

**OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION
OFFICE OF ENVIRONMENTAL PUBLIC HEALTH
DRINKING WATER PROGRAM**

In the Matter of: Portland Water Bureau's Request for Variance under 42 USC § 300g-4(a)(1)(B)	Final Order
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I. INTRODUCTION

Statutory and Regulatory Background

1. EPA drinking water regulations reflect a multiple barrier approach to assure that public water systems reliably supply safe drinking water for consumers. Examples of such barriers include: protection of source water; treatment of source water; and properly trained and certified water system operators.¹

2. In 2006, the US Environmental Protection Agency (EPA) finalized its Long-Term 2 Enhanced Surface Water Treatment Rule (LT2).² Among other provisions, this regulation contains a treatment technique standard that requires unfiltered water systems subject to federal regulation that have no current treatment for *Cryptosporidium* to: 1) treat its source water for *Cryptosporidium*; and 2) use at least two disinfectants.³

3. The Safe Drinking Water Act (SDWA), Section 1415(a)(1)(B), (42 USC § 300g-4(a)(1)(B)), permits a State that has primary enforcement responsibility to grant a variance from a specified treatment technique *if the water system “demonstrates to the satisfaction of the State that such treatment technique is not necessary to protect the health of persons because of the nature of the raw water source of such system.”*⁴ (Emphasis added)

4. The State of Oregon, Oregon Health Authority (OHA), Office of Environmental Public Health, Drinking Water Program submitted its primacy application to EPA on July 8, 2009. EPA granted Oregon interim primacy upon receipt of its application. OHA thus has the authority to consider and rule on a variance submitted pursuant to 42 USC § 300g-4(a)(1)(B).

¹ EPA publication 816-K-06-005.

² In 2006, the City of Portland challenged EPA’s LT2 rule on a variety of grounds. In November of 2007, the United States Court of Appeals for the District of Columbia Circuit upheld the rule and found that “the SDWA required EPA to choose the most stringent feasible treatment technique for *Cryptosporidium* regardless of cost benefit analysis.” *City of Portland v. EPA*, 507 F.3d 706, 716 (U.S.App.D.C. 2007).

³ 40 CFR § 141.712.

⁴ 42 USC § 300g-4(a)(1)(B).

5. Primacy requires that OHA requirements be no less stringent than EPA requirements. OHA, referred to below as the authority, has a statute that is no less stringent than EPA in the granting of variances.⁵ Under ORS 448.135:

(2) *The authority may grant variances from standards requiring the use of a specified water treatment technique if the authority:*

(a) *Determines that the use of a specified water treatment technique is not necessary to protect the public health based on the nature of the raw water source for a public water system;*

(b) Has conditioned the variance as required by the federal Safe Drinking Water Act, 42 U.S.C. 300g-4;

(c) Has announced its intent to grant a variance and has either:

(A) Held a public hearing in the area prior to granting the variance; or

(B) Served notice of intent to grant the variance either personally, or by registered or certified mail to all customers connected to the water system, or by publication in a newspaper in general circulation in the area. If no hearing is requested within 10 days of the date that notice is given, the authority may grant the variance; and

(d) Promptly notifies the administrator of the United States Environmental Protection Agency of any variance granted, as required by the federal Safe Drinking Water Act, 42 U.S.C. 300g-4. (Emphasis added).

6. Oregon Administrative Rules (OAR) address the treatment technique variances more specifically. OAR 333-061-0045(13) as it applies to treatment requirements, provides:

[OHA] may grant variances from the standards specified in OAR 333-061-0032(3)(e) through (g)⁶ requiring the use of a specified water treatment technique

⁵ 42 USC § 300g-2.

⁶ OAR 333-061-0032(3)(e) - (g) are set out below for the reader's convenience:

(3) Disinfection requirements for systems utilizing surface water or GWUDI sources without filtration. Each public water system that does not provide filtration treatment must provide disinfection treatment as follows:

* * *

(e) Unfiltered water systems must provide the level of *Cryptosporidium* inactivation specified in this subsection, based on their mean *Cryptosporidium* levels, and determined in accordance with subsection (2)(d) of this rule and according to the schedule in subsection (1)(a) of this rule.

(A) Unfiltered systems with a mean *Cryptosporidium* level of 0.01 oocysts/L or less must provide at least 2-log *Cryptosporidium* inactivation.

(B) Unfiltered systems with a mean *Cryptosporidium* level of greater than 0.01 oocysts/L must provide at least 3-log *Cryptosporidium* inactivation.

(f) Inactivation treatment technology requirements. Unfiltered systems must use chlorine dioxide, ozone, or UV as prescribed by 333-061-0036(5)(c) of these rules to meet the *Cryptosporidium* inactivation requirements of this section.

(A) Systems that use chlorine dioxide or ozone and fail to achieve the *Cryptosporidium* inactivation required in subsection (3)(e) of this rule on more than one day in the calendar month are in violation of the treatment technique requirement.

if the Authority determines that the use of a specified water treatment technique *is not necessary to protect public health based on the nature of the raw water source for a public water system*. A variance granted under this section shall be conditioned on such monitoring and other requirements as the Administrator of the U.S. Environmental Protection Agency or the Director of [OHA] may prescribe. (Emphasis added)

7. In the preface to the final LT2 rule, EPA published in the Federal Register its interpretation of how the federal variance provision applies in theory to unfiltered water systems and the *Cryptosporidium* treatment requirement of LT2.⁷ According to EPA:

If an unfiltered PWS [public water system] could show a raw water *Cryptosporidium* level 3-log lower than the Bin 1 cutoff for filtered PWSs (i.e., below 0.075 oocysts/1,000 L), this could demonstrate that no treatment for *Cryptosporidium* is necessary. The unfiltered PWS would already be achieving public health protection against *Cryptosporidium* equivalent to filtered PWSs due to the nature of the raw water source.⁸

OHA must issue variances consistent with federal interpretation of the federal Act and rules.

