

Department of Commerce, Community, and Economic Development

ALCOHOL AND MARIJUANA CONTROL OFFICE

550 West 7th Ave, Suite 1600 Anchorage, AK 99501 Main: 907.269.0350

MEMORANDUM

TO: Chair Springer and Members of the

DATE: April 4, 2018

Marijuana Control Board

FROM: Erika McConnell, Director RE: The New Frontier Research #12657

Testing Facility

On February 20, 2018, the licensee requested that they be allowed to begin operating to provide potency and microbial testing but postpone providing residual solvent testing.

I required the licensee to file an MJ-015 operating plan change, so that they could operate in a manner consistent with what was approved by the board, and I gave temporary approval to the operating plan change with the authority delegated to me by the board. The licensee began operating in mid-March.

Attachments: Email request

MJ-15

Original MJ-06

From: Jessica Alexander

To: McConnell, Erika B (CED)

Subject: New Frontier-- Approval for Lab Testing
Date: Tuesday, February 20, 2018 2:18:03 AM
Attachments: Potency Results- 5731 PoT 010218.pdf
SalmonellaPCRPT12.22.2017Results.pdf

Director McConnell,

We would very much like to speak with you regarding the status of approval for testing. We have decided to get ISO accredited now and have submitted packets of documentation for items that were identified in the gap analysis that was done at the time of inspection. We were so close to meeting the requirements that it didn't make sense not to do it now and set a precedent-- especially if we want to be respected as researchers and be able to collaborate with other respected researchers.

We have submitted validation work for the following scope of testing:

- Cannabinoid profiling
- Cannabinoid quantitation of plant, concentrates, and infused products/edibles
- PCR identification of STEC
- · PCR identification of Salmonella
- PCR identification of Aspergillus

We expect to hear back from A2LA today regarding the validation reports submitted thus far. If they accept everything, they could send our application and supporting documentation to the committee to accredit us for a limited scope of testing. This means that our lab could be approved for all of the above testing, but not for residual solvents or terpene testing until all required items related to those methods are completed and they are formally added to our scope of accreditation though the ISO accreditation process. Given that the state mandates what types of testing must be done, but does not mandate that every lab must provide all tests, would AMCO be willing to approve our lab to only do testing for cannabinoid potency/profiling and microbial testing until we add residual solvents and terpenes to our scope of accreditation through the A2LA/ISO review process? You would be informed of the status change in writing when we receive approval by the committee to add those other tests to our scope, at which time we could start to offer those tests to the public-- but ONLY AFTER AMCO NOTIFICATION AND APPROVAL. If this is acceptable, we will request that A2LA submits our application to the ISO committee for the limited scope now.

Also, we completed proficiency testing for potency and microbial (which is a required component of ISO certification) and performed very well. Please find those reports attached.

We look forward to your input. Respectfully,

Jessica Alexander, MPAS, MSCRM Co-Owner and Laboratory Director jalexander.thenewfrontier@gmail.com 2301 S. Knik-Goose Bay Rd. Unit #3A Wasilla, Alaska 99654 (907) 302-4969

The New Frontier Research

Committed to Public Safety Through Testing and Research



Alcohol and Marijuana Control Office 550 W 7th Avenue, Suite 1600 Anchorage, AK 99501 <u>marijuana.licensing@alaska.gov</u>

https://www.commerce.alaska.gov/web/amco

Phone: 907.269.0350

Alaska Marijuana Control Board

Form MJ-15: Operating Plan Change

What is this form?

This operating plan change form is required for all marijuana establishment licensees seeking to change a licensed marijuana establishment's existing operating plan, as required by 3 AAC 306.100. With this form, a licensee may request changes to as much or as little as desired of Form MJ-01 and/or the corresponding operating plan supplemental for the establishment's license type. The required \$250 change fee may be made by check, cashier's check, or money order.

Please download, complete, and submit with this form <u>only the pages</u> of Form MJ-01 and/or the corresponding operating plan supplemental that contain sections that you are requesting to change. All fields that are left blank will be considered unchanged from the existing operating plan. All fields that are completed and submitted with this form will be considered as changes to the existing operating plan and are subject to board approval. Please do not submit any wholly unchanged pages of an operating plan.

