

Requirements for an Alternative Disposition Operator – Hydrolysis

DEFINITIONS

“Hydrolysis” means the process by which the following two steps are taken:

(1) The reduction of a dead human body to its essential organic components and bone fragments by alkaline hydrolysis. “Alkaline hydrolysis” is a process using heat, pressure, agitation, and a solution of water and potassium hydroxide or sodium hydroxide in a hydrolysis chamber.

(2) The processing of the remains after removal from the hydrolysis chamber

“Hydrolysis chamber” means a purpose-built vessel that is closed and sealed on all sides, within which the hydrolysis of human remains is performed and any other attached, unenclosed, mechanical components that are necessary for the safe and proper functioning of the equipment. Allowable hydrolysis chambers for the disposition of human remains shall be capable of meeting or exceeding the time & temperature parameters defined in section 4.

“Hydrolysis wrapping” means a hydrolyzable body wrapping into which the body of a deceased person is placed prior to insertion into a hydrolysis chamber. The wrapping must consist of 100-percent protein-based material, such as silk, suede, leather, feather, fur, or wool.

“Hydrolysis facility” means a building or structure containing one or more chambers for the reduction of bodies of deceased persons by hydrolysis.

“Hydrolyzed human remains” means all recoverable bone fragments of a dead human body that are left after hydrolysis in a hydrolysis facility. “Hydrolyzed human remains” does not include foreign materials, pacemakers, or prostheses. For clarification, “hydrolyzed remains” are recoverable “human remains” referred to in subsection 1(1) of the *Act*.

“Hydrolysate” a liquid solution containing the organic products of hydrolysis. For clarification, “hydrolysate” is not “human remains” referred to in subsection 1(1) of the *Act*.

“Hydrolyzed human remains container” means a receptacle in which recoverable hydrolyzed human remains are placed after hydrolysis.

“Inurnment” means placing hydrolyzed human remains in a container suitable for placement, burial, or shipment.

“Processing” means the removal of foreign objects and the reduction of the particle size of hydrolyzed human remains by mechanical means including, but not limited to, grinding, crushing, and pulverizing to a consistency appropriate for disposition.

“Scattering” includes the authorized dispersal of hydrolyzed human remains. All references to scattering under Regulation 30/11 apply to processed hydrolyzed human remains.

PUBLIC HEALTH, SAFETY & DIGNITY

The Hydrolysis Process

1. The Licensee shall ensure that the preparation of a dead human body for hydrolysis, placement in a hydrolysis wrapping and the hydrolysis process are conducted by a licensed Funeral Director – Class 1.
2. The Licensee shall not operate the hydrolysis chamber in a manner that contradicts or conflicts with the manufacturer’s guides, recommendations and manual, unless directed to do so by the Registrar.
3. The Licensee shall ensure that every dead human body is enclosed in a hydrolysis wrapping prior to and during hydrolysis.
4. The Licensee shall ensure that the alkaline hydrolysis process is operated within the following parameters: temperature above 149°C (“>149°C”) and minimum concentration of 1 N sodium hydroxide and/or potassium hydroxide solution for at least 3 hours. There may be exceptional cases where, due to the fragility of the body (example: small children), the process must be conducted outside of these parameters.
5. The Licensee shall ensure that every chemical or solution used during hydrolysis is approved by the hydrolysis chamber manufacturer and that no other chemicals are added.
6. The co-mingling or blending of human remains during hydrolysis is prohibited. No person shall hydrolyze the remains of more than one person at the same time in the same hydrolysis chamber or introduce the remains of a second person during processing.

Hydrolysate

7. Hydrolysate must not be collected by any method for preservation by anyone.
8. Hydrolysate may only be disposed of into the municipal wastewater system in accordance with municipal approvals and requirements.

