



WASHINGTON STATE  
DEPARTMENT OF  
E C O L O G Y

# **Responsiveness Summary**

## **Concise Explanatory Statement**

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**Amendments to the Dangerous Waste Regulations  
Chapter 173-303 WAC**

**Proposed June 5, 2002  
Re-proposed October 2, 2002  
Adopted March 2003**

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**Washington State Department of Ecology  
Hazardous Waste and Toxics Reduction Program**

**March 2003**

**AO #02-03**

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**Reduce Waste**  
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## **Introduction and Background Statement**

The Department of Ecology is authorized by the State Hazardous Waste Management Act (chapter 70.105 RCW) to adopt rules regulating the management of hazardous waste. The purpose of the Hazardous Waste Management Act is to provide a comprehensive statewide framework for the regulation, control, and management of hazardous waste. Ecology's actions under this authority prevent land, air, and water pollution and conserve the natural, economic, and energy resources of the State.

The Hazardous Waste Management Act also gives Ecology the authority to carry out the Federal hazardous waste program in Washington. Further authority to carry out the Federal Resource Conservation and Recovery Act (RCRA) amendments is contained in the Model Toxics Control Act at RCW 70.105D(3)(d). Ecology is authorized under Federal regulations (40 CFR Part 271) by the U.S. Environmental Protection Agency (EPA) to administer and enforce the Federal RCRA program in Washington.

The Dangerous Waste Regulations, chapter 173-303 WAC, implement the Hazardous Waste Management Act. These regulations establish requirements for generators, transporters, and facilities that manage dangerous waste in Washington. Ecology initiated this rulemaking in response to the need to facilitate management of controlled substances by law enforcement agencies in Washington State. Many technical corrections were also made as part of the rulemaking.

## **Summary of Rule Purpose**

The main purpose of this rulemaking was to adopt a conditional exclusion for controlled substances. An emergency rule was adopted in January, 2002 and rulemaking to adopt a permanent rule was initiated shortly thereafter. When the first public hearing was held in June, 2002, testimony was given to encourage Ecology to consider expanding the exclusion to include prescription drugs as well as controlled substances, and to allow other entities to use the exclusion. Following research, analysis, and discussions with stakeholders, the exclusion was re-proposed in October 2002 to broaden the rule. Re-proposal, rather than adoption with the changes, was deemed necessary to provide an additional opportunity for public comment since the rule was broadened to include an additional class of drugs. More changes were made to the rule language following the second public hearing, primarily to include over-the-counter drugs.

The rulemaking was limited to this one significant rule. However, a number of technical corrections were also made. During the recent authorization process where EPA reviews Ecology's Dangerous Waste Regulations, a number of technical corrections were identified that Ecology should make such as citation corrections, corrected spelling, and clarifications. These were made, as were other technical corrections that had been identified since the previous rulemaking process.

## **Summary of Public Involvement Actions**

Ecology worked extensively with law enforcement representatives to determine appropriate conditions for the exclusion. Most of this work was accomplished by Ecology staff via phone conversations. Ecology also worked with the Interagency Regulatory a Committee (IRAC) regarding issues related to those who handle pharmaceuticals. This work, together with the public testimony, led to a rule that that accommodates unique situations related to those who handle controlled substances, prescription drugs, and over-the-counter drugs.

Ecology filed a pre-proposal statement of inquiry (CR101) in the Washington State Register (WSR) on February 15, 2002 to announce upcoming rulemaking and invite preliminary public comments. Between the time the first emergency rule was adopted and the proposed language finalized, Ecology worked with IRAC and broadened the proposed rule to apply to others besides law enforcement who manage controlled substances. The amendments were proposed on June 5, 2002. Following the public comment period, it was determined that the exclusion should be broadened to include pharmaceuticals and that re-proposal was necessary. The amendments were proposed on October 2, 2002. During consideration of both sets of public comments, additional discussion continued with stakeholders.

Announcement of the pre-proposal statement of inquiry and both proposed rules were announced using both Ecology's Rules List Serve and the Dangerous Waste List Serve. Approximately 1,850 subscribers were notified through Ecology's general rule list serve and 348 through the list serve specific to those interested in Dangerous Waste Regulation changes.

Following formal proposal in the State Register, public hearings were held in Lacey at the Ecology headquarters building. The first hearing was on the original proposal; the second on the re-proposal. Hearings were held as follows:

<u>City</u>	<u>Date</u>	<u>Number of People in Attendance</u>
Lacey	June 27, 2002	9
Lacey	October 27, 2002	10

The second public comment period closed on November 12, 2002. This responsiveness summary contains all of the comments that were submitted on the proposed and re-proposed amendments. The comments have been summarized and are followed by Ecology's responses.

## **Scheduled Adoption and Effective Dates**

The amendments to the Dangerous Waste Regulations were originally scheduled for adoption on August 30, 2002. The decision to re-propose the amendments pushed the

anticipated adoption date to December 30, 2002. Based on additional requests from the public during the public comment period, more time was required to research issues related to over-the-counter-drugs before the rule could be finalized. Adoption is scheduled to take place late March 2003. The amendments will be effective 31 days after they are filed with the Code Reviser's Office.

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## Concise Explanatory Statement

### Explanation of Changes to the Proposed Rule

This portion of the Responsiveness Summary shows changes that were made to the proposed rule language prior to adoption. These changes are a result of comments and additional information Ecology received following proposal of the rule amendments. Changes below in ~~strikeout~~ and underline were made to the final rule language. Each change is followed by the rationale for the change.

- 1. WAC 173-303-071(3)(nn)** ~~(nn) Controlled substances and legend drugs that are state-only dangerous wastes. Controlled substances as defined and regulated by 21 CFR Parts 1300-1399 and chapter 69.50 RCW (Schedule I through V drugs) and legend drugs as defined and regulated by chapter 69.41 RCW that are held in the custody of law enforcement agencies or possessed by any registrant or licensee as defined and regulated by 21 CFR Parts 1300-1399 and chapter 69.50 RCW and authorized to possess drugs within the state of Washington, and managed for destruction: Provided, That they are disposed of by incineration in a controlled combustion unit with a heat input rate greater than 250 million British thermal units/hour and a combustion zone temperature greater than 1500 degrees Fahrenheit or disposed by other methods approved by ecology.~~
- (i) Controlled substances, legend drugs, and over-the-counter drugs that are state-only dangerous wastes.
- (A) Controlled substances as defined and regulated by Chapter 69.50 RCW (Schedule I through V);
- (B) Legend drugs as defined and regulated by Chapter 69.41 RCW and
- (C) Over-the-counter drugs as defined and regulated by Chapter 69.60 RCW;
- (ii) Controlled substances, legend drugs, and over-the-counter drugs that are held in the custody of law enforcement agencies or possessed by any licensee as defined and regulated by Chapter 69.50 RCW or Title 18 RCW and authorized to possess drugs within the state of Washington are excluded, provided the drugs are disposed of by incineration in a controlled combustion unit with a heat input rate greater than 250 million British thermal units/hour, a combustion zone temperature greater than 1500 degrees Fahrenheit, or a facility permitted to incinerate municipal solid waste.
- (iii) For the purposes of this exclusion the term 'drugs' means:
- (A) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
- (B) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
- (C) Substances (other than food) intended to affect the structure or any function of the body of man or other animals, as defined in RCW 18.64.011(3). (Note: RCW 18.64.011(3)(d) is intentionally not included in the definition of drugs for this exclusion.)
- (iv) When possessed by any licensee the term drugs used in this exclusion means finished drug products.



**Rationale for change:** Most of the comments that Ecology received encouraged expansion of the proposed exclusion to cover more generators and more pharmaceutical waste, including “over-the-counter-drugs”. Ecology concurred with the information provided and modified the rule prior to adoption. One of the key reasons for including over-the-counter drugs is the fact that the line between prescription and over-the-counter drugs is not always clear due to the fact that many over-the-counter drugs were previously prescription drugs and this transition continues to occur. Another reason is that that the rule, as originally proposed, did not address all the drug waste that law enforcement agencies must dispose of.

The final rule language for the conditional exclusion for drug disposal now includes controlled substances, legend drugs, also known as prescription drugs, and over-the-counter drugs. All of these drugs that would designate as state-only dangerous waste when disposed are considered appropriate for this conditional exclusion.

The use of this exclusion is limited to law enforcement authorities and licensees, a state term. The term registrant, a federal term, was dropped in favor of keeping the rule specific to Washington State.

