APPLICATION INFORMATION SHEET

1	**COMPANY NAME**	FGM Processing, LLC
2	**STREET ADDRESS**	4 Oak Hollow Court
3	**CITY, STATE, ZIP**	Pikesville, MD 21208

4	**TELEPHONE NUMBER**		
	AREA CODE	**NUMBER:**	**EXTENSION:**
	703	677-7389	N/A

5	**FAX NUMBER**		
	AREA CODE	**NUMBER:**	**EXTENSION:**
	314	725-0912	N/A

6	**TOLL FREE NUMBER**		
	AREA CODE	**NUMBER:**	**EXTENSION:**
	N/A	N/A	N/A

7	**Contact Person for providing information, signing documents, or ensuring actions are taken per COMAR 10.62.19-.24**
	Name: James Manchisi
	Title: Member
	Address: 950 Francis Place Ste. 107 Saint Louis, MO 63105
	Email Address: jimmanchisi@gmail.com

8	**TELEPHONE NUMBER AND FAX FOR CONTACT PERSON**		
	AREA CODE	**TELEPHONE NUMBER:** 703-677-7389	**EXTENSION:** N/A
	AREA CODE	**FAX NUMBER:** 314-725-0912	

9	**CONTACT PERSON SIGNATURE**	
	SIGNATURE: James Manchisi	**DATE:** 10/29/2015

RECEIVED
NOV 10 2015
By

FGM Processing, LLC

On behalf of FGM Processing, LLC, Jim Manchisi, Owner and Authorized Representative, hereby submits the following **Application for Medical Cannabis Processing License**.

This Application includes the following components:

1. Application Information Sheet
2. MPIA Page
3. The completed Application
   Note that all forms contained in the Application are blank b.
4. Question 2B: Attached relevant documentation
   - Certifying that the Applicant/Licensee has adequate capitalization (maximum length 7 pages)

5. Question 3A: Attached relevant documentation
   - Certifying Maryland residency on the part of owners and/or investors (maximum length 0.75 pages)
   - Certificate of Good Standing

6. Question 3B: Attached relevant documentation
   - Certifying that the Applicant/Licensee is not in arrears regarding any tax obligation
     (maximum length 1.5 pages)

7. Addenda: sample Site Plan for reference in the Safety & Security subsection
8. Addenda: letters of support
9. Forms:
   - Completed Section U Affirmations
   - Form 2
   - Form 3
10. Forms: Owner1: Jessica White
    - Form 1
    - Form 4
    - Form 5
11. Forms: Owner2: Brian Fox
    - Form 1
    - Form 4
    - Form 5
12. Forms: Owner3: Jim Manchisi
    - Form 1
    - Form 4

Maryland Public Information Act
The following table details the questions in the attached Application that contain confidential information and should be protected under MPIA.

When the Applicant claims Public Security privilege, the Applicant seeks exemption due to the fact that the content is security information. Disclosure of this information in a public forum would compromise the security of the dispensary and would expose the dispensary to a potential theft.

When the Applicant claims Trade Secret / Confidential Commercial Information privilege, this means the Applicant seeks exemption due to the fact that it is proprietary information gathered at the Applicant's expense that is the property of the Applicant.

When the Applicant claims Individual Financial Information privilege, the Applicant avers that this is disclosure of a statement of personal net worth or personal financial data required by the Commission and filed by the Applicant to establish the Applicant's personal qualifications for the License.

When the Applicant claims Personal Information privilege, this means this is disclosure of personal information such as an individual's address.

Identification of Conf. Info	Question	Type of Privilege claimed
Adequate capitalization	Attached documentation for question 2 (b)	Individual Financial Information
Maryland residency	Attached documentation for question 3 (a)	Personal Information
Tax obligation	Attached documentation for question 3 (b)	Individual Financial Information
Sample site plan with security features	Attached in the addenda section	Public Security
Chemical Plant Manufacturing standards	1 (a)	Trade Secret / Confidential Commercial Information
Pharmaceutical Manufacturing standards, proposed products and processes, cannabinoid profiles	1 (b)	Trade Secret / Confidential Commercial Information
Consumer Product Manufacturing standards	1 (c)	Trade Secret / Confidential Commercial Information
Business Plan, including financial projections	2 (a)	Trade Secret / Confidential Commercial Information
Security: Diversion detection and security protocols	7 and 8	Public Security
Security: Emergency response protocols	9 (4) and 9 (5)	Public Security

Identification of Conf. Info	Question	Type of Privilege claimed
Security: Description of building construction	11	Public Security
Security: Description of surveillance installations	12, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 34	Public Security
Security: Description of security alarm system	13, 14, 15, 16 18, 19, 21, 22	Public Security
Security: Description of secure room security measures	20	Public Security
Security: Security-related protocols	35, 36, 37, 38, 39	Public Security
Security: Disposal of medical cannabis procedures	70, 71	Public Security

Maryland Department of Health Mental Hygiene
Maryland Medical Cannabis Commission ("MMCC")

Application for Medical Cannabis Processor License

MARYLAND
MMCC

Natalie M. LaPrade
Maryland Medical Cannabis Commission

Publication Release Date:
September 28, 2015; Revised, October 7, 2015

Application Response Deadline:
Accepting Applications Period: September 28, 2015–November 6, 2015
Business Days: M–F, 8:00 am–4:00 pm

For additional information regarding the Application process, please contact:
Natalie M. LaPrade Medical Cannabis Commission
Department of Health and Mental Hygiene
Dedicated Email Address for Applicant Questions:
dhmh.medicalcannabisApplications@maryland.gov

APPLICATION INFORMATION SHEET

1	**COMPANY NAME**	See attached completed forms

2	**STREET ADDRESS**	Street Address

3	**CITY, STATE, ZIP**	City, State, Zip

4	**TELEPHONE NUMBER**		
	AREA CODE Area Code	**NUMBER:** Number	**EXTENSION:** Extension

5	**FAX NUMBER**		
	AREA CODE Area Code	**NUMBER:** Number	**EXTENSION:** Extension

6	**TOLL FREE NUMBER**		
	AREA CODE Area Code	**NUMBER:** Number	**EXTENSION:** Extension

7	**Contact Person for providing information, signing documents, or ensuring actions are taken per COMAR 10.62.19-.24**
	Name: Name
	Title: Title
	Address: Address
	Email Address: Email Address

8	**TELEPHONE NUMBER AND FAX FOR CONTACT PERSON**		
	AREA CODE Area Code	**TELEPHONE NUMBER:** Number	**EXTENSION:** Extension
	AREA CODE Area Code	**FAX NUMBER:** Number	

9	**CONTACT PERSON SIGNATURE**	
	SIGNATURE:	**DATE:** Click here to enter a date.

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FORMS/Addenda CHECKLIST

FORM/Exhibit #	Name/Description of Exhibit	Included Yes	Not Included
Form 1	Consent for Investigation – Individual/Processor Agent	yes	
Form 2	Consent for Investigation – Business Entity	yes	
Form 3	Trade Secret & Business Data Notification	yes	
Form 4	Business Interest Identification & Authorization Form	yes	
Form 5	Investors, Agents, Owners & Managing Director Certification Statement	yes	
Addenda		yes	

SECTION A: INTRODUCTION

Maryland Department of Health and Mental Hygiene
Natalie M. LaPrade Maryland Medical Cannabis Commission

Medical Cannabis Processor License Application

The State of Maryland, Department of Health and Mental Hygiene Natalie M. LaPrade Maryland Medical Cannabis Commission ("MMCC" or "Commission") is seeking Applications from qualified Applicants interested in receiving a Medical Cannabis Processor License.

On October 1, 2013, the Commission became responsible for administering Maryland's Medical Cannabis program, the effective date of the enactment of Ch. 403, Laws of Maryland (2013); subsequently amended by Ch. 240, 256, Laws of Maryland (2014); and Ch. 251, Laws of Maryland (2015), also referred to as the Maryland Session Laws. The Commission develops policies, procedures, and regulations to implement programs to make medical cannabis available to patients in a safe and effective manner. The Commission will license medical cannabis Growers, Processors, and Dispensaries. This Program allows a qualifying patient or caregiver who is registered with MMCC to purchase medical cannabis from a licensed dispensary. See also Md. Code, Health-Gen §§13-3301-13-3316; COMAR §§10.62.01-10.62-35.

The Commission intends to award licenses to Applicants that most efficiently and effectively ensure public safety and safe access to medical cannabis.

SECTION B: Number of Processor Licenses

In accordance with COMAR 10.62.19.05(A), the Commission will pre-approve a number of licenses for licensed processors sufficient to supply the demand for medical cannabis concentrates and medical cannabis-infused products in a range of routes of administration desired by qualifying patients.

SECTION C: Processor Intention to Operate a Dispensary

A Processor planning to operate a medical cannabis dispensary **must submit a separate Dispensary Application.**

SECTION D: Processor Intention to Operate as a Grower

A Processor planning to operate a medical cannabis grower facility **must submit a separate Grower Application.**

SECTION E: TERMS AND DEFINITIONS

Please refer to the COMAR Regulations in Section 10.62.01 "Definitions," which are applicable to all MMCC license Applications. The Regulations are posted on the Maryland Medical Cannabis Commission's website at http://mmcc.maryland.gov.

For the purposes of this Application, the following terms and definitions will be used.

TERM	DEFINITION
Annotated Code of Maryland	Maryland's statutory law created by the State Legislature, the General Assembly.
Applicant	A person or entity applying for a license.
Audited Financial Statement	An audited financial statement that is: (a) Performed by a certified public accountant licensed or with practice privileges in Maryland pursuant to Business Occupations and Professions Article, Title 2, Annotated Code of Maryland; (b) Prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants; and (c) In the case of a publicly owned corporation, in conformity with the standards of the Public Company Oversight Board.
COMAR	Maryland State Regulations issued by State agencies.
Commission	The Natalie M. LaPrade Medical Cannabis Commission.
Caregiver	An individual 21 years old or older designated by a patient who has agreed to assist with a qualifying patient's medical use of medical cannabis, and for a qualifying patient younger than 18 years old, a parent, or legal guardian.
Grower Agent	An owner, an employee, a volunteer, an officer, or a director of a licensed grower.
Independent Testing Laboratory	A facility, an entity, or a site that offers or performs tests related to the inspection and testing of cannabis and products containing cannabis in the State of Maryland.
Licensed Dispensary	An entity licensed by the Commission that acquires, possess, repackages, transfers, transports, sells, distributes, or dispenses, products containing cannabis, related supplies, related products including tinctures, aerosols, oils, or ointments, or educational materials for use by a qualifying patient or caregiver.
Licensed Grower	An entity licensed by the Commission that cultivates, manufactures, packages or distributes medical cannabis to licensed processors, licensed dispensaries or registered independent testing laboratories.
Licensed Premises	The locations at which a licensed grower, licensed processor, or licensed dispensary operates.
Licensed Processor	An entity licensed by the Commission that: (a) transforms the medical cannabis into another product or extract; and (b) packages and labels medical cannabis.
Maryland Entity	A business entity registered to do business in the State of

TERM	DEFINITION
	Maryland.
Maryland Residency	One who lives in Maryland.
Medical Cannabis	Any product containing usable cannabis or medical cannabis finished product.
Medical Cannabis Concentrate	A product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of: (a) Solvents; (b) Carbon dioxide; or (c) Heat, screens, presses or steam distillation.
Medical Cannabis Finished Product	Any product containing a medical cannabis concentrate or a medical cannabis infused product packaged and labeled for release to a qualifying patient.
Medical Cannabis Infused Products	Any oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material. (b) "Medical cannabis-infused product" does not include a food as that term is defined in Health-General Article, §21-101, Annotated Code of Maryland.
Must/Shall	The referenced action is "Mandatory" and not discretionary.
Pre-Approval of License	A preliminary approval of a potential authorization (license) to conduct business as a licensed processor.
Processing	The manufacture of usable medical cannabis into a medical cannabis concentrate, or manufacture of a medical cannabis-infused product.
State	The State of Maryland, Department of Health & Mental Hygiene, or the Natalie M. LaPrade Medical Cannabis Commission.
Site Plan	A drawing and brief description of the preliminary plan for the locations of any and all buildings and any and all security measures, including walls and doors within the facility.
Third Party Reviewers	An independent reviewer (or entity) hired to assist the Commission in the evaluation of Applications.
Transportation Agent	A registered grower agent, registered processor agent or a registered dispensary agent, authorized by the Licensee to transport products containing medical cannabis, who meet the criteria specified in COMAR 10.62.18; or a licensed and bonded courier of a secure transportation company.

SECTION F: APPLICATION TIMELINE

The following represents the timeline for this project.

TASK	DATE/TIME
Applications Posted on Website	Week commencing September 28, 2015
Deadline for Submission of Applications (hard copy, electronic copy and payment) to the Commission	40 calendar days after the Application is posted
Application Evaluation, Scoring and Ranking Period by Third Party Reviewers	Anticipated completion in December 2015 / January 2016
Commission Vote on Stage One Applications at Public Meeting	Anticipated in December 2015 / January 2016
Notice of Stage One Awards via Email	Anticipated in December 2015 / January 2016
Posting of Stage One Awards on website	Anticipated in December 2015 / January 2016
Site Visits/Inspections of Stage One Applicant Premises	Following request of an Applicant for inspection.
Granting licenses by the Commission.	Following request of an Applicant for final inspection.

Stage 1: Selection
Once the Stage 1 Applicants have been determined, the Commission will inspect the Applicant's processing and cultivation (if applicable) operations as evidence of the Applicant's expertise and compliance.

Please indicate in the Application the existing operations that would serve as your inspection site location including the address and a contact to arrange for the site visit.

Stage 2: Final Approval
Upon selecting the successful Applications, the Commission shall notify all Applicants of their status by email and in writing. The Commission's decision to award or not award a license to an Applicant shall be final.

If a Licensee cannot commence operations within 365 days of being issued a pre-approval, the Commission may rescind the pre-approval.

SECTION G: APPLICATION SUBMISSION INSTRUCTIONS

Applicants must submit a complete Application package by the deadline outlined in Section F. The Application package will consist of the following:

1. A hard copy of the Applicant's completed Application and all related documents (as outlined in Section H),
2. An electronic copy of the Applicant's Application and all related documents (as outlined in Section H) in Microsoft Word format on a USB drive, and
3. The Application payment to MMCC in the form of a cashier's check or money order, only. The Application fee will be retained by the Commission and will not be returned under any circumstances.