Portland Water Bureau Water System and the Bull Run Watershed

8. The Portland Water Bureau (PWB) operates a public water system as that term is defined by OAR 333-061-0020(157). PWB directly provides water to 204,000 connections, serving an estimated population of 564,600 people. Portland also provides wholesale water year-round to 18 other public water systems serving an additional 442,000 people in Multnomah, Washington, and Clackamas counties.⁹ In addition, other people who work in or visit the Portland area consume water provided by PWB.

9. PWB uses the Bull Run watershed as its primary source of water, supplying a total of 34 billion gallons of water in 2011. PWB maintains an additional source of supply of 34 groundwater wells along the south shore of the Columbia River, which provide on average four percent of the water system's demand, as well as six additional emergency wells.¹⁰

(B) Systems that use UV light and fail to achieve the *Cryptosporidium* inactivation required in subsection (3)(e) of this rule are in violation of the treatment technique requirement.

(g) Use of two disinfectants. Unfiltered water systems must meet the combined *Cryptosporidium* inactivation requirements of subsection (3)(e) of this rule, and the *Giardia lamblia* and virus inactivation requirements of subsection (3)(a) of this rule using a minimum of two disinfectants. Each of the two disinfectants must achieve by itself, the total inactivation required for at least one of the following pathogens: *Cryptosporidium*, *Giardia lamblia*, or viruses.

⁷ 71 Fed. Reg. 728-729, January 5, 2006.

⁸ *Id.*

⁹ Drinking Water Data Online (Data Online), <http://170.104.63.9/inventory.php?pwsno=00657>.

¹⁰ Data Online, <http://170.104.63.9/inventory.php?pwsno=00657>; OHA's PWB file

10. The Bull Run watershed is located 26 miles east of Portland. The watershed, or drainage area, for the PWB intake is 102 square miles. The legal boundaries for the Bull Run Watershed Management Unit (Unit) are slightly larger than the drainage area to provide a buffer around the watershed boundary. Approximately 95 percent of the Unit is federal land administered by the U.S. Forest Service (USFS); four percent is owned by the City of Portland, and one percent is federal land administered by the Bureau of Land Management (BLM).¹¹

11. Since 1991, the Bull Run watershed drinking water source is permitted to be unfiltered because it meets the requirements outlined in OAR 333-061-0032(2). These requirements include maintaining a fully protected and controlled watershed. PWB compliance with the criteria in this rule is confirmed in a watershed survey and inspection OHA conducts each year.

12. Water from the Bull Run watershed is treated with chlorine, with sufficient contact time available to achieve at least 99.9 percent inactivation of *Giardia lamblia*, now called *Giardia intestinalis*. Water is also treated with ammonia for disinfection residual maintenance, and caustic soda for pH and corrosion control. PWB is not currently treating for *Cryptosporidium*.¹²

PWB's Request for a Variance

13. On June 7, 2011, OHA received a variance request from PWB under section 1415(a)(1)(B) of the SDWA, (42 USC § 300g-4(a)(1)(B)), and ORS 448.135(2). Specifically, PWB requests a variance from the *Cryptosporidium* treatment requirements in 40 CFR 141.712(b), (c), and (d), and OAR 333-061-0032(3)(e) through (g). Under these rules a water system using unfiltered surface water must provide at least 2-log (99%) *Cryptosporidium* inactivation. Consistent with EPA's multiple barrier approach, a minimum of two disinfectants must also be used. Granting a variance to the *Cryptosporidium* treatment provision thus necessarily requires granting a variance to the requirement to provide two disinfectants as well.

14. PWB asserts that because of the nature of the Bull Run watershed, its raw water source, treatment at the source for *Cryptosporidium* is unnecessary.

15. Specifically, PWB asserts that the following characteristics of the watershed contribute to the low prevalence of *Cryptosporidium* in the Bull Run watershed:

- (a) Limited human access to the watershed;
- (b) No grazing of domesticated livestock;
- (c) Low wildlife densities and infection prevalence;
- (d) Good soil infiltration and limited runoff;
- (e) Raw water storage reservoirs upstream of the drinking water intake dilute and attenuate the concentration of pathogens.¹³

¹¹ PWB Variance request, Section 2.

¹² Data Online, <http://170.104.63.9/inventory.php?pwsno=00657>; OHA's PWB file.

¹³ PWB Variance Request, Section 2, Section 4.

16. In support of its variance request, PWB conducted monitoring at the raw water intake for *Cryptosporidium*. Fifty liters of water were collected a minimum of four times per week from December 2009 to December 2010. In total, 10,271 liters of raw water were analyzed in 449 samples. No *Cryptosporidium* was detected.¹⁴

17. PWB collected additional water samples at upstream locations thought to have higher risk for wildlife fecal contamination. A total of 3,384 liters in 315 samples were collected over time. Four locations were sampled weekly, in addition to storm event-triggered monitoring at those and other locations. No *Cryptosporidium* was detected.¹⁵

18. PWB adapted the Pathogen Catchment Budget model as recommended by EPA to determine the fate and transport of *Cryptosporidium* in the watershed. As part of this effort, PWB collected and analyzed 307 fecal samples from 11 species of wildlife. Two *Cryptosporidium* oocysts were found in one sample from a coyote.¹⁶

19. PWB proposes an on-going monitoring program and other operational approaches to be set as conditions, should a variance be granted.

II. FINDING OF FACTS

Regulatory Scheme

1. PWB operates a public water system that is subject to federal SDWA regulations, ORS 448.115 *et seq.* and OAR 333, Division 61.

2. EPA's drinking water regulations reflect a multiple barrier approach to assure that public water systems reliably supply safe drinking water for consumers. Examples of such barriers include: protection of source water; treatment of source water; and properly trained and certified water system operators.¹⁷

3. EPA has established a maximum annual risk of infection from waterborne organisms, including *Cryptosporidium*, of 1 in 10,000 as a reasonable goal for drinking water supplies.¹⁸ EPA designed LT2 to lower the level of infectious *Cryptosporidium* in finished drinking water to less than one oocyst per 10,000 liters.¹⁹

4. EPA has determined that one oocyst per 10,000 liters statistically translates to an average concentration of 0.075 oocysts per liter for filtered systems.²⁰ Filtered systems have been determined to achieve 3-log or 99.9% reduction in *Cryptosporidium* through filtration. For

¹⁴ PWB Variance Request, Section 3.

