



Town of Dedham
Board of Health
450 Washington Street
Dedham, MA 02026
(781) 751- 9220
F: (781) 751-9229
www.dedham-ma.gov



CRYOGENIC CHAMBER THERAPY

Authority

This Regulation is promulgated pursuant to the authority granted to the Dedham Board of Health by Chapter 111, Section 31 of the Massachusetts General Laws “Boards of Health may make reasonable health regulations”.

State of Purpose

The purpose of this Regulation is to protect the customers and employees within the Town of Dedham so they may make informed decisions about using cryogenic chamber therapy and to allow local enforcement to ensure requirements are being met.

A. Definitions:

Agent- Means any duly authorized agent of the Board of Health as specified under MGL c. 111 sect. 30.

Board of Health- Town of Dedham Board of Health and its designated agents.

Certification – An official document used to provide proof that an individual was trained in a specific topic.

Consent Form- A form that must contain the following information: the cryogenic chamber therapy establishment’s name, address, and phone number; the client’s name, address, and phone number; the date, time, and length of service; confirmation through operator and client signature that the operator conducted the screening process with the client as required through these Regulations.

Cryogenic Chamber Therapy- Enveloping the body, or any part thereof, for any amount of time, with hyper-cooled air (using any chemical, including, but not limited to, liquid nitrogen) in a chamber.

Department- Town of Dedham Health Department.

Employee- Any individual who performs services for an employer.

Employer- Any individual, partnership, association, corporation, trust or other organized group or individuals that uses the services of one (1) or more employees.

Establishment- Place where cryogenic chamber therapy takes place.



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Owner(s)- Any person or entity that individually, or jointly or severally with others, owns, or controls an establishment.

Operator- Any person or entity that individually, or jointly or severally with others, owns, or controls an establishment.

Permit- A cryogenic chamber therapy permit issued by the Dedham Board of Health or its designated agents.

Cryogenic Chamber- A machine designed to provide cryogenic chamber therapy to a person.

Training – A course that teaches an individual a specific skill and/or topic.

B. General Provisions for Customers:

1. Customers seeking Cryogenic Chamber Therapy must be 18 years or older.
2. An establishment shall not provide more than one 3-minute^{1,2} Cryogenic Chamber Therapy session to any customer per calendar day.
3. Customers are not permitted to wear jewelry while receiving cryogenic chamber therapy.
4. Customers must wear protective clothing to prevent moisture/dampness on the skin and frostbite. Such clothing shall include, but is not limited to, socks, slippers, gloves, and undergarments.

C. Screening:

1. An owner or operator of an establishment shall be required to conduct screening of every customer before every cryogenic chamber therapy session. The owner or operator of an establishment must provide each customer with a consent form that states, at a minimum, that the customer should consult with their medical provider prior to undergoing any cryogenic chamber therapy session, and that customers with the following medical conditions (or history thereof) should avoid cryogenic chamber therapy:

- Heart attack or stroke
- High blood pressure
- Pregnancy
- Seizure disorder
- Reynaud’s Syndrome
- Cold allergies
- Vein thrombosis or clotting issues
- An infection or fever

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3906033/>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5411446/>



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- Pacemaker and other implanted medical devices
- Certain medications
- Claustrophobia
- Or any serious medical condition not already mentioned

2. Prior to participating in a cryogenic chamber therapy session, customers must be provided with a full description of the cryotherapy process along with a short video of explanation which clearly states there are no proven medical benefits to cryotherapy.

3. The owner or operator must inform customers that cryogenic chamber therapy is not an FDA approved medical device before each cryogenic chamber therapy session.

D. Physical Facility:

1. A defibrillator must be available in the establishment at all times. The employer and employees must be trained on using a defibrillator with the training certification valid and available in the establishment.

2. An emergency phone, clearly marked as such, must be available in the establishment at all times with a list of emergency phone numbers posted next to the phone.

3. Warning signs must be posted in a conspicuous location next to the cryogenic chamber. The signs must list the following information: (1) the health conditions identified in Section C: Screening; (2) "Cryogenic chamber therapy is not an approved FDA medical device nor is there any proven health benefits to cryotherapy."

4. OSHA Requirements: The facility must meet all OSHA requirements along with proper signage; all warning signs posted with a red background and white lettering at least two (2) inches in height.

5. All permits shall be displayed on the premises in a location that is conspicuous, open, and obvious to all people entering the establishment.

6. An oxygen deficiency monitor in good working order must be present for each cryogenic chamber.

7. Oxygen deficiency monitors shall be tested periodically in accordance with manufacturer instructions, but no less than four (4) times in a twelve (12) month period. The owner or operator shall maintain a record of testing for each oxygen deficiency monitor.

