



Indiana State Department of Agriculture

Governor Eric Holcomb

Lt. Governor Suzanne Crouch, Secretary of Agriculture and Rural Development

Bruce Kettler, Director

December 17, 2021

The Honorable Tom Vilsack  
Secretary of Agriculture  
U.S. Department of Agriculture  
1400 Independence Avenue SW  
Washington, DC 20250

RE: Docket Number: AMS-SC-19-0042 SC19-990-2 FR

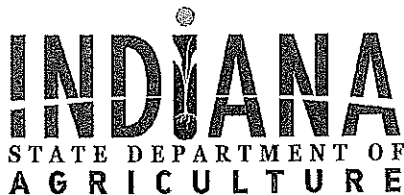
Secretary Vilsack,

We are pleased to present for the consideration of USDA the Indiana state hemp plan in response to publication of the U.S. Department of Agriculture's Interim Final Rule requirements for the *Establishment of a Domestic Hemp Production Program*, 7CFR 990, appearing in the Federal Register on January 19, 2021.

This document is offered in response to the USDA Final Rule requiring updates to our approved Indiana Hemp Plan approved in October 2020.

In response to the 2014 Farm Bill, the Indiana legislature enacted the Indiana Hemp Act cited in Indiana Code 15-15-13. Under this state code, a state research program was initiated and approved under DEA oversight. The research component was led by Purdue University and included researchers from seven other Indiana universities. The Office of Indiana State Chemist & Seed Commissioner (OISC) was designated as the lead agency for hemp regulations, not including hemp products (IC 15-15-13, see especially the duties of the state seed commissioner recorded in IC 15-15-13-12).

With adoption of the Agricultural Improvement Act of 2018 (2018 Farm Bill), the Indiana legislature modified IC 15-15-13 to bring Indiana law into conformance with the newly adopted hemp regulations represented in the 2018 Farm Bill. In addition, the Indiana legislature granted to the Office of Indiana State Chemist the authority/responsibility of drafting and adopting emergency rules. The attached emergency rules, OISC official methods, and OISC standard operating procedures represent a program that responsibly serves the hemp growers and citizens of Indiana in keeping with increased resources to meet the expected demands.



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The Office of Indiana State Chemist has added staff for inspections, increased laboratory capacity, and developed and secured a DEA Schedule 1 compliant laboratory and quality program. All OISC inspectors have been trained to standards. Frequent and meaningful communication takes place regularly with hemp growers, hemp industry advocates, hemp researchers, and law enforcement officers throughout Indiana to maintain program consistency and continuity.

Below is a synopsis of our Indiana State Hemp Plan compliance with the 2018 Farm Bill and the USDA Final Rule (7 CFR 990) published in the Federal Register March 22, 2021.

- A practice to collect, maintain, and report to the Secretary relevant, real-time information for each producer licensed or authorized to produce hemp under the state program regarding:
  - Contact Information as described in 990.70
  - Legal description of the land on which the producer will produce hemp in the state, its geospatial location and
  - The status and number of the producer's license or authorization
  - COMMENT: These data points, as listed above, are criteria met as required information in our new hemp licensing and crop management software that is currently in place.
- A procedure for accurate and effective performance-based sampling to include:
  - COMMENT: Indiana has trained samplers, trained to and above the USDA training requirements. Receivers of a crop are self-monitoring for compliance of materials to avoid taking in marijuana and being possibly charged under marijuana laws.
- A procedure for crop remediation to include:
  - ~~COMMENT: Software communication and email communication to the licensed grower to inform them of their opportunity to remediate the crop and be retested or to dispose of the crop. The remediation has two options as lined out in the Final Rule. Remediate by grinding the entire plant or remediate by removing flower material (disposing of such) and grinding the remaining plant material for secondary sampling and testing. This remediation is an option for those growers who have crop lots testing between the acceptable level of THC and up to and including 1% total THC + Measurement of Uncertainty.~~
  - Software communication and email communication to the licensed grower to Inform them of their opportunity to remediate the crop and be retested or to dispose of the crop. The remediation has two options as lined out in the Final Rule. Remediate by grinding the entire lot into a biomass or remediate by removing flower material (disposing of such) and utilizing the remaining plant material. Both remediation options must be retested for compliance. Remediation is an option for those growers who have crop lots testing above the acceptable hemp THC level.



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- A procedure and guidance for required harvest of compliant crop within 30 days of sampling.
  - COMMENT: Indiana now, through communication directly with licensed growers via our licensing and crop management software, via direct email and via group emails sent in advance of the sampling season has three methods of communication to compliant growers of their need to harvest within 30 days of sampling date. Random spot checks will also happen from our trained samplers and police agencies, led by the Indiana State Police.
- The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.
  - COMMENT: The method OISC Field Sampling MTD 0501-IS Current Version uses an increasing number of samples 5"-8" of the top of the flower material of the plant. Each variety is not to be combined and the randomly drawn samples are consolidated, kept in a chain of custody, and treated through drying as one entity.
- During the scheduled sampling collection, an authorized representative of the producer shall be present at the growing site.
  - COMMENT: The adoption of this practice has been adopted as part of the sampling protocol in the OISC Field Sampling of Hemp MTD 0501-IS Current Version

The plan must include a procedure for testing that is able to accurately identify whether the sample contains a delta-9 THC content that exceeds the acceptable hemp level based on an analysis that measures total THC on a dry weight basis.

- Any test of a representative sample that results in a valuation higher than the acceptable THC level with Measurement of Uncertainty is conclusive evidence the lot is not in compliance. After December 31, 2022 a lot that is tested in a non DEA registered laboratory shall not be further handled, processed or enter the stream of commerce and the producer shall ensure that the lot is disposed of in accordance with 7.CFR.990.27 and state regulations.
  - COMMENT: The crop, or lot to be found in violation, may be burned on site, and documented by the owner in digital video. Or, the crop may be rendered unretrievable by tillage other means that OISC and the Indiana State Police approve of.
  - COMMENT: Software communication and email communication to the licensed grower to inform them of their opportunity to remediate the crop and be retested or to dispose of the crop. The remediation has two options as lined out in the Final Rule. Remediate by grinding the entire plant or remediate by removing flower material (disposing of such) and grinding the remaining plant material for secondary sampling and testing. This remediation is an option for those growers who have crop lots testing between the acceptable level of THC and up to and including 1% total THC + Measurement of Uncertainty.



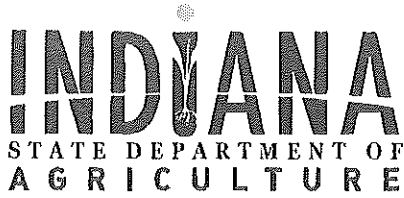
Indiana State Department of Agriculture

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- Samples of hemp from a lot shall not be comingled with samples from another lot.
  - COMMENT: This sampling standard is addressed in OISC Field Sampling of Hemp MTD 0501-IS Current Version, and in Storage, Handling, Accountability and Disposal of Hemp at the Office of Indiana State Chemist, SOP 0282-FD Current Version.
- The analytical method selected shall meet the standards of the federal rule.
  - COMMENT: This analytical methodology is addressed in OISC adopted Analysis of delta-9-tetrahydrocannabinol in hemp by gas chromatography, MTD 0500-FD Current Version; and Analysis of delta-9-tetrahydrocannabinol in hemp by liquid chromatography, MTD 0502-FD Current Version.
- A plan must consent to promptly notify the Administrator by certified mail or electronically of any occurrence of hemp that do not meet the definition, and attach records demonstrating the appropriate disposal of all of those plants, and materials in the lot from which the samples were taken.
  - COMMENT: Indiana has a protocol for burning the crop in the field that works for purposes of disposing an inadequate or non-compliant crop.
- A state plan must comply with 7 CFR 990 Violations
  - COMMENT: IC 15-15-13-13.5 and 360 IAC 2 Emergency Rules speak to negligent violations. 360 IAC 3 (DRAFT PENDING 2022) will speak to civil penalties and negligent acts.
- A state plan must include conducting of annual inspections of, at a minimum, a random sample of producers to demonstrate compliance under 7 CFR 990 and Indiana Laws.
  - COMMENT: Annual inspections including checks on compliance for records and procedural audits will be randomly conducted by OISC field staff. OISC Field Sampling of Hemp MTD - 0501-IS Current Version.
- A state plan must include procedures for submitting the information required by USDA under 7 CFR 990 to the USDA Secretary of Agriculture within 30 days after the date on which the information is received. All data must be transmitted to USDA in a format that can be received by USDA.
  - COMMENT: This requirement is met with our software that is currently in place. SOP 0309-HP Rev. 00 Hemp Administrative Procedures.
- A state plan must include a certification that the state has the resources and personnel to carry out the practices and procedures described in 7 CFR 990.
  - COMMENT: The state of Indiana and OISC has the resources to carry out a state hemp plan as outlined in the supporting state commentary above.



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Recommended for forwarding as a representation and overview of the edited Indiana state hemp program plan.

A handwritten signature in black ink, appearing to read "Mark LeBlanc".

Dr. Mark LeBlanc

State Chemist and Seed Commissioner

Office of Indiana State Chemist and Seed Commissioner

175 S University Street

West Lafayette, IN 47907

A handwritten signature in black ink, appearing to read "Bruce R. Kettler".

Bruce Kettler, Director

Indiana State Department of Agriculture

**IC 15-15-13                      Chapter 13. Industrial Hemp**

15-15-13-0.5	Administration of chapter
15-15-13-1	Application of chapter
15-15-13-2	"Agricultural hemp seed"
15-15-13-3	"Crop"
15-15-13-4	"Grower"
15-15-13-5	"Handler"
15-15-13-6	"Hemp"
15-15-13-6.5	"Hemp product"
15-15-13-7	Hemp regulations; rules; licenses; license applications
15-15-13-8	Processing applications; criminal history; issuance of license; renewal
15-15-13-9	Hemp seed; seed distributor permit; records; audit; inspections; license revocation; detention of crops; cost of testing
15-15-13-9.5	Handler license to distribute plant clones
15-15-13-10	Fees
15-15-13-11	Transporting hemp
15-15-13-12	State seed commissioner duties
15-15-13-13	Penalties; revocation
15-15-13-13.5	Negligent violations; corrective actions
15-15-13-14	Rules
15-15-13-15	Plan submission
15-15-13-16	Fees collected; expenditures; financial report; excess funds
15-15-13-17	Information to be kept by the seed commissioner
15-15-13-18	Receipts
15-15-13-19	Sale of hemp buds and flowers
15-15-13-20	Violations; penalties
15-15-13-21	Ordinances

**IC 15-15-13-0.5              Administration of chapter**

Sec. 0.5. The state seed commissioner shall administer this chapter.

*As added by P.L.165-2014, SEC.1.*

**IC 15-15-13-1                      Application of chapter**

Sec. 1. (a) Nothing in this chapter authorizes any person to violate any federal law or regulation.

(b) Nothing in this chapter authorizes the state seed commissioner to regulate a hemp product.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.2.*

**IC 15-15-13-2                      "Agricultural hemp seed"**

Sec. 2. As used in this chapter, "agricultural hemp seed" means Cannabis sativa seed that meets any labeling, quality, and other standards set by the state seed commissioner and that is intended for sale or is sold to, or purchased by, licensed growers for planting.

*As added by P.L.165-2014, SEC.1.*

**IC 15-15-13-3                      "Crop"**

Sec. 3. As used in this chapter, "crop" means any hemp grown under a single license.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.3.*

**IC 15-15-13-4                      "Grower"**

Sec. 4. As used in this chapter, "grower" means:

- (1) an individual, a partnership, a company, or a corporation that produces hemp for commercial purposes; or
- (2) a person, as part of a hemp research program conducted by a state educational institution (as defined by IC 21-7-13-32).

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.4.*

**IC 15-15-13-5 "Handler"**

Sec. 5. As used in this chapter, "handler" means an individual, a partnership, a company, or a corporation that receives hemp for scientific research, or for processing into commodities, hemp products, or agricultural hemp seed.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.5.*

**IC 15-15-13-6 "Hemp"**

Sec. 6. As used in this chapter, "hemp" means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis, for any part of the *Cannabis sativa* L. plant.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.6.*

**IC 15-15-13-6.5 "Hemp product"**

Sec. 6.5. As used in this chapter, "hemp product" means a product derived from, or made by, processing hemp plants or plant parts including derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers. However, the term does not include:

- (1) smokable hemp (as defined by IC 35-48-1-26.6); or
- (2) products that contain a total delta-9-tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3%) by weight.

*As added by P.L.190-2019, SEC.7.*

**IC 15-15-13-7 Hemp regulations; rules; licenses; license applications**

Sec. 7. (a) Subject to section 15 of this chapter, the production of, possession of, scientific study of, and commerce in hemp is authorized in Indiana. Hemp is subject to regulation by the state seed commissioner. The state seed commissioner shall adopt rules to oversee the licensing, production, and management of:

- (1) hemp; and
- (2) agricultural hemp seed.

(b) All growers and handlers must have a hemp license issued by the state seed commissioner. Growers and handlers engaged in the production of agricultural hemp seed must also have an agricultural hemp seed production license.

(c) An application for a hemp license or agricultural hemp seed production license must include the following:

- (1) The name and address of the applicant.
- (2) The name and address of the hemp operation of the applicant.
- (3) The global positioning system coordinates and legal description of the property used for the hemp operation.
- (4) If the hemp license or agricultural hemp seed production license application is made by a grower, the acreage size of the field where the hemp will be grown.
- (5) A statement signed by the applicant, under penalty of perjury, that the person applying for the hemp license or agricultural hemp seed production license has not been convicted of a drug related felony or misdemeanor in the previous ten (10) years.
- (6) A written consent allowing the state police department to conduct a state or national criminal history background check.
- (7) A written consent allowing the state police department, the state seed commissioner, or the state seed commissioner's authorized representative, if a license is issued to the applicant, to conduct aerial inspections and to enter the premises on which the hemp is grown to conduct physical inspections of hemp planted and grown by the applicant, and to ensure the plants meet the definition of hemp as set forth in section 6 of this

chapter.

(8) A nonrefundable application fee, which must include the amount necessary to conduct a state or national criminal history background check, in an amount determined by the state seed commissioner.

(9) Any other information required by the state seed commissioner.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.8.*

**IC 15-15-13-8          Processing applications; criminal history; issuance of license; renewal**

Sec. 8. (a) Each license application received under this chapter must be processed as follows:

(1) Upon receipt of a license application, the state seed commissioner shall do one (1) of the following:

(A) Forward a copy of the application to the state police department. The state police department shall do the following:

(i) Perform a state or national criminal history background check of the applicant.

(ii) Determine if the requirements under section 7(c)(5) of this chapter concerning prior criminal convictions have been met.

(iii) Return the application to the state seed commissioner along with the state police department's determinations and a copy of the state or national criminal history background check.

(B) The state seed commissioner shall do the following:

(i) Perform a state or national criminal history background check of the applicant under the same standards as the state police department would perform.

(ii) Determine if the requirements under section 7(c)(5) of this chapter concerning prior criminal convictions have been met.

(2) The state seed commissioner shall review the license application and the criminal history background check.

(b) If the state seed commissioner determines that all the requirements under this chapter have been met and that a license should be granted to the applicant, the state seed commissioner shall approve the application for issuance of a license.

(c) A hemp license or agricultural hemp seed production license expires on December 31 of the year for which the license was issued, unless revoked. A hemp license or agricultural hemp seed production license may be renewed in accordance with rules adopted by the state seed commissioner and is nontransferable.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.9.*

**IC 15-15-13-9          Hemp seed; seed distributor permit; records; audit; inspections; license revocation; detention of crops; cost of testing**

Sec. 9. (a) An agricultural hemp seed production license issued under this chapter authorizes a grower or handler to produce and handle agricultural hemp seed for sale to licensed hemp growers and handlers. A seller of agricultural hemp seed shall ensure that the seed complies with any standards set by the state seed commissioner. The state seed commissioner shall make available to growers information that identifies sellers of agricultural hemp seed.

(b) A person who sells agricultural hemp seed to a grower must be a seed distributor who has a permit under IC 15-15-1-34.

(c) All growers and handlers must keep records in accordance with rules adopted by the state seed commissioner. Upon at least three (3) days notice, the state seed commissioner may audit the required records during normal business hours. The state seed commissioner may conduct an audit for the purpose of ensuring compliance with:

(1) this chapter;



- (2) rules adopted by the state seed commissioner; or
- (3) hemp license or agricultural hemp seed production license requirements, terms, and conditions.

(d) In addition to an audit conducted in accordance with subsection (c), the state seed commissioner may inspect independently, or in cooperation with the state police department, a federal law enforcement agency, or a local law enforcement agency, any hemp crop during the crop's growth phase and take a representative composite sample for field analysis. If a crop contains an average delta-9-tetrahydrocannabinol (THC) concentration exceeding three-tenths of one percent (0.3%) on a dry weight basis, the state seed commissioner may detain, seize, or embargo the crop.

(e) The state seed commissioner may revoke a license issued under this chapter to a person that fails to cooperate with:

- (1) the state seed commissioner;
- (2) the state police;
- (3) a federal law enforcement agency; or
- (4) a local law enforcement agency;

in an inspection, or in the taking of a sample, under subsection (d).

(f) A failure to cooperate described in subsection (e) constitutes probable cause for the state seed commissioner, state police, federal law enforcement agency, or local law enforcement agency to search the premises of the licensee's hemp operation.

(g) If the state police department, a federal law enforcement agency, or a local law enforcement agency cooperates with the state seed commissioner in the detention, seizure, or embargo of a crop under this section:

- (1) the state police department, federal law enforcement agency, or local law enforcement agency; and
- (2) any officer or employee of the state police department, federal law enforcement agency, or local law enforcement agency who is involved in the detention, seizure, or embargo;

is immune from civil liability for the detention, seizure, or embargo.

(h) The state seed commissioner may order a hemp crop that is detained, seized, or embargoed for noncompliance with this chapter to be destroyed by the owner. However, except as prohibited by federal law, the grower may appeal to the state seed commissioner for the hemp crop to be diverted to a willing licensed processor for processing and sale for industrial use. A hemp crop that is detained, seized, or embargoed may not be used for cannabidiol, other extracts, oil, food, or cosmetic products that are used for humans or animals.

(i) A grower shall reimburse the state seed commissioner for the cost of testing conducted on the grower's crop under this section.

*As added by P.L.165-2014, SEC.1. Amended by P.L.139-2016, SEC.1; P.L.190-2019, SEC.10.*

#### **IC 15-15-13-9.5      Handler license to distribute plant clones**

Sec. 9.5. (a) A person who is a handler licensed under this section may distribute clones and other nonseed propagative materials of a hemp plant using the person's own labeling, if the distributor does the following:

- (1) Complies with the requirements of this chapter.
- (2) Reports the variety and quantity of each variety of the propagative material of plant sold.
- (3) Pays the inspection fee on the basis of the report.
- (4) Labels the propagative material with the information required by the state seed commissioner.
- (5) Keeps records to accurately determine the named varieties and the number of plants of each variety distributed.

(6) Grants the state seed commissioner or the state seed commissioner's authorized representative access to examine the handler's records and verify the quantity and each variety of propagative material distributed.

(7) Report, under oath, to the state seed commissioner on forms furnished by the state seed commissioner each variety and quantity of propagative material sold during each semiannual period.

(8) Any other information or conditions stated in the application.

(b) The state seed commissioner may revoke a handler's license if the commissioner determines any of the following:

(1) That the licensee has not complied with the requirements under this chapter.

(2) The report required in subsection (a) has not been submitted and is more than ten (10) days late.

(3) The report required in subsection (a) contained false information.

(4) The labeling requirements under this chapter have not been met.

(c) If the inspection fee has not been paid and is more than ten (10) days late, the state seed commissioner shall assess a late fee.

(d) Each year the:

(1) report required under subsection (a)(7); and

(2) inspection fees required under this chapter;

for the period beginning on January 1 and ending on June 30 and for the period beginning on July 1 and ending on December 31 are due not more than thirty (30) days after the end of the semiannual period.

*As added by P.L.190-2019, SEC.11.*

#### **IC 15-15-13-10 Fees**

Sec. 10. The amount of any fees charged growers and handlers by the state seed commissioner under this chapter must be sufficient to cover the cost of the administration of this chapter, including the cost of conducting audits and testing.

*As added by P.L.165-2014, SEC.1.*

#### **IC 15-15-13-11 Transporting hemp**

Sec. 11. Only a hemp licensee, the licensee's designee, or the licensee's agents may be permitted to transport hemp off a production site. When transporting hemp off the production site, the hemp licensee, designee, or agent shall have in the licensee's, designee's, or agent's possession the licensing documents from the state seed commissioner evidencing that the hemp is from certified seed produced by a licensed grower.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.12.*

#### **IC 15-15-13-12 State seed commissioner duties**

Sec. 12. The state seed commissioner is responsible for the following:

(1) Monitoring the hemp grown by any license holder.

(2) Conducting random testing of the hemp for compliance with tetrahydrocannabinol (THC) levels. The state seed commissioner may enter into agreements with one (1) or more laboratories selected by the Indiana state police department to perform testing under this subdivision.

(3) Establishing necessary testing criteria and protocols, including a procedure for testing, using post decarboxylation or other similarly reliable methods, delta-9-tetrahydrocannabinol concentration levels of the hemp produced.

(4) Establishing the minimum number of acres to be planted under each license issued under this chapter.

(5) Regulating any propagative material of a hemp plant.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.13.*

**IC 15-15-13-13 Penalties; revocation**

Sec. 13. (a) Subject to section 13.5 of this chapter, in addition to any other liability or penalty provided by law, the state seed commissioner may revoke or refuse to issue or renew a hemp license or an agricultural hemp seed production license and may impose a civil penalty for a violation of:

- (1) a license requirement;
- (2) license terms or conditions;
- (3) a rule relating to growing or handling hemp; or
- (4) section 19 of this chapter.

(b) The state seed commissioner may not impose a civil penalty under this section that exceeds two thousand five hundred dollars (\$2,500).

(c) The state seed commissioner may revoke or refuse to issue or renew a hemp license or an agricultural hemp seed production license for a violation of any rule of the state seed commissioner that pertains to agricultural operations or activities other than hemp growing or handling.

(d) Any civil penalties collected under this section shall be transferred to the Indiana state department of agriculture and used for hemp marketing and research purposes.

(e) In addition to payment of any civil penalty imposed under this section, a person who commits a violation described in subsection (a) shall reimburse the state seed commissioner for any costs incurred by the state seed commissioner for laboratory testing of material pertaining to the violation.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.14.*

**IC 15-15-13-13.5 Negligent violations; corrective actions**

Sec. 13.5. (a) Except as provided in subsection (b), the state seed commissioner shall give a person who negligently violates this chapter a reasonable time, determined by the state seed commissioner, to correct the violation without imposing a penalty under section 13 of this chapter. However, the state seed commissioner may require the person who committed the violation to comply with a corrective action plan determined by the state seed commissioner and report to the state seed commissioner on compliance with the corrective action plan.

(b) A person who commits a negligent violation of this chapter three (3) times in a five (5) year period shall immediately be ineligible to produce hemp for five (5) years.

(c) If the state seed commissioner believes that a person has knowingly or intentionally violated this chapter, the state seed commissioner shall notify:

- (1) the superintendent of the state police department; and
- (2) the prosecuting attorney of the county in which the violation occurred;

of the violation.

(d) A person who commits a negligent violation under this chapter is subject to a late fee as established by rule adopted by the seed commission.

*As added by P.L.190-2019, SEC.15.*

**IC 15-15-13-14 Rules**

Sec. 14. (a) The state seed commissioner shall adopt rules under IC 4-22-2 to implement and administer this chapter.

(b) The state seed commissioner may adopt emergency rules in the manner provided under IC 4-22-2-37.1 to comply with any federal requirement under the Agriculture Improvement Act of 2018 to implement and administer this chapter.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.16.*

**IC 15-15-13-15 Plan submission**

Sec. 15. Before December 31, 2019, the state seed commissioner, after consultation with the governor, the director of the state department of agriculture, and the superintendent of the state police department, shall submit a plan that monitors and regulates the production of

hemp to the United States Department of Agriculture. If the United States Department of Agriculture disapproves the plan, the state seed commissioner shall submit an amended plan to the United States Department of Agriculture.

