Indiana State Department of Agriculture
Governor Eric Holcomb
Lt. Governor Suzanne Crouch, Secretary of Agriculture and Rural Development
Bruce Kettler, Director

August 14, 2020

The Honorable Sonny Perdue
Secretary of Agriculture
US Department of Agriculture
1400 Independence Avenue SW
Washington DC 20250

RE: Docket Number: AMS-SC-19-004 2 SC19-990-2 IR

Secretary Perdue,

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 October 31, 2019.

This document is offered in response to the USDA suggested edits on our plan that was presented in December of 2019. (Indiana Code 15-15-13-15).

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 compliance 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.

The Office of Indiana State Chemist has hired added staff for inspections, and increased laboratory capacity, developed and secured a DEA Schedule 1 compliant laboratory and quality program. All OISC inspectors have been trained to the 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 Interim Final Rule (7 CFR 990) for hemp published in 7 CFR 990 on October 31, 2019.

- 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 (a) (1);
    - Legal description of the land on which the producer will produce hemp in the state to the extent practicable, its geospatial location; and
    - The status and number of the producer's license or authorization.
    - COMMENT: These data, as listed above, are criteria met as required information in our application forms and licensing software to be developed under contract. Commercial software is being finalized to meet the standards presented, and to facilitate the reporting required in the USDA Interim Final Rule. Operational software is expected by November 2020.

- A procedure for accurate and effective sampling of all hemp produced to include:
- COMMENT: Indiana is using Certified Crop Advisors as Third-Party Samplers to sample crop that cannot be sampled by OISC inspectors. This is mandatory prior to harvest as required in our emergency rule. Receivers of a crop are self-monitoring for compliance of materials received to avoid taking in marijuana and being possibly charged under marijuana laws. If a grower is sampled by OISC inspectors and discovered to be out of compliance, under Indiana Code 15-15-13, the crop will be ordered to be terminated and retted or destroyed. After retting, a crop may be used for its intended purpose as fiber.

    - Within 15 days prior to the anticipated harvest of the hemp plants, a sample collected by a state or federal designated person. The sample shall be collected from the flower materials and tested for delta-9 THC concentration levels as described.
    - COMMENT: The sampling program in Indiana requires 30 days advance notice by a grower of a request for sampling, which is then conducted. The grower then has up to fifteen days to harvest his crop. IAC 360 2 Section 28(p), Section 58(c)

    - Sampling method must address that no more than one per cent (1%) of the plants in the lot would exceed the acceptable hemp THC level.
    - COMMENT: The statistical assumptions supporting this requirement in the USDA rule are largely unknown, e.g., the fundamental issue of individual plant THC variance, THC distribution as a function of a crop in field, etc., are lacking. The one percent (1 %) threshold one might surmise to be a biologically unattainable level of performance standard in a field of hemp at this time. The genetics of hemp as a crop in this country are nowhere near that level of expected stability. The guidance provided does not appear to meet the rigor of standard as stated in the rule.

- 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 of Hemp MTD 0501-IS Rev. 4 (08/11/2020).

- During the scheduled sample 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 Rev. 4 (08/11/2020).

- A grower shall not harvest the hemp crop prior to samples being taken.
- COMMENT: Sampling is drawn from standing crop only as delineated in the OISC Field Sampling of Hemp MTD 0501-IS Rev. 4 (08/11/2020).

- 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. 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 (See also 21 CFR 1317.15)
  - COMMENT: 1) The crop, or lot, found to be in violation, may be burned on site and documented by an OISC inspector, or burned on site and documented by a law enforcement official, or burned on site and documented by the owner in digital video. Or, 2) The crop may be sent in a future time to a registered DEA facility that is a reverse distributor, and that may also be licensed as a hemp processor. There are currently no reverse distributors in Indiana equipped to handle volumes of hemp plants.

  - 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 Rev. 04, (08/11/2020), and, in Storage, handling, accountability, and disposal of hemp at the Office of Indiana State Chemist, SOP 0282-FD Rev. 03 08/12/2020.

  - 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 Re v. 04 (08/12/2020); and Analysis of delta-9-tetrahydrocannabinol in hemp by liquid chromatography, MTD 0502-FD Rev. 02 (08/12/2020).