Hydrolysis Chamber Maintenance and Performance Records

9. The Licensee shall ensure that all hydrolysis chambers are inspected as per the manufacturer's factory recommendations, guides, user manual, and instructions, whichever may apply. Notwithstanding the manufacturer's recommendations, the operator shall ensure that all hydrolysis chambers have a Certificate of Inspection issued by the Technical Standards and Safety Authority of Ontario and comply with the requirements of Ontario Regulation 220/01 - Boiler & Pressure Vessels.
10. The Licensee shall upon request of the Registrar, provide to the Registrar a copy of the manufacturer's factory recommendations, guides, user manual, and any written instructions and materials received at the time of purchasing the hydrolysis chamber.
11. The Licensee shall maintain copies of all inspection records for hydrolysis chambers and they are to be kept in the business premises of the Licensee.
12. The Licensee shall make available and provide a copy of all inspection records for hydrolysis chambers to a BAO inspector when requested.
13. The Licensee shall maintain, and keep in the licensed premises, archived hydrolysis chamber data that logs performance details for every hydrolysis process performed and such data must include:
 - a) Name & tag number of deceased
 - b) Date & Start time
 - c) Temperature vs. Time graph or data points when the unit reached operating temperature and when cycle was finished
 - d) Alkali concentration
 - e) Weight of deceased
 - f) Any special conditions (expected or unexpected inorganic materials, nuclear medicine information, operating parameter overrides and explanation why)
 - g) Any errors (incomplete digestion, spills, leaks, odours, power failures). Record time and details of each instance

Safety and Emergency Protocols

14. The Licensee shall ensure that all hydrolysis chambers meet the following minimum criteria:
 - a) Hydrolysis chambers must be equipped with a system to prevent any operation of the hydrolysis chamber below the minimum parameters (temperature ($>149^{\circ}\text{C}$), high pressure (4 atm) and high pH (using sodium hydroxide or potassium hydroxide in solution) for at least 3 hours.
 - b) hydrolysis chambers must be equipped with a system to prevent the drainage of liquid or hydrolysate before it has been cooled and neutralized.

- c) hydrolysis chambers must be equipped with the capability to record and store data for every occurrence that keeps track of the occurrence identifier, weight, time, duration and temperature used during the procedure.
- 15. The Licensee must create and submit to the Registrar for approval a copy of the policy to handle emergencies in case of mechanical or other failures in relation to the hydrolysis chamber's operation and must include, at a minimum, the following:
 - a) how incidents involving spills or leaks from the hydrolysis chamber will be contained.
 - b) how the deceased's remains are to be handled in case of machine failure during a hydrolysis procedure.
- 16. The Licensee shall maintain a written record of all leaks or spills from the hydrolysis chamber, including the actions taken to correct such incidents and to prevent them from happening in the future. The written record shall be made available to the BAO for inspection and review upon request.
- 17. The hydrolysis chamber must never be allowed to discharge un-neutralized, uncooled liquid into the sewer system.
- 18. The operator shall register the licensed business location as a Biomedical Waste Generator and comply with Guideline C-4 and the Environmental Protection Act.

Facility Design Requirements

- 19. The Licensee shall ensure that all aspects of hydrolysis chambers and their operations are compliant with all municipal, provincial and federal legislation of Canada, including:
 - a) Ministry of Labour and Workplace Hazardous Materials Information System (WHMIS), Occupational Health and Safety Act
 - b) Transportation of Dangerous Goods Act
 - c) Technical Standards and Safety Act 2000 (TSSA) – Boiler & Pressure Vessel regulation 220/01
 - d) Environmental Protection Act
 - e) Municipal Sewer Use Bylaws
- 20. The Licensee will obtain a Pre-Start Health and Safety Review by a Professional Engineer, Certified Industrial Hygienist, Registered Occupational Hygienist or similarly qualified person.
- 21. The operator must ensure that the hydrolysis facility where the hydrolysis chamber is located must meet the following minimum requirements:
 - a) The interior of the hydrolysis facility shall not be visible from a public area when the doors to the room are closed.

- b) The hydrolysis facility, including all its surfaces, and the equipment used in the hydrolysis facility shall be capable of being easily cleaned, sanitized and disinfected.
- c) The hydrolysis facility shall be equipped with the following:
 - i. The materials and equipment necessary to clean, sanitize and disinfect the room and the equipment used in the hydrolysis facility.
 - ii. A supply of running water with a device to prevent back-flow of water.
 - iii. A sufficient supply of personal protective equipment and clothing for each person in the hydrolysis facility handling a dead human body.
 - iv. The hydrolysis facility shall be used only for hydrolysis unless it is also an embalming room, in which case it shall be used only for hydrolysis and embalming.