The original emergency rule allowed only one burn facility, which is in Spokane, to be used for incineration of the drugs. The addition of the other combustions units (250mil BTU/hr/1500 F) was intended to broaden the availability of other burn facilities, especially for law enforcement authorities, to destroy drugs while at the same time ensuring appropriate disposal. The addition of other burn units will lessen the risk associated with having only one unit in Washington if it were to become unavailable. Having various locations to destroy drugs will also afford those who use this exclusion an opportunity to save resources such as personnel and travel time. The combustion units described in the rule are fairly large. The larger combustion units were chosen because they are required to have the necessary emission control devices and operating temperatures to ensure safe destruction of the drugs.

The state’s statutory definition of “drug” was added to the rule to make it clear what materials were intended to be eligible for the exclusion. Omission of the fourth statement in the state’s definition of drugs was intentionally left out because Ecology wanted to make it clear that the drugs eligible for this exclusion are to be finished drug product only. This would not include, for example, drug waste that is the result of a drug manufacturer’s process that has yielded an off-specification product that is not suitable for sale.

**2. WAC 173-303-620(8)(f) (8) Liability requirements.**

(f) The following subsections are incorporated by reference: 40 CFR section 260.147(f), Financial test for liability coverage, (g) Guarantee for liability coverage, (h) Letter of credit for liability coverage, (i) Surety bond for liability coverage, and (j) Trust fund for liability coverage.

**Rationale for change:** A citation was corrected.

## Comments and Responses

This section of the Responsiveness Summary contains summaries of all of the public comments that Ecology received both on the original proposal in June 2002 and the re-proposal in October 2002, and Ecology's responses. The rule was re-proposed in October to incorporate suggestions from some of the comments made on the original proposal in June. Comments and responses are organized in the order that the relevant sections appear in the Dangerous Waste Regulations. Copies of the letters and the public hearing testimony are included Appendix C.

### WAC 173-303-071(nn)

Note: Comments 1 through 17 are from the original proposal. Comments 17 through 43 are from the re-proposal where the conditional exclusion was broadened to include additional entities and pharmaceuticals.

#### **General response:**

Most of the comments Ecology received encouraged expansion of the proposed exclusion to cover more types of generators and more types of waste. Ecology concurred with much of the information provided and modified the rule prior to adoption. This rule is intended to facilitate proper disposal of pharmaceuticals from licensees and from the evidence rooms of law enforcement entities, and to encourage proper disposal of expired, recalled, or partially used pharmaceuticals.

Ecology notes that some of the pharmaceutical waste described by commenters apparently results from the distribution of free samples to the medical community by pharmaceutical companies. From Ecology's point of view, this reinforces the notion that the pharmaceutical companies have a responsibility to facilitate a return option for their products.

When disposal is necessary, Ecology believes that the "crush and flush" method of disposing pharmaceuticals "down the drain" is the least desirable disposal option. Studies of water quality are beginning to note the presence of the pharmaceutical products, and little is known about their potential impact on human health and the environment. Ecology believes that this rule will help promote the development and use of a disposal system that ensures destruction of unusable pharmaceutical products.

With the new conditional exclusion, pharmaceutical waste is excluded from the Dangerous Waste Regulations on the condition that it is managed for disposal in an incinerator. In most local jurisdictions the current municipal solid waste collection and disposal system does not utilize an incinerator for the disposal of solid waste. This means that a collection and transportation system outside of the current solid waste system will need to be provided for pharmaceutical wastes in those jurisdictions. Ecology believes that current waste management service providers will be able to offer this service to generators of pharmaceutical waste.

This rule does not change the fact that generators of pharmaceutical wastes that are dangerous waste are liable for the waste when it is not disposed of appropriately. This rule does not provide a regulatory mechanism that helps ensure that the waste is delivered to an incinerator. Ecology believes that the waste management service providers could develop a mechanism that provides generators with assurance that their waste has been destroyed in accordance with the conditions of the exclusion.

Ecology believes that the waste collection and disposal system that is developed to take advantage of this rule will provide an adequate level of protection for human health and the environment for the portion of the universe of pharmaceutical waste that would otherwise be managed within the dangerous waste system. Ecology believes an advantage of this rule will be to secure destruction for a larger portion of the pharmaceutical waste universe than would otherwise be subject to management under the dangerous waste rules.

A number of commenters noted that the current process for determining whether a waste is a dangerous waste or not is very difficult for pharmaceutical wastes. Ecology recognizes that this is the case and also believes that a simpler designation system for pharmaceutical waste could be devised, for example "listings" based on therapeutic categories, and that such a system may ultimately be necessary to effectively enforce proper management of pharmaceutical waste. However, such a system is not currently available. The rule does provide a disposal option for pharmaceutical wastes that in many cases allows the generators to avoid the difficulty of determining whether their pharmaceutical waste is regulated dangerous waste or not (the designation process).

**Comment 1:** The proposed rule does not provide destruction options for a couple of categories of very large participants. These include nursing homes, as they are not DEA registrants, and are not included in the licensee provisions of the current proposed rule. It would also not apply to patients receiving controlled substances other than utilizing the normal wastewater systems that are currently available. A lot of hospice, home care, patients who utilize large quantities of controlled substances, legend drugs included, are not included in the proposed exclusion, so there's no provision for them, as well. Our nursing home patients, all of which dispose of what I would consider a large quantity of narcotic substances, are left out of the proposed destruction rule leaving no alternative other than put it down the sewer. It also does not provide the destruction of pseudo-ephedrine.

**Response:** The conditional exclusion was re-proposed to include these categories of generators. It should be noted that if these categories were not added to the conditional exclusion, disposal down the sewer would not be an appropriate option for wastes that designate as dangerous wastes. The language of the adopted rule includes over-the-counter drugs, including pseudo-ephedrine.

**Comment 2:** The commenter stated that the proposed rule is a good start at addressing the problem and applauded Ecology for proposed the conditional exclusion, but the problem could be dealt with a little better if the exclusion was expanded.

**Response:** The rule was expanded to cover other categories of drugs and generators when it was re-proposed. It was expanded to include licensees of the State Board of Pharmacy, and to include pharmaceuticals.

**Comment 3:** The Spokane Regional Solid Waste System, due to the uniqueness of the facilities, manages solid waste from all over the world. It has a history of managing many different types of wastes.

The proposed rule addressed part of the problem that has been identified, law enforcement waste, but the proposed rule does not address pharmaceutical waste that is state-only dangerous waste. The Spokane facility will be able to manage any of the waste, either that proposed by the Ecology rule or by the language that IRAC submitted to Ecology.

**Response:** Comment noted.

**Comment 4:** The commenter encouraged Ecology to review waste categories and cover all waste drugs as defined by Section 201G of the Federal Food, Drug and Cosmetic Act. Reasons stated were that there is a lot of uncertainty, there was the disclosure by Washington State University about some drugs designating, the ephedrine issue, not knowing what drugs would come up in the future and that there are a lot of different drugs.

Uncertainty would be eliminated by expanding the conditional exclusion to cover all waste drugs. That, plus more proactive educational items will help people who manage these drugs. A defined method of disposal – not putting it down the sewer, not throwing it in the garbage can, but defining exactly where it goes, will benefit the environment greatly and make it very simple. Those managing the drugs from the disposal end wouldn't have to worry about whether they're receiving legend drugs or controlled substances; they wouldn't have to request information such as a very detailed list of how many tablets, how many milligrams of each different product from the police departments. They would be able to take all the waste and dispose of it if it all falls into the same classification. Limiting and restricting the exclusion to a specific area would require them to ask what someone has, then they will have to say what they can and can't take. Expanding the exclusion would reduce the frustration in the police departments and reduces the paperwork done at the Spokane facility.

**Response:** The conditional exclusion was expanded to include pharmaceuticals and to cover more generators of both controlled substances and pharmaceuticals. The language of the adopted rule includes over-the-counter drugs, including pseudo-ephedrine.

**Comment 5:** Ecology was quoted in an article saying that the agency never intended to classify drugs as a hazardous waste. If that's the case, let's move on and take care of them.

**Response:** The Dangerous Waste Regulations were intended to regulate waste pharmaceuticals to the extent that they meet the definition of a hazardous waste in Chapter 70.105 RCW

**Comment 6:** The commenter stated that they feel that 99% of the drug waste is handled as residential solid waste. The amount being considered for the conditional exclusion is not a large quantity; this is a very small quantity with respect to what we have and what we need to deal with. We do not see them as causing any environmental impact and/or troubles associated with permits at the Spokane facility.