- 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 destroying an inadequate or non-compliant crop. IAC 360 2 Section 40

- A state plan must comply with 7 CFR 990.6 Violations
- COMMENT: IC 15-15-13-13.5 and 360 IAC 2 emergency rules speak to negligent violations. 360 IAC 3 (DRAFT PENDING 2020) will speak to civil penalty 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 990.6 and Indiana laws.
- COMMENT: Annual inspections including checks on compliance for records and procedural audits will be randomly conducted, OISC Field Sampling of Hemp MTD 0501-IS Rev. 04, (08/11/2020)

- A state plan must include the procedures for submitting the information required by USDA under 7 CFR 990.70 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 to be met as part of the performance requirements of commercial software that is being finished. The receipt of the software and program functionality is expected in November 2020. SOP 0308-HP Rev. 00 Hemp Administrative Procedures 8/11/2020

- A state plan must include a certification that the state has the resources and personnel to carry out the practices and procedures described in 7CFR 990.
- COMMENT: The state of Indiana has the resources to carry out a state hemp plan as outlined in the supporting state commentary above.

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

Upon the successful review of the Indiana state hemp plan, Indiana would like for the plan to go into effect November 1, 2020.

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TITLE 360 STATE SEED COMMISSIONER

Emergency Rule IAC 360 2

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 December 20, 2019.

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

SECTION 1.5. "**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 2. **"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 3. **"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 4. **(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 5. **"Crop destruction" means the supervised burning of a hemp crop completely to ash, or processing of a hemp crop through a Schedule 1 registered reverse distributor so that THC is nonrecoverable from the residue.**

SECTION 6. **"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 7. **"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 8. **"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 9. **A grow site means any place or location where a hemp crop is legally grown whether outdoors or indoors.**

SECTION 10. **"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 11. **"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 12. **" 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 does not mean a hemp product.

SECTION 13. **(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 14. **(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 15. **(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 16. **(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.

(e) The basis for a claim as a researcher and a research proposal must meet the above requirements and be clearly stated and provided in a written application for a hemp license.

SECTION 17. **"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 18. **(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 18.5 “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 19. **"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.

SECTION 20. **"Official sample" means a sample taken by a representative of the state seed commissioner who has been trained 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 21. **"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 22. **(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 23. **"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**

with the acceptable hemp THC level.

SECTION 24. **(a) "THC" means delta-9-tetrahydrocannabinol.**

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

SECTION 25. **"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 26. **"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]***.**

SECTION 27. **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 28. **(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 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.

(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; or

(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.

(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 fulfill an order of destruction issued by the state seed commissioner if the hemp crop is found to be in excess the acceptable hemp THC level. The grower must secure the crop, harvest the crop within 15 days of sampling, whether notified by the state seed commissioner or not, and transport the crop to an approved Indiana reverse distributor, or burn the crop in a designated site in a manner that complies with local and state burn laws.

(q) 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 expected date of the harvest.

(r) The state seed commissioner will report to the Secretary of Agriculture relevant, real-time information for each producer licensed to produce hemp under Indiana law: 1a) Contact information including street address, city in Indiana, county, for each hemp production or hemp grow site, 1b) the acreage of each hemp production site or hemp grow site identified, and 1c) 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; And the status and license number of the licensee. Changes in records or licenses will be updated to the USDA.

(s) 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).

(t) 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. A key participant is an ~~individual~~ 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. **4) Contract growers, hemp cooperatives and similar entities are not exempt from the licensing requirements under this section.**

(u) A person who is licensed under this article [document] shall report hemp crop acreage to the USDA Farm Services Agency (FSA), 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.**

(v) **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 29. **(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:**

a. **Growing hemp, offering to grow hemp, contracting to grow hemp.**

b. **Growing agricultural hemp seed, or hemp for seed production for sowing, offering to handle, receive, or handling, agricultural hemp seed:**

i. **sale of seed for sowing or for use in research purposes as seed; or**

ii. **seed to be sown for development of new varieties; or**

iii. **seed to be sown and harvested and devitalized for a wild bird feed;**

iv. **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 30. **(a) A person that conducts the following 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. A person who transports or offers to transport hemp for commercial delivery must have the following provided by the customer to the transporter:**

(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;

(5) Only a person who is the licensee, or a family member of the licensed person, or a person who volunteers for, 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.