The Application is only considered complete if all of these components are submitted. The Applicant is responsible for delivery of all of the Application material to MMCC on or before the deadline indicated in Section F. Any Applications or related documents received after the deadline will not be accepted or considered.

Other than the redacted material, the information provided in the hard copy and electronic copy of the Application should be identical. The hard copy of the Application will be retained by MMCC for its records. Only the information that is submitted in the electronic copy of the Application as well as the electronic related documents will be sent to evaluators for review.

Applicants must use the following file naming structure when submitting electronic documents: " Applicant Name_Submission Date_ File Type." For example, the Word document file name would be "John Doe_10012015_Application." In contrast, the site plan file name would be "John Doe_10012015_Site Plan."

To ensure the integrity of the evaluation process, specific sections of the electronic copy of the Application and related documents will be redacted for the evaluation. It is the responsibility of the Applicant to redact this information in the electronic copy of the Application. Further details on what information should be redacted are outlined in Section H.

SECTION H: Evaluation and Selection Procedures

The Regional Economic Studies Institute (RESI) of Towson University has been commissioned by MMCC to conduct an evaluation of the license Applications. This section will review the evaluation process.

MMCC will upload all electronic copies of all completed Applications together with any related documents that it receives within the timeline specified in Section F onto a Secure File Transfer Protocol (SFTP) for RESI to download. RESI will review every Application that is transferred to RESI by MMCC through the SFTP to ensure that it meets the mandatory qualification criteria, including the three following points:

1. All sections of the Application that are marked as mandatory with an asterisk (*) are completed;
2. The checkboxes in Section U are marked with an affirmation to all questions posed; and
3. The electronic version of the Application (Microsoft Word document) and related documents are submitted as redacted documents.

The Word document must be devoid of any identifying information after Form 5, including the Applicant's name, the company name of the Applicant (if applicable), and the names of any investors and/or employees. The related documents must be devoid of any identifying information including the Applicant's name, the company name of the Applicant (if applicable), and the names of any investors and/or employees. Only the redacted Word document and related documents will be sent to evaluators if the Application meets the mandatory qualification criteria. Any Application that does not comply with these mandatory qualification criteria will be removed from the process and will not be evaluated.

RESI will process the Applications that meet the mandatory qualification criteria. RESI will assign unique identifying numbers to each Application and will separate each Application into sections. RESI has contracted a panel of third party evaluators, which will be composed of subject matter experts (SMEs) from across the country. Each SME will review assigned sections of the Application that align with the SME's field of expertise. The SME will be sent these sections via email. As each SME will not review the entire Application, it is of the utmost importance that the information outlined in each section of the Application is provided in that section. If section-specific information is found outside the section in which it should be, the SME will not consider that information during the evaluation process. In addition, each section has a set word count. If the word count in a section is exceeded, the SME will not review any information beyond the maximum number of words nor will the SME take into account this information during the evaluation.

Each Application section will be scored by the respective SME according to the quality of the responses provided. The scoring of the Application sections will be based on a scale of 1 to 5 as well as yes/no questions. The yes/no questions will focus on specific issues that are clearly set out in the processor regulations and that do not need further explanation from the Applicant. The scoring scale will be used to evaluate the questions that cannot be scored as yes/no and therefore need further explanation from the Applicant. Using this scale, a 3 will be given to Applications that meet the basic requirements set forth in the aforementioned regulations. A score of 1 will be given to Applications that fall significantly below meeting these basic requirements, and a score of 5 will be given to Applications that significantly exceed the basic requirements. An Application will receive a score of 0 in any section where the SME notices an egregious problem or error within that section. Any Application section receiving a 0 will be reviewed separately by the Commission to determine if the Application will continue in the evaluation process.

Using the scores provided by the SMEs in the evaluation panel, RESI will aggregate the scores from each Application, taking into account the weighting outlined in Section T of this document. RESI will rank the Applications based on these scores for the Commission to review. The Commission will make the final decision on issuing any processor licenses.

SECTION I: IMPORTANT NOTICES/DISCLAIMERS

- This Application form is an **OFFICIAL DOCUMENT** of the Maryland Medical Cannabis Commission. It **MAY NOT** be altered or changed in any fashion except to fill-in the areas provided with the information that is required. Should any alteration or revision of a question occur, the Commission reserves the right to deny the Application in its entirety, or may determine to attribute no weight to the response.
- The license to operate as a processor is a privilege.
- The burden of proving an Applicant's qualifications at all times rests on the Applicant. The Applicant accepts any and all risk of adverse public notice, criticism, emotional distress, or financial loss that may result from any action with respect to this Application. The Applicant expressly waives any and all claims for damages as a result thereof.
- The Commission may deny an Application that contains a misstatement, omission, misrepresentation, or untruth.

- An Application shall be complete in every material detail, including all of the mandatory sections that are marked with an asterisk (*).
- If the electronic version of the Application cannot be read by MMCC, the Application will be suspended and not reviewed, and the Applicant will be contacted via email. The Applicant has 3 business days from the date when the email is sent to deliver another USB drive containing the electronic version of the Application to the Commission. In the event that the Applicant fails to comply, the Application will be withdrawn and the fee may be forfeited to the Commission.
- The Commission will notify Applicants via email when their Applications are successfully received.
- The Commission may request any additional information that it determines is necessary to process and fully investigate an Application. The Applicant shall provide all information, documents, materials, and certifications at the Applicant's own expense.
- Should the Commission request any additional information that it determines necessary to process and fully investigate an Application, the Applicant shall provide the additional information within 14 business days after the request has been sent to the Applicant. If the Applicant does not provide the requested information within 14 business days, the Commission will remove the Application from the evaluation process.
- The Applicant is not able to contribute additional information after the Application is submitted, unless the Commission requests more information.
- The Applicant is under a continuing duty to promptly disclose any changes to the Commission in investors with an interest of five percent or more. **The duty to make such additional disclosures shall continue throughout any period of any license that may be granted by the Commission.**
- All notices regarding an Application submission will be sent to the email address provided on this form. The Applicant must immediately notify the Commission if the email address changes.
- An Applicant who applies for and obtains a license from the Commission may be required to submit to warrantless searches as stated in the law or regulation.
- After the Application has been submitted, the Applicant may withdraw the submitted Application only after written notice to the Commission.
- All submissions with and for this Application become the property of the Commission and will not be returned.
- **The Commission's decision to approve or deny an Application is final.**

SECTION J: Communications with MMCC

All questions about the Application or Application process must be forwarded to MMCC **by email only** at dhmh.medicalcannabisApplications@maryland.gov with the subject line "**Medical Cannabis Application Question.**"

- Questions and answers of a substantive nature will be posted on the MMCC website (http://mmcc.maryland.gov/) so that all Applicants will have access to the same information.

- For questions received after Friday, October 23, 2015, the Commission may not respond prior to the submission deadline. Applicants are therefore encouraged to identify and raise any questions as soon as possible.
- All questions must be sent to the Commission email address only. Violation of this guideline will result in disqualification.

SECTION K: Consent for Investigation - COMAR Section 10.62.19.03 (A)

An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:

1. Verify all information provided in the Application documents; and
2. Conduct a background investigation of the individual.

SECTION L: Waiver of Any Contractual, Statutory, or Common Law Obligation of Confidentiality – COMAR Section 10.62.19.03 (B), (C)

An Applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisdiction to release to and provide access to the Commission of any and all information that the Applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the Applicant.

An Applicant shall release all financial institutions, fiduciaries, and other parties from any contractual, statutory, or common law obligation of confidentiality to provide financial, personal, and background information to the Commission relevant to the Applicant's capacity to manage a licensed processor facility and the Applicant's good moral character.

SECTION M: Records & Maryland Public Information Act

All materials submitted in response to this Application will be retained by MMCC. All pages containing confidential information must be marked "Confidential."

Data submitted during the Application process, including private data on individuals or nonpublic data, may or may not be disclosed pursuant to the Maryland Public Information Act (" MPIA"). Md. Code., Gen'l Prov §§4-101-601. While there are exceptions to production contained in the statute, and certain common law privileges may apply to the data, MMCC cannot guarantee that all data submitted to it will remain confidential at all times. Be advised, however, that the MPIA does contain provisions that relate to data that is a trade secret or that contains financial information. Md. Code, Gen'l Prov §§4-335, 36. MMCC recommends that the

Applicant review the applicable law prior to submitting an Application as MMCC is unable to provide legal advice as to the absolute confidentiality of the data received.

Be further advised, that if a license is awarded to an Applicant, MMCC may use or disclose the trade secret or financial data to the extent provided by law. Any decision by the State to disclose information determined to be trade secret information or financial data will be made consistent with the MPIA and other relevant laws and regulations. Maryland Public Information Act (" MPIA"). Md. Code., Gen'l Prov §§4-101-601.

If the Applicant submits information in response to this Application that the Applicant believes to be trade secret information or financial data as defined by Maryland Statutes section Md. Code, Gen'l Prov §4-335-36, and the Applicant does not want such data used or disclosed for any purpose other than the evaluation of this proposal, the Applicant shall:

A. Clearly mark every page of trade secret or financial materials in its proposal at the time the proposal is submitted with the words "**TRADE SECRET OR FINANCIAL DATA INFORMATION**" in capitalized, underlined and bolded type that is at least 20 pt.
B. Acknowledge that the State does not assume liability for the use or disclosure of unmarked or unclearly marked trade secret information;
C. Fill out and submit the attached "Trade Secret & Financial Data Information Notification Form," specifying the pages of the proposal that are to be restricted and justifying the trade secret designation for each item. If no materials is designated as trade secret information or financial data, a statement of "None" should be listed on the form; and
D. Satisfy the statutory burden to justify any claim of trade secret information.

MMCC may reject a claim that any particular information in a response is trade secret information if it determines that the Applicant has not met the burden of establishing the content to be trade secret information under any circumstance. Use of generic trade secret language encompassing substantial portions of the proposal or simple assertions of trade secret interest without substantive explanation of the basis therefore will not be sufficient to warrant a trade secret designation. If certain information is found to constitute a "trade secret" or "financial" exception to disclosure, then, the remainder of the Proposal will become public in the event a public information request is received. Applicants should understand that only the trade secret or financial data will be redacted prior to disclosure.

The Applicant must defend any action seeking release of the materials that it believes to be trade secret information, and indemnify and hold harmless the State, its Agents, and employees, from any judgments against the State in favor of the party requesting the materials, and any and all costs connected with that defense. This indemnification survives the State's award of a license. In submitting an Application, the Applicant agrees that this indemnification survives as long as the trade secret information is in the possession of MMCC.

MMCC is required to keep all Processor Application documents in accordance with the document retention schedule adopted by the Commission after the conclusion of the license term.

Non-selected Processor Applications will be kept by MMCC for a minimum of three years after the award of the licenses.

SECTION N: AMENDING AN APPLICATION - COMAR 10.62.19.02 (D)

In the event that an Applicant amends an Application to include either a new individual investor with an interest of five percent or more, or another manager or director of the entity, then the Applicant shall forward to the Commission a copy of the request to the Central Repository.

SECTION O: Criminal History Record Check – COMAR Section 10.62.19.03

For each individual identified in the Application, an Applicant shall provide to the Director of the Central Repository:

1. Two sets of legible fingerprints taken in a format approved by the Central Repository and the Director of the FBI together with the fee authorized under Md. Code Ann., Criminal Procedure Article, §10-221(B)(7), for access to State criminal history and records for each medical cannabis processor agent and investor identified in the Application; and
2. A request that the individual's State and national criminal history record information be forwarded to the Commission.

SECTION P: How to Apply

It is recommended all potential Applicants become familiar with Md. Code, Health-Gen §§13-3301-13-3316; COMAR §§10.62.01-10.62.35; Ch. 403, Laws of Maryland (2013); Ch. 240, 256, Laws of Maryland (2014); and Ch. 251, laws of Maryland (2015), governing processor operations for the Medical Cannabis program.

Applicants should use the definitions and descriptive sections of those documents to assist in interpreting this Application. The burden of proving an Applicant's qualifications rests solely on the Applicant.

GENERAL APPLICATION INSTRUCTIONS

Read each question carefully. Answer each question completely. Do not leave blank spaces. If a question does not apply, write "Does Not Apply" or "N/A." If the correct answer to a particular question is "None," write "None." If a question has an asterisk (*), it is mandatory and must be completed. Answering a mandatory question with "Does Not Apply" or "N/A" is insufficient. Failure to submit an Application with all of the mandatory questions completed will result in the removal of the Application from the evaluation process.

- All entries on the Application should be single spaced and typed in 12-point Times New Roman font. Signatures must be in handwriting, unless otherwise stated by the

Commission, by the individual providing the information. Do not misstate or omit any material fact(s).

- All required documentation, such as business formation papers, tax returns and appendices, as well as the Application forms that comprise an Application package for a license, as listed above, **must be submitted at the time of filing this Application.** Further, the Applicant is under **a continuing duty to promptly notify** the Commission if there is a change in the information provided to the Commission.

- An Applicant shall clearly identify those portions of its Application that it deems to be confidential, proprietary commercial information, trade secrets, or financial data, and provide justification of why such materials, upon request, should not be disclosed by the State pursuant to the Public Information Act ("MPIA"), Md. Code, Gen'l Prov §§ 4-101-601. Confidential information may be contained in the Application. A blanket statement by an Applicant that its entire Application is confidential is unacceptable. Applications shall be open to public inspection only after award of a license has been made, to the extent permitted by the MPIA. The Applicant is advised that, upon request for this information from a third party, the Commission will make an independent determination whether the information may be disclosed. An Applicant or Licensee waives any liability of the State of Maryland, and its employees and Agents, the Commission, and the Department of Health and Mental Hygiene for any damages resulting from any disclosure or publication in any manner.

The Commission may request additional financial and other information as needed. COMAR 10.62.19.04(D)-(F).

APPLICATION CONTENTS

A complete Application package must include:

1. A USB drive containing a redacted Microsoft Word document as well as related documents outlined in Section H;
2. A hard copy of the Application; and
3. A two thousand dollar ($2,000) Stage 1 non-refundable Application fee in the form of a money order or a cashier's check.

The submittal of an Application constitutes acceptance of the requirements, administrative stipulations, and all of the terms and conditions of this Application. All costs and expenses incurred in submitting an Application in response to this Application will be borne by the Applicant.