**Response:** Comment noted.

**Comment 7:** The commenter thanked Ecology staff for their help working on this issue, helping those in the health care industry to try and solve some of the problems being faced in disposal of pharmaceutical waste. Proper disposal of drugs is a major concern in the protection of environment, in the protection public health and the protection of health care professionals who have no idea how to get rid of this waste.

**Response:** Comment noted.

**Comment 8:** The commenter supported including controlled substances in the proposed rule.

**Response:** Comment noted.

**Comment 9:** The commenter proposed that in the future Ecology continue to look at legend drugs and over-the-counter drugs which pose a threat to public health and to the community and to the environment, and that health care professionals will also be interested in working on this in the future.

**Response:** Ecology expanded the exclusion to include legend drugs (pharmaceuticals) when it was re-proposed. The language of the adopted rule includes over-the-counter drugs, including pseudo-ephedrine.

**Comment 10:** The commenter supports the change to the *Dangerous Waste Regulations*, especially after it was expanded to include all licensed DEA registrants, which was something they requested.

**Response:** Comment noted.

**Comment 11:** The commenter stated that they hoped that the information Ecology got on nursing homes can also be included.

**Response:** The exclusion was expanded to include this category of generators when it was re-proposed.

**Comment 12:** The commenter stated that they were there to make the Department of Ecology aware of the wider environmental problem of pharmaceutical waste management and the very difficult fit of this waste stream into the *Dangerous Waste Regulations*, specifically regarding the designation process. They have recent information from many other states who have completely abandoned the effort because the designation is so difficult. They plan to continue to work on finding practical solutions to improve pharmaceutical waste management and look forward to continuing their partnership with the Department of Ecology.

**Response:** See general response above.

**Comment 13:** The commenter thanked the staff at the Department of Ecology for the emergency rule that dealt with the problem for law enforcement agencies, and for the proposed expansion of the rule to include pharmacies and other registrants. By restricting the original draft to law enforcement, it created a significant problem for other people that possess outdated or otherwise unusable controlled substances.

**Response:** Comment noted. It should be noted that the proposed conditional exclusion for law enforcement did not at the same time bring other wastes or generators under new regulation. It may have raised awareness of some wastes that designate as dangerous waste, but it did not add new categories of waste to the regulations.

**Comment 14:** The commenter recommended that Ecology consider adding over-the-counter and legend drugs, controlled under either Chapter 69.04 RCW or Chapter 69.41 RCW to the proposed rule. This would resolve a number of problems- the fact that there are a lot of these drugs going out of date in pharmacies and pharmacists need a good way of dealing with them and law enforcement agencies that have to deal with pseudo-ephedrine. It is an over-the-counter product and as they make arrests in mini-marts where the drugs are coming from before they get to meth labs, they are coming into possession of perhaps hundreds or even thousands of tablets of these products, which are probably no more dangerous than anything else when properly incinerated.

**Response:** The exclusion was re-proposed in include pharmaceuticals. The language of the adopted rule includes over-the-counter drugs, including pseudo-ephedrine.

**Comment 15:** The commenter highly recommended that Ecology consider expanding the exemption to include over-the-counter drugs and legend (pharmaceutical) drugs and provided several examples to illustrate this recommendation. The commenter provided several examples, as follows.

- When inspecting pharmacies and conducting investigations, a lot of evidence is seized, plus they take into safekeeping or for destruction, drugs of physicians or

others that may possess drugs when they pass away or have their licenses revoked. These drugs often include controlled substances and legend drugs, and some over-the-counter drugs that must be destroyed and they rely on private industry. These can be substantial quantities of drugs that come into the Department of Health's possession. There has to be a mechanism, from their perspective, to legally dispose of these items.

- Many law enforcement agencies and narcotic task forces throughout the state make undercover purchases of pseudo-ephedrine tablets from retail outlets. This is often done in case lot quantities. Police departments involved in this activity are in possession of substantial quantities of the over-the-counter drug pseudo-ephedrine, which must be destroyed eventually.
- There is the tendency of the federal government and drug manufacturers to move legend drugs into over-the-counter status. More and more of this will happen in the future and these drugs will eventually need to be destroyed when they become unusable.
- Police, in the course of executing their duties, seize lots of legend drugs. Furthermore, there are lots of legend drugs that are being abused and are subject to abuse by individuals that they have not yet been designated as controlled substances; likely they will in the future.
- Physicians possess samples. Sometimes these are rooms full of samples, not just a drawer of samples. When the practitioner dies, it would be much more ecologically important to have them properly disposed of through established lawful means than staff members throwing them away in a trash container in the back of the building.

**Response:** See general response above.

**Comment 16:** If the sites authorized to legally destroy (incinerate at this point in time) drugs require police departments to separate or identify legend drugs or over-the-counter drugs from controlled substances, this will impose a tremendous hardship on those law enforcement agencies- to distinguish what is a legend drug, what is an over-the-counter drug, and what is a controlled substance.

**Response:** Comment noted. The addition of pharmaceuticals to the exclusion should help reduce the burden of distinguishing among the classes of drugs.

**Comment 17:** The commenter thanks the Department of Ecology for the efforts they're taking in revising present processes.

**Response:** Comment noted.

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Note: Comments 18 through 43 were made in response to the October 2002 re-proposal of the conditional exclusion.

**Comment 18:** The commenter applauded Ecology for the addition of licensees and registrants other than law enforcement and legend (prescription) drugs to the proposed rule. The proposed rule greatly simplifies the management of pharmaceutical waste and increases the likelihood that this waste will be more broadly and properly managed in Washington. The newest proposed permanent rule wording is an excellent step in the right direction. It will encourage pharmacists, physicians, nurses, physician's assistants, and others to properly and efficiently manage pharmaceutical waste. The new rule will encourage responsible product stewardship and will benefit the environment

**Response:** Comment noted.

- **Comment 19:** The commenter encouraged Ecology to permanently adopt the revised proposal and to extend it to include over-the-counter pharmaceutical waste.
- Ecology should focus on the appropriate management of pharmaceutical waste rather than upon a particular class of drug (controlled substance, legend, or over-the-counter) or the licensee or registrant that generates the waste. The controlled incineration of pharmaceutical waste is an appropriate management practice, but drug class has no relevant bearing on the hazardous waste character of pharmaceutical waste. There are numerous examples of state-only dangerous waste among lists of controlled substances, legend, and over-the-counter drugs.

Pharmaceutical waste that designates as dangerous waste is being almost universally mismanaged throughout Washington. This is because of a lack of information and training but also the enormous difficulty in designating the 10,000 drugs that are currently on the market and the new ones that continually enter the market. The reverse distribution industry, which provides most large healthcare providers with a reasonable option for the management of their unused, outdated, and otherwise not needed pharmaceuticals, is not available to many small healthcare providers. And some pharmaceutical waste from all providers (partial doses, broken, soiled, or otherwise completely unusable pharmaceuticals) does not qualify for return to a reverse distributor and is typically disposed of in either biohazardous waste, solid waste, or discharged to the sanitary sewer.

**Response:** See general response above.

**Comment 20:** The commenter applauded Ecology for the re-proposal that includes licensees and registrants and prescription drugs as well as law enforcement and controlled substances.

The commenter expressed excitement that manufacturer responsibility and product stewardship are being introduced with this new language as the role of the reverse distributor can become a model for other waste streams.

**Response:** Comment noted.



**Comment 21:** Controlled incineration is an appropriate management practice for all pharmaceutical waste, since there are numerous examples of organic, state-only dangerous waste among lists of controlled substances, legend, and over-the-counter drugs.

**Response:** See general response above.

**Comment 22:** The relatively low awareness level regarding applicable environmental regulations by the health care industry together with the complexity of regulating this waste stream has resulted in a situation where the environment has been left under-protected. Applying the Dangerous Waste Regulations to this waste stream, as currently written, seems to be a mismatch. The regulations pertain more to hazardous wastes generated by non-medical industrial processes and do not adequately take into account the unique nature of wastes generated by the medical industry. Having attempted to designate these substances under the Dangerous Waste Regulations, the commenter recognizes the difficulty and expense the health care industry faces. As the regulations currently stand, it is difficult to provide clear guidance to small quantity generators and/or households.

