CONCISE EXPLANATORY STATEMENT

Hazardous Drugs

Public Hearings: November 28 and December 1, 2011
Adoption: January 3, 2012
Effective Date: January 1, 2014

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I. Purpose of Rulemaking

During the 2011 legislative session, the Legislature passed Chapter 39, Laws of 2011 (Engrossed Substitute Senate Bill 5594) regarding the handling of hazardous drugs. Engrossed Substitute Senate Bill (ESSB) 5594 requires the Department of Labor and Industries (department) to adopt rules for the safe handling of chemotherapy and other hazardous drugs used in health care facilities regardless of the setting. The rules must be consistent with but may not exceed provisions in the National Institute for Occupational Safety and Health's (NIOSH) 2004 Alert on preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings as updated in 2010. The department conducted two stakeholder meetings to gather input from business and labor stakeholders for use in developing the draft rules. The department conducted three public hearings on the proposed rules. In addition, the department had numerous on-going discussions and meetings with hospitals, organizations representing health care personnel, and many other business and labor stakeholders to get input regarding the best way to address the needs of employers, employees, and health care patients, while at the same time ensuring the rules met the requirements of ESSB 5594 to be consistent with the NIOSH guidelines, while not exceeding them.

A. Consistency with NIOSH

Pursuant to RCW 49.17.465, the department is required to "adopt by rule requirements for the handling of antineoplastic and other hazardous drugs in health care facilities regardless of the setting." The statute requires the department's rules " be consistent with and not exceed provisions adopted by the national institute for occupational safety and health's (NIOSH)2004 alert on preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings as updated in 2010." RCW 49.17.460, Declaration -- Intent -- 2011 c 39; RCW 49.17.465. The legislature also directed the department to consider input from hospitals, organizations representing health care personnel, other stakeholders in adopting the rules. RCW 49.17.465. The department is to consider reasonable time for facilities to implement new requirements. *Id*. The statute also allows the department to incorporate updates and changes to NIOSH's guidelines. *Id.*

Given the statutory requirements that the department's rules "be consistent with but not exceed" provisions of the NIOSH Alert, it is clear that the legislature did not intend for the department to adopt verbatim the NIOSH Alert. Further, in determining what is consistent with and not exceeding the provisions of the NIOSH guidelines, the department was specifically directed to consider stakeholder input in drafting these rules. Given that the Administrative Procedures Act (APA) rulemaking provisions already require stakeholder input as part of the rulemaking process, the department has interpreted this proviso in RCW 49.17.465 as requiring a heightened level of input over the APA's requirements.

The entirety of the 2004 Alert and subsequent NIOSH related guidelines were evaluated. The essential provisions required by NIOSH are as follows: a hazard assessment to evaluate and assess the potential and degree of exposure; the use of engineering controls and personal protective equipment to eliminate or reduce exposures; and hazardous drugs policies and procedures to include safe handling and other work practices, and training. Based on stakeholder input prior to drafting the proposed rule, it was determined that in many cases using a specification approach that was too rigid and inflexible would result in rules which exceed the NIOSH guidelines. This type of approach would result in one set of requirements regardless of the hazard assessment and would not allow for consideration of the factors affecting exposure such as amount of drug prepared, the frequency and duration of drug handling, the relative toxicity and form of the drug handled, and the types of drugs handled. When taken in their entirety, the NIOSH Alert and subsequent guidelines offer flexibility to employers in many areas. Therefore, the department used a performance standard framework when possible. For example, the rule allows but does not require a "tiered approach that effectively matches the precautions to the nature of exposure..." The appropriate precautions would be based on the employer's hazard assessment which in turn would take into consideration various factors identified by NIOSH as affecting the nature of the risk such as the nature of the hazardous drugs being handled and their relative toxicity. This approach is consistent with the NIOSH Alert and subsequent guidelines and is consistent with the framework applied to many other related Division of Occupational Safety and Health (DOSH) rules, such as hazard communication and personal protective equipment. It also ensures that stakeholder input was given the serious attention directed by statute.

The NIOSH 2004 Alert and subsequent guidelines are, by design, best practices for preventing occupational exposures to hazardous drugs and do not factor other important issues such as access to medications and health care services. The department's regulations are to be mandatory minimum standards and under the statute's direction, other impacts identified by stakeholders must be considered by the department in adopting the rule. In particular, stakeholders identified limited circumstances where a strict requirement to prepare all hazardous drugs in a ventilated cabinet could have unintended consequences on the access to medications and health care services and that appropriate alternative precautions could be used to protect employees from hazardous drug exposures. Based on this input, the department worked with stakeholders to identify the following circumstances where alternative precautions may be used: where the employer's hazard assessment determines there is a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents and where the employer can document a clinical need such as a nonroutine provision of chemotherapy treatment in a remote area where facilities equipped with ventilated cabinets are not readily available and it is in the best interest of the patient to provide local care. The limited use of alternative precautions is consistent with provisions of the NIOSH 2008 guideline "Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs", which discusses the limited use

of personal protective equipment as alternative precautions in circumstances where engineering controls are not available or practical.

II. Comparison Between the Proposed Rule and the Adopted Rule (see Table 1 below)

A. Medical Surveillance

NIOSH has informed the department that it is in the process of significantly changing the recommendation for medical surveillance and anticipates revised guidelines on this issue to be published in 2012. NIOSH has received feedback on the large range of variability of the routine laboratory tests included in their current guidelines and the general lack of ability of these tests to detect adverse health effects caused by hazardous drugs. At this time, there are no useful biomarkers that can be applied to hazardous drug exposures. In addition, NIOSH is looking at the efficacy of routine use of reproductive and general health questionnaires in providing guidance concerning adverse health effects caused by hazardous drug exposures. Many stakeholders urged the department to delay the medical surveillance section of the rules until the changes are made to ensure the department's rules are consistent with and will not exceed NIOSH. The department agreed that it was appropriate to wait until NIOSH has revised its medical surveillance guidelines. Once NIOSH's revised recommendations are published, additional rulemaking will be considered, if necessary.

B. Communication with stakeholders on the discussion draft

The department received many thoughtful comments on the proposed rule prior to the scheduled public hearings. Based on these comments and in the interest of communication and transparency, the department decided to broadly circulate a discussion draft that illustrated possible changes to the proposed rule that might be responsive to many of the comments received up to that point. The department specifically stated that no decisions regarding changes to the proposed rule language would be made until the public comment period closed and all public comments were received and considered. The department clearly communicated there were no changes to the proposed rule as published and that the proposed rule would be presented and considered at the public hearings.

C. Variance between the proposed rule and the adopted rule

Under the APA, an agency is required to consider public comments on a proposed rule and make any changes is thinks necessary to the proposed rule. RCW 34.05.325. While some changes are anticipated in response to the comments or to correct problems identified by the agency itself, the APA directs agencies not to adopt a rule that is "substantially different" than the proposed rule. RCW 34.05.340(1). In determining whether an adopted rule is substantially different than the proposed rule, the following factors are considered:

(a) The extent to which a reasonable person affected by the adopted rule would have understood that the published proposed rule would affect his or her interests;

(b) The extent to which the subject of the adopted rule or the issues determined in it are substantially different from the subject or issues involved in the published proposed rule; and

(c) The extent to which the effects of the adopted rule differ from the effects of the published proposed rule.
RCW 34.04. 340(2).

In applying these factors, it is clear that the changes between the department's adopted rule and the proposed rule are not substantially different. The changes between the proposed rule and the adopted rule are specifically responsive to public comment; primarily to clarify requirements and to ensure the rule is consistent with and not exceeding NIOSH guidelines. With the exception of the medical surveillance provisions discussed above, there were no substantive changes between the elements covered in the adopted rule and the proposed rules, as both rules address the following: hazardous drugs control program; a hazard assessment; engineering controls; personal protective equipment; safe handling practices; cleaning, housekeeping, and waste handling; spill control; and training. When compared to the proposed rules, the subject matter and issues addressed in the final rule are the same, the final rule does not affect additional or different stakeholders than the proposed rule, and the effects of the final rule are consistent with the effects of the proposed rule. The differences between the proposed and adopted rule are the type of changes that the APA anticipates and good public policy encourages. The public comments speak to the merits of the rule as adopted, as well as the merits of the proposed rule. This demonstrates that the proposed rule adequately communicated to stakeholders the possible contents of the rule as adopted and that the stakeholders understood the proposed rule might be altered to the degree contained in the adopted rule.

Table 1. Comparison Between the Proposed Rule and the Adopted Rule

102 DOSH Rule Language	103 DOSH Rule Language
WAC 296-62-500 Hazardous drugs.	**WAC 296-62-500 Hazardous drugs.**
This rule provides minimum requirements for developing a hazardous drugs control program; enabling employers to provide effective, assessment-based precautions designed to minimize or eliminate occupational exposure.	This ~~rule~~ chapter provides minimum requirements for developing a hazardous drugs control program when occupational exposure to hazardous drugs is reasonably anticipated. ~~enabling employers~~ It is designed to provide effective, assessment-based precautions ~~designed~~ to minimize or eliminate occupational exposure to hazardous drugs.
Important: Hazardous drugs are covered under WAC 296-800-170, Employer chemical hazard communication--Introduction. In addition the employer must follow the requirements in WAC 296-800-160 and chapter 296-842 WAC as related to the provision of personal protective equipment and respiratory protection. Whenever there is a conflict between rule requirements the most protective requirement will take precedent.	**Important:** ~~Hazardous~~ Occupational exposure to hazardous drugs ~~are~~ is also covered under WAC-296-800-170 WAC, Employer chemical hazard communication—Introduction. In addition the employer must follow the requirements in WAC 296-800-160, Personal protective equipment (PPE) and chapter 296-842 WAC, Respirators ~~as related to the provision of personal protective equipment and respiratory protection~~. Whenever there is a conflict between rule requirements the most protective requirement will take precedent.
WAC 296-62-50005 Scope.	**WAC 296-62-50005 Scope.**
(1) This chapter applies to all health care settings that have employees with occupational exposure to hazardous drugs.	(1) This chapter applies to all employers in health care ~~settings~~ facilities regardless of the setting that have employees with occupational exposure to hazardous drugs.
	(2) Chapter application.
	(2)(a) The requirements in this rule only apply to the hazardous drugs being used in the workplace.
	(2)(b) If hazardous drugs are being used in the workplace the requirements in this rule only apply if there is reasonably anticipated exposure as defined in WAC 296-62- 50010.
	(2)(c) If there is reasonably anticipated occupational exposure to one or more hazardous drugs, the employer must develop a hazardous drugs control program as required in WAC 296-62-

	50015.
	(2)(d) For purposes of making the determinations in this section about scope and application, occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.
(2) The following lists jobs that may involve occupational exposure to hazardous drugs. This is not an exhaustive list and there may be other jobs that fall within the scope of this chapter: • Physicians and physician assistants; • Nurses (ARNPs, RNs, LPNs, nurses aids); • Patient care assistive personnel (nurses aides or technicians); • Operating room personnel; • Employees in research laboratories; • Home health care workers; • Veterinarians and veterinary technicians; • Pharmacists and pharmacy technicians; • Environmental services employees (e.g., housekeeping, laundry, and waste disposal) in health care settings; • Employees who ship, or receive hazardous drugs from the manufacturer or distributor.	~~(2)~~ (3)The following lists jobs that may involve occupational exposure to hazardous drugs. This is not an exhaustive list and there may be other jobs that fall within the scope of this chapter: • Pharmacists and pharmacy technicians.~~;~~ • Physicians and physician assistants~~;~~. • Nurses (ARNPs, RNs, LPNs~~, nurses aids~~)~~;~~. • Patient care assistive personnel (e.g. health care assistants, nursing assistants ~~nurses aides or technicians~~)~~;~~. • Operating room personnel~~;~~. ~~• Employees in research laboratories;~~ • Home health care workers~~;~~. • Veterinarians and veterinary technicians~~;~~. ~~• Pharmacists and pharmacy technicians;~~ • Environmental services employees (e.g., housekeeping, laundry, and waste disposal) in health care ~~settings~~ facilities.~~;~~ • Employees in health care facilities who ship, or receive hazardous drugs from the manufacturer or distributor.
Exemption: This chapter does not apply to the drug manufacturing sector.	~~**Exemption:** This chapter does not apply to the drug manufacturing sector.~~
WAC 296-62-50010 Definitions.	**WAC 296-62-50010 Definitions.**
Biological safety cabinet means a ventilated cabinet for compounding pharmaceutical ingredients, personnel, product, and environmental protection having an open	**Biological safety cabinet** means a ventilated cabinet for compounding pharmaceutical ingredients, personnel, product, and environmental protection having an open front with inward

front with inward airflow for personnel protection, downward high-efficiency air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. For a complete description of the different types of biologic safety cabinets see the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets*.	airflow for personnel protection, downward high-efficiency air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. For a complete description of the different types of biologic safety cabinets see the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets*.
Chemotherapy glove means a medical glove that has been approved by the Food and Drug Administration (FDA) and that meets the permeability standards of the American Society for Testing Materials (ASTM) Standard D6978 - 05.	**Chemotherapy glove** means a medical glove that has been approved by the Food and Drug Administration (FDA) and that meets the permeability standards of the American Society for Testing Materials (ASTM) Standard D6978 - 05.
Closed system drug-transfer device means a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system.	**Closed system drug-transfer device** means a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system.
Compounding aseptic containment isolator means a compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA at a minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.	~~**Compounding aseptic containment isolator** means a compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA at a minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.~~
Compounding aseptic isolator means a form of isolator	~~**Compounding aseptic isolator** means a form of isolator~~

specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).	~~specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).~~
Contaminated means materials or surfaces that have been in direct contact with a hazardous drug. Urine, fecal matter, vomit, blood, or bodily fluids from patients receiving certain hazardous drugs are considered contaminated for a minimum of forty-eight hours after administration. Containers that have held contaminated urine, fecal matter, vomit, blood, or other bodily fluids are considered contaminated until cleaned and decontaminated.	~~**Contaminated** means materials or surfaces that have been in direct contact with a hazardous drug. Urine, fecal matter, vomit, blood, or bodily fluids from patients receiving certain hazardous drugs are considered contaminated for a minimum of forty-eight hours after administration. Containers that have held contaminated urine, fecal matter, vomit, blood, or other bodily fluids are considered contaminated until cleaned and decontaminated.~~
Deactivation means treating a chemical agent (such as a hazardous drug) with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.	~~**Deactivation** means treating a chemical agent (such as a hazardous drug) with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.~~
Decontamination means inactivation, neutralization, or removal of toxic agents, usually by chemical means.	**Decontamination** means inactivation, neutralization, or removal of toxic agents, usually by chemical means.
Engineering controls means devices designed to eliminate or reduce worker exposure to hazards. Examples include biological safety cabinets, containment isolators, safer sharps devices, and safety interlocks.	**Engineering controls** means devices designed to eliminate or reduce worker exposure to hazards. Examples include biological safety cabinets, <u>laboratory fume hoods,</u> containment isolators, safer sharps devices, and safety interlocks.
Hazardous drugs means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of the following six criteria: • Carcinogenicity; • Teratogenicity or developmental toxicity; • Reproductive toxicity in humans;	**Hazardous drugs** means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control <u>(CDC)</u> or any drug that meets at least one of the following six criteria: • Carcinogenicity~~;~~<u>.</u> • Teratogenicity or developmental toxicity~~;~~<u>.</u> • Reproductive toxicity in humans~~;~~<u>.</u>

• Organ toxicity at low doses in humans or animals; • Genotoxicity; • New drugs that mimic existing hazardous drugs in structure and toxicity.	• Organ toxicity at low doses in humans or animals~~;~~. • Genotoxicity~~;~~. • New drugs that mimic existing hazardous drugs in structure and toxicity.
Health care settings means all hospitals, medical clinics, outpatient facilities, physicians' offices, retail pharmacies, home health care, veterinary clinics, and similar settings dedicated to the care of patients.	**Health care ~~settings~~ facilities** means all hospitals, ~~medical~~ clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes ~~outpatient facilities, physicians' offices, retail pharmacies, home health care,~~ veterinary ~~clinics,~~ medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients. ~~and similar settings dedicated to the care of patients~~.
HEPA filter means a high-efficiency particulate air filter rated ninety-nine and ninety-seven percent efficient in capturing 0.3-micron-diameter particles.	**HEPA filter** means a high-efficiency particulate air filter rated 99.97% efficient in capturing 0.3-micron-diameter particles.
	Isolator means a device that is sealed or is supplied with air through a microbially retentive filtration system (HEPA minimum) and may be reproducibly decontaminated. When closed, an isolator uses only decontaminated interfaces (when necessary) or rapid transfer ports (RTPs) for materials transfer. When open, it allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contaminants or unfiltered air to adjacent environments. An isolator can be used for aseptic processing, for containment of potent compounds, or for simultaneous asepsis and containment. Some isolator designs

	allow operations within the isolator to be conducted through attached rubber gloves without compromising asepsis and/or containment. **Aseptic isolator:** A ventilated isolator designed to exclude external contamination from entering the critical zone inside the isolator. **Aseptic containment isolator:** A ventilated isolator designed to meet the requirements of both an aseptic isolator and a containment isolator. **Containment isolator:** A ventilated isolator designed to prevent the toxic materials processed inside it from escaping to the surrounding environment.
Material safety data sheet (MSDS) means a summary provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which workers can protect themselves from exposure to these chemicals.	**Material safety data sheet (MSDS)** means a summary provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which workers can protect themselves from exposure to these chemicals.
Occupational exposure means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties. Factors that affect worker exposure include: • Drug handling circumstances (preparation, administration, or disposal); • Amount of drug prepared; • Frequency and duration of drug handling; • Potential for absorption; • Use of ventilated cabinets; • Personal protective equipment; • Work practices.	**Occupational exposure** means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties. ~~Factors that affect worker exposure include:~~ ~~• Drug handling circumstances (preparation, administration, or disposal);~~ ~~• Amount of drug prepared;~~ ~~• Frequency and duration of drug handling;~~ ~~• Potential for absorption;~~ ~~• Use of ventilated cabinets;~~ ~~• Personal protective equipment;~~ ~~• Work practices.~~ ~~The likelihood that a worker will experience adverse effects~~

The likelihood that a worker will experience adverse effects from hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices.	~~from hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices.~~ Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).
Ventilated cabinet means a type of engineering control designed for purposes of worker protection. These devices are designed to minimize worker exposures by controlling emissions of airborne contaminants through the following: • The full or partial enclosure of a potential contaminant source; • The use of airflow capture velocities to capture and remove airborne contaminants near their point of generation; • The use of air pressure relationships that define the direction of airflow into the cabinet. Examples of ventilated cabinets include biological safety cabinets and containment isolators.	**Ventilated cabinet** means a type of engineering control designed for purposes of worker protection. These devices are designed to minimize worker exposures by controlling emissions of airborne contaminants through the following: • The full or partial enclosure of a potential contaminant source~~;~~. • The use of airflow capture velocities to capture and remove airborne contaminants near their point of generation~~;~~. • The use of air pressure relationships that define the direction of airflow into the cabinet. Examples of ventilated cabinets include biological safety cabinets and containment isolators.
WAC 296-62-50015 Hazardous drugs control program.	**WAC 296-62-50015 Hazardous drugs control program.**
(1) By July 1, 2012 each health care setting shall develop and implement a written hazardous drugs control program specific to the workplace. The hazardous drugs control program must, at a minimum, include the following:	(1) ~~By July 1, 2012 each~~ Each health care ~~setting~~ facility ~~shall~~ covered under the scope of this chapter must develop and implement a written hazardous drugs control program ~~specific to the workplace~~. ~~The~~ Elements of the hazardous drugs control program may be located in other documents such as the employer's accident prevention program or other policies and procedures as long as they are referenced in the program. The hazardous drugs control program must, at a minimum, include the following:

