Manufacturer Training Plan, User Manual and Materials

Manufacturer Training Plan

Manufacturer training is expected to take place in October/November 2018.Following is a training plan, user manual and other materials to support that training.

The overall training approach is to educate the manufacturer on all transactions (events) that the state is tracking and why that is important. For example, when immature plant groups, plants, batches, process lots, product lots and package lots are created this is all tracked in our seed to sale system inventory. We will use a train-the-trainer approach so that ongoing training can occur at the manufacturer. Our initial training will be conducted both virtually (BioMauris) and on site at IDPH (MedPharm) for the most efficient use of resources.

Intended audience -

This training material is intended for all manufacturer employees that have accountability for tracking the seed to sale process for medical cannabidiol production. The majority of data entry happens in the manufacturing system (Leaf Logix for MedPharm) and this training is NOT intended to duplicate the training for that system. The Iowa Department of Public Health (IDPH or Department) has a seed to sale tracking system (STS) that receives significant amounts of data and information from the manufacturing system, and STS is used to ensure compliance with all state regulations that apply to manufacturing of mCBD in Iowa. It is critical that manufacturer employees understand how this system is used by the state for regulation as it is only as good as the data it is sent.

Key personnel -

There should be multiple manufacturer trainers responsible for ongoing training at the manufacturer so new employees receive orientation to this system. These may be the same trainers used for the manufacturing systems.These materials will be updated as needed and can be reused for new employee training. Transport drivers (any employees that will be transporting mCBD products to and from dispensaries or labs) will need special training on how to use the mobile transfer application to log specific transport information.

Initial training schedule -

Since new product is expected to go to market by December 1, 2018 the initial training of manufacturers will be conducted in the October/November 2018 timeframe. Specific date is tentatively set for Thursday October 18, 2018 1-3PM at IDPH 6th floor Lucas Building. Additional training sessions will be scheduled as needed.

Training approach -

We will cover a variety of “case studies” that demonstrate how the department will use the system to regulate manufacturers. Through understanding these cases and the alerts, notifications, views and reports the department receives, the manufacturer employee will understand the importance of proper data entry and logging of events.

Training Agenda

Time allotted	Item Covered	Item Description
15 minutes	Introductions	Allow all students to describe their role at the MFR
30 minutes	Definitions and Events that Trigger System Updates	Define and explain all events that cause data to be sent from MFR system to IDPH system
45 minutes	Case Studies	Review the case studies that describe how the state uses MFR data for regulation
30 minutes	Q&A	Planted questions and answers plus any that students have from training

Manufacturer User Manual

Definitions:

1. Employee Records – The State collects name, date of birth, contact information, date of an approved background check, date of hire and last date of employment. It is incumbent upon the manufacturer to update employee contact information if/when it changes. The acting employee must be identified on each action reported to the State.

2. Waste Records – **Waste** is any production material (plant, oil, product) that is disposed of. Reasons for disposal include but may not be limited to normal trimming or dead plant material, dead plants, damage, quality control issues or failure to meet regulatory requirements. Waste records are maintained for auditing purposes and include the weight, date that the material became waste and waste status. Waste status indicates whether the material has been put in the Compost Room and disposed of. Waste must be accounted for and may be audited by the State through composting up to the time it is removed from the premises.

3. Additive Records – Each **Additive** (eg. Nutrients, pesticides, solvents, etc.) that is applied to the plant and/or it's growth medium or added in the processing cycle are reported to the State for monitoring and are used to ensure consumer safety.

4. Immature Plant Group Records – All seeds, seedlings and cuttings less than 8" in height are assigned an **Immature Plant Group** ID. Immature Plant Group IDs are assigned by the manufacturer and provided to the State. The Immature Plant Group record includes strain, source (seed or cutting/mother plant), location and destruction information when applicable. The Seed to Sale traceability begins here. Each plant (see number 5) must come from an immature plant group.

5. Plant Records – Each **Plant** receives an individual plant ID when it reaches 8" in height. Plant IDs are assigned by the manufacturer and provided to the state. The plant ID continues the Seed to Sale traceability. A plant record is updated as the plant moves through the growth cycle, receives additives, produces waste and changes location. Harvest and curing information is also recorded on the plant record. Plant records link a plant to its Immature Plant Group as well as the Batch that it becomes a part of.

6. Room changes– As a plant moves through the growth cycle, its status and locations will change. This movement is recorded and sent to the state. Both status and location may be audited at any point in the plant cycle.