*As added by P.L.165-2014, SEC.1. Amended by P.L.190-2019, SEC.17.*

**IC 15-15-13-16 Fees collected; expenditures; financial report; excess funds**

Sec. 16. (a) The state seed commissioner shall pay all fees collected under this chapter to the treasurer of Purdue University.

(b) The board of trustees of Purdue University shall expend the fees on proper vouchers filed with the treasurer of Purdue University. The treasurer shall pay vouchers for the following expenses:

- (1) The employment of inspectors and seed analysts.
- (2) Procuring samples.
- (3) Printing bulletins giving the results of inspection.
- (4) Any other expenses of the Purdue University agricultural programs authorized by law and for implementing this chapter.

(c) The dean of agriculture of Purdue University shall make and submit a financial report to the governor in such form as the state board of accounts requires, showing the total receipts and expenditures of all fees received under this chapter.

(d) Excess funds from the collection of fees under this chapter are subject to IC 15-16-2-36.

*As added by P.L.165-2014, SEC.1.*

**IC 15-15-13-17 Information to be kept by the seed commissioner**

Sec. 17. (a) The seed commissioner may keep the:

- (1) names of growers and handlers who are licensed under this chapter; and
- (2) locations of licensed hemp crops;

confidential for purposes of IC 5-14-3.

(b) The seed commissioner may share confidential information under subsection (a) with the state police department, law enforcement officers (as defined in IC 35-31.5-2-185), and federal enforcement officers (as defined in IC 35-31.5-2-129).

*As added by P.L.134-2015, SEC.1. Amended by P.L.190-2019, SEC.18.*

**IC 15-15-13-18 Receipts**

Sec. 18. (a) A person who sells hemp in Indiana must:

- (1) be licensed in Indiana and in the jurisdiction where the hemp was grown; and
- (2) provide the buyer with a receipt that contains the seller's name, place of business, and license number and quantity of hemp sold.

(b) A person who buys hemp in Indiana must retain the receipt described in subsection (a)(2) for a period of two (2) years.

*As added by P.L.190-2019, SEC.19.*

**IC 15-15-13-19 Sale of hemp buds and flowers**

Sec. 19. (a) Hemp bud (as defined in IC 35-48-1-17.2) and hemp flower (as defined in IC 35-48-1-17.3) may be sold only to a processor licensed under this chapter.

(b) The state seed commissioner may impose a civil penalty under section 13 of this chapter for a violation of subsection (a).

*As added by P.L.190-2019, SEC.20.*

**IC 15-15-13-20 Violations; penalties**

Sec. 20. (a) A person who knowingly or intentionally violates:

- (1) a term, condition, or requirement of a license issued; or
- (2) a rule adopted;

under this chapter is subject to a civil penalty, determined by the state seed commissioner, not to exceed ten thousand dollars (\$10,000) per violation. The state seed commissioner may also revoke the license of a person who violates this subsection.

(b) A person who knowingly or intentionally:

- (1) grows hemp;
- (2) handles hemp; or
- (3) sells agricultural hemp seed;

not including smokable hemp (as defined by IC 35-48-1-26.6), and is not licensed under this chapter, commits a Class A misdemeanor.

*As added by P.L.190-2019, SEC.21.*

#### **IC 15-15-13-21      Ordinances**

Sec. 21. A county, city, town, or township may not adopt or enforce an ordinance restricting or regulating:

- (1) the growth, production, or processing of hemp; or
- (2) any subject regulated by this chapter.

*As added by P.L.190-2019, SEC.22.*

## TITLE 360 STATE SEED COMMISSIONER

### **Emergency Rule** LSA Document #21-350(E)

#### DIGEST

Temporarily adds provisions to update and clarify the requirements for licensing, production, and management of hemp and agricultural hemp seed. Statutory authority: IC 15-15-13-14. Effective August 9, 2021.

**SECTION 1. The definitions in this rule apply throughout this article [document].**

**SECTION 2. "Acceptable hemp THC level" means the percent distribution or range of delta-9-tetrahydrocannabinol that includes 0.3% THC or less on a dry weight basis with the measurement of uncertainty when a laboratory tests a sample for total THC. The distribution or range reported must be the delta-9-tetrahydrocannabinol content on a dry weight basis with the measurement of uncertainty.**

**SECTION 3. "Agricultural hemp seed" means Cannabis sativa seed that is derived from parent plants documented through analysis and receipt of a certificate of analysis or equivalent document to be not greater than Acceptable hemp THC level at the time of harvest. Seed must be of a specified variety and documented seed source, for the production of seed for sowing.**

**SECTION 4. "Cannabis" is the Latin name of the plant that, depending on its THC concentration level, is further defined as either "hemp", "non-compliant hemp", or "marijuana". Cannabis is a genus of flowering plants in the family Cannabaceae, of which Cannabis sativa is a species, and Cannabis indica and Cannabis ruderalis are subspecies thereof.**

**SECTION 5. "Cooperator laboratory" has the meaning of any laboratory that receives hemp, for any purpose, including as:**

- (1) a diagnostic laboratory that receives hemp; or**
- (2) an analytical laboratory.**

**A cooperator laboratory may be determined by the Indiana state police to be a cooperator for state police purposes. A cooperator laboratory that is not a state police laboratory must be licensed by the state seed commissioner to receive and handle hemp.**

**SECTION 6. (a) "Crop" means any hemp grown under a single license issued by the state seed commissioner under authority of IC 15-15-13.**

**(b) A crop may be comprised of one (1) or more fields, or grow sites.**

**(c) A crop may be comprised of the same variety or differing varieties.**

**SECTION 7. (a) "Lot" means a specific and particular amount of hemp crop grown of one variety on one space of land or in one area of a greenhouse or indoor structure.**

**(b) to include other terms used by FSA with the same meaning. FSA uses terms like "farm", "tract", "field", and "subfield".**

**SECTION 8. "Crop disposal" means complete annihilation of a hemp crop by plowing under, mulching/composting, disking, bush mower/chopper, deep burial, or burning so that THC is nonretrievable and the residue is noningestible.**

**SECTION 9. (a) "Remediation" means to grind the plant for a post harvest sampling.**

**(b) Remediation must be completed as follows:**

- (1) Either disposing of flower materials and salvaging the remainder of the plant or blending the entire**

plant into biomass plant material; and

(2) Preparing the plant in a single lot, not blended with other lots.

(c) If the farmer elects to perform remediation activities under the State plan, an additional sampling and testing of the remediated crop must occur to determine THC concentration levels.

(d) Only crops testing below the acceptable hemp THC level limit will be considered successfully remediated and thus allowed to enter the stream of commerce.

SECTION 10. "Crop termination" means the intentional causing of a hemp crop to rapidly cease its growth through cutting down the crop (severing completely the stalks of the plant), or by application of an effective herbicide. A terminated crop that is not terminated with a pesticide may be used in certain situations when specifically approved by the state seed commissioner.

SECTION 11. "Distribute" for purposes of this article *[document]* means to sell, exchange, barter, broker, supply, or to offer to provide such services, or advertise to provide such services, for hemp.

SECTION 12. "Field average" means the results of an analysis of a consolidated sampling taken from multiple places within a planted variety from a field or other hemp production site. The field average may be as a part of the crop, or as the whole of the crop depending on how the licensed grower has partitioned the crop fields, and determined to be appropriate to the situation by the state seed commissioner. The sampling and the average apply individually to each variety sown or planted, when sown or planted as segregated varieties and not mixed varietal stands, of hemp as the crop. Varieties of hemp are not mixed with other varieties to obtain a field average.

SECTION 13. A grow site means any place or location where a hemp crop is legally grown whether outdoors or indoors.

SECTION 14. "Grower" means:

(1) A person who conducts any hemp growing activity.

(2) A grower include *[sic, includes]* a person who grows hemp as part of the Indiana hemp research program under authority of the state seed commissioner.

(3) A grower who conducts an activity subject to this article *[document]* must be licensed by the state seed commissioner.

(4) A grower of clones is subject to this article *[document]* and is held to the same standards and accountabilities numerated in IC 15-15-13-9.5.

SECTION 15. "Handler" means:

(1) A person that receives hemp for any purpose and who is not the grower of the hemp but is one who is providing a service or transacting to another person. A handler must be licensed under this article *[document]*.

(2) For purposes of this article *[document]*, the term includes a person that conducts an activity or provides a service regulated under this article *[document]* as, e.g., a person that receives, transports, brokers, processes, stores, or makes available for distribution hemp, offers for sale, distribution, gifting of hemp, hemp for scientific research, or for processing into commodities or products exempted from regulation by state or federal law, or agricultural hemp seed. The term also includes cooperator laboratories licensed under this article *[document]* as competent to perform analyses of hemp.

SECTION 16. "Hemp" means:

(1) The plant *Cannabis sativa* L., and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis, for any part of the *Cannabis sativa* plant L.

(2) The term includes hemp clones, agricultural hemp seed, hemp grains, and hemp propagative materials, such as cell cultures, cuttings, grafts, other asexual methods of propagation, and all derivative and extracts of hemp as defined in law.

- (3) The term includes hemp in any stage, and raw harvested hemp (whole, chopped, shredded, cut, retted, etc.) distributed to a handler licensed under this article *[document]*.
- (4) The term includes starts, clones, and microgreens for human consumption or that will not be brought to the flowering stage or physiological maturity.
- (5) The term does not mean a hemp product.

SECTION 17. (a) "Hemp product" means a product derived from, or made by, processing hemp plants or plant parts including derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers.

(b) A hemp product is market ready, meaning it is finished and labeled or packaged for distribution. No other emendation or process of the "final product" so termed is allowed.

(c) A hemp product does not mean hemp in the growing stages, while in the ground, or the raw harvested hemp, in any form, e.g., seed, grain, chopped, shredded, cut, retted, etc.; all handlings of harvested hemp, if not a grower of the crop, must be conducted as a licensed handler under this article *[document]* up to the final market ready status.

SECTION 18. (a) "Hemp production site" means a site where hemp may be processed, stored, staged, delivered, or received, or other similar activity regulated under this article *[document]*.

(b) A hemp production site must be reported in a written application for a hemp license issued by the seed commissioner including county and GPS coordinates in decimal format.

SECTION 19. (a) "Hemp propagative material" means any part of the plant *Cannabis sativa* L. that may be used for propagation of hemp plants; the term primarily refers to propagation by asexual means, e.g., clones, cuttings, rootings, graftings, cell cultures, and the like.

(b) The term "propagative material" includes seeds for sowing that are regulated in IC 15-15-13 and this article *[document]* as "agricultural hemp seed". Agricultural hemp seed may be used for sowing a crop for any purpose for which hemp may be legally grown.

(c) The term "propagative material" does not mean "hemp grain" that is a seed used for purposes of consumption by humans or animals, or a seed used for crushing or other processing in the production of oils, flour, or meal, or other consumable matrices.

SECTION 20. (a) "Hemp researcher" means an individual who:

- (1) is employed by an Indiana institution of higher education (as defined by IC 21-7-13-32) as determined by Indiana statute; and
- (2) is technically qualified to conduct the hemp research described; and
- (3) is authorized by the employing institution to do hemp research.

(b) The term includes qualified Purdue University cooperative extension educators, agricultural center managers, and others who may have certified crop advisor certifications, or persons who are employed by and authorized by Purdue University cooperative extension management to do so.

(c) A licensed researcher is anticipated to be engaged in research in which they are the principle *[sic, principal]* investigator in small scale, noncommercial activities regulated under this article *[document]*, the primary purpose of which is to gain or contribute knowledge.

**(d) A licensed researcher as defined in this rule may participate or conduct research in conjunction with a fully licensed commercial enterprise. When research is approved at a commercial enterprise, sampling and testing requirements will be the same as those for commercial growers. Hemp grown as commercial research with an acceptable hemp THC level may be sold and distributed. Lead researchers with direct oversight of hemp research projects are subject to the Criminal History Report requirement.**



**(f) Hemp produced for research may not enter commerce and must be reported to FSA unless first officially tested by the Office of Indiana State Chemist and Seed Commissioner and found to be compliant.**

**(g) Hemp produced for research must be disposed of according to disposal requirements in this rule.**

**(h) Hemp produced for research may be subject to random inspection by the department to ensure compliance.**

SECTION 21. "Licensee" for purposes of this article *[document]* means a person who is licensed by the state seed commissioner subject to this article *[document]* to conduct an activity subject to this article *[document]*, including:

- (1) a grower (including an "agricultural hemp seed producer"); or
- (2) a handler; or
- (3) a researcher; or

a combination of these.

SECTION 22. (a) A "licensee of record" means a person who is licensed by the state seed commissioner under this article *[document]* who holds a license under which one (1) or more persons licensed under this article *[document]* are contracted to fulfill the objectives of the license held by the licensee of record.

(b) The licensee of record must assemble any reports or data required as a reporting requirement of this article *[document]*, based on the reports gathered from those reporting to the licensee of record.

SECTION 23. "Measurement of uncertainty" means the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

SECTION 24. "Negligent violation" means:

- (1) failure to provide a legal description of land on which the producer produces hemp; or
- (2) failure to obtain a license; or
- (3) producing *Cannabis sativa* L. with a delta-9-tetrahydrocannabinol concentration exceeding the acceptable hemp THC level over 1.0% + measurement of uncertainty total THC.

SECTION 25. "Official sample" means a sample taken by a representative of the state seed commissioner who has been trained according to office of Indiana state chemist or USDA hemp sampling standards to take the sample and who is authorized to maintain chain of custody for a sample representing a crop upon which a legally required determination will be made by the state seed commissioner, or information that is requested by the state seed commissioner for regulatory purposes.

SECTION 26. "Person", as applicable, means an individual, not less than 18 years of age at the time of making application for a license, a partnership, a company, a corporation, a firm, an association, a cooperative, a body politic, a joint stock association, a trustee, a receiver, a fiduciary, an assignee, any representative for any of the entities named, any organized group of persons whether incorporated or not, or like entities, conducting or advertising to conduct an activity subject to this article *[document]* or IC 15-15-13.

SECTION 27. (a) The state chemist is the state seed commissioner.

(b) The term as referenced in this article *[document]* may include the state seed commissioner's representative to whom a responsibility under IC 15-15-13 has been assigned by the state seed commissioner.

SECTION 28. "Testing THC of hemp" means the analysis of hemp for determination of total THC (THC and THCa) using a post decarboxylation or other similarly reliable method and instrumentation that has been determined by the state seed commissioner to accurately and fairly represent the total THC (THC and THCa) in a sample, that allows the state seed commissioner to be confident that the sample is within the acceptable hemp total THC level. Total THC accounts for the conversion of THCa into THC.

SECTION 29. (a) "THC" means delta-9-tetrahydrocannabinol.

(b) "THCa" means delta-9-tetrahydrocannabinolic acid.

SECTION 30. "Variety" means a subdivision of a kind characterized by growth, yield, plant, fruit, seed, or other characteristics, by which a plant can be differentiated from other plants of the same kind.

SECTION 31. "Wild Cannabis" means a *Cannabis sativa* L. plant, including the seed thereof, that is growing, or that has been harvested, not as part of a licensed cultivation. Wild Cannabis is regulated under applicable Indiana marijuana laws, unless it has been collected for purposes of research by a researcher/plant breeder licensed by the seed commissioner subject to this article [document]. **Wild Cannabis lots obtained through legal processes by university researchers must still be reported to Farm Service Agency (FSA).**

SECTION 32. A person who grows, handles, researches, distributes, conducts laboratory analyses, conducts commerce in hemp, a person who brokers hemp, or otherwise possesses or receives hemp, or otherwise conducts, offers to provide, or advertises to conduct an activity regulated under this article [document] or IC 15-15-13 must be not less than eighteen (18) years of age when first making application to be licensed under this rule, and must be licensed by the state seed commissioner and is subject to the rules and statutes set forth in Indiana law.

SECTION 33. (a) The state seed commissioner issues the following hemp licenses:

(1) Hemp growers license that shall include any person that conducts the activities of a grower (farmer, propagator, and the like):

(A) Out of doors grow sites, agricultural fields, and the like.

(B) Indoor, roofed, or contained operations, e.g., greenhouse operations, shade houses (slatted, netted, or other), cold frames, polyhouses, quonset hut, warehouses, and the like, hemp production facilities (hydroponics, grow-light houses or rooms, etc.).

(C) Agricultural hemp seed production. A person in this license category engages in the sale of seed for sowing and use in growing a crop that is fiber, grain, or a crop for cannabinoid extraction. A licensed person is subject to the federal seed code and any and all applicable Indiana seed laws, in addition to any applicable requirements subject to seed certification requirements held by Indiana Crop Improvement Association.

(D) Hemp grain is a crop grown for seed as oil, meal, flour, whole grain for consumption, or other consumption by humans or animals, as allowed by law. Hemp grain is not licensed for sowing or for seed to produce a crop.

(2) Handlers license that shall include persons who receive hemp for any reason, other [sic, than] to conduct the activity of a grower, e.g., those who transport hemp in any quantity, process, bale, harvest, inspect hemp, broker, test hemp, provide laboratory support, who receive hemp for any purpose. A person who advertises or offers to perform such services or like services is a handler. A grower of hemp does not require a license as a handler to conduct activities of a grower.

(3) Researchers license (as defined in this article [document]) employed by institutions of higher education as defined in federal and state law.

(4) It is the responsibility of a licensed person to ensure that employees, volunteers, family member [sic, members], or others servicing a hemp production site, and subject to the management of the licensee, comply with the requirements of this article [document].

(b) A hemp license application to conduct any activity subject to this article [document], or an activity regulated under IC 15-15-13, must be filed with the state seed commissioner on an official application form provided by the state seed commissioner's office:

(1) Applicants for a license shall be not less than eighteen (18) years old when first making application.

(2) An applicant shall provide the state seed commissioner with the following information on hemp production sites, on an official form provided by the state seed commissioner:

(A) legal description of the land;

(B) GPS coordinates in decimal format; and

(C) the county.

These records must be retained by the applicant and by the state seed commissioner for at least three

(3) years.

(3) Applicants must provide a valid and accurate government issued identification, such as a state driver's license, a passport, or a government identification card, if the first two (2) forms of identification are not available.

(4) Not more than sixty (60) days prior to submitting an application for a hemp license, applicants must apply for a background check through the Federal Bureau of Investigation's Identity History Summary.

(5) All background checks must be paid by the applicant to the issuing agency.

(6) An applicant must successfully pass a background check that is required by the state seed commissioner, including review of 10 years from the date of application for freedom from any drug related felonies or drug related misdemeanors. A person with a state or federal felony relating to a controlled substance is subject to a 10-year ineligibility to participate in the Indiana State Hemp Program plan from the date of the conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction occurred before that date.

(7) Any licensee lawfully with a license under the Indiana pilot program authorized by section 7606 of the USDA Agricultural Act of 2014 (7 U.S.C. 5940) before October 31, 2019, shall be exempted from paragraph (b) (6) of this rule *[subdivision (6)]*.

(8) An applicant must pay a nonrefundable application fee made to the office of Indiana state seed commissioner at the time the application is made.

(c) Neither an applicant nor a licensee shall conduct an activity regulated under this article *[document]* on property owned by, leased from, or previously submitted in an application by any person who is ineligible or was terminated or denied a license by the state seed commissioner for one (1) or both of the following reasons:

(1) Failure to obtain an acceptable criminal background check.

(2) Failure to comply with an order from the state seed commissioner or the state seed commissioner's representative.

(d) An applicant and licensee shall use a variety of hemp that has demonstrated a high degree of compliance with federal and state laws not in exceedance of the acceptable hemp THC level, and manage both a monitoring and a harvest plan that presages elevation of THC beyond the acceptable hemp THC level including especially for those varieties that are used for CBD production.

(e) An applicant must declare the intended use of the crop for each variety named in an application for license and any subsequent added or replaced varieties to an application. Any change of variety or purpose must be reported to the state seed commissioner within ten (10) days of the date of receipt of the seed or clones.

(f) An applicant must attest and provide confirmation that the applicant has a written letter of intent or buyer/grower contract for the hemp crop that is to be grown. Documentation including all information required on the application form of the state seed commissioner, e.g., buyer, location, acreage or quantity contracted, purpose of grow (CBD, fiber, grain, oil, etc.), crop monitoring plan to avoid exceeding 0.3% total THC must be made available at the time of application.

(g) An applicant must declare and attest to a DEA registered laboratory to conduct analytical testing for total THC. This paragraph *[subsection]* is enforceable as of December 31, 2022.

(h) An applicant must present as part of the application a crop testing plan that includes regular monitoring by the grower or receiving handler of the crop during growth and a plan to take the crop down if it trends in exceedance of the acceptable hemp THC level.

(i) An applicant must declare growing site(s) by field, each storage site(s), receiving sites, staging site(s), and similar activities where hemp activities subject to this article *[document]* or IC 15-15-13 may take place. Each site must be labeled, i.e., given a unique name, and state the intended function of the site, e.g., grow site, processing site, greenhouse, etc.; and reported as a decimal GPS reference.

(j) Each applicant must agree to provide an annual harvest and disposal report to be on an official

form of the state seed commissioner. Failure to provide a report will result in denial of an applicant's request for a hemp license renewal.

(k) For the year 2020, a grower or handler license issued under the 2020 Indiana research program must include a research proposal of adequate verbiage to clearly explain the intent of the research and the anticipated outcome. The research proposal must also indicate the name and contact information of a cooperating Indiana licensed researcher.

(l) Growing of hemp varieties that, based on reports, are known to run in exceedance of the acceptable hemp THC level will not be routinely approved, except by review and explicit approval by the state seed commissioner.

(m) The license application must be approved in writing by the state seed commissioner prior to conducting any hemp activity or handling of hemp receipt, such as distribution, transport of hemp, or advertises to receive, distribute, or transport hemp, agricultural hemp seed, or hemp clones.

(n) A license shall expire December 31, in the year for which the license is issued, unless revoked for cause.

(o) A license number shall be as 18\_000x - when issued by the state seed commissioner.

(p) Licensees at the time of application for a license must agree to comply with an order issued by the state seed commissioner if the hemp crop is found to be in excess of the acceptable hemp THC level.

(q) The state seed commissioner will report and provide to the USDA Secretary of Agriculture relevant, real-time information for each producer licensed to produce hemp under Indiana law:

- (1) contact information including street address, city in Indiana, county, for each hemp production or hemp grow site;
- (2) the acreage of each hemp production site or hemp grow site identified; and
- (3) license number of the grower.

The state seed commissioner shall also report a legal description of the land, or an accurate geospatial (GPS) record in decimal format, telephone number and email address (if available), and the status and license number of the licensee. Changes in records or licenses will be updated to the USDA.

(r) Indiana's official labs will report results to the USDA. It is also required that any lab used by Indiana growers and approved by the DEA (after December 31, 2022) and approved by Indiana report results to the USDA.

(s) Indiana will report to the USDA Secretary of Agriculture on USDA forms all required documents, test results, contact information, background check approval dates, and other information as required in Section 990.7 of the final rule and within 30 days of the information being received.

(t) A person who applies for a license as business must provide as part of the application for a hemp license the Employer Identification Number (Tax ID) (EIN).

(u) A business making application for a hemp license must identify "key participants" in their organization required to have a background check subject to paragraph (b)(6) of this rule *[subdivision (b)(6)]*. A key participant is an employee working in a licensed business with multiple employees within the business, in which one or more of the following conditions apply:

- (1) One who is in a supervisory role with the hemp grow site or hemp production site, the hemp lab, or hemp processing site, e.g., person who is the supervisor responsible for transit of crop, for crop production (seed purchase, planting, sale of harvested crop), receipt of crop in a processing facility; or
- (2) One who oversees workers who perform duties for which workers are in contact with hemp; or
- (3) One who is otherwise deemed necessary to be subjected to this provision by the business entity.

Contract growers, hemp cooperatives, and similar entities are not exempt from the licensing requirements under this SECTION.