The form(s) that I am requesting board approval to change is:
	Form MJ-01: Marijuana Establishment Operating Plan
	Form MJ-03: Retail Marijuana Store Operating Plan Supplemental
	Form MJ-04: Marijuana Cultivation Facility Operating Plan Supplemental
	Form MJ-05: Marijuana Product Manufacturing Facility Operating Plan Supplemental
V	Form MJ-06: Marijuana Testing Facility Operating Plan Supplemental

This form must be completed and submitted to AMCO's main office <u>prior to changing existing operations</u>. The licensed establishment's operations may not be altered unless and until the director has given temporary approval or the Marijuana Control Board (MCB) has given final approval of the changes. Please note that licensees seeking to change operating plans for multiple licenses must submit a separate completed copy of this form for <u>each license</u>.

Section 1 - Establishment Information Enter information for the business seeking to be licensed, as identified on the license application. Licensee: MJ License #: The New Frontier Research, LLC/Jessica Alexander License Type: Testing Facility **Doing Business As:** The New Frontier Research **Premises Address:** 2301 S. Knik Goose Bay Rd. #3 City: Wasilla State: Alaska ZIP: 99654

[Form MJ-15] (rev 01/11/2018)



Form MJ-15: Operating Plan Change

Section 2 - Summary of Changes

Provide a summary of the changes for which you	are requesting approval.		
The laboratory scope of testing will temporarily only incl			
1) Cannabinoid profiling for CBDV, CBDA, CBGA, CBG creams, cooking oils, and personal concentrates); 2) Concentration for all cannabinoids identified (with a to 3) Microbial testing for presence of STEC, Salmonella, 4) Moisture content of plant material; and 5) Visual inspection for foriegn matter.	otal concentration for THC and CBD, a and Aspergillus (niger, flavus, and fum	is well as CBN reported to the state/METRC); igatus) in plant and food products.	
Additionally, food products will ONLY be tested by the laduring product development. This testing includes identicannabinoids and falsely decrease or increase the camparticular food matrix (which would result in a falsely low correct these complications and provide more accurate acceptable degree, the food type will not be tested at T provide inacurate results that may create a dosing error	meation of chemicals which laisely alphabinoid concentration reading, and fow reading). In many cases, adjustmeninesults. If it is determined that adjustne New Frontier Research, as we belied.	r the general ability to extract cannabinoids fro ts can be made to the processing of that food t nents cannot correct one of these complication eve it is less harmful to provide no results than	m the ype to s to a it is to
Residual solvent testing and terpene testing will be added which time, it will be added to the scope of accreditation M15 form and by written notice provided by A2LA.	led to the laboratory's scope in the nean for the lab. AMCO will recieve notific	ar future through the process of ISO committee ation of this as a change in operating procedur	review, at es on an
S	section 3 – Declaratio	ons	
Read each statement below, and then sign your	initials in the corresponding box	to the right:	Initials
The proposed changes conform to all applicable			JA
I understand that any temporary approval grant investment I make, based upon temporary appro	ed by the director is <u>pending a fin</u> oval, is at my own risk.	al decision by the MCB; therefore, any	JA
As a marijuana establishment licensee, I declare schedules and statements, is true, correct, and constant of licensee	under penalty of unsworn falsifica omplete. -	Notary Public in and for the State of A	l
JESSACA ALEXANDER		My commission expires: 06/13/	
Printed name of licensee	Subscribed and sworn to before	e me this _/_ day of	
		Official Seal LaDonna Scheel Notary Public-State of Alanka My Comm. Expires 06/13/2019	
AMCO Director Review for Temporary Approva	l Pending Final MCB Decision:	Approved D	isapproved
Enka McConnell Printed name of Director	3/15/18 Date	V	
Either M. Connell	_		
Signature of Director			
Director Comments:			
[Form MJ-15] (rev 01/11/2018)			Page 2 of 2

License #_



Alaska Marijuana Control Board Operating Plan Supplemental Form MJ-06: Marijuana Testing Facility

Alcohol and Marijuana Control Office 550 W 7th Avenue, Suite 1600 Anchorage, AK 99501

marijuana.licensing@alaska.gov https://www.commerce.alaska.gov/web/amco

Phone: 907.269.0350

What is this form?

