



During the Medical Marijuana Testing Laboratory Application Q&A period hosted by the Department of Commerce, the Department received several questions regarding the application process. The Department is providing this guidance to assist applicants with the completion of an application for a testing laboratory license. As a reminder, the scope of this Q&A period was limited to application process matters only. General questions regarding regulations and the operation of the program are not answered in this document.

The Department also received questions regarding the issuance of licenses to testing laboratories operated by privately-held entities. The Department will not issue a Certificate of Operation to a privately-held testing laboratory until June 5, 2018, or later, which is one year from when the Department began accepting applications under O.R.C. 3796.09.

Applicants are also encouraged to review the Q&A responses from the Cultivator application period published earlier this year. Those documents are available at <http://medicalmarijuana.ohio.gov/cultivation>. This does not constitute legal advice, which should be sought from a legal professional.

#	Question	Answer
1	Form R, requiring all analytical techniques and protocols, procedures to be submitted and kept under 60 pages. Given the page limit, and the necessity of validating these protocols, we ask that applicants be allowed to submit a summary by method and title of all analytical methods. We also propose an index of SOP's rather than full text to meet the 60-page requirement, with full text available for review at any time.	The Department is aware of the volume of documents in a complete set of SOPs (Standard Operating Procedures), and is not requesting that this material be submitted in its entirety. It is recommended that applicants submit information pertaining to the structure and implementation of their SOPs, as well as a list of SOPs and their summaries, that demonstrate the ability to comply with the requirements of ISO/IEC 17025, and that will be implemented to ensure the safe and proper analytical testing of medical marijuana. (NOTE: Supplemental documents and pages in excess of the established page limits will not be reviewed.)
2	Form S, requiring 15 pages or less, we ask the same type reduction of content to include a summary of all procedures with full text available at any time requested?	Please see question #1 answer above and address the matter in a similar fashion.
3	When will the public institutes of higher education know the status and scoring of their application?	The Department anticipates having public institutes of higher education laboratory applications evaluated and awarded in January of 2018.
4	What would be the process to change the location of the lab at a later date i.e. do we have to go through the same process, we are talking about 1-2 years after being operational as we feel we will outgrow our proposed location?	Please refer to rule 3796:4-1-07 of the Ohio Administrative code: <a href="http://codes.ohio.gov/oac/3796:4-1-07v1">http://codes.ohio.gov/oac/3796:4-1-07v1</a>



5	<p>Form R, Part 1: Do we have to provide the complete SOPs for all the techniques/protocols or just provide a list as we will cross the page limit?</p>	<p>The Department is aware of the volume of documents in a complete set of SOPs, and is not requesting that this material be submitted in its entirety. It is recommended that applicants submit information pertaining to the structure and implementation of their SOPs, as well as a list of SOPs and their summaries, that demonstrate the ability to comply with the requirements of ISO/IEC 17025, and that will be implemented to ensure the safe and proper analytical testing of medical marijuana. (NOTE: Supplemental documents and pages in excess of the established page limits will not be reviewed.)</p>
6	<p>All our analytical methods are proprietary. How do I prevent the data to be in public domain?</p>	<p>Applications that are submitted may or may not be public records and subject to disclosure under the Ohio Sunshine Laws. (R.C. 149.43) While there are exceptions to production in Ohio statutes, federal law, and common law privileges, MMCP cannot guarantee that any or all data in the application will remain confidential at all times. Further, MMCP may use or disclose information contained in the application submission to the extent provided by law. Applicants are strongly encouraged to review the applicable law prior to submitting an application as MMCP is unable to provide legal advice as to the absolute confidentiality of the data received.</p>
7	<p>Do I have to provide copies of my tax forms and for how many years?</p>	<p>Please refer to Form L and Form O in the document titled “MMCP-L-1003” available at <a href="https://medicalmarijuana.ohio.gov/testing">https://medicalmarijuana.ohio.gov/testing</a></p>
8	<p>Will the Department of Commerce require from private testing laboratories the same high standards required from Ohio universities to best safeguard the public before issuing licenses?</p>	<p>Yes. All laboratories licensed under the program will be held to the same standards and will be subject to the same requirements under Chapter 3796 of the Administrative Code.</p>
9	<p>How many testing laboratories does the Department plan to license and can you share the market analysis for the Department’s decision to seek private testing laboratories to meet the demand of cultivators and processors?</p>	<p>There is no limit in rule on the number of laboratory licenses that may be issued by the Department. Projections as to the needs of the program were based on research conducted in other states with similarly structured programs and through consulting with industry experts.</p>
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<p>Can a public institute of higher education secure private investment, or should interested parties submit a private laboratory application? In other words, can private investment occur with public application, or need to submit private application? If so, is it acceptable for a public institution to submit dual applications?</p>	<p>This question pertains to University Testing Laboratory Applications and the application period for those applications is now over. As has been previously stated by the Department, the process of licensing a public institution to conduct laboratory testing is not intended to be used as an opportunity for a private entity to form a partnership with a public institution for the purpose of gaining more favorable timing or a competitive advantage over other private entities. As such, any license issued to a public institution must be for a facility that is wholly owned, funded, and operated by that institution.</p> <p>Any financial or operational partnership between a public institution and a private entity is subject to the same licensing process as a private entity alone. If a public institution forms a partnership with a private entity, the partnership would be required to submit a complete application during the same submission period as other private entities, and can expect to be evaluated and awarded in the same time frame.</p> <p><b>IMPORTANT:</b> Laboratories, regardless of ownership, are subject to the financial interest restrictions in O.A.C. 3796. An owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the cultivator, processor, or dispensary licensed by the Department or Board of Pharmacy may not have an ownership or investment interest, or compensation agreement with, or share any corporate officers or employees with a laboratory licensed under Chapter 3796. of the Revised Code or an applicant for a license to conduct laboratory testing under Chapter 3796. of the Revised Code.</p>
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