(b) 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 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.

(c) 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.

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

(e) 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 standards as applicable to their own operations.

SECTION 31. **(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, 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 32. **(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 ($1000) 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 ($2000) 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) If an inspection of a person handling or growing clones has been conducted by the state seed commissioner an inspection fee of $150 may apply, and if this inspection fee has not been paid within ten (10) days, a late fee of $150 shall be added to the original fee that was due.

(e) A laboratory fee of $150 will be charged to a licensee as permitted by law.

SECTION 33. **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 34. **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 35. **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 clones for 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 36. **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; or
(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).

SECTION 37. **(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; or
(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.

(b) It is a violation of this rule to alter, manufacture, or falsely represent or falsely 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 38. **(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.

SECTION 39. **(a) Each negligent violation shall be counted separately.**

(b) 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.

(c) 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.

(d) 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.

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

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

(g) 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.

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

(i) The Seed Commissioner shall conduct inspections to determine if corrective a corrective action plan has been implemented.

(j) A Crop cannot be planted in a comingled or mixed variety planting. Each lot must be of only one variety.

SECTION 40. **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:

(1) Hemp that is grown in a greenhouse, or other nonfield 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 by burning, or as determined by the licensee's disposal plan required as a part of the application for a license under this article *[document]*, and in a manner agreeable to the state seed commissioner, or in a manner ordered by the Indiana state police.

(2) 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 and 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). After the hemp plants are fully retted they may be moved to a processor.

(3) Hemp that is standing seed grain crop and found to be in violation of the acceptable hemp THC level shall be terminated. The seed grain may be harvested and certified for use in a processor. Grain seed shall not be used for seed for sowing. Flowers from a hemp crop that is in excess of the acceptable hemp THC level may not be removed for use as hemp flower, or hemp buds. The unused plant material must be completely burned on site, or cut down and chopped and disked into the soil.

(4) 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.

(5) 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 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.

(6) It is a violation of this rule to co-mingle hemp that is in the field or in storage 1) that has not been tested and labeled with a certificate of analysis for that particular lot or field; or 2) that is from different fields, or lots; or 3) that is of more than one variety; or 4) that is in storage, drying, or dried; or 5) hemp that ~~are~~ is in excess of the acceptable hemp THC level; or hemp that is suspected of being in excess the acceptable hemp THC level, with compliant ~~plants~~ hemp, unless combined by a reverse distributor, or allowed for processing by a licensed processor.

(7) 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.

(8) 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.

(9) 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 41. **(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 42. **(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 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) A licensed grower who grows a hemp crop that exceeds the acceptable hemp THC level three (3) years out of five (5) is subject to revocation of license for a period of five (5) years. This is a negligent violation.

(i) 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.

(j) 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.

(k) 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.

(l) 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.

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

SECTION 43. **(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 44. **(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 45. **(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 46. **(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 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 47. **(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 destruction 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 48. **(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 49. **(a) Test samples of hemp, hemp extracts, ~~or crude CBD~~ 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.

(b) 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.

(c) 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 and written permission by the state seed commissioner or the Indiana state police, subject to the existing enforcement authorities of each agency.

(d) 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.

(e) 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.

(f) 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.

(g) 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, etc.).

SECTION 50. **(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 51. **(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, use of or 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 52. **(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 destruction 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 53. **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 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 54. **(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 is 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 55. **(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 56. **(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 57. **Hemp that has exceeded the acceptable hemp THC level must be treated and disposed in like manner as marijuana:**

(1) Receivers for reverse distributions must have a Schedule 1 DEA reverse distributor registration, in addition to a license issued by the state seed commissioner. The requirements of a reverse distributor as stated by DEA shall be followed in a manner consistent with this rule.

(2) Excess hemp total THC (THC and THCa) in the possession of a licensed reverse distributor, regardless of form as an extract, or as plants or plant parts, must be destroyed so as to be irretrievable.

(3) A reverse distributor 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.

(4) Transfers of THC-containing hemp extracts or hemp that exceeds 0.3% THC to another person

must be according to federal Schedule 1 requirements for the purpose of processing by a reverse distributor.

(5) 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.

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

(7) 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)

SECTION 58. **(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.**

(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 pre harvest 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 fifteen (15) days following the date of sample collection. (e) If the producer fails to complete harvest within fifteen (15) days of sample collection, a secondary pre-harvested sample of the lot shall be required to be submitted for testing.