APPLICATION DELIVERY

- It is the Applicant's responsibility to allow sufficient time to address potential delays.
- Sole responsibility rests with the Applicant to ensure that their Application is received by MMCC on or before the submission deadline.

- Applicants are required to use a courier service to deliver the Applicant contents including the contents outlined in the "APPLICATION CONTENTS" section above.
- Late Applications will not be accepted.

MMCC Delivery Address:

Attn: Precious Wells, Administrative Specialist
Maryland Department of Health and Mental Hygiene
Maryland Medical Cannabis Commission
4201 Patterson Avenue
Baltimore, MD 21215
410-764-2400

SECTION Q: AWARDING OF LICENSE PRE-APPROVAL – COMAR Section- 10.62.19.05(D)

The Commission shall notify an Applicant who has been pre-approved for a license within 10 business days of the Commission's decision.

SECTION R Rescission of Processor License – COMAR Section- 10.62.19.06(E)

The Commission may rescind the pre-approval of a processor license if the processor is not operational within 1 year of pre-approval.

SECTION S: Denial or Disqualification of Application

MMCC may deny any Application under any of the following circumstances:

- The Application contains a misstatement, omission, misrepresentation, or untruth COMAR 10.62.19.04(B).
- The Applicant fails to submit the Application by the submission deadline.
- The Applicant fails to pay the Application fee prior to the submission deadline.
- The criminal history record information or any other evidence demonstrates an absence of good moral character. COMAR 10.62.19.05(C)(1).
- The payment of taxes due in any jurisdiction is in arrears. COMAR 10.62.19.04(B)(6).
- The Application fails to meet the mandatory criteria as outlined in Section G of this document.

MMCC may deny issuing a pre-approval of a license if, for any individual identified in the Application:

- The criminal history record information or any other evidence that demonstrates an absence of good moral character. COMAR 10.62.19.05(C)(1); or
- The payment of taxes due in any jurisdiction is in arrears. COMAR 10.62.19.05(C)(2).

SECTION T: Application Ranking and Weighted Criteria – COMAR Section 10.62.19.04 (I)

SELECTION PROCESS: Pre-Approval of License—Stage One

The Commission, or a Commission independent contractor, shall review the submitted Applications for a **pre-approval** for a license. The Applications shall be ranked based on the following weighted criteria.

Operational Factors—20%

- A detailed operational plan for the production of medical cannabis extracts and medical cannabis-infused products;
- Summaries of policies and procedures for:
  - Laboratory operations;
  - Processing;
  - Packaging.

Safety and Security Factors—20%

- A detailed plan or information describing the security features and procedures;
- A detailed plan describing how the processor will prevent diversion;
- A detailed plan describing safety procedures.

Commercial Laboratory, Pharmaceutical Manufacturing, and Consumer Products Production Factors—15%

- Experience, knowledge, and training in:
  - Chemical plant management;
  - Pharmaceutical manufacturing;
  - Consumer product production.

Production Control Factors—15%

- A detailed quality control plan;
- A detailed inventory control plan;
- A detailed medical cannabis waste disposal plan.

Business and Economic Factors—15%

- A business plan:
  - Demonstrating a likelihood of success;

  - Demonstrating a sufficient business ability and experience on the part of the Applicant;
  - Providing for appropriate employee working conditions, benefits, and training;
- Demonstrating of adequate capitalization;
- A detailed plan evidencing how the processor will enforce the alcohol and drug free workplace policy.

Additional Factors—15%

- Demonstrated Maryland residency among the owners and investors;
- Evidence that the Applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions;
- A detailed plan evidencing how the processor will distribute to dispensaries;
- A list of proposed medical cannabis extracts and medical cannabis-infused products to be produced with proposed cannabinoid profiles, including:
  - Varieties with high cannabidiol content;
  - Whether the product has any demonstrated success in alleviating symptoms of specific diseases or conditions.

SECTION U: Affirmation Section

The Applicant understands the following:

	Yes	No
1. The burden of proving an Applicant's qualifications rests on the party applying for the license.	☐	☐
2. The Commission may deny an Application that contains a misstatement, omission, misrepresentation, or untruth.	☐	☐
3. An Application shall be complete in every material detail.	☐	☐
4. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an Application.	☐	☐
5. The party applying for the license shall provide requested additional information by the close of business of the 14th business day after the request has been received by the Applicant.	☐	☐
6. If the party applying for the license does not provide the requested information within 14 business days, the Commission may consider the Application to be suspended.	☐	☐
7. The Commission intends to award the licenses to the best Applications that most efficiently and effectively ensure public safety and safe access	☐	☐

	Yes	No
to medical cannabis and medical cannabis-infused products.		
8. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted Applications. The Applications shall be ranked based on weighted criteria.	☐	☐
9. The party applying for the license will provide an amended Application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.	☐	☐
10. For each individual identified in the Application specified in Regulation .02B(1) and (2) of this chapter, an Applicant will provide to the Director of the Central Repository:		
a. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each processor agent and investor identified in the Application; and	☐	☐
b. A request that the individual's state and national criminal history record information be forwarded to the Commission.	☐	☐
11. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the Application:		
a. The criminal history record information or background information demonstrate an absence of good moral character; or	☐	☐
b. The payment of taxes due in any jurisdiction is in arrears.	☐	☐
12. The Commission may rescind pre-approval of a processor license if the processor is not operational within 1 year of pre-approval.	☐	☐
13. The Commission may issue a processor license on a determination that:		
a. The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;	☐	☐
b. All inspections are passed and all of the Applicant's operations	☐	☐

	Yes	No
conform to the specifications of the applicable regulations;		
a. The proposed premises:		
i. Are under the legal control of the Applicant;	☐	☐
ii. Comply with all zoning and planning requirements; and	☐	☐
iii. Conform to the specifications of the Application as pre-approved pursuant to the applicable regulations; and	☐	☐
iv. The first year's license fee specified in COMAR 10.62.35 has been paid.	☐	☐
14. The Commission may deny transfer of an interest in a license if, for any proposed transferee:		
a. The criminal history record information or the background investigation demonstrate an absence of good moral character; or	☐	☐
b. The payment of taxes due in any jurisdiction is in arrears.	☐	☐
15. The Commission, after review of the criminal history record information, may disqualify any prospective registered processor agent from registration for an absence of good moral character or if the payment of taxes in any jurisdiction is in arrears.	☐	☐
16. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.	☐	☐

Please review and answer the following:

	Yes	No
1. The party applying for the processor license irrevocably gives consent to the Commission and persons authorized by the Commission to:		
a. Verify all information provided in the Application documents; and	☐	☐
b. Conduct a background investigation of the individual(s).	☐	☐
2. The party applying for the processor license waives any contractual, statutory, or common law obligation of confidentiality and authorizes any government agency in any jurisdiction to release to and provide access to the Commission of any and all information the Applicant has provided to	☐	☐

	Yes	No
any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the Applicant.		
3. The party applying for the processor license releases all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the Applicant's capacity to manage a licensed processor facility and the Applicant's good moral character.	☐	☐
4. All processor Agents affiliated with this Application are 21 years old or older at the time of Application.	☐	☐
5. All of the processor Agents affiliated with this Application have never been convicted of a felony drug offense	☐	☐

An Applicant Shall Commit to the Following:

	Yes	No
1. All processor Agents will be 21 years or older.	☐	☐
2. The party applying for the license commits to having any and all processor Agents registered with the Commission before the agent may volunteer or work for a Licensee.	☐	☐
3. The party applying for the license commits to registering a processor agent by submitting to the Commission:		
a. The name, address, date of birth and Social Security Number of a processor agent;	☐	☐
b. Documentation of the submission of fingerprints of the processor agent to the Central Registry; and	☐	☐
c. The request for the criminal history record information of the processor agent to be forwarded to the Commission.	☐	☐
4. The Applicant will not register a prospective processor agent if the prospective processor agent has ever been convicted of a felony drug offense.	☐	☐
5. The party applying for the license will provide an amended Application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5	☐	☐

	Yes	No
percent or more, or another manager or director of the entity, even after a license is issued.		
6. For each individual identified in the Application the processor agent commits to requiring any prospective medical cannabis processor agent register with the Commission before the Applicant will employ the agent or permit the agent to volunteer for the Applicant.	☐	☐
7. If an Applicant is issued a pre-approval for a license the party applying for the license commits to submitting to the Commission, as part of its Application:		
a. An audited financial statement for the Applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the Applicant; and	☐	☐
b. Payment of the stage 2 Application fee specified in COMAR 10.62.35.	☐	☐
8. The party applying for the license commits to having no interest of 5 percent or more of a license issued pursuant to this chapter assignable or transferable unless:		
a. The Commission has received notice in a manner determined by the Commission of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;	☐	☐
b. The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;	☐	☐
c. The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and	☐	☐
d. The transferee has paid the required fee specified in COMAR 10.62.35.	☐	☐
9. The party applying for the license acknowledges that a Licensee is eligible to apply to renew a license every 2 years.	☐	☐
10. The party applying for the license acknowledges that ninety days before the expiration of a license, the Commission will notify the Licensee of the:		

	Yes	No
a. Date on which the license expires;	☐	☐
b. Process and the fee required to renew the license; and	☐	☐
c. Consequences of a failure to renew the license.	☐	☐
11. The party applying for the license acknowledges that at least 30 business days before a license expires a Licensee shall submit:		
a. The renewal Application as provided by the Commission;	☐	☐
b. Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more;	☐	☐
c. To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and	☐	☐
d. Payment of the fee specified in COMAR 10.62.35.	☐	☐
12. The party applying for the license acknowledges that the Commission shall renew a license that meets the requirements for renewal as stated in COMAR 10.62.19.08(C).	☐	☐
13. The party applying for the license acknowledges that the Commission shall issue to each registered processor agent an identification card that shall include a photograph of the face of the registered processor agent taken no more than 6 months before the date of the Application.	☐	☐
14. At all times at the premises of a Licensee, every processor agent shall visibly wear the identification card issued to the registered processor agent by the Commission.	☐	☐
15. The party applying for the license commits to renewing the identification card every 2 years.	☐	☐
16. If a registered processor agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the Licensee commits to:		
a. Reporting the loss, destruction or theft to a the Commission;	☐	☐
b. Applying for a replacement card; and	☐	☐

	Yes	No
c. Paying a replacement card fee specified in COMAR 10.62.35.	☐	☐
17. As soon as possible upon termination of a registered processor agent's association with a Licensee, the Licensee commits to:		
a. Take custody of the terminated registered processor agent's identification card;	☐	☐
b. Obtain any keys or other entry devices from the terminated registered processor agent; and	☐	☐
c. Ensure the terminated registered processor agent can no longer gain access to the premises of the Licensee.	☐	☐
18. Within 1 business day of the termination of a registered processor agent's association with a Licensee, the Licensee commits to:		
a. Notify the Commission:		
i. Of the termination and the circumstances of a termination;	☐	☐
ii. Whether the terminated registered processor agent has returned the agent's identification card; and	☐	☐
iii. Initiate delivery of the terminated registered processor agent's identification card to the Commission.	☐	☐
19. The party applying for the license acknowledges that the Commission will revoke an identification card of a processor agent upon receiving notification that a processor agent is no longer associated with a Licensee.	☐	☐
20. The party applying for the license acknowledges that if a registered processor agent does not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.	☐	☐
21. The party applying for the license acknowledges that the Licensee shall require a prospective processor agent to submit to a drug screen before commencement of association.	☐	☐
a. The party applying for the license acknowledges that the drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.	☐	☐
b. In addition to the drugs to be screened in accordance with the	☐	☐

	Yes	No
procedures set forth in COMAR 17.09.04-.08, the screen shall include any other drugs as required by the Commission.		
22. The party applying for the license acknowledges that unless medically justified, a prospective processor agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.	☐	☐
23. The party applying for the license acknowledges that a registered processor agent shall retain training materials and attendance records and make the training materials available for inspection.	☐	☐
24. The party applying for the license acknowledges that a registered processor agent shall declare in writing that the registered processor agent will adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.	☐	☐
25. The party applying for the license acknowledges that the Licensee will retain the declaration in the registered processor agent's personnel record.	☐	☐
26. The party applying for the license commits to notifying the Commission that the Licensee has verified that no registered processor agent has been convicted of a felony drug offense, every year, on a date determined by the Commission.	☐	☐
27. The party applying for the license commits to locating the premises of a Licensee within Maryland.	☐	☐
28. The party applying for the license commits to conspicuously displaying the processor license at the location where the Licensee is authorized to operate.	☐	☐
29. The party applying for the license commits conforming the premises and operations to all local zoning and planning requirements.	☐	☐
30. The party applying for the license commits to notifying the Commission before any major renovation or modification is undertaken.	☐	☐
31. The party applying for the license acknowledges that if the Commission does not renew a license due to a failed inspection or an inadequate Application for renewal, the Licensee may apply for reinstatement by:		
a. Submitting a plan to correct the deficiencies noted during an inspection; and	☐	☐
b. Amending the Application for renewal.	☐	☐

	Yes	No
32. The party applying for the license acknowledges that the Commission may decline to renew a license if:		
a. The plan to correct deficiencies identified in an inspection is deficient;	☐	☐
b. The amended Application for renewal is deficient; or	☐	☐
c. The Licensee has repeatedly failed inspections.	☐	☐
33. The party applying for the license acknowledges that a Licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:		
a. Shall cease operations at all premises; and	☐	☐
b. May not process medical cannabis.	☐	☐
34. The party applying for the license acknowledges that a license may be reinstated upon:		
a. Payment of the reinstatement fee specified in COMAR 10.62.35; and	☐	☐
b. Submission of a reinstatement Application approved by the Commission.	☐	☐
35. The party applying for the license may apply to change the location of the Licensee's operation.	☐	☐
36. The party applying for the license, to change the location of the Licensee's operation, must submit an Application to the Commission along with the fee specified in COMAR 10.62.35.	☐	☐
37. The party applying for the license, to change the location of the Licensee's operation, may not begin processing medical cannabis at a new location until all inspections have been passed.	☐	☐
38. The party applying for the license commits to providing the Commission or law enforcement agency for just cause with any recording of security video surveillance as requested.	☐	☐

The undersigned attests that the Applicant organization will adhere to the statutory/regulatory

requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

_____ _____

Signature Date

See attached completed forms.
Printed Name

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: See attached completed forms.
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis Choose an item.
(Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

_____ _____

Signature of Applicant Date

See attached completed forms.
Printed Name of Applicant

NOTARY

The undersigned, a Notary Public in and for the County of _____, in the State of _____, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This _____ day of _____, 20___, and to which witness my hand and seal.