(1) (a) A current hazard assessment;	(1) (a) ~~A current hazard assessment;~~ A written inventory of hazardous drugs in the workplace.
(1) (b) A written inventory of hazardous drugs in the workplace;	(1) (b) ~~A written inventory of hazardous drugs in the workplace;~~ A current hazard assessment for hazardous drugs for which there is reasonably anticipated occupational exposure.
(1) (c) A description of the hazardous drugs training program;	~~(1) (c) A description of the hazardous drugs training program;~~
(1) (d) Hazardous drugs policies and procedures including, but not limited to:	~~(1) (d)~~ (1)(c) Hazardous drugs policies and procedures including, but not limited to:
(1)(d) (i) Personal protective equipment;	~~(1)(d) (i) Personal protective equipment;~~ (1)(c)(i) Engineering controls (equipment use and maintenance).
(1)(d) (ii) Engineering controls (equipment use and maintenance);	~~(1)(d) (ii) Engineering controls (equipment use and maintenance);~~ (1)(c)(ii) Personal protective equipment.
(1)(d) (iii) Safe handling practices (receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs);	(1)(~~d~~c) (iii) Safe handling practices (receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs)~~;~~.
(1)(d) (iv) Cleaning, housekeeping, and waste handling;	(1)(~~d~~c) (iv) Cleaning, housekeeping, and waste handling~~;~~.
(1)(d) (v) Spill control;	(1)(~~d~~c) (v) Spill control~~;~~.
(1)(d) (vi) Medical surveillance;	~~(1)(d) (vi) Medical surveillance;~~
(1)(d) (vii) Personnel issues (such as exposure of pregnant workers);	(1)(~~d~~c) (vi~~i~~) Personnel issues (such as exposure of pregnant workers)~~;~~.
(1)(d) (viii) Training;	(1)(~~d~~c) (vii~~i~~) Training~~;~~.
(1)(d) (ix) Recordkeeping.	~~(1)(d) (ix) Recordkeeping.~~
Note: Elements of the hazardous drugs control program may be located in other documents such as the employer's accident prevention program or other policies and procedures as long as they are referenced in the program.	~~**Note:** Elements of the hazardous drugs control program may be located in other documents such as the employer's accident prevention program or other policies and procedures as long as they are referenced in the program.~~
Reference: Refer to the most current **NIOSH list of antineoplastic and other hazardous drugs in healthcare settings** for guidance on developing and maintaining a hazardous drugs list.	~~**Reference:** Refer to the most current **NIOSH list of antineoplastic and other hazardous drugs in healthcare settings** for guidance on developing and maintaining a hazardous drugs list.~~

	(2) A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to a variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.
(2) Review and update the written hazardous drugs control program on at least an annual basis and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices.	(~~2~~3) Review and update the written hazardous drugs control program ~~on at least an annual basis~~ annually and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices.
(3) Seek input from employees who handle hazardous drugs and from other employees who may be exposed to hazardous drugs as a result of the performance of their duties regarding the quality and effectiveness of the hazardous drugs control program.	(~~3~~4) Seek and consider input from employees who ~~handle hazardous drugs and from other employees~~ may be exposed to hazardous drugs as a result of the performance of their duties regarding the quality and effectiveness of the hazardous drugs control program.
WAC 296-62-50020 Hazard assessment.	**WAC 296-62-50020 Hazard assessment.**
(1) Each health care setting must conduct initial and at least annual hazard assessments in order to determine the appropriate protective actions to be taken.	(1) Each health care ~~setting~~ facility covered under the scope of this chapter must conduct ~~initial and at least annual~~ hazard assessments in order to determine the appropriate ~~protective actions~~ precautions to be taken. These assessments may be limited to the hazardous drugs for which there is reasonably anticipated occupational exposure.
(2) The assessment must include, but is not limited to, the following:	(2) ~~The assessment~~ Assessments must include~~, but is not limited to,~~ the following elements as appropriate:
(2) (a) Total working environment;	(2) (a) ~~Total working environment;~~ Personal protective equipment.
(2) (b) Equipment (i.e., ventilated cabinets, closed-system drug transfer devices, glovebags, needleless systems, and	(2) (b) ~~Equipment~~ Engineering controls (~~i.e.,~~ e.g., ventilated cabinets, closed-system drug transfer devices, glovebags, and

personal protective equipment);	needleless systems~~, and personal protective equipment);~~).
(2) (c) Physical layout of work areas;	(2) (c) Physical layout of work areas~~;~~.
(2) (d) Types of drugs being handled;	(2) (d) Types of hazardous drugs being handled~~;~~ .
(2) (e) Volume, frequency, and form of drugs handled (tablets, coated versus uncoated, powder versus liquid);	(2) (e) Volume, frequency, packaging and form of hazardous drugs handled (tablets, coated versus uncoated, powder versus liquid)~~;~~.
(2) (f) Equipment maintenance;	(2) (f) Equipment maintenance~~;~~.
(2) (g) Decontamination and cleaning;	(2) (g) Decontamination and cleaning~~;~~.
(2) (h) Waste handling;	(2) (h) Waste handling~~;~~.
(2) (i) Potential exposures during work, including hazardous drugs, bloodborne pathogens, and chemicals used to deactivate hazardous drugs or to clean drug-contaminated surfaces;	(2) (i) Potential hazardous drug exposures during work operations, ~~including hazardous drugs, bloodborne pathogens, and chemicals used to deactivate hazardous drugs or to clean drug-contaminated surfaces;~~ such as drug preparation and administration.
(2) (j) Routine operations;	~~(2) (j) Routine operations;~~
(2) (k) Spill response;	(2) (~~k~~j) Spill response~~;~~.
(2) (l) Waste segregation, containment, and disposal.	~~(2) (l) Waste segregation, containment, and disposal.~~
	(3) Conduct a hazard assessment as part of the hazardous drugs control program update and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices.
	Note: The likelihood that a worker will experience adverse effects from exposure to hazardous drugs varies depending upon the relative toxicity and absorptive properties of a drug, the amount, duration and frequency of contact, and the lack of proper work precautions.
WAC 296-62-50025 Personal protective equipment (PPE).	**WAC 296-62-~~50025~~ 50030 Personal protective equipment (PPE).**
(1) Conduct a PPE hazard assessment and provide appropriate PPE at no cost to employees.	(1) When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct ~~Conduct~~ a PPE ~~hazard~~ assessment and provide and ensure use of appropriate PPE ~~at no cost to employees.~~ in accordance with WAC 296-800-

	160, Personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.
	(2) Use appropriate PPE whenever handling body fluids and contaminated laundry.
(2) Gloves.	(~~2~~3) Gloves.
(2) (a) Wear appropriate gloves when handling hazardous drugs or when there is potential contact with hazardous drug contaminated materials or surfaces.	~~(2) (a) Wear appropriate gloves when handling hazardous drugs or when there is potential contact with hazardous drug contaminated materials or surfaces.~~
(2) (b) Use powder-free chemotherapy gloves when handling chemotherapy drugs or when there is potential contact with chemotherapy contaminated items or surfaces.	~~(2) (b)~~ (3)(a)Use powder-free chemotherapy gloves when handling chemotherapy drugs or when there is potential contact with chemotherapy contaminated items or surfaces.
Note: Consider using chemotherapy gloves for hazardous drugs that are not chemotherapy drugs or for which no information is available.	~~Note: Consider using chemotherapy gloves for hazardous drugs that are not chemotherapy drugs or for which no information is available.~~
(2) (c) Provide latex-free gloves to employees with latex sensitivities.	~~(2) (c)~~ (3)(b) Provide latex-free gloves to employees with latex sensitivities.
(2) (d) Wear two pairs of gloves whenever there is a risk of exposure to hazardous drugs, e.g., during compounding, administering, handling contaminated bodily fluids and linens, and cleaning up hazardous drug spills.	~~(2) (d)~~ (3)(c) Wear two pairs of gloves ~~whenever~~ when there is a significant risk of breakage or contamination or permeation, ~~exposure to hazardous drugs,~~ e.g., during compounding, extended handling periods, ~~administering, handling contaminated bodily fluids and linens~~, and cleaning up large hazardous drug spills.
(2) (e) Make sure that the outer glove extends over the cuff of the gown.	~~(2) (e) Make sure that the outer glove extends over the cuff of the gown.~~
(2) (f) Instruct all employees to inspect gloves for physical defects before use.	~~(2) (f) Instruct all employees to inspect gloves for physical defects before use.~~
(2)(g) Change gloves every thirty minutes or when torn, punctured, or contaminated.	~~(2)(g)~~ (3)(d) Change gloves every thirty to sixty minutes or when torn, punctured, or contaminated.
Note: Glove thickness cannot be relied upon as the sole determination of protection. It is important to evaluate test information provided by the glove manufacturer and other research that demonstrates permeation resistance to the	~~Note: Glove thickness cannot be relied upon as the sole determination of protection. It is important to evaluate test information provided by the glove manufacturer and other research that demonstrates permeation resistance to the~~

specific hazardous drug being handled.	~~specific hazardous drug being handled.~~
(3) Protective clothing.	(~~3~~4) Protective clothing.
(3) (a) Wear gowns whenever there is the possibility of a splash or spill, or contact with contaminated materials or surfaces, including opening drug packages, handling vials or finished products, labeling hazardous drug containers, disposal of waste and all activities associated with drug administration.	(~~3~~4) (a) Wear gowns whenever there is ~~the~~ a reasonable possibility of a hazardous drug splash or spill such as in compounding, preparing and administering hazardous drugs. ~~, or contact with contaminated materials or surfaces, including opening drug packages, handling vials or finished products, labeling hazardous drug containers, disposal of waste and all activities associated with drug administration.~~
(3) (b) Wear gowns made of polyethylene-coated polypropylene or other protective material as determined by the PPE hazard assessment. Make sure the gown has a closed front, long sleeves, and elastic or knit cuffs.	(~~3~~4) (b) Wear gowns made of polyethylene-coated polypropylene or other nonabsorbent, nonlinting protective material as determined by the PPE hazard assessment. Make sure the gown has a closed front, long sleeves, and elastic or knit cuffs.
(3) (c) Remove and dispose of gowns at the end of drug handling activities, when leaving the drug handling area and as soon as possible when damaged or contaminated.	(~~3~~4) (c) Remove and dispose of gowns at the end of hazardous drug handling activities, when leaving the hazardous drug handling area and as soon as possible when damaged or contaminated.
(3) (d) If no permeation information is available, change gowns every two to three hours.	(~~3~~4) (d) If no permeation information is available, change gowns every two to three hours or when contaminated after a splash or spill.
(4) Face protection. Wear a full-face shield when splashes to the eyes, nose, or mouth may occur. Examples include cleaning a spill or performing a procedure such as bladder instillation.	~~(4)~~ (5) Face protection. Wear a full-face shield or a mask and eye protection as appropriate when splashes to the eyes, nose, or mouth may occur~~. Examples~~; examples include cleaning a spill or performing a procedure such as bladder instillation.
(5) Respiratory protection.	(~~5~~6) Respiratory protection.
(5) (a) Use N95 or equivalent respiratory protection during spill clean up and whenever there is risk of exposure to hazardous drug particulates.	(~~5~~6) (a) Use N95 or equivalent respiratory protection during spill clean up and whenever there is a significant risk of inhalation exposure to hazardous drug particulates.
(5) (b) Use an appropriate full-facepiece chemical cartridge-type respirator whenever there is a significant risk of exposure to hazardous drug vapors or gases (e.g., for	(~~5~~6) (b) Use an appropriate ~~full-facepiece~~ chemical cartridge-type respirator ~~whenever there is a significant risk of exposure to hazardous drug vapors or gases (e.g.,~~ for events such as large

events such as large spills when an intravenous (IV) bag breaks or a line disconnects and leaks).	spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects ~~and leaks)~~.
(6) Dispose of PPE immediately after use or whenever contaminated.	(~~6~~7) ~~Dispose of~~ Disposable PPE must be discarded into appropriate containers immediately after use or as soon as feasible after contamination. Reusable PPE must be properly cleaned and decontaminated after use or ~~whenever contaminated~~ contamination.
WAC 296-62-50030 Engineering controls.	**WAC 296-62-~~50030~~ 50025 Engineering controls.**
(1) Use engineering controls to eliminate or minimize employee exposure to hazardous drugs. Examples of engineering controls include, but are not limited to:	(1)Evaluate and implement appropriate ~~Use~~ engineering controls to eliminate or minimize employee exposure ~~to hazardous drugs~~. Examples of engineering controls include, but are not limited to:
(1) (a) Biologic safety cabinets;	~~(1) (a) Biologic safety cabinets;~~
(1) (b) Containment isolators;	~~(1) (b) Containment isolators;~~
(1) (c) Closed system transfer devices;	(1) (~~c~~a) Closed system transfer devices~~;~~.
(1) (d) Safer sharps devices;	(1) (~~d~~b) Safer sharps devices~~;~~.
(1) (e) Safety interlocks.	(1) (~~e~~c) Safety interlocks.
	(1)(d) Ventilated cabinets.
(2) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.	~~(2) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.~~
(3) General ventilation. Make sure that storage areas have sufficient general exhaust ventilation to dilute and remove airborne contaminants.	~~(3) General ventilation. Make sure that storage areas have sufficient general exhaust ventilation to dilute and remove airborne contaminants.~~
Note: Depending on the physical nature and quantity of the stored drugs, consider installing a dedicated emergency exhaust fan that is large enough to quickly purge airborne contaminants from the storage room in the event of a spill and prevent contamination in adjacent areas.	~~**Note:** Depending on the physical nature and quantity of the stored drugs, consider installing a dedicated emergency exhaust fan that is large enough to quickly purge airborne contaminants from the storage room in the event of a spill and prevent contamination in adjacent areas.~~
(4) Ventilated cabinets.	~~(4)~~ (2)Ventilated cabinets.
(4) (a) Prepare (mix, compound, crush, pour liquid) hazardous drugs inside an appropriate ventilated cabinet	~~(4)~~(2) (a) Prepare (e.g., mix, compound, crush~~, pour liquid~~) hazardous drugs inside an appropriate ventilated cabinet

designed to prevent release into the work environment.	designed to prevent release into the work environment. When asepsis is not required, a Class I biosafety cabinet or isolator intended for containment applications may be sufficient.
(4) (b) When selecting ventilated cabinets based on the need for aseptic processing make sure to use ventilated cabinets designed for both hazardous drug containment and aseptic processing. When asepsis is not required, a Class I biosafety cabinet or isolator intended for containment applications may be sufficient.	(2)(a)(i) Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g., crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.~~(4) (b) When selecting ventilated cabinets based on the need for aseptic processing make sure to use ventilated cabinets designed for both hazardous drug containment and aseptic processing. When asepsis is not required, a Class I biosafety cabinet or isolator intended for containment applications may be sufficient.~~
(4) (c) Do not use supplemental engineering or process controls (such as needleless systems, glovebags, and closed system drug transfer devices) as a substitution for ventilated cabinets.	(2)(a)(ii) Chemotherapy drugs must be prepared in an appropriate ventilated cabinet with the exception of circumstances where the employer can document evidence of a clinical need (eg., there is a nonroutine need to provide chemotherapy treatment, compounding services are not readily available, and it is in the best interest of the patient to provide local care). In such circumstances alternate precautions must be instituted as described above. ~~(4) (c) Do not use supplemental engineering or process controls (such as needleless systems, glovebags, and closed system drug transfer devices) as a substitution for ventilated cabinets.~~
(4) (d) Equip ventilated cabinets with a continuous monitoring device to confirm adequate airflow before each use.	~~(4) (d)~~ (2)(b)Equip ventilated cabinets with a continuous monitoring device to confirm adequate airflow before each use.
(4) (e) Use a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one hundred percent of the filtered air to the outside.	~~(4) (e)~~ (2)(c) Use filtering media that is approved by the cabinet manufacturer and is appropriate for the agent being captured, such as a high-efficiency particulate air filter (HEPA filter) for

	exhaust, and where feasible, exhaust ~~one~~ one-hundred percent of the filtered air to the outside unless the employer can provide an evidence-based justification to do otherwise.
(4) (f) Install the outside exhaust so that the exhausted air is not pulled back into the building by the heating, ventilating, and air conditioning systems or by the windows, doors, or other points of entry.	~~(4) (f)~~ (2)(d) Install the outside exhaust so that the exhausted air is not pulled back into the building by the heating, ventilating, and air conditioning systems or by the windows, doors, or other points of entry.
(4) (g) Place fans downstream of the HEPA filter so that contaminated ducts are maintained under negative pressure.	~~(4) (g)~~ (2)(e) Place fans downstream of the filter so that contaminated ducts are maintained under negative pressure.
(4) (h) Do not use a ventilated cabinet that recirculates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the HEPA filter.	~~(4) (h)~~ (2)(f) Do not use a ventilated cabinet that recirculates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the ~~HEPA~~ filter.
(4) (i) Develop and implement maintenance and cleaning procedures that ensure the effectiveness and safety of the ventilated cabinet.	~~(4) (i)~~ (2)(g)Develop and implement maintenance and cleaning procedures that ensure the effectiveness and safety of the ventilated cabinet.
(4)(i) (i) Field-certify biosafety cabinet performance, in accordance with National Sanitation Foundation/American National Standards Institute Standard 49, after installation, relocation, maintenance, repairs to internal components, HEPA filter replacement, and every six months thereafter.	~~(4)(i)~~(2)(g) (i) Field-certify biosafety cabinet performance, in accordance with National Sanitation Foundation/American National Standards Institute Standard 49, after installation, relocation, maintenance, repairs to internal components, HEPA filter replacement, and every six months thereafter or as recommended by the manufacturer.
(4)(i) (ii) Select appropriate performance and test methods for containment isolators, at a minimum, conduct leak and containment integrity tests in accordance with current American Glovebox Society guidelines. In addition perform a HEPA filter leak test for those containment isolators that utilize HEPA filtration.	~~(4)(i)~~ (2)(g)(ii) Select appropriate performance and test methods for ~~containment~~ isolators, depending on the type (containment-only or aseptic containment), the operating pressure (positive or negative and designed magnitude), and toxicity of the hazardous drug. ~~at~~ At a minimum, conduct leak and containment integrity tests in accordance with current American Glovebox Society guidelines. In addition perform a HEPA filter leak test for those ~~containment~~ isolators that utilize

	HEPA filtration.
(4)(i) (iii) Prominently display a current field-certification label on the ventilated cabinet.	~~(4)(i)~~ (2)(g)(iii) Prominently display a current field-certification label on the ventilated cabinet.
(4)(i) (iv) Make sure that workers performing maintenance are familiar with applicable safety procedures, warned about hazards, and trained in appropriate work techniques and PPE needed to minimize exposure.	~~(4)(i)~~ (2)(g)(iv) Make sure that workers performing maintenance are familiar with applicable safety procedures, warned about hazards (e.g., through the provision of material safety data sheet or other equivalent information resources), and trained in appropriate work techniques and PPE needed to minimize exposure.
(4)(i) (v) Remove all hazardous drugs and chemicals, and decontaminate the ventilated cabinet before beginning maintenance activities.	~~(4)(i)~~ (2)(g)(v) Remove all hazardous drugs and chemicals, and decontaminate the ventilated cabinet before beginning maintenance activities.
(4)(i) (vi) Notify occupants in the affected areas immediately before the maintenance activity begins, and place warning signs on all affected equipment.	~~(4)(i)~~ (2)(g)(vi) Notify occupants in the affected areas immediately before the maintenance activity begins, and place warning signs on all affected equipment.
(4)(i) (vii) Deenergize the ventilated cabinet in accordance with chapter 296-803 WAC, Lockout/Tagout (control of hazardous energy).	~~(4)(i)~~ (2)(g)(vii) De-energize the ventilated cabinet in accordance with chapter 296-803 WAC, Lockout/Tagout (control of hazardous energy).
(4)(i) (viii) Decontaminate and bag equipment parts removed for replacement or repair before they are taken outside the facility.	~~(4)(i)~~ (2)(g)(viii) Decontaminate and bag equipment parts removed for replacement or repair before they are taken outside the facility.
(4)(i) (ix) Seal used filtration media in plastic immediately upon removal, and dispose as contaminated waste.	~~(4)(i)~~ (2)(g)(ix) Seal used filtration media in plastic immediately upon removal, and dispose as contaminated waste.
(5) Institution of effective ventilation controls must be accomplished by December 1, 2012.	~~(5) Institution of effective ventilation controls must be accomplished by December 1, 2012.~~
Note: Consult the following documents for performance test methods and selection criteria for ventilated cabinets: (a) *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets (CDC/NIH).* (b) *NSF/ANSI 49, Class II (laminar flow) Biosafety Cabinetry.*	**Note:** Consult the following documents for performance test methods and selection criteria for ventilated cabinets: (~~a~~1) *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets (CDC/NIH).* (~~b~~2) *NSF/ANSI 49, Class II (laminar flow) Biosafety Cabinetry.*
WAC 296-62-50035 Safe handling practices.	**WAC 296-62-50035 Safe handling practices.**
(1) Receiving and storage.	(1) Receiving and storage.