It is important to further expand the conditional exclusion to encompass all pharmaceuticals- including over-the-counter drugs. The three classes of drugs (controlled substances, legend, and over-the-counter) are based not on toxicity or environmental hazards, but on marketing, potential for diversion/abuse and use. Ignoring over-the-counter drugs in the proposed language creates dissimilar policies for drugs which are (from an environmental perspective) similar or identical.

**Response:** See general response above.

**Comment 23:**

The commenter thanked Ecology for considering the recent amendments to the proposed rule, and requested that additional recommendations for rule changes also be considered. Current regulation would require the designation of approximately 10,000 drug entities and more than 40,000 different drug products on the market today. The focus of the regulation should be on the management of all pharmaceuticals, and not on particular drug classes of pharmaceuticals, since the potential hazardous nature of pharmaceuticals is not limited to particular drug classes. Current legislation is directed toward controlled and legend drugs, and should also include over-the-counter pharmaceuticals that have been authorized for human use.

**Response:** See general response above.

**Comment 24:** Managed incineration of pharmaceuticals is an appropriate mechanism for disposal of pharmaceuticals, as practiced by several States in the U.S., and the country of Australia.

**Response:** Comment noted.

**Comment 25:** Pharmaceutical product designation as State “dangerous waste” extends to all classes of pharmaceuticals, regardless if the pharmaceutical is hazardous or not. Since the data needed to establish environmental safety is not available for the great majority of pharmaceuticals, the products are regarded as “dangerous waste”, with no economical mechanism for disposal. Managed incineration would benefit our environment, since hazardous, and potentially hazardous, products will be removed from the environment via controlled incineration that is economically feasible.

**Response:** Ecology would like to clarify that State dangerous waste designation does not extend to all pharmaceuticals, or classes of pharmaceuticals “regardless if the pharmaceutical is hazardous or not”. Only those pharmaceuticals that designate because of a federal or state designation listing, characteristic, or criteria are considered dangerous waste. Ecology agrees that designation is difficult, which is one of the reasons that the conditional exclusion was re-proposed- to reduce the burden on the health care industry.

**Comment 26:** The proposed amendment does not address the needs of the health care industry for the disposal of drugs incident to patient administration. Current proposed regulation would require the disposal of this material via incineration, which would require that partial doses of remaining medication in a syringe (incident to patient administration), be kept on site and stored. This practice would substantially compromise the safety of health care workers and patients, as this material would be recoverable from storage sites and containers, leading to increased abuse and addiction by health care workers, and a compromise of patient care. Narcotics (partial doses, incident to patient administration) are universally wasted via the sink or toilet to prevent the drug from being recovered. To change this practice requires that the drug be retained, stored, and accounted for. That will substantially increase the cost to the health care industry, and make the stored drugs available to diversion, and risk patient safety.

The largest hospital in Seattle, disposes of approximately 1.36 pounds of drugs annually via the sink or toilet, because there is no safer mechanism to dispose of them. Other hospitals can be expected to dispose of a lesser quantity on an annual basis in Washington. Although these quantities are small, the hazards of inappropriate access is still very substantial to patients and health care workers, and no environmental impact has ever been demonstrated from narcotics.

**Response:** The conditional exclusion addresses controlled substances and pharmaceuticals. These are all conditionally excluded from dangerous waste regulation provided they are incinerated. Disposal via incineration at a non-hazardous waste permitted facility was deemed an appropriate alternative to disposal at a permitted treatment, storage, and disposal facility. While the conditional exclusion might not solve all of the health care industry’s issues, it greatly lessens the burden of waste management. With the conditional exclusion in place, generators who would otherwise be medium or large quantity generators may become conditionally exempt small quantity generators.

As such, there are other disposal options available. Ecology is amenable to discussing these other issues with the commenter.

**Comment 27:** No allowance is made in the proposed amendment for the disposal of the huge quantities of intravenous solutions used in the hospital industry. These solutions are composed of glucose, saline and other nutritionally based aqueous solutions for human intravenous use. Waste solutions are routinely disposed of via the sinks in every hospital in the state. To require that these solutions be destroyed as State only “dangerous waste” will increase health care costs substantially for the residents of Washington, yet no hazard can be shown to the environment in the current waste practices. Logistically, the storage of these solutions, would consume the entire storage capabilities of every institution that requires them to treat patients, in a matter of days.

**Response:** From the commenter’s description, it is not clear that such solutions would designate as dangerous waste. To designate, a waste must fail certain tests or meet certain criteria. A glucose or nutritionally based aqueous solution does not sound as though it would be a toxic waste, for example. If they do designate, it is possible that they could be managed via the “domestic sewage exclusion”. Ecology staff would be interested in further discussing this with the commenter.

**Comment 28:** The commenter submitted a draft report titled *Pharmaceutical Waste Survey* as an addendum to their testimony. The report provides data on the quantity and nature of wastes generated by the health care industry as well as some insights into the industry’s practices and needs that were gleaned through the survey process.

**Response:** Comment noted.

**Comment 29:** The commenter requested that Ecology expand the conditional exclusion further to encompass over-the-counter drugs for the reasons expressed during the public hearing. The classifications of controlled substances, legend drugs and over-the-counter drugs are changeable, depending upon forces outside the control of the Department of Ecology. The following wording was suggested-

“Drugs regulated by the Drug Enforcement Administration (DEA) Schedules I through V that are held by any licensee or registrant of the state authorized to possess these drugs or that are held in the custody of law enforcement agencies within the state of Washington; and drugs as defined by Section 201 (g) of the Federal Food, Drug and Cosmetic Act (excluding compressed gases and radioactive drug products); and managed for destruction: Provided, [that they are disposed of by incineration in a controlled combustion unit with a heat input rate greater than 250 million British thermal units/hour and a combustion zone temperature greater than 1500 degrees Fahrenheit or disposed by other methods approved by Ecology.] “

**Response:** See general response above.

**Comment 30:** The commenter thanked Ecology for attention to the problem of pharmaceuticals entering the environment and noted that it is only a small step in a large problem.

**Response:** Comment noted.

**Comment 31:** Ecology should include over-the-counter drugs in the conditional exclusion along with controlled substances and legend drugs because this will allow even handling and lessen confusion. The following reasons were given:

- Preliminary data gathered by IRAC on quantities and disposition of waste pharmaceuticals in the health care industry in Washington indicates that the quantities of drugs that will be impacted by the rule change is quite small in relation to other wastes.
- IRAC is after the appropriate management of all pharmaceuticals regardless of their class, class being defined as legend, over-the-counter, or controlled substances. Depending on how many milligrams of ibuprofen are in something it becomes legend or over-the-counter. It's not based on environmental hazard – it's based on marketing and its use, and it's based on its propensity for diversion and abuse, but not on the environment.
- Preliminary research they have done shows overwhelmingly that those in the health care industry, with the exception of large hospitals and pharmacies, know very little about regulations, if anything at all; nothing about the *Dangerous Waste Regulations* and certainly not their applicability to medications that they can no longer use. The IRAC pharmaceutical work group was formed at their request; to find out '*what do we properly do?*'
- In very small facilities – not hospitals, pharmacies, nor nursing homes that are serviced by pharmacies - but in the small clinics, for example, there's very little waste, but what is wasted, with the exception of DEA controlled substances, is often wasted down the drain or put into the biohazards bag. Neither method is sufficient to render these things inactive in the environment, which is why we're after combustion or something that turns up later.
- The designation process is logical and works well with industrial process chemicals, but that's not the case with the wide variety of pharmaceuticals. This is a class of waste, that to be managed in an environmentally safe way, must be managed in a different way
- We've confirmed that the following over-the-counter drugs designate in Washington as state-only dangerous waste: aspirin, ibuprofen, Dimetapp, Dramamine, dandruff shampoos, epinephrine.

**Response:** See general response above.

**Comment 32:** The commenter congratulated and thanked the Department of Ecology for their forethought in including legend drugs and controlled substances in this conditional exclusion.

**Response:** Comment noted.

**Comment 33:** The commenter has conducted surveys with hospitals, pharmacies and medical clinics to collect data on the amount of pharmaceutical waste incorrectly disposed to sanitary sewer, solid waste and biohazardous waste streams and has come to realize that the Washington State *Dangerous Waste Regulations* are quite a mismatch for managing pharmaceutical waste. The commenter deferred to the testimony that was given in the public hearing held on June 27, 2002 (see comments 1 through 17).

