither a registered nurse nor a *certified* industrial hygienist. CABR, Tr. 12/3/07, at 117. She had inspected the WW Oncology clinics five years before the current inspection, to assess the hazards of blood-borne pathogens.

As an industrial hygienist, Ms. Cunningham was focused on the recognition, prevention and control of environmental factors in the workplace which may cause illness or impaired health, in contrast to Dr. Gordon, whose focus as an oncologist was on treating cancer patients. Dr. Gordon admitted that he knew nothing about industrial hygiene.¹⁰⁹

2. WW Oncology Did Not Preserve A *Frye* Challenge, And Ms. Cunningham's Opinions Were Not Based On Novel Scientific Theories

At the hearing, WW Oncology challenged Ms. Cunningham's expertise under ER 702 by asserting that "she simply doesn't have the scientific background under the *Frye* analysis" to testify as to the cause and effect of exposure to chemotherapy drugs.¹¹⁰ At no time did WW Oncology present any evidence that Ms. Cunningham's opinions were not generally accepted in the relevant scientific community.¹¹¹ WW Oncology's objection went only to Ms. Cunningham's qualifications under ER 702; a *Frye* challenge was not raised by the employer's vague, out-of-context use of the word *Frye*. See generally *Lewis*, 145 Wn. App. at 321, n.15 (failure to raise a challenge to acceptance of a theory in the relevant medical community waives the challenge).

Moreover, WW Oncology did not even use the words "novel" or "*Frye*" in its Petition for Review to the three-member Board; instead

¹⁰⁹ See Part IV. D. *supra*.

¹¹⁰ CABR, Tr. 11/14/07, Cunningham at 43.

¹¹¹ This is not surprising, since Ms. Cunningham's opinions regarding the hazards of chemotherapy were consistent with those advanced by WW Oncology's own witnesses as well as every publication contained or discussed in the record.

arguing that Ms. Cunningham was not qualified under ER 702, and that Dr. Gordon was more persuasive than Ms. Cunningham.¹¹² WW Oncology thus waived any *Frye* argument regarding the nature of the scientific evidence. A petition for review “shall set forth in detail the grounds therefore and the party filing the same shall be deemed to have waived all objections or irregularities not specifically set forth therein.” RCW 51.52.104. *Allan v. Dep’t of Labor & Indus.*, 66 Wn. App. 415, 422, 832 P.3d 489 (1992) (“Notwithstanding the merits of her petition, Allan waived this objection because it was not set out in her petition for review of the ruling of the Industrial Appeals Judge as required by RCW 51.52.104.”)

In any event, a *Frye* challenge in this factual context must fail. In both civil and criminal cases, Washington courts follow what is known as the “*Frye* test” for admissibility of novel scientific evidence. *Ruff v. Dep’t of Labor & Indus.*, 107 Wn. App. 289, 300, 28 P.3d 1 (2001). Under *Frye*, evidence derived from a scientific theory is admissible only if the theory has achieved general acceptance in the relevant scientific community. *Id.* The rule is concerned only with whether the expert’s underlying theories and methods are generally accepted. *Id.* The result – the conclusion reached by the expert in the case at hand – is by definition fact-specific and need not be generally accepted in the scientific community. *Id.* Thus, a *Frye* analysis need not be undertaken with respect to evidence that does

¹¹² CABR at 8 (Employer’s Petition for Review).

not involve new methods of proof or new scientific principles from which conclusions are drawn. *Id.*

Ms. Cunningham's opinions were based on articles from reputable, peer reviewed, scientific sources, including NIOSH papers; the *OSHA Technical Manual* from the federal Department of Labor; papers from the Oncology Nursing Society, the *Journal of Oncology Pharmacy Practice*, and the American Society for Health System Pharmacists; and the manufacturers' Material Safety Data Sheets for many of the chemicals used by WW Oncology.¹¹³ The scientific methods used in the research reported in these sources were methods generally accepted in the scientific community; they were not novel or questionable. A *Frye* analysis is simply not applicable here. "*Frye* analysis need not be taken with respect to evidence that does not involve new methods of proof or new scientific principles from which conclusions are drawn." *Ruff*, 107 Wn. App. at 300. The Board did not err in admitting Industrial Hygienist Cunningham's testimony about the recent research in her field.

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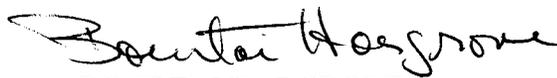
¹¹³ CABR, Tr., 11/14/07, Cunningham at 45-63.

V. CONCLUSION

For the foregoing reasons, this Court should deny WW Oncology's appeal and affirm the decisions of the Superior Court and the Board of Industrial Insurance Appeals.

RESPECTFULLY SUBMITTED this 17th day of June, 2009.

ROBERT M. MCKENNA
Attorney General



BOURTAI HARGROVE
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Attorney for Respondent

APPENDIX A

BEFORE THE BOARD OF INDUSTRIAL INSURANCE APPEALS
STATE OF WASHINGTON

1 IN RE: WESTERN WASHINGTON) DOCKET NO. 07 W0071
2 ONCOLOGY, P.S.)
3 CITATION & NOTICE NO. 310284104) PROPOSED DECISION AND ORDER

4 INDUSTRIAL APPEALS JUDGE: Ward J. Rathbone

5 APPEARANCES:

6
7 Employer, Western Washington Oncology, P.S., by
8 AMS Law, P.C., per
9 Aaron K. Owada

10 Department of Labor and Industries, by
11 The Office of the Attorney General, per
12 Bourtai Hargrove, Assistant

RECEIVED
MAR 25 2008
ATTORNEY GENERAL'S OFFICE
LABOR & INDUSTRIES DIVISION
OLYMPIA, WASHINGTON

13 The employer, Western Washington Oncology, P.S., (WWO) filed an appeal with the
14 Department of Labor and Industries' Safety Division on March 20, 2007, from Citation and Notice
15 No. 310284104, dated February 20, 2007, in which the Department alleged: (1) a serious violation
16 of WAC 296-62-11007 (Item 1-1) with a penalty of \$4,500; (2) a serious violation of
17 WAC 296-800-14005 (Item 1-2) with a penalty of \$3,000; and (3) a serious violation of
18 WAC 296-800-16015(1) (Item 1-3) with a penalty of \$4,500, for a total penalty assessment of
19 \$12,000. Pursuant to an order issued on October 25, 2007, Item 1-1 and Item 1-2 were vacated.
20 Pursuant to an order issued on October 23, 2007, Item 1-3 was amended to allege a serious
21 violation of WAC 296-800-16040 with an assessed penalty of \$4,500. The Citation and Notice, as
22 amended, is **AFFIRMED AS MODIFIED**.