_____
Notary Public

_____
Printed Name

Stamp or Seal

My Commission Expires: _____, 20____

FORM 2

AUTHORIZATION FOR RELEASE OF INFORMATION-BUSINESS ENTITY

Business Entity Name: See attached completed forms.
Name of Person Completing Form: Name of Person Completing Form
(Authorized Representative)

[Type text] is an Authorized Representative, empowered by the Business Entity to execute this form on its behalf.
[Type text] is an Applicant for a Medical Cannabis Choose an item.
(Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about the Business Entity. The Business Entity irrevocably gives its consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of the Business Entity; and (3) to have access to any and all information that the Business Entity has provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about the Business Entity.

By executing this Authorization, the Business Entity authorizes any of the following entities to release to the Commission any and all information about the Business Entity that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, the Business Entity expressly waives, releases, discharges and forever holds harmless and agrees to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

_____ _____

Signature of Authorized Representative Date

See attached completed forms.
Printed Name of Authorized Representative

NOTARY

The undersigned, a Notary Public in and for the County of _____, in the State of _____, certifies that the above named individual, as an Authorized Representative of _____, appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This _____ day of _____, 20___, and to which witness my hand and seal.

_____
Notary Public

_____
Printed Name

Stamp or Seal

My Commission Expires:_____, 20____

FORM 3

Trade Secret & Financial Data Notification

[Type text] is an Applicant for a Medical Cannabis Choose an item. License. [Type text] understands that the Commission is an entity of the State of Maryland and any documents or data that is submitted to the State of Maryland may be disclosed by the State pursuant to a Maryland Public Information Act ("MPIA") Request.

While the MPIA permits certain exclusions from disclosure, [Type text] understands the State makes no guarantees or promises that such data will not be disclosed. [Type text] has reviewed the MPIA, as it is available online at http://www.lexisnexis.com/hottopics/mdcode. [Type text] understands that other helpful resources may be found at www.oag.state.md.us/Opengov.

[Type text] understands that the documents or data it provides to the State of Maryland may not be confidential, or if confidential, may or may not be disclosed pursuant to a MPIA request.

_____ _____

Signature of Person or Authorized Representative Date

See attached completed forms.
Printed Name

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
See attached completed forms.	[Type text]	[Type text]	[Type text]
[Type text]	[Type text]	[Type text]	[Type text]
[Type text]	[Type text]	[Type text]	[Type text]
[Type text]	[Type text]	[Type text]	[Type text]

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

_____ _____

Name- Signature Date

See attached completed forms.
Name- Printed

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation. [Type text]	Yes ☐	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports. [Type text]	Yes ☐	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation. [Type text]	Yes ☐	No ☐
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation. [Type text]	Yes ☐	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation. [Type text]	Yes ☐	No ☐
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation. [Type text]	Yes ☐	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☐
8. If you are employed by the State, please state the name, agency and position. [Type text]		
9. I acknowledge that I fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and Any activity regarding cannabis that does not comply with Maryland law or regulations is a violation of State law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges.	Yes ☐	No ☐
10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☐	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☐	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☐	No ☐

Dated this _____day of _____, 20_____.

_____
Signature of Owner/ Managing Director

See attached completed forms.
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this _____day of _____, 20_____.

(SEAL)

_____
Notary Public

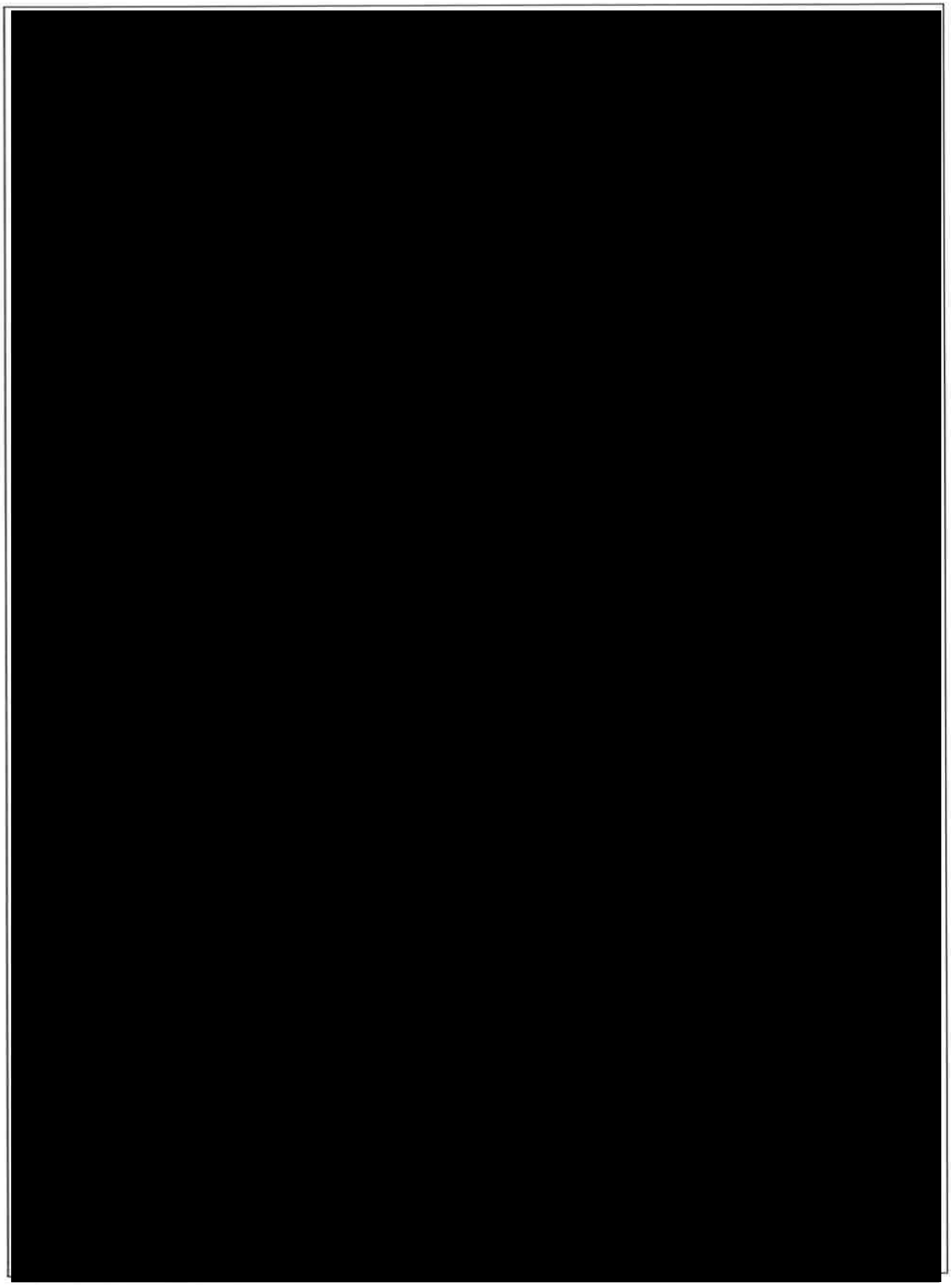
10.62.19.04

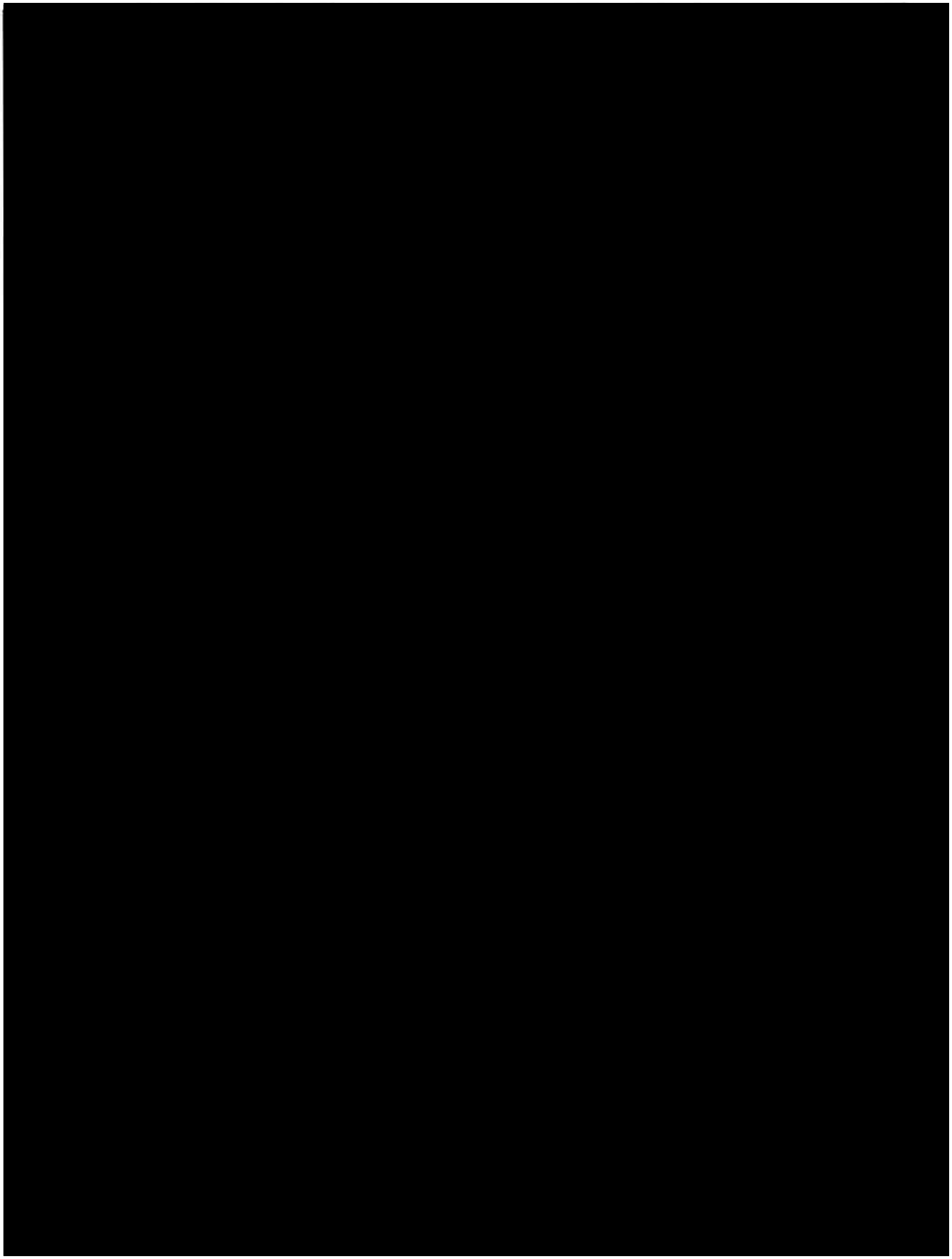
1. Please describe how the Applicant will address the following commercial laboratory, pharmaceutical manufacturing, and consumer products production factors:

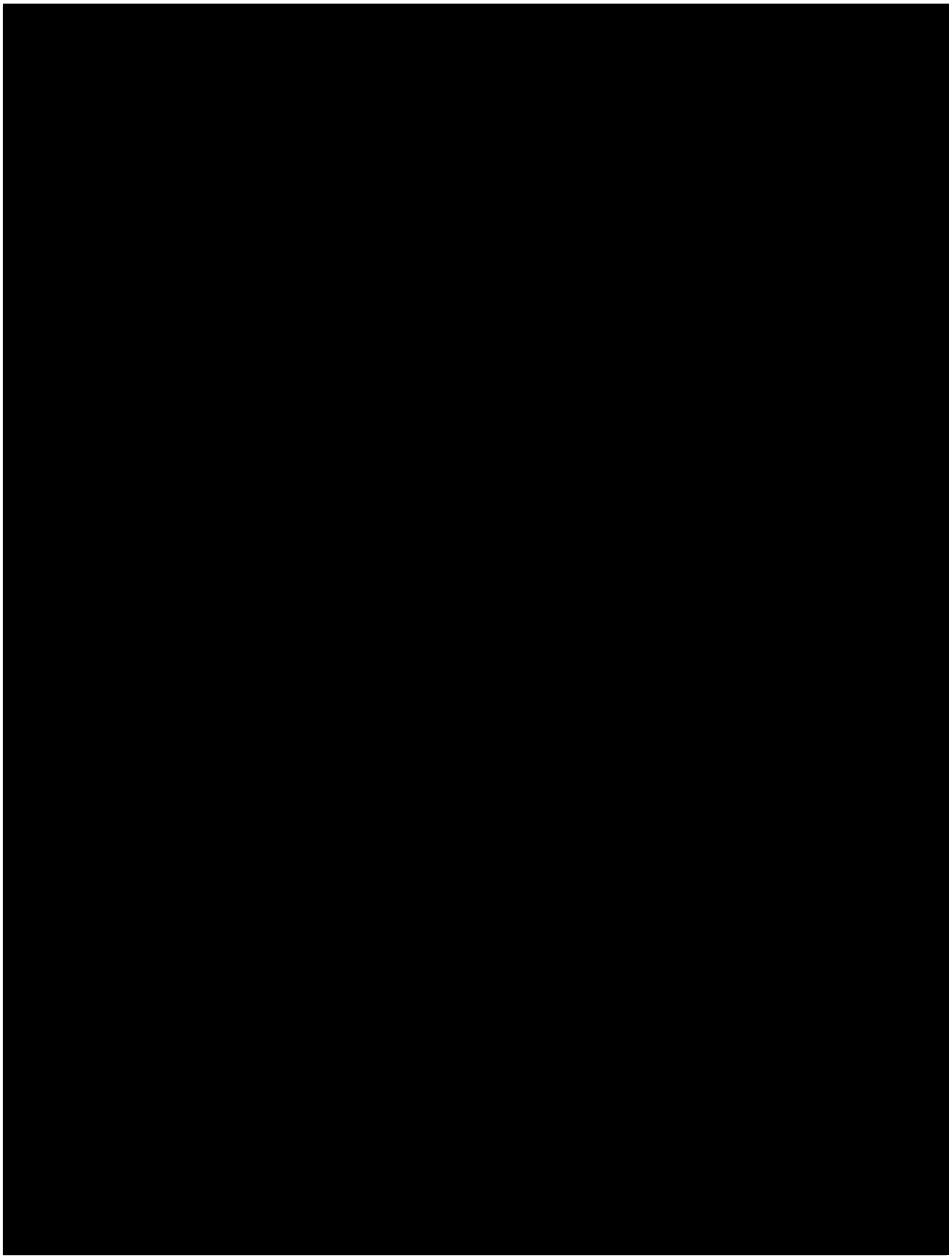
a. chemical plant manufacturing, *

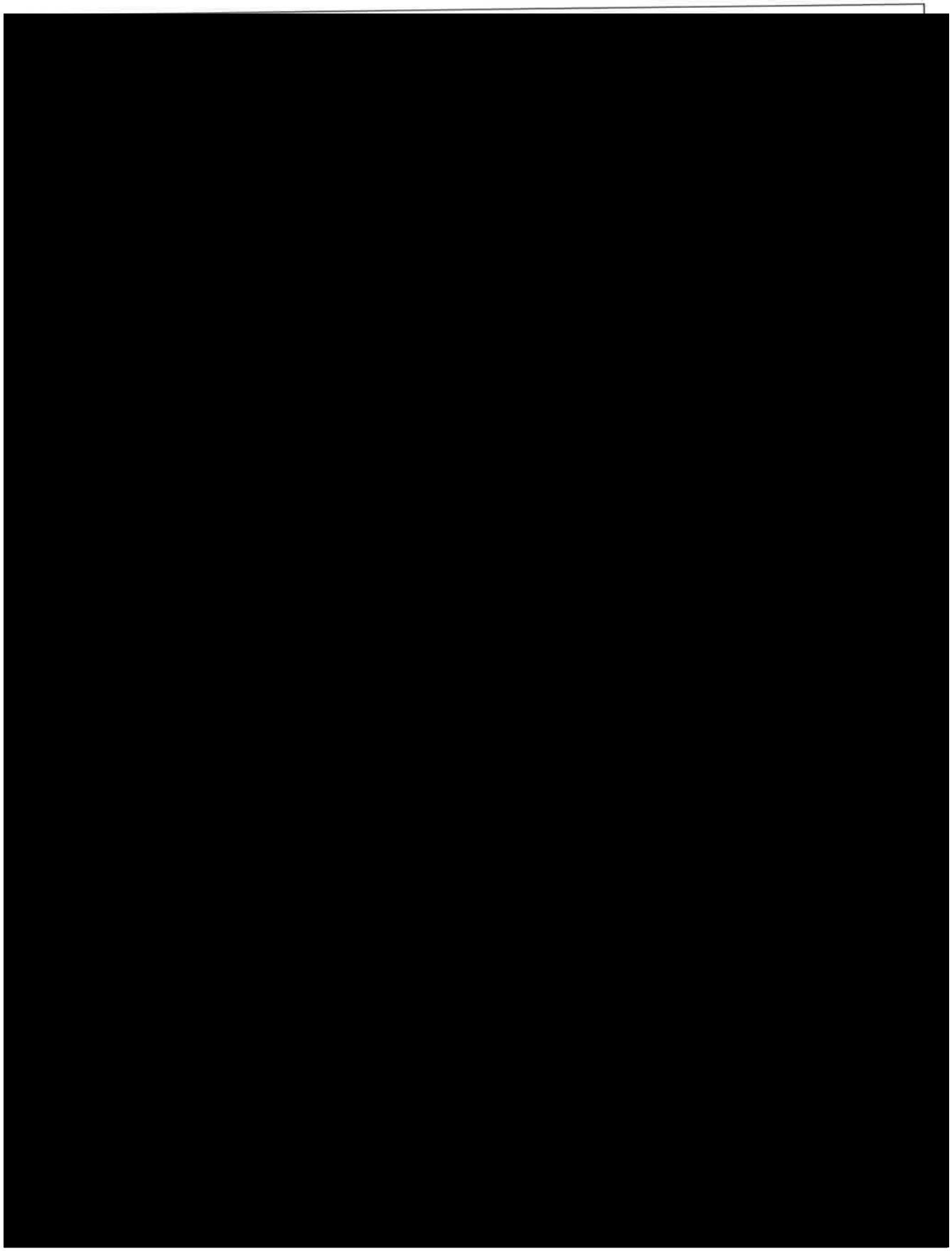
(a) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 40% of the Commercial Laboratory subsection. Maximum length 2,250 words.]

[redacted]









[redacted]

b. pharmaceutical manufacturing, and *

(b) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 40% of the Commercial Laboratory subsection. Maximum length 2,250 words.]

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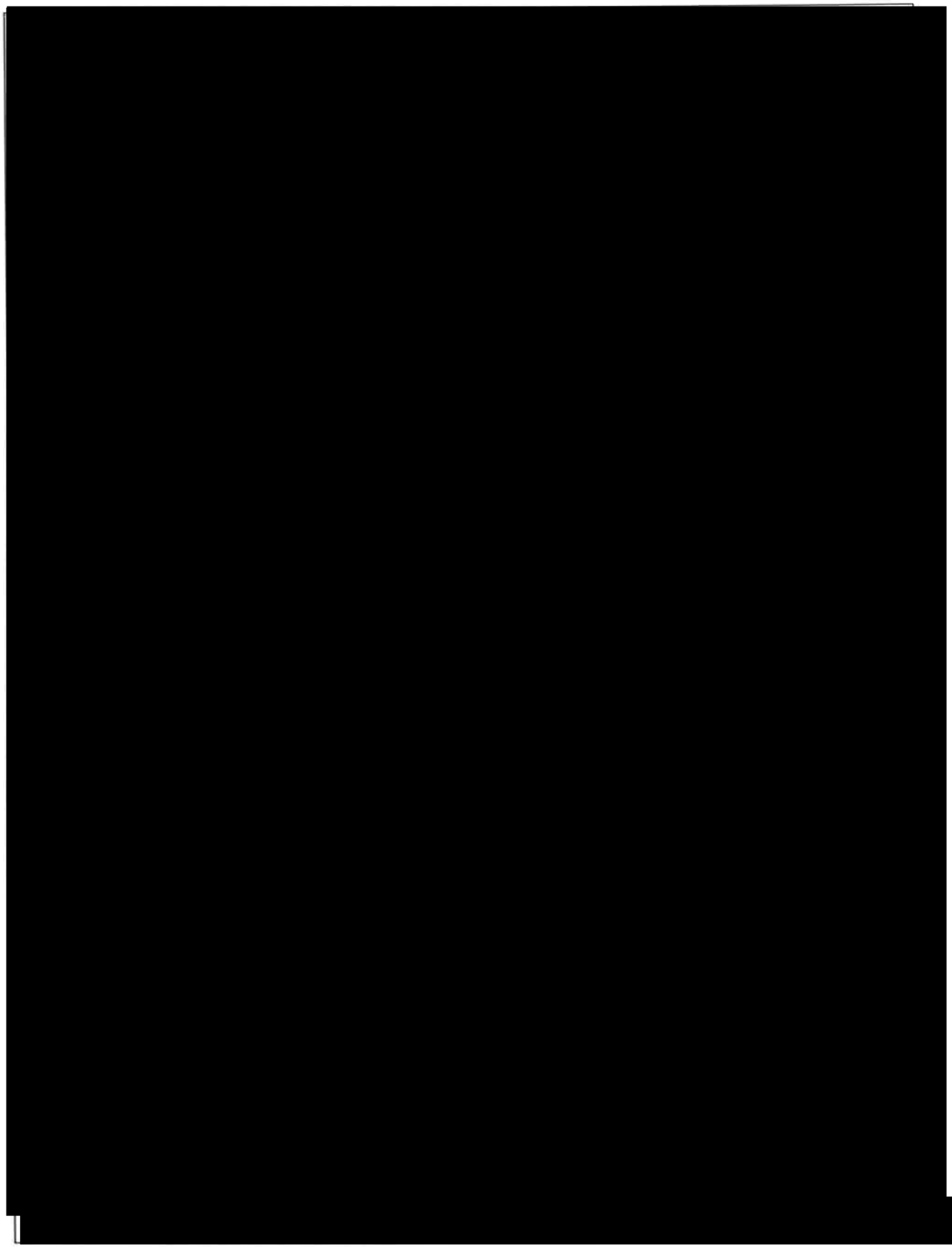