(1) (a) Make sure that all hazardous drug containers received from the manufacturer, distributor, another pharmacy, or medical clinic are labeled.	~~(1) (a) Make sure that all hazardous drug containers received from the manufacturer, distributor, another pharmacy, or medical clinic are labeled.~~
(1) (b) At a minimum wear appropriate gloves when opening and unpacking shipping containers, and transporting hazardous drugs.	~~(1) (b) At a minimum wear appropriate gloves when opening and unpacking shipping containers, and transporting hazardous drugs.~~
(1) (c) Store hazardous drugs separately from other drugs, and in a manner that minimizes the potential for spills.	~~(1) (c) Store hazardous drugs separately from other drugs, and in a manner that minimizes the potential for spills.~~
(1) (d) Prohibit the use of unventilated areas for drug storage.	~~(1) (d) Prohibit the use of unventilated areas for drug storage.~~
(1) (e) Transport hazardous drugs in closed containers that minimize the risk of breakage.	~~(1) (e) Transport hazardous drugs in closed containers that minimize the risk of breakage.~~
(2) Labeling.	~~(2) Labeling.~~
(2) (a) Label hazardous drug containers in accordance with WAC 296-800-170, Employer chemical hazard communication.	(~~2~~1) (a) Label hazardous drug containers in accordance with WAC 296-800-170, Employer chemical hazard communication-- Introduction.
(2) (b) Label pharmaceutical waste containers in accordance with WAC 173-303-200, Accumulating dangerous waste on-site. See the Washington state department of ecology pharmaceutical waste web site for more information.	(~~2~~1) (b) ~~Label pharmaceutical waste containers in accordance with WAC 173-303-200, Accumulating dangerous waste on-site. See the Washington state department of ecology pharmaceutical waste web site for more information.~~ Store and transport hazardous drugs in a manner that minimizes the risk of breakage.
(3) Preparing.	(~~3~~2) ~~Preparing~~ Preparation and Administration.
(3) (a) Provide work areas that are devoted solely to preparing hazardous drugs and limited to authorized personnel.	(~~3~~2) (a) Provide designated work areas ~~that are devoted solely to~~ for the ~~preparing~~ preparation of hazardous drugs and ~~limited to authorized personnel~~ limit access during preparation.
(3) (b) Coordinate tasks associated with preparing and administering hazardous drugs to minimize exposure risks.	(~~3~~2) (b) Coordinate tasks associated with preparing and administering hazardous drugs ~~to minimize~~ for the most effective control of worker exposure. ~~risks.~~
(3) (c) Use engineering controls such as closed-system transfer devices, glovebags, and needleless systems when transferring hazardous drugs from primary packaging	~~(3) (c) Use engineering controls such as closed-system transfer devices, glovebags, and needleless systems when transferring hazardous drugs from primary packaging (such as vials) to~~

(such as vials) to dosing equipment (such as infusion bags, bottles, or pumps).	~~dosing equipment (such as infusion bags, bottles, or pumps).~~
(3) (d) Spike and prime the IV tubing and syringes inside an appropriate ventilated cabinet, never in the patient's room.	(~~3~~2) (~~d~~c) Spike and prime the IV tubing and prepare syringes in a manner that most effectively limits occupational exposure. ~~inside an appropriate ventilated cabinet, never in the patient's room.~~
	(2) (d) Do not remove tubing from an IV bag containing a hazardous drug.
(3) (e) When drug preparation is complete, seal the final product in a clear plastic bag or other sealable container for transport before removing it from the ventilated cabinet.	(~~3~~2) (e) When drug preparation is completed ~~complete, seal the final product in a clear plastic bag or other sealable container for transport before removing it from the~~ in a ventilated cabinet~~.~~:
(3) (f) Seal and decontaminate all waste containers inside the ventilated cabinet before removing them from the ventilated cabinet.	~~(3) (f)~~ (2)(e)(i) Seal the final product in a plastic bag or other sealed container for transport before taking it out of the ~~and decontaminate all waste containers inside the ventilated cabinet before removing them from the ventilated~~ cabinet.
	(2)(e)(ii) Seal and wipe all waste containers inside the ventilated cabinet before removing them from the cabinet.
(3) (g) Remove outer gloves and sleeve covers (if used) and bag them for disposal while inside the ventilated cabinet.	~~(3) (g)~~ (2)(e)(iii) Remove all outer gloves and sleeve covers ~~(if used)~~ and bag them for disposal while inside the ~~ventilated~~ cabinet.
(4) Administering.	~~(4) Administering.~~
(4) (a) Ensure that staff has been trained and follow policies and procedures regarding the safe administration of hazardous drugs and related patient care. Examples include, but are not limited to; oral, intravenous, intramuscular or subcutaneous injections, topical, intracavitary, and aerosol administration.	~~(4) (a) Ensure that staff has been trained and follow policies and procedures regarding the safe administration of hazardous drugs and related patient care. Examples include, but are not limited to; oral, intravenous, intramuscular or subcutaneous injections, topical, intracavitary, and aerosol administration.~~
(4) (b) Use engineering controls to transfer and administer hazardous drugs.	~~(4) (b) Use engineering controls to transfer and administer hazardous drugs.~~
(4) (c) Wear appropriate personal protective equipment when administering hazardous drugs.	~~(4) (c) Wear appropriate personal protective equipment when administering hazardous drugs.~~

(4) (d) Spike and prime administration sets prior to adding the drug to the bag.	~~(4) (d) Spike and prime administration sets prior to adding the drug to the bag.~~
(4) (e) Do not remove tubing from an IV bag containing a hazardous drug.	~~(4) (e) Do not remove tubing from an IV bag containing a hazardous drug.~~
(4) (f) Do not disconnect tubing at other points in the system until the tubing has been thoroughly flushed.	~~(4) (f) Do not disconnect tubing at other points in the system until the tubing has been thoroughly flushed.~~
	(3) Waste handling.
	(3)(a) Dispose of pharmaceutical waste in accordance with applicable state and federal regulations.
(4) (g) Place contaminated waste and other disposable items directly into a designated waste container.	~~(4) (g)~~ (3)(b) Place ~~contaminated waste and other~~ disposable items ~~directly into a~~ in designated ~~waste~~ containers.
	(4) Personal hygiene.
(4) (h) Personal hygiene. Prohibit eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in work areas where hazardous drugs may be found.	(~~h~~4a) ~~Personal hygiene.~~ Prohibit eating~~,~~ or drinking~~, smoking, applying cosmetics or lip balm, and handling contact lenses~~ in ~~work~~ areas where hazardous drugs ~~may be found~~ are handled.
(5) Handwashing. Wash hands with soap and water before donning gloves, immediately after removal, and whenever hands become contaminated.	(~~5~~ b) ~~Handwashing.~~ Wash hands with soap and water before donning gloves, immediately after removal, and whenever hands become contaminated.
(6) Laundry. Place contaminated laundry in leakproof, labeled or color-coded containers.	~~(6) Laundry. Place contaminated laundry in leakproof, labeled or color-coded containers.~~
WAC 296-62-50040 Cleaning, housekeeping, and waste handling.	**WAC 296-62-50040 Cleaning~~,~~ and housekeeping~~, and waste handling~~.**
(1) Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs are present.	(1) Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs are present.
(2) Perform cleaning and decontamination work in areas that are sufficiently ventilated to prevent buildup of hazardous airborne concentrations.	(2) ~~Perform cleaning and decontamination work in areas that are sufficiently ventilated to prevent buildup of hazardous airborne concentrations~~ Do not clean contaminated equipment in unventilated areas.
(3) Clean work surfaces with an appropriate deactivation agent and cleaning agent before and after each continuous	(3) Clean work surfaces ~~with an appropriate deactivation agent and cleaning agent~~ before and after each continuous activity and

activity and at the end of the work shift.	at the end of the work shift.
(4) Wear appropriate gloves for cleaning and decontamination work.	~~(4) Wear appropriate gloves for cleaning and decontamination work.~~
(5) Wear a gown and face protection whenever splashing or contact with contaminated materials or surfaces is possible.	~~(5) Wear a gown and face protection whenever splashing or contact with contaminated materials or surfaces is possible.~~
(6) Wear appropriate gloves and gown when handling linens, feces, or urine from patients who have received hazardous drugs within the last forty-eight hours that may be excreted in the urine or feces. In some cases handling precautions may need to be extended beyond forty-eight hours; e.g., Cisplatin may be excreted in urine for up to seven days.	~~(6) Wear appropriate gloves and gown when handling linens, feces, or urine from patients who have received hazardous drugs within the last forty-eight hours that may be excreted in the urine or feces. In some cases handling precautions may need to be extended beyond forty-eight hours; e.g., Cisplatin may be excreted in urine for up to seven days.~~
(7) Place hazardous drug contaminated waste in designated pharmaceutical waste containers and dispose of in accordance with Washington state department of ecology dangerous waste requirements, chapter 173-303 WAC.	~~(7) Place hazardous drug contaminated waste in designated pharmaceutical waste containers and dispose of in accordance with Washington state department of ecology dangerous waste requirements, chapter 173-303 WAC.~~
(8) Waste containers must be:	~~(8) Waste containers must be:~~
(8) (a) Leakproof and appropriate for intended use, e.g., containers holding sharps must be puncture resistant;	~~(8) (a) Leakproof and appropriate for intended use, e.g., containers holding sharps must be puncture resistant;~~
(8) (b) Color-coded or labeled;	~~(8) (b) Color-coded or labeled;~~
(8) (c) Located as close as feasible to the immediate area where contaminated waste is generated or can be anticipated to be found;	~~(8) (c) Located as close as feasible to the immediate area where contaminated waste is generated or can be anticipated to be found;~~
(8) (d) Maintained upright throughout use;	~~(8) (d) Maintained upright throughout use;~~
(8) (e) Not allowed to overfill;	~~(8) (e) Not allowed to overfill;~~
(8) (f) Closed except when in use, and prior to removal or replacement.	~~(8) (f) Closed except when in use, and prior to removal or replacement.~~
WAC 296-62-50045 Spill control.	**WAC 296-62-50045 Spill control.**
(1) Develop written spill response procedures based on the hazardous drugs present and potential spill or release conditions.	(1) Develop written spill response procedures based on the hazardous drugs present and potential spill or release conditions.
(2) Spill procedures must include, at a minimum:	(2) Spill procedures must include, at a minimum:

(2) (a) Description of who is authorized to respond and under what circumstances;	(2) (a) Description of who is authorized to respond and under what circumstances~~;~~.
(2) (b) PPE (including respiratory protection) for various drugs and spill sizes;	(2) (b) PPE ~~(including respiratory protection)~~ for various hazardous drugs and spill sizes~~;~~.
(2) (c) Location and use of spill kits or clean-up materials, and personal protective equipment;	(2) (c) Location and use of spill kits or clean-up materials. ~~, and personal protective equipment;~~
(2) (d) Possible spreading of material, and area containment and signage;	(2) (d) Possible spreading of contamination, ~~material,~~ and area containment and signage~~;~~.
(2) (e) Reporting and evaluating the circumstances surrounding spills and releases;	(2) (e) Reporting and evaluating the circumstances surrounding spills and releases~~;~~.
(2) (f) Restricted access to hazardous drug spills.	(2) (f) Restricted access to hazardous drug spills.
	(2)(g) Waste disposal.
(3) Provide spill kits or clean-up materials near all potential spill sources.	(3) ~~Provide~~ Locate spill kits or clean-up materials near all potential spill sources.
(4) Dispose of all clean-up materials in an appropriate pharmaceutical waste container.	~~(4) Dispose of all clean-up materials in an appropriate pharmaceutical waste container.~~
Note: See chapter 296-824 WAC, Emergency response for requirements regarding response to spills that create significant safety and health risks. See the scope of chapter 296-824 WAC for further guidance. See WAC 296-800-150, first aid for emergency washing requirements.	**Note:** See chapter 296-824 WAC, Emergency response for requirements regarding response to spills that create significant safety and health risks, ~~See the scope of~~ and ~~chapter 296-824 WAC for further guidance. See~~ WAC 296-800-150, ~~first aid~~ First-aid summary for emergency washing requirements.
WAC 296-62-50050 Medical surveillance.	~~**WAC 296-62-50050 Medical surveillance.**~~
(1) Make confidential medical evaluations available to employees who directly handle hazardous drugs, and others who may come directly into contact with patient wastes within forty-eight hours after receiving a hazardous drug (e.g., nurses aides, laundry workers) under the following schedule:	~~(1) Make confidential medical evaluations available to employees who directly handle hazardous drugs, and others who may come directly into contact with patient wastes within forty-eight hours after receiving a hazardous drug (e.g., nurses aides, laundry workers) under the following schedule:~~
(1) (a) Upon hire and on a scheduled basis thereafter;	~~(1) (a) Upon hire and on a scheduled basis thereafter;~~
(1) (b) Following acute exposures;	~~(1) (b) Following acute exposures;~~
(1) (c) At the time of job termination or transfer (exit evaluation).	~~(1) (c) At the time of job termination or transfer (exit evaluation).~~

(2) Ensure that all medical evaluations are performed by or under the supervision of a licensed health care provider (LHCP), and are provided at no cost to the employee and at a reasonable time and place.	~~(2) Ensure that all medical evaluations are performed by or under the supervision of a licensed health care provider (LHCP), and are provided at no cost to the employee and at a reasonable time and place.~~
(3) The medical evaluations must include:	~~(3) The medical evaluations must include:~~
(3) (a) A health questionnaire that includes reproductive and occupational information.	~~(3) (a) A health questionnaire that includes reproductive and occupational information.~~
(3) (b) Baseline and periodic laboratory work as indicated based on the health hazards of the hazardous drugs the employee is exposed to or reasonably likely to be exposed to.	~~(3) (b) Baseline and periodic laboratory work as indicated based on the health hazards of the hazardous drugs the employee is exposed to or reasonably likely to be exposed to.~~
(3) (c) A physical examination at the time of hire and as indicated based on the health questionnaire, changes in health status or laboratory work findings.	~~(3) (c) A physical examination at the time of hire and as indicated based on the health questionnaire, changes in health status or laboratory work findings.~~
(3) (d) Additional testing and examinations as recommended by the LHCP.	~~(3) (d) Additional testing and examinations as recommended by the LHCP.~~
Note: Many hazardous drugs may affect the production of blood cells and may cause bladder damage. Because of this many authoritative bodies (e.g., NIOSH, the Occupational Health and Safety Administration, and the Oncology Nursing Society) recommend a complete blood count with differential, and examination for blood in the urine. Additional laboratory work, such as liver function testing, may be indicated.	~~**Note:** Many hazardous drugs may affect the production of blood cells and may cause bladder damage. Because of this many authoritative bodies (e.g., NIOSH, the Occupational Health and Safety Administration, and the Oncology Nursing Society) recommend a complete blood count with differential, and examination for blood in the urine. Additional laboratory work, such as liver function testing, may be indicated.~~
(4) Provide the LHCP the following information:	~~(4) Provide the LHCP the following information:~~
(4) (a) A description of the employee's duties as they relate to the employee's exposure;	~~(4) (a) A description of the employee's duties as they relate to the employee's exposure;~~
(4) (b) The employee's exposure levels or anticipated exposure levels;	~~(4) (b) The employee's exposure levels or anticipated exposure levels;~~
(4) (c) A description of the personal protective equipment and respiratory protection used or to be used;	~~(4) (c) A description of the personal protective equipment and respiratory protection used or to be used;~~
(4) (d) Information available from previous medical	~~(4) (d) Information available from previous medical~~

examinations of the employee, which is not readily available to the LHCP.	~~examinations of the employee, which is not readily available to the LHCP.~~
WAC 296-62-50055 Training.	**WAC 296-62-~~50055~~ 50050 Training.**
(1) Provide hazardous drugs training to all employees with occupational exposure at the time of their initial job assignment, on a regular basis, and whenever changes in the workplace occur that may affect occupational exposure.	(1) Provide hazardous drugs training to all employees with occupational exposure at the time of their initial job assignment~~,~~ and on a ~~regular~~ regularly scheduled basis thereafter. ~~, and whenever changes in the workplace occur that may affect occupational exposure.~~
(2) Employee training includes, but is not limited to, the following elements:	~~(2) Employee training includes, but is not limited to, the following elements:~~
(2) (a) A review of the hazardous drugs control program and how to access a copy of the program;	~~(2) (a) A review of the hazardous drugs control program and how to access a copy of the program;~~
(2) (b) An explanation of and how to access material safety data sheets (MSDSs);	~~(2) (b) An explanation of and how to access material safety data sheets (MSDSs);~~
(2) (c) Sources of exposure to hazardous drugs;	~~(2) (c) Sources of exposure to hazardous drugs;~~
(2) (d) Health hazards of the hazardous drugs in the work area, including the possible physical symptoms or effects of exposure;	~~(2) (d) Health hazards of the hazardous drugs in the work area, including the possible physical symptoms or effects of exposure;~~
(2) (e) Steps employees can take to protect themselves from exposure to hazardous drugs in the workplace, including specific procedures to protect employees from exposure to hazardous chemicals. Specific procedures may include:	~~(2) (e) Steps employees can take to protect themselves from exposure to hazardous drugs in the workplace, including specific procedures to protect employees from exposure to hazardous chemicals. Specific procedures may include:~~
(2)(e) (i) Personal protective equipment;	~~(2)(e) (i) Personal protective equipment;~~
(2)(e) (ii) Engineering controls;	~~(2)(e) (ii) Engineering controls;~~
(2)(e) (iii) Safe handling practices;	~~(2)(e) (iii) Safe handling practices;~~
(2)(e) (iv) Cleaning, housekeeping, and waste disposal;	~~(2)(e) (iv) Cleaning, housekeeping, and waste disposal;~~
(2)(e) (v) Spill control;	~~(2)(e) (v) Spill control;~~
(2)(e) (vi) System for reporting exposure incidents and hazardous conditions.	~~(2)(e) (vi) System for reporting exposure incidents and hazardous conditions.~~
(2) (f) Medical surveillance.	~~(2) (f) Medical surveillance.~~
(3) Initial and periodic assessments of preparation and	~~(3) Initial and periodic assessments of preparation and~~

administration technique.	~~administration technique.~~
(4) The training must be conducted in a manner which the employees are able to understand.	~~(4)~~ (2) ~~The training must be conducted in a manner which the employees are able to understand.~~ Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.
Note: This training will suffice for the training on hazardous drugs required under WAC 296-800-170, Employer chemical hazard communication--Introduction.	~~**Note:** This training will suffice for the training on hazardous drugs required under WAC 296-800-170, Employer chemical hazard communication--Introduction.~~
WAC 296-800-50060 Recordkeeping.	~~**WAC 296-800-50060 Recordkeeping.**~~
(1) Training records.	~~(1) Training records.~~
(1) (a) Maintain current training records for each employee.	~~(1) (a) Maintain current training records for each employee.~~
(1) (b) Training records must include the following:	~~(1) (b) Training records must include the following:~~
(1)(b) (i) Dates of training sessions;	~~(1)(b) (i) Dates of training sessions;~~
(1)(b) (ii) Contents or a summary of the training sessions;	~~(1)(b) (ii) Contents or a summary of the training sessions;~~
(1)(b) (iii) Names and job titles of employees taking the training.	~~(1)(b) (iii) Names and job titles of employees taking the training.~~
(2) Medical and exposure records. Establish and maintain employee medical and exposure records in accordance with chapter 296-802 WAC, Employee medical and exposure records.	~~(2) Medical and exposure records. Establish and maintain employee medical and exposure records in accordance with chapter 296-802 WAC, Employee medical and exposure records.~~
(3) Spill records. Maintain spill records and evaluation findings for at least one year from the date of the spill or release.	~~(3) Spill records. Maintain spill records and evaluation findings for at least one year from the date of the spill or release.~~
	WAC 296-62-50055 Implementation Plan.
	(1) Effective dates.
	(1)(a) The written hazardous drugs control program must be completed and implemented by January 1, 2014 with the exception of (b) and (c) of this subsection.
	(1)(b) Employee training must be implemented by July 1, 2014.
	(1)(c) Installation of appropriate ventilated cabinets must be completed by January 1, 2015.
	(2) The department will work with stakeholders to implement

	this chapter by doing the following:
	(2)(a) Establish a hazardous drugs advisory committee to discuss new NIOSH recommendations, scientific and technological developments and other unanticipated issues related to rule implementation. This committee will include employer and employee representatives of the health care industry and representatives of affected state agencies. It may provide recommendations to the department regarding appropriate actions.
	(2)(b) Work with trade associations, labor unions and other representatives from the health care industry to develop model programs for implementation of these rules in a variety of health care facilities and settings. The department will provide education, training and consultation services to ensure that these model programs are widely distributed and can be effectively utilized.
	(2)(c) Establish a hazardous drugs web page, and post relevant resources, sample programs and forms.