23 **PROCEDURAL AND EVIDENTIARY MATTERS**

24 On November 14, 2007 and March 14, 2007, the parties agreed to include the Jurisdictional
25 History, as amended, in the Board's record. That history establishes the Board's jurisdiction in this
26 appeal.

27 The September 27, 2007 perpetuation deposition of Carol Hulse is hereby published and
28 appended as part of the record of these proceedings. All objections are overruled and any motions
29 are denied.

30 On October 10, 2007, the Department filed a Motion to Amend Citation and Notice
31 No. 310284104 "by vacating Violation 1, Item 1 and Violation 1, Item 2. There will be no change to
32 Violation 1, Item 3. Vacating Violations 1-1 and 1-2 will reduce the penalty from \$12,000 to \$4,500.

1 Pursuant to CR 15(c), the amendment will relate back to the date of the original citation." (See
2 *Motion to Amend Citation*).

3 On October 18, 2007, the Department filed a Second Motion to Amend Citation and Notice
4 No. 310284104 with an attached Memorandum in Support of Department's Second Motion to
5 Amend Citation. The pertinent portion of the Second Motion provided, in pertinent part:

6 [B]y changing Violation 1-3 to read as follows:

7 **Violation 1, Item 3-----Type of Violation: Serious**

8 Washington Administrative Code (WAC) violated: 296-800-16040.

9 The employer did not enforce the use of necessary personal protective
10 equipment (PPE), in that Western Washington Oncology did not ensure
11 that employees mixing or working with chemotherapy complied with
12 safety rules and WISHA regulations by wearing a gown that adequately
13 protected them against liquid aerosols and splashes. Employees in
14 some clinics wore Gown 241 by Graham Medical, which is inadequate
15 protection for contact with liquid chemicals such as chemotherapy.

16 Assessed penalty: \$4,500.00.

17 See *Department's Second Motion to Amend Citation* at 1.

18 The employer filed an objection to the motion on October 22, 2007, with attached exhibits
19 and, alternatively, requested a continuance in the event the Department's Motion was granted. On
20 October 19, 2007, a hearing was conducted concerning the Department's Motions to amend. On
21 October 23, 2007, an Interlocutory Order was issued Granting the Department's Second Motion to
22 Amend Citation and Granting Employer's Request for a Continuance. On October 25, 2007, an
23 Interlocutory Order was issued Granting the Department's First Motion to Amend Citation.

24 Neither the Department nor the employer requested a review of either order. At the original
25 hearing on November 14, 2007, a supplemental ruling was issued that vacated Item 1-1 and 1-2.
26 At that hearing, the parties agreed to include the Jurisdictional History in the Board's record. The
27 history establishes the Board's jurisdiction in this appeal. A continued hearing was completed on
28 December 3, 2007. At the conclusion of the second hearing, counsel for the parties requested an
29 opportunity to submit "Post-Hearing Briefs." The Department filed a brief on December 20, 2007,
30 and the employer submitted a "Closing Brief" on January 14, 2008. The comments contained in
31 those documents have been carefully considered and the authorities cited have been repeatedly
32 reviewed in the issuance of this Proposed Decision and Order.

In addition, counsel for the parties participated in a telephone conference on March 14,
2008, and waived notice of the conference. The proposed Jurisdictional History was further

1 reviewed and the parties agreed to the following amendments: the entry for March 19, 2007, was
2 deleted; the entry for March 20, 2007, was amended to state "February 26, 2007;" and the following
3 language in that entry "Received at DLI on 03/19/07 as a P&RR and forwarded to BIIA" was
4 deleted.

5 **ISSUES**

- 6 (1) Did Western Washington Oncology violate WAC 296-800-16040 by
7 failing to require employees to wear gowns that adequately protected
8 them from antineoplastic drugs when they were mixing and/or
9 administering chemotherapy to cancer patients?
- 10 (2) Whether the assessed total penalty of \$4,500 is appropriate?

11 **EVIDENCE**

12 Western Washington Oncology, P.S., (WWO) previously operated oncology clinics in
13 Western Washington and was recently purchased by St. Peter's Providence Hospital on October 1,
14 2007. On August 24, 2006, WWO had facilities located in Centralia, Aberdeen, and Lacey. At that
15 time, a function of WWO was to admixture and administer chemotherapy (antineoplastic drugs, aka
16 a cytotoxic drug) and other supportive drugs to patients with cancer. Exposure to antineoplastic
17 drugs can be toxic and terminal to healthy cells as well as cancer cells. Therefore, exposure
18 outside of the skin can cause irritation, rash, itching, and damage to the skin. Absorption through
19 the skin or inhalation can cause systemic effects such as leukemia, birth defects, and premature
miscarriage.

20 During the course of the proceedings in this matter, the following exhibits were admitted and
21 carefully considered:

22	Exhibit No. 3:	White lab coat
23	Exhibit No. 4:	MSDS sheets
24	Exhibit No. 5:	Chemical Hygiene Plan
25	Exhibit No. 6:	Accident Prevention Plan
26	Exhibit No. 8:	Curriculum Vitae
27	Exhibit Nos. 9, 10, 11, 12:	Photographs
28	Exhibit No. 14:	Accident Prevention Program
29	Exhibit No. 15:	Yellow gown
30	Exhibit No. 16:	National Guideline Clearing House, page 4
31	Exhibit No. 17:	OSHA Technical Manual, page 12
32	Exhibit No. 19:	PPE WAC

33 Exhibit No. 2 was identified at the November 14, 2007 hearing; however, it was not offered
34 into evidence and has not been considered in this decision.

35 The testimony of the following witnesses was provided during these proceedings, has been
36 carefully considered, and repeatedly reviewed:

1 (1) Margaret Cunningham: A certified Industrial Hygienist 3, certified in 1993, who is
2 employed by the Department of Labor and Industries and conducts between 40 and 50 inspections
3 each year. On August 24, 2006, she commenced an inspection of the WWO clinic in Centralia,
4 pursuant to a complaint that employees were allegedly exposed to chemotherapy because the
5 biosafety cabinet in which they mixed the chemotherapy did not constitute adequate protection.

6 Ms. Cunningham observed a nurse standing at the biosafety cabinet where chemotherapy is
7 mixed who was wearing a yellow-colored gown (Graham Medical 241-N) that was a bonded
8 nonwoven gown with no coating. Another nurse who was administering chemotherapy was
9 pregnant and wearing the same yellow-type gown. Other nurses were observed who were not
10 wearing gowns while administering chemotherapy.