(f) it is a violation of this article for a producer to harvest any cannabis prior to samples being taken.

SECTION 59. **(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 or IC15-15-13 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.

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) SECTION 60. **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 $750.00 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 61. **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) Destruction 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.

(7)

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STANDARD OPERATING PROCEDURE

Controlled Drug Substances

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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.

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 overnight.

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.

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.

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.

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

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

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:
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STANDARD OPERATING PROCEDURE

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

Role	Name	Title
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Reviewed and Approved By	H. Dorota Inerowicz, Ph.D.	Feed Chromatography Laboratory Supervisor
Reviewed and Approved By	Carrie A. Leach	Quality Assurance Director

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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

a. Hemp, upon receipt, must be stored in a locked freezer or dryer [1] under the control of the Feed Chromatography Laboratory Supervisor, or designee.
b. 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

a. Hemp samples will be given a number according to field sample collection and chain of custody procedures [1].
b. Inspectors will relinquish custody of field samples to the laboratory upon delivering to laboratory personnel. Laboratory personnel must sign Form 99, Hemp Sample Chain of Custody, when taking custody of samples [1].
c. Each sample will be given a uniquely identifiable Labworks number once entered into Labworks from OCM [1].

3. Accountability

a. 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.
b. If a discrepancy is noted in the quantity on-hand of a hemp sample as compared to hard-copy forms or eWorksheets Hemp 45 or 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

a. Samples are documented through the use of or eWorksheets Hemp 45 and Hemp 57 in Labworks, or, if the eWorksheets are unavailable, hard-copy forms 45, Hemp Weight Worksheet and 57, In-Process

Hemp Sample Weight. These forms record initial sample weights, in-process sample weights and the weights of all containers used for both initial and in-process samples [3].

b. Hard-copy forms 45, Hemp Weight Worksheet and 57, In-Process Hemp Sample Weight or eWorksheets Hemp 45 and Hemp 57 also record the sample identification, analysis codes, percent moisture and drying method used, either dryer or oven [3].
c. Location of the sample will be updated within Labworks each time the sample is moved from one location to another.
d. In the event the eWorksheets are unavailable, weights will be manually recorded on hard copies of Hemp 45 and Hemp 57. Once the eWorksheets are again available, all data from the hard copies will be added to the eWorksheets in Labworks.
e. Hard-copy forms 45 and 57 are considered non-critical paper forms [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 either hard-copy forms 45, Hemp Weight Worksheet or eWorksheet Hemp 45.
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. Plant material will be dried in the sampling sacks in the drying chamber at approximately 32°C for 5 to 7 days.
d. Drying may also be performed in an oven in the laboratory in the temperature range of 60°C to 70°C for a minimum of 18 hours
e. After drying the sample weight will be recorded on Form 45 [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].

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. Form 45, Hemp Weight Worksheet
2. Form 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

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 *Analysis of Delta-9-Tetrahydrocannabinol and Cannabidiol in Hemp by Gas Chromatography*

1. 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

Reviewed:
Reviewed:
Reviewed:

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

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STANDARD OPERATING PROCEDURE

Hemp Program Administrative Procedures at the Office of Indiana State Chemist

Role	Name	Title
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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

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.

e. All license information must be current and changes are recorded in the software application

3. 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].

4. 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.

5. 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 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 15th of the year. This will include total planted acres, total disposed acres and total harvested acres.

iv. A test results report will be submited 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.

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METHOD

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

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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

Standards, Quality Control, and Reference Materials:

a. Cannabinoids standard, 1000 µg/mL, each THC, CBD, CBN from Restek or other supplier
b. Δ^9-Tetrahydrocannabinol (THC) standard, 1000 µg/mL from Cerilliant, Restek, or other reference standard supplier.
c. Matrix control: Plant material matching the hemp matrix and containing no analyte of interest.
d. Matrix blank solution: extract of oregano, spinach, or hemp samples, previously tested and found to contain no detectable THC.
e. Matrix spike: A test portion of matrix control fortified with a known concentration of THC.
f. 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.