III. Summary of Comments Received and Department Response

The department has analyzed all the comments received on the proposed rule in detail and responses to these comments by category are listed below. While this list represents the majority of all the comments, some individual comments may not be listed if the issue raised and response provided are adequately represented and additional entries would be duplicative.

General Comments	Department Response
The National Institute for Occupational Safety and Health (NIOSH) Alert suggests that healthcare facilities examine the risk posed by the medications on the list and develop policy and procedure to minimize the risk. However, the draft rules from L&I apply to all medications on the list. L&I makes no distinction between IV chemotherapy and oral contraceptives, they must be treated the same.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)* *A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
We are very concerned with the tremendous financial impact adoption of these rules would create. We are concerned about the continued ability to administer the most effective and cost efficient medications to the patients served in our hospitals and Rural Health Centers (RHCs). We do not dispute the fact that certain drugs are hazardous and must be handled and disposed of in a safe and proper manner. However many of the medications included on this list are oral medications that have been widely used for years and are essential for the wellbeing of the patients we serve. For	By allowing employers to develop a hazardous drugs control program based on the workplace hazard assessment, and allowing for individual circumstances such as might be encountered in rural health care facilities, compliance with the rule will not result in reduced health care access. L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing

example, risperidone, oral contraceptives, zonisamide, and paroxetine are medications we have administered thousands of times, yet the proposed rules would essentially eliminate their use based on the very strict handling and disposal procedures, which we believe are unnecessary. Our inability to abide by these new over-reaching rules may prohibit us from stocking these medications. It could mean we would have to refuse to admit patients who are receiving them.	the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
We strongly object to your decision to not provide a small business economic impact statement.	A Cost-Benefit Analysis and a Small Business Economic Impact Statement are not required for a proposed rule where the content of the rule is explicitly and specifically dictated by statute. In this case, the legislature explicitly and specifically directed DOSH to adopt by rule requirements for the handling of hazardous drugs and further directed that those requirements be consistent with and not exceed provisions adopted by NIOSH Alert. The stated legislative intent was to require health care facilities to follow rules requiring compliance with provisions consistent with all aspects of NIOSH's Alert regardless of the setting in order to protect health care personnel from hazardous exposure to such drugs.
The scope of the chapter is too broad unless the list of hazardous drugs is limited.	Engrossed Substitute Senate Bill (ESSB) 5594 defines hazardous drugs and the rule is consistent with the statute. However, while a drug may be on the NIOSH Alert list, the NIOSH Alert and the rule recognize that some drugs defined as hazardous pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
The hazardous drugs control program and hazard assessment sections are overly broad. The rule calls for each health care setting to develop a hazardous drugs control program even if it does not use, store, or distribute hazardous drugs.	L&I agrees that the proposed rule lacked clarity and has clarified that the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. The rule states:

	WAC 296-62-50020(1) *Each health care facility covered under the scope of this chapter must conduct hazard assessments in order to determine the appropriate precautions to be taken. These assessments may be limited to the hazardous drugs for which there is reasonably anticipated occupational exposure.*
Unless a tiered approach is adopted the safe handling practice section is overly broad and will present undue burdens.	L&I agrees that the proposed rule lacked clarity. Recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors the rule allows employers to develop a tiered approach to handling hazardous drugs. This is consistent with the overall guidance in the NIOSH Alert documents and this clarification has been added to the final rule: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
Most veterinary clinics do not use the vast majority of the drugs on the list, but the few drugs the average vet uses are not in nearly the same toxicity category as the antineoplastic drugs on the very same list… The vast majority of veterinarians know what is to be handled with caution and what is not a problem, I think the rules as a whole will not be followed at all and let the chips fall where they may because they are not practical.	L&I agrees that the proposed rule lacked clarity. The rule has been clarified to indicate that it applies only to hazardous drugs for which there is reasonably anticipated occupational exposure and allows for a tiered approach for the drugs requiring protective measures.
The department is taking a guideline that is all inclusive and making exceptions.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to

	hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
Does the recently released proposed rules on the Safe Handling of Hazardous Drugs fall under the moratorium on non-critical rule making?	The Governor's rule moratorium does not suspend the development of critical rulemaking. Specifically the moratorium does not apply to rule making that is required by federal or state law.
Consider further clarity in the draft rule to address the list of hazardous drugs. In the NIOSH Alert 2004, page 40, the list is clarified as a "sample list intended to guide health care providers in diverse practice settings. Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, intact medications such as coated tablets or capsules that are administered to patients without modifying the formulation)". We recommend the qualifier in the above paragraph be added or preferably remove the oral solid dosage forms listed.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to,*

	handling, storing, cleaning, preparing and engineering controls. The rule also states: *WAC 296-62-50010* *…..Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)…….*
The deadlines incorporated into the draft CR 102 rule are not reflective of practical considerations for their implementation in affected provider settings such as nursing homes.	L&I agrees and the effective dates contained in the final rule are as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
We urge the department to incorporate appropriate 'physical plant/structure' rules such that nursing homes are not unduly burdened with compliance requirements that have little or no risk-avoidance benefit given the nature of the resident population served.	L&I appreciates the comment. The rule language is consistent with the NIOSH Alert and has not been changed. Additional 'physical plant/structure' rules would exceed the NIOSH Alert.
Delay adoption of the CR-103 or issue a new, reasonable but effective, formal proposed rule by obtaining appropriate stakeholder input, and regrouping to create a rule that not only protects workers but does so without inappropriately impacting healthcare costs via training, engineering controls, and patient access and flow.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.*

	Ventilation controls - January 1, 2015.
Without appropriate tiering of various hazardous drugs based on a risk rating, many drugs will be included in this bill for training, personal protection, and other controls.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
I believe L&I needs to slow down this process.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
The flexibility offered by a tiered approach to differentiate highly hazardous drugs from those which are considered more routine is the best way to afford safety precautions for workers.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs

	and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
We feel that the current time table is restrictive – proceeding under the current time table of Adoption by January 3, 2012, does not allow for adequate stakeholder feedback.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
The draft rules are unclear. They do not provide proper levels of tiered exposure risk. There is a huge difference between a packaged birth control pill and a chemotherapeutic in powdered form. There is a huge difference between once a week compounding of an estrogen or progestin versus compounding 20 such prescriptions a day. The rule makes no such differentiation.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added:

	WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls. The rule also states: *WAC 296-62-50010* *…..Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)…….*
We are concerned that the July 1, 2012 date does not provide adequate time for development of extensive new policies, practices and training programs required under this proposed regulation.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.* In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.

We would suggest that, if any of these draft regulations are a repeat of current, other WACs, that you incorporate those issues by referencing the appropriate WAC, and not simply repeating the language in another rule. Should there be changes in those other regulations, the Department will thereby avoid having to continually amend these rules.	L&I agrees that this approach can be effectively used in some instances and has incorporated reference where appropriate. For example, the personal protective equipment section in the final rule reads: *WAC 296-62-50030(1)* *When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, Personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.*
We respectively request that the Department rescind the CR 102, reconvene stakeholder meetings and work to make the proposed rules more accurately reflect potential hazards in specific settings.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. The rule language is consistent with and does not exceed the NIOSH Alert. However, L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
The time line for both the development of the rule as well as the implementation is too aggressive. There is a general feeling that the process for stakeholder feedback, modifications and publication is being rushed to meet certain time frames. Sufficient time to obtain and review all interested stakeholder's feedback as well as thoughtfully craft wording that meets the intent of the Department of Labor and Industries is essential. This would allow for realistic input in time to plan for and budget for some of the key recommendations in the rule. This rule is the first of its kind in the nation and needs to be written such that future States can refer to it as a guiding document. Pull back the original CR 102 and reissue with	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.*

feedback received from the hearings.	*Ventilation controls - January 1, 2015.* In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.
The ability to successfully implement this rule very much hinges on an organizations ability to conduct an assessment of agents used and their relative risk to an employee (e.g. risk of oral contraceptive tablet vs. injectable cyclophosphamide). Clearly state the intent of L&I regarding the use of a risk stratification system.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
We strongly urge the addition of language in this chapter that clearly and closely follows the NIOSH 2010 Sample Drug List recommendation that facilities create their own list of drugs based on the NIOSH list. In doing so, organizations would be bound by the definition of a hazardous drug listed in this draft rule and must circulate the drug list to its employees for approval. We recommend the following language: "Based on the assessment in (2) above, each organization should create its own list of drugs used by its employees considered to be hazardous. This list should take into account references such as the NIOSH listing of hazardous drugs,	ESSB 5594 states explicitly that "hazardous drugs" include all those identified by NIOSH. The rule language is consistent with the NIOSH Alert and ESSB 5594. No change has been made to the final rule. However, L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a

MSDS's, AHFS, as well as drug types, and occupational exposure risk. A risk stratification of high risk hazardous drug or low risk hazardous drug can be assigned to this list. PPE, engineering controls, safe handling practices, cleaning, spill control, and medical surveillance plans can be determined by the risk stratification. Once made, newly purchased drugs should be evaluated against the organization's hazardous drug criteria."	tiered approach for the drugs requiring protective measures
The discussion draft includes key changes that are necessary which were not in the CR102 draft rule. Recognition of varying risk of occupational exposure for drugs considered hazardous by NIOSH and the need for tiered strategies for protection. Changes to timelines that are more realistic.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
No recognition of the request for inclusion of language allowing for a determination of non-significance or limited significance.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions*

	approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls. While the department concluded that establishing a system for employer or agency determinations of non-significance would be administratively unworkable and conducive to inconsistencies with NIOSH, the rule does address the concern in a different way by its application to situations with reasonably anticipated exposure and its allowance of a tiered approach.
Timelines which do not allow sufficient time for guidance document utilization.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.* In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.
The hazardous drugs rule does not provide for any tiered strategies for dealing with different levels of hazardous drugs that are outlined in the	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing

NIOSH publications.	the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
The implementation schedule outlined in the current rule makes it difficult, if not impossible to comply.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.* In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.
Many of the medications deemed as being hazardous are oral medications	L&I agrees that some hazardous drugs pose less risk than others.

that are very widely used such as anti-depressants and birth control, yet the proposed rules would essentially eliminate their use based on the very strict handling and disposal procedures. These increased regulations include employees working in vent hoods, wearing double gloves, having their blood drawn, wearing gowns, having confidential medical evaluations on a scheduled basis, and the business using a high-efficiency particulate air filter, and increased storage, as hazardous drugs cannot be stored with non-hazardous. We request that this bill be delayed until a comprehensive review can be performed that will ensure that the conditions are reasonable and less costly.	To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
It is important to understand that the NIOSH list includes many drugs other than chemotherapy agents, such as oral contraceptives, antibiotics and mental health drugs. It must be understood that there are levels of risk associated with these medications, and the manipulation and packaging of these medications also dictates the amount of risk involved. Mandating that all pharmacies must handle any drug on the NIOSH list with the same level of control as one would need with the compounding of chemotherapeutic agents is simply wrong.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*

The rule should clearly separate the types of drugs for which even minimal exposure would be dangerous from drugs that, due to the packaging or risk, do not require the same level of concern.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
Where flexibility is given in the rule and there should be a requirement that the Department will engage with stakeholders in developing guidelines for implementation and language should be inserted that gives the regulated entity some assurance of a safe harbor if they follow the Department's developed guidelines and instructions.	L&I believes that there has been adequate stakeholder input and that all rulemaking requirements have been met in order to adopt the rule at this time. However, the effective dates contained in the final rule have been extended as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.* In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.

I have reviewed the NIOSH list of Antineoplastic and other hazardous drugs that will require special handling once the new rules are in place. I see that cyclosporin is included, as it should be when used as an Antineoplastic agent, however, it is also the active ingredient in dry eye treatments such as Optimmune and Restasis. I believe that these preparations (and any similar preparation) should be specifically named as exempt from these regulations. Likewise for the use of cyclosporin in extremely low doses as a treatment for chronic allergies. AS a general practitioner, I have no antineoplastic agents in my hospital, but Optimmune ointment is a staple, and does not require special handling.	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
Supportive of phased-in implementation dates for putting a hazardous drugs control program in place, completing employee training, installing appropriate ventilation and cabinets.	L&I agrees.
Strongly discourage unnecessary delays in completing the rule-making process.	L&I agrees.
(NIOSH) List includes drugs that don't appear to be that hazardous.	The definition of hazardous drugs in the rule is consistent with ESSB 5594 and is consistent with and does not exceed the NIOSH Alert. No change has been made to the final rule language. L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated

	occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
The drugs being handled at our retail, community pharmacies have very low hazardous potential. We respectfully request the Department exempt out retail pharmacies using the NIOSH verbiage as its justification. According to NIOSH "Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened)" Based on this language we ask the Department add language, "These rules do not apply to retail pharmacies that maintain and dispense hazardous drugs without altering their drug formulations".	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.* The rule also states: WAC 296-62-50010 *…..Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)……*
The department, in our estimation, has not followed proper procedures regarding cost benefit analysis and small business economic impact statements required under the APA and the state's Regulatory Fairness Act.	A Cost-Benefit Analysis and a Small Business Economic Impact Statement are not required for a proposed rule where the content of the rule is explicitly and specifically dictated by statute. In this case, the legislature explicitly and specifically directed DOSH to adopt by rule requirements for the handling of hazardous drugs and further directed that those requirements be consistent with

	and not exceed provisions adopted by NIOSH. The stated legislative intent was to require health care facilities to follow rules requiring compliance with provisions consistent with all aspects of NIOSH's Alert regardless of the setting in order to protect health care personnel from hazardous exposure to such drugs.
I am equally concerned with the proposed changes to the practice of pharmacy (drugs defined by but not limited to the NIOSH list) which include storage, ventilation, ventilated cabinets/hoods, separate processing areas, disposal requirements, protective equipment (gowns, masks, gloves) spill equipment, housekeeping and medical surveillance for employees.	L&I agrees that not all hazardous drugs need to be handled using the highest level of precautions and that a risk based approach may be more practical, while at the same time providing effective employee protection, in some health care settings. Consistent with the overall guidance in the NIOSH Alert documents, the final rule recognizes this by the addition of this statement. *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.* In addition, the rule provides implementation time for the development of resources and to allow employers to implement effective, assessment based hazardous drugs control programs.
WAC 296-62-500 Hazardous drugs, WAC 296-62-5005 Scope and WAC 296-50010 Definitions	
We appreciate the addition of the flow chart as it clarifies when a Hazardous Drug Control Plan is required. "Reasonably anticipated occupational exposure" is a preventative approach and is appropriate.	L&I agrees and has modified the guidance on chapter application to add clarity. The final rule language reads: *WAC 296-62-50005(2)* *(2) Chapter application* *(a) The requirements in this rule only apply to the hazardous drugs*

	being used in the workplace *(b) If hazardous drugs are being used in the workplace the requirements in this rule only apply if there is reasonably anticipated exposure as defined in WAC 296-62-50010* *(c) If there is reasonably anticipated occupational exposure to one or more hazardous drugs the employer must develop a hazardous drugs control program as required in WAC 296-62-50015* *(d) For purposes of making the determinations in this section about scope and application occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.* This language is consistent with language in other DOSH rules and the NIOSH Alert guidelines.
Why "nurses aids" are struck from examples of "nurses" is unclear. Nurses aids may definitely be at risk for occupational exposure to hazardous drugs. In addition, it is unclear why health care assistants are examples of "patient assistive personnel." Is this to clarify that patient assistive personnel must have a health care credential for this rule to apply to them? We agree that health care assistants may also be at risk for occupational exposure to hazardous drugs. However, other personnel that do not have a health care credential may also be at risk.	L&I agrees that the proposed language lacked clarity. The rule has been clarified by adding "nursing assistants" as an example.
The definition of health care settings is overly broad	In addressing this concern L&I notes that ESSB 5594 applies to "health care facilities…in all settings" and the NIOSH Alert documents apply to "hazardous drugs in health care settings." In order to be consistent with both the statute and the NIOSH Alert documents L&I has clarified in the final rule that: *WAC 296-62-50010*

	Health care facilities *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.*
In preparation for implementing the regulations, a question was asked regarding whether our research institution would be considered a "health care setting" as we do not provide any patient care services on the research side.	In addressing this concern L&I notes that ESSB 5594 applies to "health care facilities…in all settings" and the NIOSH Alert documents apply to "hazardous drugs in health care settings." In order to be consistent with both the statute and the NIOSH Alert documents L&I has clarified in the final rule that: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patient.*
We appreciate the use of the term "potential" in relation exposure to hazardous drugs. Including potential exposures is a preventative approach, which not only protects the employee, but helps to decrease unnecessary health care costs, claim costs and employee pain and suffering, by avoiding treatment resulting from exposure to hazardous drugs.	L&I agrees with the intent of this comment and has modified the definition of occupational exposure to use the term "reasonably anticipated exposure." This term clarifies that occupational exposure applies to circumstances where exposure to hazardous drugs is directly related to employees' duties and activities. For example, it can be reasonably anticipated that occupational exposure to hazardous drugs may occur when compounding hazardous drugs. This is consistent with the overall guidance in the NIOSH Alert documents. The definition of occupational exposure has been changed to read:

	WAC 296-62-50010 ***Occupational exposure*** *means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties. Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).*
In the definition of "deactivation," more definition and criteria is needed for what is a "less hazardous agent." For example, how is "less hazardous" agent defined in research, what criteria needs to be met to be identified as a less hazardous agent, what is the expected end product, how does a less hazardous agent impact human health differently.	L&I appreciates this comment but concluded that allowing flexibility in the hazard assessment would be preferable to a more specific definition that would go beyond that used by NIOSH.
In the definition of a "biological safety cabinet," the different types of cabinets should be listed, as is standard in other health and safety WAC's. We appreciate the use of the terms "dangerous waste" and "exposure incident." Although they are not terms currently used by NIOSH, this provides additional clarity. Washington does have the option to create higher standards than those in current NIOSH recommendations.	The definition of "biologic safety cabinet" includes a reference to Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.* This document provides comprehensive descriptions of the different types and uses of biologic safety cabinets. The terms "dangerous waste" and "exposure incident" would have exceeded the NIOSH Alert and it is not in the final rule.
Technology on these isolators is changing rapidly and the rule should not prohibit facilities from using the safest, most advanced isolator. Define the isolator's purpose. Do not proscribe how it should work or you'll need to revise this rule regularly. For example, some compounding isolators are not designed to have exchanges and have static HEPA filtered air inside the mixing chamber that is vented and replaced only when pressure changes require. In addition,	L&I agrees and the rule allows the use of appropriate ventilated cabinets. As long as the cabinet provides appropriate protection, e.g., the filtering material is appropriate for the contaminant and is installed and maintained per manufacturer's instructions; it will generally be acceptable under the rule.

while an interlock is used in these devices, there is no way to prevent the mixing of air in the room with that of the antechamber on the box which does have air from the mixing space. In summary, this may be a tough standard to meet with hospitals that have these glove boxes in place. Replacement costs for these can be $20 - $40K.	
In reviewing NIOSH publication on the list of antineoplastic and other hazardous drugs updated in 2010 it states the following: "the definition of hazardous drugs used in this alert is based on an ASHP definition that was originally developed in 1990 (ASHP 1990). Thus the definition may not accurately reflect the toxicity criteria associated with the new generation of pharmaceuticals entering the healthcare setting. For example, bioengineered drugs target specific sites in the body; and although they may or may not be toxic to the patient, some may not pose a risk to health care workers." The definition of occupational exposure exceeds the NIOSH Alert. See conditions of exposure.	While L&I appreciates the comment, the definition of occupational exposure establishes criteria for the application of the rule's requirements that are consistent with and do not exceed the NIOSH Alert. No change has been made to the final rule.
We believe that the guidelines put forth in the (NIOSH) alert were intended to apply to large hospital systems with dedicated departments where most of the work with antineoplastics and hazardous drugs is done at specific locations and where the potential exposure to certain hazardous drugs occurs frequently. The guidelines were not designed for a clinical setting where usage rates are lower and many of the highly hazardous drugs are not used.	The NIOSH Alert defines health care settings broadly and the definition of health care facility in the rule is consistent with and does not exceed the NIOSH Alert. However, L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
The definition for contamination includes a provision that fluids from patients receiving certain hazardous drugs are considered contaminated for a minimum of 48-hours after administration.	L&I agrees and this definition is not in the final rule.
Definitions: Occupational Exposure: Add the word absorption following skin. The provision that "Occupational exposure is determined independent of the use of personal protective equipment" is in direct conflict with the provision stating "Factors that affect the degree and type of occupational exposure include…personal protective equipment. The	L&I agrees that this language lacked clarity. In the final rule the language it has been clarified that only: *WAC 296-62-50005(2)(d)* *For purposes of making the determinations in this section about*

definition states "reasonably anticipated" inhalation, skin absorption, ingestion or injection contact." It doesn't seem reasonable to anticipate such with the use of PPE, ventilated cabinets, etc.	*scope and application, occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.*
After the introduction there is a section titled "Important". This section lists additional rules that apply: WAC 296-800-170, Chemical Hazard Communication; WAC 296-800-160, Personal Protective Equipment, and WAC 296-842, Respiratory Protection. The scope of the rule includes research laboratories. Chapter 296-828, Hazardous Chemical in Labs should be included in this section.	The NIOSH Alert does not include reference to the Hazardous Chemicals in Laboratories rule. No change has been made to the final rule language.
The enabling legislation (ESB 5594) directed L&I to adopt rules for the handling of certain drugs in health care facilities. The draft language of the rules issued with the CR102 and the subsequent discussion draft refer to health care settings not health care facilities. As currently drafted the rules exceed the statute by including companies and research institutions that are not health care facilities. We believe that health care facility needs to be a defined term. A review of the NIOSH guidelines clearly refers to health care workers in settings where drugs are handled and administered to patients.	L&I agrees that the rule proposal language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.*
"*Occupational Exposure*": We appreciate and support the language added in the discussion draft that acknowledges additional factors affecting occupational exposure such as drug formulation and packaging, relative toxicity, and the last paragraph in this definition pertaining to relative toxicity. However, the definition for occupational exposure includes the following statement: "Occupational exposure is determined independent of the use of personal protective equipment." The use of the word "independent" leads the reader to believe that personal protective equipment alone cannot protect a worker from occupational exposure. This would require any pharmacy that provides estrogen supplements or splits low hazard drug pills to develop a hazardous drug program at such a cost	L&I agrees that this language lacked clarity. In the final rule the language it has been clarified that only: *WAC 296-62-50005(2)(d)* *For purposes of making the determinations in this section about scope and application occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.*

to the pharmacy that they would likely be forced to forgo providing estrogen or any other drug on the NIOSH list. A glove can adequately mitigate this type of hazard. Please delete or clarify this sentence.	
"*Contaminated*": This definition is not included in NIOSH and thus exceeds it and the scope of the law. Further, WSHA strongly objects to any definition of contaminated human waste that would require facilities to know if patients were exposed to hazardous drugs prior to coming into their facilities. This provision would require any hospital emergency room to treat human waste as hazardous regardless if they dispensed hazardous drugs. The impact in rural hospitals alone will be significant. Please delete this definition.	L&I agrees and this definition has been removed from the final rule.
We recommend that the Department revise its proposed definition of health care settings to delete the reference to "research laboratories." (See WAC 296-800-50010). In the alternative, we recommend either that the phrase "laboratories related to patient care activities" be substituted for the term "research laboratories" or that the term "research laboratory" be coupled with a parenthetical clarification such as "research laboratories (directed to patient care)."	L&I agrees that the proposed rule language lacked clarity regarding the coverage of research laboratories. The final rule language has been clarified to read: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.*
The inclusion in the scope of "employees in research laboratories" needs clarification.	L&I agrees that the proposed rule language lacked clarity regarding the coverage of research laboratories. The final rule language has been clarified to read: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this*

	includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.
Washington has nearly 180 medicine take-back programs for residential sources of unwanted medicines, as of November 2011, and the applicability of this proposed rule to take-back programs is unclear.	The rule only applies to health care facilities where a health care provider provides care to patients. Take-back programs would not be covered under the rule, unless they also provide care to patients.
I respectfully recommend that the rule not be made applicable to drug and pharmaceutical manufacturing, drug discovery, and pharmaceutical research facilities and activities. Our company and employees are already protected by similar occupational safety and health rules	L&I agrees that the proposed rule language lacked clarity regarding the coverage of research laboratories. The final rule language has been clarified to read: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.*
In the definition of a "biological safety cabinet," the different types of cabinets should be listed, as is standard in other health and safety WAC's. We appreciate the use of the terms "dangerous waste" and "exposure incident." Although they are not terms currently used by NIOSH, this provides additional clarity. Washington does have the option to create higher standards than those in current NIOSH recommendations.	The definition of "biologic safety cabinet" includes a reference to Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.* This document provides comprehensive descriptions of the different types and uses of biologic safety cabinets.
Under the definition of occupational exposure, additional language is added about when a hazardous drug may pose a significant risk of occupational exposure. While this narrative provides some helpful context, clarification	L&I agrees that the elements listed may affect the degree and risk of exposure, but do not necessarily determine occupational exposure. As such, these elements have been moved to the Hazard

is needed as to how this affects development and implementation of a Hazardous Drugs Control Program.	Assessment section.
Add statement: "The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.	L&I appreciates this comment but believes that this explicit statement is unnecessary.
Add "or containment isolator" to the definition of compounding aseptic containment isolator.	L&I agrees. The final rule adds a definition for "containment isolator."
Add a statement to the definition of hazardous drugs : "Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation, including intact medications such as coated tablets or capsules that are administered to patients without modifying the formulation. If solid dosage forms are altered, crushed, opened, or otherwise modified, they may pose a risk. Intact medications that are not hazardous in their original form may be exempted by a health care setting employer from its list of hazardous drugs after a hazard assessment. However, oral solid dosage forms that have been altered, crushed, opened or otherwise modified may pose a risk and cannot be excluded."	L&I agrees with the intent but believes this clarification is better placed with the definition of occupational exposure. The final rule includes this wording: *WAC 296-62-50010* *….Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).*
Add "dosage formulation of the drugs handled" to replace "form (intact tablets, coated versus uncoated or crushed, powder versus liquid)" in definition of occupational exposure	L&I has added this language to the occupational exposure definition.
Add definitions for safety sharps devices and safety interlocks	L&I appreciates this suggestion but believes these terms are in general use and do not require specific definition in this rule.
Remove "employees in research laboratories" from the scope section and eliminate "research laboratories" from the definition section. Also, replace the definition of "health care settings" with a definition for "health care facilities" consistent with RCW 70.37.020.	L&I agrees that the proposed rule language lacked clarity regarding the coverage of research laboratories. The final rule language has been clarified to read: *WAC 296-62-50010* ***Health care facilities*** *means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this*

	includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.
Add "non-venting, airtight, leak proof" to the definition for closed system transfer devices.	The definition in the rule is identical to that used by NIOSH and the proposed change would exceed NIOSH Alert documents. No change has been made.
Add "closed system transfer devices" to the definition of engineering controls.	Engineering controls are not limited to the list of examples in the definition and therefore L&I did not believe it was necessary to add another.
Definitions of aseptic containment isolator, and compounding aseptic isolator - Technology on these isolators is changing rapidly and the rule should not prohibit facilities from using the safest, most advanced isolator. Define the isolator's purpose. Do not proscribe how it should work or you'll need to revise this rule regularly. For example, some compounding isolators are not designed to have exchanges and have static HEPA filtered air inside the mixing chamber that is vented and replaced only when pressure changes require. In addition, while an interlock is used in these devices, there is no way to prevent the mixing of air in the room with that of the antechamber on the box which does have air from the mixing space. In summary, this may be a tough standard to meet with hospitals that have these glove boxes in place. Replacement costs for these can be $20 - $40K.	L&I agrees that isolator technology may change and that these definitions may be overly prescriptive. The final rule uses the definition of "isolator" from the NIOSH Alert. This definition allows flexibility and is consistent with the intent of the Alert.
Regarding the definition of hazardous drugs - In reviewing NIOSH publication on the list of antineoplastic and other hazardous drugs updated in 2010 it states the following: "the definition of hazardous drugs used in this alert is based on an ASHP definition that was originally developed in 1990 (ASHP 1990). Thus the definition may not accurately reflect the toxicity criteria associated with the new generation of pharmaceuticals	ESSB 5594 states explicitly that "hazardous drugs" include all those identified by NIOSH. The rule language is consistent with the NIOSH Alert and ESSB 5594. No change has been made to the final rule. However, L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide

entering the healthcare setting. For example, bioengineered drugs target specific sites in the body; and although they may or may not be toxic to the patient, some may not pose a risk to health care workers."	variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
Regarding the definition of occupational exposure – Tying occupational exposure to the performance of an employee's duties exceeds the NIOSH Safety Alert	L&I appreciates the comment. The NIOSH Alert applies to "all workers who handle hazardous drugs (for example, pharmacy and nursing personnel, physicians, operating room personnel, environmental services workers, workers in research laboratories, veterinary care workers, and shipping and receiving personnel)." It is clear that the alert applies to workers who directly handle or have secondary exposures to hazardous drugs as related to their job duties. Incidental exposures that may occur in a healthcare setting are not specifically addressed by the alert. The definition of "occupational exposure" makes it clear that the rule applies to employees who have reasonably anticipated risk of exposure to hazardous drugs as a result of the performance of their duties. No changes have been made to the final rule language.
For defining occupational exposure, I think it's important that we adopt some sort of guideline that illustrates that occupational exposure must be of a formulation and to the extent that it will invariably produce systemic drug levels at or above nontoxic levels. It's important to define that because anyone in retail setting will be exposed on a routine basis to powder from paroxetine, estrogen, risperdal, so forth and so on. However, those medications are not delivered transdermally unless they are prepared accordingly. They must be prepared in a preparation that will deliver across the stratum corneum and will deliver at therapeutic levels. Even at that extent, it is difficult to deliver them at toxic levels. So to assume that a powder exposed to the skin would produce a toxic level could be a misassumption,	ESSB 5594 states explicitly that "hazardous drugs" include all those identified by NIOSH. The rule language is consistent with the NIOSH Alert and ESSB 5594. The definition of "occupational exposure" makes it clear that the rule applies to employees who have reasonably anticipated risk of exposure to hazardous drugs as a result of the performance of their duties. *WAC 296-62-50010* ***Occupational exposure*** *means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties. Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved,*

	or if capsules are pierced or opened). The rule also recognizes the following: *WAC 296-62-50020* *The likelihood that a worker will experience adverse effects from exposure to hazardous drugs varies depending upon the relative toxicity and absorptive properties of a drug, the amount, duration and frequency of contact, and the lack of proper work precautions.* However, L&I agrees that not all hazardous drugs need to be handled using the highest level of precautions and that a risk based approach may be more practical, while at the same time providing effective employee protection, in some health care settings. Consistent with the overall guidance in the NIOSH Alert documents, the final rule recognizes this by the addition of this statement. *WAC 296-62-50015(2)* *A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
Under this proposed rule, there are many new burdens to health care facilities such as ours, including how we determine hazardous drugs. While NIOSH has defined a list of hazardous drugs that would require administration of the program, the list will be fluid and ever-changing. The burden created for our facility will be the need to determine new hazardous drugs, and it will require additional training and coordination with our pharmacy suppliers to ensure that hazards are communicated	L&I appreciates this comment. The rule requirements for determining hazardous drugs are consistent with and do not exceed the NIOSH Alert. The rule states the following criteria for determining whether a drug is hazardous: *WAC 296-62-50010* *Hazardous drugs means any drug identified as hazardous by the*

clearly.	*National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control (CDC) or any drug that meets at least one of the following six criteria:* • *Carcinogenicity.* • *Teratogenicity or developmental toxicity.* • *Reproductive toxicity in humans.* • *Organ toxicity at low doses in humans or animals.* • *Genotoxicity.* • *New drugs that mimic existing hazardous drugs in structure and toxicity.* Additionally, the hazardous drug control is required to be reviewed and updated "…annually and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices."
Wording such as "anticipated" and "reasonable" are open to interpretation. For example, in our setting, if a nurse crushes oral risperidone tablets several days per week, but uses the device we have supplied (with plastic sleeves for the crushed tablet), we believe this would not result in exposure. Does L&I agree with this assessment?	L&I agrees the rule proposal lack clarity. The final rule language clarified under WAC 296-62-50005(2)(d) states the following: *WAC 296-62-50005(2)(d)* *For purposes of making the determinations in this section about scope and application occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.*
WAC 296-62-50015 Hazardous drugs control program and WAC 296-50020 Hazard assessment	
The volume, frequency, handling practices of drugs in compounding or manipulating the original form must include aerosolizing.	L&I appreciates the comment and believes the intent has been met insofar as inhalation hazards are addressed in the sections on respiratory protection and hazard assessments. No changes have been made to the final rule language.
"Bloodborne pathogens" in 1(d) should be changed to "body fluids or tissues that contain hazardous drugs." There already exists a standard for bloodborne pathogens, and its mention does not fit this section.	L&I agrees that exposure to bloodborne pathogens is adequately addressed in WAC 296-823. The reference to bloodborne pathogens is not in the final rule.

When documenting the hazard assessment, in addition to the name of the person performing of the assessment; education, training, and experience to demonstrate a person's ability to perform an adequate assessment must be required.	L&I has determined that requiring a competent person responsible for conducting the hazard assessment would exceed the NIOSH Alert. This requirement is not in the final rule.
We support referencing the "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings" as this provides a consistent standard for any drug.	L&I agrees. ESSB 5594 states explicitly that "hazardous drugs" include all those identified by NIOSH. The rule language is consistent with the NIOSH Alert and ESSB 5594. No change has been made to the final rule. However, L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures.
While we appreciate requiring personnel policies addressing management of employees who are pregnant, breast-feeding, or trying to conceive, men must also be included in this preventative measure. The negative impact of hazardous drugs to the human reproductive system is well supported by research, particularly among nurses studied. We recommend that employers and employees should receive training on this issue as well.	L&I appreciates the comment, however the NIOSH Alert includes the development of policies and procedures that address and define "Personal issues (such as the exposure of pregnant workers)". The final rule includes this language but does not exceed it.
Hazardous drugs policies and procedures: The guidance from NIOSH specifically requires written policies about the medical surveillance of health care workers and all phases of hazardous drug handling – including receipt and storage, preparation, administration, housekeeping, decontamination and clean up, and disposal of unused drugs, contaminated spills, and patient wastes. There are no requirements for policies and procedures related to personal protective equipment; engineering controls, spill control, personnel issues, training and/or recordkeeping.	The NIOSH alert addresses procedures for personal protective equipment, engineering controls, spill control, personnel issues and training. The rule's requirements for programs and policies in the final rule are consistent with and do not exceed the overall guidance in the NIOSH Alert documents. The rule does not include requirements for medical surveillance or recordkeeping.
Hazardous drugs control program: The designation of a program administrator exceeds NIOSH guidelines. A nursing home or boarding	L&I agrees that this requirement would exceed the NIOSH Alert and it is not in the final rule.

home safety committee or QI committee may actually be charged with program administration; further, contracted personnel (i.e., pharmacy, worker's comp program managers, etc. could potentially be retained to conduct assessments, etc.)	
We suggest amending language under 296-62-50015(1): "Seek input from workers who handle hazardous drugs when developing these policies and other programs to prevent exposure," and then eliminate 296-62-50015 (3) as it exceeds the NIOSH standards and is too subjective.	The NIOSH Alert recommends that employers "seek" and "use" input from workers. This language in the final rule, including the phrase "seek and consider input from employees" is consistent with and does not exceed the overall guidance in the NIOSH Alert documents.
Under 296-62-50015 (2) , Skilled nursing and assisted living providers are concerned about the need for continual updating of the hazardous drugs list based on changing client population. Suggested revision: "Review and update the written hazardous drugs control program on at least an annual basis and as outlined by policy and procedure.	L&I agrees that the language was not sufficiently clear. The final rule has been clarified to read: *WAC 296-62-50015(3)* *Review and update the written hazardous drugs control program annually and whenever changes that affect occupational exposure occur,…* This language is consistent with and does not exceed the NIOSH Alert.
Section WAC 296-62-50015 (1) requires each health care setting covered by the rule to develop and implement a written hazardous drugs control program specific to the workplace by July 1, 2012. It is conceivable the rule promulgation process will take a number of months to complete. An effective date of January 1, 2013 will provide a reasonable time period to develop and implement an effective written program.	L&I agrees and the effective date for the implementation of the hazardous drugs control program contained in the final rule is as follows: *WAC 296-62-50055(1)(a)* *Hazardous drugs control program – January 1, 2014.*
Small business impact for an additional FTE if there were a requirement to have program administer that has sufficient training or experience to oversee the program development, coordinate implementation, and conduct required assessments	L&I agrees that this requirement exceeds the NIOSH Alert and it is not in the final rule.
There are a number of L&I standards requiring a written program. L&I has	L&I agrees with the intent of this comment and has included the

generally developed written program templates to assist employers in developing effective programs meeting the rule requirements. A written program template should be included in the rule as a resource.	following implementation plan in the rule: *WAC 296-62-50055(2)* *The department will work with stakeholders to implement this chapter by doing the following* *Establish a hazardous drugs advisory committee to discuss new NIOSH recommendations, scientific and technologic developments and other unanticipated issues related to rule implementation. This committee will include employer and employee representatives of the health care industry and representatives of affected state agencies. It may provide recommendations to the department regarding appropriate actions.* *Work with trade associations, labor unions and other representatives from the health care industry to develop model programs for implementation of these rules in a variety of health care facilities and settings. The department will provide education, training and consultation services to ensure that these model programs are widely distributed and can be effectively utilized.* *Establish a hazardous drugs web page, and post relevant resources, sample programs and forms.*
WAC 296-62-50015(a) We are concerned that a program administer with "sufficient training" does not exist. When asked at the public hearing who would meet this requirement the response was it could be a nurse, a pharmacist, a doctor, etc. We did not receive training in this specific topic in pharmacy school, nor have we seen the availability of continuing education programs on this topic. We believe the same would be true for nurses and doctors. The wording could also have significant legal implications in the event of a lawsuit. In other words, L&I may believe healthcare practitioners are trained in this topic and the training would hold up in court, but neither is true. Therefore, we suggest part (a) be deleted.	The requirement to identify a program administrator would have exceeded the NIOSH Alert and is not included in the final rule.