(v) A person who is licensed under this article *[document]* shall report hemp crop acreage to the USDA Farm Services Agency (FSA), and to the AMS/USDA including the following:

- (1) Street address, if available, and geospatial (GPS) location for each production or grow site where hemp will be grown or handled.
- (2) Acreage dedicated to the growing of hemp, or greenhouse, or indoor square footage dedicated to the growing of hemp, must be reported.
- (3) License number of the grower.
- (4) The purpose of the crop as fiber, grain, CBD, or other.

(w) A licensee agrees to allow unrestricted access during business hours to all buildings, fields, crops, handling facilities, and records for cultivation and production of hemp to the state seed commissioner, or the state seed commissioner's authorized representative, state police department, an authorized third party sampler, or the USDA.

SECTION 34. (a) Hemp grower/agricultural hemp seed producer: A person that conducts the following activities or advertises to conduct the following activities, or like activities, must be in possession of a hemp grower license issued by the state seed commissioner:

- (1) Growing hemp, offering to grow hemp, contracting to grow hemp.
- (2) Growing agricultural hemp seed, or hemp for seed production for sowing, offering to handle, receive, or handling, agricultural hemp seed:
  - (A) sale of seed for sowing or for use in research purposes as seed; or
  - (B) seed to be sown for development of new varieties; or
  - (C) seed to be sown and harvested and devitalized for a wild bird feed;
  - (D) seed to be sown and harvested and used as an FDA/USDA approved food for humans or animals.

(b) Selling hemp seed for sowing, a person selling agricultural hemp seed in Indiana must be a licensed seedsman under Indiana seed law (360 IAC 1) and must obtain a grower's license as an agricultural hemp seed grower. A person selling hemp seed in Indiana is subject to the federal seed code and all Indiana seed law requirements regulating the sale, labeling, reporting, and distribution of seed.

SECTION 35. (a) A person who receives, possesses, or processes hemp, whether from a facility or not, or offers to process hemp as a middle step in moving from the grow site, or from another processor, to manufacturing must be licensed as a handler. Examples of processing include, but are not limited *[sic, to]* the following kinds of activities:

- (1) Use of any hemp plant part or clone for drying, extraction, distillation, crushing, pressing, desiccation, devitalizing, and the like.
- (2) Any process that subjects hemp to a physical or chemical activity on any hemp, such as, but not limited to, extracting, shredding, cleaning, baling, carding, stripping, drying, freeze drying, decanting, filtering, using in a digester, and similar processing, and the like.

(b) A person, who makes available a facility, to receive hemp for any purpose, offers to receive hemp, for purposes of preparing, storing, drying, manufacturing, or producing a hemp-manufacturing step, or a legal hemp product.

(c) A person who distributes hemp clones and is not a grower is subject to IC 15-15-13-9.5.

(d) For a handler license (examples of types: processor, transporter, service provider (harvest, storage, laboratory testing, and like activities determined to be acceptable by the state seed commissioner). In addition to the above, as applicable, a processor handler must maintain a list of all solvents and extracting solutions used in processing, retain records for two (2) years of any laboratory analyses on the runs, especially to track testing for metals, mycotoxins, pesticides, or similar contaminants and adulterants. The processor must maintain and have available for inspection by ISDH or OISC a food safety plan and practice compliant with 21 CFR Part 111, or 21 CFR Part 501, or Indiana state department of health *[sic, Indiana department of health]* standards as applicable to their own operations.

(e) A person that conducts transportation activities or advertises to conduct these activities and who is not a grower conducting these activities for their own crop management purposes and not those of another must be in possession of a hemp handler license issued by the state seed commissioner. **No prohibition of movement of hemp through Indiana is allowed.**

(f) A person who transports or offers to transport hemp must have the following in their immediate possession while transporting hemp under a handler license, and must provide:

- (1) Evidence of a current valid, hemp handler or research license from the state seed commissioner;
- (2) The driver must hold a valid driver's license with photo ID and current legal address of the driver;
- (3) An invoice or delivery document showing to whom the hemp is to be delivered, the full address, telephone number, variety of hemp, and quantity of hemp; and
- (4) A valid certificate of analysis issued by a competent laboratory showing the total THC for the hemp transported, or a copy of such certificate.

Only a person who is the licensee, or a family member of the licensed person, or a person who or is working for the licensed hemp person may transport his/her own hemp and is required to be in possession of the same requirements as the above.

SECTION 36. (a) Required Actions for Hemp Growers. A grower who is aware a hemp crop grown under their license is in excess of the acceptable hemp THC level, whether notified by the state seed commissioner or not, shall:

- (1) secure the crop;
- (2) harvest the crop within thirty (30) days of sampling; or and transport the crop to an approved Indiana reverse distributor; or
- (3) dispose of the crop in a designated site in a manner that complies with local and state burn laws;
- (4) verify disposal of the crop with the state seed commissioner.

(b) A request for an official growing season sample must be made in writing to the state seed commissioner not less than 30 calendar days prior to expected harvest, and be requested that the inspection be conducted in a field that is within 15 days of harvest at the time of the requested sampling to be accomplished, and include the exact location of the crop to be sampled and the date of the harvest. Harvest must happen within 30 days of this official sampling.

SECTION 37. (a) A person conducting research on hemp, or doing plant breeding research as a hemp researcher, and:

- (1) employed by an institution of higher education; or
  - (2) employed by a commercial entity that conducts research on hemp;
- must be licensed by the state seed commissioner.

(b) The following are requirements of a researcher license:

- (1) A researcher must be in the employ of an institution of higher education (as defined by IC 21-7-13-32); and
- (2) Must be an individual who is academically qualified, or qualified through demonstration of relevant experience; and
- (3) Must be authorized by the institution in which he/she is employed to conduct research on hemp.

(c) The expected research protocol requires an individual to be in possession of, physically handle, walk fields or other hemp production sites, or likely to be physically in contact with hemp, whether in laboratory, storage and warehouse sites, or grow sites, and other sites of contact.

(d) The state seed commissioner may waive some license requirements for Purdue University Cooperative Extension Educators and Purdue Agricultural Center managers, or other academic institution faculty, who are not actively managing their own research as a principle [*sic, principal*] researchers [*sic, researcher*], but are advising growers in an authorized state research program, or for purposes of working with cooperators or assisting growers in conducting research.

(e) A person conducting hemp research may be exempted subject to the approval of the seed commissioner from the requirements of minimum acreage as described in this article *[document]* and is exempted or bears reduced costs for license fees as determined by the state seed commissioner in this article *[document]*.

(f) The cost of a background check, if any, will be the responsibility of an applicant.

(g) For the 2020 growing season, a cooperating researcher employed by a legally recognized academic institution under IC 15-15-13, and subject to employment conditioned upon compliance with Indiana drug laws, does not need to be licensed for purposes of serving as an advisor to a licensee, but must be registered with the state seed commissioner and complete the standard application form.

(h) A licensee must be qualified as a researcher as defined by Indiana law, and must also present and have approved in writing by the state seed commissioner a detailed research proposal and an investigational site that is restricted in size (not commercial sized).

SECTION 38. (a) Upon completion of an application for a license or renewal of a license for grower or handler license, a nonrefundable payment of not more than one thousand dollars (\$1,000) shall be paid to the office of Indiana state seed commissioner. This fee is due for grower and handler applications, or not more than two thousand dollars (\$2,000) for both.

(b) A grower or handler in possession of hemp, hemp clones, or agricultural hemp seed, without having an approved license issued by the state seed commissioner, or reporting a grow site location shall be assessed a late fee of seven hundred fifty dollars (\$750) in addition to the required nonrefundable application fee to obtain a license. This fee shall not be counted as a civil penalty. This is a negligent violation.

(c) A change of record fee of fifty dollars (US \$50) shall be applied to any request for a change in field, to cancel a grow site, or to add a grow site, or to replace a grow site, or other hemp production site, or handling site after a license has been issued.

(d) A remediation sampling, travel, and laboratory fee of \$325 will be charged to a licensee as permitted by law.

SECTION 39. A license application for any hemp activity regulated under this article *[document]* for which a license is required for conducting a regulated activity any given year may be initiated when publicly announced by the state seed commissioner, but no earlier than October 1 of the year preceding the year for which the license is sought.

SECTION 40. An applicant for renewal of a hemp license issued under this article *[document]* is subject to any and all requirements of an applicant for a license.

SECTION 41. The state seed commissioner may revoke a license issued under IC 15-15-13 to a person that fails to cooperate with:

- (1) the state seed commissioner;
- (2) the state police;
- (3) a federal law enforcement agency;
- (4) a local law enforcement agency; or
- (5) in an inspection, or in taking of a sample of any hemp crop during the crop's growth phase; or
- (6) the seed commissioner may revoke the license of a person that grows, sells, or distributes hemp or any of the following:
  - (A) That the licensee has not complied with the requirements under IC 15-15-13-9.5.
  - (B) The report required in IC 15-15-13-9.5 subsection (a) *[sic, IC 15-15-13-9.5(a)]* has not been submitted and is more than ten (10) days late.
  - (C) The report required in IC 15-15-13-9.5 subsection (a) *[sic, IC 15-15-13-9.5(a)]* contained false information.
  - (D) The labeling requirements under IC 15-15-13-9.5 have not been met.

SECTION 42. The state seed commissioner may revoke or refuse to issue or renew a hemp license or an agricultural hemp seed production license for:

- (1) a violation of a license requirement;
- (2) a violation of license terms of conditions, including falsification or misrepresentation of license;
- (3) a violation of IC 15-15-13 or a rule relating to the growing or handling of hemp;
- (4) discovery of a drug conviction of a licensee after a license has been issued;
- (5) a person who violates IC 15-15-13-19 in the sale of hemp buds (as defined in IC 35-48-1-17.2) or hemp flowers (as defined in IC 35-48-1-17.3); or
- (6) a violation of this rule.

SECTION 43. (a) It is a violation of this rule:

- (1) to present as valid an expired license; or
- (2) to change, without notification of the state seed commissioner, the content of any truthful information on a license issued by the state seed commissioner; or
- (3) to misrepresent oneself as the person licensed to another; or
- (4) to falsely state information filed with the state seed commissioner in application for any hemp license, causing the licensed grower to no longer be eligible for a future license and immediately losing the current license;
- (5) to fail to notify the state seed commissioner in writing of an error on a license issued by the commissioner and to seek correction in a timely manner; or
- (6) to fail to report in decimal format any changes to previously reported hemp grow or production sites;
- (7) to harvest any cannabis prior to samples being taken by office of Indiana chemist representatives or approved third party samplers.

(b) It is a violation of this rule to alter, manufacture, falsely represent or present a license that has been issued by the state seed commissioner in any form other than as originally presented on state seed commissioner's official form.

SECTION 44. The state seed commissioner shall revoke or refuse to issue or renew a hemp license or an agricultural hemp seed production license for a licensee found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence.

SECTION 45. (a) A licensed grower may request on an application form provided by the state seed commissioner that:

- (1) the name of the licensed grower or handler be held as confidential;
- (2) the licensed hemp grow site may be held as confidential for purposes of IC 5-14-3.

(b) The state seed commissioner shall make available to growers information that identifies sellers of agricultural hemp seed. The seller of agricultural hemp seed shall provide the state seed commissioner with the business name, business address (number, street, city, state, county, and zip code) and other data, if any, e.g., telephone number with area code, website address. This information is to be posted on the state seed commissioner's website.

(c) Hemp growers and handlers may choose to release their contact information to the public and mark it as not confidential. These not confidential grower's contact information will be posted on the agency website.

**(d) Growers information is not confidential from police, USDA or the US Attorney General's office.**

SECTION 46. (a) Negligent violations document instances of when the statute or rule are violated. Negligent violations include:

- (1) A grower who fails to report a legal description of the land on which hemp is grown;**
  - (2) A grower who produces cannabis exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation if they make reasonable efforts to grow hemp and the cannabis does not have a total delta-9 tetrahydrocannabinol concentration of more than 1.0 percent on a dry weight basis.; or**
  - (3) failure to obtain a license.**
-



**(b) A producer may not be found to have committed more than one negligent violation per year.**

**(c) Three (3) negligent violations in a five (5) year period shall result in the immediate revocation of the person's hemp license and prohibition to apply for a hemp license or be a participant to a hemp license issued by the state seed commissioner for a period of five (5) years from the date of the third violation.**

**(d) A person who is negligently without a license or fails to report a grow or processing site must complete an application form and submit to the state seed commissioner within seven (7) business days all required fees including penalties to gain compliance.**

**(e) Hemp found to be produced in violation of this rule, such as hemp produced on a property not disclosed by the licensed producer or without a license, would be subject to the same disposal provisions as for cannabis testing above the acceptable hemp THC level. Further, if it is determined a violation was committed with a culpable mental state greater than negligence, the state seed commissioner shall report the violation to the Indiana state police and the US Attorney General.**

**(f) A person who negligently grows a crop so that it exceeds the acceptable hemp THC level shall abide the order of the state seed commissioner to secure the crop and to conduct the activities allowed by law, or otherwise required by the law.**

**(g) Harvesting or cutting of hemp without a license is not a negligent violation and is punishable to the extent allowed by law.**

**(h) Distribution of hemp without a license is not a negligent violation and is punishable to the extent allowed by law.**

**(i) Upon determination of a negligent violation the licensee must report the following information in writing to the state seed commissioner for a period of two (2) years:**

- (1) Report the acreage planted and selection of a variety of hemp, or varieties of hemp that are reported to be compliant with achieving and not exceeding the acceptable hemp THC level;**
- (2) Monitor the crop regularly through a sampling plan acceptable to the state seed commissioner, and using a competent laboratory for monitoring THC levels in the crop prior to harvest; and**
- (3) During the growing season reporting on a weekly basis or as timely and consistent with the monitoring plan agreed with the state seed commissioner;**
- (4) The licensee name, address, if applicable, and GPS coordinates in decimal format, of the monitored site(s);**
- (5) The license number of the licensee who is reporting; and**
- (6) Maintaining a log of all testing activities and results that can be examined by the state seed commissioner upon request.**

**(j) Negligent violations are not subject to federal, state, tribal, or local government criminal enforcement action.**

**(k) The seed commissioner shall conduct inspections to determine if a corrective action plan has been implemented. The corrective action plan must include a way for the producer to choose compliant varieties and to confirm suppliers are permitted in Indiana. Requirements of the corrective action plan are:**

- (1) a reasonable date to correct the [sic] violation;**
- (2) reporting requirements for 2 years from date of the negligent violation;**
- (3) negligent violations are not subject to federal, state, tribal, or local government criminal enforcement action;**
- (4) provides that a negligent violation 3 times within a [sic] 5-year period is ineligible to produce hemp for a period of 5 years from the date of the 3rd violation;**
- (5) state government shall conduct inspections to determine if corrective action plan has been implemented.**

**Additional requirements may be added by the state seed commissioner.**

(l) A crop cannot be planted in a comingled *[sic]* or mixed variety planting. Each lot must be of only one variety.

SECTION 47. Unless otherwise prescribed by law, the following practices may be considered for approval by the state seed commissioner upon receipt of an appeal of an order to destroy a hemp field or identifiable portion thereof, by a grower:

(a) Hemp that exceeds the acceptable hemp THC level must be disposed of or remediated in accordance with the USDA's Remediation and Disposal Guidelines issued January 15, 2021

(b) Hemp that is grown in a greenhouse, or other non-field grow site, in violation of this rule or IC 15-15-13, and that is without recourse to be used in another legal processor, shall be destroyed in manner approved in the USDA's Remediation and Disposal Guidelines issued January 15, 2021 or as determined by the licensee's disposal plan required as a part of the application for a license under this rule and in a manner agreeable to the state seed commissioner, or in a manner ordered by the Indiana state police.

(c) Hemp that is a standing fiber crop grown out of doors in a field and found to be in violation of the acceptable hemp THC level shall be terminated in accordance with USDA's Remediation and Disposal Guidelines issued January 15, 2021.

(1) Standing fiber hemp that exceeds the acceptable hemp THC level that is intended for remediation may not moved from the site, although the retting process may be managed by on-site rolling of the crop, for a minimum of 15 days for retting (a request for inundated retting must be requested by the licensed grower and approved by the state seed commissioner).

(2) After the hemp plants are fully retted they must be retested for compliance before entering commerce.

(d) Hemp that is standing seed grain crop and found to be in violation of the acceptable hemp THC level shall be terminated in accordance with USDA's Remediation and Disposal Guidelines issued January 15, 2021.

(1) The seed or grain from a seed gain crop that exceeds the acceptable hemp THC level that is intended for remediation may be harvested and certified for use in a processor. Such grain seed shall not be used for seed for sowing.

(2) Flowers and other plant material from a hemp crop for seed grain production that is in excess of the acceptable hemp THC level must be disposed of in-in accordance with USDA's Remediation and Disposal Guidelines issued January 15, 2021.

(3) The state seed commissioner shall provide notice of the determination of noncompliance in writing to the licensee or his/her designee as designated on the license application, and the order to destroy the identified crop within a timeframe determined by the state seed commissioner. The order shall further include an order to terminate the crop and to hold and not move from the site any hemp without explicitly written approval and direction by the state seed commissioner.

(4) An appeal to the state seed commissioner must be made in writing on an official form of the state seed commissioner by the licensee with full explanation of the basis for a request for redirect of the crop for other purposes. For purposes of a crop, or material that is in processing stages that is equal to or in excess *[sic, of]* the acceptable hemp THC level the state seed commissioner may forward such request to the Indiana state police or to federal Drug Enforcement Administration officials for determination under their jurisdiction.

(5) It is a violation of this rule to co-mingle *[sic]* hemp that is in the field or harvested and in storage if crop was above the acceptable level of hemp and has not successfully been remediated:

(A) that has not been tested and labeled with a certificate of analysis for that particular lot or field; or

(B) that is from different fields, or lots; or

(C) that is of more than one variety; or

(D) that is in storage, drying, or dried; or

(E) hemp that is in excess of the acceptable hemp THC level; or

(F) hemp that is suspected of being in excess *[sic, of]* the acceptable hemp THC level, with compliant hemp, unless combined by a reverse distributor, or allowed for processing by a licensed processor.

(6) Plants of different varieties, and plants of the same variety from separate fields or sites, must be segregated one (1) from the other, so as to visually and readily differentiate the separate entities. Failure to clearly and unambiguously separate the entities may result in loss of all commingled crop.

(7) Biomass or bioresidue resulting from the growing or processing of hemp must be processed and/or disposed of in compliance with all applicable federal, state, and local requirements.

(8) It is a violation of this rule to dispose of biomass, bioresidues, or crop in a manner that causes harm to humans, animals, soils, air, or water.

SECTION 48. (a) A person who violates an order of the state seed commissioner that is authorized subject to IC 15-15-13 or this article *[document]* shall be subject to the maximum civil penalty allowed under law.

(b) A violation of hemp statutes or administrative rules subject to the state seed commissioner does not prevent the state seed commissioner from communicating fully with another agency for consideration of enforcements under any other state or federal law by another agency.

SECTION 49. (a) A person who grows hemp must use named varieties of hemp seed or hemp clones purchased from reputable dealers.

(b) Hemp seed or hemp clones in commerce must comply with Indiana seed law and federal seed code with regard to testing, labeling, and all other requirements as applicable to the entity under consideration.

(c) Each variety of hemp used must be accurately declared on a label written according to federal seed code and Indiana seed laws, and must be from source parentage of plants known to be compliant with federal and state law of *[sic]* not in excess of the acceptable hemp THC level.

(d) For hemp, agricultural hemp seed, and hemp clones, "variety not stated" as provided in 360 IAC 1-3-8(c) is not an allowed declaration.

(e) In no circumstances shall any person use wild Cannabis seed, or seed from hemp in excess of 0.3% THC dry weight, as representing hemp, agricultural hemp seed, or be used as a basis for clones or a crop, unless that person is licensed by the state seed commissioner as a hemp breeder developing new hemp lines for eventual introduction into commerce.

(f) A person who grows, distributes, or sells hemp, offers or advertises the growing, sale, or distribution of hemp subject to this rule must be licensed by the seed commissioner under IC 15-15-13-1-34 *[sic]*. Sales of agricultural hemp seed must be compliant with 360 IAC 1.

(g) It is a violation of this rule to use seed that is sourced from a crop that is not a reliable source of hemp as defined as 0.3% THC or below.

(h) The performance of hemp varieties and their biological compliance with total THC the acceptable hemp THC level, when grown in Indiana may be posted by the state seed commissioner. The state seed commissioner may cooperate with the Purdue University Cooperative Extension Service, Indiana Crop Improvement Association, and other resources deemed valuable by the state seed commissioner.

(i) A variety of hemp must be compliant with expected inherited traits including the acceptable hemp THC level or less to be regulated under this article *[document]*. Varieties outside this range exceeding this limit may be regulated as marijuana by authorities.

(j) A variety that is not yet developed for market by a hemp plant breeder may be temporarily labeled for research and production purposes but must meet all federal and state varietal labeling standards if introduced into the marketplace.

**(k) In addition to being tested as required under 360 IAC 1 or seed laws of the United States and Indiana, a variety that makes claim of feminized seed must also be tested by an AOSCA laboratory to confirm the percent feminized seed claim on the label.**

**(l) For clones, the conditions of IC 15-15-13-9.5 apply.**

**SECTION 50. (a) A person who is licensed as a researcher, or a researcher hemp breeder of agricultural hemp seed, who is employed to conduct research in an area of investigation applicable to hemp by a university or college as defined in IC 15-15-13 and who is a person licensed by the state seed commissioner in the precommercialization development phases of seed quality, trait, and trait stabilization development, and increase for production, and related hemp commercialization development efforts may have fees waived by the state seed commissioner.**

**(b) Minimal growing space requirements for growing hemp under this rule may be waived in writing by the state seed commissioner to accommodate low volumes of breeder seed or propagative material.**

**(c) Research and breeder seed grown or contained in space less than that required of normal production shall be reported to law enforcement, and the plants shall be labeled individually with the licensed grower's license number and a sequential numbering of individual plants.**

**(d) Test results from a research and development licensee may, at the state seed commissioner's discretion, be accepted in lieu of sampling by the state seed commissioner's office.**

**(e) This waiver ceases when the licensed breeder's agricultural hemp seed is:**

**(1) sold to another person;**

**(2) is grown by the licensee in quantity great enough to supply quantities for the minimum acreages required by this article [document], or minimum acreage for the planting of clones; or**

**(3) after a period of 5 years from the first application, made for that seed variety.**

**(f) Any person doing harm or destroying a breeder plot managed by a researcher licensed under this article [document] is subject to maximum civil penalty allowed subject to administration by the state seed commissioner.**

**SECTION 51. (a) Labeling required for agricultural hemp seed, clones, and other propagative materials is subject to any and all other labeling regulations pertaining to plant seed and propagative material in Indiana.**

**(b) All claims and verifications of the plants as hemp must be retained as an accurate statement of propagative source of the seed, or the clone, or other propagative material as from parentage of plants that were tested and demonstrated to meet the definition of hemp.**

**(c) "Variety not stated" as provided in 360 IAC 1-3-8(c)(4) is not acceptable for hemp plants, agricultural hemp seed, or clones.**

**(d) Variety grown must be stated in writing on an application for a hemp license.**

**SECTION 52. (a) Each hemp production site must be accurately declared in a decimal GPS format to the state seed commissioner as part of the application and license process.**

**(b) Hemp production sites may be monitored by local police authorities, the state seed commissioner, or Indiana state police using aerial monitoring with or without notification by the state police to the crop licensee.**

**(c) A hemp grow site or hemp production site shall not be located in a residence or located in close proximity to a residence.**

SECTION 53. (a) Each licensee shall file with the state seed commissioner a harvest and distribution report at the end of the growing season. Failure to file a report will result in a refusal to renew a license presented by an applicant in the consecutive year. The report shall be filed with the state seed commissioner not later than thirty (30) days after the harvest or distribution (sale, ship, etc.). Depending on the requirements of a growing season, it is expected that reports will be filed no later than November 1.

(b) A licensee who is a contractor must file their report with the contracting party in a timely manner. It is the responsibility of the person who is the licensee of record to summarize all contractor reports and to meet the requirements of this SECTION in filing to the state seed commissioner.