Reagents:

a. Methanol: Fisher Scientific, ACS grade or equivalent

Equipment:

a. Gas Chromatograph with flame ionization detector (GC-FID) – Agilent 7890B or equivalent.
b. Analytical column: HP-5MS UI, part # 19091S-431UI, 15m x 0.25mm x 0.25 µm Agilent or equivalent
c. 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
d. Moisture analyzer: Mettler Toledo HC103 Halogen Moisture Analyzer or equivalent
e. Analytical mill or grinder: Magic Bullet food blender, grains grinder or equivalent suitable grinder
f. Geno Grinder 2010 or equivalent shaker
g. Pipettes: 10 to 1000 µL
h. 60 mL syringes
i. 0.45 µm or 0.22µm PTFE syringe filters.
j. 50 mL Centrifuge tubes
k. Plastic specimen cups with caps

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METHOD

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

l. 50 mL bottle top dispenser

C. PROCEDURE

1. Definitions

a. Δ^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.

2. Sample Drying

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

3. Sample Preparation and Handling

a. All weights captured in the process of sample preparation are either recorded on hard-copy Form 57, In-Process Hemp Sample Weights, Form 45 Hemp Weight Worksheets or in the Labworks LIMS excel eWorksheet Hemp 57 or Hemp 45 [1]
b. Dried samples are milled through a sieve no greater than 1.5 mm sieve to obtain a uniform, powder-like consistency.
c. Small-size samples (<20g) can be homogenized to powder-like consistency with a mortar and pestle.
d. After homogenization, the moisture content is determined by testing -2g of sample at 95°C with a moisture analyzer. The percent moisture content is recorded in the hard-copy of Form 57 or the Labworks eWorksheet.. If sample weight is less than 10g then a 1g portion will be used for moisture analysis.
e. If the moisture content is above 15% [2,3,4], additional oven drying of the sample is necessary.
f. The grinder and mortar and pestle must be cleaned between each sample using the following steps:
    i. First, brush the analytical mill or mortar and pestle;
    ii. Second, spray them with a jet of air;

iii. Rinse them at least three times with ethanol;
iv. Finally, air-dry either by simple exposure to air or by contact with a directed stream of air.

g. All of the samples in pre-labeled specimen cups will be stored in a locked freezer or refrigerator. The standard will be stored in a locked freezer.

4. Standard Preparation and Sample Analysis

a. Matrix blank solution - weigh 0.2 g of matrix blank material (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
b. The stock standard solution—is a cannabinoids mixture in methanol of 1000 µg/mL each CBD, CBN, THC, from Restek or equivalent.
c. For the preparation of the calibration standards solutions at 3.0, 5.0, 10.0, 20.0, 40.0, 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 Table1.

Table 1. Preparation of calibration standard solutions

Level	Stock std solution volume, µL	Matrix blank solution– volume, µL	Total Dilution Volume, µL	THC Concentration, µg/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	80.0	920.0	1000.0	80.0	1.60

d. To prepare the continuing calibration verification (CCV) standard of 10.0µg/mL, add 1000 µL of the matrix blank solution to a GC vial. Remove and discard 10.0µL 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.

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METHOD

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

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 minutes.
e. Allow suspended material to settle for at least one hour.
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.
g. Dispense a 1 mL aliquot of the sample solution into a 2 mL amber GC autosampler vial and proceed with analysis.
h. Remaining sample extract will be stored in the locked sample refrigerator until analysis is completed.
i. Method blank: Transfer 40 mL methanol to a 50 mL centrifuge tube and shake for 5.0 minutes.

6. Sample analysis: chromatographic conditions

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

Oven

Initial temp.	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 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:
   1. Agilent HP-5 30m x 0.32mm x 0.25um, 19091J-413 or equivalent
   2. Instrument conditions:

Oven
Initial temp. 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 time: 13.1 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

D. Instrument parameters may be adjusted to optimize chromatography.
E. Injector precision – Make repeat injections of the CCV standards until the sum of 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 and a matrix blank solution 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 should be within ± 15% of each other. If results for duplicates exceed ±15% a new portion of the sample 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. QC samples are repeatedly analyzed in different 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 ± 2 standard deviations from the mean of previous determinations. If one of the QC results falls outside ± 2 standards deviation but is within ± 3 standard deviations the QC results are still acceptable. If both QC results are outside ± 3 standard deviations results from the sample set are rejected. The sample extracts will be 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 µg/mL) to 0.20g of matrix control. The equivalent level of THC in a hemp sample is 0.1%:
[(0.2 mL volume of spike solution)*(1000 µg/mL THC stock standard solution)/0.2 x 10^6 µg matrix control ~~blank~~ sample]*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].
c. The calibration correlation coefficient (r2) must be ≥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.
d. 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±15% accuracy.
e. CCVs injections are required to be included in the sample sequence at the beginning of the sample set, after every 5-7 sample~~s~~ injections, and at the end of the sample set.
f. 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.

