

3796:3-3-01**Processor enforcement.**

(A) The submission of an application that results in the issuance of a provisional license or certificate of operation for a processor irrevocably gives the department consent to conduct all inspections necessary to ensure compliance with the processor's application, state law, Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code. The department may conduct the inspection independently, or may work with other departments, state agencies, or local authorities, including the department of agriculture, the division of industrial compliance and the state fire marshal, to ensure compliance with the processor's application, state law, Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.

(B) An inspector conducting an inspection pursuant to this section rule shall be accompanied by a type 1 key employee during the inspection. The inspector may:

(1) Review and make copies of all records maintained in accordance with rule 3796:3-2-08 of the Administrative Code;

(2) Enter any room in the facility;

(3) Inspect facility vehicles;

(4) Review the policies and procedures of the processor, including methods of operating;

(5) Survey the premises and any off-site facilities;

(6) Inspect all equipment, instruments, tools, materials, machinery, or any other resource used to process medical marijuana and manufacture medical marijuana products;

(7) Request access to locked areas in the facility;

(8) Question licensed employees at the location; and

(9) Obtain samples for testing of any medical marijuana products processed at the facility, chemicals and ingredients used in processing medical marijuana, any labels or containers for medical marijuana, or any raw packaged medical marijuana.

(C) A pre-approval inspection of a processor that is required before the department issues a certificate of operation to a processor possessing a provisional license under rule 3796:3-1-06 shall occur at a mutually agreeable time. The department shall rely on the facility's application, Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code to facilitate the inspection and ensure compliance of the facility. Upon the completion of the

pre-approval inspection, the department may issue:

- (1) A certificate of operation in accordance with rule 3796:3-1-06 of the Administrative Code, at which point the facility will be permitted to begin operations; or
  - (2) A written statement listing the deficiencies identified during the inspection that must be remedied before a certificate of operation will be issued by the department.
    - (a) Upon receipt a statement of deficiencies, the processor shall develop a plan of correction for each deficiency and submit the plan in writing to the department for approval within ten business days after receipt of the statement of deficiencies, unless a written extension is issued by the department.
    - (b) The plan of correction must include specific requirements for corrective action that will be performed within thirty calendar days after the department's acceptance of the plan of correction, or the remaining time period under paragraph (B) of rule 3796:3-1-06 of the Administrative Code, whichever is greater.
    - (c) If the plan of correction submitted is not acceptable to the department or would prevent the facility from obtaining a certificate of operation in accordance with rule 3796:3-1-06 of the Administrative Code, the department may either direct the medical marijuana licensee to resubmit a plan of correction or the department may develop a directed plan of correction with which the processor must comply. Upon acceptance of the written plan of correction, the department and the processor will sign a mutually binding agreement defining the terms under which the processor will be issued a certificate of operation. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.
    - (d) The department shall re-inspect a processor upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall issue a certificate of operation. If the corrective measures do not meet the requirements of the written plan of correction, the department shall take action in accordance with rule 3796:5-6-01 of the Administrative Code.
- (D) The department may, at any time it determines an inspection is needed, with or without notice, conduct an inspection of a processor to ensure compliance with the facility's application, state law, Chapter 3796. of the Revised Code and the rules promulgated in accordance with paragraph (A) of this rule. An inspection of a

processor may include, without limitation, investigation of standards for safety from fire on behalf of the department by the local fire protection agency. If a local fire protection agency is not available, the state fire marshal may conduct the inspection after the medical marijuana processor pays the appropriate fee to the state fire marshal for such inspection.

(E) Following an inspection conducted pursuant to paragraph (D) of this rule, the department shall issue an inspection report that documents the following:

(1) The observations and findings of the inspection;

(2) The outcome of the inspection;

(3) Any suggestions for the processor to take into consideration; and

(4) If applicable, a written statement listing the deficiencies identified during the inspection.

(a) Upon receipt of a statement of deficiencies, the processor shall develop a plan of correction for each deficiency and submit the plan to the department for approval within ten business days after receipt of the statement of deficiencies, unless a written extension is issued by the department.

(b) The plan of correction must include specific requirements for corrective action that will be performed within thirty calendar days. If the plan of correction submitted is not acceptable to the department, the department may either direct the processor to resubmit a plan of correction or the department may develop a directed plan of correction with which the processor must comply. Upon acceptance of the written plan of correction, the department and the processor will sign a mutually binding agreement defining the terms agreed upon by the parties. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.

(c) The department shall re-inspect a processor upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall indicate such on the inspection report and conclude the inspection. If the corrective measures do not meet the requirements of the written plan of correction, the department shall take action in accordance with rule 3796:5-6-01 of the Administrative Code.

(F) If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, risk to public health, or the occurrence of a prohibited activities under rule 3796:5-6-02 of the Administrative Code, the

department may take immediate action authorized under rule 3796:5-6-01 of the Administrative Code.

(G) To prevent destruction of evidence, diversion or other threats to public safety, the department may order an administrative hold of medical marijuana or medical marijuana product or any books and records of any licensee. The department may assess the costs of an investigation, including travel and the time of any and all employees, to a licensee.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	R.C. 3796.03, 3796.14
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