7. Batch Records – Upon reaching the flowering stage all plants will be assigned to a Batch. The batch ID is assigned by the manufacturer and provided to the State. A **Batch** is a group of plants that are grown, cultivated and harvested under substantially similar conditions. The Batch record links a plant to the process lot it becomes a part of, continuing the required traceability and auditability.

8. Harvest Records – **Harvest** occurs when the plant is cut down. When a plant is harvested the wet weight of that harvested plant is required. Dry weight is required at the end of curing, allowing calculation of moisture loss. Notification is sent to the State if moisture loss is outside of defined normal limits.

9. Process lot Records –The Process Lot Record begins with the input of biomass (ground, cured plant material) and records input and output data for each state of processing through purification. The **Process Lot** is the output of purified oil. At each processing state input and output is required. Notification is sent to the state if conversion rates are outside of defined normal limits. The Process Lot ID is assigned by the manufacturer and provided to the State.

10. Product Lot Records – A **Product Lot** is the formulated, finished product in its bulk state, not yet packaged for sale. The Product Lot Record links this product to the Process Lot(s) that it contains and is the ID on which all Product Recalls are based. The Product Lot ID is assigned by the manufacturer and provided to the State.

11. Package Lot Records – The **Package Lot** is the packaged, labelled, saleable form of the product. A single Product Lot may become multiple package lots to account for different unit sizes and distribution procedures. The Package Lot record is linked to the Product Lot and is a required item on the Transfer Record (see number 12). The Package Lot ID is assigned by the manufacturer and provided to the state.

12. Transfer Records – Any time mCBD products are moved from the manufacturer to a dispensary or lab, a Transfer Record is required. The **Transfer** contains origin, destination, driver, vehicle, estimated duration and arrival time and product information as well as the Transport Manifest (PDF). The Transport Manifest is required for law enforcement verification while in transit as well as audit purposes. The Transfer ID is assigned by the manufacturer and provided to the State. Transfers change inventory, which is tracked across the supply chain.

13. Return Transfer Records – **Return Transfer** Records perform the same function as Transfer Records however the product is being transferred back from dispensaries or labs due to returns, recalls, excess sample material sent to labs, etc.

14. Recalls– Product **Recall** may be initiated by the manufacturer or State and is instituted on the Product Lot. When a Product Lot is recalled, notification is sent to the State, manufacturer and dispensaries to initiate the process of recovering the recalled product for destruction. The dispensaries will contact patients and caregivers who have purchased the product.

15. Inventory Reconciliation – State requirements dictate bi-weekly physical inventory reconciliation reporting. **Inventory Reconciliation** is a reporting of the physical quantity by count or weight of each room. Any time the physical count recorded on the reconciliation differs from the system count notification will be sent to both the manufacturer and the State. If the discrepancy is not mitigated, law enforcement is notified 72 hours after the deviant reconciliation was supplied.

Case Studies:

1. **Inventory reconciliation -**
   The manufacturer is required to conduct a physical inventory of all plants, extracts and finished goods that exist in the facility every two weeks. This is a mechanism to identify potential diversion of products and production materials (oil and plant), or possible issues with the manufacturer or states' tracking procedures. The department receives a report of plant count and/or weight by room, extraction processing inventory and finished product inventory. The system will alert the department if the physical inventory does not match the system inventory records. For example, if the flowering room shows 100 plants (by plant ID) and the physical inventory shows 200 plants in the flowering room, an alert will be sent to the department that records don't match and a reconciliation action will need to be taken. The state will use the reconciliation reports to identify why a discrepancy exists. Inaccurate inventory counts could be due to a system data transfer error or an employee's failure to follow proper procedures (e.g. indicate that a plant changed rooms). To avoid auditing issues, any event that could result in an inventory discrepancy (e.g. plant removed from a batch) needs to be logged accurately and in a timely manner. At several steps in the manufacturing process, including inventory reconciliation, the name of the employee who performed the action is logged and sent to the state.

   The manufacturer has 72 hours to reconcile after receiving an alert that the system inventory does not match. If there is suspected diversion, the manufacturer is required to notify law enforcement within this time. If there is not suspected diversion, and more time is needed to reconcile to the system, the manufacturer shall create an action plan that outlines what steps are being taken to reconcile. This action plan is due within two business days after reconciliation efforts have failed. For this reason, we recommend the manufacturer conducts physical inventory every other Monday. This allows until Thursday to reconcile and until the following Monday to have an action plan, if unable to reconcile by Thursday. If there is a holiday on the Monday where physical inventory is due, we recommend the physical inventory happens on the Friday prior to the holiday.