11 On August 31, 2006, Ms. Cunningham inspected the Aberdeen clinic, but did not observe
12 any nurses mixing chemotherapy because that was undertaken behind closed doors. She was not
13 able to subsequently observe any nurse mixing or administering chemotherapy at the Lacey clinic.
14 A closing conference was conducted on February 6, 2007, at the Lacey office with Melody
15 Eddington and Linda Cooper.

16 Ms. Cunningham contended that a gown necessary to protect nurses who are mixing
17 chemotherapy infusion must be able to resist liquid splashes and liquid contact. She determined
18 that a gown with polyethylene coating would provide the necessary protection, but the gown
19 (Graham Medical 241-N) utilized by the nurses at WWO did not constitute adequate protection. She
20 concluded a violation of WAC 296-800-1640 by WWO was "serious" because of the ill effect that an
21 employee could experience from exposure to chemotherapy including skin rash, irritation, cancer
22 (leukemia), and reproductive effects. She considered the nurses who mix chemotherapy at the
23 biosafety cabinet and/or administer chemotherapy to patients were at risk of exposure.

24 Ms. Cunningham assigned a severity of 6 and a probability of 3 due to literature that
25 indicated such exposure would not occur to a large number of employees. She confirmed the total
26 penalty was \$4,500. She assessed a poor rating of good faith because of information indicating
27 employees had warned management of the risk, but there was no effective response. An additional
28 \$900 was included in her assessment. She considered the history of WWO was average and rated
29 the workforce as "small." 11/14/07 Tr. at 86. The penalty was reduced by \$900 and the total
30 penalty assessed was \$4,500.

31 (2) Leah Guilford-Elenes: She is a registered nurse and a certified oncology nurse. She
32 has been employed by WWO for eight years and was working at the Aberdeen clinic on August 24,

1 2006. She has mixed chemotherapy and administered it to patients during the course of her
2 employment. She has always worn a blue impervious gown when mixing chemotherapy. However,
3 she wore a white lab coat when administering chemotherapy until September 2007 when she
4 started wearing a blue gown. She indicated other nurses administering chemotherapy started
5 wearing the blue gowns in September 2007, but wore white lab coats prior to that time.

6 (3) Christina Batchelor-Hancock: She is presently an admixture technician and was
7 acting in that capacity on August 24, 2006. She has worked in the Aberdeen clinic since 2003, has
8 mixed chemotherapy in a biosafety cabinet on a daily basis, and has worn a blue impervious gown
9 from the inception. However, she noted nurses who administered chemotherapy to patients wore
10 lab jackets until September 2007.

11 (4) Lori Lindley: She is a registered nurse and a certified oncology nurse. She was hired
12 by WWO in 2001 and terminated her employment in December 2006. In 2003, she started to mix
13 chemotherapy in a biosafety cabinet at the Aberdeen clinic and initially wore the yellow gown for
14 protection, but subsequently wore the blue gown. In 2003, she would wear a white lab jacket while
15 administering chemotherapy. In February 2006, Ms. Lindley attended WISHA training that
16 recommended wearing the blue gowns when mixing and administering chemotherapy.

17 (5) Robert Kent Hilkemeier: He is a registered nurse and a certified oncology nurse who
18 was employed by WWO at the date of the inspection on August 24, 2006. He was assigned to the
19 Centralia clinic and mixed and administered chemotherapy. At those times, he wore either a lab
20 jacket or a yellow gown.

21 (6) Carol Hulse: She is a registered nurse and was employed by WWO until April 2006.
22 She started as a treatment nurse and was assigned as full-time nurse manager of the
23 chemotherapy staff in June 2002. She confirmed the company supplied lab jackets to nurses who
24 were mixing chemotherapy and noted some nurses wore yellow gowns that provided better
25 protection. She indicated that "probably in the last year I was there we got the—they were blue
26 gowns that were impervious to anything, liquids" Hulse Dep. at 23.

27 (7) Marsh Justus: She is a registered nurse and a certified oncology nurse who was
28 employed by WWO in June 2006 and eventually assigned to the Centralia clinic. She started
29 mixing chemotherapy in 2001 and utilized long sleeve shirts. In approximately 2002, she started
30 wearing yellow isolation gowns or white lab coats. After the inspection of August 24, 2006, she
31 used a blue impermeable gown when mixing. Prior to that date, she would wear a yellow gown or
32 white lab jacket when administering chemotherapy prior to the WISHA inspection.

1 (8) Shanna Ishler: She is a registered nurse, was employed by WWO in January 2005,
2 and is assigned to the Lacey clinic. During the latter portion of 2005 and the year of 2006, she
3 administered chemotherapy to patients at the Lacey clinic. During that period, she wore a blue
4 mixing gown of impermeable material consisting of polyethylene coating.

5 (9) Dr. Steven Gordon: He is a physician who previously completed a fellowship in
6 medical oncology and is a Board certified oncologist. He has been practicing for approximately
7 30 years, including 24 years in oncology. Based on available information, he concluded that an
8 employee is not exposed to any occupational hazard or risk while mixing antineoplastic drugs inside
9 a biological safety cabinet if wearing a yellow gown similar to Exhibit No. 15 and wearing gloves.
10 Further, he determined that low-permeable gowns are permissible as established by guidelines
11 issued by the Oncology Nursing Society.

12 (10) Melody Ann Edgington: She is the interim director of oncology at Providence Western
13 Washington Oncology and was chief executive officer for WWO from April 2006 to September 30,
14 2007, with responsibility for daily operations, oversight of clinic activities, and strategic planning. In
15 2002, she was the practice administrator for WWO and requested the Department of Labor and
16 Industries to conduct a consultation concerning an accident prevention program.

17 (11) Ann Gaylor Anderson: She is an industrial hygienist who was hired by the Department
18 of Labor and Industries in 1987 and was assigned as a compliance industrial hygienist in 1988. In
19 1995 she was transferred to the consultation group and assisted employers in developing safety
20 programs. In 2002 Ms. Anderson responded to the request by WWO regarding an accident
21 prevention program. She personally reviewed the work practices of WWO employees, but did not
22 recommend utilization of impermeable gowns while administering antineoplastic drugs to patients.
23 She considered WWO was a "much more cooperative and interested in employee safety and health
24 based upon the fact that they had a written accident prevention program . . . had regular safety
25 meetings . . . requested a consultation with the WISHA consultation group, which . . . essentially
26 provided a recommendation for them if they were ever inspected by compliance." 12/3/07 Tr.
27 at 116.