This operating plan supplemental form is required for all applicants seeking a marijuana testing facility license and must accompany the Marijuana Establishment Operating Plan (Form MJ-01), per 3 AAC 306.020(b)(11). Applicants should review Chapter 306:

Article 6 of the Alaska Administrative Code. This form will be used to document how an applicant intends to meet the requirements of those regulations. If your business has a formal operating plan, you may include a copy of that operating plan with your application, but all fields of this form must still be completed per 3 AAC 306.020 and 3 AAC 306.615(2).

What additional information is required for testing facilities?

Applicants must identify how the proposed establishment will comply with applicable regulations regarding the following:

- Prohibitions
- · Testing practices and procedures
- · Employee qualification and training
- Security
- · Reporting and records retention

This form must be submitted to AMCO's main office before any marijuana testing facility license application will be considered complete.

Section 1 - Establishment Information

Enter information for the business seeking to be licensed, as identified on the license application.

Licensee:	The New Frontier Research LLC	License	Number:	12657	
License Type:	Marijuana Testing Facility			<u> </u>	4.00
Doing Business As:	The New Frontier Research				
Premises Address:	2301 South Knik-Goose Bay Road Unit #3				
City:	Wasilla	State:	ALASKA	ZIP:	99654

FEB 27 2018

ALCOHUL MARIJUANA CONTROL OFFICE STATE OF ALASKA



marijuana.licensing@alaska.gov

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https://www.commerce.alaska.gov/web/amco

Phone: 907.269.0350

Anchorage, AK 99501

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Section 2 - Prohibitions

Applicants should review 3 AAC 306.610 and be able to answer "Agree" to all items below.		
The marijuana testing facility will not:	Agree Di	sagree
Sell, deliver, distribute or transfer any marijuana or marijuana product to a consumer, with or without compensation	V	
Allow any person to consume marijuana or marijuana product on its licenses premises	V	
Section 3 – Testing Practices and Procedures		

Review the requirements under 3 AAC 306.615, 3 AAC 306.635 – 3AAC 306.645, and 3 AAC 306.660, and identify how the proposed establishment will meet the listed requirements.

Describe each test the marijuana testing facility will offer:

The New Frontier Research will offer the following testing:

Cannabinoid profiling for d9-THC, THCA, CBD, CBDA, CBN, CBGA, CBG, CBC, d-8THC and CBC and cannabinoid concentration for d9-THC, THCA, CBD, CBDA, and CBN.

- Marijuana plant material (flower and trim)
- Concentrates or extracts (for those testing potency only)
- Infused products

Microbial screening for Shiga-Toxin producing Escherichia Coli (STEC), Salmonella, Aspergillus Fumigatus, Aspergillus Flavus, and Aspergillus Niger.

- Marijuana plant material (flower and trim)
- Infused products

Foreign Matter Inspection:

- Marijuana plant material (flower and trim)
- Concentrates or extracts
- Infused products

Moisture Content

- Marijuana plant material (flower and trim)

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[Form MJ-06] (rev02/12/2016)

Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

https://www.commerce.alaska.gov/web/amco Phone: 907.269.0350

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Alcohol and Marijuana Control Office 550 W 7th Avenue, Suite 1600 Anchorage, AK 99501

marijuana.licensing@alaska.gov

Standard Operating Procedure Manual (3 AAC 306.640):

Applicants for marijuana testing facilities must have a written procedures manual with detailed instructions explaining how to perform each testing method the applicant or marijuana testing facility uses, and minimum standards for each test. Applicants should be able to answer "Agree" to all items below.