8. Cryogenic chambers must have an automatic shut-off when oxygen levels fall below 20%.

9. Owners and operators shall clean and sanitize cryogenic chambers in accordance with manufacturer instructions. Owners and operators shall maintain a record of cleaning for each cryogenic chamber.



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E. Employee Training:

1. All employees, employers, owners, and operators must have proof of valid Basic Life Support CPR and defibrillator class-based training.
2. All employees, employers, owners, and operators shall be trained in the use of cryogenic chambers in accordance with manufacturer guidelines. Records of trainings must be kept up to date and available for review at all times.
3. The establishment owner must have periodic training reviews outlining the use of cryogenic chambers with all staff at a minimum of two (2) times within a twelve (12) month period. Records of trainings must be kept up to date and available for review at all times.

F. Permit, Application, and Fees:

1. To operate a cryogenic chamber therapy establishment in the Town of Dedham, an owner or operator must possess a current and valid permit to operate a cryogenic chamber therapy establishment issued by the Department.
2. The Board shall grant the permit if the applicant submits an application furnished by the Department, including maintenance records and procedures, copies of warning signs, cleaning/sanitizing procedures and logs, training records, Basic Life Support CPR and defibrillator class-based training records, and anything else deemed necessary by the Board, and, in the opinion the Board, the proposed establishment will be operated in a manner that will protect the health, safety, and welfare of customers, and is consistent with these regulations.
3. All permits expire on the thirty-first (31st) day of December each year.
4. Permit holders intending to renew a current permit shall submit the appropriate renewal application(s) provided by the Department along with the applicable fee, as determined by the Board of Health, before the thirty-first (31st) day of December.
5. New applications shall be accepted throughout the year. The Department shall make reasonable efforts to act on completed applications within thirty (30) days of receipt.
6. No permit is transferable in any way.
7. A completed application to operate a cryogenic chamber therapy establishment must be submitted to the Department annually, no later than November 15th, and a permit must be issued by the Department for annual renewal. Maintenance records and procedures, copies of warning signs, cleaning/sanitizing procedures and logs, training records, Basic Life Support CPR and defibrillator class-based training records, and anything else deemed necessary by the Board, must be submitted and updated as necessary with the annual permit application.



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8. Prior to initial approval to operate a cryogenic chamber therapy establishment, a completed application, including floor plans, cryogenic chamber equipment specification sheets (chamber machinery, oxygen monitors, and defibrillators), employee training plan and certifications, valid Basic Life Support CPR and defibrillator class-based training records, maintenance and sanitation plans, and anything else deemed necessary, must be submitted for review by the Department.

9. The applicant shall answer every question truthfully and completely and supply all information requested in the application. The applicant shall submit the completed application to the Department. False statements shall constitute grounds for denial.

10. The applicant shall submit a non-refundable application fee with their application. An application is not considered complete unless accompanied by the applicable fee.

11. Permit to operate a cryogenic chamber therapy establishment fees are as follows:

- a. Review of new or upgraded establishment: \$100.00
- b. Annual permit application: \$350.00
- c. Per cryogenic chamber: \$50.00

G. Enforcement and Inspections:

1. The Board of Health and its designated agents shall enforce the provisions of this regulation. Any agent of the Board of Health may, according to law, enter upon premises at any reasonable time to inspect for compliance.

2. Upon request by an agent of the Board of Health, an owner or operator shall furnish all information required to enforce and monitor compliance with this regulation.

3. The Board of Health may, after providing opportunity for a hearing, order the revocation of a Permit to Operate a Cryogenic Chamber Therapy Establishment of one or more particular operations for:

- a. Serious or repeated violations of this regulation.
- b. Interference with the Board of Health or its designated agent in the performance of its duty.
- c. For keeping or submitting any misleading or false records or documents required by the regulations.

H. Variance:

1. The Board of Health may vary the application of any provision of this regulation with respect to any particular case, when, in the Board's opinion, the enforcement thereof would do manifest injustice; provided that the decision shall not conflict with the intent and spirit of this regulation.



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2. A request for a variance shall be submitted in writing. The Board of Health may ask for supporting evidence in order to consider the variance request. The request shall not be deemed complete until all such requested evidence has been received by the Department.

3. Any variance granted under this section may be subject to qualification, revocation, suspension, or expiration. A variance granted may be revoked, modified, or suspended in whole or in part, only after the holder thereof has been notified in writing and has been given an opportunity to be heard in accordance with this regulation.

4. Any variance granted by the Board of Health shall be in writing. A copy of any such variance, while it is in effect, shall be available to the public at all reasonable hours at the Department. A copy of the variance shall also be on file in the usual place of practice of the applicant.

I. Effective Date:

This regulation shall take effect on August 20, 2021.

Town of Dedham Board of Health

Leanne Jasset, Chair

Mary Ellard, Vice Chair

Noreen Guilfoyle, Member