

## RULE-MAKING ORDER PERMANENT RULE ONLY

**CR-103P (December 2017)** (Implements RCW 34.05.360)

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DATE: December 07, 2020

TIME: 2:50 PM

WSR 21-01-039

Agency: State Board of Health
Effective date of rule:
Permanent Rules
Other (specify) (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be
stated below)
Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?  ☐ Yes ☐ No If Yes, explain:
<b>Purpose:</b> Chapter 246-500 WAC. The State Board of Health adopted amendments to incorporate requirements for newly established methods of final disposition of human remains into existing rules for the handling of human remains. Engrossed Substitute Senate Bill (ESSB) 5001 (chapter 432, Laws of 2019) established alkaline hydrolysis and natural organic reduction as allowed methods of final disposition of human remains in Washington. The rule incorporates these new methods into existing requirements for the handling of human remains and adds new requirements specific to these methods of disposition to help prevent and control health hazards.
Citation of rules affected by this order:
New: WAC 246-500-053, WAC 246-500-055
Repealed: none
Amended: WAC 246-500-010, WAC 246-500-020, WAC 246-500-030, WAC 246-500-040, WAC 246-500-050
Suspended: none
Statutory authority for adoption: RCW 43.20.050(2)(f)
Other authority:
PERMANENT RULE (Including Expedited Rule Making)  Adopted under notice filed as WSR 20-19-144 on 09/23/2020 (date).  Describe any changes other than editing from proposed to adopted version: In addition to minor editing, an introduction sentence was added to WAC 246-800-010 for clarity, and clarification was added to WAC 246-500-055 that testing requirements for contaminant levels in human remains reduced through natural organic reduction apply until such time that the required number of tests meet the parameters identified in the rule, and that the testing be done by a third-party laboratory to ensure that tests are done by an entity experienced in testing for contaminants before the testing requirements are phased out.  If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:
Name: Samantha Pskowski Address: PO Box 47990 Olympia WA 98504-7990 Phone: (360) 789-2358 Fax: N/A TTY: 711 Email: samantha.pskowski@sboh.wa.gov Web site: https://sboh.wa.gov/Rulemaking/CurrentRulesandActivity/HandlingofHumanRemains Other:

## Note: If any category is left blank, it will be calculated as zero. No descriptive text.

A section may be counted in more than one category.						
The number of sections adopted in order to comply	with:					
Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted at the request of a	nongo	vernmenta	al entity:			
	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted in the agency's own	n initia	ative:				
	New	<u>2</u>	Amended	<u>5</u>	Repealed	<u>0</u>
The number of sections adopted in order to clarify, s	stream	line, or ref	orm agency p	procedu	ıres:	
	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
The number of sections adopted using:						
Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>2</u>	Amended	<u>5</u>	Repealed	<u>0</u>
Date Adopted: 11/09/2020		Signature	:			
Name: Michelle A. Davis			1/.	n (		
Title: Executive Director			Mich	llict	Lavis	

- WAC 246-500-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
- (1) "Alkaline hydrolysis" or "hydrolysis" means the reduction of human remains to bone fragments and essential elements in a licensed hydrolysis facility using heat, pressure, water, and base chemical agents.
- (2) "Barrier precaution" means protective attire, equipment, or other physical barriers worn to protect or prevent exposure of skin and mucous membranes of the wearer to infected or potentially infected blood, tissue, and body fluids, hazardous chemicals, dust, and other potentially hazardous materials.
- $((\frac{(2)}{(2)}))$  <u>(3)</u> "Burial\_transit permit" means a form, approved and supplied by the state registrar of vital statistics as described in chapter  $((\frac{70.58}{(20.58)}))$  <u>70.58A</u> RCW, identifying the name of the deceased, date and place of death, general information, disposition and registrar and sexton information.
- (( $\frac{(3)}{(3)}$ ))  $\underline{(4)}$  "Coroner" means the county official as described under chapter 36.24 RCW and RCW 36.16.030.
- $((\frac{4}{1}))$  "Department" means the Washington state department of health.
- $((\frac{5}{)}))$  (6) "Effluent" means the liquid end-product following alkaline hydrolysis. For the purpose of this chapter, this does not meet the definition of human remains.
- (7) "Embalmer" means a person defined and licensed under chapter 18.39 RCW.
- ((+6))) (8) "Funeral establishment" means a place of business defined and licensed under chapter 18.39 RCW.
- $((\frac{7}{1}))$  <u>(9)</u> "Funeral director" means a person defined and licensed under chapter 18.39 RCW.
- ((8))) (10) "Health care provider" means any person having direct or supervisory responsibility for the delivery of health care, including persons credentialed in Washington state under Title 18 RCW and military personnel providing health care within Washington state regardless of licensure.
- $((\frac{9}{}))$  (11) "Human remains" or "remains" means the body of a deceased person, in any stage of decomposition, ((and includes cremated human)) including remains following the process of cremation, alkaline hydrolysis, or natural organic reduction, but ((excludes)) not including archaeological ((resources)) skeletal remains under chapter 27.53 RCW.
- $((\frac{10}{10}))$  "Local health officer" means a licensed physician defined and appointed under RCW 70.05.050.
- $((\frac{(11)}{(11)}))$  (13) "Local registrar of vital statistics" means the local health officer or administrator who registers certificates of birth and death occurring in  $(\frac{(his\ or\ her)}{110})$  their designated registration district under chapter  $(\frac{(70.58)}{110})$  70.58A RCW.
- $((\frac{(12)}{(12)}))$  "Medical examiner" means a physician appointed by the county legislative authority to replace the coroner under RCW 36.24.190.
- ((\frac{(13)}{13})) (15) "Natural organic reduction" means the contained, accelerated conversion of human remains to soil.