22. Structure or Sump to Contain Spills; Floor Drains Blocked

- a) Surfaces and interior coatings, including, but not limited to, floors, ramps, stairs, ceilings, walls, doors, frames, casework, bench tops, and furniture, to be cleanable, non-absorbent, and resistant to scratches, stains, moisture, chemicals, and repeated decontamination.
- b) Flooring should be continuous, non-porous and impervious to chemicals used in the facility. The flooring materials must continue uninterrupted upon the length of all walls within the facility, to at least the extent needed to prevent migration of hydrolysate, chemistry and other potential leakage under the base of all walls.
- c) Floors must withstand loading in accordance with function.
- d) Floors, ramps and stairs must be slip-resistant according to function.
- e) Floor in the facility must be connected to a secondary containment tank, berm, tray, sump or other structure to contain spills. Floor drains must be blocked during the hydrolysis process to prevent the introduction of hazardous substances into the wastewater system.

23. Furnishings & Storage

- a) All chair and table surfaces shall be scratch, stain, moisture and chemical resistant and non-absorbent.
- b) Adequate storage provision for separation of incompatible chemicals including corrosion resistant shelving and secondary containment.
- c) Window coverings should be adequate to prevent outside visibility.

24. Ventilation

- a) All air exhausted from the room where the hydrolysis chamber is used will be exhausted to the outside of the building without recirculation.

25. Services (Plumbing, Electrical, Waste)

- a) Sinks to be placed to facilitate hand washing upon exit from the hydrolysis facility.
- b) Each sink must have an overflow outlet.

- c) Emergency eyewash and deluge shower equipment to be provided in accordance with facility activities.

RELATIONSHIP WITH PUBLIC AND CONSUMER PROTECTION

- 26. Unless otherwise specified in these conditions, all sections of Ontario Regulation 30/11 with respect to contracts and price lists apply by replacing the words cremation or cremated remains with hydrolysis or hydrolyzed human remains.
- 27. Unless otherwise specified in these conditions, sections 185 to 191 of Ontario Regulation 30/11 with respect to refusal to cremate, identification tags, burial permits, assisted cremation and by-laws apply by replacing the words cremation or cremated remains with hydrolysis or hydrolyzed human remains.
- 28. Notwithstanding Section 1.1 of the Act, the operator shall not describe hydrolysis as cremation. The process must be identified on any form or printed material as hydrolysis.
- 29. The operator shall not describe the hydrolysis process as having any benefit or advantage over other forms of disposition or disparage other forms of disposition.
- 30. All contracts for services between the operator (or agent of the operator) and the consumer must include following statement:

“Hydrolysis is a chemical process that uses the heated solution of water and alkaline under pressure and agitation to reduce a body to components of liquid and bone. The resulting bone fragments are dried and reduced. The liquid (hydrolysate) is disposed of into a wastewater treatment system.”
- 31. Section 53 of Ontario Regulation 30/1 applies to unclaimed hydrolyzed human remains as it does to unclaimed cremated human remains.
- 32. No hydrolyzed human remains shall be removed from the hydrolysis facility, unless the hydrolyzed human remains have been processed so that they are suitable for scattering or inurnment.
- 33. The Licensee shall ensure that any non-organic materials such as, but not limited to, dental gold and medical devices are separated from the hydrolyzed human remains. The operator’s contract for hydrolysis must disclose how these materials will be disposed of.
- 34. The operator shall not permit the hydrolysis of a dead human body unless the operator has received:
 - a) a certificate issued by the coroner authorizing the hydrolysis or cremation,
 - b) a burial permit issued by a municipality verifying the registration of death, and

- c) an application for hydrolysis signed by the person with legal authority to authorize the disposition of the human remains.
35. Sections 31 and 125 of Ontario Regulation 30/11 are modified to:
- a) permit the hydrolysis of a dead human body with a pacemaker;
 - b) not permit the hydrolysis of a dead human body if the body has a radioactive implant, except that a body that has a radioactive implant can be hydrolyzed if it is at least two years after the day the body received the implant; and
 - c) eliminate the references to casket.
36. Upon completion of the process the operator shall provide a certificate of hydrolysis with the hydrolyzed human remains to the person with the legal authority to claim them.