August 30, 2024

# Guidance Bulletin: Implementation Timeline for Total Yeast & Mold Count Testing, Preventative Measures, and Sterilization/Remediation Options for Licensees

## ***Introduction***

The Mississippi Medical Cannabis Program (MMCP) is providing the following guidance regarding the necessity of Total Yeast & Mold Count (TYMC) testing requirements for medical cannabis, the Mississippi State Department of Health's decision to extend the grace period for implementation of TYMC testing by 60 days to allow licensed medical cannabis establishments additional time to prepare for TYMC testing, the steps that licensed medical cannabis establishments may take to as preventative measures to ensure the cultivation and production of safe, compliant medical cannabis products, and the methods of sterilization/remediation that may be considered and/or undertaken by licensees. We make this and other guidance available to current and prospective licensees to ensure the consistent understanding of policies among all regulated entities and to further enhance the good faith partnership between the State of Mississippi, its residents and stakeholders.

## ***Necessity of TYMC Testing of Medical Cannabis Products***

Medical cannabis can harbor harmful microorganisms like yeasts and molds, posing significant risks, especially to immunocompromised consumers. TYMC testing ensures that products are free from harmful levels of these contaminants, which can lead to infections and other health complications. Compliance with TYMC testing is essential to meet regulatory safety standards and to protect public health.

- *Product Quality Assurance*

Regular TYMC testing helps maintain the consistency and purity of cannabis products, ensuring each batch meets safety standards. This testing also helps prevent costly recalls, protecting the brand's reputation and ensuring that product safety is maintained, which is crucial in the medical cannabis industry.

- *Consumer Protection*

Consumers, especially those using medical cannabis for serious health conditions, require assurance that their products are safe and contaminant-free. Regular testing builds consumer trust and ensures that patients receive safe and effective medicine.

- *Economic and Legal Considerations*

Compliance with TYMC testing standards is necessary to avoid legal liabilities. Meeting these standards also allows producers access to broader markets, potentially expanding business opportunities.

- *Preventing Cross-Contamination*

In production and processing facilities, yeast and mold can spread and contaminate multiple batches. Regular testing helps identify and address contamination sources, ensuring that all products remain safe throughout the supply chain.

***Next Steps for Licensees***

During the supplemental 60-day grace period for implantation of TYMC testing, licensees should:

- evaluate their current standard operating procedures (SOPs);
- determine what, if any, additional protocols will be utilized to address readiness for this test;
- revise each SOP to include new or modified procedures including detailed processes for sterilization/remediation methods of those that are permissible that the licensee will utilize in its commercial cannabis activities; and,
- submit same to MMCP via the Licensing Portal as a "Business Update".

*Preventative Measures*

In the burgeoning medical cannabis industry, maintaining safety and compliance is essential. As the market expands, it is crucial for cannabis cultivators and manufacturers to strictly follow rigorous quality assurance and regulatory standards. Each stage of the process, from cultivation

through extraction and beyond, requires careful planning and execution to ensure product safety, effectiveness, and adherence to regulations. While there are many potential sources of contamination throughout the lifecycle of the cannabis plant, there are simple yet impactful ways to mitigate and prevent contamination from its various sources including but not limited to the following practices:

- *Controlled Environment Cultivation*

  Maintaining optimal humidity and temperature levels is crucial to preventing mold growth. Proper air circulation and filtration, including HEPA filters, can help remove airborne contaminants from the growing environment.

- *Sanitation and Hygiene*

  Implementing strict cleaning protocols for equipment and surfaces, along with enforcing personnel hygiene standards, reduces the likelihood of microbial contamination.

- *Genetic Selection and Plant Health*

  Choosing mold-resistant strains and maintaining plant health through proper nutrients, water, and light reduces susceptibility to mold and yeast infections.

- *Harvesting and Drying Techniques*

  Harvesting at optimal maturity and drying cannabis in controlled environments with low humidity and adequate airflow prevents mold development. Achieving a moisture content of 12-14% is recommended.

- *Packaging and Storage*

  Using moisture-resistant packaging and storing cannabis in cool, dry environments with stable conditions prevents mold growth during storage.

- *Regular Monitoring and Testing*

  Routine testing of plants, harvested materials, and final products ensures that contamination is detected early, allowing for quick remediation. Environmental monitoring helps identify potential contamination sources.

*Permissible Sterilization/Remediation Methods*

The following methods may be utilized by licensed medical cannabis establishments for purposes of sterilization/remediation of medical cannabis and/or medical cannabis products:

- Extraction[1]
- Ozone Remediation
  - Pros: Effective at killing a wide range of microorganisms and leaves no harmful residues.
  - Cons: Can degrade volatile compounds, potentially altering the product's quality. Requires careful control due to health risks associated with ozone exposure.
- UV Light Remediation
  - Pros: Non-chemical method effective against surface contaminants.
  - Cons: Limited penetration and potential degradation of cannabinoids and terpenes with prolonged exposure.
- Radio Frequency (RF) Remediation
  - Pros: Provides uniform heating and is efficient for large-scale operations.
  - Cons: Potential for localized overheating, which may degrade product quality, and high energy consumption.
- Ionizing Irradiation

[1] This method is explicitly included in the current regulations as a remediation option. *See* 15 Miss. Admin. Code Pt. 22, R. 5.5.4.

- Pros: Highly effective at sterilizing cannabis and is widely accepted in various industries.
- Cons: Consumer resistance due to misconceptions about radioactivity.

In summary, the choice of remediation method depends on the specific needs of the cultivator/processor, the level of contamination, desired product quality, consumer preferences, and regulatory requirements. Each licensed medical cannabis establishments must update its SOPs to identify the specific method(s) that the licensee intends to utilize in its commercial cannabis activities and include a detailed step-by-step explanation describing the process(es).

*Additional Guidance Specific to Licensed Medical Cannabis Testing Entities*

Licensed medical cannabis testing laboratories may conduct R&D testing for TYMC during the 60-day delayed implementation period; however, for this 60-day period, R&D testing for TYMC should not be entered into the state authorized seed-to-sale system, METRC. The results may be used by the licensee as an information tool to guide decision-making regarding the licensee's standard operating procedures and any changes that may be necessary to achieve and maintain compliance with MMCP regulations, including mandatory testing requirements.

For purposes of reporting the results of compliance testing in METRC during the extended 60-day grace period, licensed testing labs should enter an N/A value for the TYMC analyte with a note that clearly indicates testing occurred during the sanctioned extension. MMCP will work with METRC to ensure that a process is in place to allow these products to move forward to the retail market.

***Conclusion***

The extended 60-day grace period ends October 29, 2024. **From and after October 30, 2024, TYMC testing will be required for all medical cannabis and medical cannabis products as per MMCP regulations.** As a reminder, please note that MSDH regulations serve as the minimal requirements that medical cannabis establishments must meet in order to be licensed and maintain that licensure status. With the ultimate goals of patient and product safety, MSDH encourages all licensees to implement continuous improvement processes to ensure not only compliance, but positive outcomes for the production of medical cannabis and patient safety.

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