¹⁵ PWB Variance Request, Section 3.

¹⁶ PWB Variance Request, Section 4.2.2.

¹⁷ EPA publication 816-K-06-005.

¹⁸ 54 Fed Reg 27486, June 29, 1989.

¹⁹ 71 Fed. Reg. 658, January 5, 2006.

²⁰ *Id.*

PWB, EPA has stated that if PWB were to sample 10,250 liters and find no *Cryptosporidium*, they would meet the threshold of 0.075 oocysts per 1,000 liters with 90% confidence.²¹

5. LT2 regulates the genus *Cryptosporidium*, and does not differentiate between species. Thus, all *Cryptosporidium* oocysts must be counted for purposes of determining compliance with the LT2 rule and for purposes of determining whether a variance may be granted.

6. At this time, Method 1623 is the only EPA-approved method for detecting *Cryptosporidium* oocysts. EPA has not approved any methods for quantifying *Cryptosporidium* infectivity or distinguishing between various species of *Cryptosporidium*. Therefore, OHA cannot legally quantify infectivity or distinguish between various species for purposes of determining whether PWB qualifies for a variance or is in compliance with variance conditions.

7. The 1996 amendments to SDWA require EPA to review its drinking water regulations every six years.²² In August 2011, EPA published its plan for reviewing significant regulations in accordance with an Executive Order issued by President Obama.²³ Review of the LT2 rules was included in EPA's plan and that process began in 2011.²⁴ EPA is currently holding stakeholder meetings to discuss and identify areas of the LT2 rule for possible revision. EPA plans to complete its review of the LT2 rule no later than 2016. Regardless of whether the LT2 rule is being reviewed and may be amended in the future, OHA must apply the federal regulations currently in effect.

8. Absent a variance under 42 USC § 300g-4(a)(1)(B) and ORS 448.135, PWB is required to treat its source water to inactivate or remove 99% of *Cryptosporidium* and use a minimum of two disinfectants no later than April 1, 2014.

***Cryptosporidium* Biology and Human Health Risks**

9. *Cryptosporidium* is a genus of related protozoan parasites. Over 20 species of *Cryptosporidium* have been identified to date. Several of these species or their subtypes are known to infect humans frequently, others infrequently, and others are not known to infect humans.²⁵

10. The human illness associated with *Cryptosporidium* is called cryptosporidiosis. Most documented cryptosporidiosis outbreaks to date have been linked to the *C. parvum* or *C. hominis* species of the *Cryptosporidium* genus.

²¹ E-mail correspondence between Yone Akagi, PWB, and Marie Jennings, Mike Finn, and Stephanie Harris, EPA (September 1, 2009, November 2, 2009, and November 5, 2009); and PWB Variance Request, Appendix I.

²² [Http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/regulations.cfm](http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/regulations.cfm).

²³ *Id.*

²⁴ *Id.*

²⁵ Xiao L. Molecular epidemiology of cryptosporidiosis: an update. *Exp Parasitol* 2009;124:80-9; Xiao L, Cama V. *Cryptosporidium*. in *Manual of Clinical Microbiology*, 10th ed. Versalovic J, ed. Washington DC: ASM Press. 2011: pp. 2180–89.

11. *C. parvum* can be carried by humans and several non-human species, principally cattle and sheep, especially the young of those species.²⁶ Humans are the only known reservoir of *C. hominis*.

12. The potential for epidemic human disease caused by other *Cryptosporidium* species is less certain,²⁷ although many are potentially pathogenic for humans.²⁸ At least one outbreak, in the United Kingdom, has been caused by one of these other species (*C. cuniculus*).²⁹

13. The infective stage of the *Cryptosporidium* parasite, the oocyst, is shed in the feces of infected hosts. Oocysts are relatively resistant to environmental degradation and can survive for weeks or months under some conditions; oocysts are also highly resistant to disinfection with chlorine products. Filtration, ultraviolet light, and boiling are recognized methods to remove or inactivate *Cryptosporidium*.

14. Cryptosporidiosis is transmitted by the fecal-oral route, i.e., humans become infected by consumption of feces from infected humans or animals. Well-documented exposure pathways include: contact with fecally contaminated recreational water (e.g., swimming pools, water slides, fountains); consumption of fecally contaminated drinking water; person-to-person spread (e.g., in daycare centers); consumption of unpasteurized milk or cider; and contact with infected livestock or their environments. Most recognized disease outbreaks to date have been waterborne or from direct animal contact. Recreational water exposures (e.g., swimming pools) are the most common source of outbreaks in the U.S. today.³⁰

15. Infected animals and people can excrete as many as 10,000,000 oocysts per gram of stool.³¹ Studies with human volunteers have demonstrated that a low dose of *C. parvum* (as few as 10 oocysts) may be sufficient to cause infection in healthy adults. Strains vary in their infectivity and pathogenicity.³²

16. *Cryptosporidium* infections are often asymptomatic. Illness, when it occurs, is characterized by mild to severe diarrhea, sometimes watery, usually accompanied by moderate to severe abdominal cramps. Nausea, vomiting, and low-grade fever may also occur. Illness can be intermittent and prolonged, lasting days to several weeks in most persons, and occasionally even

²⁶ Jiang J, Alderisio KA, Xiao L. Distribution of *Cryptosporidium* genotypes in storm event water samples from three watersheds in New York. *Appl Environ Microbiol* 2005;71:4446-54.

²⁷ Xiao L. Molecular epidemiology of cryptosporidiosis: an update. *Exp Parasitol* 2009;124:80-9.

²⁸ Chappell CL, Okhuysen PC, Langer-Curry RC, Akiyoshi DE, Widmer G, Tzipori S. *Cryptosporidium meleagridis*: infectivity in healthy adult volunteers. *Am J Trop Med Hyg* 2011;85:238-42; Xiao L. Molecular epidemiology of cryptosporidiosis: an update. *Exp Parasitol* 2009;124:80-9.