28 DECISION

29 In appeals filed under the Washington Industrial Safety and Health Act, it is the Department
30 that has the burden of proving both the existence of a violation and the appropriateness of the
31 resulting penalty. *In re Richard A. Castle, et ux, dba Olympia Glass Co.*, Dckt. No. 95 W445
32 (November 15, 1996). In order to establish a serious violation of a Department rule, the

1 Department is required to establish a probability of death or serious bodily harm could result from a
2 workplace condition "unless the employer did not, and could not with the exercise of reasonable
3 diligence, know of the presence of the violation." RCW 49.17.180(6); *In re The Erection Company*
4 (*II*), BIIA Dec., 88, W142 (1990).

5 Accordingly, in an appeal involving a serious WISHA violation, the Department must prove:

- 6 (a) the applicability of the cited standard,
- 7 (b) the employer's noncompliance with the standard's terms,
- 8 (c) employee access to the violative conditions, and
- 9 (d) the employer's actual or constructive knowledge of the violation (i.e. the
10 employer either knew, or with the exercise of reasonable diligence could
11 have known, of the violative conditions).

11 *In re Longview Fibre Company*, Dckt. No. 02 W0321 (November 5, 2003).

12 WAC 296-800-16040 is entitled "Require your employees to use necessary PPE on the job"
13 and instructs employers that "You must: Require your employees to use necessary PPE on the
14 job." A review of Board decisions indicates that this regulation has never been directly addressed,
15 particularly as it relates to mixing and/or administering chemotherapy.

16 WAC 296-800-16005 is entitled "Do a hazard assessment for PPE" and requires employers
17 to "Look for and identify hazards or potential hazards in your workplace and determine if PPE is
18 necessary for the job."

19 WAC 296-800-16010 is entitled "Document your hazard assessment for PPE" and mandates
20 that employers:

21 Verify that a hazard assessment for PPE has been done at your
22 workplace and complete a written certification (paper or electronic
23 format) that includes the:

24 Name of the workplace

25 Address of the workplace you inspected for hazards

26 Name of person certifying that a workplace hazard assessment
27 was done

28 Date(s) the workplace hazard assessment was done

29 Statement identifying the document as the certification of hazard
30 assessment for PPE for the workplace.

31 WAC 296-800-16015 is entitled "Select appropriate PPE for your employees" and directs
32 employers to:

1 (1) Select appropriate PPE.

2 Select appropriate PPE for your employees if hazards are
3 present, or likely to be present.

4 Select PPE for each at-risk employee to use for protection from
5 the hazards identified in your workplace hazard assessment.

6 (2) Select PPE that properly fits each at-risk employee.

7 WAC 296-800, and related regulations, do not specifically require the use of impervious
8 gowns for antineoplastic drugs. However, WWO previously determined that such drugs constituted
9 a workplace hazard and was necessarily required to provide appropriate PPE for its employees.
10 The testimony of Ms. Edgington established that WWO recognized the need for an accident
11 prevention program and the "difficulty finding credible and specific material to medical clinics."
12 12/3/08 Tr. at 93.

13 Ms. Edgington recalled Ms. Anderson provided recommendations in 2002 that included
14 "annual WISHA training . . . put in place a chemical hygiene plan for our lab for bloodborne
15 pathogens . . . and add a protective barrier with the lab coat . . . for all . . . employees." 12/3/08 Tr.
16 at 94. She confirmed the annual safety training addressed personal protective equipment for the
17 lab staff and the chemotherapy staff.

18 Prior to the inspection of August 24, 2006, Ms. Edgington had not received any complaints
19 from employees concerning the gowns utilized during mixing and/or administering chemotherapy.
20 Based on her inspection, Ms. Cunningham recommended venting the hoods of the cabinets and
21 changing from yellow gowns to the blue gowns. Consequently, the employer modified its program
22 to direct the use of blue gowns.

23 The essence of the Department's citation is that WWO "failed to require the use of
24 appropriate protective gowns for nurses or technicians working with cytotoxic chemicals."
25 *Department's Post-Hearing Brief* at 2. During her inspection, Ms. Cunningham noted that
26 employees in the three clinics administered chemotherapy while wearing scrubs, white lab coats, or
27 the yellow Graham gown 242. Although, the admixture technicians in the Aberdeen clinic wore blue
28 splash-resistant gowns when mixing cytotoxic drugs, the technicians in the Centralia and Lacey
29 clinics did not.

30 Ms. Cunningham's inspection of August 24, 2006, was precipitated by a complaint that,
31 "alleged . . . nurses were being exposed to chemotherapy because the biosafety cabinet was not
32 adequate protection for them." 11/14/07 Tr. at 40. The inference is that one or more employees
33 were disgruntled due to the failure of WWO to provide blue gowns and/or to promulgate and enforce

1 more stringent requirements during the mixing and administering of chemotherapy. The evidence
2 clearly establishes that exposure to antineoplastic drugs can be toxic and chemotherapy can be
3 hazardous if coming into contact with skin or inhaled.

4 One of the difficulties in assessing the alleged violation in this appeal is that WWO sought
5 and received the recommendations of the Department in 2002 regarding an effective accident
6 prevention program. Ms. Anderson considered the functions of WWO, but did not recommend the
7 requirement of wearing impermeable gowns when processing antineoplastic drugs. At that time,
8 her conclusions may have been consistent with the state of information concerning the use of
9 yellow gowns.

10 However, between the period of 2002 and Ms. Cunningham's inspection of August 24, 2006,
11 further experience with these drugs indicated that impermeable gowns were appropriate during the
12 mixing and administering chemotherapy. Nevertheless, Dr. Gordon's opinion was that guidelines
13 published by professional societies indicated low-permeable gowns were sufficient protective gear
14 for people who mixed and/or administered chemotherapy. He personally conducted experiments
15 with liquids to test absorption by the yellow gowns and concluded the material provided adequate
16 protection from exposure.

17 It is obvious that the blue impermeable gown is preferable during the process of mixing
18 and/or administering chemotherapy. WWO challenges the citation on the basis that the yellow
19 gowns are adequate and were instituted on the basis of Ms. Anderson's recommendations of 2002.
20 However, it is the responsibility of WWO to remain cognizant of changes in medical practices and
21 by the date of Ms. Cunningham's inspection, the blue impermeable gowns were known to provide
22 more complete protection during exposure to chemotherapy.