Th	The marijuana testing facility will ensure that the standard operating procedure manual:	gree Di	isagre
	Is available to each employee at all times	V	
	Will cover at least the required procedures listed under 3 AAC 306.640	V	
	Describe the marijuana testing facility's standard operating procedure for each test the facility will offer:		
	Cannabinoid profiling/potency: Marijuana plant, concentrates, and infused products will be tested for cannabinoid content and plant material will be ground to a powder to ensure that the sample is homogenous. The following cannabinoids will be profiled quantitated: d9-THC, d8-THC, THCA, CBD, CBDA, CBDV, CBG, CBGA, CBN, and CBC. THC and THCA will be combined for total con as will CBD and CBDA. Samples will be tested using a high performance liquid chromatograph with UV detector or PDA detector. will be reported as the concentration in mg/g and as the % of product weight. The cannabinoid profile will be reported through to customers. For infused product testing, customers will be required to provide a "matrix blank" sample that is not infused with cannabis prio submitting any infused samples. This sample will be used to determine the following: 1) Presence of other components in the product which may co-elute with cannabinoids and would give a falsely elevated level or cannabinoids; 2) Presence of other components in the product which may suppress or enhance cannabinoid signals on chromatography and givinaccurate readings; and 3) If cannabinoids can be sufficiently extracted from the specific matrix type using the main TNFR protocol for infused products provide an accurate reading of the actual cannabinoid levels. If this cannot be accomplished, variations in solvent amount, extra time, and solvent types will be employed to develop a method of successfully recovering cannabinoids from that matrix type. If cannot be accomplished to provide >80% process efficiency, the infused products will not be tested at the New Frontier Research such a time as this can be accomplished. The potency of each single serving in a multi-unit package will be reported and must be 20 % of the manufacturer's target. Samples will be failed if the potency is more than 20% variation or if the product is not homo from serving to serving in a multi-serving package.	and centrati Potence METRC or to of to action this ch until e within ogenous	ion, cy and
	Microbial Detection: Cannabis flower/shake/trim and infused edible products will be tested for microbial pathogens. Testing wi done by realtime PCR for detection of Salmonella, STEC (shiga-toxin producing escherichia coli) and Aspergillus Fumigatus, Aspe Flavus and Aspergillus Niger per the attached protocols. Customers must submit 3 grams of product for testing, as each test is reto report levels of colony forming units per 1 gram sample and each test requires separate enrichments and testing.	ergillus	
	Moisture Content: Cannabis plant material will be tested for moisture content after homogenization using a moisture balance.		
	Visual Inspection: Prior to homogenization, samples will be inspected under microscopy for gross contamination. Pictures of sar will be taken and filed with final reports.	nples	

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Phone: 907.269.0350

Anchorage, AK 99501

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Laboratory Testing of Marijuana and Marijuana Products (3 AAC 306.645):

A licensed marijuana testing facility must meet minimum standards for laboratory testing. Applicants should be able to answer "Agree" to all items below.

Th	ne marijuana testing facilityapplicant has:	Agree Di	sagree
	Read and understands and agrees to the requirements listed under 3 AAC 306.645	V	
	Describe the acceptable range of results for each test the marijuana testing facility will offer:		
	Potency: All test results will undergo a technical review in order to ensure product meets accept standards. Potency will be reported as the concentration in mg/g and as a % of production of the concentration of the concentration in mg/g and as a % of production of the concentration of the concentratio		nt.
	Microbial Screening: - Less than 1 (one) colony forming unit (CFU/g) is the acceptable limit for Shiga-producing Escherichia Coli (STEC), Salmonella species and Aspergillus fumigatus, A flavus, and Aspergillus niger-fungus. If greater than or equal to 1 (one) colony-forming detected in a one-gram sample then the sample is failed.	spergillu	IS
	Foreign Matter: FDA Standards based on The Defect Levels Handbook -Samples will be inspected for human hair, insect parts, non-mammalian hairs of and the sample will be failed for presence of more than 1 per gram; -Samples will be inspected for miscellaneous matter (soil, sand, etc) and the sample failed for the presence of more than 5 fragments per gram; -Visible mold; and -Excrement of any kind.		



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Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Section 6 – Reporting and Records Retention		
Applicants should review 3 AAC 306.670 – 3 AAC 306.675 and be able to answer "Agree" to all items below.		
Reporting, Verification (3 AAC 306.670):		
The marijuana testing facility applicant:	Agree Di	sagree
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(a)	V	
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(b)	V	
Records Retention (3 AAC 306.675):		
The marijuana testing facility applicant:	Agree Dis	sagree
Has read, understands, and agrees to the records retention requirements listed in 3 AAC 306.675	V	
I declare under penalty of perjury that I have examined this form, including all accompanying schedules and statement of my knowledge and belief find it to be true, correct, and complete.	nts, and to	the bes
Signature of licensee Official Seal Teresa Bishop		
Jessica Alexander Notary Public-State of Alaska My Comm. Expires 06/13/2019		
Printed name		10
Subscribed and sworn to before me this 21_day of	, 20	18.

My commission expires: 06/13

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12657 The New Frontier Research

Original Application (MJ-06)

Considered in July 2017



Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

What is this form?