- (16) "Reduction" means an accelerated conversion of human remains into bone fragments, essential elements, or soil by cremation, alkaline hydrolysis, or natural organic reduction.
- (17) "Reduction facility operator" means the person(s) registered and licensed with the funeral and cemetery board through WAC 308-47-090 to operate a crematory, alkaline hydrolysis equipment, or natural organic reduction facility.
  - (18) "Refrigerate" means:
- (a) Placing in a mechanically cooled unit maintained at a maximum temperature of 48°F in a licensed funeral establishment; or
- (b) Placing in a mechanically cooled unit maintained at a maximum temperature of 48°F or packing with dry ice or leak-resistant sealed ice packs outside of a funeral establishment.

AMENDATORY SECTION (Amending WSR 06-17-182, filed 8/23/06, effective 9/23/06)

- WAC 246-500-020 Contact with human remains. (1) Funeral directors, embalmers, medical examiners, coroners, health care providers, and others directly handling or touching human remains must:
- (a) Wash hands and other exposed skin surfaces with soap and water or equivalent immediately and thoroughly after contact with human remains, blood, or body fluids;
- (b) Use barrier precautions if a procedure involves potential contact with blood, body fluids, or internal tissues of the deceased or hazardous chemicals, dust, or other potentially hazardous material;
- (c) Not eat, drink, or smoke in areas where handling of human remains or body fluids takes place;
- (d) Use reasonable precautions to prevent spillage of body fluids during transfer and transport of human remains including, when necessary:
- (i) Containing, wrapping, or pouching with materials appropriate to the condition of the human remains; and
- (ii) Obtaining approval from the coroner or medical examiner prior to pouching any human remains under their jurisdiction( $(\div)$ ).
  - (e) Wash hands immediately after gloves are removed;
- (f) Take precautions to prevent injuries by needles, scalpels, instruments, chemicals, and equipment during use, cleaning, and disposal;
- (g) Properly disinfect or discard protective garments and gloves immediately after use;
- (h) Properly disinfect all surfaces, instruments, and equipment after contact with human remains, blood, or body fluids;
- (i) Provide appropriate means for disposing of body fluids, blood, tissues, and wastes or for retaining them for final disposition with the body  $((\cdot))$ , including:
- (i) All autopsy rooms, morgues, preparation rooms, and other places where human remains are handled must be equipped with impervious containers with disposable, impervious liners and tightly fitting closures  $(\cdot, \cdot)$ ;
- (ii) Body fluids, blood, tissues, and wastes removed from human remains must be kept with the body or disposed in accordance with local ordinances and other applicable laws and rules for infectious waste( $(\cdot)$ );

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- (iii) A sewage system approved by the local health officer or the department may be used for the disposal of blood  $((\frac{and}{and}))_{\perp}$  other body fluids  $((\frac{1}{and}))_{\perp}$  and effluent; and
- (iv) All containers and liners used to receive solid or fluid materials removed from human remains must be cleaned and disinfected immediately after use, interred with the body, or disposed in accordance with local ordinances and other applicable laws and rules for infectious waste.
- (2) Persons responsible for transfer or transport of human remains ((must)) <u>shall</u> clean and disinfect equipment and the vehicle if soiled with body fluids or any other portion of human remains.

AMENDATORY SECTION (Amending WSR 06-17-182, filed 8/23/06, effective 9/23/06)

## WAC 246-500-030 Refrigeration or embalming of human remains. (1) Funeral directors, embalmers, and others assisting in the preparation of human remains for final disposition ((must)) shall refrigerate

or embalm the remains upon receipt.