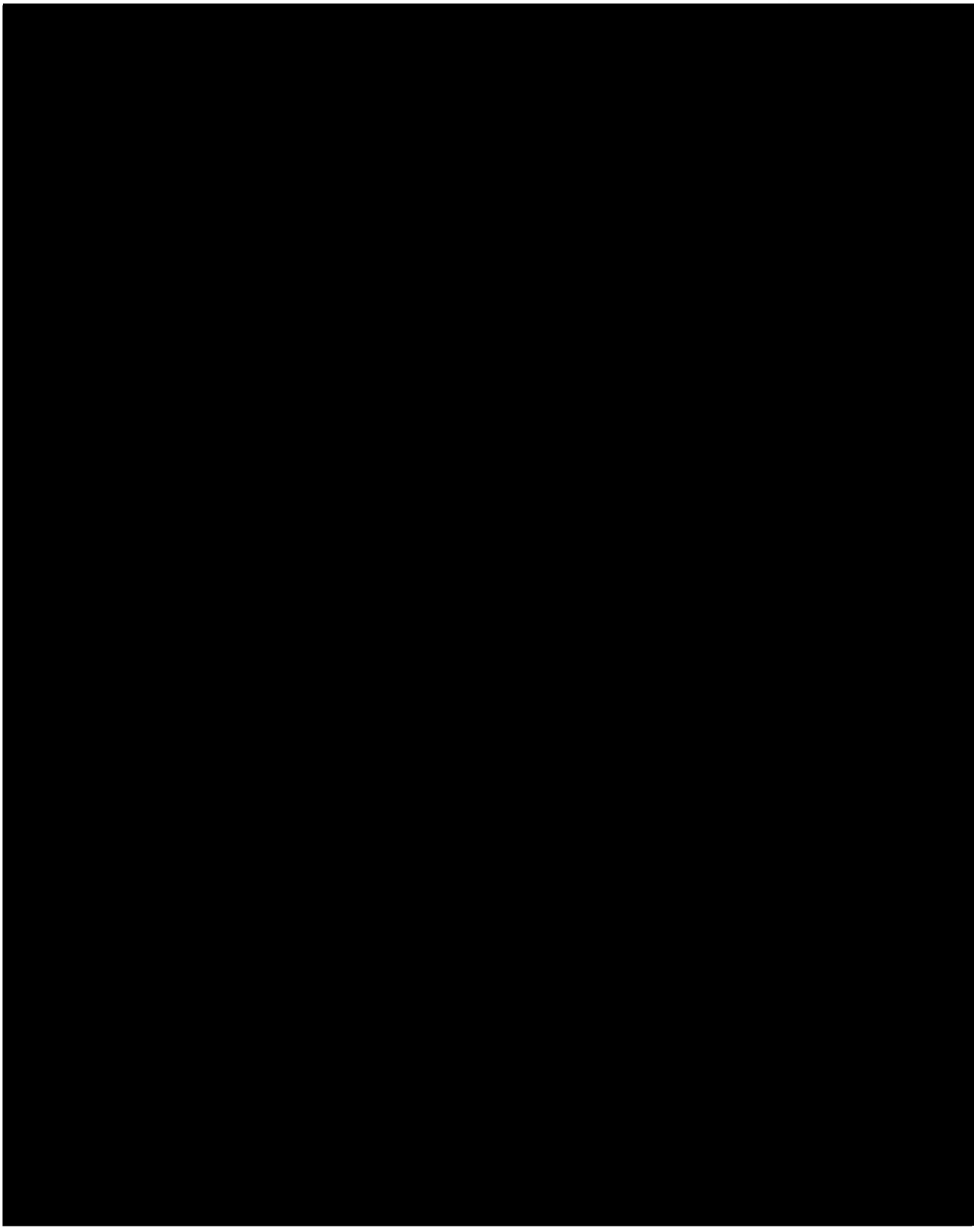

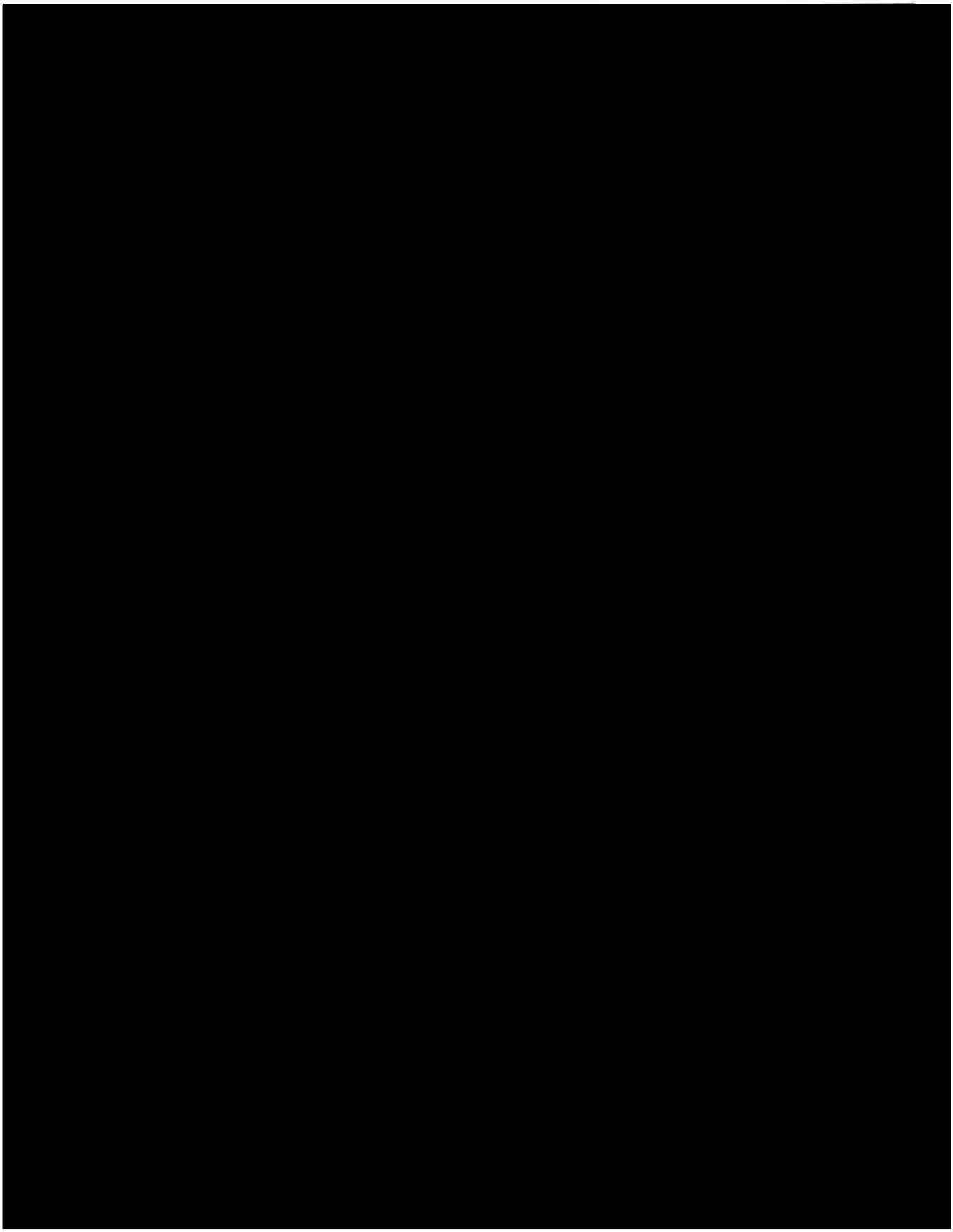

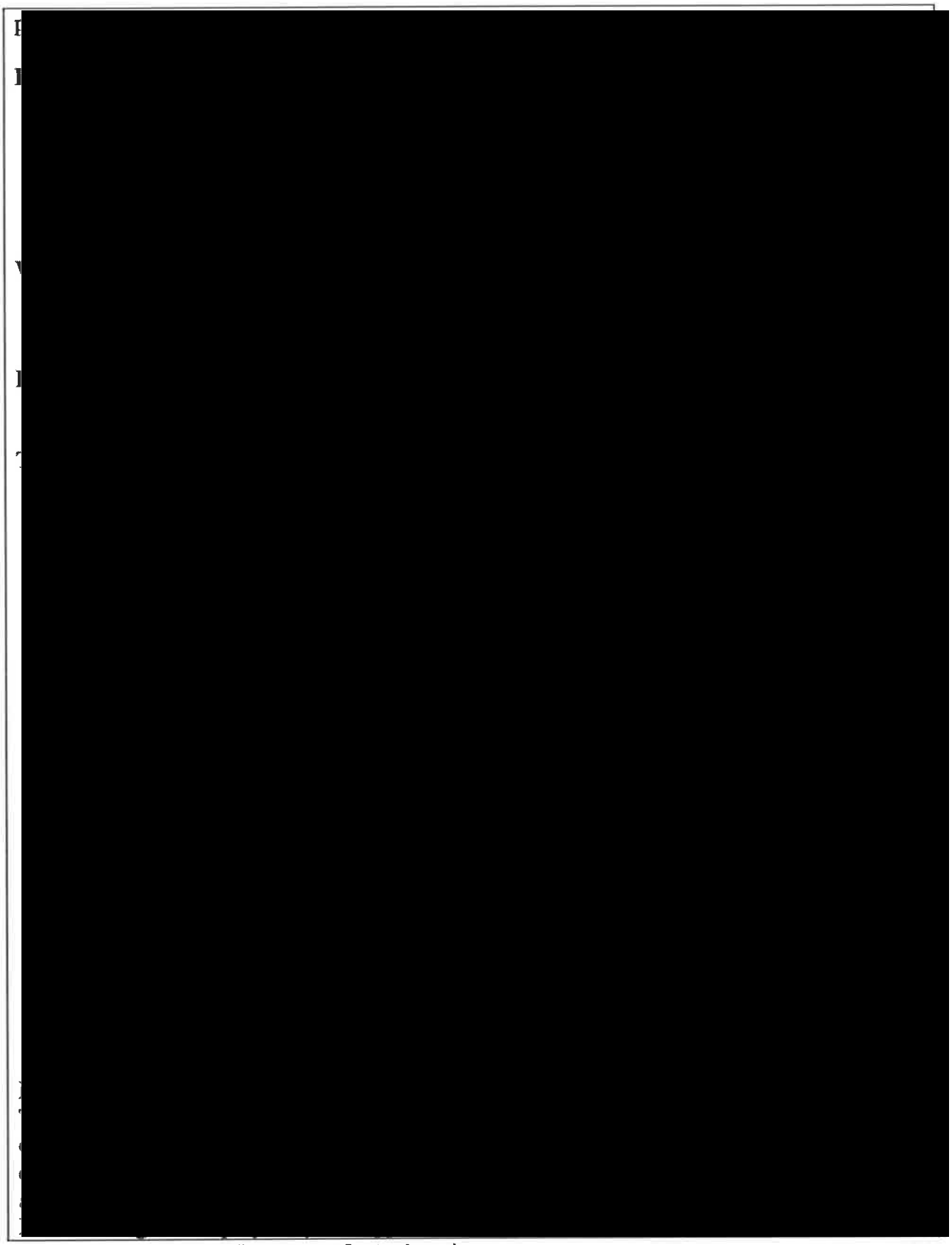

c. consumer product manufacturing. *

(c) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 20% of the Commercial Laboratory subsection. Maximum length 2,250 words(s).]

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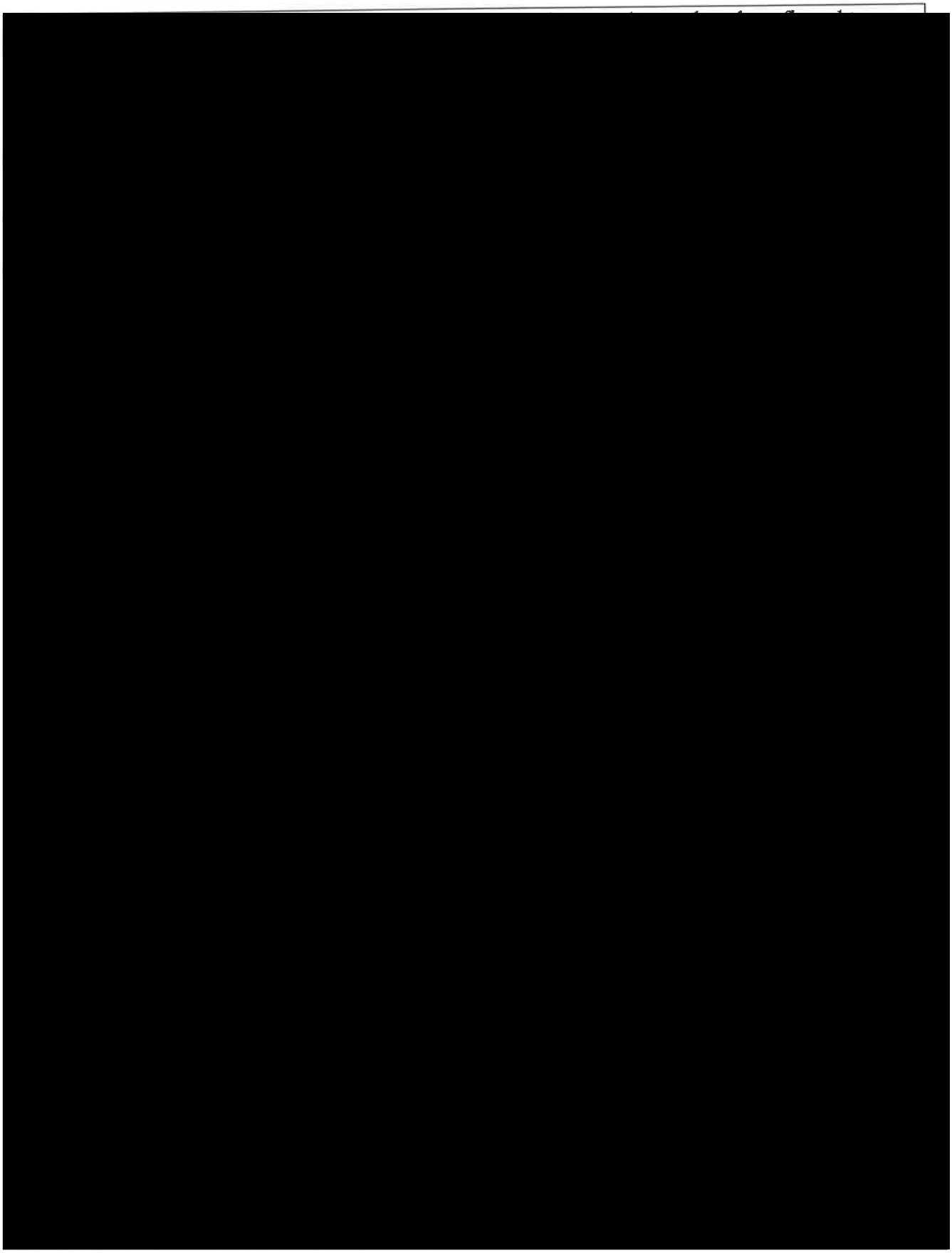