²⁹ Chalmers RM, Robinson G, Elwin K, Hadfield SJ, Xiao L, Ryan U, et al. *Cryptosporidium* sp. rabbit genotype, a newly identified human pathogen. *Emerg Infect Dis*. 2009 May;15(5):829-30; . Xiao L, Cama V. *Cryptosporidium*. in *Manual of Clinical Microbiology*, 10th ed. Versalovic J, ed. Washington DC: ASM Press. 2011: pp. 2180–89.

³⁰ Yoder JS, Harral C, Beach MJ. Cryptosporidiosis surveillance—United States, 2006–2008. *MMWR Surveill Summ* 2010;59:1-14.

³¹ Chappell CL, Okhuysen PC, Langer-Curry R, et al. *Cryptosporidium hominis*: experimental challenge of healthy adults. *Am J Trop Med Hyg* 2006;75:851-7; DuPont HL, Chappell CL, Sterling CR, Okhuysen PC, Rose JB, Jakubowski W. The infectivity of *Cryptosporidium parvum* in healthy volunteers. *N Engl J Med* 1995;332:855-9.

³² EPA 71 Fed.Reg. 658. Jan.5, 2006.

a month or longer. Sex, age, or pregnancy are not risk factors, however very small infants may be more susceptible to dehydration resulting from diarrhea.³³

17. Severely immunocompromised persons (e.g., AIDS patients; solid organ transplant patients on immunosuppressive therapies; certain cancer patients on certain therapies) may suffer prolonged and potentially intractable diarrhea from *Cryptosporidium* infection. Such severe cryptosporidiosis was common among AIDS patients before the advent of effective antiretroviral therapy, and remains a risk if CD4 cell counts drop below approximately 100 cells/microliter.³⁴

18. For many years there was no effective specific therapy for cryptosporidiosis. In 2004, the FDA licensed nitazoxanide for all persons at least one year of age. Clinical trials have demonstrated reductions in the duration of diarrhea among immunocompetent children and adults; the effectiveness of nitazoxanide therapy has not been demonstrated among immunocompromised patients.

Cryptosporidiosis Surveillance and Outbreak Data

19. Cryptosporidiosis has been officially reportable to health authorities in Oregon since 1995, although some reports were made as early as 1988. Prior to 2007, local health departments were not expected to follow-up on individual case reports absent some indication of an outbreak or other unexplained increase in incidence. Reporting and follow-up procedures in Multnomah, Clackamas, and Washington Counties are typical for Oregon counties.

20. Public health disease surveillance data are an amalgam of reports that mostly originate from private laboratories. Laboratory confirmation of cryptosporidiosis from fecal matter can be difficult; both false positive and false negative results are common. One recent study found that only 56 percent of positive results from these tests were likely true positives.³⁵ Untrustworthy laboratory data further compromise the ability of a public health authority to recognize and investigate outbreaks.

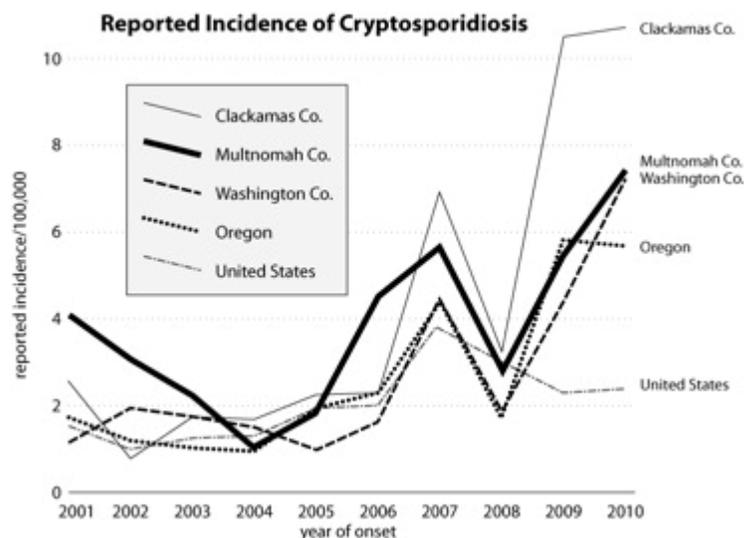
21. If multiple cryptosporidiosis cases report shared exposures (e.g., swimming in the same pool) or the number of cases increases above historical norms, a cluster investigation may ensue. Unlike bacterial pathogens such as *Salmonella* or *Escherichia coli* O157, *Cryptosporidium* cannot be readily genotyped in a private laboratory or at the Oregon State Public Health Laboratory (OSPHL), which means that it is relatively difficult to identify outbreaks and outbreak-associated cases. For all practical purposes, this means that clustered cases are only recognized as such if the spike is self-apparent to the reporter or the public health epidemiologist (e.g., normally a certain county only sees 0–2 cases/month, and suddenly they get 10 reports in 1 week).

³³ [Http://www.cdc.gov/parasites/crypto/gen_info/infect.html](http://www.cdc.gov/parasites/crypto/gen_info/infect.html).

³⁴ Kaplan JE, Hanson D, Dworkin MS, et al. Epidemiology of human immunodeficiency virus-associated opportunistic infections in the United States in the era of highly active antiretroviral therapy. Clin Infect Dis 2000;30 Suppl 1:S5-14.

³⁵ Robinson TJ, Cebelinski EA, Taylor C, Smith KE. Evaluation of the positive predictive value of rapid assays used by clinical laboratories in Minnesota for the diagnosis of cryptosporidiosis. Clin Infect Dis 2010;50:e53-5.

22. Long-term trends in the incidence of cryptosporidiosis in Multnomah, Clackamas, and Washington Counties or the United States as a whole are difficult to interpret (see figure below). From 2001 to 2010, rates in these three counties tend to be higher than the Oregon and U.S. rates, although these rates generally track together. This co-linearity suggests that the apparent changes are largely driven by broader trends in diagnostic practices (e.g., changes in testing frequencies and test modalities) rather than changes in disease incidence.



23. Twelve outbreaks of cryptosporidiosis have been recognized and investigated in Oregon since 1990. Other outbreaks have been linked to recreational water contact (swimming pools and water parks), veterinary exposure to calves, and person-to-person transmission in hospital settings. No outbreaks of cryptosporidiosis have been linked to the Portland water supply.

