MEMORANDUM

TO: Cannabis Regulatory Commission Board
FROM: Jeff Brown, Executive Director
SUBJECT: Consideration of Testing Laboratory License Applications
DATE: May 24, 2022

EXECUTIVE SUMMARY

On August 19, 2021, the Cannabis Regulatory Commission (herein referenced as “Commission” or “CRC”) adopted rules pursuant to P.L. 2021, C.16 which established the licensure process for cannabis businesses and testing laboratories. N.J.A.C. 17:30-6 through 7 outlines the application process and requirements for both conditional license applicants and annual license applicants. The rules also include the eligibility requirements and limitations for Social Equity Businesses, Diversely-Owned Businesses, and Impact Zone Businesses.

This memo outlines the process and recommendations concerning 4 applications for cannabis testing laboratory licenses. These applications have been reviewed, scored, and are recommended for approval by CRC Staff.

Pursuant to regulations on cannabis business licensure, the CRC issued a Notice of Application Acceptance (“Notice”) on November 9, 2021, which outlined the specific criteria for each application type and the dates on which the CRC would begin accepting applications. The Notice of Application Acceptance also outlined the specific priority by which applications would be reviewed by the CRC.

On December 15, 2021, the CRC began accepting applications for Class 1 Cultivation, Class 2 Manufacturing, and Testing Laboratory licenses.

On March 15, 2021, the CRC began accepting applications for Class 5 Retailer licenses.

AUTHORITY

Pursuant to N.J.S.A. 24:6I-18, the Commission shall license testing laboratories that perform testing services. The governing regulations at N.J.A.C. 17:30-6.1(c)(2) and N.J.A.C. 17:30-15.1(b) provide that the Commission shall announce a date of the initial acceptance of license applications in the New Jersey Register, on the Commission website, to the Commission email list, and at a Commission public meeting.

The governing regulations at N.J.A.C. 17:30-15.2(e) provide that the Commission shall approve a testing laboratory license provided that: 1. An applicant submits a sufficient application as outlined in N.J.A.C. 17:30-15.2(b); 2. An applicant is qualified for a testing laboratory license pursuant to
An applicant submits a testing laboratory license application fee in accordance with N.J.A.C. 17:30-7.17.

BACKGROUND

On August 19, 2021, the Commission adopted rules pursuant to P.L. 2021, C.16 which established the licensure process for cannabis businesses and testing laboratories. N.J.A.C. 17:30-15 outlines the application process and requirements for the licensing of testing laboratories.

The rules require the CRC to issue a Notice in the New Jersey Register that includes the application requirements for conditional and annual license applications. That Notice must include:

- Measures by which the license applicant will be scored;
- Maximum scores for each individual measure; and
- The total score required for a license applicant to be approved for a license.

On November 9, 2021, the CRC adopted a Notice in accordance with N.J.A.C. 17:30, Subchapters 6 and 7. That Notice was announced and approved at the CRC’s November 9, 2021, public meeting, posted on the CRC’s website, distributed to the CRC’s email list, and was published in the New Jersey Register on December 6, 2021.

The Notice of Application Acceptance was updated twice to correct typographical errors.

Pursuant to N.J.A.C. 17:30-6.1, in addition to the scoring measures and mandatory requirements for license applicants, the Notice also included a detailed list of application priority. Applications are reviewed in accordance 1) with the priority list included in the Notice and 2) in the order in time in which they are received.

The Notice can be found on the CRC’s website.¹

In summary, the Notice of Application Acceptance:

- Prioritizes the review and scoring of Social Equity Business license applicants, which are businesses owned by individuals from Economically Disadvantaged Areas or who have past marijuana or hashish convictions, in both conditional and annual license categories;
- Prioritizes conditional license applicants over annual license applicants;
- Provides that microbusiness applicants are given priority in every category of license application; and

• Establishes pass/fail scoring criteria that comply with the statute and rules by which applications will be reviewed.
• Recognizing that safe products must be available to patients and consumers testing laboratory license applications are included in priority 1A.

TESTING LABORATORY LICENSURE REVIEW

Testing Laboratories are given the highest priority designation for licensure review. These applications are reviewed and scored based upon the measures outlined in the Notice of Application Acceptance and governing regulations at N.J.A.C. 17:30-15.1 through 15.5.

Testing Laboratories were given the highest priority because having adequate third-party lab testing capacity is critical for ensuring safe, well-regulated cannabis and cannabis products.

