

OFFICE OF THE SECRETARY OF STATE
BEV CLARNO
SECRETARY OF STATE
JEFF MORGAN
INTERIM DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR
800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 65-2020

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
09/24/2020 12:51 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary rules to allow a usable hemp matrix for cannabis PTs for pesticides and potency

EFFECTIVE DATE: 09/24/2020 THROUGH 03/22/2021

AGENCY APPROVED DATE: 09/23/2020

CONTACT: Heather Owens
971-291-2568
publichealth.rules@state.or.us

800 NE Oregon St.
Portland, OR 97232

Filed By:
Heather Owens
Rules Coordinator

NEED FOR THE RULE(S):

Oregon Environmental Laboratory Accreditation Program (ORELAP) has a memorandum of understanding with a proficiency testing (PT) provider to travel to Oregon and prepare an adequate number of PT samples for ORELAP accredited cannabis laboratories for the year. Due to COVID-19, this provider is no longer able to travel to Oregon to prepare these samples. Usable marijuana cannot be transported across state lines. Therefore, usable hemp will be used to create cannabis PT samples that can be transported across state lines. This will allow the PT provider to mail the hemp PTs directly to ORELAP accredited cannabis laboratories. The temporarily amended rules will allow with the written permission of ORELAP the use of a usable hemp matrix when a usable marijuana matrix is unavailable for cannabis PT samples.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, accredited cannabis laboratories and regulated entities that rely on accredited cannabis laboratories for compliance testing of cannabis. These rules need to be adopted promptly so that the semiannual analysis of cannabis PTs can continue unabated and the protection of public health is ensured.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

N/A

AMEND: 333-064-0120

RULE SUMMARY: The Oregon Health Authority (Authority), Public Health Division, Oregon Laboratory Accreditation Program (ORELAP) is making temporary amendments to administrative rules in chapter 333-0, division 64 - 0120, pertaining to proficiency testing (PT) for laboratories accredited for cannabis testing. The temporary rules will allow ORELAP to approve the use of usable hemp matrix PTs when usable marijuana matrix PTs are unavailable for cannabis pesticide and potency analyses. These amendments are directly related to COVID-19 travel restrictions that will preempt ORELAP's PT provider from traveling to Oregon to prepare for ORELAP the normal contingent of usable

marijuana PT samples.

Amendments to OAR-333-064-0120 "Proficiency Testing for Laboratories Accredited for Cannabis Testing": Update to the rule language to allow with the written permission from ORELAP the use of a usable hemp matrix for PT samples for cannabis pesticide and potency analyses when a usable marijuana matrix is unavailable.

CHANGES TO RULE:

333-064-0120

Proficiency Testing for Laboratories Accredited for Cannabis Testing

The purpose of a proficiency testing (PT) study is to provide a means for ORELAP to evaluate a laboratory's performance, under specified conditions related to a given set of criteria in a specific area of accreditation, through analysis of PT samples provided by an external source.¶

- (1) A laboratory accredited to test marijuana items must at all times have two successful PT studies out of the most recent three attempts for each field of accreditation for which the laboratory holds accreditation.¶
 - (a) The closing dates of a PT study for a particular field of accreditation can be no more than seven months apart.¶
 - (b) The opening date of a PT study for a particular field of accreditation must be at least seven calendar days after the closing date of the previous PT study for the same field of accreditation.¶
- (2) For purposes of this rule a PT study is a scheduled PT study or a supplemental PT study.¶
- (3) When a laboratory submits its PT study results to the PT vendor, the laboratory must:¶
 - (a) Ensure that the information provided to the vendor reflects accurate information about the laboratory that corresponds to the information in the laboratory's accreditation or application for accreditation, including but not limited to:¶
 - (A) The laboratory's name and address;¶
 - (B) The laboratory's ORELAP ID number; and¶
 - (C) The method and analyte codes.¶
 - (b) Instruct the PT vendor to send the PT results directly to ORELAP.¶
- (4) Any of the following will be considered to be an unsuccessful PT study and if a study was done, may not be counted toward the laboratory's PT history of the most recent three attempts:¶
 - (a) If a PT study for a particular field of accreditation is not performed within seven months, the laboratory will be charged with a failed study for each analyte.¶
 - (b) A PT study for a particular field of accreditation that has an opening date less than seven days from the closing date of the previous PT study for that same field of accreditation.¶
 - (c) Information on study results received from the vendor does not match any of the items in 333-064-0120(3).¶
- (5) For pesticide and potency analyses in usable marijuana, a laboratory must use PT samples made with a usable marijuana matrix. If a usable marijuana matrix is unavailable, then a PT sample made with usable hemp matrix may be used with written permission from ORELAP. If a PT sample made with a usable hemp matrix is used for accreditation of potency analysis, then the PT vendor must prepare the sample in usable hemp material itself and may not provide a separate spiking solution with the sample.¶
- (6) In accordance with ORS chapter 183, the Oregon Health Authority may:¶
 - (a) Suspend the affected field of accreditation if a laboratory fails to comply with this rule.¶
 - (b) Revoke the affected field of accreditation if a laboratory fails three consecutive PT studies or fails to participate in a PT study as is required by these rules.¶
- (7) For purposes of this rule a successful PT study means the testing results have been evaluated as acceptable.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555