

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978
Part 83
PHARMACEUTICAL-GRADE CANNABIS LICENSED FACILITY OPERATIONS

333.8301 Physical location.

Sec. 8301.

A pharmaceutical-grade cannabis licensed facility shall establish legal control of its physical location. The physical location shall meet all applicable state and local zoning laws.

History: Add. 2013, Act 268, Imd. Eff. Dec. 30, 2013

Popular Name: Act 368

333.8303 Records; notification; prohibited acts; destruction of marihuana determined not pharmaceutical-grade cannabis; standards; manner of irradiation.

Sec. 8303.

(1) A pharmaceutical-grade cannabis licensed facility shall maintain on the premises a record of the name, address, and date of birth of each officer, director, partner, member, manager, or employee of that licensed facility. The licensed facility shall obtain the individual's identification and have a criminal history check conducted to determine if that individual is qualified to work at or be associated with the licensed facility under this article.

(2) A pharmaceutical-grade cannabis licensed facility shall notify the department in writing within 10 days after an officer, director, partner, member, manager, or employee ceases to work at or otherwise be associated with the licensed facility.

(3) A pharmaceutical-grade cannabis licensed facility shall not acquire, possess, cultivate, deliver, transfer, transport, supply, sell, or dispense pharmaceutical-grade cannabis for any purpose except as provided in this article.

(4) A pharmaceutical-grade cannabis licensed facility shall not possess more than the amount of pharmaceutical-grade cannabis plants or dried pharmaceutical-grade cannabis allowed in its inventory as prescribed in rules promulgated under this article.

(5) A pharmaceutical-grade cannabis licensed facility shall destroy all marihuana that it cultivates or that is otherwise in its possession that is determined not to be pharmaceutical-grade cannabis. A licensed facility shall keep records of its activities under this subsection in order to verify its compliance to the department.

(6) Pharmaceutical-grade cannabis shall meet the following standards:

Microbiological

Microbiological Analysis FPL Specifications

Total coliforms	<3 MPN/g
Std. plate count aerobic	<100 CFU/g
Std. plate count anaerobic	<100 CFU/g
Escherichia coli	Absent
Salmonella	Absent
Staphylococcus aureus	<100 CFU/g
Yeast and molds	<100 CFU/g

Mycotoxins

Test	Specification
Aflatoxin B1	<20 $\hat{\mu}$ g/kg of substance
Aflatoxin B2	<20 $\hat{\mu}$ g/kg of substance
Aflatoxin O1	<20 $\hat{\mu}$ g/kg of substance
Aflatoxin O2	<20 $\hat{\mu}$ g/kg of substance
Ochratoxin A	<20 $\hat{\mu}$ g/kg of substance

Heavy Metals

Metal	NHP Acceptable Limits
	Âµg/kg bw/day
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

(7) A licensed facility shall irradiate all pharmaceutical-grade cannabis in the manner determined by the department before delivering that pharmaceutical-grade cannabis to another person.

History: Add. 2013, Act 268, Imd. Eff. Dec. 30, 2013
Popular Name: Act 368

333.8305 Facility as profit or nonprofit entity.

Sec. 8305.

A pharmaceutical-grade cannabis licensed facility may be a profit or nonprofit entity.

History: Add. 2013, Act 268, Imd. Eff. Dec. 30, 2013
Popular Name: Act 368

333.8307 Operation.

Sec. 8307.

A pharmaceutical-grade cannabis licensed facility may operate on any calendar days of the week, but shall do all of the following:

- (a) Prohibit smoking or consumption of marihuana on its premises.
- (b) Maintain all records required under this article on its premises.
- (c) Make the licensed premises available for inspection and search by the department, by law enforcement officers, and by any other state, federal, or local governmental agency authorized by law or department rule to inspect the premises of the licensed facility under this act, during regular business hours and when the licensed premises are occupied by the licensee or a clerk, servant, agent, or employee of the licensee. Evidence of a violation of this act or rules promulgated under this act discovered under this subsection may be seized and used in an administrative or court proceeding.

History: Add. 2013, Act 268, Imd. Eff. Dec. 30, 2013
Popular Name: Act 368

333.8309 Liability.

Sec. 8309.

In addition to the provisions of section 2946 of the revised judicature act of 1961, 1961 PA 236, MCL 600.2946, in a product liability action against a pharmaceutical-grade cannabis licensed facility, pharmaceutical-grade cannabis is not defective or unreasonably dangerous, and the pharmaceutical-grade cannabis licensed facility is not liable, if the product sold was tested and determined to meet the standards for pharmaceutical-grade cannabis under this article.

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