(c) The report shall include the *[sic, following]* minimal information:

- (1) License number.
- (2) County.
- (3) A statement verifying the crop type(s) (fiber, seed, oil, CBD, etc.).
- (4) Variety(s) of the hemp.
- (5) Grow site(s) of each variety, and cite by contractor.
- (6) Acres planted.
- (7) Acres harvested.
- (8) Total quantity produced (pounds per acre, plants per square foot, etc.) by variety.
- (9) Disposition of the crop(s) (sold, processed, destroyed, etc.).
- (10) Production costs per unit.
- (11) Wholesale or retail value of the crop(s) per unit.
- (12) Names of buyers (in state or out of state).
- (13) Other data requests may be added by the state seed commissioner.

(d) The state seed commissioner shall consolidate the report and combine summary data so as to not reveal any one (1) source of data. The consolidated data may be discussed with the ISDA and with an industry economic round table to help in market decisions for industry and to identify supporting regulatory needs.

(e) Reports of all persons reporting as individuals or as a licensee of record must be sent to: Office of Indiana State Chemist & Seed Commissioner, Attn: Seed Administrator, 175 S. University Street, West Lafayette, IN 47907-2063, or on forms provided by the state seed commissioner.

SECTION 54. (a) Hemp that is grown as a crop must be maintained within the crop site(s). Plants escaped and proximal to the crop must be eradicated.

(b) It is a violation of this rule to sow, scatter, or dump hemp seed indiscriminately, without a dedicated crop site, approved for production by the state seed commissioner.

(c) It is a violation to sell viable hemp seeds or clones for wildlife plantings.

(d) Hemp plants outside a licensed crop site and control may be subject to disposal when legally authorized by Indiana state police, local law enforcement agencies, county weed boards, and other jurisdictions established by Indiana law as having control of nuisance weeds, or agencies having control of land under federal control including CRP lands, filter strips, and similar managed sites.

SECTION 55. (a) Hemp bud (as defined in IC 35-48-1-17.2) and hemp flower (as defined in IC 35-48-1-17.3) may be sold only to a processor licensed under this article *[document]*.

(b) Use of hemp, hemp flowers, or hemp buds as a floral bouquet or as an element of a floral bouquet is prohibited.

(c) Hemp buds, hemp flowers, and all hemp must be sourced from plants that are 0.3% THC or below. It is a violation of this rule to sell as hemp any material that is in excess of lawfully established limits.

SECTION 56. (a) A request for an official growing season sample must be made in writing to the state seed commissioner not less than 30 calendar days prior to expected harvest, and be requested that the inspection be conducted in a field that is within 30 days of harvest at the time of the requested sampling to be accomplished, and include the exact location of the crop to be sampled and the expected date of the harvest. Once sampled, the crop must be harvested or disposed of within thirty (30) days.

(b) Test samples of hemp, hemp extracts, may be transferred to a person licensed under this article [document], or who is licensed under the hemp laws of the receiving state to accomplish the following, only if the material transferred is from a crop with an acceptable hemp THC level. Examples for which such samples may be expected include, but are not limited to:

- (1) to test the quality, or purity of the extract, or raw hemp for compliance with buyer standards, or legal definition of hemp; or
- (2) to test the hemp or hemp extract, for compliance with health, safety, or contaminants, or acceptable contaminant levels, or concentration levels; or
- (3) to monitor or mitigate, purify, dilute, concentrate, mitigate and define other business liabilities relative to processing and production concerning a hemp material prior to final production and packaging for commercial distribution.

(c) Test samples must be fully consumed by the test procedure. It is a violation of this rule to submit samples that are in excess of the sample size required for testing, or sample runs, required to conduct the analysis.

(d) It is a violation subject to maximum extent of penalty allowed by law to divert a noncompliant extract to a nonlicensed person, or to remove an extract of hemp from a licensed handler/processor without notification to the [sic] and written permission by the state seed commissioner or the Indiana state police, subject to the existing enforcement authorities of each agency.

(e) Documentation of a test sample shall include: the license number of the licensee (submitter), the name of the licensee (submitter), county in which the operation is sited, the extract's known characterization, its intended use, a statement of rationale for the requested testing, a list of the analytes to be monitored, a statement of expected test results, the method of extraction for the sample (specific solvents, cold press, mechanical, CO2, distillation, etc.), quantity of the sample, quantity of material represented by the sample, and the license number of the testing laboratory or firm, name of the laboratory or person.

(f) Test results must be retained for three (3) years by the licensee (submitter) to document the batch or representative sampling tested. Results must be made available upon request presented by the state seed commissioner.

(g) The person receiving a sample for analysis must be licensed in addition to any person who is not an employee of the licensee and is a transporter, a broker, or sample collector.

(h) A certificate of analysis shall be made available to the state seed commissioner or law enforcement officer upon request. An exception may be made for plant material that is to be tested for THC levels to a qualified laboratory, for which THC levels are not yet known, in which case full chain of custody reports of material delivered, date and times of delivery, signature and confirmation of the quantity and type of material received, and an assigned test number or lot number given by the service provider. After the test is determined, the test results presented as a certificate of analysis (COA) including total THC must be provided to the authority making the request (e.g., Indiana state police, Drug Enforcement Administration, Food and Drug Administration, office of Indiana state chemist, a local law enforcement agency, Indiana state department of health [sic, Indiana department of health], etc.).

SECTION 57. (a) To provide increased capacity in making determinations of analytical compliance with federal and state hemp laws, the state seed commissioner may license a willfully participating analytical laboratory to conduct analyses of hemp for total THC, or other cannabinoids, or constituent compounds and nutritive evaluations or determinations (nitrogen, etc.), or disease. Upon completion of an application prescribed by this article [document], signed by the laboratory manager, of its agreement to the following:

(1) To own or to possess under their control on their premises analytical instrumentation capable of accurately analyzing using gas or liquid chromatography with detection. Any and all instruments used in the analyses of hemp must comply with the following:

(A) The analytical equipment must operate under written procedures for calibrating, maintenance, and record retention.

(2) A laboratory under this SECTION must be certified by a nationally recognized standard, such as the most current ISO17025, or similar standard approved by the state seed commissioner.

(3) A laboratory must apply for and receive a Schedule 1 Registration from the Drug Enforcement Administration.

(4) All training records of personnel establishing competencies for hemp analyses must be retained and made available for review by the state seed commissioner or his/her representative.

(5) The state seed commissioner may post on the OISC website a list of laboratories licensed to conduct analyses for hemp.

(6) A laboratory must comply with all other federal or local laws including a determination if the laboratory requires a Drug Enforcement Administration Schedule 1 registration to address any samples that may exceed 0.3% THC. This DEA Schedule 1 document shall be required as part of the application process for any laboratory accepting out-of-state hemp for analyses prior to the state seed commissioner approving an Indiana cooperator hemp laboratory license.

(7) A laboratory licensed under this SECTION must demonstrate to the satisfaction of the state seed commissioner strict adherence to chain of custody and record keeping best practices.

(8) A laboratory manager must agree to submit the laboratory to an audit by OISC personnel to confirm their ability to comply with Indiana law and to be evaluated to remain in good standing.

(9) A laboratory manager must notify the state seed commissioner of any noncompliant calibrations, performance qualifications, or any other adverse actions that may affect the data or data quality, provided to the state seed commissioner.

(10) To pay the nonrefundable application fees.

(11) A laboratory operated by the Indiana state police for purposes of hemp or marijuana analyses is exempted from this requirement.

SECTION 58. (a) Except for the expressed purposes and licensing by the state seed commissioner for hemp plant breeding, or hemp research by a person licensed under this article *[document]*, the collection, sale, offering to sell, *[sic, or]* use of or *[sic]* wild Cannabis is a violation of this rule. Such actions may be enforceable by Indiana state police or local law enforcement agencies under other statutory authorities.

(b) The collection, possession, commingling of wild Cannabis with a licensed varietal hemp crop, or a crop purported to be a varietal hemp crop, is a violation of this rule unless a license has been issued by the state seed commissioner under this rule explicitly permitting this activity in writing, and notification or permission from the Indiana state police.

(c) It is a violation of this rule to present any wild Cannabis as hemp, or to present as hemp any hemp that has not been tested and demonstrated to comply with this article *[document]*.

SECTION 59. (a) Growing hemp plants or possessing hemp material in quantities less than the minimum is a violation of this rule.

(b) The required growing areas for hemp in Indiana are as follows:

(1) Production field (seed sown) 10 contiguous acres minimum (grain/seed/fiber/seed oil).

(2) Production field (clones, cuttings) – 1 acre (contiguous) minimum, with a minimum of one thousand five hundred (1,500) plants grown as a single plot (CBD and other cannabinoids, feminized seed).

(3) Agricultural hemp seed breeding farm – not to exceed 5 acres (AOSCA standards).

(4) Minimum indoor grow greenhouse - 2,000 square feet, with a minimum of one thousand five hundred (1,500) plants (for production of clones), or 300 mature plants for cannabinoid production.

(5) Hoop house or slat house, or like, for production of starts only - 2,000 square feet, with a minimum of one thousand five hundred (1,500) plants (for production of clones), or 300 mature plants for cannabinoid production.

(6) Indoor – 2,000 square feet as measured in square feet of area, or as rotational compactor, or similar

technology, with one thousand five hundred (1,500) plants (for production of clones), or 300 mature plants for cannabinoid production or feminized seed production.

(c) It is a violation of this rule to grow less than the quantities indicated for the identified site, unless the activity is hemp research conducted by a university employed hemp researcher as defined in this article [document] or a licensed hemp breeder as described in this article [document].

(d) The size dimensions stated for the respective grow sites are each expected to be an area fully utilized for growing hemp in the grow operation within the space designated.

(e) Grow sites utilizing less than the minimum growing area or with fewer than the expected numbers of plants may be subject to orders of disposal by the state seed commissioner.

(f) Mother plants for hemp propagation and cloning may be over wintered, not to exceed 100 total plants. Mother plants are not allowed in a residence.

SECTION 60. The following hemp records must be accurately maintained and made available to the state seed commissioner upon at least three (3) days notice by the state seed commissioner:

(1) Legal description of the land, county, and GPS coordinates in decimal format, on which hemp is being grown or was grown over the past two (2) years.

(2) Legal description of the location including GPS coordinates in decimal format, county, and address, for any facility, fixed or mobile, used to store, process, receive, or ship hemp, whether for the licensee or another.

(3) Records and invoices of any and all hemp seed or propagule purchases made in the past three (3) years.

(4) Records of a licensed grower that must include:

(A) name (person);

(B) address;

(C) county;

(D) variety and quantity of each variety grown/sold;

(E) in the case of clones, the quantity, shall include the number of plants of each variety grown/sold;

(F) delivery date of seed/clones received and delivery date of seed/clones sold;

(G) plant material, include [sic, including] name and address of the purchaser, the purchaser's license number;

(H) for the 2020 license year, a copy of the approved research plan, and demonstration of data being collected as required by the research plan.

(5) A person who buys hemp in Indiana must retain the receipt of the seller, which must include the seller's name, place of business, Indiana license number (and any out-of-state license number, if held), variety(s), and quantity by variety of hemp sold.

(6) For a handler who is a processor of hemp, the following additional records are required to be maintained and to be presented upon demand by the state seed commissioner:

(A) A list of any and all extracting solvents and description of extracting methods including solvent concentrations, purity, grade, and source with brand and catalogue number, used by the licensee in processing hemp.

(B) Documentation of acceptable use of a chemical as a solvent for the purpose intended by documented reference to federal applicable codes or references or from the regulatory agency overseeing the final product in the market place.

(C) Records for weed management and identification of weeds in the production area known to be harmful to humans or animals and methods of control to avoid including them in processing.

(D) A copy of the food safety plan, or hazard identification and hazard mitigation plan, and compliance plans for Food and Drug Administration, 21 CFR Part 111 must be made available upon request by the OISC or other authorized state or federal regulatory or enforcement agency.

(E) A copy of the licensee's site safety plan, and, as appropriate to the situation, a copy of the



state fire marshall's *[sic, marshal's]* facility inspection report of the processor site.

(F) It is a violation of this article *[document]* to handle or otherwise process hemp, or use extractants or solvents to process hemp in a residence or out building associated with a residence.

(G) The certificates of analyses (COA) of all lots produced by a grower shall be retained by the licensee for not less than two (2) years and made available upon request.

SECTION 61. (a) Sale of hemp must be conducted by a person licensed under this article *[document]*.

(b) Sale of hemp grown by an Indiana licensed grower may be sold and distributed to a person who is licensed under the hemp laws of the receiving state able to receive the hemp legally in that state.

(c) Any hemp sold must be tested by a cooperator hemp laboratory or the laboratory of the state seed commissioner to perform the testing for total THC and determined to be compliant with state and federal laws. If tests are completed by the laboratory of the state seed commissioner those test results will be the final determination of acceptable hemp THC level in the lot sampled.

(d) Indiana persons who receive hemp sourced from another state must be licensed:

(1) A person who receives hemp must have a certificate of analysis that reports total THC and the date(s) of the analyses.

(2) A person who receives for delivery hemp that is not compliant with Indiana law and is not legally allowed to be sold in Indiana must reject such materials and state in writing the reason for rejection to the seller.

(e) Sales invoices for the sale of agricultural hemp seed must state that "sales or further distribution of hemp seed sold to the person shown in the invoice, are prohibited, unless the person is a licensed seed vendor".

(f) Sales invoices for hemp shall include both on one (1) form:

(1) vendor information, including the name of the vendor, the hemp license number of vendor, the legal physical address of the business (street number, street, city, state, zip code, county), the phone number (including area code), website, and email address, as well as the date of the sale (including the month, day, year); and

(2) purchaser information, including the name, physical address (as above) of the purchaser, the license number of the purchaser.

The invoice shall name the variety (varieties) transacted, and quantity and form (chopped, baled, fresh cut, dried, etc.) of each variety transacted.

(g) It is prohibited to sell or distribute hemp seed as garden seed packets, or in quantities smaller than 50 pounds, except to a person who *[sic]* licensed as a researcher and used for educational purposes by a researcher or cooperative extension educator, or by one who is licensed to breed agricultural hemp seed as a developer of new varieties of hemp.

(h) Persons selling or advertising the sale of hemp, agricultural hemp seed, or hemp clones must be licensed and must sell to a person who is licensed by the state seed commissioner, or one who is legally licensed in another state, and must retain the following records for each transaction of hemp seed and make such records available upon request by the state seed commissioner:

(1) Name, address (street number, street, city, state, zip code, county), and license number of the purchaser of the hemp as well as the seller.

(2) Identity of the variety purchased and brand, and the quantity of each variety or brand.

(3) Amount of hemp sold or number of clones sold.

(4) Signature of the person presenting a current and valid government issued identification to the vendor.

(i) These records shall be retained for two (2) years from the date of sale and may be requested by the state seed commissioner under IC 15-15-13-18.

(j) Documentation of compliance with IC 24-4-21 and IC 24-4-22 for low THC products shall be made available upon request by the state seed commissioner prior to release to market.

SECTION 62. (a) A person who buys hemp in Indiana must retain the receipt described in IC 15-15-13-18(a)(2) for a period of two (2) years.

(b) The receipt shall contain the seller's name, place of business (full street address and county), and hemp license number, and variety and quantity of hemp sold.

(c) The receipt of a hemp sale and purchase is a document that may be requested by the state seed commissioner under IC 15-15-13-18.

SECTION 63. (a) Grow sites, handling sites, and contact information of a licensee shall be considered by the state seed commissioner as public information, unless the licensee commits to one (1) of the following statements on an application provided by the state seed commissioner, submitted in writing at the time of filing a license application with the state seed commissioner:

- (1) the licensee requests that their grow sites, handling sites, and contact information be excluded from public reporting by the state seed commissioner and held to be confidential by the state seed commissioner; or
- (2) the licensee requests that the grow site be excluded from public reporting by the state seed commissioner, but grow site locations may be shared between any two (2) licensed growers within a five (5) mile radius of one another.

(b) A licensee may request a change in their reporting status upon renewal of a hemp license.

SECTION 64. Hemp that has exceeded the acceptable hemp THC level must be treated and disposed in like manner as marijuana:

**(1) Remediation can be performed in accordance with Section 47 of this rule on crops that do not meet the acceptable hemp THC level.**

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(2) Excess hemp total THC (THC and THCa) in the possession of a grower or handler, regardless of form as an extract, or as plants or plant parts, must be disposed so as to be irretrievable and non-ingestible.

(3) A grower who is aware a hemp crop grown under their license is in excess of the acceptable hemp THC level, whether notified by the state seed commissioner or not, shall:

- (A) harvest the crop within thirty (30) days of sampling;
- (B) securely maintain the entire crop on the farm or property where the crop was grown;
- (C) coordinate with the state seed commissioner for the disposal to be witnessed by the Indiana state police or their local law enforcement designee;
- (D) dispose of the crop in a designated site in a manner that complies with local and state burn laws and this rule;
- (E) verify disposal of the crop with the state seed commissioner, including photographic or video evidence of disposal.

(4) Disposal must occur on the farm or property where the crop was grown.

(5) A handler must destroy all excess THC in their control whether:

- (A) as a separated extract obtained through extraction of desired legally held cannabinoids, e.g., CBD, CBN, or other legal cannabinoid; or
- (B) as unprocessed hemp plant material that cannot be redeemed for other legal use.

Only extracts of cannabinoids containing not more than the acceptable hemp THC level are compliant.

(6) Transfers of THC-containing hemp extracts or hemp that exceeds 0.3% THC to another person are not allowed.

(7) With the exception of reference standards of THC used by a laboratory for the purpose of hemp analyses by a cooperator hemp laboratory licensed by the state seed commissioner, transport of THC in an extracted form across state lines is prohibited. A person who transports THC extract or hemp

that comes from a tested crop above the acceptable hemp THC level is subject to revocation of a license issued by the state seed commissioner.

(8) Oversight of disposal of THC materials, regardless of form as an extract or plants, or plant parts, must be according to federal DEA regulations.

(9) It is a violation of this rule to allow crop tested above the acceptable hemp THC level to be moved off of the property of the grower or handler. This crop shall not be sold, transported, or processed and must be destroyed. Growers and handlers must set up procedures that prohibit handling, processing, or entering the stream of commerce of any hemp grown where the acceptable hemp THC level is noncompliant (15-15-13-9) *[sic, (IC 15-15-13-9)]*.

SECTION 65. (a) The state seed commissioner shall follow the field sampling protocols adopted in the Office of Indiana State Chemist & Seed Commissioner MTD 0501-IS, Field Sampling of Hemp. Standard sampling and performance-based sampling procedures will be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot.

(b) The state seed commissioner shall follow the testing and analytical protocols for determining total THC using gas chromatography or liquid chromatography with detection adopted in the Office of Indiana State Chemist & Seed Commissioner MTD 0500-FD, Analysis of Delta-9-tetrahydrocannabinol in Hemp by Gas Chromatography; or MTD 0502-FD, Analysis of delta-9-tetrahydrocannabinol in Hemp by Liquid Chromatography.

(c) For official preharvest sampling it must be conducted by the state seed commissioner's authorized agent or performed by an authorized third party sampling agent, using the same sampling method.

(d) The producer shall harvest the crop not more than thirty (30) days following the date of sample collection.

(e) If the producer fails to complete harvest within thirty (30) days of sample collection, a secondary preharvested sample of the lot shall be required to be submitted for testing.

(f) It is a violation of this article *[document]* for a producer to harvest any cannabis prior to samples being taken.

(g) Third party samplers may not collect samples from their own growing facilities.

SECTION 66. (a) It is a violation of this article *[document]* to present information in written or in any form to the state seed commissioner as true that is factually false.

(b) It is a violation of this article *[document]* to falsify any document issued by the state seed commissioner.

(c) A person who violates either (a) or (b) above *[subsection (a) or (b)]* is subject to a \$9,500 fine and permanent revocation of a license. A license may only be renewed if the penalty has been paid in full and the time obligation has been met.

(d) Any person subject to this article *[document]* who materially falsifies any information contained in an application to participate in the Indiana state hemp program shall be ineligible to participate in the program.

(e) If a licensee has been determined by the state seed commissioner to have violated this article *[document]* or IC 15-15-13 with a culpable mental state greater than negligence, the state seed commissioner shall immediately report the licensee to:

- (1) the U.S. Attorney General; and
- (2) the Indiana attorney general; and
- (3) the superintendent of the Indiana state police.

(f) A licensee who has been determined by the state seed commissioner to have violated this article [document] or IC 15-15-13 with a culpable mental state greater than negligence, i.e., intentionally, knowingly, willfully, or recklessly, is not subject to consideration as a violator of those actions as negligent violations.

(g) A producer who violates this article [document] in a culpable mental state greater than negligence shall be reported to the US Attorney General and the chief law enforcement officer of the state or tribal government.

(h) Civil penalties may not be stacked; consideration of abeyance shall apply as a discretionary option for only one (1) violation per person for any considered time. Any subsequent civil penalties may result in negation and withdrawal of the abeyance and a requirement to pay the accumulated full amount of the civil penalties due:

(1) The state seed commissioner may hold in abeyance, for a period up to five (5) years, portions or all of a rightfully charged civil penalty to allow time for corrective action plan where the violator is cooperating and has activity to regain compliance, if the violation is subject to correction that requires time or investment, and is an option believed by the state seed commissioner to gain compliance now and in the future, and the violator cooperates with the state seed commissioner Three (3) negligent violations as defined in the 2018 Agriculture Improvement Act, and defined in this article [document], including those for which a civil penalty may be lawfully applied by the state seed commissioner, in a five (5) year period shall result in a revocation of the license for five (5) years.

(2) Knowing or intentional violations of IC 15-15-13 or this rule will result in a revocation of license and will be turned over to the Indiana state police, where the violation is one subject to their jurisdiction.

(3) The state seed commissioner may consult with the director of the Indiana department of agriculture or the superintendent of the state police regarding an abeyance.

(4) Failure to be a grower and to not be licensed is subject to a late fee of \$750 plus any applicable licensing fees payable to the state seed commissioner.

(5) A knowing or intentional violation, as in (2) above [subdivision (2)], is not a negligent violation and may be subject to either IC 15-15-13-19 or IC 15-15-13-20.

(6) Failure to pay civil penalties within the period ordered by the seed commissioner shall result in a revocation of a license or the nonrenewal of a license, if a license is up for renewal.

SECTION 67. Failure to cooperate with an audit, records check, inspection, taking of a sample, lawfully initiated by the state seed commissioner may result in one (1) or more of the following actions taken by the state seed commissioner:

(1) Revocation of the license.

(2) Probable cause inspection of the property(s) where licensed activities are presented to the state seed commissioner as part of the license application.

(3) Detention, seizure, or embargo of a crop based on violation of this rule and failure to comply with an order.

(4) Disposal of the crop by order of the state seed commissioner based on violation of this rule and failure to comply with an order.

(5) Payment to the state seed commissioner for any costs of testing conducted.

(6) A person who impedes an activity of the state seed commissioner that is lawfully authorized is subject to:

(A) faces revocation of license; and

(B) commits a Class C misdemeanor.

Reviewed:
Reviewed:
Reviewed:

Office of Indiana State Chemist  
175 S. University St.  
West Lafayette, IN 47907

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## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

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Issued Date:	06/18/2021
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## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

#### A. INTRODUCTION

This method (MTD) establishes guidelines for the analysis of hemp. The scope of this MTD is limited to preparation of hemp plant material for analysis followed by determination of THC level by Gas Chromatography with Flame Ionization Detection (GC-FID).

#### B. MATERIALS AND INSTRUMENTATION

##### 1. Standards, Quality Control, and Reference Materials:

- Cannabinoids standard, 1000 µg/mL, each THC, CBD, CBN from Restek or other supplier
- $\Delta^9$ -Tetrahydrocannabinol (THC) standard, 1000 µg/mL from Cerilliant, Restek, or other reference standard supplier.
- Matrix control: Plant material matching the hemp matrix and containing no analyte of interest. This could be oregano, spinach, or hemsps samples that were previously tested and found to contain no detectable THC.
- Matrix blank solution: extract of Matrix Control.
- Quality reference material from the PT Hemp program will be analyzed as QC samples.
- Matrix spike: A test portion of matrix control fortified with a known concentration of THC. (This will only be needed if no QC sample is available for analysis.)
- Method control: A solvent (extractant) blank to which all reagents are added as for analysis of hemp samples; the method control is carried through the entire analytical procedure.