9. Results

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

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METHOD

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

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

M – % moisture content as determined by moisture analyzer
%THC $_{\text{as-is basis}}$ –THC level (%) determined by instrument software before adjustment for moisture content.
%THC $_{\text{dry weight basis}}$ – THC level (%) after adjustment for moisture content

b. Final results will be reported in % to two decimal places.

10. 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].
b. Accuracy was determined by analyzing two sets of 5 replicates of matrix blank spiked at 0.1% and 0.3% THC.
c. 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.
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 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].
e. 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-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.
f. Accuracy, precision, measurement of uncertainty, LOD, and LOQ are presented below.

Table 2

Cannabinoid	Accuracy (%)	Precision (%)	LOD(%)	LOQ (%)	MU (%)
THC	99	4.4	0.02	0.04	±0.09

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METHOD

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

11. Sample Acceptance Criteria

a. Based on the measurement of uncertainty calculation, if THC concentration is greater than 0.39%, 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. A test result greater than 0.39% 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.

12. 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 will be 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 [12]. Analytical extracts for those samples will be submitted for disposal and collected by REM [1].

D. REFERENCES

1. SOP 0282-FD, *Storage, Handling, Accountability, and Disposal of Hemp at the Office of Indiana State Chemist*, OISC
2. 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
3. Industrial Hemp, Technical Manual, Health Canada, September 1, 2000
4. 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
5. EM-PF-002, “Agilent 6890 Gas Chromatograph”
6. AOAC SMPR 2019.003 Standard Method Performance Requirements (SMPRs) Quantitation of Cannabinoids in Plant Materials of Hemp (low THC Varieties Cannabis sp.
7. Method evaluation - reports – OISC Feed Laboratory, “Analysis of Delta-9-THC and Cannabinol in Hemp by Gas Chromatography” 06/06/2019 – 06/14/2019.
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.
14. Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp -USDA website: https://www.ams.usda.gov/rules-regulations/hemp/rulemaking-documents

E. FORMS

1. Form 45 Rev.01 Hemp Weight Worksheet
2. Form 57 Rev.00 In-Process Hemp Sample Weight

F. 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.
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, *Analysis of - 9-Tetrahydrocannabinol and Cannabidiol in Hemp by Ultra Powered Liquid Chromatography* 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, *Controlled Drug Substances*, 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 reverences 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 ±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 ±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	To comply with state or USDA regulations

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METHOD

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

	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."'	
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 www.nordtest.info.	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

Reviewed:
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METHOD

Field Sampling of Hemp

Role	Name	Title
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Reviewed and Approved By	Carrie A. Leach	Quality Assurance Director

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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

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. Sample: Material taken from the hemp plant, placed into a sampling bag, and given a sample number.

2. 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 . 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.
b. Grow-sites not sampled by OISC will be sampled by Certified Crop Advisors (CCA).
c. All sampling will be conducted 15 days prior to the growers anticipated harvest date.
d. 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.
e. 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.
f. 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 you are sampling.
g. Present OISC inspection authority identification credentials to the individual(s) being inspected. Present a business card, if needed.
h. Issue a Notice of Inspection to the individual(s) being inspected.

3. 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.

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Field Sampling of Hemp

4. 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.4 will be followed for sampling.

5. Sampling

a. To collect samples, the inspector shall inspect the entire field of plants including the boarders, 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, follow these sampling methods:
    i. Hemp grown from authoritatively credentialed clones, collect 5 buds by cutting approximately one (1) to one and a half (1.5) inches off the top of the hemp plant.
    ii. For non-cloned hemp, or hemp not authoritatively credentialed, collect at least 30 buds by cutting approximately one (1) to one and a half (1.5) inches off the top of the hemp plant.
d. For hemp grown for fiber, seed or seed oil, collect buds by cutting approximately one (1) to one and a half (1.5) inches from top of the plant from at least 30 random hemp plants.
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. 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.
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.