24. In 1992, an outbreak of cryptosporidiosis (5,000-15,000 cases) linked to municipal drinking water was recognized and investigated in Jackson County, Oregon. Surface water from the city of Talent's poorly functioning filtration plant was confirmed to be a source, but whether surface-influenced spring water feeding the separate Medford water supply was also part of the problem was never resolved. The Talent water source was of poor quality, including both run-off from agricultural lands and effluent from the Ashland sewage treatment plant.³⁶

25. Dozens of other drinking water-associated cryptosporidiosis outbreaks have been reported in the U.S., Canada, Europe, Australia, and elsewhere. Many of these outbreaks involved surface water sources from areas with heavy livestock and human presence that were overwhelmed by anomalous circumstances, such as exceptional rainfall events or treatment failures. However, outbreaks have occurred in filtered systems with high-quality water sources (e.g., Las Vegas, Nevada).³⁷ A massive outbreak in 1993 affected an estimated 400,000 persons

³⁶ Leland D, McAnulty J, Keene W, Stevens G. A cryptosporidiosis outbreak in a filtered water supply. JAWWA 1993;85(6):34-42.

³⁷ Goldstein ST, Juranek DD, Ravenholt O, et al. Cryptosporidiosis: an outbreak associated with drinking water despite state-of-the-art water treatment. Ann Intern Med 1996;124:459-68.

in Milwaukee, Wisconsin.³⁸ No cryptosporidiosis outbreaks linked to community surface water supplies have been identified in the U.S. since 1993.³⁹

Bull Run Water Monitoring and Laboratory Results

26. During one year (December 2009 to December 2010) of monitoring and analyzing 449 samples from the intake of Bull Run source water totaling 10,271 liters, no *Cryptosporidium* oocysts were detected. Three hundred and fifteen samples were also collected from upstream locations to characterize the presence of *Cryptosporidium* in the watershed, and no oocysts were detected.⁴⁰

27. All of PWB's *Cryptosporidium* testing was performed by Analytical Services, Inc., a laboratory approved under EPA's Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* in Water, using Method 1623. Modifications to this method were accepted by OHA and EPA and were intended to improve the *Cryptosporidium* recovery rate.

28. Matrix spike recovery, a quality control verification process, was employed no less frequently than every 20 samples. The purpose of this verification process was to assure that if *Cryptosporidium* oocysts were present in water samples, the laboratory would be able to detect them despite any possible limitations in laboratory methodology or interference by the contents of the Bull Run water itself. Over the one-year monitoring period *Cryptosporidium* oocyst recovery was 28.8 percent. In other words, for every 100 oocysts purposely added to the sample, the laboratory detected an average of 28.8. The average recovery for the upstream location sampling was 48.8 percent. These recovery rates are within the range of 13 to 111 percent that EPA allows for Method 1623.⁴¹

29. The distribution of matrix spike recovery data from the Information Collection Rule Supplemental Study is presented in Table 5 of EPA Method 1623. In the study, 430 water samples were collected from 87 water sources and distributed to different laboratories using EPA approved analytical methods. Among these laboratories, 60 percent of matrix spike recoveries for *Cryptosporidium* oocysts were 40 percent or higher, and about 28 percent had matrix spike recoveries less than 30 percent.⁴² Therefore, the 28.8% recovery performance of the samples for PWB's variance application is at the lower end of the recovery rates found in this study.

30. Independent of the PWB variance request, a separate study of *Cryptosporidium* in the Bull Run reservoir was conducted from June 1999 to May 2000. Out of 97 water samples collected using Method 1623, nine samples showed a combined total of 14 oocysts, and matrix spike recovery averaged 73.7 percent. Using the cell culture-PCR method, two of 89 samples

³⁸ MacKenzie WR, Hoxie NJ, Proctor ME, et al. A massive outbreak in Milwaukee of *Cryptosporidium* infection transmitted through the public water supply. *New Engl J Med* 1994;331:161-7.

³⁹ Yoder JS, Harral C, Beach MJ. Cryptosporidiosis surveillance—United States, 2006-2008. *MMWR Surveill Summ* 2010;59:1-14.

⁴⁰ PWB Variance Request, Section 3 and Section 4.

⁴¹ EPA Method 1623, Table 3.

⁴² EPA Method 1623, Table 5.

were found to have a presence of *C. parvum*; one was the bovine genotype, and the other possibly representing a new genotype from a wild animal host.⁴³

31. Prior to the compliance monitoring or sampling done for the variance request, PWB sampled for *Cryptosporidium* at the Bull Run intake monthly from September 2000 to November 2002, for a total of 28 samples. Analysis using Method 1622 and 1623 detected five *Cryptosporidium* oocysts. Recovery data were not reported to OHA.

32. PWB collected 26 samples at the intake from Bull Run between December 2002 and November 2004. Analysis using Method 1622 and 1623 did not detect any *Cryptosporidium* oocysts. EPA accepted these as grandparented data for the initial compliance round as required in LT2.⁴⁴ Matrix spike recoveries were 20 percent and 57 percent.

33. Total and fecal coliforms and *Giardia* are indicators of fecal contamination in water. PWB's fecal and total coliform monitoring data and the *Giardia* data generally correlate with PWB's *Cryptosporidium* sampling data and indicate that Bull Run water is from a low-contamination environment.

34. Oregon drinking water rules require PWB to sample and test five days per week for total coliforms or fecal coliforms.⁴⁵ Water samples collected at the Bull Run intake and tested for fecal or total coliforms have, since PWB began testing, been below the maximum allowable level. This sampling data has allowed PWB in part to meet the criteria required to remain unfiltered.

35. The 449 samples mentioned in paragraph 26 above were also analyzed for *Giardia* and a total of 58 cysts were detected.