The commenter asked that Ecology consider including over-the-counter drugs in the exclusion. Over-the-counter drugs are not necessarily less toxic by dangerous waste standards than controlled substances or legend drugs. For example, aspirin or acetylsalicylic acid has an LD 50 of 200 mgs/kg and designates as a toxicity category state-only dangerous waste. This puts aspirin in a not dissimilar category as chemotherapy drugs – considered the most toxic of all pharmaceuticals by many health care professionals.

Examples of other over-the-counter drugs that designate under the state-only portion of the rules include the active ingredient in Dimetapp which is brompheniramine; Chlor-Trimeton which is an antihistamine; ibuprofen, which is the active ingredient in Advil; and the active ingredient in Dramamine, which is Dimenhydrinate. Including over-the-counter drugs in the proposed rule change would greatly increase the chance that all pharmaceutical waste that designates as state-only waste would be safely disposed and decrease the chance that these wastes end up on our environment.

**Response:** See general response above.

**Comment 34:** The commenter offered the following information. Environmental Health and Safety at the University of Washington manages its facilities, one of which is a 450 bed hospital. They ship approximately one cubic yard box a month of non-DEA pharmaceuticals, which were either prescribed and not used by the patients or expired or for some reason cannot be used. Random sampling from several of these containers has shown that approximately 70 percent of the volume of the cubic yard box is packaging. Only 30 percent of the volume is actually the pills that are in there. And that the pills make up about 70 percent of the weight. So most of what's going to go out is going to be plastic, paper, foil, etc. from bubble packs and packages.

**Response:** Comment noted.

**Comment 35:** The commenter thanked the Department of Ecology for working on this issue.

**Response:** Comment noted

**Comment 36:** The commenter referred to previous testimony- see Comments 7, 8, and 9. At that time, the commenter testified that they would like to include controlled substances, legend drugs, and over-the-counter drugs because of a pseudo-effedrine problem into the rule. The commenter stated that they would like to change the wording of their earlier testimony, and instead of listing the different classes, just say all pharmaceuticals be included in the rule, for the reasons that other people who testified mentioned too. Including all over-the-counter drugs and all pharmaceuticals will be a major reduction in diversion. It's going to be an improvement in drug abuse in the state of Washington and a major step in the war on drugs.

**Response:** Comment noted. See general response above.

**Comment 37:** The commenter supports the proposed rule change. It is a positive step.

**Response:** Comment noted.

**Comment 38:** The commenter would like the proposed rule to be expanded to include over-the-counter drugs. The hazardous nature of drugs does not necessarily conform to arbitrary drug class distinctions. Legend drugs have become designated as controlled substances, over-the-counter drugs were formerly legend drugs and are now over-the-counter; there are many situations where legend drugs will likely become controlled substances. There are situations where over-the-counter drugs are precursors to legend drugs and controlled substances. Like pseudo-effedrine being a precursor to methamphetamine.

Virtually all health care providers utilize reverse-disposal companies. The amounts of drugs being generated are somewhat minimal in nature and really don't have a major impact on incineration sites in the state of Washington. The Pharmacy Board supports the previous comments regarding disposal of drugs incidental to patient administration (see Comments 1, 26, and 27).

**Response:** See general response above.

**Comment 39:** The commenter thanked the Ecology Department for the proposed regulations and asked Ecology to expand them.

**Response:** Comment noted. See general response above.

**Comment 40:** The current regulation would require designation of a great many drugs, probably greater than 10,000. There are probably over 40,000 drug products on the market commonly called pharmaceuticals designed for human use. That's an

overwhelming number that is pragmatically impossible for the health care industry to try to figure out how to manage in various buckets or categories.

The commenter asked Ecology to expand the conditional exclusion to include all pharmaceuticals in general because there is no ability to classify drugs as being hazardous in one category and not another. It's very simple to establish probably fifty to a hundred different ways to categorize pharmaceuticals – none of them would be sufficient to designate the drug as being hazardous to the environment at all. There isn't one system able to do this – there are too many exceptions.

The health care industry utilizes reverse distributors or systems to get products back to the manufacturer where they can. Actual active drug wasted into the environment through the sewer system or the landfill system is extremely small. In two of the largest hospitals in Seattle combined, that probably amounts to less than two pounds a year of active drug going down through the sewer system or the landfill systems. Everything else is collected and returned to some system. But that two pounds probably represents several hundred thousand different dosage administrations to patients with a little bit of leftover for incidental use. Trying to categorize those is almost next to impossible for the health care industry. There's got to be a simpler, more effective way to allow them to get rid of these extremely small quantities of drugs.

What they're doing right now would probably be largely in compliance with the proposed amendment if it was expanded to include all pharmaceuticals. It would give them an adequate way for disposal of these materials that they can't get rid of through reverse distributors. Australia is currently using this system for incineration for their products and it is apparently working well there.

**Response:** See general response above.

**Comment 41:** The commenter supports the proposed amendment, but would like to see it expanded to include all pharmaceuticals, including over-the-counter products because it would greatly benefit the public and probably help to reduce future health care costs. A lot of the amounts of drugs are extremely small quantities. When you look at packaging and all the other things in tablets and capsules – the active drug is very small.

The commenter noted that all the drugs mentioned in Comment 33 were legend drugs before they became over-the-counter drugs.

The commenter gave examples of cases- one case with the Pharmacy Board where the Bellevue Police Department evidence custodians didn't know what they had. There were thousands of legend drugs and it was some sort of Medicare fraud, but without the conditional exclusion, the police department would be stuck with the drugs. The commenter noted that they think that in the future there will be more and more pseudo-effedrine products, plus as it becomes more difficult for them to obtain those products, the focus will shift to other combination over-the-counter products.

There was another case where a charity organization had drugs donated to them. Most of them were outdated. Federal laws do not allow exportation of outdated drugs; a lot of legitimate organizations that do not want to deal with the disposal issue are giving these drugs to these charity organizations. There were also four cases of pseudo-effedrine. If we don't give people an adequate outlet to dispose of drugs, they'll find a more deceptive way to do it.

**Response:** See general response above.

**Comment 42:** The commenter stated that the City of Spokane as well as the owner of the Spokane Regional Waste Energy facility will be able to receive any designated waste from this exclusion and is ready to provide that service whether it be controlled substances, legend drugs, and/or over-the-counter drugs.

They support the addition of over-the-counter drugs to the exclusion. It will remove uncertainty and assist law enforcement agencies. It is more expedient for them as well as better for the environment in the sense that there is a defined direction for where these wastes go. There are many over-the-counter drugs, but there is also uncertainty because of the legend drugs, over-the-counter drugs changing, and the controlled substances changing from one category to another.

Ecology should look at precursors to some of the controlled substances.

People disposing of drugs want to know what the right thing to do is. And the commenter wants to be able to tell them. But not having the right information to make that classification has been difficult. It is difficult just getting those disposing of drugs to recognize what RCRA or the dangerous waste rules are. Plus, there is the need to separate the over-the-counter, legend, and controlled substances.

**Response:** See general response above.

**Comment 43:** The commenter encouraged Ecology to look at the standards for complying with the combustion of solid waste and see if, rather than creating another standard, an existing reference in Ecology rule could be used. 1500 degree F varies from the standards that the Spokane Incinerator is required to meet in order to reduce emissions to the environment. They have a specific 1800 degrees for at least one second for solid waste. And they maintain a lot of other parameters in order to make sure that it is done properly and without harm to the environment.

**Response:** See general response above.



**WAC 173-303-090(5)(a)(iv)**

**Comment 44:** Under -090(5)(a)(iv) Ecology needs to remove the reference to organic peroxides as ignitable waste by deleting reference to "173.128". Ecology needs to also begin an update to "Chemical Testing Methods for Designating Dangerous Waste" publication #97-407 Dated February 1998 to remove this provision. This document was finalized at the same time as the organic peroxide provision was added to -090(5)(a)(iv). Ecology has inadvertently created a new class of state-only waste by adding organic peroxides.

**Response:** Oxidizers were previously located at 49 CFR 173.151, and later moved to 173.127 and .128. When DOT amended their rules, the oxidizers in section 151 were split off and put into sections .127 and .128. (.127 is "oxidizers"; .128 is "organic peroxides"). When Ecology first added 49 CFR 173.151 to the Dangerous Waste Regulations, "oxidizers" and "organic peroxides" were part of the definition/criteria for ignitable waste. When Ecology later amended WAC 173-303-090(5)(a)(iv) by changing the reference from 173.151 to 173.127 and .128, no additional wastes became regulated and Ecology did not bring an additional division of DOT hazardous materials into regulation.