2. **Waste -**
   The manufacturer is required to track waste and demonstrate that it went through the proper disposal process. The department tracks the count and/or weight of all inventory at the beginning and end of each process. Any waste (loss of) inventory needs to be recorded and will be deducted from inventory and added to waste (the compost room). For example, if unusable material is trimmed from a plant during any growth phase, it

must be weighed and moved to the compost room. If a tagged plant dies, it needs to be moved to compost and recorded as waste. The time/date and reason for destruction must be reported. The employee(s) collecting and transferring the waste to compost are required to log the events. Any material moved to the compost room will be destroyed and no longer part of physical inventory.

3. Additives -

The manufacturer is required to track all additives being applied to plants, such as fertilizer or pesticides. Input quantity of solvents (e.g. ethanol) added during the extraction process is also logged. The department receives reports on these activities with the name of the employee that applied the additive. Time, date, quantity and product details of each additive are reported as well. For example, if a test of the final product shows excessive trace pesticides in the product lot, the department can track that product lot back to the process lot (oil), group of plants (batch) and even individual plants that had the specific pesticide applied to it, the quantity, frequency etc. This allows the state to evaluate the manufacturers' procedure in regard to product safety.

4. Product Recall -

The department is responsible for ensuring that any product that is unsafe for the public can be located and returned to the manufacturer for destruction. This would include product sold to patients or caregivers and unsold dispensary inventory. The state system allows recalled product to be traced back to the product lot, process lot, batch and plants from which it originated. The state and manufacturer may then be able to identify the cause of the defect. In the event of a recall (initiated by either the manufacturer or the department) this product tracking will enable us to notify all dispensaries, labs, patients and caregivers with the recalled product of procedures for returning it to the manufacturer for disposal.

5. Harvest weight -

The manufacturer is responsible to track all weights coming in and out of the harvest process to ensure moisture loss levels are in an acceptable range, as measured by the difference between a plant's "wet" weight after harvest and "dry" weight after curing. If a plant's moisture loss exceeds the percentage determined by the state, then an alert is sent to the department to audit the reason for the abnormal moisture loss. An abnormal amount of weight change between harvest and curing could indicate to the state that there was additional loss due to factors other than moisture loss. Details of the specific plant(s) that exceeded weight loss standards and the employees that weighed them are included.

6. Transfers -

The State is responsible for maintaining a chain of custody record of all mCBD product that is transferred from the manufacturer to lab and dispensaries, as well as all returns back to the manufacturer. For this reason, the department system is the system of record for all transfers. The department has developed a mobile application that will be used by drivers, dispensaries and labs to record the delivery of all product. Based on travel distance, the estimated time to complete the delivery will be recorded and all stops (gas, restroom, other stops) will be recorded in the app to accurately capture drive time. If this expected drive time is exceeded by an unusual amount of time, the department is notified with an alert. The time that the delivery started and was accepted by the recipient are all

recorded. Upon arrival, the recipient will inspect the contents of the shipment to verify its accuracy and that all items are in good condition. The driver and recipient employee are also recorded by signature.

7. **Transfer Return -**
   If the dispensary or lab rejects the transfer in part or whole (wrong order, damaged contents etc), then the return of product must also be logged as a return transfer. The manufacturer is now the recipient of this return, so all times and individuals involved in the return are recorded. The same issues can arise on a return that arise on delivery. Return transfers are logged in the same way as normal product transfers, including recording of stops and package inspections upon arrival except the manufacturer will be the recipient.

8. **Lab Testing -**
   The State is accountable to ensure all mCBD products are safe for consumption by the citizens of Iowa. The State uses ISO certified test labs to ensure that contaminants (metals, toxins, microbials, pesticides, solvents) are not present beyond stated limits in the finished product. Additive tracking is a critical component for root cause analysis when any contaminant tests fail. Product will be traced back to product lot, process lot, batch and plant to determine if additives contributed to failed tests.