23 Although the yellow low-permeable gowns may have satisfied the prior medical standard,
24 WWO failed to modify its accident prevention program to upgrade PPE. The regulations require
25 nothing less than this constant vigilance and mandate hazard assessment. Such reviews are
26 continual in their nature; five year intervals are simply not adequate, particularly for occupations
27 related to the daily contact with chemotherapy.

28 Based on these factors, WWO's failure to provide such impermeable gowns is a violation of
29 the intent of WAC 296-800-16040. Although the yellow gowns may have been a form of protection
30 from hazardous exposure, the evidence establishes that such gowns were not the best garments to
31 use by technicians and constituted a risk of serious injury. Moreover, if the yellow gowns arguably
32

1 satisfied the language of WAC 296-800-16040, Ms. Cunningham observed certain nurses at the
2 Centralia clinic who did not even wear the yellow gowns while administering chemotherapy.

3 In the final analysis of the extensive record in this matter, the testimony of Ms. Cunningham
4 concerning her observations during the inspection of WWO premises is more persuasive than the
5 evidence submitted by WWO. The nurses and technicians perform admirable services in treating
6 patients with cancer. Necessarily, such health providers are exposed to health hazards that exceed
7 most occupations. In the pursuit of fulfilling their duties, they are entitled to expect the maximum
8 protection available. The regulations recognize this rudimentary fact and are designed to require
9 employers to supply equipment that reflects the most recent scientific information. Anything less is
10 contrary to the purpose of the Washington Industrial Safety and Health Act.

11 Although WWO is to be congratulated for its immediate and cooperative response to
12 Ms. Cunningham's inspection by providing impermeable blue gowns, there is no adequate answer
13 for failing to do so before the inspection. The preponderance of evidence establishes that this issue
14 had been raised prior to the inspection and galvanized the Department to investigate the matter.
15 Fortunately, no employee has suffered any known health consequence. However, such a fortuitous
16 turn of events does not indicate compliance with WAC 296-800-16005.

17 Ms. Cunningham considered WWO should not receive a positive rating for good faith and
18 increased the basic penalty by \$900. However, it must be remembered that, up to that point in
19 time, WWO was acting in accordance with the Department's earlier recommendations. In addition,
20 WWO promptly responded to Ms. Cunningham's report and immediately provided the blue gowns
21 that the Department presently requires. These actions do not warrant a poor rating for good faith
22 and the \$900 was improperly assessed. The appropriate total penalty assessed is \$3,600.

23 Accordingly, Citation and Notice No. 310284104 issued on February 20, 2007, as amended,
24 is affirmed as modified.

25 **FINDINGS OF FACT**

- 26 1. On February 12, 2007, the Department of Labor and Industries Division
27 of Occupational Safety and Health conducted an inspection of the
28 premises operated by Western Washington Oncology, P.S., located at
29 1800 Cooks Hill Road, Suite F, Centralia, Washington 98531. On
February 6, 2007, a closing conference was conducted.

30 On February 20, 2007, as a result of the inspection, the Department
31 issued Citation and Notice No. 310284104, alleging a serious violation
32 of WAC 296-62-11007 (Item 1-1) with an assessed penalty of \$4,500, a
serious violation of WAC 296-800-14005 (Item 1-2) with an assessed
penalty of \$3,000, and a serious violation of WAC 296-800-16015(1)

1 (Item 1-3) with an assessed penalty of \$4,500, for a total penalty
2 assessed of \$12,000.

3 On February 26, 2007, the employer filed a Notice of Appeal with the
4 Department of Labor and Industries Safety Division that was forwarded
5 to the Board on March 20, 2007. On March 21, 2007, the Board issued
6 a Notice of Filing Appeal, assigned Docket No. 07 W0071, and directed
7 that further proceedings be conducted on the merits.

8 2. The employer, Western Washington Oncology, PS., (WWO) previously
9 operated oncology clinics in Western Washington and was purchased
10 by St. Peter's Hospital on October 1, 2007. On August 24, 2006, WWO
11 had facilities in Centralia, Aberdeen, and Lacey, Washington. At that
12 time, WWO provided services to patients with cancer that including
13 mixing and administering chemotherapy.

14 3. Exposure to antineoplastic drugs (chemotherapy) can be toxic and
15 terminal to healthy cells as well as cancer cells. Accordingly, exposure
16 outside the skin can cause irritation, rash, itching, and damage to the
17 skin. Absorption through the skin and/or inhalation can cause systemic
18 effects such as leukemia, birth defects, and premature miscarriage.

19 4. On August 24, 2006, Margaret Cunningham, a certified Industrial
20 Hygienist 3, employed by the Department of Labor and Industries,
21 conducted an inspection of the WWO clinic in Centralia, Washington.
22 This inspection was precipitated by complaints filed by employees who
23 were allegedly exposed to chemotherapy as a result of inadequate
24 protection. Ms. Cunningham observed a nurse at a biosafety cabinet
25 where chemotherapy was being mixed. The nurse was wearing a
26 low-permeable, yellow-colored gown (Graham Medical 241-N) that was
27 a bonded nonwoven gown with no coating. Another nurse who was
28 pregnant was administering chemotherapy and wearing a similar yellow
29 gown. Other nurses were observed by Ms. Cunningham who were not
30 wearing any gowns while administering chemotherapy.

31 5. During the course of her inspection, Ms. Cunningham noted that
32 employees in the three clinics administered chemotherapy while wearing
scrubs, white lab coats, or the yellow Graham gown 242. Based on her
inspection, Ms. Cunningham recommended changing from the yellow
gowns to impermeable blue gowns. WWO immediately modified its
accident prevention program and directed employees who were
exposed to chemotherapy to wear blue gowns.

6. As of August 24, 2006, WWO failed to comply with the requirements of
WAC 296-800-16040 and did not require employees to wear gowns that
adequately protected them from antineoplastic drugs during the course
of mixing and/or administering chemotherapy to cancer patients.

7. On October 25, 2007, Item 1-1 and Item 1-2 in Citation and Notice
No. 310284104 issued on February 20, 2007, were vacated pursuant to
a motion filed by the Department on October 10, 2007.

- 1 8. On October 23, 2007, Item 1-3 in Citation and Notice No. 310284104
2 was amended to allege a serious violation of WAC 296-800-16040 with
3 an assessed penalty of \$4,500.
4 9. For this violation, Item 1-3, of WAC 296-800-16040, the probability of an
5 accident is 3 and the severity is 6. The base penalty amount is \$4,500.
6 The history of WWO is average and the workforce is small for a
7 reduction of \$900. The total adjusted base penalty is \$3,600.