When Ecology amended the Dangerous Waste Regulations and updated Chemical Test Methods in 1998, a comment was received requesting that the reference to 49 CFR 173.128 be deleted. Ecology responded then, as it does again now, with the information that when the citation was corrected, both references were retained since oxidizers were defined as both "oxidizer" and "organic peroxide". As a way of providing more information, the University of the Sciences in Philadelphia web page on safe handling of reactive and peroxide forming chemical states: "Organic peroxides are a special class of compounds that have unusual stability problems that make them among the most hazardous substances normally handled in laboratories. Peroxide formation has been responsible for many serious explosions."

**WAC 173-303-090(7)(a)(viii)**

**Comment 45:** Under -090(7)(a)(viii) Ecology needs to remove the reference to Division 1.5 as reactive waste. Ecology also needs to begin an update to "Chemical Testing Methods for Designating Dangerous Waste" publication #97-407 Dated February 1998 to remove this provision. This document was finalized at the same time as the Division 1.5 provision was added to -090(7)(a)(viii). Ecology has inadvertently created a new class of state-only waste by adding Division 1.5 to the reactive provision.

**Response:** Ecology intentionally added Division 1.5 when the Dangerous Waste Regulations were amended in 1998 and when Chemical Testing Methods was updated. Division 1.5 was viewed as a higher risk than the Division 1.4 explosives. The federal waste code D003 should be assigned all reactive waste.

## WAC 173-303-620

**Comment 46:** Ecology should delete the references to 40 CFR 264.147(f) through (j) in -620(8)(b) and rely on -620(8)(f) to provide the reference. The reference to 40 CFR 264.147(f) through (j) in -620(8)(b) is redundant to the incorporation already in existence in -620(8)(f) and should be deleted. The reference to 40 CFR 264.147(b) already requires compliance with the owner or operator's chosen financial assurance mechanism. Note that the way the proposed section is worded implies that all financial assurance mechanisms must be executed.

The reference in 620(8)(f) should also be corrected to reference 40 CFR 264.147(f) through (j) instead of 40 CFR 260.147, which does not exist.

**Response:** The reference at WAC 173-303-620(8)(f) will be corrected in the final rule. While Ecology agrees that the reference to 40 CFR 264.147(f) through (j) appears redundant, rather than change it at this time, Ecology staff are considering rewriting the subsection in a future rulemaking to parallel the structure of -620(4) and -620(8) so that the liability section will be consistent in format and referencing with the other sections. Although not as clear as it should be, the existing wording does not mean that all financial assurance mechanisms must be executed.

## WAC 173-303-920

**Comment 47:** Adding a new section (Petitions –State delisting) to address state delisting provisions exceeds the criteria for this rulemaking to “make technical corrections” because of the potentially extensive process associated with rulemakings adding approved delisting petitions to WAC 173-303.

The USDOE currently has a state delisting in place without a rulemaking process taking place (refer to letter from the Nuclear Waste Program dated December 7, 1995). This rulemaking process will introduce questions regarding the status of the delisting petition in place at the Hanford Facility in Richland, WA. See 40 CFR 261 Appendix IX in Table 2 under DOE-RL. Ecology needs to re-propose this section at a later date to include the Hanford Facility's existing delisting petition (and any others approved to date in Washington State) to avoid impacts to current programs.

In the past when processing the Hanford Facility delisting petition, Ecology has said that there are no resources for processing delisting petitions. Given the current budget environment, Ecology needs to explain on the re-proposal how the resources will be obtained and maintained to support rulemaking activities for state delisting petitions.

**Response:** The proposed new section was withdrawn from the proposal and not adopted. Ecology's intention in proposing this section was that it would be a placeholder in rule where at a future time, delistings could be listed. It would not be rulemaking to approve delistings. Ecology does not currently have delisting authority for federally regulated

wastes and was not seeking to expand its program or authority to process delisting petitions. The new section would have been a place for federally approved delistings that were subsequently approved by the state for a particular waste by a particular generator. No delistings were proposed to be added at this time. The commenter is correct that such a section would not be accurate unless it also contained any past delistings that Ecology had approved.

**Individuals and Organizations Providing Comment  
Comment Cross Reference Table**

#	Commenter/Address	Comment Response Number
1	Stan Jeppesen Board of Pharmacy 1300 Quince St Olympia, WA 98501	1,23,24,25,26,27 ,39,40
2	Damon Taam Spokane Regional Solid Waste System 808 W Spokane Falls Blvd Spokane, WA 99201	2,3,4,5,6,42,43
3	Phil Schoeneman P.S. Industries Inc 1100 Second Ave, Ste B-1 Seattle, WA 98101	7,8,9,36
4	Debra Oliver Interagency Regulatory Analysis Committee 130 Nickerson St #100 Seattle, WA 98109	10,11,12,28,29,30,31,35
5	Don Williams Board of Pharmacy – Dept of Health PO Box 47863 Olympia, WA 98504-7863	13,14
6	Richard D. Morrison Dept. of Health PO Box 47863 Olympia, WA 98504-7863	15,16,17,37,38
7	Joel B. Hebdon U.S. Dept of Energy MSIN A5-58, PO Box 500 Richland, WA 99352	44,45,46,47
8	Alan B. Jones 17629 N.E. 138 <sup>th</sup> St. Redmond, WA 98052-1226	18,19
9	Cheri Grasso 130 Nickerson St #100 Seattle, WA 98109	32,33
10	Doug Gallucci Po Box 354400 Seattle, WA 98195	34

11	Randy Flett PO Box 47863 Olympia, WA 98504-7863	41
12	David Waddell King County Water & Land Resources Division 130 Nickerson St. Suite 100 Seattle, WA 98109-1658	19,20,21
13	Ken Armstrong Local Hazardous Waste Management Program in King County 150 Nickerson St. Suite 100 Seattle, WA 98109	20,22

## **Appendix A**

### **Preamble to the Proposed Rule**

## **Preamble to the Proposed Rule Amendment**

**June 2002**

Law enforcement agencies within the state of Washington confiscate drugs, including controlled substances, during the course of their work. The controlled substances are kept as evidence until the case is adjudicated. When no longer needed as evidence, law enforcement agencies follow their own policies for the destruction of the controlled substances. These policies include incineration, witnessed by a law enforcement officer. There is only one waste-to-energy facility in Washington that is currently able to take these wastes; however its permit prohibits the burning of dangerous waste. Some controlled substances designate as state-only dangerous wastes in the State of Washington. This conditional exclusion will make it possible for these wastes to be disposed of at the waste to energy facility.

Controlled substances collected by law enforcement agencies within the state of Washington must be handled according to law enforcement policy to assure consistency in handling procedures. Deviations from the policy can put the law enforcement agency at risk for liability, loss of accreditation of their evidence rooms, and may impact case development. Law enforcement agencies have limited budgets for evidence disposal and varying disposal needs. The absence of the option for incinerating controlled substances is an impediment to a necessary element of police work.

This conditional exclusion from the Dangerous Waste Regulations applies only to wastes that are regulated as state-only dangerous waste; that is, they are not also regulated under federal hazardous waste regulations. Ecology does not have the authority to exempt any drug that is a regulated waste under federal law from regulation. The drugs that are regulated as state-only dangerous waste are regulated primarily due to their toxicity. Incineration is an appropriate method of disposal for these low volume, low toxicity wastes.

An emergency rule was adopted on January 25, 2002 to exempt these wastes. A permanent rule is being proposed to conditionally exempt the same wastes covered by the emergency rule. In addition, the conditional exclusion is being expanded to include controlled substances held by facilities that are licensees or registrants of the State Board of Pharmacy (Board) or Drug Enforcement Administration (DEA). These facilities include hospitals, pharmacies, universities and reverse distributors. Expanding the rule to include these additional facilities will make it easier for them to comply with the regulations on the management and disposal of controlled substances implemented by the Board and the DEA. It will provide them with an option that improves their ability to comply with other regulations.

Based on input Ecology received during the public hearing that was held in June 2002 for the proposed conditional exclusion for controlled substances, the exclusion has been expanded to include legend drugs. Legend drugs are a class of drugs also known as prescription drugs. Ecology reviewed information that was provided by representatives of the pharmaceutical and medical community that was presented at that hearing. The inclusion of legend drugs will provide better handling and disposal options like those found for controlled substances.