- (2) Funeral directors, embalmers, and others assisting in the preparation of human remains for final disposition may delay refrigeration upon receipt or remove human remains from refrigeration for the following activities:
  - (a) Embalming;
  - (b) Transporting;
  - (c) Cremating, reducing by alkaline hydrolysis, or burying;
- (d) ((Viewing for identification for a period of time not to exceed one hour by a person able to identify the deceased;)) Reducing by natural organic reduction;
- (e) Washing, anointing, clothing, praying over, reading to, singing to, sitting with, guarding, viewing, or otherwise accompanying the deceased for a period of time not to exceed twenty-four hours by persons acting according to the directions of the deceased or the person having the right to control the disposition of the remains under RCW 68.50.160, provided that anyone directly touching the remains uses barrier precautions according to requirements under WAC 246-500-020 (1)(b); or
- (f) As otherwise approved by the local health officer after evaluating specific circumstances, the need to protect public health, and recognition of religious beliefs.
- (3) A funeral director, embalmer, or other person assisting in the preparation of human remains for final disposition ((must)) shall prohibit activities otherwise allowed under subsection (2)(d) of this section if the human remains are confirmed to have or suspected of having one or more of the following conditions:
- (a) Prion disease infection, mycobacterium tuberculosis infection, Ebola virus disease infection;
- (b) Contagious disease infection which may be a public health hazard as identified by the local health officer or medical examiner;
- (c) A radioactive seed implant within thirty days of death until such time that thirty days have elapsed or the organ containing the seed(s) has been removed;
- (d) Containing a nuclear pacemaker until such time that the nuclear pacemaker is removed; or

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- (e) Perishing as a result of a radiologic incident or accident, unless a written release is provided by the department of health office of radiation protection or other state or federal agency in charge of the response to the radiological incident or accident.
- (4) A funeral director, embalmer, or other person assisting in the preparation of human remains for final disposition shall prohibit activities otherwise allowed under subsection (2)(e) of this section if informed by a local health officer or medical examiner that such activities would pose a direct threat to human health.
- $((\frac{4}{}))$  Nothing in this section restricts the authority of a coroner or medical examiner when human remains are under  $(\frac{his}{her})$  their jurisdiction in accordance with RCW 68.50.010.

AMENDATORY SECTION (Amending WSR 06-17-182, filed 8/23/06, effective 9/23/06)

WAC 246-500-040 Transportation of human remains. (1) A person((s)) who transports human remains ((must)) shall:

- (a) Use effective hygienic measures consistent with handling potentially infectious material; and
- (b) Obtain a burial-transit permit from the ((local health officer or)) local registrar of vital statistics or ((file a notice of removal)) initiates a report of death with the local registrar where the death occurred according to requirements of RCW ((70.58.230)) 70.58A.210 prior to transporting human remains from one registration district to another.
- (2) Prior to transporting human remains by common carrier, the person((s)) responsible for preparing and handling the remains ((must)) shall:
- (a) Enclose the human remains in a leak-resistant container placed inside another leak-resistant, securely constructed shipping container to prevent the release of all body fluids;
- (b) Obtain and enclose the burial-transit permit in a sturdy envelope; and
  - (c) Attach the burial-transit permit to the shipping container.
- (3) The person((s)) responsible for human remains routed to the point of final destination on a burial-transit permit:
- (a) May temporarily hold the remains at a stopover point within the state of Washington for funeral or other purposes without an additional permit; and
- (b) ((Must)) Shall surrender the burial-transit permit to the  $((sexton\ or\ crematory\ official))$  person in charge of the funeral establishment, reduction facility, or cemetery authority at the point of interment or ((cexton)) reduction.
- (4) ((Sextons and cremation officials)) A person in charge of the funeral establishment, reduction facility, or cemetery authority shall accept the burial-transit permit as authority for interment in a cemetery or for (( $\frac{1}{1}$ )) reduction within the state of Washington.

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- WAC 246-500-050 ((Cremated)) Human remains reduced through cremation. (1) Other than the provisions in this section and WAC 246-500-010, this chapter does not apply to human remains after cremation.
- (2) A local registrar, in cooperation with the Washington state <u>funeral and</u> cemetery board, may issue a <u>burial-transit</u> permit for disposition of cremated human remains. The permit for the disposition of cremated remains may be used in connection with the transportation of cremated remains by common carrier or other means.
- (3) The local registrar or the department of health may issue a <u>burial-transit</u> permit for the disposition of cremated human remains which have been in the lawful possession of any person, firm, corporation, or association for a period of ninety days or more. This permit will specify that the disposition of cremated remains must be consistent with Washington state laws and rules.