##### 2. Reagents:

- Methanol: Fisher Scientific, ACS grade or equivalent

##### 3. Equipment:

- Gas Chromatograph with flame ionization detector (GC-FID) – Agilent 7890B or equivalent
- Analytical column: Agilent HP-5MS UI, part # 19091S-431UI, 15m x 0.25mm x 0.25 µm Agilent HP-5 30m x 0.32mm x 0.25µm, 19091J-413 or equivalent
- Balance: top loading balance with two decimal place reading with capacity equal or greater to the maximum gross weight of the samples to be weighed
- Moisture analyzer: Mettler Toledo HC103 Halogen Moisture Analyzer or equivalent
- Cutting mill or grinder: Magic Bullet food blender, grains grinder or equivalent suitable grinder
- Sieve: 1.5 mm or smaller

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

- g. Geno Grinder 2010 or equivalent shaker
- h. Pipettes capable of measuring 3 to 1000  $\mu$ L
- i. Syringes for filtering samples
- j. 0.2  $\mu$ m PTFE syringe filters or syringeless filter vials
- k. 50 mL Centrifuge tubes, preferably low binding centrifuge tubes
- l. Plastic specimen cups with caps
- m. 50 mL bottle top dispenser compatible with methanol.
- n. Solvent control: A solvent used as an extract

## C. PROCEDURE

### 1. Definitions

- a.  $\Delta^9$ -Tetrahydrocannabinol (THC): A cannabinoid, the primary psychoactive compound occurring naturally in marijuana and hemp.
- b. Cannabinol (CBN). A cannabinoid occurring mostly as a metabolite of tetrahydrocannabinol.
- c. Equivalent: Instrumentation, materials, or equipment equal in value that will not change the outcome of results.
- d. Hemp: Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis including consideration of the measurement of uncertainty.
- e. Total THC is the value determined after the process of decarboxylation, or the application of the conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total delta-9 tetrahydrocannabinol content derived from the sum of the THC and THCA content and reported on a dry weight basis. This post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, such as gas chromatography through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample.

### 2. Sample Drying

- a. Samples are to be dried according to SOP 0282-FD [1].

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

#### 3. Sample Preparation and Handling

- All weights captured in the process of sample preparation are recorded in the LabWorks eWorksheet Hemp\_57\_GC, or on a hard copy of eWorksheet Hemp\_57\_GC [1 -Forms].
- Dried samples are milled through a sieve no greater than 1.5 mm sieve to obtain a uniform, powder-like consistency.
- Small-size samples (<10g) can be homogenized to powder-like consistency with a mortar and pestle.
- After homogenization, the moisture content is determined by testing approximately 2g of sample at 95°C with a moisture analyzer. The percent moisture content is recorded in the eWorksheet Hemp\_57\_GC; tab 57.b\_RESERVE\_WT. If sample weight is less than 10g then approximately 1g portion will be used for moisture analysis.
- If the moisture content is above 15% [2,3,4], additional oven drying of the sample is necessary. The additional drying time is decided by the analytical chemist and should be kept to a minimum amount of time to obtain an adequate result. Typically, the additional drying is less than one hour.
- The grinder and mortar and pestle must be cleaned between each sample using the following steps:
  - First, brush the analytical mill or mortar and pestle.
  - Second, spray them with a jet of air.
  - Rinse them at least three times with ethanol.
  - Finally, air-dry either by simple exposure to air or by contact with a directed stream of air.
- All the samples in pre-labeled specimen cups shall be stored in a locked freezer or refrigerator. Standards must be stored in a locked freezer.

#### 4. Calibration Standards Preparation

- Matrix blank solution - weigh 0.2 g of matrix control (oregano, spinach or hemp containing no THC) into a 50-mL centrifuge tube. Add 40 mL of MeOH proceed with extraction as described in C.5.d-g. Ensure matrix blank solution is filtered through 0.2µm PTFE syringe filter, since larger volume is required for standard preparation.
- The stock standard solution is a cannabinoids mixture in methanol of 1000 µg/mL each CBD, CBN, THC, from Restek or equivalent.
- For the preparation of the calibration standards solutions at 3.0, 5.0, 10.0, 20.0, 40.0, 60.0, 80.0 µg/mL, add 1000 µL of matrix blank solution to each GC vial, remove the specified volume of matrix blank solution, and replace it with the same volume of stock standard solution. See Table 1 for details.



Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Gas Chromatography

Table 1. Preparation of calibration standard solutions

Level	Stock std solution volume, $\mu\text{L}$	Matrix blank solution—volume, $\mu\text{L}$	Total Dilution Volume, $\mu\text{L}$	THC Concentration, $\mu\text{g/mL}$	Equivalent %THC concentration in hemp
Std 1	3.0	997.0	1000.0	3.0	0.06
Std 2	5.0	995.0	1000.0	5.0	0.10
Std 3	10.0	990.0	1000.0	10.0	0.20
Std 4	20.0	980.0	1000.0	20.0	0.40
Std 5	40.0	960.0	1000.0	40.0	0.80
Std 6	60.0	940.0	1000.0	60.0	1.20
Std 7	80.0	920.0	1000.0	80.0	1.60

- d. To prepare the continuing calibration verification (CCV) standard of 10.0 $\mu\text{g/mL}$ , add 1000  $\mu\text{L}$  of the matrix blank solution to a GC vial. Remove and discard 10.0 $\mu\text{L}$  of matrix blank solution and replace this volume by adding the same amount of stock standard solution.
- e. CCV standards should be prepared separately, preferably from a standard stock solution from a different vendor.

#### 5. Sample Preparation

- a. Prepare the hemp sample as described in C.3, Sample Preparation and Handling.
- b. Weigh 0.2 g  $\pm$  0.05 g prepared hemp sample into a 50-mL centrifuge tube and record the weight.
- c. Add 40 mL methanol to the centrifuge tube. Cap and shake to ensure that the entire sample is wet.
- d. Place on the Geno Grinder 2010 and shake for 5 minutes.
- e. Allow suspended material to settle for at least one hour.
- f. Filter sample through a 0.2 $\mu\text{m}$  PTFE syringe filter into a 2 mL amber GC autosampler vial or use 0.2 $\mu\text{m}$  syringeless filter vials. Sample should fill at least half the vial.
- g. Remaining sample extract will be stored in the locked sample freezer until analysis is completed.
- h. Method blank: Transfer 40 mL methanol to a 50 mL centrifuge tube and shake for 5.0 minutes.

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

#### 6. Sample Analysis: Chromatographic Conditions

- a. Operation of the GC/FID instrument will be in accordance with EM-PF-002 [5].
- b. Short Column GC Analysis Conditions:
  - Column: Agilent HP-5MS, 15m x 0.25mm x 0.25um, 19091S-431UI or equivalent.
  - Instrument conditions:
    - Oven:
 

Initial Temperature / Ramp:	200°C; hold 0.1min Ramp 20°C/min to 250°C; hold 3.0 min Ramp 30°C/min to 280°C; hold 2.0 min
Total Run Time:	8.6 min
    - Front inlet
 

Mode:	Split
Split ratio:	10:1
Inlet temp:	250 °C
Helium flow:	1.5 mL/min
Injection vol:	1 µL
    - Detector FID/GC
 

Detector temp:	300°C
Air flow:	350 mL/min
Nitrogen flow:	25 mL/min
Hydrogen flow:	30 mL/min
- c. Long Column Conditions:
  - Column: Agilent HP-5 30m x 0.32mm x 0.25um, 19091J-413 or equivalent
  - Instrument conditions:
    - Oven
 

Initial Temperature / Ramp:	200°C; hold 1.0min Ramp 11°C/min to 250°C; hold 4.55 min Ramp 30°C/min to 280°C; hold 2.0 min
Total Run Time:	13.1 min
    - Front inlet
 

Mode:	Split
Split ratio:	10:1
Inlet temp:	250 °C
Helium flow:	1.5 mL/min

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

Injection vol:	1 $\mu$ L
▪ Detector FID/GC	
Detector temp:	300°C
Air flow:	350 mL/min
Nitrogen flow:	25 mL/min
Hydrogen flow:	30 mL/min

- d. Instrument parameters may be adjusted to optimize chromatography.
- e. Injector precision – Make repeat injections of the CCV standards until the peak area for three consecutive injections agree within 2.5%.

#### 7. Quality Control

- a. Each set of samples is required to contain a method control, a matrix blank solution, and solvent control run at least one time as well as a quality control (QC) sample to be run in duplicate. Each sample set is required to contain a randomly chosen sample run in duplicate.
- b. If no QC sample is available, then a matrix spike must be prepared and analyzed in place of the QC sample.
- c. Instrument response for samples should be within the method calibration range. If the instrument response for THC is greater than highest calibration standards, the sample extract will be diluted with the extraction solvent to fall within the calibration range.
- d. Results for duplicate samples, including QC samples, should be within  $\pm 15\%$  of each other. If duplicate results exceed  $\pm 15\%$ , new samples will be extracted and re-tested.
- e. The Method Control and Matrix Control should not contain THC at a level greater than the method's limit of detection (LOD).
- f. Duplicate QC samples are analyzed in all sample sets. If available, Quality Reference Material (QRM) can be used as a QC sample. The results for THC concentration should be within set limits based on earlier analyses of the sample. These limits are  $\pm 2$  standard deviations from the mean of previous determinations. If either one of the QC duplicate results falls outside  $\pm 2$  standard deviation but is within  $\pm 3$  standard deviations the QC results are still acceptable. If both QC results are outside  $\pm 3$  standard deviations, the sample set results are rejected. New portions of the samples and the QC sample will be extracted and re-tested.

#### 8. Matrix Spike Preparation

- a. For inclusion in the sample set when no QC is available, fortify a 0.20g matrix blank by adding 0.2 mL of THC stock standard solution (1000  $\mu$ g/mL) to 0.20g of matrix control. The equivalent level of THC in a hemp sample is 0.1%:

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

$[(0.2 \text{ mL volume of stock standard solution}) \times (1000 \text{ } \mu\text{g/mL THC stock standard solution}) / 0.2 \times 10^6 \text{ } \mu\text{g matrix control sample}] \times 100\%$

- b. For the matrix spike range of 0.05 – 0.5%, recovery should fall within the range of 85 – 118%, according to AOAC SMPR 2019.003 Quantitation of Cannabinoids in Plant Materials of Hemp (low THC Varieties Cannabis sp.) [6].

#### 9. System Suitability – Acceptance Criteria

- a. The calibration correlation coefficient ( $r^2$ ) must be  $\geq 0.995$ . The set of calibration standards are required to be run at least two times, at the beginning and the end of the sequence. If one of the calibration standards level is outside the calibration curve it can be omitted as an outlier. However, two or more calibration standards level cannot be omitted.
- b. Calibration integrity will be calculated for each set of samples by running a continuing calibration verification standard. The results of calibration integrity will be documented in the sample set report. Continuing calibration verification results should be within  $\pm 15\%$  accuracy.
- c. CCVs injections are required to be included in the sample sequence at the beginning of the sample set and at the end of the sample set.
- d. CCVs injections are also required to boarder sample injections with a maximum of 5 samples.
- e. The %RSD for at least five injections of CCV must be less than 2.5 %. If results fail to meet accuracy and %RSD expectation, results from the sample set are rejected. The sample extracts will be re-tested.

#### 10. Results

- a. Results will be calculated based on dry weight basis according to the following formula:

$$\%THC_{dry \text{ weight basis}} = \frac{\%THC_{as \text{ is basis}}}{\left(\frac{100 - M}{100}\right)}$$

M – % moisture content as determined by moisture analyzer

%THC<sub>as-is basis</sub> – THC level (%) determined by instrument software before adjustment for moisture content.

%THC<sub>dry weight basis</sub> – THC level (%) after adjustment for moisture content

- b. Results will be reported in % to two decimal places.

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

#### 11. Accuracy, Precision, Measurement Uncertainty, and Detection Limits

- a. Single-Laboratory Method Evaluation was performed on the new Agilent 7890B GC instrument in June 2019 (June 5-June 14, 2019) [7] according to the *AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanical* [8].
  - Accuracy was determined by analyzing two sets of 5 replicates of matrix blank spiked at 0.1% and 0.3% THC.
  - To evaluate the repeatability (precision) as relative standard deviation (%RSD), four replicates of the quality reference material (QRM) samples were tested on three days. The within-day, between-day, and total standard deviations were calculated.
  - The combined expanded measurement uncertainty (MU) was determined by considering repeatability within laboratory ( $u_r$ ), accuracy ( $u_{bias}$ ) and  $u(C_{ref})$ , the last two terms based on calculations from interlaboratory comparison (proficiency testing). A coverage factor  $k = 2$  was used in the calculations, providing a level of confidence of approximately 95% [13, 14].
  - Limit of Detection (LOD) and Limit of Quantitation (LOQ) were calculated according to the Wisconsin Department of Natural Resources. [9] as  $LOD = S_d(t\text{-test})$  and  $LOQ = 10S_d$ , where  $S_d$  is standard deviation of response for blank samples spiked with THC at 0.1%. The student's t-test for four degrees of freedom at 99% confidence.
  - Accuracy, precision, measurement of uncertainty, LOD, and LOQ are presented below in Table 2.

Table 2

Cannabinoid	Accuracy (%)	Precision (%)	LOD (%)	LOQ (%)	MU (%)
THC	99	4.4	0.02	0.04	±0.08

#### 12. Sample Acceptance Criteria

- a. Based on the measurement of uncertainty calculation, if THC concentration is greater than 0.38%, the samples are considered failing and will be retested using a new sample portion. Retesting will be performed by liquid chromatography method, MTD 0502-FD [10] which will be used as a confirmation method and the results will be reported as a final.
- b. Test result greater than 0.38% THC will be considered conclusive evidence that at least one Cannabis plant, or part of a plant, from the composite sample [11] contains a THC concentration over the limit allowed for hemp.

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

#### 13. Sample Disposal

- After the sample results have been submitted to the client, the sample extracts, analytical extracts, and the raw samples will be submitted for disposal and will be collected by REM. See a sample disposal procedure in the SOP 0282-FD [1].
- The raw samples with THC levels failing to meet acceptance criteria will be treated as a Schedule 1 controlled substance [12]. Analytical extracts for those samples will be submitted for disposal and collected by REM [1].

#### D. CALCULATIONS

$$\%THC_{dry\ weight\ basis} = \frac{\%THC_{as\ is\ basis}}{\left(\frac{100 - M}{100}\right)}$$

M – % moisture content as determined by moisture analyzer

%THC <sub>as-is basis</sub> – THC level (%) determined by instrument software before adjustment for moisture content.

%THC <sub>dry weight basis</sub> – THC level (%) after adjustment for moisture content

#### E. SAFETY

- No additional safety requirements

#### F. REFERENCES

- SOP 0282-FD, *Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist*, OISC
- PT-METH-031, Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID), Colorado Department of Agriculture, Original Revision, Effective 09/23/2014
- Industrial Hemp, Technical Manual, Health Canada, September 1, 2000
- Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products – manual for use by National Drug Analysis Laboratories, United Nations Office on Drug and Crime, 2009
- EM-PF-002, “Agilent 6890 Gas Chromatograph”
- AOAC SMPR 2019.003 Standard Method Performance Requirements (SMPRs) Quantitation of Cannabinoids in Plant Materials of Hemp (low THC Varieties Cannabis sp.)
- Method evaluation - reports – OISC Feed Laboratory, “Analysis of Delta-9-THC and Cannabinol in Hemp by Gas Chromatography” 06/06/2019 – 06/14/2019.

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

8. AOAC Guidelines for Single Laboratory Validation of Chemical methods for Dietary Supplements and Botanical
9. Wisconsin Department of Natural Resources, April, 1996. PUBL-TS-056-96.
10. MTD 0502-FD *Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography*, OISC
11. MTD 0501-IS, *Field Sampling of Hemp*, OISC
12. SOP 0295-FD, *Controlled Drug Substances*, OISC
13. B. Magnuson, T. Naykki, H. Hovind, M. Krysell, E. Sahlin, Handbook for calculation of measurement uncertainty in environmental laboratories, Nordtest Report TR537 (ed.4) 2017. Available from [www.nordtest.info](http://www.nordtest.info).
14. Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp -USDA website: <https://www.ams.usda.gov/rules-regulations/hemp/rulemaking-documents>

#### G. FORMS

1. eWorksheet Hemp\_57\_GC In-Process Hemp Sample Weight

#### H. REVISION

1. Revision 00 on 09/25/2015: Initial Issuance
2. Revision 01 on 07/14/2017 (a) Changed laboratory shaker to Geno Grinder 2010 in section B.h (Justification: to instrumentation purchase. The laboratory shaker was replaced). (b) Added to section C.2 "Sample Drying" that samples 20g and below can be dried in the oven rather than first drying in the drying chamber (Justification: A small amount of sample will dry quicker in the oven). (c) Added to section C.2 "Sample Drying" instruction for drying small amounts of sample in the dryer. (Justification: In order for analysts to know how the sample should be dried). (d) Added to section C.3 "Sample Preparation and Handling" that a mortar and pestle may be used to grind a sample with no stems or seeds. (Justification: for small amounts of sample with no stems or seeds using a mortar and pestle rather than grinder mill will decrease the probability of sample loss). (e) Changed the cleaning procedure in section C.3 so that items are not washed with soap and water first (Justification: blowing with air and rinsing three times in methanol will clean equipment making soap and water unnecessary). Made editorial changes. (f) added attachment 1 "Laboratory Tolerances for THC Levels in Industrial Hemp" (Justification: For further clarification of disposition of crop with levels above 1% THC. (f) Made editorial changes.
3. Revision 02 on 08/16/2019

Change	Justification
a. Moved matrix control, Matrix spike and method control to from the definitions to newly named Standards, Quality Control and Reference Materials	To include in the list of standards and reference materials rather than to define.



Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

b. Removed sample drying procedures	These procedures are outlined in SOP 0282-FD making the section duplicative.
c. Added that weights can be recorded on hard copy forms 57 and 45 or the LIMS eWorksheets 57 and 45	LIMS eWorksheets are now available for use with the implementation of Labworks.
d. Removed the requirement to divide seeds and stems from other plant material prior to homogenization.	The entire plant material will be homogenized for analysis.
e. Updated Table 1	Preparation of the intermediate standard solution was introduced to increase the accuracy of the lowest standard
f. Added to section C.6.e that at least five CCV injections are run prior to starting analysis that should fall below 3% RSD.	To ensure suitability of instrument prior to analyzing samples
g. Changed the sample acceptance criteria to THC concentration greater than 0.399%	To clarify when a sample is considered failed
h. Added a reference to MTD 0502-FD, <i>Analysis of - 9-Tetrahydrocannabinol and Cannabidiol in Hemp by Ultra Powered Liquid Chromatography</i> to section C.11 Sample Acceptance Criteria.	Samples that fail to meet 0.399%THC concentration will be analyzed on using UPLC to confirm the failing result.
i. Changed Section C. 12 Sample disposal to include reference to SOP 0295-FD, <i>Controlled Drug Substances</i> , OISC.	OISC is registered with the DEA as an analytical laboratory for schedule 1 controlled drug substances. Hemp samples failing to meet the 0.399%THC concentration will be considered marijuana and will be treated as a controlled substance.
j. Added references to AOAC Guidelines for Single Laboratory Validation of Chemical methods for Dietary Supplements and Botanical and ICH Harmonised Tripartite Guidelines (2005) Validation of Analytical procedures: Text and Methodology Q2 (R1)	These were referred to during evaluation and validation of this method.
k. Updated Method evaluation - reports – OISC Feed Laboratory, "Analysis of Delta-9-THC and Cannabinol in Hemp by Gas Chromatography" from 9-15-2018 and 09-17-2015 to 06/06/2019 – 06/14/2019.	An evaluation was done for the development of this method. The new dates reflect new data collected.
l. Removed references to Marijuana Potency Testing- Quick and Easy by GC and LC, Restek Application Note	Agilent column is used as an example instead of Restek column.
m. EPA Guidelines, Method 8000C, Determinative Chromatographic Separations, March 2003	EPA Guidelines was replaced with ICH Harmonised Tripartite Guidelines (2005) Validation of Analytical procedures
n. Changed revision history to a table format	In order to make it easier to see the changes and justifications.
o. Made editorial changes	NA

#### 4. Revision 03 on 12/16/2019

Change	Justification
a. Added that samples will be milled though a 1mm sieve	To improve homogeneity.
b. Adding detail in section C.3.d on measurement of moisture content.	For clarification.
c. Removed use of the intermediate standard	Decreases the waste of the stock standard.
d. Section C.7 Quality Control, if samples fall outside the calibration curve, samples will be diluted and retested rather than reported as >1.6	To provide more accurate results
e. Section C.7 Quality Control, added that samples will be retested if duplicates exceed the $\pm 15\%$	To provide guidance
f. Added section C.10 Results to determine final results on a dry weight basis	To comply with state or USDA regulations
g. Measurement of Uncertainty was calculated as combined expanded MU.	To comply with state or USDA regulations



Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

h. Updated acceptance criteria to reflect the measurement uncertainty calculation of $\pm 0.095$ .	Measurement uncertainty was calculated
i. Removed the sentence "For THC values greater than 0.395% to 1.0%, the State Seed Commissioner may review the product for either suitability of use or redirected use, subject to the approval of Indiana State Police. For more information see attachment 1, "Laboratory Tolerances for THC Levels in Industrial Hemp."	To comply with state or USDA regulations
j. Changed reference 9 from ICH Harmonised Tripartite Guidelines (2005) Validation of Analytical procedures: Text and Methodology Q2 (R1) to Wisconsin Department of Natural Resources, April, 1996. PUBL-TS-056-96	Previous ICH reference did not adequately explain the experimental results for LOD and LOQ.
k. Added reference 13 B. Magnuson, T. Naykki, H. Hovind, M.Krysell, E. Sahlin, Handbook for calculation of measurement uncertainty in environmental laboratories, Nordtest Report TR537 (ed.4) 2017. Available from <a href="http://www.nordtest.info">www.nordtest.info</a> .	To determine measurement of uncertainty.
l. Made editorial changes	NA

#### 5. Revision 04 on 08/12/2020

Change	Justification
a. Removed signatures from the cover page.	Approval signatures are captured in QT9 electronically, making the need for handwritten signatures redundant.
b. Definition of matrix control moved before matrix blank solution	For clarification.
c. Added in section C. 3 dried samples will be milled through a sieve no greater than 1.5mm	To comply with USDA testing procedures
d. Changed 1g sample quantity to 2g to determine moisture content	2g sample should provide better repeatability on the moisture analyzer as suggested by the vendor
e. Changed the temperature from 100°C to 95°C to determine moisture content	Moister tested at 95°C is in better agreement with water content determined by Karl Fisher methodology.
f. Changed section C.6.a and added section C.b	For clarification – conditions for alternative longer GC column added
g. Changed the measurement of uncertainty and rounded to two decimal places in table 2.	Revised MU calculation to include within-laboratory repeatability and interlaboratory comparison, following USDA guidance. Results reported to grower are to two decimal places. Changed for consistency.
h. Changed title of reference 5.	The SMPR was published and no longer in-process.
i. Made editorial changes	NA
j. Reference 14 added	Provide USDA guidance

#### 6. Revision 05 on 06/18/2021

Change	Justification
a. Updated equipment used	Pipettes listed did not reflect ranges used in procedure
b. Added definition of total THC	For consistency with USDA documentation
c. Updated references to form 45 and form 57 to eWorksheet HEMP_57	Action item from change control
d. C.3.c – updated sample size from <20g to <10g	For clarification.
e. Added additional standard 1.20% to calibration curve	To provide more accurate results
f. Removed C.5.f "If the solution is not clear, centrifuge and filter through a 0.45 µm, or smaller, syringe filter. This step is meant to prolong the life of the column. If the solution is clear this step is optional."	Filtering sample is not optional
g. Added 0.2µm syringeless filter vials in equipment section and in sample preparation	For clarification.
h. C.7.d. Added duplicate QC samples. Moved from C.7.g	Duplicate samples and QC samples should have the same criteria for run repeatability.