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Article 6 of the Alaska Administrative Code. This form will be used to document how an applicant intends to meet the requirements of those regulations. If your business has a formal operating plan, you may include a copy of that operating plan with your application, but all fields of this form must still be completed per 3 AAC 306.020 and 3 AAC 306.615(2).

What additional information is required for testing facilities?

Applicants must identify how the proposed establishment will comply with applicable regulations regarding the following:

- Prohibitions
- Testing practices and procedures
- · Employee qualification and training
- Security
- · Reporting and records retention

This form must be submitted to AMCO's main office before any marijuana testing facility license application will be considered complete.

Section 1 - Establishment Information

Enter information for the business seeking to be licensed, as identified on the license application.

Licensee:	The New Frontier Research LLC	License	Number:	1265	7
License Type:	Marijuana Testing Facility				
Doing Business As:	The New Frontier Research				
Premises Address:	2301 South Knik-Goose Bay Road	Unit #3			
City:	Wasilla	State:	ALASKA	ZIP:	99654

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Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Section 2 - Prohibitions

Applicants should review 3 AAC 306.610 and be able to answer "Agree" to all items below.		
The marijuana testing facility will not:	Agree	Disagre
Sell, deliver, distribute or transfer any marijuana or marijuana product to a consumer, with or without compensation	√	
Allow any person to consume marijuana or marijuana product on its licenses premises	✓	

Section 3 – Testing Practices and Procedures

Review the requirements under 3 AAC 306.615, 3 AAC 306.635 – 3AAC 306.645, and 3 AAC 306.660, and identify how the proposed establishment will meet the listed requirements.

Describe each test the marijuana testing facility will offer:

The New Frontier Research will offer:

Potency Analysis for concentration of THC, THCA, CBD, CBDA and CBN.

- Marijuana plant material (flower and trim)
- Concentrates or extracts
- Products

Microbial screening for Shiga-toxin producing Escherichia Coli (STEC), Salmonella Species, Aspergillus fumigatus, Aspergillus Flavus, and Aspergillus niger.

- Marijuana plant material (flower and trim)
- Products

Residual Solvents:

- Concentrates or extracts

Foreign Matter Inspection:

- Marijuana plant material (flower and trim)
- Concentrates or extracts
- Products





Alaska Marijuana Control Board Operating Plan Supplemental Form MJ-06: Marijuana Testing Facility

Phone: 907.269.0350

Standard Operating Procedure Manual (3 AAC 306.640):

Applicants for marijuana testing facilities must have a written procedures manual with detailed instructions explaining how to perform each testing method the applicant or marijuana testing facility uses, and minimum standards for each test. Applicants should be able to answer "Agree" to all items below.

should be able to answer "Agree" to all items below.	
The marijuana testing facility will ensure that the standard operating procedure manual:	Agree Disagree
Is available to each employee at all times	V
Will cover at least the required procedures listed under 3 AAC 306.640	V
Describe the marijuana testing facility's standard operating procedure for each test the facility will o	ffer:
Potency: Marijuana and marijuana concentrates and products will be tested for cannabinoid cont Cannabis inflorescence (flowers) or "trim" will be used for potency testing. Plant material will be gis homogenous. The quartering method will be used to make sure the sample is homogenous and Concentrate liquids will be thoroughly stirred or mixed before sampling to make sure samples are such, as resins, will be ground and thoroughly mixed before they are tested, and as with finished quartering method will be used to obtain representative samples for testing. Samples will be teste protocols in a high performance liquid chromatograph with UV detector. Potency will be reported in mg and as the % of product weight and must be within +/-10% standard deviation of the mean. profile will be reported through METRC and to customers. The following cannabinoids will be profile-THC, THCA, THCV, CBD, CBDA, CBDV, CBG, CBGA, CBN, and CBC. THC and THCA will be concentration, as will CBD and CBDA. In edible product testing, the potency of each single servir package will be reported and must be within 20 % of the manufacturer's target. Samples will be famore than 20% variation, the product is not homogenous from serving to serving in a multi-servin more than 60 mg in the test lot package. Microbial: Cannabis inflorescence (flowers) or "trim" will be used for potency testing. Plant materisthe quartering method will be used to make sure the sample is homogenous and representative. by qPCR for detection of salmonella, STEC (shiga-toxin producing escherichia coli) and Aspergill Aspergillus flavus and Aspergillus niger per the attached protocols. Residual Solvents: Using an analytical balance, 100 mg of sample concentrates or extracts will be placed in testing vial to be evaluated for the presence of Butanes, Heptanes, Benzene, Toluene, 1 Xylenes (meta-xylenes, para-xylenes, or ortho-xylenes) using a head space gas chromatography spectrometry per attached protocols.	round to make sure it d representative. homogenous. Solids plant material, the ed per the attached as the concentration. The cannabinoid filed: d9-THC, e combined for total ing in a multi-unit ailed if the potency is g package, or there is al will be ground and Testing will be done us fumigatus,
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Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Laboratory Testing of Marijuana and Marijuana Products (3 AAC 306.645):