Other proposed changes to the regulations include correcting citations and other typographical errors. During the recent authorization process that Ecology underwent with the Environmental Protection Agency (EPA), several minor corrections were noted for consistency with the federal hazardous waste regulations. These changes add no new requirements.

### **Re-proposal- October 2002**

Law enforcement agencies within the state of Washington confiscate drugs, including controlled substances, during the course of their work. The controlled substances are kept as evidence until the case is adjudicated. When no longer needed as evidence, law enforcement agencies follow their own policies for the destruction of the controlled substances. These policies include incineration, witnessed by a law enforcement officer. There is only one waste-to-energy facility in Washington that is currently able to take these wastes; however its permit prohibits the burning of dangerous waste. Some controlled substances designate as state-only dangerous wastes in the State of Washington. This conditional exclusion will make it possible for these wastes to be disposed of at the waste to energy facility.

Controlled substances collected by law enforcement agencies within the state of Washington must be handled according to law enforcement policy to assure consistency in handling procedures. Deviations from the policy can put the law enforcement agency at risk for liability, loss of accreditation of their evidence rooms, and may impact case development. Law enforcement agencies have limited budgets for evidence disposal and varying disposal needs. The absence of the option for incinerating controlled substances is an impediment to a necessary element of police work.

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An emergency rule was adopted on January 25, 2002 to exempt these wastes. A permanent rule is being proposed to conditionally exempt the same wastes covered by the emergency rule. In addition, the conditional exclusion is being expanded to include controlled substances held by facilities that are licensees or registrants of the State Board of Pharmacy (Board) or Drug Enforcement Administration (DEA). These facilities include hospitals, pharmacies, universities and reverse distributors. Expanding the rule to include these additional facilities will make it easier for them to comply with the regulations on the management and disposal of controlled substances implemented by the Board and the DEA. It will provide them with an option that improves their ability to comply with other regulations.

Based on input Ecology received during the public hearing that was held in June 2002 for the proposed conditional exclusion for controlled substances, the exclusion has been expanded to include legend drugs. Legend drugs are a class of drugs also known as prescription drugs.



Ecology reviewed information that was provided by representatives of the pharmaceutical and medical community that was presented at that hearing. The inclusion of legend drugs will provide better handling and disposal options like those found for controlled substances.

Other proposed changes to the regulations include correcting citations and other typographical errors. During the recent authorization process that Ecology underwent with the Environmental Protection Agency (EPA), several minor corrections were noted for consistency with the federal hazardous waste regulations. These changes add no new requirements.

# **Appendix B**

## **Public Notices**

# **Appendix B**

## **Public Notices**



PREPROPOSAL STATEMENT OF INQUIRY

(RCW 34.05.310)

CR-101 (7/22/01)

Do NOT use for expedited rule making

Agency: Department of Ecology *ACR #0202 02-03 BS*

subject of possible rule making: The scope of this rulemaking to amend Chapter 173-303 WAC is to propose a rule based on the emergency rule Ecology adopted on January 25, 2002 (WSR 0204-030) that conditionally excludes certain controlled substances held as evidence by law enforcement agencies in Washington State. The proposal may include legend drugs not covered under the emergency rule. In addition, the rulemaking will correct typographical errors, make technical corrections such as correcting citations and other necessary clarifications based on the recent authorization process.

a) Statutes authorizing the agency to adopt rules on this subject: Chapter 70.105 RCW and Chapter 43.21A RCW

b) Reasons why rules on this subject may be needed and what they might accomplish: The emergency rule was adopted to allow local waste to energy facilities to accept controlled substances for disposal. Prior this exclusion, such facilities could not accept controlled substances for disposal leaving no appropriate disposal option for law enforcement agencies in Washington State that must destroy controlled substances according to their handling procedures. The emergency rule is in effect for 120 days. A permanent rule will be proposed before the emergency rule expires. No other substantive changes will be proposed as part of the rule making; however, technical corrections will be proposed such as typographical errors, correcting citations, and clarifications.

c) Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: Ecology is coordinating with law enforcement agencies within Washington State that regulate these wastes. Ecology has been in discussion with state and local law enforcement agencies, and with Spokane County where the municipal incinerator is located that can accept these conditionally excluded wastes. Ecology is and will continue to communicate with them via meetings, phone calls, electronic means such as list serves, and written communication.

(d) Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study

Other (describe) This rule is being developed through a process of discussing all aspects of the situation with the effected entities. Communication that led to development of the emergency rule language is a basis for the next step of developing a proposal. This communication will continue, together with notification of a broader range of stakeholders throughout the rule making process using Ecology websites, list serves, and interested persons mailing lists.

(e) How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:

(List names, addresses, telephone, fax numbers of persons to contact; describe meetings, other exchanges of information, etc.)

For information on the substantive content of the conditional exclusion contact:  
Ty Thomas, PO Box 7600, Olympia, WA 98502, e-mail [ttho461@ecy.wa.gov](mailto:ttho461@ecy.wa.gov), (360) 407-6758

For information on the rule process and the technical corrections contact:  
Chipper Hervieux, PO Box 7600, Olympia, WA 98502, e-mail [pher461@ecy.wa.gov](mailto:pher461@ecy.wa.gov), (360) 407-6756

NAME (TYPE OR PRINT) Greg Sorlie, HWTR Program Manager	
SIGNATURE <i>Greg Sorlie</i>	
TITLE Program Manager	DATE 2/15/02

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STATE OF WASHINGTON

FEB 15 2002

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PROPOSED RULE MAKING (RCW 34.05.320)

CR-102 (7/22/01) Do NOT use for expedited rule making

Agency: Department of Ecology

A.O. #02-03

- Original Notice, Supplemental Notice, Continuation of WSR

- Preproposal Statement of Inquiry was filed as WSR 02-05-054 ; or Expedited Rule Making -- Proposed notice was filed as WSR \_\_\_\_; or Proposal is exempt under RCW 34.05.310(4).

(a) Title of rule: (Describe Subject) Dangerous Waste Regulations, chapter 173-303 WAC

Purpose: To adopt a conditional exclusion for controlled substances based on an emergency rule that was adopted on January 25, 2002, and to make technical corrections.

Other identifying information:

(b) Statutory authority for adoption: Chapters 70.105 and 70.105D RCW

Statute being implemented: Chapter 70.105 RCW

(c) Summary: A conditional exclusion is being proposed to allow controlled substances that are held as evidence by law enforcement agencies or that are managed by licensees and registrants of the State Board of Pharmacy or Drug Enforcement Administration to be destroyed in incinerators. Other changes are technical corrections.

Reasons supporting proposal: The existing regulations are a barrier to feasible management of these substances and there is a suitable alternative that will be allowed by this proposal.

Table with 3 columns: Name of Agency Personnel Responsible for, Office Location, Telephone. Rows for Drafting, Implementation, and Enforcement.

(e) Name of proponent (person or organization): Department of Ecology. Private, Public, Governmental checkboxes.

(f) Agency comments or recommendations, if any, as to statutory language, implementation, enforcement and fiscal matters:

(g) Is rule necessary because of: Federal Law?, Federal Court Decision?, State Court Decision? Yes/No checkboxes and citation: 40 CFR 266.205 (d) and (e)

(h) HEARING LOCATION:

Washington Department of Ecology 300 Desmond Drive Lacey, WA 98502

Submit written comments to:

Patricia Hervieux - pher461@ecy.wa.gov PO Box 47600 Olympia, WA 98504-7600 FAX (360) 407-6715 By 5 pm July 12, 2002 For questions, call (360) 407-6756

Date: June 27, 2002 Time: 10:30 to 11:50( am)

DATE OF INTENDED ADOPTION: August 30, 2002

Assistance for persons with disabilities: Contact Marnie Black by June 17, 2002

TDD (360) 407-6006 or (360) 407-6759

CODE REVISER USE ONLY

NAME (TYPE OR PRINT)

Linda Hoffman

SIGNATURE

Handwritten signature of Linda Hoffman

TITLE

Deputy Director

DATE

5/14/02

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02-11-101

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PROPOSED RULE MAKING (RCW 34.05.320)

CR-102 (7/22/01) Do NOT use for expedited rule making

A.O. #02-03

Agency: Department of Ecology

- Preproposal Statement of Inquiry was filed as WSR 02-05-054 ; or
Expedited Rule Making -- Proposed notice was filed as WSR \_\_\_\_\_ ; or
Proposal is exempt under RCW 34.05.310(4).

