Department of Commerce, Community, and Economic Development

ALCOHOL & MARIJUANA CONTROL OFFICE

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Marijuana Control Board Meeting Agenda Online – Zoom Meeting Anchorage, AK

# Tuesday, September 21, 2021 at 3:00 pm

Join Zoom Meeting

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Meeting ID: 824 7940 3697 Passcode: 340949

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All times are approximate. Lunch break from 12:00 noon to 1:00 pm.

The Board may go into executive session at any time when appropriate under AS 44.62.310(b) and (c).

ADMINISTRATION

3:00 pm

A. Call to Order

3:00 pm

B. Roll Call

Nick Miller, Industry Member and Chair Bruce Schulte, Public Member and Vice Chair Christopher Jaime, Public Safety Member Eliza Muse, Public Health Member

Glen Klinkhart, Director

Richard Moses, for Joan Wilson, Assistant Attorney General Rick Helms, Program Coordinator Carrie Craig, Records and Licensing Supervisor

#### C. Approval of Agenda

Bruce S. motions to approve the agenda. Eliza M. seconds. None opposed, motion carries. Motion taken again due to Mr. Jaime's auditory issues. None opposed, motion carries.

#### BOARD GOVERNANCE

3:10 pm

*Christopher J. cannot hear the meeting – reconnects successfully. There are no changes to be reported by the board members.* 

BOARD CONSIDERATION		3:15 pm	3:15 pm	
А.	License #15124	Fairbanks Analytical Testing, LLC	<u>TAB 1</u>	
	Licensee:	Fairbanks Analytical Testing, LLC		
	License Type:	Marijuana Testing Facility		
	Premises Address:	1521 Stacia Street, Suite A		
		Fairbanks, AK 99701		
	Local Government:	City of Fairbanks, Fairbanks North Star Borough		
	For Consideration:	Probation violation/Reconsideration		

Director Klinkhart summarizes the background history. As of September 17, 2021 (suspension end date) there were still 15 items that have been not been completed. The Director asks the Board to review the evidence and discuss it with the witnesses.

Lance Wells, counsel for F.A.T. is present, Ron Eads and Dylan Macomber, licensees, are present. Dylan states that they have responded to all 15 items and have gone back and forth – they are stuck and don't know where to go from here.

Steve Crupi, with DEC – EHL Quality Manager, is present and provides a one-page summary of the findings from the audit. As of 9/20/21 there are 14 findings still open. There are three critical findings that are still open: Microbiology SOP, Potency Data Defensibility/Traceability, Proficiency Testing Scored Results. Mr. Crupi explains why these items are critical. Since the suspension start date, there has been increased communication between the parties.

Nick M. asks Mr. Crupi where F.A.T. should go next. Mr. Crupi says the three critical findings should be addressed first and gives explanations how they can find resources to get these completed. Nick M. asks how long should it take? Mr. Crupi says F.A.T. need to be focused on the audit and not worried about the future – it could be done within the next month if they are completely focused on the audit.

Bruce S. asks Dylan's thoughts on why the standard operations procedures (SOPs) went from 25 pages to 80+ pages. Ron Eads answers that they complied with the audit. There was a lot of back and forth – either giving too much information or not enough. Goal posts keep changing. Proficiency testing is more expensive than Mr. Crupi stated - \$12,000 not \$3500. There is no funding. He states he would like DEC to write the SOPs.

Bruce S. asks Mr. Crupi about the personnel resumes – is it required for everyone? Steve says the regulations require the technical manager however the compliance letter requires more staff. Bruce S. asks if the same standards are upheld for other labs. Steve says yes. Bruce S. is concerned about moving targets. Steve speaks to the history of the creation of the standards and the compliance document. Ron Eads states they feel that they have not been treated fairly. Another lab had a similar issue but was given a recommendation - not a deficiency.

*Eliza M. doesn't have any questions. She is thinking about further clarifying regulations and wants this process to be fair for everyone.* 

Christopher J. states that they will be held to higher standard because they are on probation. It is not DEC's job to write their SOPs. Asks Mr. Crupi about the second critical finding. Steve says there were multiple findings to retrieve the data for verification – they can't access the data when onsite – encrypted. In mid-August F.A.T. provided some data, but it is not traceable so therefore it's not defensible. Christopher J. says there are still 14 deficiencies – what's going on? Steve says the target is getting missed – not in sync. Christopher J. asks if these are achievable targets and are the other testing facilities being held to same standards. Steve says yes to both.

Dylan Macomber says the auditors have not cited the CFR references. Cannot find any of the documentation – how can they be cited then? Says the SOPs only needed minor changes – was preapproved. It doesn't seem reasonable and fair to rewrite the SOPs and complete the rest of the audit in 30 days. And why would it be dangerous for DEC to write the SOPs?

Bruce S. states that F.A.T. needs to devote more energy to this process but yet understands their frustrations. He suggests one-on-one meetings with a neutral moderator to help them reach compliance.

Christopher J. says it is a public health/safety issue. If they can't reach compliance, they shouldn't operate. He believes they should remain suspended until they are in compliance. Ron Eads says that would put them in bankruptcy – they need funding and states they can complete the audit findings that came out on the 20<sup>th</sup> in a week. Christopher J. says they had months to be working on this.

Nick M. asks Steve about deficiencies on this audit versus recommendations for the same findings on another audit. Steve can't comment without additional information. Examples are given by both regarding good laboratory practices.

Bruce S. asks Steve if he has a SOP that is the gold standard that he could show F.A.T. as an example. Steve has SOPs in their operation for testing that he could share - the danger is that it will not represent their mode of operation – may not all be pertinent for F.A.T. Discussion between Bruce S. and Dylan about the thermometer calibration deficiencies. Bruce S. asks Steve is what Dylan explained was correct? Steve says it's not wrong, its incomplete and he provides further details on the findings that Dylan did not previously mention.

*Christopher J. suggests continuing suspension with delegation to the Director to lift the suspension once they are in compliance.* 

Dylan has more questions – why didn't they ask for everything up front? Ron Eads agrees – they want more.

Bruce S. asks the Director if he would be able to be the one to sit at that table and moderate. Director Klinkhart is open to options, but doesn't want to be in the position where he makes a decision for the Board. Bruce S. states that clarity is needed, perhaps fly a DEC auditor to F.A.T. to assist them in person.

Christopher J. motions to continue the suspension with delegation and if corrected, the license can be reissued. AMCO to provide transportation for Crupi's team to assist hands on to get the issues resolved. Bruce S. seconds.

Nick M. states his expectations and says if more than 12 days – he wants to know from the Director about it and get back together. Steve Crupi says the auditors can travel and in person is a great idea. **None opposed, motion carries.** 

Nick M. asks Richard Moses if F.A.T. agrees to daily updates to the Director to forward to the Board is appropriate. It is. F.A.T. agrees. Director Klinkhart would like both parties to provide updates. Agreed.

### BOARD COMMENTS

There are none.

### NEXT MARIJUANA CONTROL BOARD MEETING

The next meeting is scheduled for October 26-28, 2021, in Anchorage and online via Zoom. All applications must be deemed complete by AMCO examiners <u>and</u> all other information for inclusion in the board's packets must be received by **October 8, 2021.** 

## **ADJOURN**

4:50 pm: Bruce S. motions to adjourn. None opposed, motion carries.