36. On January 4, 2012, PWB reported that a sample collected at the Bull Run drinking water intake on December 30, 2011 detected one *Cryptosporidium* oocyst and one *Giardia* cyst. A sample taken from the South Fork Bull Run Station #35 on the same day also detected one *Cryptosporidium* oocyst. On January 9, 2012, PWB reported that two *Cryptosporidium* oocysts were detected from a sample collected January 5, 2012, at Station #35. These samples were collected due to a rain event that led to high stream flows. Following the receipt of these results PWB began sampling 200 liters each week at the intake, with no subsequent detections of *Cryptosporidium* up to the time this order was issued.

Wildlife Scat Sampling

37. There is no EPA-approved standard method to analyze wildlife fecal samples for *Cryptosporidium* oocysts, although there are standard methods to analyze human fecal samples for *Cryptosporidium*. Analytical Services, Inc. analyzed wildlife fecal samples for *Cryptosporidium* oocysts using a different method - a combination of immunomagnetic

⁴³ LeChevallier et.al., Comparison of Method 1623 and Cell Culture-PCR for Detection of *Cryptosporidium* spp. in Source Waters.

⁴⁴ Per OHA file: EPA letter to PWB, July 2, 2007; 40 CFR § 141.712.

⁴⁵ OAR 333-061-0036(6)(b).

separation to capture and concentrate the oocysts and immunofluorescence microscopy to visualize and identify them. Modifications to validate the method included spiking feces with oocysts and tracking the efficiency of recovery. Matrix spike mean recoveries ranged by species from 6.3 percent to 55.8 percent, with an average of 29.1 percent for all species.

38. Between August 31, 2009 and April 21, 2011, PWB collected and analyzed 307 fecal samples from 11 species of wildlife. Two *Cryptosporidium* oocysts were found in one sample from a coyote. Since the variance application was submitted, on-going sampling found *Cryptosporidium* in a fecal sample from a bobcat, with 6,900 oocysts per gram of fecal material detected.⁴⁶

Legal Protections for the Bull Run Watershed

39. The legal boundaries for the Bull Run Watershed Management Unit (Unit) are slightly larger than the drainage area; this difference in physical size provides a geographic buffer around the drainage area boundary. Approximately 95 percent of the Unit is federal land administered by USFS; four percent is owned by the City of Portland, and one percent is federal land administered by BLM.⁴⁷

40. In 1892, a presidential proclamation declared the Bull Run area as a national Forest Reserve.⁴⁸

41. In 1904, Congress passed the Bull Run Trespass Act that prohibits domestic animals from grazing in the Bull Run Forest Reserve and limits access into the area to certain federal, state and city employees.⁴⁹

42. In 1977, Congress passed the Bull Run Act that established the Bull Run Management Unit.⁵⁰ The Act also specifies that the Unit be managed to ensure "pure clear raw potable water" for persons in the Portland metropolitan area.⁵¹

43. In 1996, Congress passed the Oregon Resources Conservation Act of 1996, which prohibits "the cutting of trees in that part of the Unit consisting of the hydrographic boundary of the Bull Run River Drainage, including certain lands within the unit and located below the headworks of the City of Portland, Oregon's water storage and delivery project, as depicted in a map dated July 22, 1996 and entitled 'Bull Run River Drainage'."⁵²

44. In 1995, the BLM Salem District issued a Record of Decision and Resource Management Plan consisting of management objectives, land use allocations, and management direction on BLM-administered lands, including protecting and enhancing water quality within the Unit.

⁴⁶ PWB response to OHA's questions, 9/11/11, page 3.

⁴⁷ See Appendix A, Map.

⁴⁸ Proclamation 332 (June 17, 1892).

⁴⁹ 33 Stat. 526, Chapter 1774 (April 28, 1904).

⁵⁰ Public Law 95-200, Sec. 2(b)(November 23, 1977).

⁵¹ *Id.*, Preamble.

⁵² S. 1662, 104th Congress (1995 - 1996)

45. In 2001, Congress passed the Little Sandy Protection Act, increasing the square miles of the Unit and prohibiting timber cutting in the Unit.⁵³

46. In July 2007, USFS, Mt. Hood National Forest and PWB signed the Bull Run Watershed Management Unit Agreement specifying how the parties intend to jointly manage the Unit, consistent with federal law. The agreement is effective for 20 years with a review every five years.

47. In 2010, the City of Portland passed an ordinance, City Code 21.36.050, prohibiting tree cutting on City-owned land within the Unit.

48. Both USFS and BLM have issued closure orders, closing the Unit to unauthorized access.⁵⁴

Bull Run Watershed Characteristics

49. Topography in the Bull Run watershed is characterized by streams cutting through historic lava flows. Approximately 12 percent of the watershed has slope angles greater than 50 percent due to the down-cutting streams. The Bull Run watershed is heavily vegetated, covered by approximately 55 percent mature and old growth (large conifers) and another 41 percent in various stages of re-growth and reforestation (medium conifers and broadleaf). Wildlife found in the watershed includes deer, elk, cougar, coyote, black bear, hare, and rodents.⁵⁵

50. The soils in the forested areas of the watershed are complex organic ground cover. The soils have high infiltration capacities and are well-drained. Areas that are open or have limited shrub cover are considered more vulnerable to erosion. Approximately four percent of the Bull Run watershed is in this category. Exposed rocks and soils in the watershed include some volcanic soils, with mostly gravelly-silt loams that have high infiltration capacity. Overall, the combination of mature forest cover and high infiltration capacity of soils results in low potential for soil erosion in the Bull Run watershed.⁵⁶

51. A total of 222 miles of roads have been constructed within the Unit over time. As of 2010, 112 miles of these roads have been decommissioned. Through both active and passive processes, reforestation and rehabilitation have been initiated on the decommissioned roads. These projects are collaborations between USFS and PWB.⁵⁷

⁵³ Public Law 107-30 (August 20, 2001).

⁵⁴ Forest Service Order No. M-H-2007-1; BLM Temporary Closure Order 1610 (November 24, 2009); BLM Permanent Closure Order 4310-33, effective December 2, 2011; *See* Appendix B for complete list of documents that control activities within the Unit.

⁵⁵ PWB Variance Request. Land use percentages from figure 2.3 in section 2.1. Old growth defined as the sum of giant conifer and large conifer land use percentage and re-growth and reforestation is the remainder of the forest types, Pages 2-1 to 2-4.