- Original Notice
Supplemental Notice
to WSR 02-11-101
Continuance of WSR \_\_\_\_\_

(a) Title of rule: (Describe Subject) Dangerous Waste Regulations, chapter 173-303 WAC

Purpose: To adopt a conditional exclusion for prescription drugs, and for controlled substances based on an emergency rule that was adopted on January 25, 2002, and to make technical corrections.

Other identifying information:

(b) Statutory authority for adoption: Chapters 70.105 and 70.105D RCW

Statute being implemented: Chapter 70.105 RCW

(c) Summary: A conditional exclusion is being proposed to allow controlled substances that are held as evidence by law enforcement agencies or that are managed by licensees and registrants of the State Board of Pharmacy or Drug Enforcement Administration to be destroyed in incinerators. Other changes are technical corrections.

Reasons supporting proposal: The existing regulations are a barrier to feasible management of these substances and there are suitable alternatives that will be allowed by this proposal.

Table with 3 columns: (d) Name of Agency Personnel Responsible for, Office Location, Telephone. Rows include Drafting (Ty Thomas), Implementation (Greg Sorlie), and Enforcement (Greg Sorlie).

(e) Name of proponent (person or organization): Department of Ecology. Options: Private, Public, Governmental.

(f) Agency comments or recommendations, if any, as to statutory language, implementation, enforcement and fiscal matters:

(g) Is rule necessary because of: Federal Law? Federal Court Decision? State Court Decision? Yes/No options and citation: 40 CFR 266.205 (d) and (e)

(h) HEARING LOCATION:

Washington Department of Ecology
300 Desmond Drive
Lacey, WA 98502

Date: October 29, 2002 Time: 10:30 to 11:45 (am)

Assistance for persons with disabilities: Contact Marnie Black by October 25, 2002

TDD (360) 407-6006 or (360) 407-6759

NAME (TYPE OR PRINT)

Linda Hoffman

SIGNATURE

Handwritten signature of Linda Hoffman

TITLE

Deputy Director

DATE

9/16/02

Submit written comments to:

Patricia Hervieux - pher461@ecy.wa.gov
PO Box 47600 Olympia, WA 98504-7600
FAX (360) 407-6715 By 5 pm November 12, 2002
For questions, call (360) 407-6756

DATE OF INTENDED ADOPTION: December 30, 2002

CODE REVISER USE ONLY

Stamp area containing: CODE REVISER'S OFFICE STATE OF WASHINGTON FILED, SEP 17 2002, and handwritten numbers 313 and 02-19-099.

**Hervieux, Patricia R.**

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**From:** Dumar, Laurie  
**Sent:** Wednesday, February 20, 2002 3:24 PM  
**To:** ECOWACTRACK@listserv.wa.gov  
**Subject:** Update to the Department of Ecology's Laws and Rules Web Site on Wednesday, February 20, 2002

The Department of Ecology's Laws and Rules Web Site was updated on Wednesday, February 20, 2002.

UPDATES INCLUDE:

**RULE-MAKING PRE-PROPOSAL**

Pre-proposal for amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html>

**RULE-MAKING ADOPTION**

Adoption of amendments to Chapter 173-312 WAC - Coordinated Prevention Grants  
<http://www.ecy.wa.gov/laws-rules/activity/wac173312.html>

Adoption of amendments to Chapter 173-216 WAC, State Waste Discharge Permit Program,  
Chapter 173-220 WAC, National Pollutant Discharge Elimination System Permit Program,  
Chapter 173-226 WAC, Waste Discharge General Permit Program  
<http://www.ecy.wa.gov/laws-rules/activity/wac173216a.html>

Thank you for using WAC Track!

Have a good day!

Laurie Dumar  
Dept. of Ecology  
Rules Unit  
Phone: 360.407.6606  
Fax: 360.407.6989

**Hervieux, Patricia R.**

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**From:** Dumar, Laurie  
**Sent:** Tuesday, May 21, 2002 9:29 AM  
**To:** ECOWACTRACK@listserv.wa.gov  
**Subject:** Update to the Department of Ecology's Laws and Rules Web Site on Tuesday, May 21, 2002.

Update to the Department of Ecology's Laws and Rules Web Site on Tuesday, May 21, 2002.

UPDATES INCLUDE:

Emergency rule for Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html>

Proposed amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html#Rule-making-proposal>

Public hearing information for proposed amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
[http://www.ecy.wa.gov/laws-rules/hearings.html#Chapter 173-303 WAC - Dangerous waste regulations](http://www.ecy.wa.gov/laws-rules/hearings.html#Chapter-173-303-WAC-Dangerous-waste-regulations)

Notice Of Public Comment Period And Public Workshops Draft 303(D) Listing Policy  
<http://www.ecy.wa.gov/laws-rules/misc/wsr0211103.pdf>

Thank you for using WAC Track!  
Have a good day!

Laurie Dumar  
Dept. of Ecology  
Rules Unit  
Phone: 360.407.6606  
Fax: 360.407.6989

Visit the Laws and Rules Web Site at:  
<http://www.ecy.wa.gov/laws-rules/index.html>



**Hervieux, Patricia R.**

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**From:** Dumar, Laurie  
**Sent:** Thursday, September 19, 2002 11:36 AM  
**To:** ECOWACTRACK@listserv.wa.gov  
**Subject:** Update to the Department of Ecology's Laws and Rules Web Site on Thursday, September 19, 2002

The Department of Ecology's Laws and Rules Web Site was updated on Thursday, September 19, 2002.

UPDATES INCLUDE:

**RULE-MAKING PROPOSAL**

Supplemental notice for proposed amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html>

**RULE-MAKING WITHDRAWAL**

Notice of withdrawal for original pre-proposal (CR-101) for Chapter 173-201a WAC - Water quality standards for surface waters of the State of Washington  
<http://www.ecy.wa.gov/laws-rules/activity/wac173201a.html>

**RULE-MAKING PRE-PROPOSAL**

Pre-proposal to amend Chapter 173-201a WAC - Water quality standards for surface waters of the State of Washington  
<http://www.ecy.wa.gov/laws-rules/activity/wac173201a.html>

Thank you for using WAC Track!

Have a nice day!

Laurie Dumar  
Dept. of Ecology  
Rules Unit  
Phone: 360.407.6606  
Fax: 360.407.6989

**Hervieux, Patricia R.**

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**From:** Hervieux, Patricia R.  
**Sent:** Thursday, February 21, 2002 10:18 AM  
**To:** DW-RULES@listserv.wa.gov  
**Cc:** Hervieux, Patricia R.  
**Subject:** Dangerous Waste Regulation Rulemaking

Rulemaking Pre-proposal

Pre-proposal for amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html>

Chipper Hervieux  
Hazardous Waste and Toxics Reduction Program  
Department of Ecology  
pher461@ecy.wa.gov  
(360) 407-6756

**Hervieux, Patricia R.**

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**From:** Hervieux, Patricia R.  
**Sent:** Tuesday, May 21, 2002 10:34 AM  
**To:** DW-RULES@listserv.wa.gov  
**Cc:** Hervieux, Patricia R.  
**Subject:** Proposed Amendments to the Dangerous Waste Regulations

A second emergency rule has been filed to conditionally exclude controlled substances for law enforcement agencies since the first one expires in a few days. (The first one was adopted on January 25, 2002.) An expanded conditional exclusion and some technical corrections will be proposed on June 5, 2002. Information on these rules can be found at the following web sites.

Emergency rule for Chapter 173-303 WAC - Dangerous Waste Regulations  
<http://www.ecy.wa.gov/laws-rules/activity/wac173303.html>

Proposed amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
[http://www.ecy.wa.gov/laws-rules/activity/wac173303.html#Rule-making proposal](http://www.ecy.wa.gov/laws-rules/activity/wac173303.html#Rule-making%20proposal)

Public hearing information for proposed amendments to Chapter 173-303 WAC - Dangerous Waste Regulations  
[http://www.ecy.wa.gov/laws-rules/hearings.html#Chapter 173-303 WAC - Dangerous waste regulations](http://www.ecy.wa.gov/laws-rules/hearings.html#Chapter%20173-303%20WAC%20-%20Dangerous%20waste%20regulations)

Chipper Hervieux  
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