The process for the review of testing laboratory applications includes the following chronological steps:

1. Priority Assignment – Applications are assigned to their relevant priority level based on responses to questions on the application. This assignment occurs for all applicants after they submit their applications into the licensing system.

2. Priority Verification – Once assigned a priority, the applications are then reviewed to ensure the applicant has submitted the proper documentation to support their priority assignment. If they have submitted the documentation, they remain in queue to be reviewed. If they have not submitted proof to back up their priority designation, the application is marked for rejection and curing.

3. Completeness Review – Applications are reviewed for completeness to ensure everything required by the Notice and N.J.A.C. 17:30-15.2 is included in the application, including evidence of ISO 17025 certification. If an application is deemed incomplete, it is marked for rejection and curing.

4. Scoring – Applications that have been deemed complete are then scored in accordance with the rubric in the Notice. Applications receive full points if they pass a measure, and no points if they fail. All of the required submissions outlined below are reviewed and scored. Testing laboratories need to score 200 points to be advanced. If an application fails in scoring, it is marked for rejection and curing. The required submissions for scored measures to be submitted by testing laboratories are as follows:

   a. Business and Management Plan- which includes a description of the business, value proposition to consumers, financing for business, pricing plans, market analysis and a complete management profile for the testing laboratory;
   b. Regulatory Compliance Plan;
c. Plan to obtain liability insurance;

d. Safety and Security Plan- which includes an overview of compliance with security regulations under N.J.A.C. 17:30-9.10;

e. Standard Operating Procedures for Adverse Event Reporting, Quality Assurance/Control, Inventory Control/Storage/Diversion Prevention, Recordkeeping, Secure Transport, Sampling and Testing Cannabis, and Reporting of Test Results for Cannabis;

f. Evidence of ISO 17025 Certification.
   i. Testing Laboratory applicants are required to submit evidence of ISO 17025 certification from an accreditation body that requires conformance by the testing laboratory to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) general requirements for the competence of testing and calibration laboratories (ISO/IEC 17025 standards), as they may be updated or revised, in order to ensure equipment is routinely inspected, calibrated, and maintained.

5. Qualification and Financial Review – Following scoring, testing laboratory applications and applicants are investigated to ensure compliance with all qualification, limitations, and other provisions regarding ownership/operation of testing laboratories:
   a. N.J.A.C. 17:30-15.3 (Testing laboratory license qualification)
   b. N.J.A.C. 17:30-6.8 (Limitations on license holders, owners, principals, passive investors, financial sources, management services contractors and vendor contractors);
   c. N.J.A.C. 17:30-6.9 (Management services agreements); and
   d. N.J.A.C. 17:30-6.10 (Financial source agreements).

6. Inspection – The Office of Compliance and Investigations has scheduled inspections for each Testing Laboratory proposed for license issuance. Staff recommends approval of these licenses pending final site inspection. Final site inspections will include on-site evaluation of the testing laboratory, storage facilities, and transport vehicles (as appropriate), walk-through of processes established by the testing laboratories’ Standard Operating Procedures, and verification that each testing laboratory maintains evidence of all certifications, accreditations, and registrations that each testing laboratory holds according to the application submissions.

7. Quality Control – Any application that is deemed eligible for approval following a qualification review, is then given a quality control review to ensure that the determination is accurate.

8. Recommendation to the CRC Board – Applications that pass a quality control check are then recommended for approval to the board for full licensure.
RECOMMENDATION

This recommendation is for the approval of x testing laboratories.

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<tr>
<th>Number</th>
<th>Applicant ID</th>
<th>Applicant Business Name</th>
<th>License Type</th>
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<tbody>
<tr>
<td>1</td>
<td>1173</td>
<td>Trichome Analytical LLC</td>
<td>Testing Lab</td>
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<tr>
<td>2</td>
<td>1328</td>
<td>New Jersey Cannalytics LLC</td>
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<td>3</td>
<td>1757</td>
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<td>4</td>
<td>1903</td>
<td>Sriven Labs LLC</td>
<td>Testing Lab</td>
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These applications have been deemed compliant with their priority designation, deemed complete, and scored for potential approval. They have also been reviewed for license-holder qualification provisions, for license-holder limitations, and any proposed financial source or management services agreements have received an initial review.

CRC staff have determined that these license applications are eligible for approval by the CRC and that these license applicants are eligible to hold testing laboratory licenses.

Therefore, CRC staff recommend the CRC Board **APPROVE** these applications for licensure, pending final site inspection by the Office of Compliance and Investigations.