Code:	MTD 0500-FD Rev. 05
Supersedes:	MTD 0500-FD Rev. 04
Issued Date:	06/18/2021
Effective Date:	07/01/2021

## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography

i.	C.7.f Removed retesting the same extracts for failing samples. Added new portions of samples will be extracted and tested.	To provide guidance
j.	C.9.a Added "If one of the calibration standards level is outside the calibration curve it can be omitted as an outlier. However, two or more calibration standards level cannot be omitted."	For clarification.
k.	Table 2: Updated MU% from 0.09% to 0.08%	To provide more accurate results
l.	Made editorial changes	NA

Reviewed:
Reviewed:
Reviewed:

Office of Indiana State Chemist  
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Code:	MTD 0501-IS Rev. 08
Supersedes:	MTD 0501-IS Rev. 07
Issued Date:	12/13/2021
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## METHOD

### Field Sampling of Hemp

Role	Name	Title
Document Owner	D. Brett Groves	Chief Inspector/Auditor
Reviewed and Approved By	Mark LeBlanc, Ph.D.	State Chemist & Seed Commissioner
Reviewed and Approved By	David Snell	Quality Assurance Director

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

#### A. INTRODUCTION

The purpose of this Method (MTD) is to provide instruction for sampling hemp plants in the field to be tested for THC content at the Office of Indiana State Chemist (OISC). The scope of this MTD is limited to OISC feed, seed, and fertilizer inspection staff or other staff authorized, in writing, by the State Seed Commissioner.

#### B. MATERIALS AND INSTRUMENTATION

- a. Garden Shears
- b. Nitrile Gloves
- c. OISC Chain of Custody Seals and Labels
- d. Device for taking pictures
- e. OISC Official identification
- f. Mesh sampling bag of material known to be free from THC
- g. Paper sampling bag of material known to be free from THC
- h. Tool apron
- i. Device for accessing the electronic version of any of the forms referenced in this method e.g., OISC Case Management (OCM) Hemp Collection form
- j. Alcohol/disinfection wipes
- k. Incremental Counter
- l. Unmanned Aerial Vehicle (UAV) or drone

#### C. PROCEDURE

##### 1. Definitions

- a. Atypical plant sample: A uniquely numbered sample not part of the total count collected in a composite field sample, which represents plants that are not like the majority of other plants in the field.
- b. CBD: Cannabidiol
- c. Composite field sample: The combination of individual plant sample collections placed into a sampling bag from a single variety of hemp all of which appear to be similar in growth habit or reported to be the same variety by the grower.
- d. Hemp: *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

- a total delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis including consideration of the measurement of uncertainty.
- e. Plant tissue: the foliage, bud material, inflorescence, stems, involucral leaves and buds, or seeds that may be collected during sampling.
- f. Lot: A contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout the area. The term lot also means the terms “farm”, “tract,” “field,” and “subfield”.
- g. Sample: Material taken from the hemp plant, placed into a sampling bag, and given a sample number.

### 2. Inspector Training

- a. All inspectors sampling hemp shall review and understand this sampling procedure. New inspectors shall train with an experienced inspector in the field until both the new inspector and experienced trainer agree that the new inspector is qualified to sample hemp.
- b. In-field training requirements shall meet or exceed USDA training requirements.

### 3. On-Site Routine Sampling

- a. Growers will contact the OISC by written request 30 days prior to harvesting hemp by completing the Request for Hemp Sampling form found on the OISC Website: <https://www.oisc.purdue.edu/hemp/index.html>.
- b. All sampling will be conducted 30 days prior to the growers anticipated harvest date.
- c. OISC inspectors will contact the grower prior to inspecting to ensure the grower is present during sampling. If grower fails to meet with the inspector, do not sample and contact the Chief Inspector/Auditor or Seed Administrator for further direction.
- d. Once at the inspection site, the field may not match GPS coordinates associated with the OISC hemp license exactly. If the field is off from the OISC hemp license GPS coordinates by approximately one eighth (1/8) mile or more, contact the Chief Inspector/Auditor or Seed Administrator. Do not sample the field, but remain on site until instructed to complete the sampling assignment by the Chief Inspector/Auditor or Seed Administrator.
- e. Contact the Chief Inspector/Auditor or Seed Administrator if size of field or number of plants reported on license application does not match the actual field or greenhouse being sampled.
- f. Present OISC inspection authority identification credentials to the individual(s) being inspected. Present a business card, if needed.

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

- g. Issue a Notice of Inspection to the individual(s) being inspected.

#### 4. Annual Inspections

- a. The Chief Inspector/Auditor will choose growers at random for annual inspection
- b. The annual inspection checklist in OCM will be used to conduct the annual audits.
- c. If sampling of growers coincides with the annual inspection, it shall be completed as in C.2.

#### 5. For Cause Sampling

- a. If a tip or complaint regarding an unlicensed grower, incorrect GPS coordinates, or unusual activities occurs, OISC will contact the State Police.
- b. If, after the State Police have investigated and a request for an OISC inspector to sample occurs, OISC will require the State Police to escort the OISC inspector while completing the task.
- c. If the grower is in attendance during the inspection, the inspector will present OISC inspection authority identification credentials and the Notice of Inspection.
- d. Section C.5 will be followed for sampling.

#### 6. Sampling

- a. To collect samples, the inspector shall inspect the entire field of plants including the borders, corners, and middle. Each variety of hemp should be sampled separately to comprise a composite sample provided the varieties are not commingled.
- b. The use of unmanned aerial vehicles (UAVs), or drones, may be used to photograph or survey a field.
- c. Hemp grown for CBD, other cannabinoid extracts, or for other purposes in lots  $\leq 1$  acre collect 5 buds by cutting from the flowering tops of plants, when flowering tops are present, approximately five to eight inches in length from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), or “central cola” (cut stem that develops into a bud) of the flowering top of the plant.
- d. For lots of hemp greater than 1 acre, collect five (5) buds plus one (1) bud for each additional acre from the flowering tops of plants, when flowering tops are present, approximately five to eight inches in length from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), or “central cola” (cut stem that develops into a bud) (see table 1). For all fields that are in-between acreage, round up to the larger acre size (e.g 1.2 acres would be 2 acres of minimum samples).

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

**Table 1**

<b>Acres</b>	<b>Minimum samples</b>
≤1	5
2	6
3	7
4	8
5	9
6	10
7	11
8	12
9	13
10	14
≥11	15

- e. Garden shears shall be cleaned using alcohol wipes prior to taking a sample and in-between sampling different varieties.
- f. Use only one set of gloves per sample.
- g. An incremental counter can be used by the inspector to count the number of samples taken.
- h. Each variety sampled will be given a unique identification number.
- i. Sample stickers will be issued to inspectors at the beginning of the year and on as needed basis.  
[2]
- j. Samples of atypical plants should be taken as unique samples and not mixed with the composite sample. Samples should be marked as atypical with description(s) in the comments section on hard-copy OISC Form 39 Field Sampling of Hemp and the OCM electronic OISC Hemp Collection eform.
- k. If possible, take a photograph of the atypical plant next to a typical plant prior to sampling in order to compare the atypical plant(s) to other typical plants in the field.
- l. If atypical plants look similar, they can be collected as a composite sample and given the same sample identification number. If the inspector is unsure whether the atypical plants are similar in appearance, each will be sampled separately and given unique field sample numbers.

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

- m. Composite samples shall be placed in a mesh sampling bag sealed with chain of custody labels. Tie-off the mesh sampling bag as close to the opening of the bag as possible and wrap the chain of custody label around the knot.
- n. Mesh sampling bags can be placed in paper sampling bags to prevent loss of plant material and possible cross-contamination.
- o. Samples shall be kept in a cooler with a frozen gel pack when being transported or stored.

#### 7. Post-Harvest Appeal Sampling Procedures

- a. Growers may appeal %THC results if under 1% THC and within OISC laboratory's measurement of uncertainty [7].
- b. Growers must harvest the crops and either remove all buds and homogenize the remainder of the crop or homogenize the entire crop, including the buds.
- c. If buds are removed prior to homogenization, verification of bud removal must be sent to the Seed Administrator.
- d. Inspectors must ensure the entire, post-harvest variety is accounted for and uniform.
- e. If the entire post-harvest variety is not accounted for or uniform, do not sample and contact the Chief Inspector/Auditor or Seed Administrator for instructions.
- f. Sample by either doing a grab-sample with your hand or use a one (1) cup measuring cup.
- g. Official post-harvest, appeal samples will consist of either five (5) handfuls or five (5) cups of homogenized hemp sample.
- h. Use new nitrile gloves for each variety being sampled.
- i. Randomly collect at least one cup or one handful of material per post-harvest container. If there are less than five containers of the variety, randomly chose five samples from the containers present.
- j. Place the official post-harvest, appeal sample in a paper sampling bag.
- k. Seal the paper bag with a chain of custody seal [2].
- l. A separate official post-harvest, appeal sample must be taken for each variety.
- m. Samples shall be kept in a cooler with a frozen gel pack when being transported or stored.

#### 8. Documentation of Samples



Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

- a. Complete the appropriate sections of the OCM electronic OISC Hemp Collection Form and the hard-copy OISC Form 39, Hemp Field Sampling.
- b. Sample number, variety, number of samples taken from that variety, type of plant material sampled, and if the plant is atypical will be documented as well as any comments or descriptions that need to be included on the OCM electronic Hemp Collection form and Form 39.
- c. Sample number stickers may be added directly to Form 39, Hemp Field Sampling, during sampling.
- d. Form 90, Receipt of Sample, will be filled-out and signed by the inspector to document all samples collected from the hemp grower.
- e. The hemp grower should sign Form 90, Receipt of Sample, acknowledging the samples taken by the inspector. If the hemp grower refuses to sign Form 90, Receipt of Sample, the inspector will document this on the form.
- f. Any supporting documentation given to the inspector by the hemp grower will be attached to Form 90, Receipt of Sample.
- g. Hemp Sample Chain of Custody Task in OCM, will be used when relinquishing custody of samples to OISC personnel. Samples may be relinquished to another inspector or OISC representative to deliver to the laboratory. A laboratory representative must electronically sign the OCM Chain of Custody Task and affirm delivery when samples are relinquished to the hemp laboratory.
- h. If there is evidence of tampering or a difference between the number of samples taken from the hemp grower and the number of samples submitted to OISC personnel, or the laboratory, the Chief Inspector/Auditor and the Quality Assurance Unit will be notified and a CAPA will be opened [3].
- i. Maintenance of the samples will be done according to SOP 0282-FD [4].
- j. Form 39, Hemp Field Sampling and Form 90, Receipt of Sample are considered non-critical paper forms [5].

### 9. Procedure Safety Considerations

- a. By Indiana Law (IC 15-15-13-9(c)) inspections conducted by OISC that target records held by a grower or handler, the grower or handler must be given at least three (3) days-notice prior to an

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

audit of records. This advance notice applies to record audits, not to growing crops or handler sites.

- b. Always notify your supervisor of what hemp field sites you are visiting, days, and approximate times, and update immediately if any changes are to be made in the day's schedule.
- c. Courtesy communications will be made with Indiana State Police and local law enforcement to alert them as to when and where OISC inspectors will be in fields and related information. This communication may assist in avoiding delays when encountering law enforcement personnel.
- d. Use caution when asked to ride with a grower in their vehicle or other mode of transportation. Where possible, follow in your own vehicle. Hemp is not a species that can be abused for recreational use. However, if you encounter persons that you do not recognize as authorized persons at the growing site, or encounter situations that cause you concern, leave the field and site immediately and contact your supervisor or the state police as appropriate.
- e. See SOP 0271-GN, *Avoiding Violent Confrontation for OISC Field Staff* for additional information [6].

#### 10. Electronic Records and Documentation Preservation

- a. Legible electronic evidence may be created from hard-copy evidence by scanning or photographing.
- b. Convert all pertinent documents, records, and forms to a legible electronic format and attach with the OCM hemp collection eform. Retain hard-copies of documentation until the Chief Inspector/Auditor, or designee confirms that the OCM documentation data has been created.
- c. Attach all photographs to the appropriate OCM hemp collection eform.
- d. Electronic evidence documentation should be created and entered into OCM as soon as practical after it has been collected.
- e. Records, either electronic or hard-copy, shall be retained for five (5) years.

#### D. REFERENCES

1. MTD 0500-FD "Analysis Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography", OISC
2. SOP 0223-IN "Feed, Fertilizer and Seed Inspections" OISC
3. SOP 0226-GN "Corrective and Preventive Action", OISC
4. SOP 0282-FD "Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist", OISC

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175 S. University St.  
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Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

5. SOP 0275-GN “Paper Form Control”, OISC
6. SOP 0271-GN, “Avoiding Violent Confrontation for OISC Field Staff”, OSIC
7. MTD 0502-FD, “Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography”, OSIC

#### E. FORMS

1. Form 39 Field Sampling of Hemp
2. Form 90, Receipt for Samples

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

#### F. REVISION

1. Revision 00 on 08/28/2015 (a) Initial Issuance
2. Revision 01 on 07/03/2019 (a) Added Unmanned Aerial Vehicles (UAV) or drone to the materials and instrumentation list, (Justification: UAVs and drones are synonymous and can be used during sampling). Added to section C.2 On-Site Routine Sampling that growers will contact OSIC 30 days prior to harvesting and that grow-sites will be chosen randomly. (Justification: hemp will be sampled 30 days prior to harvest and the decision is made by the Chief Inspector/Auditor which ones will be sampled). (c) Added to section C.2 On-Site Routine Sampling that GPS coordinates of the site will be checked prior to sampling the field. If GPS coordinates do not match when the inspector is sampling, the Chief Inspector/Auditor and State Chemist and Seed Commissioner will be contacted. (Justification: to describe the practice. Hemp fields that do not match GPS coordinates given at the time of licensing are considered marijuana). (d) Changed section C.2.k to state the chain of custody seal will be affixed to the sampling bag rather than “stapled”. (Justification: the seal is not stapled). (e) Added to section C.4 Sampling that at least 30 flower heads will be collected from hemp grown for CBD and that flower heads are not collected from hemp grown for fiber, feed or seed oil. (Justification: CBD is extracted from the flower head and therefore will be tested for THC content while fiber, feed or seed oil plants do not go through an extraction process). (f) Added to section C.4 Sampling that the samples will be kept in a cooler with a frozen gel pack for no longer than two days. (Justification: Samples can be kept cool for two days in the cooler in order for inspectors to drop off to the laboratory). (g) Changed Form 39 title from Field Sampling of Industrial Hemp to Hemp Field Sampling. (Justification: the term industrial hemp is no longer used). (h) Added to Form 39 Type of hemp being sampled. (Justification: to document this information). Form 39 is now on Rev. 01. (i) Removed the chain of custody page from form 39 and made it its own form, Form 99 Hemp Sample Chain of Custody. (Justification: samples may be transferred from inspector to inspector or OSIC personnel then to the laboratory. This form captures the full chain of custody). (j) Added SOP 0271-GN “Avoiding Violent Confrontation for OISC Field Staff” as a reference. (Justification: for inspectors’ instruction on how to avoid violent confrontation). (k) Added section C.7 Electronic Records and Documentation Preservation. (Justification: to give guidance that all hard copy records must be converted to electronic to attach in OCM as well as any photographs taken, and that all public records are retained for five years). (l) Added that a courtesy call to the hemp extension specialist may be made. (Justification: To communicate to extension where sampling is happening by OISC. The hemp extension specialist may want to be present during sampling. (m) Added that the field if the OISC hemp license GPS

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

coordinates by approximately one eighth (1/8) mile or more, contact the Chief Auditor/Inspector or Seed Administrator. Do not sample the field, but remain on site until instructed to complete the sampling assignment by the Chief Inspector/Auditor or Seed Administrator. (Justification: To provide guidance on how far off the coordinates a field may be, before no longer being considered hemp). (n) Made editorial changes.

3. Revision 02 on 12/16/2019:

Change	Justification
a. Added “bud material” and “stems” to the definition of plant material	For clarification
b. Added OISC the grower must submit written request for field sampling and to contact the Chief Inspector/Auditor or Seed Administrator if size of field or number of plants reported on license application does match the actual field or greenhouse you are sampling.	To provide guidance that the grower submission for sampling must be a written request.
c. Added to contact the Chief Inspector/Auditor or Seed Administrator if size of field or number of plants reported on license application does match the actual field or greenhouse you are sampling.	As guidance for the inspector to contact the Chief Inspector/Auditor or Seed Administrator should the number of plants not match the license.
d. Added instruction to section C.4 Sampling differentiating between hemp plants and verified clones	These hemp plants will be sampled differently. Instruction was added to provide guidance.
e. Made editorial changes	NA

4. Revision 03 on 12/19/2019

Change	Justification
a. Changed “the grower must submit written request for field sampling and to contact the Chief Inspector/Auditor or Seed Administrator if size of field or	The word “not” was omitted from the sentence. Inspectors should contact the Chief Inspector/Auditor or Seed Administrator if the size of field or number of plants reported on

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

number of plants reported on license application does match the actual field or greenhouse you are sampling.” To “the grower must submit written request for field sampling and to contact the Chief Inspector/Auditor or Seed Administrator if size of field or number of plants reported on license application does <b>not</b> match the actual field or greenhouse you are sampling,” in section C.2.d	the license application does not match the field.
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#### 5. Revision 04 on 08/11/2020

Change	Justification
a. Added that samples will be collected prior to 15 days from harvest.	To comply with USDA requirements for state hemp plans.
b. Added section C.3 Annual Inspections	To comply with USDA requirements for state hemp plans.
c. Made editorial changes	NA

#### 6. Revision 05 on 09/21/2020

Change	Justification
d. Removed “If varieties are comingled, sample as a mixed field.” From section C.5 Sampling	Each lot will be sampled separately.
e. Changed sampling to cutting the bud 1 to 1.5 inches of the plant in section C.5 Sampling for all hemp plant types	Only the bud will be sampled.
f. Removed “Stems and seeds may be collected during the sample collection process but are not necessary,” in section C.5 Sampling.	Stems and seeds will not be collected during the sampling process.

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

g. Made editorial changes	NA
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#### 7. Revision 06 on 05/21/2021

Change	Justification
a. Added the definition of lot to the definitions section.	To provide guidance and comply with the USDA final hemp rule.
b. Changed amount of sample collected in section C.5 Sampling, from 1 to 1.5 inches to 5 to 8 inches and included additional information regarding what part of the plant is sampled.	The USDA Final Hemp Rule Sampling Procedures requires 5-8 inches of the top of the plant and what part of the plant be collected while sampling. MTD was updated to comply.
c. Added post-harvest appeal sampling, section C.6	USDA Final Hemp Rule allows for post-harvest appeal. Sampling procedures were added to provide guidance and comply with the final rule.
h. Removed “Not all grow-sites will be sampled by OISC in the state of Indiana. Grow-sites will be chosen randomly by the Chief Inspector/Auditor i. Grow-sites not sampled by OISC will be sampled by Certified Crop Advisors (CCA).” From C.2	All grow-sites will be sampled, by OISC inspection staff, not CCAs.
f. Removed “The Purdue Extension Hemp Specialist, may be contacted prior to sampling a field either through <a href="mailto:hemp@purdue.edu">hemp@purdue.edu</a> or at 765.496.1567, and may choose to be present during the sampling process, however; this courtesy communication will not delay inspector sampling of a field” from section C.8	This will no longer be available to growers.
g. Added a reference to MTD 0502-FD, “Analysis of Delta- 9-	Post-harvest appeal sampling allows for post-harvest appeal of those plants less than 1% THC and within the laboratory’s measurement

Code:	MTD 0501-IS Rev.078
Supersedes:	MTD 0501-IS Rev.07
Issued Date:	12/13/2021
Effective Date:	01/13/2022

## METHOD

### Field Sampling of Hemp

Tetrahydrocannabinol in Hemp by Liquid Chromatography”, OSIC	of uncertainty. 1% THC measurement of uncertainly is calculated in the reference LC method.
h. Made editorial changes	NA

8. Revision 07 on 11/10/2021

Change	Justification
a. Remove reference to form 99 Hemp Chain of Custody	Electronic chain of custody task in OCM implemented; form 99 is obsolete.
b. Made editorial changes	NA

9. Revision 08 on 12/13/2021

Change	Justification
c. Added C(2) “Inspector Training” section to require new inspectors to be trained by experienced inspectors, and are required to meet or exceed USDA training requirements	To comply with USDA requirements for state hemp plans.



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175 S. University St.  
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Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
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## METHOD

### Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

Role	Name	Title
Document Owner	H. Dorota Inerowicz, Ph.D.	Feed Chromatography Laboratory Supervisor
Reviewed and Approved By	Ping Wan	Pesticide Laboratory Supervisor
Reviewed and Approved By	Courtney Moore	QA/QC Specialist

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

### A. INTRODUCTION

This method (MTD) establishes guidelines for the analysis of hemp. The scope of this MTD is limited to preparation of hemp plant material for analysis followed by determination of THC level by Liquid Chromatography with UV detection.

### B. MATERIALS AND INSTRUMENTATION

#### 1. Standards, Quality Control and Reference Materials

- a. Cannabinoids standard, 1000 µg/mL, each THC, CBD, CBN from Restek or other supplier
- b.  $\Delta^9$ -Tetrahydrocannabinol (THC) standard, 1000 µg/mL from Cerilliant, Restek, or other reference standard supplier
- c.  $\Delta^9$ -Tetrahydrocannabinolic Acid (THC-A), 1000-µg/mL from Cerilliant or another supplier
- d. Matrix control: Plant material (oregano, spinach, or hemp samples, previously tested and found to contain no detectable THC) matching the hemp matrix and containing no analyte of interest
- e. Matrix spike: A test portion of matrix control fortified with a known concentration of THC or THCA. (This will only be needed if no QC sample is available for analysis.)
- f. Quality reference material from the PT Hemp program will be analyzed as QC samples.
- g. Method control: A solvent (extractant) blank to which is carried through the entire analytical procedure
- h. Solvent control: A solvent used as an extractant

#### 2. Reagents

- a. Methanol: Fisher Scientific, American Chemical Society (ACS) grade or equivalent

#### 3. Equipment:

- a. Liquid Chromatograph: Instrument capable of solvent mixing and of maintaining a constant pulseless flow of mobile phase. Acquity H-class UPLC system with UV detector from Waters or equivalent. Waters Alliance HPLC can be used as equivalent with Waters 996 PDA detector.
- b. Analytical column: Restek Raptor ARC-18 100 mm X 2.1 mm ID or equivalent
- c. Balance: Top loading balance with at least two decimal place reading with capacity equal or greater to the maximum gross weight of the samples to be weighed.
- d. Moisture analyzer: Mettler Toledo HC103 Halogen Moisture Analyzer or equivalent
- e. Cutting mill or grinder: Magic Bullet food blender, grains grinder or another suitable grinder
- f. Sieve: 1.5 mm or smaller
- g. Geno Grinder 2010 or equivalent shaker
- h. Pipettes capable of measuring 3 to 1000 µL
- i. Syringes for filtering samples if syringeless filter vials are not used
- j. 0.2 µm PTFE syringe filters or syringeless filter vials

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

- k. 50 mL Centrifuge tubes, preferably low binding centrifuge tubes
- l. Plastic specimen cups with caps
- m. 50 mL Bottle top dispenser compatible with methanol

### C. PROCEDURE

#### 1. Definitions

- a.  $\Delta^9$ -Tetrahydrocannabinol (THC): A cannabinoid, the primary psychoactive compound occurring naturally in marijuana and hemp.
- b.  $\Delta^9$ -Tetrahydrocannabinolic Acid (THC-A): acidic form of THC occurring in the raw hemp plants. THC-A decomposes to THC by decarboxylation at about 125 ~ 150 °C.
- c. Cannabinol (CBN): A cannabinoid occurring mostly as a metabolite of tetrahydrocannabinol.
- d. Hemp: Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.
- e. Equivalent: Instrumentation, materials, or equipment equal in value that will not change the outcome of results.
- f. Total %THC: The percent THC reported after analysis which is the sum of the percentage by weight of THC-A multiplied by 0.877 plus the percentage by weight of THC. Calculated according to the USDA definition of total THC, see below: "Total THC is the value determined after the process of decarboxylation, or the application of the conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total delta-9 tetrahydrocannabinol content derived from the sum of the THC and THCA content and reported on a dry weight basis. This post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, such as gas chromatography through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in each sample. The total THC can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact. This technique requires the use of the following conversation: [total THC = (0.877 x THCA)+THC] which calculates the potential total THC in a given sample [13].