8 **CONCLUSIONS OF LAW**

- 9 1. The Board of Industrial Insurance Appeals has jurisdiction over the
10 parties to and subject matter of this appeal.
11 2. Item 1-1 and Item 1-2 in Citation and Notice No. 310284104 are vacated
12 pursuant to a motion filed by the Department.
13 3. On August 24, 2006, the employer, WWO, did commit a serious
14 violation of WAC 296-800-16040 as alleged in Item 1-3 in the amended
15 Citation and Notice No. 310284104. The total penalty for this serious
16 violation is established as \$3,600.
17 4. Citation and Notice No. 310284104 is affirmed as modified with a total
18 penalty assessed of \$3,600.

19 It is **ORDERED**.

20 DATED: MAR 24 2008

21 
22 Ward J. Rathbone
23 Industrial Appeals Judge
24 Board of Industrial Insurance Appeals
25
26
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31
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APPENDIX B

296-800-160 << 296-800-16005 >> 296-800-16010

WAC 296-800-16005

No agency filings affecting this section since 2003

Do a hazard assessment for PPE.

You must:

- Look for and identify hazards or potential hazards in your workplace and determine if PPE is necessary on the job.

Note: PPE alone should not be relied on to provide protection for your employees. PPE should be used after all other reasonable means of reducing hazards have been carried out. Identifying hazards in your workplace should be built into your regular routine. You should take active steps to get rid of all identified hazards. For example, you can:

- Consider other ways to get hazardous jobs done.
- Reduce hazardous materials or processes.
- Apply engineering controls to reduce or eliminate hazards.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16005, filed 5/9/01, effective 9/1/01.]

296-800-16005 << 296-800-16010 >> 296-800-16015

WAC 296-800-16010

No agency filings affecting this section since 2003

Document your hazard assessment for PPE.

You must:

• Verify that a hazard assessment for PPE has been done at your workplace and complete a written certification (paper or electronic format) that includes the:

- Name of the workplace
- Address of the workplace you inspected for hazards
- Name of person certifying that a workplace hazard assessment was done
- Date(s) the workplace hazard assessment was done
- Statement identifying the document as the certification of hazard assessment for PPE for the workplace

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16010, filed 5/9/01, effective 9/1/01.]

296-800-16010 << 296-800-16015 >> 296-800-16020

WAC 296-800-16015

No agency filings affecting this section since 2003

Select appropriate PPE for your employees.

You must:

- (1) Select appropriate PPE.
 - Select appropriate PPE for your employees if hazards are present, or likely to be present.
 - Select PPE for each at-risk employee to use for protection from the hazards identified in your workplace hazard assessment.
- (2) Select PPE that properly fits each at-risk employee.

Note: The hazards in your workplace have special rules that apply to them.

For information about PPE for specific workplaces, see these WISHA rule books:

Construction Work	Chapter 296-155 WAC
Electrical Workers	Chapter 296-45 WAC
Firefighters	Chapter 296-305 WAC
General Occupational Health Standards	Chapter 296-62 WAC
General Safety and Health Standards	Chapter 296-24 WAC
Logging Operations	Chapter 296-54 WAC
Pulp, Paper and Paper Board Mills and Converters	Chapter 296-79 WAC
Ship Repairing, Ship Building and Shipbreaking	Chapter 296-304 WAC
Ski Area Facilities and Operations	Chapter 296-59 WAC
Telecommunication	Chapter 296-32 WAC
Textile Industry	Chapter 296-301 WAC

Note: For help in selecting PPE for your employees, you have several options. You may:

- Visit the OSHA web site <http://www.osha-slc.gov/SLTC/personalprotectiveequipment/index.html>.
- Call 1-800-4BE SAFE (1-800-423-7233) for guidelines for selecting PPE.
- Consult with safety and health professionals knowledgeable in this area. See resource section for links to professional organizations.
- Discuss PPE choices with your employees.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-23-060, § 296-800-16015, filed 11/20/01, effective 12/1/01; 01-11-038, § 296-800-16015, filed 5/9/01, effective 9/1/01.]

296-800-16015 << 296-800-16020 >> 296-800-16025

WAC 296-800-16020

Agency filings affecting this section

Provide PPE to your employees.

You must provide PPE at no cost to employees if the PPE is:

- The type that would not reasonably or normally be worn away from the workplace, such as single use or disposable PPE.
- Required to comply with a safety and health standard to protect employees wherever hazards exist from:
 - Processes
 - Environmental hazards
 - Physical, chemical, or radiological hazards or
 - Mechanical irritants that could cause injury or impairment to the function of any body part through absorption, inhalation, or physical contact.

Table-X: Employer Responsibility for Providing PPE
 *This table provides examples only and is not all-inclusive.

Part of Body	PPE employers are required to provide at no cost to employees.	Items in which employer payment is not required.
Head	Bump caps.	
	Hard hat.	---
	Nonconductive head protection.	
Eye and Face	Face shields.	Nonspecialty prescription safety eyewear.
	Goggles.	
	Laser safety goggles.	
	Nonprescription eye protection.	
	Prescription eyewear inserts/lenses for full-face respirators.	
Ear	Welding and diving helmets.	
	Hearing protection.	---
Hand/Arm	Aluminized gloves.	Hand protection used only for keeping clean or for cold weather with no safety or health consideration.
	Barrier creams (unless used solely for weather-related protection).	
	Chemical resistant gloves/aprons/	
	clothing.	
	Mesh cut proof gloves.	
	Mesh or leather aprons.	
	Nonspecialty gloves if	

	required to protect from dermatitis, severe cuts, or abrasions.	
	Rubber insulating gloves.	
	Rubber sleeves.	
Foot	Metatarsal foot protection.	Nonspecialty safety-toe protective footwear such as steel-toe shoes or boots.
	Rubber boots with steel toes.	
	Shoe covers - toe caps and metatarsal guards.	Sturdy work shoes.
	Special boots for longshoremen working logs.	Lineman's boots. Logging boots required under chapter 296-54 WAC.
Other	Atmosphere-supplying respirators (escape only).	Long sleeve shirts. Long pants.
	Climbing ensembles used by linemen such as belts and climbing hooks.	Ordinary cold weather gear (coats, parkas, cold weather gloves, winter boots).
	Level A - fully encapsulated chemical protective suits.	Ordinary rain gear.
	Level B - chemical protective clothing.	Dust mask/respirators used under the voluntary use provisions in chapter 296-842 WAC.
	Personal fall arrest systems.	
	Personal fall restraint systems.	Back belts. Sunglasses.
	Firefighting PPE (helmet, gloves, boots, proximity suits, full gear).	Sunscreen.
	Ladder safety device belts.	
	Personal floatation devices (life jackets).	
	Class II or III high visibility garments that meet ANSI 107-2004 specifications.	
	Respiratory protection.	
	SCBA (self-contained breathing apparatus).	
	Welding PPE.	
	Window cleaner's safety straps.	

