641—154.28(124E) Inspection by department or independent consultant. A manufacturer is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

154.28(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The manufacturing facility;

c. Vehicles used for transport or delivery of medical cannabidiol or plant material;

d. Financial information and inventory documentation;

e. Physical and electronic security alarm systems; and

f. Other inspections as determined by the department.

154.28(2) *Local safety inspections.* A manufacturer may be subject to inspection of its manufacturing facility and grounds by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol manufacturing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.28(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

a. The department has reasonable grounds to believe that the manufacturer is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations; or

b. The department has reasonable grounds to believe that the manufacturer was the cause or source of contamination of medical cannabidiol.

154.28(4) *Compliance required.* A manufacturer shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer license as authorized by these rules.

d. At the department's request and in a timely manner, a manufacturer shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]