#### 2. Sample Drying

- a. If performing confirmation testing from a failing GC analysis, a new sample will be taken from the reserve stored in freezer.
- b. Samples are to be dried according to SOP 0282-FD [1].

#### 3. Sample Preparation and Handling

- a. If performing confirmation testing from a failing GC analysis, grinding of sample will not occur since reserve sample will be used. Ensure reserve sample is brought to room temperature prior to measuring moisture content.

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

- b. All weights captured in the process of sample preparation are recorded in the LabWorks eWorksheet Hemp\_57\_LC, or on a hard copy of eWorksheet Hemp\_57\_LC [1].
- c. Dried samples are milled through a sieve no greater than 1.5 mm screen to obtain a uniform, powder-like consistency.
- d. Small-size samples (<10g) can be homogenized to powder-like consistency with a mortar and pestle.
- e. After homogenization, the moisture content is determined by testing approximately 2g of sample at 95°C with a moisture analyzer. The percent moisture is recorded in the eWorksheet Hemp\_57\_LC; tab 57.b\_RESERVE\_WT. If sample weight is less than 10g then approximately 1g portion will be used for moisture analysis.
- f. If the moisture content is above 15% [2, 3], additional oven drying of the sample is necessary. The additional drying time is decided by the analytical chemist and should be kept to a minimum amount of time to obtain an adequate result. Typically, additional drying is less than one hour.
- g. The grinder and mortar and pestle must be cleaned between each sample using the following steps:
  - First brush the cutting mill, grinder, or mortar and pestle.
  - Second spray them with a jet of air.
  - Rinse them at least three times with ethanol.
  - Finally, air-dry either by simple exposure to air or by contact with a directed stream of air.
- h. All the samples in their pre-labeled specimen cups will be stored in a locked freezer or refrigerator. The standard will be stored in a locked freezer.

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

### 4. Calibration Standards Preparation

- a. The stock standard solution is a mixture in methanol of 1000 µg/mL, each CBD, CBN, THC from Restek or equivalent.
- b. The THC-A stock standard solution is 1000-µg/mL THC-A from Cerilliant or equivalent.
- c. The THC stock standard solution is 1000-µg/mL THC from Cerilliant or equivalent.
- d. Six calibration standards at the levels listed in the Table 1 are prepared in methanol as follows: add 1000µL of methanol to each HPLC vial. Remove the specified volumes of methanol individually, (notice that multiple standards are added) and replace it with the same volume of standard stock solutions (C.4.a and C.4.b).

Table 1 Preparation of Calibration Standard Solutions

Level	Standard (µg/mL)	Amount (µL)	Dilution (mL)	Concentration (µg/mL)	%THC, THC-A
6	1000	80	1.0	80	1.6
5	1000	40	1.0	40	0.8
4	1000	20	1.0	20	0.4
3	1000	10	1.0	10	0.2
2	1000	5	1.0	5	0.1
1	1000	3	1.0	3	0.06

- e. The continuing calibration verification standards (CCV) are prepared at 10 µg/mL by mixing THC and THC-A standard stock solutions in methanol (C.4.b and C.4.c). Follow the same procedure of preparation as the calibration standards.

### 5. Sample Preparation

- a. Prepare the hemp sample as described in C.3: Sample Preparation and Handling.
- b. Weigh 0.2 g ± 0.05 g prepared hemp sample into a 50-mL centrifuge tube and record the weight.
- c. Add 40 mL methanol to the centrifuge tube. Cap and shake to ensure that the entire sample is wet.
- d. Place on the Geno Grinder 2010 and shake for 5 min.
- e. Allow suspended material to settle for at least one hour.
- f. Filter sample through a 0.2µm PTFE syringe filter into a 2 mL amber GC autosampler vial or use 0.2µm syringeless filter vials.
- g. Remaining sample extract will be stored in the locked sample freezer until analysis is completed.
- h. Method blank: Transfer 40 mL methanol to a 50 mL centrifuge tube and shake for 5.0 minutes.

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

### 6. Sample Analysis: Chromatographic Conditions

- a. Analysis is performed on UPLC. Two different analysis conditions are given below, bullet points c and d.
- b. Operation of the UPLC system with PDA detector will be in accordance with Acquity UPLC H-Class System Guide, Waters [4].
- c. Method using Restek column
  - Column: Restek Raptor ARC-18 100 mm X 2.1 mm ID, guard column from Restek or equivalent
  - Column temperature: 50°C.
  - Mobile Phase: A: 0.1% formic acid in water, Channel B: 0.1% formic acid in acetonitrile, Gradient, A:B: 25:75 initial to 0:100 at 4.67 min, back to 25:75 at 4.68 min, continue 25:75 up to 6.67min
  - Flow rate: 0.310 mL/min
  - Injection volume: 2 µL
  - Detection wavelength: 220 nm
- d. Method using Waters column
  - Column: Waters Cortecs UPLC Shield RP18 1.6 µm, 100 x 2.1 mm
  - Column temperature: 35 °C
  - Mobile phase: A; 0.1% TFA in Water : B; Acetonitrile (41:59) isocratic
  - Flow rate: 0.7 mL/min
  - Injection volume: 2 µL
  - Detection wavelength: 228 nm
- e. Instrument parameters may be adjusted to optimize chromatography.
- f. Equivalent columns can be used

### 7. Quality Control

- a. Each set of samples is required to contain a method control and solvent control run at least one time, as well as a quality control sample (QC) to be run in duplicate. Each sample set is required to contain a randomly chosen sample to be run in duplicate.
- b. If no QC sample is available, then a matrix spike must be prepared and analyzed in place of the QC sample.
- c. Instrument response for samples should be within the method calibration range. If the instrument response for THC or THC-A, is greater than highest calibration standards, the sample extract will be diluted with the extraction solvent to fall within the calibration range.
- d. Results for duplicate samples, including QC samples, should be within  $\pm 15\%$  of each other. If results for duplicates exceed  $\pm 15\%$ , new portion of the samples will be extracted and re-tested.
- e. The Method Control (method blank) should not contain THC or THC-A at a level greater than the method's limit of detection (LOD).

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

- f. Duplicate QC samples are analyzed in all sample sets. If available, Quality Reference Material (QRM) can be used as a QC sample. The results for THC, THC-A concentration should be within set limits based on earlier analyses of the sample. These limits are  $\pm 2$  standard deviations from the mean of previous determinations. If either one of the QC duplicate results falls outside  $\pm 2$  standards deviation but is within  $\pm 3$  standard deviations the QC results are still acceptable. If both QC results are outside  $\pm 3$  standard deviations, the sample set results are rejected. New portions of the samples and the QC sample will be extracted and retested.

### 8. Matrix Spike Preparation

- a. For inclusion in the sample set when no QC is available, a 0.20g matrix control is fortified by addition of 0.2 mL of THC stock standard solution (1000  $\mu\text{g/mL}$ ) and 0.2 mL of THC-A standard stock solution to 0.20g of matrix control. The equivalent level of each THC and THC-A in the hemp sample is 0.1%. Below is the calculation for the percent THC in the hemp sample. A similar calculation would also be used to determine the THC-A percentage.

$$[(0.2 \text{ mL volume of spike solution}) \times (1000 \mu\text{g/mL THC stock standard solution}) / 0.2 \times 10^6 \mu\text{g matrix control sample}] \times 100\%$$

- b. For the matrix spike in the range 0.05 - 0.5% recovery should fall within the limits of 85 - 118 % according to AOAC SMPR 2019.003 Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.) [5].

### 9. System Suitability – Acceptance Criteria

- a. The calibration correlation coefficient ( $r^2$ ) must be  $\geq 0.995$ . The set of calibration standards are required to be run at least two times, at the beginning and the end of the sequence. If one of the calibration standards is outside the calibration curve it can be omitted as an outlier, but two calibration standards cannot be omitted as outliers.
- b. Calibration integrity will be calculated for each set of samples by running a CCV standard. Standard at the level of 10  $\mu\text{g/mL}$  will be used as a CCV and should be prepared separately, preferably from standard stock solution from a different vendor. The results of calibration integrity will be documented in the sample set report. Continuing calibration verification results should be within  $\pm 15\%$  accuracy.
- c. CCV injections are required to be included in the sample sequence at the beginning of the sample set and at the end of the sample set.
- d. CCV injections are also required to bracket sample injections with a maximum of 5 samples.



Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

- e. The relative standard deviation (%RSD) for at least five injections of CCV must be less than 2.5%. If results fail to meet accuracy and %RSD expectation, results from the sample set are rejected. The sample extracts will be re-tested.

### 10. Results

- a. The percentage of THC on as is basis is the sum of the percentage by weight of THC-A multiplied by 0.877 plus the percentage by weight of THC.
- b. Results will then be calculated based on dry weight basis according to the following formula:

$$\%THC_{dry\ weight\ basis} = \frac{\%THC_{as\ is\ basis}}{\left(\frac{100 - M}{100}\right)}$$

M – % moisture content as determined by moisture analyzer

%THC<sub>as-is basis</sub> – THC level (%) determined by instrument software before adjustment for moisture content.

%THC<sub>dry weight basis</sub> – THC level (%) after adjustment for moisture content

- c. Results will be reported in % to two decimal places.
- d. Results are reported as a total %THC<sub>dry weight basis</sub>.

### 11. Accuracy, Precision, Measurement Uncertainty and Detection Limits

- a. Single-Laboratory Method Evaluation was performed on the new Acquity H-class UPLC system in June/July 2019 (June 11- August 1, 2019) [6] according to the AOAC *Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanical* [7].
- b. Accuracy was determined by analyzing two sets of 5 replicates of matrix blank for each analyzed commodity. THC and THCA were spiked at 0.1% and 0.3% level.
- c. To evaluate the repeatability (precision) as %RSD, four replicates of the QRM samples were tested on three days. The within-day, between-day, and total standard deviations were calculated.
- d. The combined expanded measurement uncertainty (MU) was determined by considering repeatability within laboratory ( $u_r$ ), accuracy ( $u_{bias}$ ) and  $u(Cref)$ , the last two terms based on the calculations from interlaboratory comparison (proficiency testing). A coverage factor  $k = 2$  was used in the calculations, providing a level of confidence of approximately 95% [12,13].
- e. The Limit of Detection (LOD) and Limit of Quantitation (LOQ) were calculated according to the ICH Harmonised Tripartite Guidelines [8] as  $LOD = 3.3\sigma/S$  and  $LOQ = 10\sigma/S$ , where  $\sigma$  is standard deviation of the response and  $S$  = slope of the calibration curves of each tested cannabinol.



Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

Table 2 Results of accuracy, precision, measurement of uncertainty, LOD and LOQ

Cannabinoid	Accuracy (%)	Precision (%)	LOD (%)	LOQ (%)	MU (%)
THC	113	6.9	0.01	0.04	
THCA	94	2.1	0.01	0.04	
THC total					±0.10

### 12. Sample Acceptance Criteria

- a. If THC concentration analyzed by gas chromatography [9] is greater than 0.38%, the samples are considered failing and will be retested using a new sample portion by this MTD.
- b. Retesting by this MTD is used as a confirmation method and LC results are reported as a final.
- c. A LC test result greater than 0.40% THC will be considered conclusive evidence that at least one Cannabis plant, or part of a plant, from the composite sample [10] contains a THC concentration over the limit allowed for hemp.

### 13. Upper Limit for Appeal Samples

- a. Measurement of uncertainty for the samples at the level 1% of THC were determined as ±0.18%. These criteria refer to remediated, appeal samples.

### 14. Column Shutdown Procedure and Storage Conditions

- a. The UPLC method that uses the Restek Raptor ARC-18 100 mm X 2.1 mm ID column and the Restek guard column should be flushed with acetonitrile and water to remove the formic acid from the system. The column should be stored in Acetonitrile:Water [60:40].
- b. The UPLC method using the Waters Cortecs UPLC Shield RP18 1.6 µm, 100 x 2.1 mm should be flushed with acetonitrile and water to remove trifluoroacetic acid from the system. The column should be stored in 100% Acetonitrile.

### 15. Sample Disposal

- a. After the sample results have been submitted to the client, the sample extracts, analytical extracts, and the raw samples will be submitted for disposal and collected by REM. See a sample disposal procedure in the SOP 0282-FD [1].
- b. The raw samples with THC levels failing to meet acceptance criteria will be treated as a Schedule 1 controlled substance [11]. Analytical extracts for those samples will be submitted for disposal and collected by REM [1].

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

### D. CALCULATIONS

1. Calculation for percent THC in hemp sample

$$[(0.2 \text{ mL volume of spike solution}) * (1000 \text{ } \mu\text{g/mL THC stock standard solution}) / 0.2 \times 10^6 \text{ } \mu\text{g matrix control sample}] * 100\%$$

2. Calculation for determining % THC on dry weight basis.

$$\%THC_{dry \text{ weight basis}} = \frac{\%THC_{as \text{ is basis}}}{\left(\frac{100 - M}{100}\right)}$$

M – % moisture content as determined by moisture analyzer

%THC<sub>as-is basis</sub> – THC level (%) determined by instrument software before adjustment for moisture content.

%THC<sub>dry weight basis</sub> – THC level (%) after adjustment for moisture content

- a. Results will be reported in % to two decimal places.
- b. Results are reported as a total %THC<sub>dry weight basis</sub>.

### E. SAFETY

1. No additional safety requirements

### F. REFERENCES

1. SOP 0282-FD, *Storage, Handling, Accountability, and Disposal of Industrial Hemp at the Office of Indiana State Chemist*, OISC
2. Industrial Hemp, Technical Manual, Health Canada, September 1, 2000
3. Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products – manual for use by National Drug Analysis Laboratories, United Nations Office on Drug and Crime, 2009
4. Acquity UPLC H-Class System Guide, Waters Corporation  
[https://www.waters.com/webassets/cms/support/docs/acquity\\_uplc\\_h-class\\_system\\_guide.pdf](https://www.waters.com/webassets/cms/support/docs/acquity_uplc_h-class_system_guide.pdf)
5. AOAC SMPR 2019.003 Standard Method Performance Requirements (SMPRs) for *Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties Cannabis sp.)*.
6. Method evaluation - reports – OISC Feed Laboratory, “Method Evaluation for Total Delta-9-Tetrahydrocannabinol and Total Cannabidiol in Hemp by Liquid Chromatography” 06/11/2019 – 08/1/2019.
7. AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanical

Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
Issued Date:	07/15/2021
Effective Date:	07/15/2021

## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

8. ICH Harmonised Tripartite Guidelines (2005) Validation of Analytical procedures: Text and Methodology Q2 (R1).
9. MTD 0500-FD Rev02, *Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Gas Chromatography*, OISC
10. MTD 0501-IS, *Field Sampling of Hemp*, OISC
11. SOP 0295-FD, *Controlled Drug Substances*, OISC
12. B. Magnuson, T. Naykki, H. Hovind, M. Krysell, E. Sahlin, Handbook for calculation of measurement uncertainty in environmental laboratories, Nordtest Report TR537 (ed.4) 2017. Available from [www.nordtest.info](http://www.nordtest.info)
13. Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp -USDA website: <https://www.ams.usda.gov/rules-regulations/hemp/rulemaking-documents>

### G. FORMS

1. eWorksheet Hemp\_57\_LC In-Process Hemp Sample Weight

### H. REVISION

1. Revision 00 on 09/16/2019: Initial Issuance
2. Revision 01 on 12/16/2019:

Change	Justification
a. Added that samples will be milled through a 1mm sieve	To improve homogeneity.
b. Adding detail in section C.3.d on measurement of moisture content.	For clarification.
c. Removed use of the intermediate standard	Decreases the waste of the stock standard.
d. Section C.7 Quality Control, if samples fall outside the calibration curve, samples will be diluted and retested rather than reported as >1.6	To provide more accurate results
e. Section C.7 Quality Control, added that samples will be retested if duplicates exceed the $\pm 15\%$	To provide guidance
f. Added section C.10 Results to determine final results on a dry weight basis	To comply with state or USDA regulations
g. Measurement of Uncertainty was calculated as combined expanded MU.	To comply with state or USDA regulations
h. Updated acceptance criteria to reflect the measurement uncertainty calculation of $\pm 0.089$ .	Measurement uncertainty was calculated
i. Removed the sentence "For THC values greater than 0.395% to 1.0%, the State Seed Commissioner may review the product for either suitability of use or redirected use, subject to the approval of Indiana State Police. For more information see attachment 1, "Laboratory Tolerances for THC Levels in Industrial Hemp."	To comply with state or USDA regulations
j. Added reference 12 B. Magnuson, T. Naykki, H. Hovind, M. Krysell, E. Sahlin, Handbook for calculation of measurement uncertainty in environmental laboratories, Nordtest Report TR537 (ed.4) 2017. Available from <a href="http://www.nordtest.info">www.nordtest.info</a> .	To determine measurement of uncertainty.
k. Made editorial changes	NA

3. Revision 02 on 08/12/2020

Change	Justification
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Code:	MTD 0502-FD Rev. 03
Supersedes:	MTD 0502-FD Rev. 02
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## Analysis of Delta- 9-Tetrahydrocannabinol in Hemp by Liquid Chromatography

a. Removed signatures from the cover page.	Approval signatures are captured in QT9 electronically, making the need for handwritten signatures redundant.
b. Definition of matrix control moved before matrix blank solution	For clarification.
c. Added in section C. 3 dried samples will be milled through a sieve no greater than 1.5mm	To comply with USDA testing procedures
d. Changed 1g sample quantity to 2g to determine moisture content	2g sample should provide better repeatability on the moisture analyzer as suggested by the vendor
e. Changed the temperature from 100°C to 95°C to determine moisture content	Moister tested at 95°C is in better agreement with water content determined by Karl Fisher methodology.
f. Changed section C.6.a and added section C.b	For clarification-conditions for UPLC column were updated and conditions for alternative column were added
g. Changed the measurement of uncertainty and rounded to two decimal places.	Revised MU calculation to include within-laboratory repeatability and interlaboratory comparison, following USDA guidance. Results reported to grower are to two decimal places. Changed for consistency.
h. Changed title of reference 6.	The SMPR was published and no longer in-process.
i. Made editorial changes	NA
j. Reference 13 added	Provide USDA guidance

### 4. Revision 03 on 07/14/2021

Change	Justification
a. Definition of matrix control moved before matrix blank solution	For clarification.
b. Added sieve, pipette range of 3uL, and syringless filter tubes to equipment list	To reflect equipment used in procedure
c. Added Total THC definition to C.1.f	For consistency with USDA documentation
d. Added clarification that if performing confirmation testing then drying steps and milling steps will not be performed.	Confirmation testing uses reserve sample form initiate GC evaluation.
e. Updated references to form 45 and form 57 to eWorksheet HEMP 57	Action item from change control
f. Added new QC samples will be extracted if QC failure occurs. C.7.f	For clarification.
g. Updated section C.9 from "instrument Calibration" to "System Suitability – Acceptance criteria"	For harmonization with GC method
h. Added C.14 "Column Shutdown Procedure and Storage Conditions"	Specific storage conditions for columns used
i. Removed C.6.e "Method on HPLC"	HPLC is no longer used for LC Hemp testing
j. Made editorial changes	NA

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Code:	SOP 0282-FD Rev. 05
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Issued Date:	11/10//2021
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## STANDARD OPERATING PROCEDURE

### Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist

Role	Name	Title
Document Owner	D. Brett Groves.	Chief Inspector/Auditor
Reviewed and Approved By	Mark LeBlanc, Ph.D.	State Chemist & Seed Commissioner
Reviewed and Approved By	H. Dorota Inerowicz, Ph.D.	Feed Chromatography Laboratory Supervisor
Reviewed and Approved By	David Snell	Quality Assurance Director

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Issued Date:	11/10/2021
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## STANDARD OPERATING PROCEDURE

### Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist

#### A. SCOPE

This standard operating procedure (SOP) describes internal practices taken for storage, handling, accountability, and disposal of hemp at the Office of Indiana State Chemist (OISC).

#### B. PURPOSE

This SOP outlines the procedures utilized at OISC for the storage, handling, accountability, and disposal of hemp and potential drug substances.

#### C. PROCEDURE

##### 1. Storage

- Hemp, upon receipt, must be stored in a locked oven, dryer, or freezer [1] under the control of the Feed Chromatography Laboratory Supervisor, or designee.
- The locked devices must be kept locked at all times while storing hemp unless an OISC employee requires the hemp for testing. Samples must immediately be locked after use of sample is complete. Individuals must follow procedures outlined in section C.4 for documentation of hemp samples.

##### 2. Handling

- Hemp samples will be given a number according to field sample collection and chain of custody procedures [1].
- Inspectors will relinquish custody of field samples to the laboratory upon delivering to laboratory personnel. Laboratory personnel must electronically sign Hemp Sample Chain of Custody Task in OCM and affirm delivery when taking custody of samples [1].
- Each sample will be given a uniquely identifiable Labworks number once entered into Labworks from OCM [1].

##### 3. Accountability

- When work on the hemp sample is completed, the unused portion of the sample must be returned to storage and immediately locked according to procedures outlined in section C.4.
- If a discrepancy is noted in the quantity on-hand of a hemp sample as compared to hard-copy forms or eWorksheet Hemp\_57 the Feed Chromatography Laboratory Supervisor and Quality Assurance Unit will be notified immediately and a CAPA will be opened [2].

##### 4. Documentation of Sample

- Samples are documented through the use of eWorksheet Hemp\_57 in LabWorks, or, if the eWorksheets are unavailable, hard-copy of e-Worksheet Hemp\_57. These forms record initial sample

Code:	SOP 0282-FD Rev. 05
Supersedes:	SOP 0282-FD Rev. 04
Issued Date:	11/10/2021
Effective Date:	12/10/2021

## STANDARD OPERATING PROCEDURE

### Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist

weights, in-process sample weights and the weights of all containers used for both initial and in-process samples [3].

- b. eWorksheet Hemp\_57 also records the sample identification, analysis codes, percent moisture and drying method used, either dryer or oven [3].
- c. eWorksheet HEMP\_57 is further appended with a \_GC or \_LC to differentiate weight data by testing process. There is no difference between the worksheets.
- d. eWorksheet Hemp\_57 has 3 tabs for recording weights: 57.a\_OVEN\_WT, 57.b\_RESERVE\_WT, and 57.c\_SAMPLE\_WT. 57.a is used to capture weight data collected during the drying process. 57.b is used to capture weights after grinding and sample gross sample weight, sample + container and moisture percentage. 57.c is used to capture analytical sample weights and percent moisture that is used to calculate total percent THC for a run.
- e. Location of the sample will be updated within Labworks each time the sample is moved from one location to another.
- f. In the event the eWorksheets are unavailable, weights will be manually recorded on hard copies of eWorksheets Hemp\_57, found in Labworks file folder. Once the eWorksheets are again available, all data from the hard copies will be added to the eWorksheets in Labworks.
- g. Hard-copy form Hemp\_57 is considered non-critical paper form [5].

#### 5. Sample Drying

- a. Samples will be weighed when brought into the lab and the initial weight of the wet plant material documented on eWorksheet HEMP\_57; 57.a\_OVEN\_WT.
- b. To avoid growth of mold, and preliminary loss of moisture from the wet samples, drying should begin within twelve hours after samples have arrived at the laboratory.
- c. Drying will be performed in an oven in the laboratory in the temperature range of 60°C to 70°C for a minimum of 18 hours
- d. Plant material may also be dried in the sampling sacks in the drying chamber at approximately 32°C for 5 to 7 days if oven is not available.
- e. After drying, the sample weight will be recorded on eWorksheet HEMP\_57; 57.a\_OVEN\_WT [3,4]
- f. The analysis of moisture and THC potency in the dried material is performed according to MTD 0500-FD [3,4].