⁵⁶ PWB Variance Request Section 2.2, pages 2-4 to 2-5.

⁵⁷ PWB response to OHA's questions, 9/11/11. Section 2.7.3. Page 2-12.

52. Characteristics of the watershed that would increase the risk of the PWB water source being contaminated with *Cryptosporidium* are primarily large wildlife populations, poor soil infiltration, and large areas vulnerable to erosion. Potential changes in the climate, especially changes in precipitation type from snow to rain and changes in storm patterns from low-intensity/long-duration to high-intensity/short-duration, could increase the potential for soil erosion.

Potential Human Impact

53. While access to the Unit is generally closed to the public, there are segments of popular recreational trails within the Unit, including 8.3 miles of the Pacific Crest Trail, 1.3 miles of the Huckleberry Trail, and 1.4 miles of the Oneonta Creek Trail. Approximately 2-3 total miles of the Pacific Crest and Oneonta Creek Trails are within the watershed itself. USFS estimates usage to be in the range of 2-12 hikers per day when the trails are accessible. Pack animals on these trails are reported to be very rare.⁵⁸

54. Sanitary facilities exist within and adjacent to the watershed. Within the watershed, two seasonal portable toilets are near the northwest edge of Bull Run Lake, and two portable toilets and a toilet with a closed holding tank are located at the southwest end of Bull Run Reservoir #1. All four portable toilets are traded out on a regular schedule and the closed holding tank is emptied regularly. Outside of the watershed at the southwest end of the Bull Run Reservoir #2, the headworks facility has sanitary facilities, including a septic system and two portable toilets. A pit toilet is also located near Hickman Butte, just outside the watershed.⁵⁹

55. Since 2009, BLM has constructed a 9 mile network of mountain biking trails on land adjacent to the Unit's southern boundary.⁶⁰ The Sandy Ridge mountain bike trail system is within 2 miles of the watershed.⁶¹ BLM reported that approximately 15,000 riders used these trails in 2011, based on infrared trail counting devices and car counts at the trailhead. An additional 3.75 miles of trails are expected to be constructed in 2012.⁶²

56. Most of the land adjacent to the boundary of the Unit consists of public and private forest, designated wilderness, and national scenic area. Less than 2 percent of land adjoining the Unit is in agriculture or livestock use. The closest private land is less than a half mile from the watershed.⁶³

III. CONCLUSIONS OF LAW

1. An unfiltered drinking water system such as that operated by PWB is required to treat its water for *Cryptosporidium*, and use a minimum of two disinfectants no later than April 1, 2014.⁶⁴

⁵⁸ PWB response to OHA's questions, 9/11/11, Page 4-5 and Map 1A-1.

⁵⁹ PWB response to OHA's questions, 9/11/11, Page 3-4 and Map 1A-1.

⁶⁰ Email from Adam Milner, BLM Salem District, 3/2/12.

⁶¹ PWB response to OHA's questions, 9/11/11, Page 5 and Map 1A-1.

⁶² Email from Adam Milner, BLM Salem District, 3/2/12 and 3/9/12.

⁶³ PWB response to OHA's questions, 9/11/11, Pages 2, 4-5 and Map 1A-1.

⁶⁴ 40 CFR § 141.712; OAR 333-061-0032(1)(a)(F)(iii) and 333-061-0032(3)(e) to (g).

2. PWB can be granted a variance from the *Cryptosporidium* raw water treatment requirement if the OHA is satisfied that, due to the nature of the raw water source, treatment is not necessary to protect the public's health.⁶⁵

3. In determining whether treatment is necessary to protect the public's health, OHA, in addition to considering the conditions of the watershed, must find that PWB demonstrated the average annual *Cryptosporidium* concentration in the raw water is below 0.075 oocysts per 1,000 liters.

4. PWB has shown that:

(a) The Bull Run source water legal protections limit people and exclude livestock, the primary hosts for two species of *Cryptosporidium*, from the watershed;

(b) There appears to be a low occurrence of *Cryptosporidium* found in wildlife scat in the watershed;

(c) The soil in the watershed has high infiltration capacity, which is favorable for filtering *Cryptosporidium* oocysts before transport to surface waters in the watershed; and

(d) During the one year of monitoring to support the variance application no *Cryptosporidium* was detected in the water samples that were collected and analyzed, thus meeting EPA's threshold that the *Cryptosporidium* level in the raw water is below 0.075 oocysts per 1,000 liters.

5. Based on the information submitted by PWB in its variance application, its response to comments, and other information gathered by OHA, PWB has demonstrated to the satisfaction of OHA that treatment for *Cryptosporidium* at the Bull Run watershed intake is not necessary to protect public health because of the nature of the raw water source.

IV. ORDER

It is therefore ordered that:

1. PWB's variance request IS GRANTED, subject to the following conditions:

(a) **Watershed Protection:**

PWB must:

A. Ensure that all legal and operational protections for the Unit are maintained at current levels or strengthened.

B. Monitor known trespass points on a routine basis, and make all reasonable efforts to eliminate potential unauthorized entry.

⁶⁵ 42 USC § 300g-4(a)(1)(B); ORS 448.135(2); OAR 333-061-0045(13).

C. Ensure that any human sewage within the Bull Run watershed is contained within portable toilets or permanent sanitary facilities. Where possible portable toilets or sanitary facilities are to be kept at least 200 feet from any stream, lake, or reservoir within the watershed, except when being transported for disposal outside the watershed. Any portable toilet that cannot be physically located more than 200 feet from a stream, lake, or reservoir must have secondary containment to prevent the release of waste. PWB must ensure that pump-outs and transport of portable toilets are performed with extreme caution to prevent spills and releases.