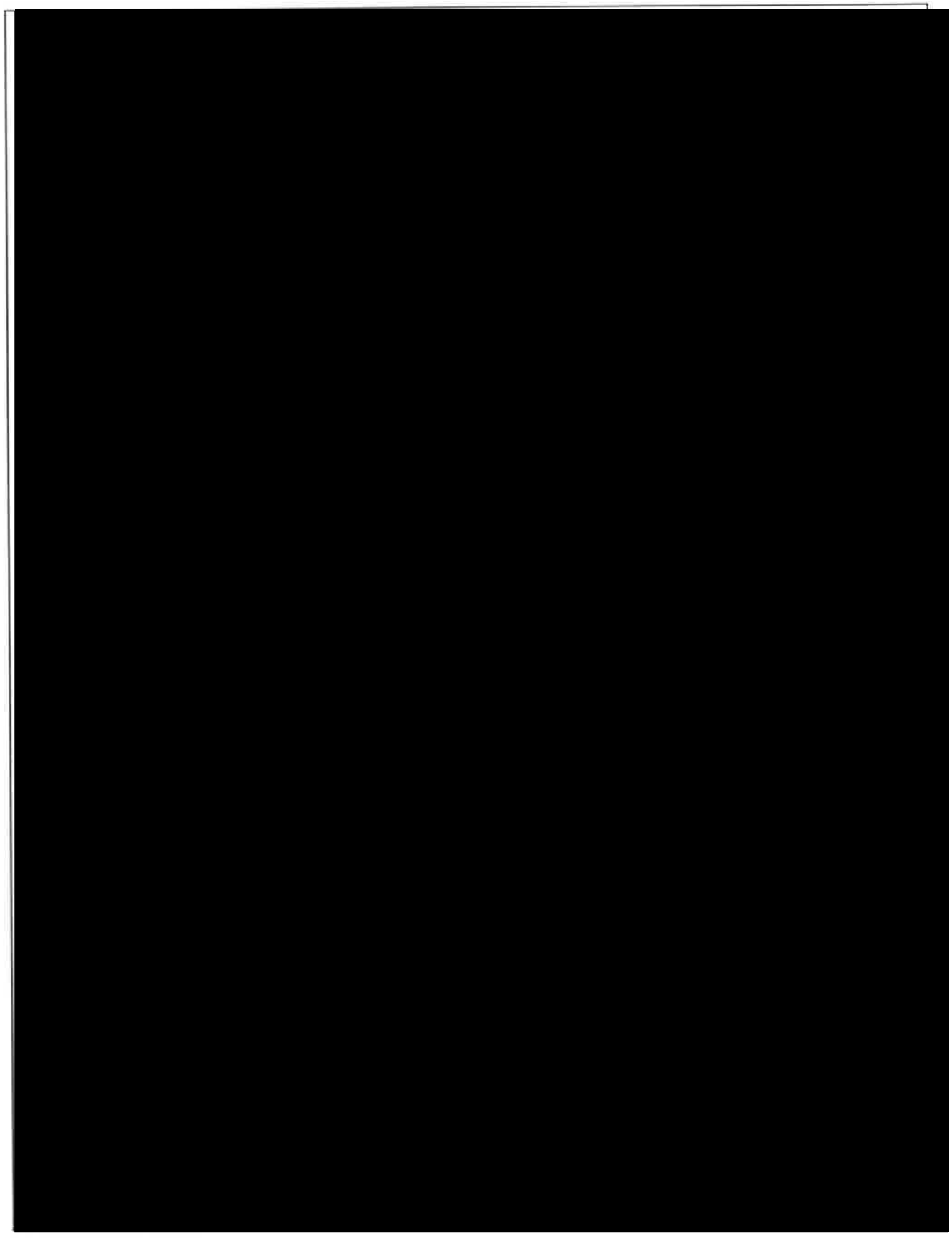

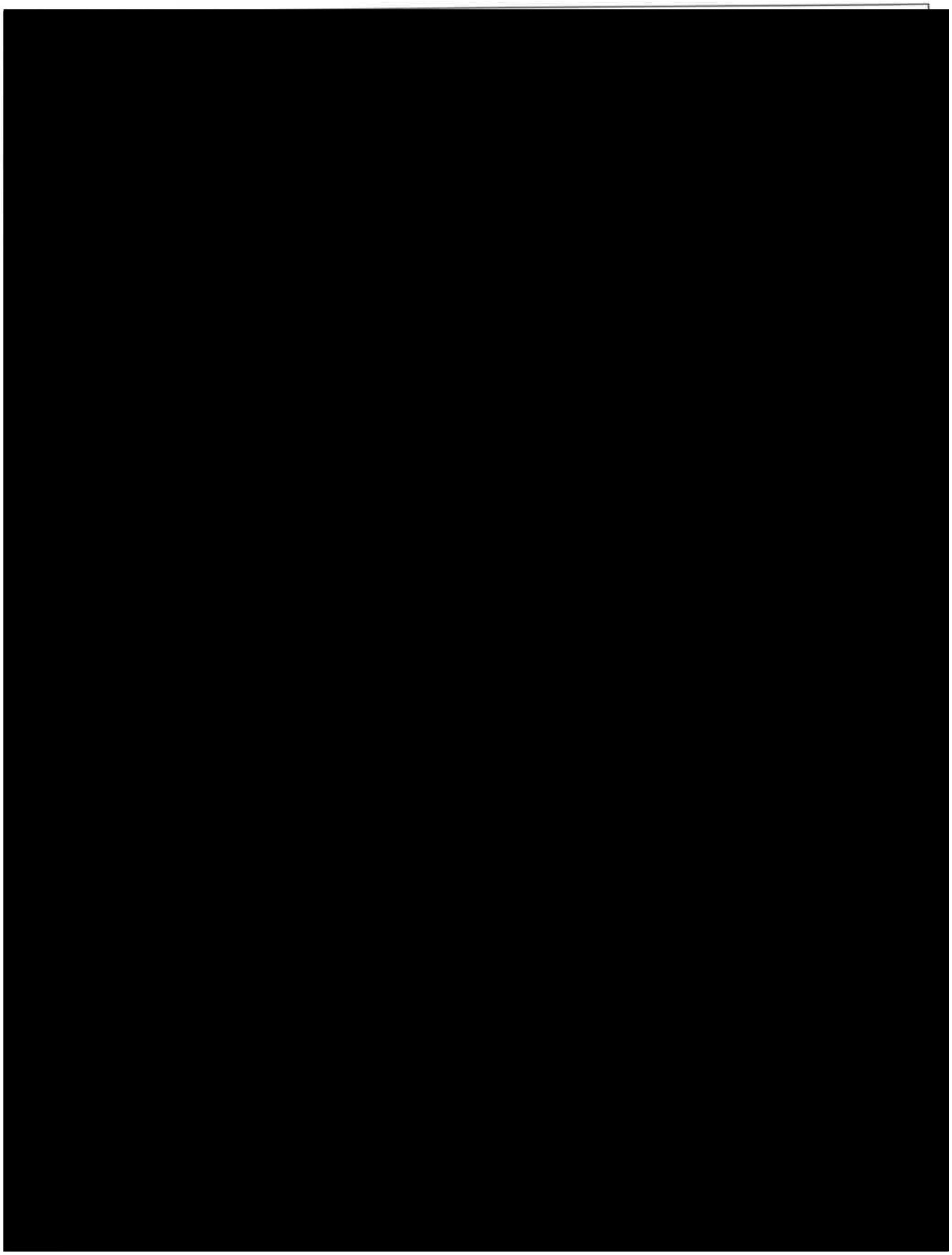

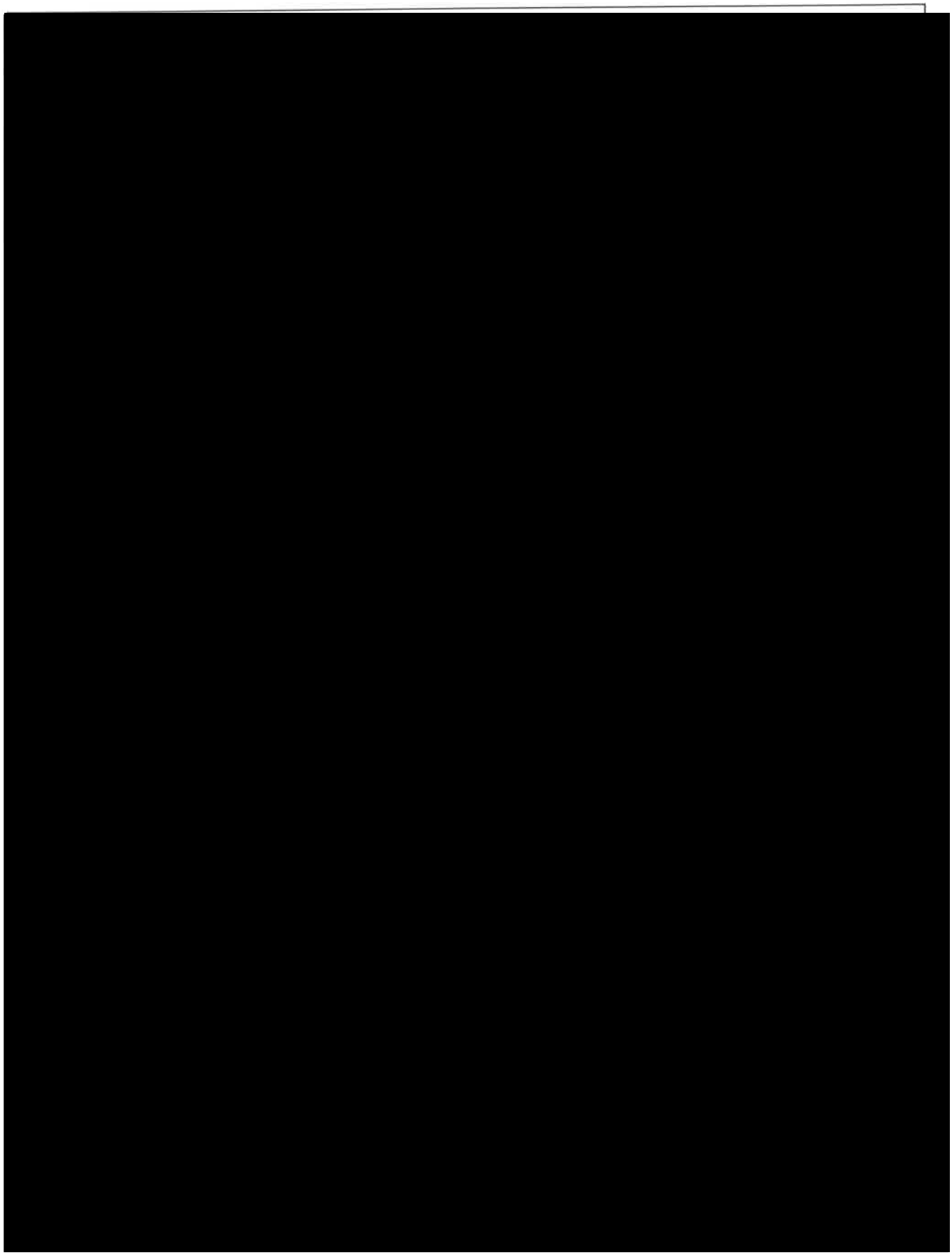

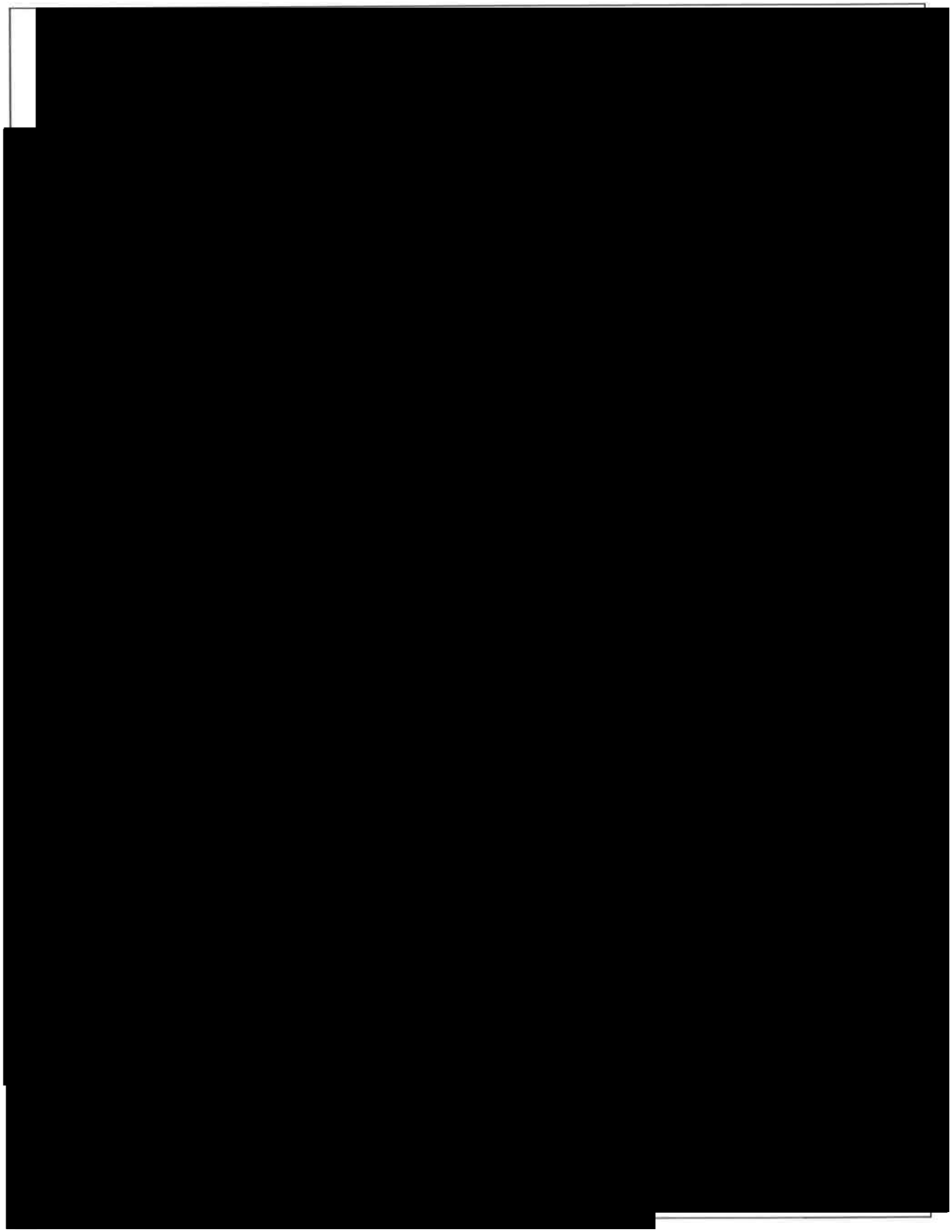

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2. Please describe how the Applicant will address the following business and economic factors:

a. a business plan that (i) demonstrates a likelihood of success and (ii) demonstrates a sufficient business ability and experience on the part of the Applicant, *

(i) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 20% of the Business and Economic subsection. Maximum length 3,150 words.]
(ii) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 20% of the Business and Economic subsection. Maximum length 3,150 words.]