We support linking the hazard assessment to occupational exposure such as "A current hazard assessment for hazardous drugs *for which there is reasonably anticipated occupational exposure."*.	L&I agrees.
We do not support any changes that might add a requirement for a "Designation of a program administrator…" A program administrator is not a provision that is included in any of the NIOSH guidance documents and thus, exceeds the scope of the law.	L&I agrees and this language is not in the final rule.
We supports the addition of a note in the hazard control plan section that acknowledges that precautions are dependent upon risk, such as "Published guidelines generally advocate a standard or universal precautions approach however, due to the variety of factors that affect occupational exposure, some health care settings may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used." However, not only precautions are dependent upon risk, but also handling, storing, cleaning, engineering, and preparing hazardous drugs, as well as conducting medical surveillance on workers exposed to hazardous drugs. We request that you change the sentence to read, "For example, a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to handling, storing, cleaning, engineering, and preparing hazardous drugs, as well as conducting medical	L&I agrees with the intent of this comment and, consistent with the overall guidance in the NIOSH Alert documents, has clarified the rule language to read: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*

surveillance on workers exposed to hazardous drugs."	
While we support a note in the hazard control plan section that acknowledges that precautions are dependent upon risk and allowing a tiered approach, we do not support the reference to minimal requirements "Such approaches must be consistent with any minimum requirements in this chapter (e.g. washing hands whenever contaminated or placing contaminated laundry in leak proof containers)." In some of the sections of the proposed rule there is only one requirement, not a minimum requirement (e.g. 50035). In others, it is not clear which requirements are "minimum" and which are not (e.g. 50040). This sentence is vague and intent is difficult to ascertain. Please delete it.	L&I agrees and this language is not in the final rule.
50020(2)(e) Please change to "Volume, frequency, packaging, and form of hazardous drugs handled…" so that drugs dispensed in blister packs, such as birth control, are clearly excluded from this rule.	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50020(2)(e)* *Volume, frequency, packaging and form of hazardous drugs handled (tablets, coated versus uncoated, powder versus liquid).*
The language[regarding written programs] is too prescriptive and will require continuous annual updating to maintain relevance.	The requirement to update written programs on an annual basis is consistent with and does not exceed the NIOSH Alert. No change was made to the final rule language.
Section WAC 296-62-50015 (3) requires that employers "… seek input from employees …" "… regarding the quality and effectiveness of the hazardous drugs control program." There needs to be clarification on how often this input should be sought. It is suggested that the rule be revised so employee input is considered when the written program is developed, during annual reviews, or whenever there are changes in drugs and/or processes.	The NIOSH Alert recommends that employers "seek" and "use" input from workers. The language in the final rule, including the phrase "seek and consider input from employees" is consistent with and does not exceed the overall guidance in the NIOSH Alert documents.
Some facilities may need additional time to implement a Hazardous Drugs Control Program. We support providing additional time for facilities to	L&I agrees and the effective date contained in the final rule is as follows:

accomplish this.	*WAC 296-62-50055(1)(a)* *Hazardous drugs control program – January 1, 2014.*
This date (July 1, 2012 hazardous drugs control program effective date) is not possible. The date that is included needs to allow facilities enough time to incorporate compliance documentation *and* allow enough time for bargaining units to sign off on new hazardous drug control programs.	L&I agrees and the effective date contained in the final rule is as follows: *WAC 296-62-50055(1)(a)* *Hazardous drugs control program – January 1, 2014.*
WAC 296-62-50020 We feel that "relative toxicity and "occupational exposure" are very difficult, if not impossible to define. We are unaware of available data or standards which state the threshold of exposure resulting in relative toxicity for each hazardous drug on the NIOSH guidelines. We do not know of experts in this field who could define these terms for each medication and author hazard assessments. We suggest the wording be deleted.	L&I agrees that it would have been overly prescriptive to have required a formal analysis of relative toxicity for each hazardous drug during the hazard assessment. The wording is not in the final rule.
What is required for a mixing area for low hazard drugs	The rule allows the employer to develop precautions based on a workplace risk assessment. Specific policies and procedures regarding drug preparation are workplace specific and would include, but are not limited to, consideration of engineering controls, personal protective equipment, work flow, and housekeeping.
Add language clarifying that the written inventory of hazardous drugs will include "those drugs that do not pose a significant risk of direct occupational exposure because of their dosage formulation and will not be treated as hazardous drugs…for the purpose of complying with this chapter.	L&I appreciates the intent of this comment but believes the scope and application of the rule is adequately clear under WAC 296-62-50005(c): *If there is reasonably anticipated occupational exposure to one or more hazardous drugs , the employer must develop a hazardous drugs control program as required in WAC 296-62-50015.* Therefore, the inventory must include all hazardous drugs in the workplace for which there is reasonably anticipated occupational exposure.

Modify the wording regarding the requirement for the hazard assessment to be conducted by qualified, trained staff.	L&I concluded that this requirement would have exceeded the NIOSH Alert documents and it is not in the final rule.
Add a requirement that hazardous drugs be added to chemical hazard communication plans required by WAC 296-800-170.	L&I appreciates the intent of this comment but believes that the specific proposed addition is unnecessary. The rules already notes that "occupational exposure to hazardous drugs is also covered under WAC 296-800-170."
Make the following language change to section 296-62-50020(2) (1) Each health care setting must conduct initial and at least annual hazard assessments that assess the relative risk of toxicity from occupational exposure in order to determine the appropriate protective actions to be taken.	L&I appreciates the comment but believes that it would have been overly prescriptive to have required a formal analysis of relative toxicity for each hazardous drug during the hazard assessment. The wording is not in the final rule. However, recognizing that the risk of experiencing adverse medical consequences from exposure to hazardous drugs is influenced by drug toxicity, among other factors, the following note has been included in the final rule: *WAC 296-62-50020* *The likelihood that a worker will experience adverse effects from exposure to hazardous drugs varies depending upon the relative toxicity and absorptive properties of a drug, the amount, duration and frequency of contact, and the lack of proper work precautions.*
In section 296-62-50020(3)(i) WSHA objects to the use of the word "potential" as the conditions of exposure are spelled out in the NIOSH Alert.	L&I appreciates the comment. NIOSH provides examples of conditions that carry occupational exposure. These are simply examples and are not all inclusive. The language and use of the potential in section 296-62-50020(2)(i) is consistent with the intent of NIOSH and the definition of occupational exposure in this rule. The final rule language reads: *WAC 296-62-50020(2)(i)* *Potential hazardous drug exposures during work operations, such as drug preparation and administration.*
Include the following factors that determine the degree of occupational exposure will be used to determine the hazard in the hazards assessment	L&I agrees with the intent of the comment and the final rule language for hazard assessment includes consideration of the type

• Formulation of a drug • Relative toxicity of a drug • Packaging of a drug • Amount of drug handled.	of hazardous drugs being handled and the volume, frequency, packaging, and form of hazardous drugs handled (tablets, coated versus uncoated, powder versus liquid. While relative toxicity is not included in the listed factors, the following note has been included in the final rule: *WAC 296-62-50020* *The likelihood that a worker will experience adverse effects from exposure to hazardous drugs varies depending upon the relative toxicity and absorptive properties of a drug, the amount, duration and frequency of contact, and the lack of proper work precautions.* The rule also states: *WAC 296-62-50010* *…..Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)……*
Change language in section 296-62-50015(1)(a) to read: A current hazard assessment *specific to the organizatio*n.	L&I agrees that the rule language lack clarity. In order to add clarity the final rule language has been changed to read: *WAC 296-62-50020(1)* *Each health care facility covered under the scope of this chapter must conduct hazard assessments in order to determine the appropriate precautions to be taken. These assessments may be limited to the hazardous drugs for which there is reasonably anticipated occupational exposure.*
Change language in section 296-62-50015(1)(d) to read Hazardous drugs policies and *procedures that recognize variable levels of risk of adverse effects* from occupational exposure including, but not limited	L&I agrees that some hazardous drugs pose less risk than others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to

to:	hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
WAC 296-62-50025 Personal protective equipment (PPE) - changed to WAC 296-62-50030	
Providing personal protective equipment at no cost to the employee is not in the NIOSH Alert.	L&I agrees and has clarified that employers must provide personal protective equipment at no cost to employees as required under chapter 296-800-160 WAC, Personal protective equipment.
The provisions regarding the use of personal protective equipment are quite prescriptive. The NIOSH Alert states that employers should provide workers with proper PPE on the basis of a risk assessment as required by OSHA. The prescriptive standards described in the proposed rule are not supported in the Alert.	L&I agrees that the rule proposal lacked clarity and has clarified the language in the final rule to read: *WAC 296-62-50030(1)* *When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, Personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.*
With regards to the requirement to dispose gowns after each use, we are unaware of research that suggests this frequency. We suggest, instead, to require disposal of a gown when contamination or gown contact with hazardous drugs is evident. This protects against aerosol particles from potential hazardous drugs that accumulate on a gown.	L&I appreciates the comment and has adopted final rule language that is consistent with and does not exceed the NIOSH Alert. *WAC 296-62-50030(4)(c)* *Remove and dispose of gowns at the end of hazardous drug handling activities, when leaving the hazardous drug handling area and as*

	soon as possible when damaged or contaminated.
This language (re: use of a full face respirator) exceeds the provisions in "PPE for Healthcare Workers who work with Hazardous Drugs" found on p. 2-3	L&I agrees that the use of a full-face piece respirator may not be necessary in every situation. Consistent with the overall guidance in the NIOSH Alert documents, the requirement that canister-type respirators be full-face is not in the final rule.
On p. 13 of NIOSH it states to dispose of gowns, not PPE. Some PPE is not disposable (such as cartridge-type respirators). "PPE for Healthcare Workers who work with Hazardous Drugs" states "Donning and removal of PPE should follow local hospital procedures and the manufacturer's instructions" (Workplace Solutions, 2008, p. 2)	L&I agrees that the proposal lacked clarity and the final rule language has been clarified to read: *WAC 296-62-50030(7)* *Disposable PPE must be discarded into appropriate containers immediately after use or as soon as feasible after contamination. Reusable PPE must be properly cleaned and decontaminated after use or contamination.*
"Inspect gloves for defects before use and change gloves on a regular basis. Changing recommendations vary from 30–60 minutes [NIOSH 2004; ASHP 2006]. Whenever gloves are damaged or contact with a drug is known or suspected, carefully remove and dispose of them properly." This is from "PPE for Health Care Workers who Work with Hazardous Drugs" p. 2 published in 2008. Since it's later than 2004, this should supersede the 2004 guideline. It does not require a 30 minute change.	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50030(3)(d)* *Change gloves every thirty to sixty minutes or when torn, punctured, or contaminated.*
This ruling will require many more staff to be donning personal protection equipment. If this is necessary, we have no problem ensuring its use. However, because of the inclusive of many inappropriate drugs, personal protection equipment will be likewise inappropriate worn. This may seem to be a harmless oversight, but anyone who was involved in the recent H1N1 events, quickly learned that healthcare ran out of masks and gloves. Manufacturers could not keep pace with the supply demands. Costs increased due to supply and demand factors. Also the cost of waste skyrocketed and would again if many more staff are using much more protective devices- most of which are not necessary and should be reconsidered in redrafting this ruling.	L&I agrees that the rule proposal lacked clarity and has clarified the language in the final rule to read: *WAC 296-62-50030(1)* *When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, Personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.* L&I also agrees that some hazardous drugs pose less risk than

	others. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.*
WAC 296-62-50025 (3)(a): Amend the language to conform with the NIOSH standard: "Wear gowns whenever there is a reasonable possibility of a hazardous drug splash or spill as in compounding or administration of hazardous drugs."	L&I agrees and has clarified the final rule language to read: *WAC 296-62-50030(4)(a)* *Wear gowns whenever there is a reasonable possibility of a hazardous drug splash or spill such as in compounding, preparing and administering hazardous drugs.*
WAC 296-62-50025 (3)(b) Amend the definition to move from a prescriptive requirement: "Wear nonabsorbent, nonlinting gowns as determined by the hazard assessment."	L&I appreciates the comment but believes that by providing a choice of gowns the language is not overly prescriptive. It is also, consistent with and does not exceed the NIOSH Alert. No amendment has been made to the final rule language.
WAC 296-62-50025 (3)(c) Amend the language to require that if no permeation information is available, change gowns every two to three hours <u>or immediately after a spill or splash.</u> This change then conforms with NIOSH provisions.	L&I appreciates the intent of the comment. The final rule language has been clarified to require gown changes when "contaminated after a splash or spill", rather than "immediately after" because spills can occur without contamination.
WAC 296-62-50025 *(5) Respiratory Protection.*	L&I agrees and the final rule language has been clarified to read:

Use N95 or equivalent respiratory protection during spill cleanup and whenever there is risk of exposure to hazardous drug particulates. We suggest "and whenever there is risk" should be modified to include the word "significant."	*WAC 296-62-50030(6)(a)* *Use N95 or equivalent respiratory protection during spill clean up and whenever there is a significant risk of inhalation exposure to hazardous drug particulates.*
WAC 296-62-50025 *Note: Consider using chemotherapy gloves for hazardous drugs that are not chemotherapy drugs or for which no information is available.* We believe the "note" should be deleted. Why would facilities have to use chemotherapy gloves for medications which are not chemotherapy?	L&I agrees and the note has been deleted in the final rule.
A nurse would have to wear double gloves and a gown to administer oral contraceptives.	L&I agrees that it is unnecessary to double glove in all circumstances and has clarified the rule to state that double gloving is only required when permeation may be a factor such as compounding chemotherapy agents, or when there is a risk of breakage such as cleaning up a large spill. Gowns are only required when there is a reasonable possibility of a hazardous drug splash or spill. Double gloving and gowning is not required when administering drugs such as oral contraceptives.
We appreciate language that requires providing, at no cost to the employee, personal protective equipment when working with hazardous drugs such as handling vials, compounding and administering hazardous drugs, and performing housekeeping activities. This is consistent with current regulations for respiratory protection and blood borne pathogen control.	L&I agrees and has clarified that employers must provide personal protective equipment at no cost to employees as required under chapter 296-800-160 WAC, Personal protective equipment.
With regards to the requirement to dispose gowns after each use, we are unaware of research that suggests this frequency. We suggest, instead, to require disposal of a gown when contamination or gown contact with hazardous drugs is evident. This protects against aerosol particles from potential hazardous drugs that accumulate on a gown.	L&I appreciates the comment and has adopted final rule language that is consistent with and does not exceed the NIOSH Alert. *WAC 296-62-50030(4)(c)* *Remove and dispose of gowns at the end of hazardous drug handling activities, when leaving the hazardous drug handling area and as soon as possible when damaged or contaminated.*

We appreciate the selection and use of respirators as required in 296-842 WAC. This is necessary preventative measure, since studies show that nurses exposed to hazardous drugs have been found with metabolites in their system, and their children showed signs of exposure. This is due to hazardous drugs brought home unintentionally on their clothes. Sometimes, route of exposure is unknown, and can include respiratory exposure.	L&I agrees. The final rule language, consistent with the overall guidance in the NIOSH Alert documents, reads: *WAC 296-62-50030(6)* *Respiratory Protection.* *a. Use N95 or equivalent respiratory protection during spill clean up and whenever there is a significant risk of inhalation exposure to hazardous drug particulates.* *b. Use an appropriate chemical cartridge-type respirator for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects*
Consistent with existing health and safety regulations for respiration protection, the following language on the use of surgical N95 level respirator protection must be added: Fit-testing and education on respiration protection must be included. We appreciate the requirement to use full-face elastomeric respirators.	L&I does not see the necessity of repeating the requirements of the Respiratory Protection Standard. The rule states that employers must ensure the use of appropriate PPE in accordance with chapter 296-842 WAC, Respirators.
50025*(2)(d)(a)* Please change this sentence to "When indicated by the hazard assessment, make sure that the outer glove extends over the cuff of the gown." While the hazard profile of some hazardous drugs would indicate this precaution, it would be necessary for other drugs and add cost without adding any meaningful protection to workers.	The double gloving procedure described is standard medical practice and does not need to be described in the rule. This language is not included in the final rule.
50025 *(3)(a)* Suggest amending the requirement to conform with NIOSH standard: "Wear gowns whenever there is a reasonable possibility of a hazardous drug splash or spill as in compounding or administration of hazardous drugs."	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50030(4)(a)* *Wear gowns whenever there is a reasonable possibility of a hazardous drug splash or spill as in compounding or administration of hazardous drugs.*

50025(*3) (b)* Please change this sentence to "Wear nonabsorbent, nonlinting gowns made of polyethylene-coated polypropylene or other protective material as determined by the PPE hazard assessment. Make sure the gown has a closed front, long sleeves, and elastic or knit cuffs." As written, this sentence is too prescriptive and will not allow facilities to adapt unforeseen technologies that add at least the same protections at potentially lower costs. For example, gown coating could change. In the second sentence, please describe the desired effect, not how it should occur. "The gown should protect skin."	L&I appreciates the comment but believes that by providing a choice of gowns the language is not overly prescriptive. It is also consistent with and does not exceed the NIOSH Alert. L&I has replaced "other appropriate material" with "other nonabsorbent, nonlinting protective material" to make the rule more consistent with the NIOSH Alert documents.
50025 *(3) (c)* If no permeation information is available, change gowns every two to three hours or immediately after a spill or splash. (Conforms with NIOSH provisions.)	L&I appreciates the intent of the comment. The final rule language has been clarified to require gown changes when "contaminated after a splash or spill", rather than "immediately after" because spills can occur without contamination.
50025 *(6)* WSHA supports the additional statement "Reusable PPE must be properly cleaned and decontaminated after use or contamination."	L&I agrees.
Appropriate guidance on glove selection is not provided. Provide a link for guidance on proper glove selection.	L&I has committed to work with stakeholders to develop these types of resources as described in section 296-62-50055, implementation plan.
Delete the Note regarding glove thickness.	L&I agrees that this is not necessary and it is not in the final rule.
Allow for the selection of other appropriate face protection based on the hazard assessment.	L&I agrees. The final rule language has been clarified to read: *WAC 296-62-50030(5)* *Wear a full face shield or a mask and eye protection as appropriate when splashes to the eyes, nose, or mouth may occur; examples include cleaning a spill, or performing a procedure such as bladder instillation.*
Allow for the use of a half-face cartridge respirator or PAPR with chemical cartridges based on the respirator hazard assessment.	L&I agrees. The final rule language has been clarified to read: *WAC 296-62-50030(6)(b)* *Use an appropriate chemical cartridge-type respirator for events*

	such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects .
We are concerned that implementation of the proposed regulations as currently written could disrupt medication regimens for patients who are currently stable of paroxetine and resperidol. The proposed handling procedures would be extremely unsettling to some of our patients, some who are paranoid due to their mental illness and are already reluctant to accept medications.	L&I believes this comment is related to the requirements for personal protective equipment (PPE). L&I agrees that the use of PPE is not necessary for all hazardous drug preparation and administration activities. Consistent with the overall guidance in the NIOSH Alert documents, the final rule language has been clarified to allow the employer to determine use procedures based on the PPE hazard assessment and reads: *WAC 296-62-50030(1)* *When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, Personal protective equipment, and chapter 296-842 WAC, Respirators.* The rule also states: *WAC 296-62-50010* *…..Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)…..*
Add specific language requiring that each health care setting conduct a PPE assessment and provide PPE at no cost to employees who handle hazardous drugs.	L&I agrees with the intent of this comment and has addressed it in the final rule with language requiring that the PPE assessment be done in accordance with WAC 296-800-160 and Chapter 296-842 WAC.
Add specific language addressing "hazardous drug packages" and products "containing hazardous drugs" to the paragraph covering the use of gowns when there is a possibility of a splash or spill	L&I agrees with the intent of this comment but believes that the language in the rule is sufficiently clear about its broad coverage without the additional detail.