A licensed marijuana testing facility must meet minimum standards for laboratory testing. Applicants should be able to answer "Agree" to all items below.

The marijuana testing facility applicant has:	Agree	Disagre
Read and understands and agrees to the requirements listed under 3 AAC 306.645	√	П

Describe the acceptable range of results for each test the marijuana testing facility will offer:

Potency:

All test results will undergo a technical review in order to ensure product meets acceptable standards. Potency will be reported as the concentration in mg and as the % of product weight and must be within +/-10% standard deviation of the mean.

Microbial Screening:

 Less than 1 (one) colony forming unit (CFU/g) is the acceptable limit for Shiga-toxin producing Escherichia Coli (STEC), Salmonella species and Aspergillus fumigatus, Aspergillus flavus, and Aspergillus niger-fungus. If greater than or equal to 1 (one) colony-forming unit is detected in a one-gram sample then the sample is failed.

Solvents:

- Solvent-based concentrates are tested for residual solvent content. Results are in parts per million (ppm).

Acceptable Limits per Gram are:

- -Butanes: less than 800 parts per million (ppm)
- -Heptanes: Less than 500 parts per million (ppm)
- -Benzene: Less than 1 parts per million (ppm)
- -Toluene: Less than 1 parts per million (ppm)
- -Hexane: Less than 10 parts per million (ppm)
- -Total Xylenes (meta-xylenes, para-xylenes, or ortho-xylenes): Less than 1 parts per million (ppm) ***If a sample exceeds any one of these concentration levels, the sample is failed.

Foreign Matter: FDA Standards based on The Defect Levels Handbook

- -Samples will be inspected for human hair, insect parts, non-mammalian hairs or feathers and the sample will be failed for presence of more than 1 per gram.
- -Samples will be inspected for miscellaneous matter (soil, sand, etc) and the sample will be failed for the presence of more than 5 fragments per gram.

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Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Section 4 - Employee Qualification and Training

Review the requirements under 3 AAC 306.625 – 3 AAC 306.630, and identify how the proposed establishment will meet the listed requirements.

Proficiency Testing Program (3 AAC 306.625):

Describe how the marijuana testing facility will ensure the scientific director and all testing analysts are proficient in utilizing testing equipment and analyzing samples:

It is our belief that cannabis laboratories should be mandated to demonstrate competency through an internationally-accepted standards that has been developed for proper analytical laboratory operations. The New Frontier Research will demonstrate competency by immediately pursuing accreditation by the International Organization for Standardization (ISO) 17025 standards within 12 months. ISO standards cover testing and calibration performed using standard methods, non-standard methods, and laboratory developed methods. ISO standards are not ambiguous and are universally accepted. To achieve accreditation, this testing facility will work with a third-party ISO 17011-accredited ILAC to provide assurance that the laboratory produces consistent and reliable results according to ISO 17025 criteria for cannabinoid potency measurement (THC and CBD). The third-party organizations which conduct the Inter-laboratory Proficiency Tests (IPT) must also be certified by ISO, under yet another set of standard criteria, ISO 17043.

The Laboratory Director will develop policies and procedures to ensure that: the laboratory follows the ISO 17025 criteria, including good lab practices (GLPs); maintains internal standard operating procedures and quality controls; instruments are properly calibrated, maintained, and repaired; and that the lab follows an adequate chain of custody protocol to store and manage samples.