Additional Materials

Process Flow Diagrams for Iowa Seed to Sale Tracking

Plant to Harvest

https://docs.google.com/drawings/d/1FKl9nyNUjLcVqHxZXAWx-fCzuuCgY2tBgt9jR7ObNTQ/edit?usp=sharing

Harvest to Transfer

https://drive.google.com/open?id=1qmq1YbUJKk1VaGzgWSixd4Z7IpMwJGpEcJQEEpoVfxg

Sub-Processes

https://drive.google.com/open?id=1npxrfSRMhPAo6IoCVeMo8aEe6_UJctw33lJ5wjKZqZ8

Employee Information

https://drive.google.com/open?id=11Gcy5A26C5Nh9IcV7l8nljTvB0kVNiTzEfMYPJgVXs8

Transfer Information

Insert link to transfer app diagram

Inventory Management

The chart below demonstrates the changes in inventory collected by the State for management and auditing purposes. Failure to provide complete and accurate data around these actions may result in Inventory Reconciliation discrepancies, audit discrepancies and law enforcement intervention. Your diligence in reporting is the key to a successful partnership with the Iowa Department of Public Health mCBD Program.

Event	Increase	Decrease
Waste is collected	Waste weight/count	Plant count/weight, oil weight, products
Immature plant groups created	Seeds, Cuttings	N/A
Plants tagged	Plants	Immature plants
Production materials change rooms	Original room contents	New room contents
Batches created	Batches	N/A
Plants harvested and weighed [JM1]	Moisture loss	Plant weight
Process lots created	Process lots, oil weight	Plant weight
Product lots created	Product lots	Oil weight
Package lots created	Products, Packages	Product lots

Shipments in transit	Transfer contents	Inventory at manufacturer facility

Frequently Asked Questions for the employees:

1. What are the critical events that the department tracks to ensure the manufacturer is compliant with Iowa regulations? Why is the state tracking each of these events?
    a. Inventory records and reconciliation- identify diversion or system issues
    b. Waste records- Diversion and proper logging of all aspects of inventory
    c. Additive records- Identify possible safety issues in manufacturing process
    d. Batch, process and product lot identification records- Allow traceability throughout the entire manufacturing process
    e. Harvest records- Capture moisture loss to ensure levels are acceptable
    f. Transfers and return records- Record where all product is at any given time. Ensure the contents match the record

2. What will happen if physical inventory does not match the system inventory records?
    a. An alert is sent to the department that records do not match
    b. An inquiry will be made of the manufacturer to determine discrepancy
    c. Root cause will be determined and steps taken to avoid in the future
    d. The manufacturer has 72 hours to reconcile. If they are unable to reconcile within that time period, an action plan to complete reconciliation is due to the department within two business days following failed reconciliation efforts.

3. What information is recorded in the manufacturer's waste records? Why is the department interested in these records?
    a. Waste weight, date/time, employee, reason
    b. Plant and other material is in compost that is accounted for so active inventory is accurate - waste reduces active inventory and increases compost
    c. Steps to improve and avoid in the future

4. What information is recorded when additives are applied to plants (or solvents added to a process lot)? Why is the department interested in this information?
    a. Record the type and quantity of additive applied
    b. Record the plants or batch additive is applied to
    c. Record employee performing application
    d. Additives and solvents could be the root cause of a product safety issue and the department uses this information to evaluate the success of the program.

5. What are the records that need to be maintained for a product recall to be effective?
    a. Product lot ID on all products (finished packaged goods)
    b. Associated to process lot (oil used for products)

c. Associated to batch (plants used to extract oil)
d. Associated to plants in batch (plants in each batch)
e. Associated to immature plants (plants origin)
f. Associated to mother plant (clone origin)
g. Current location of all recalled products, including patients and caregivers who purchased them.

6. Why are plants weighed directly after harvest and again after curing? What happens if this weight change exceeds accepted norms?
    a. To calculate the moisture loss to compare against industry norms.
    b. State is alerted
    c. Root cause analysis and possible audit
    d. Steps to improve and take corrective action

7. What are the important factors to consider in a transfer or return? What signifies completion of a transfer?
    a. Drivers have a mobile app to enter all data for the transfer
    b. All stops along the route are logged.
    c. The trip is timed to ensure reasonable delivery times are maintained without gaps
    d. Both the driver and the recipient will sign the transport manifest
    e. Any partial or full rejection of shipment will result in a return transfer
    f. The manufacturer is responsible for all transfers and disposals from returns
    g. The items on the transport manifest match the contents in the vehicle.

Other Materials

- **Screenshots of Salesforce system**
- **Screenshots of Mobile Transfer Application**
- **Contact information for additional questions**