Add "hazardous" to several references to "drug" in the section on gowns.	L&I agrees and has done this.
Delete language requiring the use of gowns made of polyethylene-coated polypropylene or other appropriate material and replace it with reference to standards adopted by the Association of the Advancement of Medical Instrumentation.	L&I appreciates the comment but believes that by providing a choice of gowns the language is not overly prescriptive. It is also consistent with and does not exceed the NIOSH Alert. L&I has replaced "other appropriate material" with "other nonabsorbent, nonlinting protective material" to make the rule more consistent with the NIOSH Alert documents.
Add sentence requiring disposal of textiles contaminated with a hazardous substance in specially marked laundry containers and then in additional impervious containers.	L&I believes this language would exceed NIOSH and the change has not been made.
Delete the sentence requiring powder free chemotherapy gloves when handling chemotherapy gloves and replace it with "hazard assessment will determine type of garment to use."	L&I believes that making this change would not be consistent with the NIOSH Alert documents. The language has not been changed.
Delete the sentence requiring polyethylene-coated polypropylene or other nonabsorbent, nonlinting protective material as determined by the PPE hazard assessment and replace it with "hazard assessment will determine type of garment to use."	L&I appreciates the comment but believes that by providing a choice of gowns the language is not overly prescriptive. It is also consistent with and does not exceed the NIOSH Alert. L&I has replaced "other appropriate material" with "other nonabsorbent, nonlinting protective material" to make the rule more consistent with the NIOSH Alert documents.
Delete the sentence requiring an appropriate full-facepiece chemical cartridge-type respirator and replace it with "hazard assessment will determine type of protection to use."	L&I appreciates the intent of this comment and has changed the language in the final rule by deleting the specific requirement for a "full facepiece chemical cartridge-type respirator" and replacing with "an appropriate chemical cartridge-type respirator."
Change the language in section 296-62-50025(1) to read Conduct a PPE hazard assessment to determine appropriate PPE based on occupational exposure to hazardous drugs. Based on this assessment, provide appropriate PPE at no cost to employees.	L&I agrees that the selection of appropriate PPE is the employer's responsibility and believes it should be based on the employer's PPE hazard assessment as require in WAC 296-800-160, personal protective equipment, and WAC 296-800-842, respirators. The final rule language reads: *WAC 296-62-50030(1)* *When there is reasonably anticipated exposure to hazardous drugs*

	each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.
Change the language in section 296-62-50025(4)(d) If no permeation information is available, change gowns every 2 to 3 hours or when grossly contaminated.	L&I agrees that the proposed language is not consistent with current NIOSH guidance. The final rule language reads: *WAC 296-62-50030(4)(d)* *If no permeation information is available, change gowns every two to three hours or when contaminated after a splash or spill.*
Change the language in section 296-62-50025(5)(b) to read Use an appropriate full-face piece chemical cartridge respirator for events such as large spills when an intravenous (IV) bag breaks or a line disconnects and leaks).	L&I agrees that the proposed language is not consistent with current NIOSH guidance. The final rule language reads: *WAC 296-62-50030(6)(b)* *Use an appropriate chemical cartridge-type respirator for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects.*
Change the language in section 296-62-50025(6) to read Dispose of disposable or clean, cleanable PPE immediately after use or whenever contaminated	L&I agrees that the proposed rule language lacked clarity. The final rule language reads: *WAC 296-62-50030(7)* *Disposable PPE must be discarded into appropriate containers immediately after use or as soon as feasible after contamination. Reusable PPE must be properly cleaned and decontaminated after use or contamination.*
WAC 296-62-50025 needs to reference that some setting are excluded from the requirement to conduct a PPE assessment based on the lack of risk due to the toxicity, formulation, etc., of the drugs in that setting.	L&I agrees the proposed rule lack clarity. The final rule language states that a PPE assessment must be conducted when there is reasonably anticipated exposure to hazardous drugs. Drug formulation may be considered in determining whether or not there is occupational exposure.

	WAC 296-62-50010 ***Occupational exposure*** *means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties. Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).*
WAC 296-62-50030 Engineering controls – changed to WAC 296-62-50025	
There are approximately 20 medications on the list which are used currently or in the recent past at our facilities. Risperidone is prescribed to over 200 patients at one major facility alone. All our facilities manipulate dosage forms, i.e. crush tablets, for patients with swallowing issues and for patients who are suspected of noncompliance with taking medications. None of our facilities have the ventilation systems required by these draft rules for storage of or crushing these medications. None have adequate room for separate storage areas for these medications in patient care areas.	L&I agrees that the proposed rule lacked clarity. The rule clarifies the following: *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.* The rule also states: *WAC 296-62-50010* *….Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation)…..* L&I agrees that the use of ventilated cabinets is not necessary when crushing or splitting drugs such as Resperidone if appropriate alternate precautions are taken (e.g., isolating the

	tablet by using a protective plastic sleeve during crushing) in the hazardous drugs control program.
In the case of a home infusion company that does very low volume hazardous drug compounding would a BSC with closed system transfer devices require outside venting, if addressed in the employers hazard assessment?	When the use of ventilated cabinets is necessary the rule states that the cabinet should be ventilated to the outside when feasible, and allows for use of cabinets that are not designed to be exhausted to the outside where the employer can justify use. The final rule language has been clarified to read: *WAC 296-62-50025(2)(c)* *Use filtering media that is approved by the cabinet manufacturer and is appropriate for the agent being captured, such as a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one-hundred percent of the filtered air to the outside unless the employer can provide an evidence based justification to do otherwise.*
The deadline for compliance with the institution of engineering controls (ventilated cabinets) is impractical to achieve in many cases.	L&I agrees and the effective date for implementation of appropriate ventilated cabinets has been moved to January 1, 2015.
The board is concerned with the impact on access to patient care if a community pharmacy, for example, must add significant costs or remodel to accommodate the installation of a laminar flow hood to meet the rule requirements as stated for oral solid dosage form. Many of the identified oral solid agents represent high volume (top 20) prescribed medications. We understand pharmacies may choose to not carry these medications.	L&I agrees that the proposed rule lacked clarity. The rule clarifies that *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
We appreciate the language requiring installation of outside exhaust so that it is at least twenty-five feet from air intakes, points of building entry such	The proposed language would have exceeded the NIOSH Alert and it is not in the final rule.

as windows and doors, and areas that may be populated. Twenty-five feet is a common standard.	
We appreciate the requirement that employees, including contract workers, performing maintenance are informed of the hazardous drugs compounded by having access to material safety data sheets. However, Material Safety Data Sheets, may not be alone sufficient. In instances where MSDS sheets are not currently used, such as for newly available pharmaceuticals, other reference material must be made available. We recommend the language, "material safety data sheets or other equivalent information sources" so that employees always have access to information they need to identify and handle potential and known hazardous drugs safely.	L&I agrees and the final rule language , consistent with the overall guidance in the NIOSH Alert documents, reads: *WAC 296-62-50025(2)(g)(iv)* *Make sure that workers performing maintenance are familiar with applicable safety procedures, warned about hazards (e.g., through the provision of material safety data sheets or other equivalent information resources), and trained in appropriate work techniques and PPE needed to minimize exposure.*
The technology is evolving. Do not define the specific type of (ventilated cabinet) filter.	L&I agrees and a specific requirement to use HEPA filters is not in the rule.
Many of the newer cabinets are designed to exhaust as little as 30 % of the air to conserve energy. This would require most facilities to replace their cabinets with older ones.	L&I appreciates the comment. The rule language is consistent with the NIOSH Alert and has not been changed.
Affected facilities' 2012 budgets are set. All health care organizations in the state are experiencing serious cost pressures and/or anticipating future cost pressures. In order to implement any new ventilation controls affected facilities will need at least two years to properly budget for these changes.	L&I agrees and the effective dates contained in the final rule are as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
WAC 296-62-50030 Engineering Controls: For skilled nursing and assisted living providers, the concept of engineering controls must be tied to a tiered assessment regarding the potential for exposure to hazardous drugs. For high census Medicaid providers, the issue is particularly problematic given that there are no funds for such engineering controls.	L&I appreciates the comment. To be consistent with the NIOSH Alert documents in recognizing the various risks presented by the wide variety of hazardous drugs and exposure factors, the rule's requirements only apply to hazardous drugs for which there is reasonably anticipated occupational exposure and then allows a

	tiered approach for the drugs requiring protective measures. This clarification has been added: *WAC 296-62-50015(2)A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.* The final rule language has also been clarified to clearly state that it is the employer's responsibility: *WAC 296-62-50025(1)* *Evaluate and implement appropriate engineering controls to eliminate or minimize employee exposure….*
Section WAC 296-62-50030(5) requires that the implementation of effective ventilation controls be accomplished by December 1, 2012. The implementation of effective ventilation controls might require significant planning, engineering and capital. An implementation date of January 1, 2014 is a more pragmatic target date. In the interim, employees could be protected with appropriate administrative controls and personal protective equipment.	L&I agrees and the effective dates contained in the final rule are as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
WAC 296-62-50030 What is the definition of "general exhaust ventilation"? This should not apply if the hazard assessment determines a low occupational exposure risk. (e.g. unit dose packaging, little or no exposure to medications etc.).	L&I agrees that the language was not sufficiently clear and it is not in the final rule.
WAC 296-62-50030 Our facilities crush medications on a daily basis, more	L&I agrees and the final rule language has been clarified to read:

than "the occasional or limited need" yet we believe that a nurse using the device provided to crush tablets is a low risk of exposure. Therefore, we suggest *(e.g., the occasional or limited need to crush a hazardous drug tablet)* be removed from the wording.	*WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
We are also concerned that the equipment and ventilation requirements for medication storage would make operation of clinic pharmacies cost-prohibitive, and could result in key mental health medications to be no longer carried.	L&I agrees and the storage ventilation language is not in the final rule.
50030*(1)* Please change this statement to read: "Use engineering controls, if needed as determined by the hazard assessment, to eliminate or minimize employee exposure to hazardous drugs." Without this addition, a reasonable reader could interpret this statement to intend that engineering controls are always required, regardless of the hazard assessment. This would add many millions of dollars to the provision of health care and negatively impact patient care and hospital operations without adding any additional protections to many workers.	L&I agrees that the proposed rule language lacked clarity and has been clarified to read: *WAC 296-62-50025(1)* *Evaluate and implement appropriate engineering controls to eliminate or minimize employee exposure….*
We support changing WAC 296-62-50030(3) to the following: Make sure that areas where hazardous drugs are stored (e.g., bulk pharmacy storage areas, medication rooms) have general exhaust ventilation in order to dilute and remove airborne contaminants.	L&I appreciates the comment. The storage ventilation language is not in the final rule.
We support adding provisions for the use of alternative precautions when the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs. We support the following language regarding the alternative precautions: (4 "These may include temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures." The addition of the word "temporarily"	L&I agrees that the proposed language lacked clarity. Consistent with the overall guidance in the NIOSH Alert documents, the final rule language has been clarified to read: *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment*

will allow staff to be protected from occasional procedures without major modifications to work spaces or work flow that would add costs to health care without adding additional protection to workers.	*determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
We support adding the following provisions: "Chemotherapy drugs must be prepared in an appropriate ventilated cabinet unless the employer can provide an evidence - based justification to do otherwise." The justification should be based on real evidence (e.g. a research study) and not limited to a clinician's justification.	L&I agrees that an evidence based judgment is appropriate and, consistent with the overall guidance in the NIOSH Alert documents, the final rule language reads: *WAC 296-62-50025(2)(a)(ii)* *Chemotherapy drugs must be prepared in an appropriate ventilated cabinet with the exception of circumstances where the employer can document evidence of a clinical need (e.g., there is a nonroutine need to provide chemotherapy treatment, compounding services are not readily available, and it is in the best interest of the patient to provide local care). In such circumstances alternate precautions must be instituted as described above.*
WAC 296-62-50030(4)(c), prohibits the routine use of supplemental engineering or process controls as a substitution for ventilated cabinets. This would mean that a closed-system transfer device could not be used to routinely administer a low hazard drug, such as Depo-Provera. Clarification is needed to show that this is determined by the hazard assessment to allow some flexibility.	L&I agrees that the proposed rule language lacked clarity. This language is not in the final rule.
We support changing WAC 296-62-50030(4)(e) as follows: "Use filtering media that is approved by the cabinet manufacturer and is appropriate for the agent being captured, such as a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one-hundred percent of the filtered air to the outside unless the employer can provide an evidence-based justification to do otherwise." As we have previously stated, some of the newer cabinets are designed to protect workers and reduce costs by exhausting as little as 30 percent of the air.	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50025(2)(c)* *Use filtering media that is approved by the cabinet manufacturer and is appropriate for the agent being captured, such as a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one-hundred percent of the filtered air to the outside unless the employer can provide an evidence-based*

Without this provision, these newer, more energy efficient cabinets will need to be replaced at significant cost without adding any additional protections to workers.	*justification to do otherwise.*
We request WAC 296-62-50030(4)(i)(ii) be changed to the following to come into compliance with NIOSH: "Select appropriate performance and test methods for containment isolators, depending on the type (containment-only or aseptic containment), the operating pressure (positive or negative and designed magnitude), and the toxicity of the hazardous drug, at a minimum, conduct leak and containment integrity tests in accordance with current American Glovebox Society guidelines. In addition, perform a HEPA filter leak test for those containment isolators that utilize HEPA filtration." Without this addition, this provision exceeds NIOSH. (2004 Safety Alert, p. 16)	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50025(2)(g)(ii)* *Select appropriate performance and test methods for containment isolators, depending on the type (containment only or aseptic containment), the operating pressure (positive or negative and designed magnitude), and toxicity of the hazardous drug. At a minimum, conduct leak and containment integrity tests in accordance with current American Glovebox Society guidelines. In addition perform a HEPA filter leak test for those isolators that utilize HEPA filtration.*
Please change WAC 296-62-50030(4)(i)(iv) to the following to come into compliance with NIOSH: "Make sure that workers performing maintenance are familiar with applicable safety procedures, warned about hazards (e.g., through the provision of material safety data sheets or other equivalent information resources), and trained in appropriate work techniques and PPE needed to minimize exposure." (2004 Safety Alert, p. 16)	L&I agrees and the following language was added to the rule: WAC 296-62-50025(2)(g)(iv) …. *"e.g., through the provision of material safety data sheets or other equivalent information resources"* ….
We requests that the ventilation control effective date be December 31, 2014 to allow enough time for facilities to plan for the expenditures without severely impacting hospital finances.	L&I agrees and the effective dates contained in the final rule are as follows: *WAC 296-62-50055(1)* *Hazardous drugs control program – January 1, 2014.* *Employee training - July 1, 2014.* *Ventilation controls - January 1, 2015.*
The costs of physical plant modification with regard to vent requirements that have been suggested by the draft rules represent a potentially	L&I agrees that facilities need adequate time to plan and budget for significant engineering changes. However, unlimited

crippling financial blow to private practices and to hospitals which are not yet in compliance at a time when their practice patterns are in flux. The suggestion that the physical plant changes could be phased in within another 2 or 3 years fails to recognize the changes that are occurring in the market place. This deadline is arbitrary and could force programs to drop out of the market place or to spend thousands and thousands of dollars on capital investment which is not synchronized with the needs of the communities they serve. We propose that the new rules grandfather the current physical plants used in these facilities. This grandfathering would cease for each facility when (due to their own capacity needs and local practice patterns) they make any changes to their pharmacies that require a building permit. Facilities could then adapt to the new rules when the permit trigger is activated rather than merely to satisfy an arbitrary date set by Labor and Industries.	grandfathering would not be consistent with the NIOSH Alert documents. The final rule requires that ventilation controls be implemented by January 1, 2015. L&I believes this is sufficient time to evaluate, plan, and budget for necessary engineering controls and strikes an appropriate balance between worker protection and legitimate business needs.
No clarity of how tablet splitting will be handled. If tablet splitting is considered manipulation of a product and requires a ventilated cabinet, it is highly likely that these tablets would no longer be able to be split by pharmacists, pharmacy technicians and nurses.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
Potentially the hospital shall be required to build an entirely different area to check in hazardous drugs, and another to prepare hazardous drugs.	L&I agrees that the proposed rule language lacked clarity regarding storage requirements. The final rule language has been clarified to read: *WAC 296-62-50035(1)(b)* *Store and transport hazardous drugs in a manner that minimizes the risk of breakage.*

Remove the statement about BSC's being ventilated cabinets since not all BSCs are ventilated. Make the statement consistent with the BMBL.	L&I appreciate the comments. In the context of the rule biosafety cabinet refers to Class I, II, and III biosafety cabinets as described by NIOSH and the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.* This is consistent with and does not exceed the NIOSH Alert. No change has been made to the final rule.
The list of ventilated cabinets can be more specific and does not include fume hoods (if asepsis is not required). Revise examples of ventilated cabinets to include specific ventilated biological safety cabinets (Class II B2, Class II A2 with thimble connection), fume hood, containment isolators, or similar local ventilation.	L&I agrees that laboratory fume hoods are engineering controls and that they are specifically listed in the NIOSH definition of engineering controls. The final rule language includes laboratory fume hoods: *WAC 296-62-50010* ***Engineering controls*** *means devices designed to eliminate or reduce worker exposure to hazards. Examples include biological safety cabinets, laboratory fume hoods, containment isolators, safer sharps devices, and safety interlocks.*
Engineering control examples revise to read "appropriate ventilated enclosure (fume hood, BSC or other local exhaust)."	The examples are consistent with and do not exceed the NIOSH Alert. Additional examples are not necessary and were not added to the final rule.
Remove the note regarding consideration of dedicated exhaust because it is not helpful.	L&I agrees that the proposed rule language lacked clarity and did not provide significant protections. This language is not in the final rule.
Ventilated cabinets – provide the option of a fume hood as well.	The list of engineering controls in 296-62-50025 is not meant to be all inclusive. In order to be consistent with NIOSH fume hoods have been in included in the definition of engineering controls. The final rules language reads: *WAC 296-62-50010*