Initial training on equipment and methods-- The New Frontier Research has contracted with a Shimadzu training team to have their PhD and equipment representative come to our site for 3 days of on-site training in methodology and equipment trouble-shooting. All laboratory technicians will be required to attend this initial training in its entirety. Thereafter, regular proficiency testing will be done every 6 months to ensure the reliability of the laboratory's methods and to help monitor performance for specific tests or measurements. Proficiency testing requires that the laboratory analyzes one or more samples of unknown composition provided by an independent third party. The laboratory measures the samples according to a given set of instructions and reports the results to the administrator of the test. The values reported by the laboratory are compared to an average, or study mean, and the reference (assigned) value. The results are considered "acceptable" if they fall within the acceptance limits

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ALCONOL MARBUANA COMMON OFFICE
STATE OF ALASKA



Alaska Marijuana Control Board

Operating Plan Supplemental

Form MJ-06: Marijuana Testing Facility

Scientific Director (3 AAC 306.630):

All marijuana testing facilities must employ a scientific director with responsibilities and qualifications set out in 3 AAC 306.630 and 3 AAC 306.640(b).

Name the scientific director and describe how he/she meets the qualifications set out in 3 AAC 306.630(b).

Jessica Alexander, MPAS, MSCRM

- --Associate's degree in Allied Health Science from Austin Community College
- -Bachelor's degree in Allied Health Science with a minor in Chemistry from St. Edward's University in Austin, Texas
- --Master's degree in Physician Assistant Studies from The University of North Texas Health Science Center in Fort Worth, Texas
- -Master's degree in Clinical Research Management (Pharmaceutical Research) from the School of Biomedical Sciences at the University of North Texas Health Science Center in
- -Additionally, all coursework was completed for a PhD in Molecular Cell Biology & Genetics and research was initiated, but the Department of Defense could not continue funding thesis/research on mitigation of nitric oxide species in blast injuries of tourniqueted limbs due to budget cuts. Participated in graduate school research analyzing frozen procine tissue samples collected during cardiac bypass surgery and another research project to analyze tissue samples from decubitus ulcers for angiogenic growth factor levels after pulse-pressured oxygen therapy

- --Current laboratory director in the state of Alaska for 2 laboratories with success in management of processes; development and implementation of QA/QI programs; experienced in personnel training and periodic competency testing, as well as meeting American Proficiency Institute standards for lab and personnel; and successfully passing a state audit without any citations or request
- -Experience and formal education in clinical research management (pharmaceutical research)
 --More than 10 years of experience in laboratory testing—biological and analytical
- -- Experienced program coordinator for genetic research project involving multiple universities

Section 5 - Security

Review the requirements under 3 AAC 306.650, and identify how the proposed establishment will meet the listed requirements.

Chain of Custody (3 AAC 306.650):

Describe how the marijuana testing facility will meet the chain of custody requirements as listed in this section:

Samples must arrive at TNFR in an approved container with a tamper-proof seal and must be marked with a unique METRC identifier and accompanied by a METRC manifest. If the sealed METRC identifier or manifest is missing, then the sample will not be accepted. Before any analysis is started, the required information will be recorded on the Sample Receiving & Tracking form, entered into the METRC system and to the TNFR Laboratory Information Management System, and the sample will be placed in secure area. The storage and movement of product samples within the TNFR premises will be tracked on the lower portion of the Sample Receiving & Internal tracking form (see attached). Samples removed for testing will be noted on this form. The unused portion of the sample will be kept in the secure storage area until all requested tests are completed and the results are reviewed. Marijuana waste and unused samples will be rendered unusable by mixing them with used organic solvents and disposed of in the organic waste barrels, in view of video surveillance system.

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Section 6 - Reporting and Records Retention

Applicants should review 3 AAC 306.670 – 3 AAC 306.675 and be able to answer "Agree" to all items below.	
Reporting, Verification (3 AAC 306.670):	
The marijuana testing facility applicant:	Agree Disagree
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(a)	✓
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(b)	✓
Records Retention (3 AAC 306.675):	
The marijuana testing facility applicant:	Agree Disagree
Has read, understands, and agrees to the records retention requirements listed in 3 AAC 306.675	✓
I declare under penalty of perjury that I have examined this form, including all accompanying schedules and staten of my knowledge and belief find it to be true, correct, and complete.	nents, and to the best
Signature of licensee	
Jessica Alexander	
Printed name Subscribed and sworn to before me this 19 day of April	20 <u>17</u> .
Official Seal Robert H. Smith Notary Public-State of Alaska My Comm. Expires 11/09/2020 Notary Public in and for	
My commission expires:	11/09/2020
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additional Space as Needed):				
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