6. Documentation of Samples

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. Form 99, Hemp Sample Chain of Custody, 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 will sign Form 99 when custody of samples are relinquished to the hemp laboratory. All unused signature spaces should be marked NA.
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 Form 90, Receipt of Sample and Form 99, Hemp Sample Chain of Custody are considered non-critical paper forms [5].

7. 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 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. The Purdue Extension Hemp Specialist, may be contacted prior to sampling a field either through hemp@purdue.edu 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.
e. 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.
f. See SOP 0271-GN, *Avoiding Violent Confrontation for OISC Field Staff* for additional information [6].

8. 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.

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METHOD

Field Sampling of Hemp

D. REFERENCES

1. MTD 0500-FD "Analysis of 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
5. SOP 0275-GN "Paper Form Control", OISC
6. SOP 0271-GN, "Avoiding Violent Confrontation for OISC Field Staff", OSIC

E. FORMS

1. Form 39 Field Sampling of Hemp
2. Form 90, Receipt for Samples
3. Form 99, Hemp Sample Chain of Custody

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 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	As guidance for the inspector 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.	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 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 **not** match the actual field or greenhouse you are sampling," in section C.2.d	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 the license application does not match the field.

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.
g. Made editorial changes	NA

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METHOD

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

Role	Name	Title
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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. Δ^9-Tetrahydrocannabinol (THC) standard, 1000 μg/mL from Cerilliant, Restek, or other reference standard supplier.
c. Δ^9-Tetrahydrocannabinolic Acid (THC-A), 1000-μg/mL from Cerilliant or other supplier.
d. Matrix control: Plant material matching the hemp matrix and containing no analyte of interest.
e. Matrix blank solutions: extract of oregano, spinach, or hemp samples, previously tested and found to contain no detectable THC.
g.
h. Matrix spike: A test portion of matrix control fortified with a known concentration of THC or THCA.
i. Method control: A solvent (extractant) blank to which all reagents. The method control is carried through the entire analytical procedure.
j. 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 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. Analytical mill or grinder: Magic Bullet food blender, grains grinder or other suitable grinder.
f. Geno Grinder 2010 or other shaker
g. Pipettes: 10 to 1000 μL
h. 60 mL syringes
i. 0.45 μm or 0.22 μm PTFE syringe filters.

j. 50 mL Centrifuge tubes
k. Plastic specimen cups with caps
l. 50 mL Bottle top dispenser

C. PROCEDURE

1. Definitions

a. Δ^9-Tetrahydrocannabinol (THC): A cannabinoid, the primary psychoactive compound occurring naturally in marijuana and hemp.
b. Δ^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.

2. Sample Drying

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

3. Sample Preparation and Handling

a. All weights captured in the process of sample preparation are either recorded on hard-copy Form 57, In-Process Hemp Sample Weights, Form 45 Hemp Weight Worksheets or in the Labworks LIMS excel eWorksheet Hemp 57 or Hemp 45 [1].
b. Dried samples are milled through a sieve no greater than 1.5 mm screen to obtain a uniform, powder-like consistency.
c. Small-size samples can be homogenized to powder-like consistency with a mortar and pestle.
d. After homogenization, the moisture content is determined by testing 2g of sample at 95°C with a moisture analyzer. The percent moisture is recorded in the hard-copy of Form 57 or the LabWorks eWorksheet. If sample weight is less than 10g then a 1g portion will be used for moisture analysis.
e. If the moisture content is above 15% [2, 3], additional oven drying of the sample is necessary.
f. The grinder and mortar and pestle must be cleaned between each sample using the following steps:
    i. First brush the analytical mill or mortar and pestle;

ii. Second spray them with a jet of air;
iii. Rinse them at least three times with ethanol;
iv. Finally air-dry either by simple exposure to air or by contact with a directed stream of air.

g. All of 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.

4. Standard Preparation and Sample Analysis

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.

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). See Table1.