D. Propose a plan to OHA by June 1, 2012, for conducting field inspections and water and scat sampling within the Bull Run watershed. OHA will approve a final plan by August 1, 2012, and implementation must be initiated in the Fall of 2012. The plan must include but is not limited to:

i. Objectives, methodology, rationale for selected approach, sample collection, analytical methods, and quality control specifications.

ii. Semi-annual field inspections of high-risk areas, including the boundary of the watershed, the fence around the diversion pool, tributaries where wildlife is known to exist in higher concentrations, any suspected locations of illicit activities or human entry/camping, high risk soil erosion areas, or other areas as identified by PWB. One of these inspection events must occur during dry weather (peak hiking season and peak riparian grazing), and one must occur in the wet weather season (during a period of time without snow on the ground on the inspected area). Observations to be noted during the inspections include the visual presence of debris or water contamination, trash, human wastes, high concentrations of wildlife scat, evidence of fire or landslides, and any evidence of domesticated animal wastes. Any suspicious activity or potential *Cryptosporidium* source, excluding wildlife, should be fully investigated and re-inspected as necessary.

iii. Semi-annual environmental sampling in priority locations identified during the field inspections. At a minimum, this must include sampling wildlife scat in high risk areas, and sampling water in tributaries previously identified as high risk due to erosion potential, wildlife habitat, or evidence of storm impacts. The sites may be based on previous monitoring results, a combination of continuous stations and/or those selected probabilistically.

(b) **Intake Monitoring**

A. PWB must have all samples analyzed by a laboratory using EPA approved Method 1623, or another EPA-approved method that applies at the time samples are taken. PWB is encouraged to make use of improvements to Method

1623 as they become available and must utilize the method or approved modification most likely to achieve the highest recovery of oocysts at that time. The laboratory PWB uses must run matrix spike recoveries at least monthly.

B. Observation Monitoring:

i. Beginning April 1, 2012, PWB must conduct observation monitoring for *Cryptosporidium*, consisting of sampling at least 100 liters over at least two days each week.

ii. PWB must conduct observation monitoring when the turbidity at the intake is less than 5.5 NTU regardless of whether the water is being delivered to customers.

iii. Each day the turbidity at the intake is greater than 2.0 NTU but less than 5.5 NTU PWB must sample 50 liters for *Cryptosporidium*.

iv. The samples taken in accordance with 1(b)(B)(ii) and (iii) of this Order count towards the observation monitoring requirement.

C. Demonstration Monitoring:

i. If any one sample detects a presence of *Cryptosporidium*, PWB must increase its frequency of monitoring in order to demonstrate the *Cryptosporidium* concentration is less than 0.075 oocysts per 1,000 liters.

ii. PWB must begin demonstration monitoring no later than the week following the day the positive sample is reported to PWB, and the monitoring shall consist of sampling a minimum of 13,334 liters in a year. At a minimum, PWB must sample 250 liters per week over at least four days, plus an additional 334 liters throughout the year.⁶⁶

iii. PWB must conduct demonstration monitoring when the turbidity at the intake is less than 5.5 NTU regardless of whether the water is being delivered to customers.

iv. Each day the turbidity at the intake is greater than 2.0 NTU but less than 5.5 NTU PWB must sample 50 liters for *Cryptosporidium*.

v. The samples taken in accordance with 1(b)(C)(iii) and (iv) of this Order count towards the demonstration monitoring requirement.

⁶⁶ A week shall be considered Sunday through Saturday. The annual average concentration must be calculated from the day following a positive sample during observation monitoring, through the same date as the positive sample the following year.

vi. If after one year the average *Cryptosporidium* concentration is less than 0.075 oocysts per 1,000 liters, PWB may resume observation monitoring.

(c) **Reporting and Notification:**

PWB must:

A. Maintain a system for documenting the watershed inspections, monitoring, and investigation results in accordance with the plan approved by OHA under paragraph 1(a)(D) of this Order. All results must be reported to OHA on an annual basis in a Bull Run Watershed Report that also includes maps of inspection and sampling locations. OHA will work with PWB to identify any actions necessary to address outstanding issues.

B. Notify OHA, Environmental Public Health, Drinking Water Program within 24 hours of any laboratory results from either the watershed or the intake that include any *Cryptosporidium* detections.

C. At a minimum, send a press release to Portland-metro media outlets and post information on its website if *Cryptosporidium* is detected at the intake.

D. Post information on its website, including this Order, explaining that it does not treat for *Cryptosporidium* because it is operating under a variance issued in accordance with federal and state law.

E. Submit the following information to OHA, Environmental Public Health, Drinking Water Program no later than 10 days after the end of the first month following the month when the intake samples are collected: sample collection date, sample type (field or matrix spike), sample volume filtered in liters, analysis method used, the number of oocysts counted, and a summary of this information for the reporting month and the previous eleven months.

F. Timely notify OHA, Environmental Public Health, Drinking Water Program of any circumstances that may impact any of the conditions in this Order, including but not limited to land management decisions, environmental events, or structural changes within or on land immediately adjacent (lands abutting the watershed boundary or within a 3-mile buffer from the boundary) to the Unit boundaries.

(d) **Access to Watershed; Information:**

PWB must allow OHA or its designee, upon request, access to the watershed, laboratory results and pertinent documents, in order to assess compliance with this Order or for special studies.

2. This variance is valid for a period of ten (10) years, beginning on the date this Final Order is signed.

3. OHA shall revoke this variance if after one year on demonstration monitoring the average *Cryptosporidium* concentration of PWB's samples is greater than or equal to 0.075 oocysts per 1,000 liters. Revocation of the variance will include a schedule for PWB to install treatment required by LT2.

4. OHA may revoke this variance at any time if:

(a) PWB does not comply with this Order;

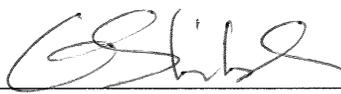
(b) OHA believes that the lack of *Cryptosporidium* treatment is posing an unreasonable threat to the public's health;

(c) Conditions in the watershed change to such a degree that the facts supporting the variance no longer support the basis for OHA granting the variance; or

(d) PWB requests that OHA terminate the variance and issue a schedule for the installation of treatment.

5. If EPA amends the LT2 rule in a manner that affects the provision and conditions of this variance, OHA may withdraw, amend, or revoke this Order in a manner that is consistent with federal law.

Dated this 14th day of March, 2012



Gail R. Shibley, JD, Administrator
Office of Environmental Public Health
Public Health Division, Oregon Health Authority