## NEW SECTION

- WAC 246-500-053 Human remains reduced through alkaline hydrolysis. (1) Other than the provisions in this section and WAC 246-500-010, this chapter does not apply to human remains after alkaline hydrolysis.
  - (2) A hydrolysis facility must:
- (a) Operate a high-temperature purpose built vessel, that reaches a minimum temperature of two hundred fifty degrees Fahrenheit for a minimum of thirty minutes during the reduction process; or
- (b) Operate a purpose built vessel, for which third-party validation testing is provided demonstrating the reduction process destroys prions, and achieves sterilization in both the water and airspace, according to the manufacturer's specifications. The testing criteria must include a matrix-assisted laser desorption/ionization time of flight (MALDI-TOF) mass spectrometry peptide sizing analysis and a 6 spore log reduction or greater in the level of *Bacillus* spores. An operator shall retain this documentation on-site and be able to provide it upon request to state or local health officials.
- (3) A local registrar, in cooperation with the Washington state funeral and cemetery board, may issue a burial-transit permit for disposition of human remains reduced through alkaline hydrolysis. The permit for the disposition of remains reduced through alkaline hydrolysis may be used in connection with the transportation of remains reduced through alkaline hydrolysis by common carrier or other means.
- (4) The local registrar or the department of health may issue a burial-transit permit for the disposition of human remains reduced through alkaline hydrolysis which have been in the lawful possession of any person, firm, corporation, or association for a period of ninety days or more. This permit will specify that the disposition of remains reduced through alkaline hydrolysis must be consistent with Washington state laws and rules.

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- WAC 246-500-055 Human remains reduced through natural organic reduction. (1) Other than the provisions of this section and WAC 246-500-010, this chapter does not apply to human remains after natural organic reduction.
  - (2) A natural organic reduction facility operator shall:
- (a) Collect material samples for analysis that are representative of each instance of natural organic reduction using a sampling method such as described in the U.S. Composting Council 2002 Test Methods for the Examination of Composting and Compost, Method 02.01-A through E;
- (b) Analyze each instance of reduced human remains for physical contaminants. Reduced remains must have less than 0.01 mg/kg dry weight of physical contaminants which include, but are not limited to, intact bone, dental filings, and medical implants;
- (c) Analyze, using a third-party laboratory, the reduction facility's reduced human remains according to the following schedule:
- (i) The reduction facility's initial twenty instances of reduced human remains for the parameters identified in Table 500-A, and any additional instances of human remains necessary to achieve twenty reductions meeting the limits identified in Table 500-A;
- (ii) Following twenty reductions meeting limits outlined in Table 500-A, analyze, at minimum, twenty-five percent of a facility's monthly instances of reduced human remains for the parameters identified in Table 500-A until eighty total instances have met the requirements in Table 500-A;
- (iii) The local health jurisdiction may require tests for additional parameters under (b) and (c) of this subsection.
- (d) Not release any human remains that exceed the limits identified in Table 500-A; and
- (e) Prepare, maintain, and provide upon request by the local health jurisdiction, an annual report each calendar year. The annual report must detail the facility's activities during the previous calendar year and must include the following information:
  - (i) Name and address of the facility;
  - (ii) Calendar year covered by the report;
  - (iii) Annual quantity of reduced human remains;
- (iv) Results of any laboratory analyses of reduced human remains; and
- (v) Any additional information required by the local health jurisdiction.

(f)

Table 500-A Testing Parameters

Metals and other testing parameters	Limit (mg/kg dry weight), unless otherwise specified
Fecal coliform	< 1,000 Most probable number per gram of total solids (dry weight)
or	
Salmonella	< 3 Most probable number per 4 grams of total solids (dry weight)
Arsenic	≤ 20 ppm
Cadmium	≤ 10 ppm

Lead	≤ 150 ppm
Mercury	≤ 8 ppm
Selenium	≤ 18 ppm

- (3) A local registrar, in cooperation with the Washington state funeral and cemetery board, may issue a burial-transit permit for disposition of human remains reduced through natural organic reduction. The permit for the disposition of remains reduced through natural organic reduction may be used in connection with the transportation of remains reduced through natural organic reduction by common carrier or other means.
- (4) The local registrar or the department of health may issue a burial-transit permit for the disposition of human remains reduced through natural organic reduction which have been in the lawful possession of any person, firm, corporation, or association for a period of ninety days or more. This permit will specify that the disposition of remains reduced through natural organic reduction must be consistent with Washington state laws and rules.