	Engineering controls *means devices designed to eliminate or reduce worker exposure to hazards. Examples include biological safety cabinets, laboratory fume hoods, containment isolators, safer sharps devices, and safety interlocks.*
Consider allowing unfiltered exhaust out of the building as is the case for other hazardous chemicals.	The rule language regarding filtering of cabinet exhaust is consistent with and does not exceed the NIOSH Alert. No change was made to the final rule language.
Clarify language on general ventilation to ensure that it does not conflict with building codes.	L&I agrees. This section has been deleted from the final rule.
Clarify that biosafety cabinets are not required to draw an injection at bedside or med room.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
Allow grandfathering for facilities that require changes for "venting and hoods" but "currently do not have state of the art equipment."	L&I agrees that facilities need adequate time to plan and budget for significant engineering changes. However, unlimited grandfathering would not be consistent with the NIOSH Alert documents. The final rule requires that ventilation controls be implemented by January 1, 2015. L&I believes this is sufficient time to evaluate, plan, and budget for necessary engineering controls and strikes an appropriate balance between worker protection and legitimate business needs.
Changer requirement for engineering controls to be determined by the hazardous assessment.	L&I appreciates the comment. The hazard assessment includes a requirement to assess engineering controls. It is not necessary to repeat this requirement in the engineering controls section. The

	final rule language reads: *WAC 296-62-50025(1)* *Evaluate and implement appropriate engineering controls to eliminate or minimize employee exposure…..*
General ventilation – need to define sufficient ventilation.	L&I agrees with the concern expressed. The requirement is not included in the final rule.
One new program in particular right now is geared at delivering sensitive medications to schizophrenic and bipolar populations that often are hard to reach and find it difficult to get to clinics. There is a long-acting antipsychotic that is on the list of hazardous medications. There is a new program sponsored by psychiatrists, manufacturers, and retail pharmacies to deliver this medication via injection in a retail pharmacy setting. This legislation completely inhibits that from happening because we cannot afford to install the necessary equipment or use the necessary protective equipment on a routine basis to deliver this population.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50025(2)(a)(i)* *Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g. crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.*
WAC 296-62-50035 Safe handling practices, WAC 296-62-50040 Cleaning, housekeeping, and waste handling, and WAC 296-62-50045 Spill control	
The linens of hundreds of patients would have to be processed as hazardous waste.	L&I agrees that the rule proposal lacked clarity and has clarified the final rule language to read: *WAC 296-62-50030(2)* *Use appropriate Personal Protective Equipment (PPE) whenever handling body fluids and contaminated laundry.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.
Facilities do not want to store birth control and mental health drugs with	L&I appreciates the comment. The final rule language has been

chemotherapy drugs. If they are forced to store birth control separately many will be unable to and this will limit access to birth control and mental health drugs in Washington.	clarified to read: *WAC 296-62-50035(1)(b)* *Store and transport hazardous drugs in a manner that minimizes the risk of breakage.*
There are two concerns: (1) it is impossible for organizations to know if a patient received a hazardous drug in another facility; (2) could put organizations at risk of violating HIPPA. It should be noted that some drugs are altered after the body processes them and as a result are no longer toxic. (the 48 hour thing)	L&I agrees and consistent with the overall guidance in the NIOSH documents, the final rule language has been clarified to read: *WAC 296-62-50030(2)* *Use personal protective equipment whenever handling body fluids and contaminated laundry.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.
No health care organization has enough purchasing power to demand that a manufacturer or distributor label a hazardous drug container. This provision will limit access to chemotherapy and other necessary medical treatments.	L&I agrees and this requirement is not in the final rule. Consistent with the overall guidance in the NIOSH Alert documents, the final rule language reads: *WAC 296-62-50035(1)(a)* *Label hazardous drugs containers in accordance with WAC 296-800-170, Employer chemical hazard communication.*
How would anyone know if the vomit, urine, or stool left behind in public bathrooms, garages, or lobbies are that of someone taking a hazardous drug? This will require all hospitals to treat all human waste as contaminated. Swedish will be required to provide special training and equipment to a broad spectrum of employees. All of whom, again, would require training, and use protective equipment. Finally, all human waste will have to be disposed of as hazardous waste. For Swedish, regular waste costs about 12cents/pound; biohazardous waste 76-90 cents/pound, and hazardous waste (for which this would be classified) up to an astounding $3.60/pound. A business impact analysis was not conducted;	L&I agrees that the rule proposal lacked clarity and the final rule language has been clarified to read: *WAC 296-62-50030(2)* *Use personal protective equipment whenever handling body fluids and contaminated laundry.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.

had it been, these sorts of significant factors would have become apparent.	
Laundry workers at Hospital Central Services Association, the central laundry facility for many Puget Sound Hospitals wear proper Personal Protective Equipment (PPE), including gloves, masks and face shields to handle soiled linen. All linen is considered infectious and requires this type of handling. Because of this, there is no need to include the Laundry section on page 15 in the November discussion document. Further, because all soiled linen is treated as infectious requiring PPE with mask and face shield, there is no reason to place said linen in a specially colored bag. Bags supplied by HCSA are leak proof thus in compliance now. There is no need for any special handling for soiled linens.	L&I appreciates the comment, however laundry operations that are not part of health care facilities where a health care provider provides health care to patients are not covered. L&I agrees that the rule proposal lacked clarity and the final rule language has been clarified to read: *WAC 296-62-50030(2)* *Use personal protective equipment whenever handling body fluids and contaminated laundry.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.
The new section WAC 296-62-50045 Spill Control is unnecessary. The requirement is met under WAC 296-824 Emergency Response including the training component. Hospitals in Washington State are required to have trained spill teams or to use outside vendors for emergency spill response.	L&I appreciates the comment, however the language in the spill control section, with minor changes, is consistent with and does not exceed the NIOSH Alert.
The collection of feces and urine for disposal as dangerous waste per the Department of Ecology Dangerous Waste Rules will require EVS technicians to perform this step. All feces and urine would then need to be stored and samples sent to laboratories for testing to determine if in fact it does designate for this disposal method. What is the scientific data that now requires this step?	L&I agrees that the rule proposal lacked clarity. The rule does not add any additional requirements regarding pharmaceutical waste handling than what is already required by existing federal (EPA) and state (department of Ecology) regulations. The final rule language has been clarified to read. *WAC 296-62-50030(2)* *Use personal protective equipment whenever handling body fluids and contaminated laundry.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.

Must containers be cleaned after holding hazardous drugs? By Ecology rule, the cleaning solution cannot be put down the drain but must be collected and sent out as a dangerous waste again adding unnecessary cost to the hospital.	L&I appreciates the comment. The final rule language is as follows: *WAC 296-62-50040(1)* *Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs are present.* This language does not mention drug containers and is not meant to be applied to them.
WAC 296-62-50035 Safe Handling Practices: (d) Prohibit the use of unventilated areas for drug storage; most facility-based LTC providers store medications on medications carts; as drafted, this provision has significant financial implications.	L&I agrees that this language lacks clarity and does not provide significant protection. It is not in the final rule.
WAC 296-62-50040 Unless L&I can provide a reference to an "*appropriate deactivation agent* for the medications we are using, we suggest the wording be deleted.	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50040(3)* *Clean work surfaces before and after each continuous activity and at the end of the work shift.*
We support changing WAC 296-62-50035(1) to require that hazardous drug containers are labels, that hazardous drugs be stored in a manner that minimizes the potential for spills and cross contamination, that hazardous drugs be transported in a manner that minimizes the risk of breakage, and delete the provision on drug storage ventilation.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50035(1)* *(a) Label hazardous drug containers in accordance with WAC 296-800-170, Employer chemical hazard communication--Introduction.* *(b) Store and transport hazardous drugs in a manner that minimizes the risk of breakage.*
We support changing WAC 296-62-50035(3) to clarify the following: hazardous drug preparation areas are designated areas for the preparation of hazardous drugs where access is limited during preparation; engineering	L&I agrees and the final rule language has been clarified to read: *WAC 296-62-50035(2)*

controls are to be used to minimize occupational exposure to hazardous drugs; Spike and prime the IV tubing and prepare syringes in a manner that limits occupational exposure which generally will require the use of a ventilated cabinet. Delete the provision requiring sealing and decontaminating all waste containers inside the ventilated cabinet before removing them from the ventilated cabinet.	*(a) Provide designated work areas for the preparation of hazardous drugs and limit access during preparation.* *(b) Coordinate tasks associated with preparing and administering hazardous drugs for the most effective control of worker exposure.* *(c) Spike and prime the IV tubing and prepare syringes in a manner that most effectively limits occupational exposure.* *(d) Do not remove tubing from an IV bag containing a hazardous drug.* *(e) When drug preparation is completed in a ventilated cabinet:* *(i) Seal the final product in a plastic bag or other sealed container for transport before taking it out of the cabinet.* *(ii) Seal and wipe all waste containers inside the ventilated cabinet before removing them from the cabinet.* *(iii) Remove all outer gloves and sleeve covers and bag them for disposal while inside the cabinet.*
We request WAC 296-62-50035(4)(b) the following change be made to this section: "As required by the hazard assessment, use engineering controls to transfer and administer hazardous drugs." It is critical that any reasonable person will understand that PPE may be sufficient to transfer and administer some hazardous drugs. For example, Depo-Provera shots do not need to be loaded in a vented hood.	L&I believes that use of engineering controls is sufficiently addressed in section 296-62-50025 of the final rule. Additional specific language regarding engineering controls for transfer and administration of drugs is not in the final rule.
WAC 296-62-50040(6) Please delete this section. There is no reference anywhere in NIOSH related to laundry. Including it clearly exceeds NIOSH guidelines and state law.	L&I agrees that specific references to laundry operations might exceed the NIOSH Alert and no such language is in the final rule. However, L&I does note that in order to be consistent with the NIOSH Alert documents laundry workers in health care facilities are covered by the provisions in the rule.

We support deleting WAC 296-62-50040*(6)*	L&I agrees. There are no requirements in the final rule referencing patients who may have received hazardous drugs within the last forty eight hours.
Under WAC 296-62-50040(7) without clarification it will be extremely costly to comply with this provision. As stated above, there is no way for an organization to know if a patient's waste has been contaminated within the previous 48 hours. This will add significant costs to health care at a time when government is requiring decreased costs.	L&I agrees that the rule proposal lacked clarity. The rule does not add any additional requirements regarding pharmaceutical waste handling than what is already required by existing federal (EPA) and state (department of Ecology) regulations. The final rule language has been clarified to read. *WAC 296-62-50035(3)(a)* *Dispose of pharmaceutical waste in accordance with applicable state and federal regulations.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.
WAC 296-62-50040(8) This section could cause confusion if the Department of Ecology changes its regulations regarding hazardous waste disposal. WSHA requests this section be changed to simply refer to Ecology's WACs and details be included in guidance documents.	L&I agrees that this language lacked clarity and may exceed the NIOSH Alert. The final rule language reads: *WAC 296-62-50035(3)(a)* *Dispose of pharmaceutical waste in accordance with applicable state and federal regulations.* In addition, the rule states that during the time before the implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.
WAC 296-62-50045 Please delete this chapter or change it to refer to Ecology's WACs. As stated above, it could cause confusion if the Department of Ecology changes its regulations regarding hazardous waste	L&I appreciates the comment, however the language in the spill control section, with minor changes, is consistent with and does not exceed the NIOSH Alert.

disposal. Provide additional detail in guidance documents.	In addition, the rule states that during the time before these implementation dates the department will establish a hazardous drugs advisory committee, work with stakeholders to develop model programs, and post resources and sample programs on its website.
Safe handling practices – change the statement to specify proper transport so that gloves are not required.	L&I agrees that PPE use should be determined by the PPE hazard assessment. This language is not in the final rule.
Handling of contaminated waste in a small hospital setting where the secretary or other workers on site may respond may be problematic.	L&I agrees that the rule proposal lacked clarity. The rule does not add any additional requirements regarding pharmaceutical waste handling than what is already required by existing federal (EPA) and state (department of Ecology) regulations. The final rule language has been clarified to read. *WAC 296-62-50035(3)(a)* *Dispose of pharmaceutical waste in accordance with applicable state and federal regulations.* Proposed language requiring attention to linens and wastes from patients receiving hazardous drugs within the previous forty eight hours has been deleted from the rule.
WAC 296-62-50050 Medical surveillance	
Requiring the employer to pay for medical exams is extraordinarily overstepping the line of what the duty of L and I's function is. It makes sense for the employer to be on the hook if an injury occurs but not to screen everyone who punches the time clock. As an example a pre exposure blood screen for someone who might handle oxytocin would have to be on a monthly basis to detect any pregnancy that might be in jeopardy if the employee has a needle stick and injects some! I do not believe there is any solid evidence to say that pre exposure exams will provide any preventative benefit	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.

We appreciate the inclusion of all employees in medical surveillance programs. Regardless of level of exposure, this approach provides protection for everyone in the facility, not just employers and employees.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Frequency of confidential medical evaluations to employees must be annual. Medical evaluations upon hire, in the event the employee experiences a health issue that could interfere with safe respirator use and on an annual basis are standard practice for medical surveillance.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
This is more prescriptive than NIOSH and thus, exceeds the legislative mandate. NIOSH does not require that employers pay for medical evaluations. April 2007. (providing at a reasonable time and place and at no cost)	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
All categories of potentially involved staff would be required to have medical surveillance. What baseline tests, labs, xrays should we take? At what point does our organization invade the personal habits of its employees to limit the ultimate risk on itself? Cost of labs and exams would be absorbed through our employee health at a great (unplanned/unbudgeted) cost. Anyone involved in the respiratory protection program knows firsthand what it takes to have staff complete a medical questionnaire, be fit tested for a potentially life-saving respirator according to OSHA guidelines, and conduct such fit testing annually. I estimate that Sour organization spends about $100,000 to support the respiratory program across all its campuses	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.

and clinics. The cost and resources for this program would be at least quadrupled in order to meet medical surveillance requirements as it currently is ill-defined and broadly spelled out in the proposed rule. NIOSH had indicated that they are providing revisions to medical surveillance in Quarter 1, 2012. We would be wise to follow suit with their recommendations. We need evidence-based protocols to follow.	
There is no evidence that medical surveillance of all people involved is necessary, practical, cost effective or effective.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Another great area of concern is medical surveillance. This area creates both the greatest risk of significant future compliance costs, and we feel it is the least evidence-based area contained within the new rules. We have been advised by NIOSH researcher Dr. Thomas Connor, a key author of the guidelines, that "NIOSH is currently working on revising the document on medical surveillance for healthcare workers who are exposed to hazardous drugs (and should have) the revised document available after the first of the year." In further comments, he indicated that the NIOSH medical surveillance guidelines will be revised significantly to reflect the lack of an evidence basis.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
The sole reference to medical surveillance is found in the 2004 NIOSH Alert, page 2. Employers of health care workers are encouraged to have written policies about the medical surveillance of health care workers. The provisions in the draft rule far exceed that provision, and in fact, require providers to make medical evaluations available to anyone who handles or comes in contact with hazardous drugs and patient wastes. There is no support for this provision.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Medical Surveillance – we continue to believe that this provision exceeds	While L&I appreciates the comment the final rule deletes medical

the NIOSH standards.	surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Section WAC 296-62-50050 (1)(a) requires medical surveillance be offered "upon hire and on a scheduled basis thereafter." The phrase "on a scheduled basis thereafter" needs to be defined. It is suggested the rule read: "… as recommended by the licensed health care provider."	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Section WAC 296-62-50050 (3)(a) requires the medical evaluation include a health questionnaire. There are a number of L&I standards requiring medical questionnaires. L&I has generally developed the medical questionnaire as part of the rule. The medical questionnaire should be included in the rule as a resource.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
WAC 296-62-50050 We are concerned with the financial impact of these rules and also the lack of standards for what surveillance would have to be done for staff working with oral medications categorized by NIOSH as hazardous. Consider adding the wording "based on known risks of the employees specific hazardous drug exposure" after "*as recommended by the LHCP*" in section 3b and 3c.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
It is understood that NIOSH issued the original alert as recommendations. This is in part due to the lack of evidence behind some of the recommendations. One that clearly has no evidence is the requirement for	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because

a Medical Surveillance program as written in the draft document. The requirement for medical exams and laboratory testing must be removed due to cost, lack of evidence, and uncertainty with what to do with the data, For example, based on a risk stratification, it may be appropriate to collect information on employee familiarity with NIOSH, safety equipment used, major exposures/spills, and years worked with chemotherapy. NIOSH is aware of this and re-evaluating this section as well.	NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Please delete this chapter. According to Dr. Thomas Connor, Biologist at NIOSH, "NIOSH is currently revising the document on medical surveillance for health care workers who are exposed to hazardous drugs. We have received feedback on the large range of variability of routine laboratory tests and their lack of ability to detect adverse health effects caused by these drugs. At this time, there are no useful biomarkers that can be applied to these exposures. Routine use of reproductive and general health questionnaires may provide some guidance concerning adverse health effects, but this has not been demonstrated with these types of exposures." NIOSH expects new guidelines after the first of the year.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
L&I is requiring medical surveillance without exceptions as NIOSH allows.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
Including requirements not in the NIOSH guidelines. For example, providing medical surveillance at no cost to the employee is not in the guideline.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that

	time what requirements, if any, should be added to the rule regarding medical surveillance.
Still requires Medical Surveillance of all employees which is exceedingly costly and does not elicit usable data or biomarkers to protect people. All provisions need to be evidence based. The area of medical surveillance creates both the greatest risk of significant future compliance costs, and is the least evidence-based of the proposed new rules.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
The language of WAC 296-62-50055 Medical surveillance is a tremendous cost burden in the low risk arena of non-compounding pharmacies.	While L&I appreciates the comment the final rule deletes medical surveillance to ensure that precautions adopted will be consistent with and will not exceed NIOSH. This is appropriate because NIOSH is currently updating medical surveillance guidelines. DOSH will review the updated guidelines and determine at that time what requirements, if any, should be added to the rule regarding medical surveillance.
WAC 296-62-50055 Training	
Job titles change often enough that this would be difficult to keep current. (training)	L&I agrees and the final rule language has been clarified to require that training be provided in accordance with WAC 296-800-17030, Employer chemical hazard communication.
WAC 296-62-50055 (1) requires training be provided during "initial job assignment, on a regular basis, and whenever changes in the workplace occur that may affect occupational exposure." The phrase "on a regular basis" needs to be defined. It is suggested that "on a regular basis" be defined as refresher training every 3 years.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50050(2)* *Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.*
WAC 296-62-50055(d) Training: This provision is overly prescriptive. We suggest this revision in language: "Potential adverse risks of hazardous drugs in the workplace."	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50050(2)*

	Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.
50055*(2)(d)* This provision seems overly prescriptive. WSHA suggests the following alternative language: "Potential adverse risks of hazardous drugs in the workplace."	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50050(2)* *Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.*
There is a lack of clarity about what is required in a facility where the drug mix is always changing. This regulation requires that training occur whenever a change in exposure occurs. In long-term care, remaining in compliance with these new regulations would be extreme time-consuming and expensive and ultimately could affect access to care.	L&I agrees that the proposed rule language lacked clarity. The final rule language has been clarified to read: *WAC 296-62-50050(2)* *Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.*
WAC 296-62-50060 Recordkeeping	
No comments received.	L&I has deleted this section as it exceeds NIOSH.