Table 1 - Calibration Levels:

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

d. 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. 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.
g. Dispense a 1 mL aliquot of the sample solution into a 2 mL amber LC autosampler vial and proceed with analysis.
h. Remaining sample extract will be stored in the locked sample refrigerator until analysis is completed.
i. Method blank: Transfer 40 mL methanol to a 50 mL centrifuge tube and shake for 5.0 minutes.
j. Matrix blank solution: Weigh 0.2g of matrix control material (oregano, spinach or hemp containing no THC, and THC-A) into a 50 mL centrifuge tube. Add 40 mL of methanol and proceed with extraction as described C.5.d-g.

6. Sample analysis: chromatographic conditions

Analysis can be performed on UPLC or HPLC instrument.
Operation of the LC system with PDA detector will be in accordance with EM-PF-005 [4]

a. Method on UPLC Restek column
   i. Column: Restek Raptor ARC-18 100 mm X 2.1 mm ID, guard column from Restek or equivalent
   ii. Column temperature: 50°C.
   iii. Mobile Phase: Channel 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
   iv. Flow rate: 0.310 mL/m
   v. Injection volume: 2.00 µL
   vi. Detection wavelength: 220 nm

b. Method on UPLC - Waters column
   i. Column: Waters Cortecs UPLC Shield RP18 1.6 µm, 100 x 2.1 mm
   ii. Column temperature: 35 ºC
   iii. Mobile phase: A; 0.1% TFA in Water : B; Acetonitrile (41:59) isocratic
   iv. Flow rate: 0.7 mL/min
   v. Injection volume: 2 µL
   vi. Detection wavelength: 228 nm

c. Method on HPLC
   i. Column: Kinetex 2.6.um Polar C18, 150 x 4.6 mm ID, guard column from Phenomenex or equivalent
   ii. Column temp: 35 ºC
   iii. Mobile phase: A: water with 0.1% formic acid
   iv. B: Acetonitrile with 0.1 % formic acid

v. Gradient: 70% B to 100 % B in 6 min
vi. Flow rate: 1.2 mL/min
vii. Injection volume: 10 µL or less
viii. Detection wavelength: 210 nm

Instrument parameters may be adjusted to optimize chromatography.

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 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 should be within ± 15% of each other. If results for duplicates exceed ±15% a new portion of the sample 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).
f. The QC samples are samples repeatedly analyzed in different 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 ± 2 standard deviations from the mean of previous determinations. If one of the QC results falls outside ± 2 standards deviation but is within ± 3 standard deviations the QC results are still acceptable. If both QC results are outside ± 3 standard deviations, results from the sample set are rejected. The sample extracts will be re-tested.

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 µg/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 a hemp sample is 0.1%:

   [(0.2 mL volume of spike solution)*(1000 µg/mL THC stock standard solution)/0.2 x 10^6 µg matrix control sample]*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. Instrument Calibration

a. The calibration correlation coefficient (r^2) must be ≥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.
b. Calibration integrity will be calculated for each set of samples by running a CCV standard. Standard at the level of 10 µg/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 ±15% accuracy.
c. The CCV injections are required to be included in the sample sequence at the beginning of the sample set, after every 5 - 7 samples injections, and at the end of the sample set.
d. 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. Results will 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 $_{\text{as-is basis}}$ –THC level (%) determined by instrument software before adjustment for moisture content.

%THC $_{\text{dry weight basis}}$ – THC level (%) after adjustment for moisture content

b. Final results will be reported in % to two decimal places.
c. Results are reported as a total %THC, the sum of the percentage by weight of THC-A multiplied by 0.877 plus the percentage by weight of THC.

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 = 3.3σ/S and LOQ=10σ/S, where σ is standard deviation of the response and S= slope of the calibration curves of each tested cannabinol.

Accuracy, precision, measurement of uncertainty, LOD, and LOQ are presented in Table 2.

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 0.39%, 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. 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].

D. 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. EM-PF-005 *Waters Alliance HPLC/PDA Operation*, OISC.
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
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
13. Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp -USDA website: https://www.ams.usda.gov/rules-regulations/hemp/rulemaking-documents

E. FORMS

1. Form 45 Rev.01 Hemp Weight Worksheet
2. Form 57 Rev.00 In-Process Hemp Sample Weight

F. 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 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 ±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 ±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 www.nordtest.info.	To determine measurement of uncertainty.
k. Made editorial changes	NA

3. Revision 02 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 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