#### 6. Disposal

- a. Disposal of samples after testing that are found to be classified as hemp [3,4] will be done via the Radiological and Environmental Management (REM). REM will pick up and incinerate hemp samples.
- b. The Labworks location of the sample will be updated to “disposed”.
- c. A sample, once tested, found to be above the acceptable limit for hemp [3,4] will be stored and disposed of via SOP 0295-FD [6].

Code:	SOP 0282-FD Rev. 05
Supersedes:	SOP 0282-FD Rev. 04
Issued Date:	11/10/2021
Effective Date:	12/10/2021

## STANDARD OPERATING PROCEDURE

### Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist

#### D. REFERENCES

1. MTD 0501-IS *Field Sampling of Hemp*
2. SOP 0226-GN *Corrective and Preventive Action*
3. MTD 0500-FD *Analysis of Delta-9-Tetrahydrocannabinol and Cannabidiol in Hemp by Gas Chromatography*
4. MTD 0502-FD *Analysis of Delta-9-Tetrahydrocannabinol and Cannabidiol in Hemp by Liquid Chromatography*
5. SOP 0275-GN *Paper Form Control*
6. SOP 0295-FD, *Controlled Drug Substances*, OISC

#### E. FORMS

1. eWorksheet 57, In-Process Hemp Sample Weight

#### F. REVISION

1. Revision 00 08/28/2015: Initial Issuance.
2. Revision 01 04/09/2017: (a) Form 38 "Hemp Storage, Handling, Accountability and Disposal" was revised to include all weights in grams and the total number of samples disposed of with REM was removed. (Justification: All samples are calculated in grams; this was added for clarifications. Samples below the 1% THC level are treated like other lab samples and the total number sent to REM does not need to be tracked. See Change Control Form 2016-005 #1022). (b) The percent moisture calculation was removed from section C.6. (Justification: Percent moisture will no longer be calculated. Drying the sample to a constant weight will be the determining factor for whether the sample is dry enough for analysis. See Change control number 2016-005 #1022). (c) added to section C.6 that samples will be dried in the drying chamber until they are observed as brittle (Justification: when plant material becomes brittle is considered at a low enough moisture content for analysis). (d) Form 57, "In-process Hemp Sample Weights" was created to document the weights of the stems and seeds. (Justification: in order to track the stem and seed weights. See Change control number 2016-005 #1022). (e) Made editorial changes.
3. Revision 02 on 12/13/2019:

Change	Justification
a. Removed "industrial" from description of hemp.	The term industrial hemp is no longer used
b. Added the use of Labworks eworksheets	Labworks is the newly implemented LIMS software used in the hemp laboratory.
c. Moved "Disposal" from section C.4 to section C.6	For the SOP to flow more logically



Code:	SOP 0282-FD Rev. 05
Supersedes:	SOP 0282-FD Rev. 04
Issued Date:	11/10/2021
Effective Date:	12/10/2021

## STANDARD OPERATING PROCEDURE

### Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist

d. Removed reference to forms Form 38, Industrial Hemp Storage, Handling, Accountability, and Disposal Form 45, Industrial Hemp Weight Worksheet Form 47, Relinquishment of Hemp Samples to Indiana State Police Form 57, In-Process Hemp Sample Weights	Guidance on the use of these forms was moved to MTD 0500-FD <i>Analysis of Delta-9-Tetrahydrocannabinol and Cannabidiol in Hemp by Gas Chromatography</i>
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#### Revision 03 on 08/12/2020

Change	Justification
a. Removed signatures from the cover page.	Approval signatures are captured in QT9 electronically, making the need for handwritten signatures redundant.
b. Added oven drying conditions	An oven for drying hemp was purchased this year
c. Added reference to MTD 0502-FD Analysis of Delta-9-Tetrahydrocannabinol and Cannabidiol in Hemp by Liquid Chromatography	An LC method for analysis was developed for hemp testing.
d. Made editorial changes	NA

#### Revision 04 on 06/18/2021

Change	Justification
a. Added oven to storage location	New equipment added since last revision
b. Updated form 45 and form 57 to eWorksheet Hemp 57	Action item from change control
c. Edited to make oven drying the preferred method of drying Hemp samples	New equipment added since last revision
d. Made editorial changes	

#### Revision 05 on 10/21/2021

Change	Justification
a. Remove reference to form 99 Hemp Chain of Custody; C.2.b.	Electronic chain of custody task in OCM implemented; form 99 is obsolete.

Reviewed:
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Code:	SOP 0295-FD Rev. 02
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## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

Role	Name	Title
Document Owner	Carrie A. Leach	Quality Assurance Director
Reviewed and Approved By	H. Dorota Inerowicz, Ph.D	Feed Chromatography Laboratory Supervisor
Reviewed and Approved By	Robert D. Waltz, Ph.D.	State Chemist & Seed Commissioner
Reviewed and Approved By	Courtney Moore	Quality Assurance Specialist

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# STANDARD OPERATING PROCEDURE

## Controlled Drug Substances

### A. PURPOSE

The Drug Enforcement Administration (DEA) defines a controlled drug substance as any compound categorized in Title 21 of the Code of Federal Regulations, Part 1308 as a Schedule I, II, III, IV or V substance. The purpose of this Standard Operating Procedure (SOP) outlines the procedures used for the storage, accountability and disposal of controlled drug substances as well as record maintenance at the Office of Indiana State Chemist (OISC).

### B. SCOPE

This procedure shall apply to all individuals involved in the sampling, handling, analysis or disposal of schedule I controlled drug substances. Refer to SOP 0282-FD [1] for the storage, handling, accountability and disposal of hemp.

### C. PROCEDURE

#### 1. Definitions

- a. Hemp: Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.
- b. Controlled Substance: a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V. The term does not include distilled spirits, wine, malt beverages, or tobacco.

#### 2. Storage and Security

- a. Controlled drug substances, upon receipt, must be placed into locked storage within OISC under the control of the Quality Assurance Director or Feed Chromatography Laboratory Supervisor.
- b. The hemp laboratory is a locked laboratory with access only by those who directly analyze, or audit the samples or records.
- c. All samples above 0.3% THC will be stored inside a combination locked freezer, or at ambient inside a key-locked safe. A lock-box may be used if separation of expired and non-expired controlled drug substances is required.
- d. Because the controlled drug substances received are in milligram or gram quantities, the safes, freezers, and lock boxes do not need alarms.
- e. Locked storage locations can be found in table 1.
- f. Combination locks will be changed upon termination of any employee with access to the combinations.
- g. Any copies of combinations or keys to locked storage boxes or safes will be stored in a push button combination key box in the hemp laboratory.

Code:	SOP 0295-FD Rev. 02
Supersedes:	SOP 0295-FD Rev. 01
Issued Date:	8/11/2020
Effective Date:	8/13/2020

## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

- h. Prior to the analysis of hemp, samples will be stored in a locked air dryer. Key to the dryer is maintained by the Feed Chromatography Laboratory Supervisor, or an analyst assigned to the analysis of the samples [1].
- i. All controlled drug substance samples must be returned to a locked storage location the same day they were removed. Controlled drug substance samples must not be kept in any other location over-night.

**Table 1**

Locked Storage	Location	Lock Type
Refrigerator	OISC Hemp Laboratory	Combination
Freezer	OISC Hemp Laboratory	Combination
Safe	OISC Hemp Laboratory	Key
Cash Box	OISC Hemp Laboratory	Key
Locked Cabinet for Records	OISC Hemp Laboratory	Key

### 3. Authorized Users

- a. Anyone who has access to the handling of controlled substances, the locked box, or any key or combination to where controlled substances are stored is considered an authorized user.
- b. Prior to personnel becoming an authorized user for the handling of controlled substances, REMCS Form 6, Controlled Substance Program Security Release, must be completed.
- c. A background check for felony or misdemeanor drug violations must be performed and passed as negative findings for all personnel identified as authorized users.
- d. A list of authorized users must be documented on Authorized User List, REMCS Form 5.
- e. REMCS Form 5, Authorized User List must be updated when changes in personnel happen that affect the list.
- f. A copy of updated forms REMCS Form 5, Authorized User List will be sent to the REM Biosafety Officer.

### 4. Use of DEA Form 222 and Purchasing Controlled Substances

- a. OISC is registered with the DEA as an analytical laboratory. As a registered analytical laboratory, OISC receives pre-numbered DEA 222 carbon-copy forms. OISC is responsible for the disposition of every DEA 222 form received.
- b. DEA Form 222 is required for ordering schedule I or II controlled substances. OISC is authorized to handle Schedule I controlled drug substances.
- c. An inventory of all pre-numbered DEA 222 forms are kept on REMCS Form 4, Purdue University Record of DEA Form 222 Use.
- d. If there is a request for work or collaboration with OISC laboratories involving schedule I controlled substances, OISC, as the purchaser, must transmit a Form 222 to the individual requesting the work.

Code:	SOP 0295-FD Rev. 02
Supersedes:	SOP 0295-FD Rev. 01
Issued Date:	8/11/2020
Effective Date:	8/13/2020

## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

- e. No more than twenty (20) items may be entered on each line of the DEA form 222. The total number of items must be indicated on the form by entering the last line completed in the appropriate box.
- f. OISC, as the purchaser, fills-out the number of packages, size of the package and name of item. The purchaser must also record name and address of the supplier on the form.
- g. No alterations will be made on the form. If errors are made void and retain all copies of the partially used form and use another DEA 222 form to provide the correct information.
- h. Only the DEA Registration License Holder is authorized to sign a DEA Form 222, unless a DEA prescribed power of attorney has been executed.
- i. The DEA license holder for OISC is the Quality Assurance Director.
- j. A photocopy of the form is kept by OISC as the purchaser. The original form is retained by the supplier.
- k. Controlled substance samples must be received by an authorized user within 60 days of transmittal of the form.
- l. The Quality Assurance Director, or designee, must record the number of containers furnished for each item and the date each is received.
- m. Purchasing records must be kept and recorded on REMCS Form 2, Record of Controlled Substance Purchases. Records include, and must contain:
  - i. Copy of DEA form 222
  - ii. Copy of invoice
  - iii. Copy of the shipping document
  - iv. Copy of the packing slip
  - v. Name, address and DEA registration number of company from which the controlled substance was purchased
  - vi. Name of controlled substance purchased
  - vii. Size and strength of the controlled substance purchased
  - viii. Amount purchased (which should match the amount received)
- n. The purchasing record(s) must be annotated with the handwritten date of receipt and initials of person receiving the controlled substance. The date written on this document(s) must match the date entered in the "Date Received" column of REMCS Form 2, Record of Controlled Substance Purchases.
- o. These records must be maintained per section C.8 Maintenance of Records even if a business office or purchasing department keeps all purchasing records.
- p. If OISC is the supplier for controlled drug substances, the number and date shipped must be filled out by quality assurance director. A photocopy of the form must be sent to the purchaser and originals must be kept according to section C.8.

Code:	SOP 0295-FD Rev. 02
Supersedes:	SOP 0295-FD Rev. 01
Issued Date:	8/11/2020
Effective Date:	8/13/2020

## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

#### 5. Inventory of Controlled Substances

- a. An inventory log is maintained on REMCS Form 1, Controlled Substances Physical Inventory found on the REM website.
- b. After initially receiving DEA registration, or if all controlled substances have been disposed, prior to receiving any new controlled substances, “Zero Inventory” must be documented on the REMCS Form 1, Controlled Substances Physical Inventory.
- c. DEA Requires inventory every two (2) years, however, REM requires annual inventory in addition to the requirements in the steps below.
- d. Every time a new controlled substances is brought in to the laboratory that is different from any controlled substance currently inventoried, an inventory must be completed. For example, Controlled Substance “A” is documented on the physical inventory form with the amount that was initially received. A month later Controlled Substance “B” is received which is different from Controlled Substance A. A complete inventory will be done upon receipt of Controlled Substance B, to record how much of Controlled Substance A is left, and the amount of the Controlled Substance B received.
- e. If any controlled substance amount is zero (0) it will be recorded as zero on the physical inventory form.
- f. All expired controlled substances will be included on the inventory, clearly marked as “expired” and kept in a separate locked box from useable controlled substances.
- g. A weigh-in and weigh-out procedure will be done every time a controlled substance is removed and replaced into locked storage. Follow weigh-in, weight-out procedures outlined in SOP 0282-FD, *Storage, Handling Accountability, and Disposal of Hemp at the Office of Indiana State Chemist* [1].
- h. Temperature of where the controlled substances are stored will be checked twice daily with a digital thermometer.
- i. Form 101, Temperature of Controlled Substance Freezer will be used to document the temperature.
- j. Temperature will not be checked on weekends or non-business days and will in indicated on the form as such.
- k. The controlled substance freezer is continuously monitored by a data logger. Data from the logger will be used to make freezer compliance decisions.

#### 6. Disposal

- a. Any hemp sample, once tested, found to be above 0.3% THC [2, 3] may be given to the individual holding the DEA registration for the Indiana State Police Laboratory. These samples will remain in locked storage until pick-up or shipment can be coordinated with the Indiana State Police Laboratory.
- b. For those samples, once tested, found to be above 0.3% THC that the Indiana State Police Laboratory do not want, disposal will be done through REM.

Code:	SOP 0295-FD Rev. 02
Supersedes:	SOP 0295-FD Rev. 01
Issued Date:	8/11/2020
Effective Date:	8/13/2020

## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

- c. REM will take custody of the samples and forward DEA Form 41 to DEA with a projected two-week disposal date.
- d. REM will contact a police witness to be onsite during the disposal.
- e. Never dump controlled substances down a drain or dispose without police witness.
- f. Form 47, Relinquishment of Controlled Substance Samples will include the sample number, percent THC level of the sample, and final gross weight of the sample.
- g. Weight of samples must be taken at room temperature. Samples will be moved from sub-ambient storage to the safe in order for them to equilibrate to room temperature prior to weighing.
- h. Form 47, Relinquishment of Controlled Substance Samples is considered a critical controlled paper form [4]

#### 7. Theft or Significant Loss

- a. If controlled substances samples are found missing, both REM and DEA will be notified upon discovery of the missing samples. Notification should occur immediately upon discovery and without delay. A CAPA will be issued to investigate the circumstances of the missing sample(s).
- b. DEA form 106, Report of Theft or Loss of Controlled Substances, should be used to detail the circumstances of the theft or significant loss in conjunction with the CAPA.
- c. If significant loss occurs, both REM and DEA will be notified. It will be decided whether the loss should be documented on a DEA form 106 or on a REM form. Notification should occur immediately upon discovery and without delay and a CAPA issued.
- d. Notification of local law enforcement may also occur.
- e. If a sample is spilled where significant loss occurs, the sample will be weighed after the loss and documented, with an explanation of the loss, on REM form 1, Controlled Substances Physical Inventory.

#### 8. Maintenance of Records

- a. Forms, and any records pertaining to controlled substances, will be maintained via Table 2.

**Table 2**

Document	Storage Location	Retention	Maintained By
REMCS Form 1, Controlled Substances Physical Inventory	OISC Hemp Laboratory	5 years	Authorized Users
REMCS Form 2, Record of Controlled Substance Purchases	OISC Hemp Laboratory	5 years	Authorized Users
REMCS Form 4, Purdue University Record of DEA Form 222 Use	OISC Hemp Laboratory	5 years after last record is used	Authorized Users

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## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

REMCS Form 5, Authorized User List	OISC Hemp Laboratory	5 years	After 5 years moved to individual training files, indefinitely by the QA Unit
REMCS Form 6, Controlled Substance Program Security Release	OISC Hemp Laboratory	5 years	After 5 years moved to individual training files, indefinitely by the QA Unit
Additional Records, including purchasing records	OISC Hemp Laboratory	5 years	Authorized Users
DEA Form 41	OISC Hemp Laboratory	5 years	QA Director
DEA Form 222	OISC Hemp Laboratory	5 years	QA Director

#### D. REFERENCES

1. SOP 0282-FD, *Storage, Handling, Accountability and Disposal of Hemp at the Office of Indiana State Chemist*, OISC
2. MTD 0500-FD *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Gas Chromatography*, OISC
3. MTD 0502-FD *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Liquid Chromatography*, OISC
4. SOP 0275-GN, *Paper Form Control*, OISC

#### D. FORMS

1. REMCS Form 1, Controlled Substances Physical Inventory, REM
2. REMCS Form 2, Record of Controlled Substance Purchases, REM
3. REMCS Form 4 Purdue University Record of DEA Form 222 Use, REM
4. REMCS Form 5, Authorized User List, REM
5. REMCS Form 6, Controlled Substance Program Security Release, REM
6. DEA Form 222
7. DEA Form 41
8. DEA Form 106
9. Form 101, Temperature of Controlled Substance Freezer

#### E. REVISION

1. Revision 00 on 10/07/2019: Initial Issuance.
2. Revision 01 on 01/14/2020

Change	Justification
a. Removed reference to room numbers of hemp laboratory	For security purposes
b. Made editorial changes	NA



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## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

#### 3. Revision 02 on 08/13/2020

Change	Justification
a. Removed signatures from the cover page.	Approval signatures are captured in QT9 electronically, making the need for hand written signatures redundant.
b. Updated use of DEA form 222 in section C.4	DEA form 222 has changed and is no longer a carbon copy form. Instructions include how to complete and make copies of the form.
c. Added form 101 Temperature of Controlled Substance Freezer	The temperature will be checked twice a day and recorded on the form, however compliance decisions of the freezer temperature will be made based on the data logger data.
d. Removed the requirement to fill out Form 47, Relinquishment of Controlled Substances Samples	Controlled substance samples are documented on both DEA forms 222 and 41 in addition to REM forms. This form was redundant.
e. Made editorial changes	NA

Reviewed:
Reviewed:
Reviewed:

Office of Indiana State Chemist  
175 S. University St.  
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## STANDARD OPERATING PROCEDURE

### Hemp Program Administrative Procedures at the Office of Indiana State Chemist

Role	Name	Title
Document Owner	Mark LeBlanc, Ph.D	State Chemist & Seed Commissioner
Reviewed and Approved By	D. Brett Groves	Chief Inspector/Auditor
Reviewed and Approved By	Donald Robison	Seed Administrator
Reviewed and Approved By	Courtney Moore	QA/QC Specialist

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## STANDARD OPERATING PROCEDURE

### Hemp Program Administrative Procedures at the Office of Indiana State Chemist

#### A. SCOPE

This standard operating procedures (SOPs) applies to reporting and administrative functions of the hemp section at the Office of Indiana State Chemist (OISC).

#### B. PURPOSE

The purpose of this SOP is to establish procedures for the administrative functions and reporting requirements that need to be generated for internal purposes, provided to USDA or any other entity where reporting hemp grower, handler, licensing, testing, inspection or facility information is required as part of the Office of Indiana State Chemist's hemp program.

#### C. PROCEDURE

##### 1. Definitions

- a. Facility: Any hemp related business entity holding an OISC hemp license and subject to OISC inspection.
- b. Licensee: A grower, handler, or business facility that has been granted a hemp license through OISC.
- c. Third-party: Testing or sampling not done by OISC agency representatives

##### 2. OISC Hemp Licensing Software

- a. Licenses for growers and handlers are generated at OISC through a Mi-Co licensing software application built specifically for OISC hemp licensing needs.
- b. Information required from growers and handlers include:
  - i. Name(s)
  - ii. Address(es)
  - iii. Email address(es)
  - iv. Telephone number(s)
  - v. Geospatial coordinates of hemp fields, if applicable
  - vi. Full business name and principal location of facilities, if applicable
  - vii. Names and titles of key participants
  - viii. Employer Identification Number (EIN), if applicable
  - ix. Any results conducted by a third-party sampling or laboratory including names, address, and contact information of the third-party entity.
- c. Each grower, handler or facility is given a unique license number that remains constant over the years.
- d. Any changes to licensed growers and handlers or facilities are captured in the software application either through a licensee portal accessed via a username and password by each designated facility representative or licensee, or by an OISC representative with software administrative rights to make changes in the software application.

Code:	SOP 0308-HP Rev.02
Supersedes:	SOP 0308-HP Rev.01
Issued Date	08/25/2021
Effective Date:	08/27/2021

## STANDARD OPERATING PROCEDURE

### Hemp Program Administrative Procedures at the Office of Indiana State Chemist

- e. All license information must be current and changes are recorded in the software application

#### 3. Performance Based Sampling Protocol

- a. OISC will only conduct a facility and/or record inspection of all licensees of the type “University Research”, whose hemp will not enter the stream of commerce.
- b. All licensees are subject to official sampling if hemp has entered the marketplace as a result of the facility/records inspection.

#### 4. Hemp Testing at OISC

- a. All results from %THC potency testing conducted in OISC laboratories are stored in a Laboratory Information Management System (LIMS) [1,2]
- b. This software application contains compliant and non-compliant results run according to OISC methods [1,2].

#### 5. Corrective Action Plans for Negligent Violations

- a. OISC shall conduct inspections to determine if corrective action plans have been implemented for negligent violations.
- b. Corrective action plans for any hemp licensee in violation of IC 15-15-13-13.5 *Negligent Violations; Corrective Actions* shall be in place for a minimum of two (2) years from the date of their approval.
- c. Corrective actions plans will, at a minimum include:
  - i. **The date the negligent violation was discovered by OISC.**
  - ii. The date by which the producer shall correct each negligent violation.
  - iii. Steps to correct each negligent violation.
  - iv. A description of the procedures to demonstrate compliance.

#### 6. Reporting

- a. Any information, data collected, changes to data or information collected as part of the licensing or testing process at OISC is searchable and can be exported from any of the supporting software applications to collect hemp grower, handler, laboratory or third-party information.
- b. All data collected that requires reporting from any entity including United States Department of Agriculture (USDA), U.S. Drug Enforcement Administration (DEA), Farm Service Agency (FSA) or any other interested party can be submitted electronically.
- c. Data will be maintained as real-time as possible and ad-hoc reporting or requests from any interested party can be produced from OSIC supporting software applications.
- d. Reports shall be sent to USDA, found at the following link <https://www.ams.usda.gov/rules-regulations/hemp/forms>, as below;
  - i. A state hemp producer report shall be submitted on the first day of each month. If that date falls on a holiday or weekend the reports shall be submitted next business

Code:	SOP 0308-HP Rev.02
Supersedes:	SOP 0308-HP Rev.01
Issued Date	08/25/2021
Effective Date:	08/27/2021

## STANDARD OPERATING PROCEDURE

### Hemp Program Administrative Procedures at the Office of Indiana State Chemist

- day. This report will include new producers, changes to existing producers and background check information.
- ii. A state hemp disposal report shall be submitted on the first day of each month. If that date falls on a holiday or weekend the reports shall be submitted next business day. This report shall only include disposed total acreage of plant material that was disposed due to testing above the acceptable delta-9 tetrahydrocannabinol (THC) level [2] and disposed of in accordance with the Controlled Substance Act (CSA) and DEA regulations.
  - iii. A state hemp annual report shall be submitted by December 15<sup>th</sup> of the year. This will include total planted acres, total disposed acres and total harvested acres.
  - iv. A test results report will be submitted not more than 30 days after the date on which the information was received. All samples tested, including any non-compliant results, shall be reported to USDA and shall include license number, name, business address, and DEA registration number of laboratory as well as sample identification number, date of test and report, identification of a retest and test result(s). The test results report is not found on the <https://www.ams.usda.gov/rules-regulations/hemp/forms> website, but will be provided to USDA in an electronic format.

#### D. REFERENCES

1. MTD 0500-FD, *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Gas Chromatography*, OISC
2. MTD 0502-FD, *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Liquid Chromatography*, OISC

#### E. Forms

NA

#### F. REVISION

1. Revision 00 on 08/11/2020: Initial issuance
2. Revision 01 on 9/08/2020

Change	Justification
a. Added to C.5.d.iv that non-compliant results are reported	For clarification. All samples tested are reported including any non-compliant results.

3. Revision 02 on 08/25/2021

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## STANDARD OPERATING PROCEDURE

### Hemp Program Administrative Procedures at the Office of Indiana State Chemist

Change	Justification
a. Add C.3 Performance Based Sampling Protocol	Needed section for compliance with state regulations