Items such as aprons,
lab coats, goggles,
disposable gloves, shoe
covers, etc., used in
medical/

laboratory settings to
protect from exposure to
infectious agents.

[Statutory Authority: RCW 49.17.010, 49.17.040, 49.17.050, 49.17.060, 09-05-071, § 296-800-16020, filed 2/17/09, effective 4/1/09. Statutory Authority: RCW 49.17.010,[49.17].040 , and [49.17].050, 01-23-060, § 296-800-16020, filed 11/20/01, effective 12/1/01; 01-11-038, § 296-800-16020, filed 5/9/01, effective 9/1/01.]

296-800-16020 << 296-800-16025 >> 296-800-16030

WAC 296-800-16025

No agency filings affecting this section since 2003

Train your employees to use PPE.

You must:

- Communicate your PPE selection decision to each at-risk employee.
- Provide training to each employee who is required to use PPE on the job. Each affected employee must be trained to know at least the following:
 - When PPE is necessary
 - What PPE is necessary
 - How to put on, take off, adjust, and wear PPE
 - Limitations of PPE
 - Proper care, maintenance, useful life, and disposal of PPE.
- Make sure before an employee is allowed to perform work requiring the use of PPE that the employee can:
 - Demonstrate an understanding of the training specified above; and
 - Demonstrate the ability to use PPE properly.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-23-060, § 296-800-16025, filed 11/20/01, effective 12/1/01; 01-11-038, § 296-800-16025, filed 5/9/01, effective 9/1/01.]

296-800-16025 << 296-800-16030 >> 296-800-16035

WAC 296-800-16030

No agency filings affecting this section since 2003

Retrain employees to use PPE, if necessary.

You must:

• Retrain an employee when you have reason to believe the understanding, motivation, and skills required to use the PPE has not been retained. Circumstances where retraining is required include:

- Changes in the workplace that make previous training out of date.
- Changes in the types of PPE to be used make previous training out of date.
- Work habits or demonstrated knowledge indicate that the employee has not retained the necessary understanding, skill, or motivation to use PPE.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16030, filed 5/9/01, effective 9/1/01.]

296-800-16030 << 296-800-16035 >> 296-800-16040

WAC 296-800-16035
Document PPE training.

No agency filings affecting this section since 2003

You must:

- Document in writing that each employee using PPE has received and understood the required training.

This documentation must include:

- Name of each employee
- Date(s) of training
- Subject of the training

Note: Documentation may be stored on a computer as long as it is available to safety and health personnel from the department of labor and industries.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16035, filed 5/9/01, effective 9/1/01.]

296-800-16035 << 296-800-16040 >> 296-800-16045

WAC 296-800-16040

Require your employees to use necessary PPE on the job.

No agency filings affecting this section since 2003

You must:

- Require your employees to use necessary PPE on the job.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16040, filed 5/9/01, effective 9/1/01.]

296-800-16040 << 296-800-16045 >> 296-800-16050

WAC 296-800-16045

No agency filings affecting this section since 2003

Keep PPE in safe and good condition.

You must:

- Make sure all PPE is safe for the work to be performed. It must:
 - Be durable.
 - Fit snugly.
 - Not interfere with the employee's movements.
- Make sure PPE is used and maintained in a clean and reliable condition.
 - Defective equipment MUST NOT be used.
- Make sure if employees provide their own PPE, that it is adequate for the workplace hazards, and maintained in a clean and reliable condition.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16045, filed 5/9/01, effective 9/1/01.]

296-800-16045 << 296-800-16050 >> 296-800-16055

WAC 296-800-16050

No agency filings affecting this section since 2003

Make sure your employees use appropriate eye and face protection.

You must:

- Make sure that employees exposed to hazards that could injure their eyes and/or face use appropriate protection.

Examples of these hazards include:

- Flying particles.
- Molten metal.
- Liquid chemicals.
- Acids or caustic liquids.
- Chemical gases or vapors.
- Any light that could injure the eyes such as lasers, ultraviolet, or infrared light.
- Objects that puncture.

• Make sure employees exposed to hazards from flying objects have eye protection with side protection, such as safety glasses with clip-on or slide-on side shields.

- Make sure eye protection for employees who wear prescription lenses:

- Incorporates the prescription into the design of the eye protection; or
- Is large enough to be worn over the prescription lenses without disturbing them.

• Make sure PPE used to protect the eyes and face meet the following specific ANSI (American National Standards Institute) standards. Most commercially available PPE is marked with the specific ANSI requirements.

- PPE bought before February 20, 1995, must meet ANSI standard Z87.1-1968.
- PPE bought on or after February 20, 1995, must meet ANSI standard Z87.1-1989.

– If you use eye or face protection that does not meet these ANSI standards, you must show they are equally effective.

Note: ANSI is the American National Standards Institute that publishes nationally recognized safety and health requirements. Their address is:

ANSI (American National Standards Institute)
1819 L Street NW
Washington, DC 20036
Phone: (202) 293-8020
Fax: (202) 293-9287
<http://www.ansi.org>

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 02-16-047, § 296-800-16050, filed 8/1/02, effective 10/1/02; 01-23-060, § 296-800-16050, filed 11/20/01, effective 12/1/01; 01-11-038, § 296-800-16050, filed 5/9/01, effective 9/1/01.]

296-800-16050 << 296-800-16055 >> 296-800-16060

WAC 296-800-16055

No agency filings affecting this section since 2003

Make sure your employees use appropriate head protection.

You must:

(1) Make sure employees wear appropriate protective helmets.

- Where employees are exposed to hazards that could cause a head injury. Examples of this type of hazard include:

- Flying or propelled objects.

- Falling objects or materials.

- Where employees are working around or under scaffolds or other overhead structures.

- That helmets meet the following specific ANSI standards (most commercially available PPE is marked with specific ANSI requirements):

- Protective helmets bought before February 20, 1995, must meet ANSI standard Z89.1-1969.

- Protective helmets bought after February 20, 1995, must meet ANSI standard Z89.1-1986.

- If you use protective helmets that do not meet these ANSI standards, you must show they are equally effective.

(2) Make sure employees working near exposed electrical conductors that could contact their head wear a protective helmet designed (that meet the above ANSI standards) to reduce electrical shock hazard.

- Caps with metal buttons or metal visors must **not** be worn around electrical hazards.

(3) Make sure employees working around machinery or in locations that present a hair-catching or fire hazard wear caps or head coverings that completely cover their hair.

- Employees must wear a hair net that controls all loose ends when:

- Hair is as long as the radius of pressure rolls with exposed in-running nip points.

- Hair is twice as long as the circumference of exposed revolving shafts or tools in fixed machines.

- Employees must wear a hair covering of solid material when:

- The employee is exposed to an ignition source and may run into an area containing class-1 flammable liquids, such as ether, benzene, or combustible atmospheres if their hair is on fire.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16055, filed 5/9/01, effective 9/1/01.]

296-800-16055 << 296-800-16060 >> 296-800-16065

WAC 296-800-16060

No agency filings affecting this section since 2003

Make sure your employees use appropriate foot protection.

You must:

(1) Use appropriate foot protection.

- Where employees are exposed to hazards that could injure their feet. Examples of these hazards are:

- Falling objects

- Rolling objects

- Piercing/cutting injuries

- Electrical hazards

- That meets specific ANSI requirements. (Most commercially available PPE is marked with specific ANSI requirements.)

- PPE bought before February 20, 1995, must meet ANSI standard Z41.1-1967.

- PPE bought after February 20, 1995, must meet ANSI standard Z41-1991.

- If you use foot protection that does not meet these ANSI standards, you must show it is equally effective.

(2) Make sure your employees wear calks or other suitable footwear to protect against slipping while they are working on top of logs.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 01-11-038, § 296-800-16060, filed 5/9/01, effective 9/1/01.]

296-800-16065 << 296-800-16070 >> 296-800-170

WAC 296-800-16070

No agency filings affecting this section since 2003

Make sure your employees are protected from drowning.

You must:

(1) Provide and make sure your employees wear personal flotation devices (PFD).

- When they work in areas where the danger of drowning exists, such as:
 - On the water.
 - Over the water.
 - Alongside the water.

Note: Employees are not exposed to the danger of drowning when:

- Employees are working behind standard height and strength guardrails.
- Employees are working inside operating cabs or stations that eliminate the possibility of accidentally falling into the water.
- Employees are wearing an approved safety belt with a lifeline attached that prevents the possibility of accidentally falling into the water.

You must:

- Provide your employees with PFDs approved by the United States Coast Guard for use on commercial or merchant vessels. The following are appropriate or allowable United States Coast Guard-approved PFDs:

Type of PFD	General Description
Type I	Off-shore life jacket - effective for all waters or where rescue may be delayed.
Type II	Near-shore buoyant vest - intended for calm, inland water or where there is a good chance of quick rescue.
Type III	Flotation aid - good for calm, inland water, or where there is a good chance of rescue.
Type V	Flotation aids such as boardsailing vests, deck suits, work vests and inflatable PFDs marked for commercial use.

Note: • Commercially available PFDs are marked or imprinted with the type of PFD.

- Type IV PFDs are throwable devices. They are used to aid persons who have fallen into the water.

You must:

- Inspect PFDs before and after each use for defects and make sure that defective PFDs are not used.

(2) Provide approved life rings with an attached line on all docks, walkways, and fixed installations on or adjacent to water more than five feet deep.

- Life rings must:

- Be United States Coast Guard approved 30 inch size.

- Have attached lines that are at least 90 feet in length.
- Have attached lines at least 1/4 inch in diameter.
- Have attached lines with a minimum breaking strength of 500 pounds.
- Be spaced no more than 200 feet apart.
- Be kept in easily visible and readily accessible locations.
- Life rings and attached lines must:
 - Be maintained to retain at least 75 percent of their designed buoyancy and strength.
 - Be provided in the immediate vicinity when employees are assigned work at other casual locations where the risk of drowning exists.
 - Work assigned over water where the vertical drop from an accidental fall would be more than 50 feet, must be subject to specific procedures as approved by the department.

[Statutory Authority: RCW 49.17.010, [49.17].040, and[49.17].050 . 02-16-047, § 296-800-16070, filed 8/1/02, effective 10/1/02; 01-11-038, § 296-800-16070, filed 5/9/01, effective 9/1/01.]

APPENDIX C

Resources

Links

L&I (State of Washington Department of Labor and Industries)

Homepage:

<http://www.lni.wa.gov>

To find the L&I office nearest you:

<http://www.wa.gov/lni/pa/direct.htm>
1-800-4BE SAFE (1-800-423-7233)

L&I training opportunities:

WISHA - <http://www.lni.wa.gov/Safety>

NIOSH (National Institute for Occupational Safety & Health)

<http://www.cdc.gov/niosh/homepage.html>

4676 Columbia Parkway
Cincinnati, OH 45226-1998
Phone: (800) 356-4674

Northwest Center for Occupational Safety and Health Training

<http://depts.washington.edu/envhlth/conted/ce/index.html>

4225 Roosevelt Way NE, Ste. 100
Seattle, WA 98105
Phone: (206) 543-1069
Fax: (206) 685-3872

OSHA (Occupational Safety and Health Administration)

<http://www.osha.gov>

200 Constitution Ave. NW
Washington, DC 20210
Phone: (800) 321-6742

Region 10 Office
111 Third Ave. Suite 715
Seattle, WA 98101-3212



COURT OF APPEALS
DIVISION II

NO. 38877-4-II-01

STATE OF WASHINGTON

**COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON**

WESTERN WASHINGTON
ONCOLOGY, P.S.,

Appellant,

v.

WASHINGTON STATE
DEPARTMENT OF LABOR AND
INDUSTRIES,

Respondent.

**CERTIFICATE OF
SERVICE**

I certify that on the 17th day of June, 2009, I caused a true and correct copy of the BRIEF OF RESPONDENT and this CERTIFICATE OF SERVICE to be served upon the parties herein, in the above-entitled action, as indicated below:

Aaron Owada
AMS LAW PC
975 Carpenter Rd. NE Ste 201
Lacey, WA 98516

Attorney for Appellant

- US Mail Postage Prepaid
- Certified Mail Postage Prepaid
- State Campus Mail
- ABC/Legal Messenger
- UPS Next Day Air
- Fax
- Hand Delivered

ORIGINAL

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Dated this 17th day of June, 2009 at Olympia, Washington.


MARILYN WHITFELDT
Legal Assistant
(360) 586-7752