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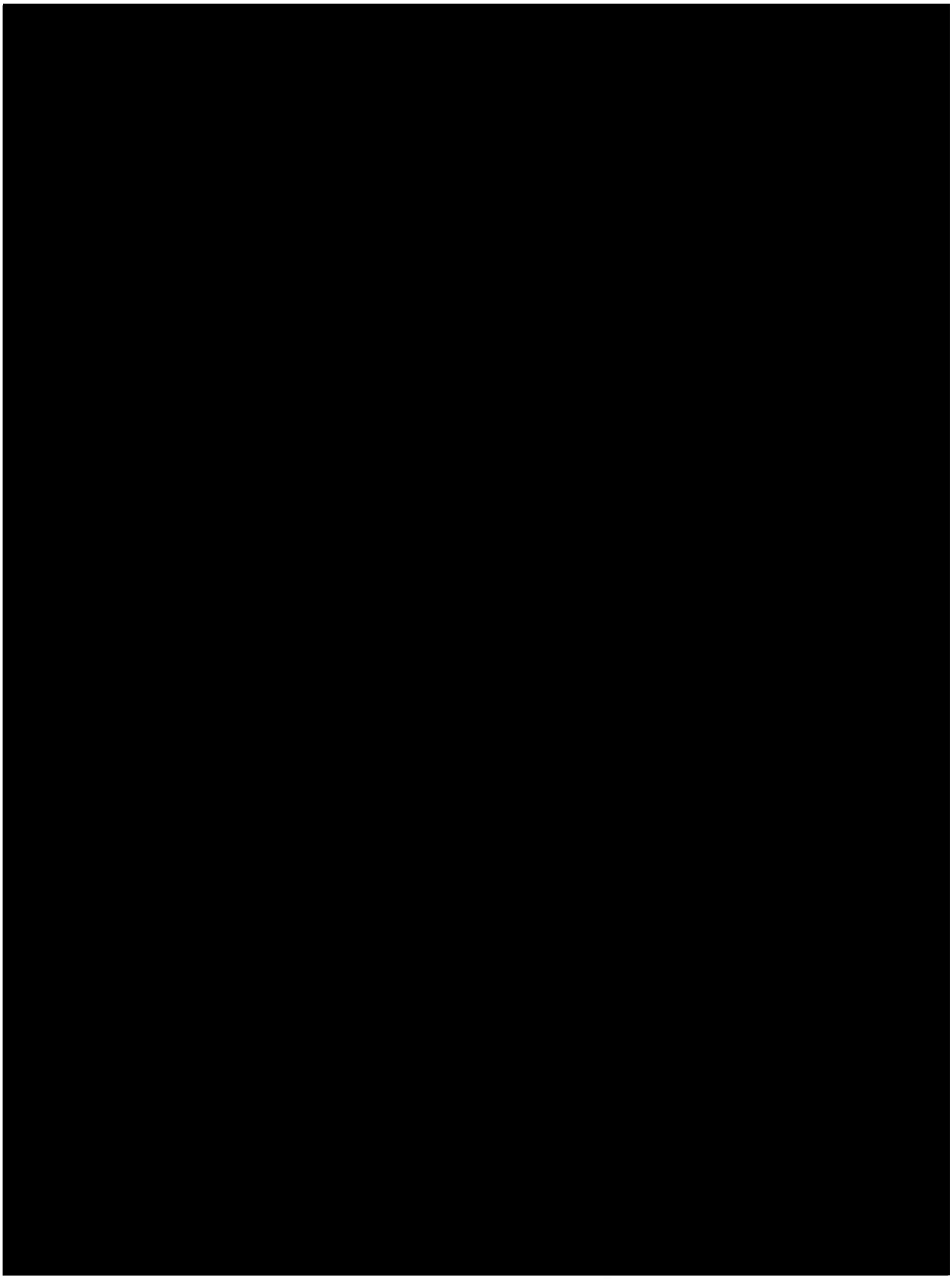
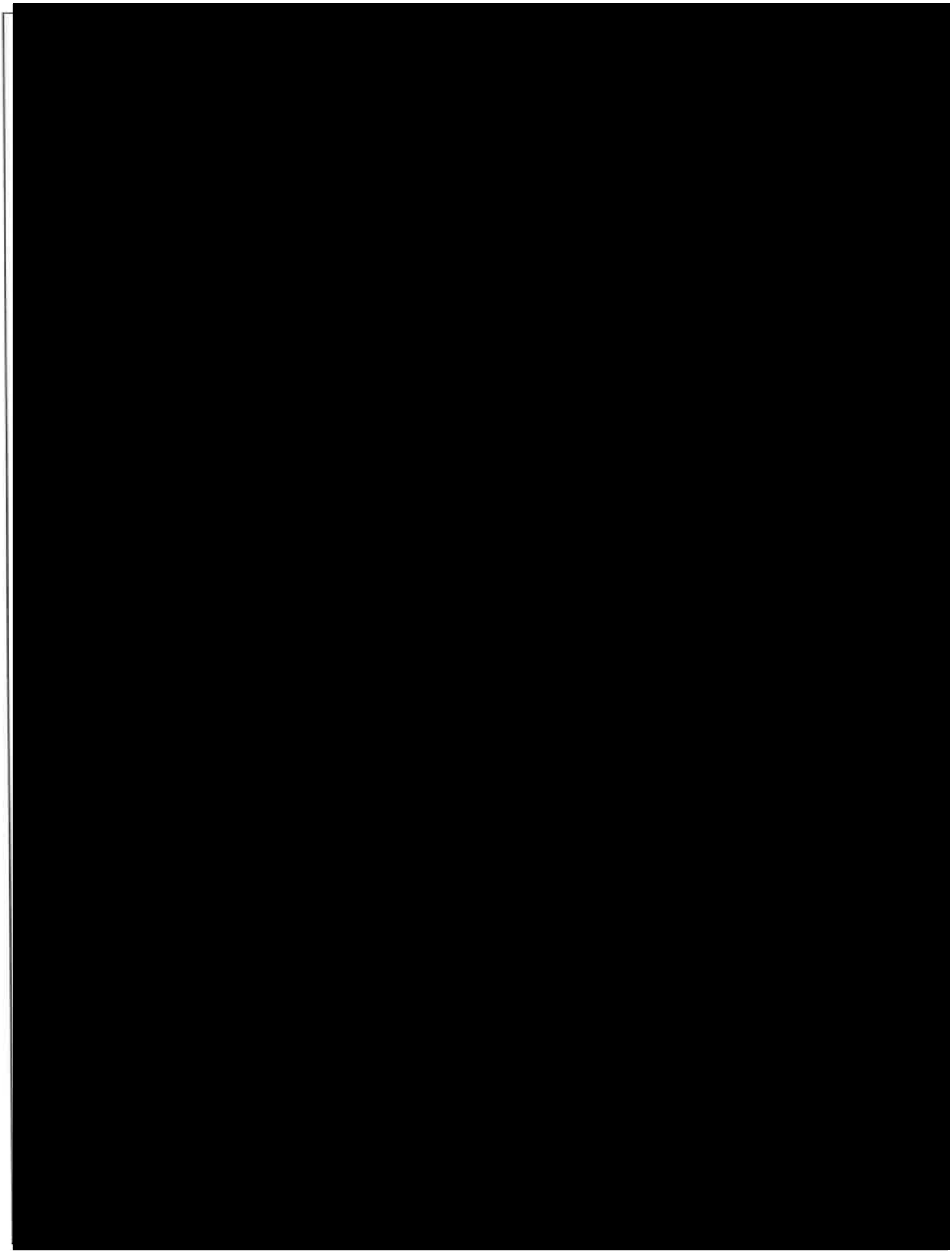
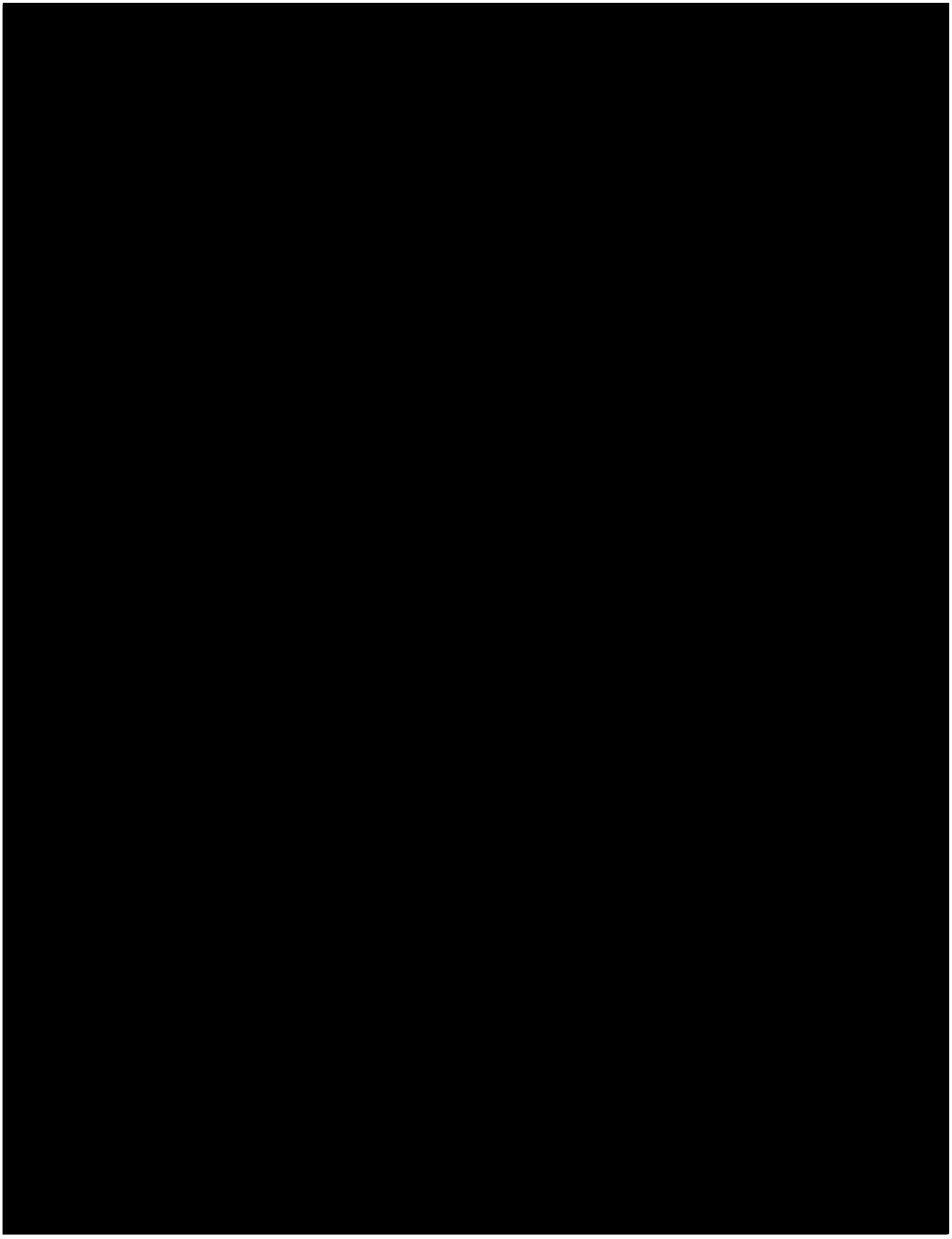
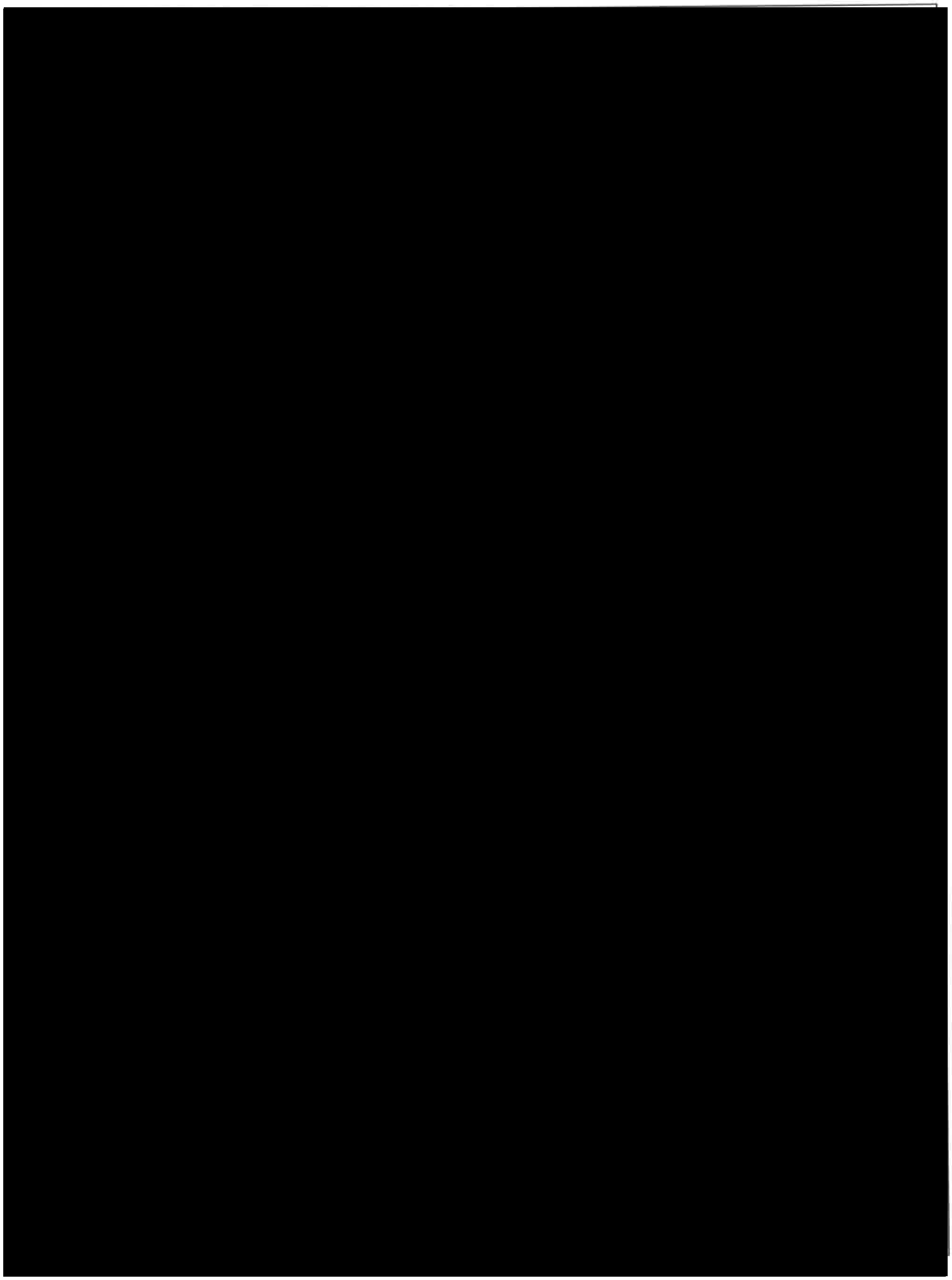
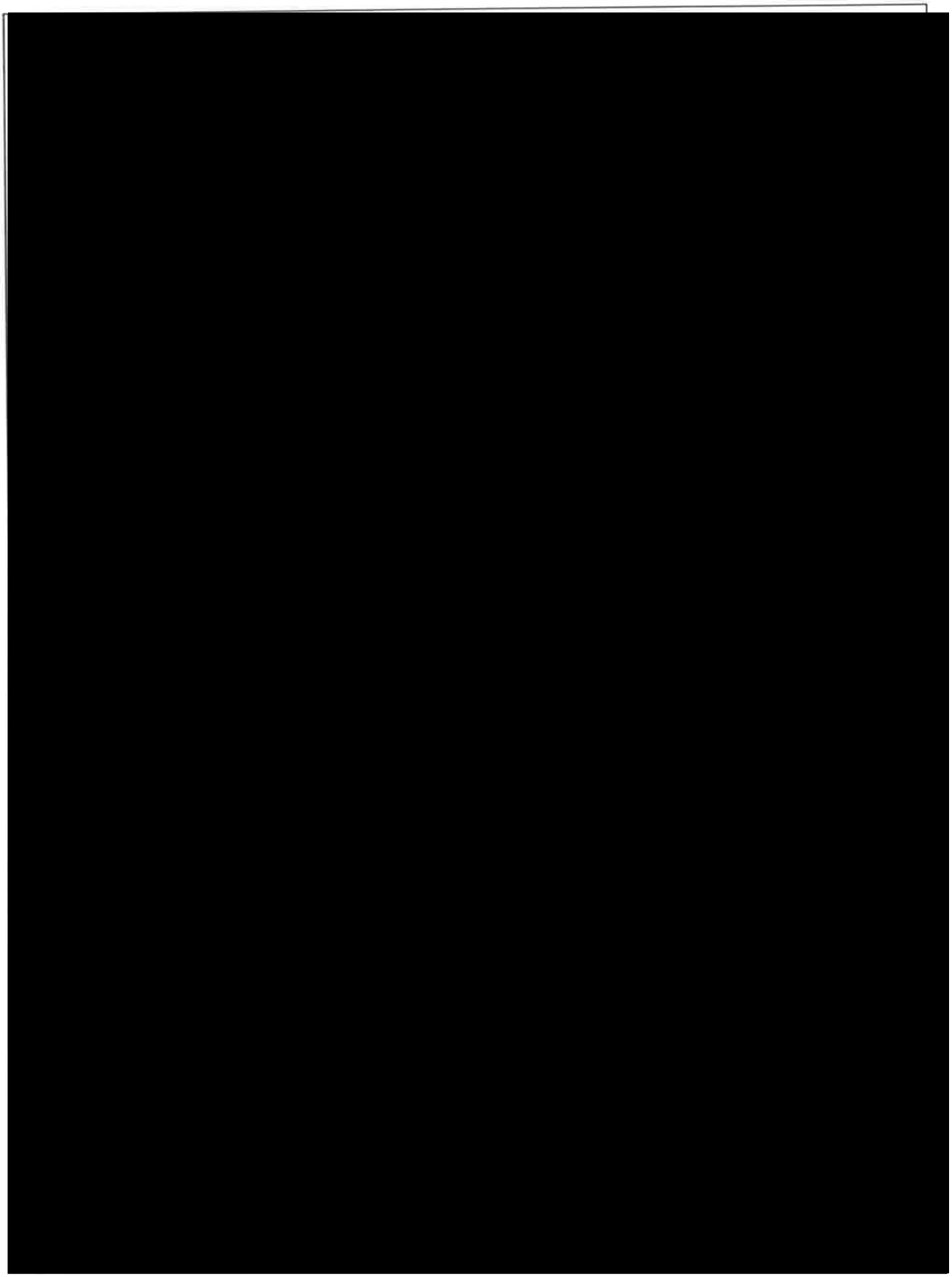
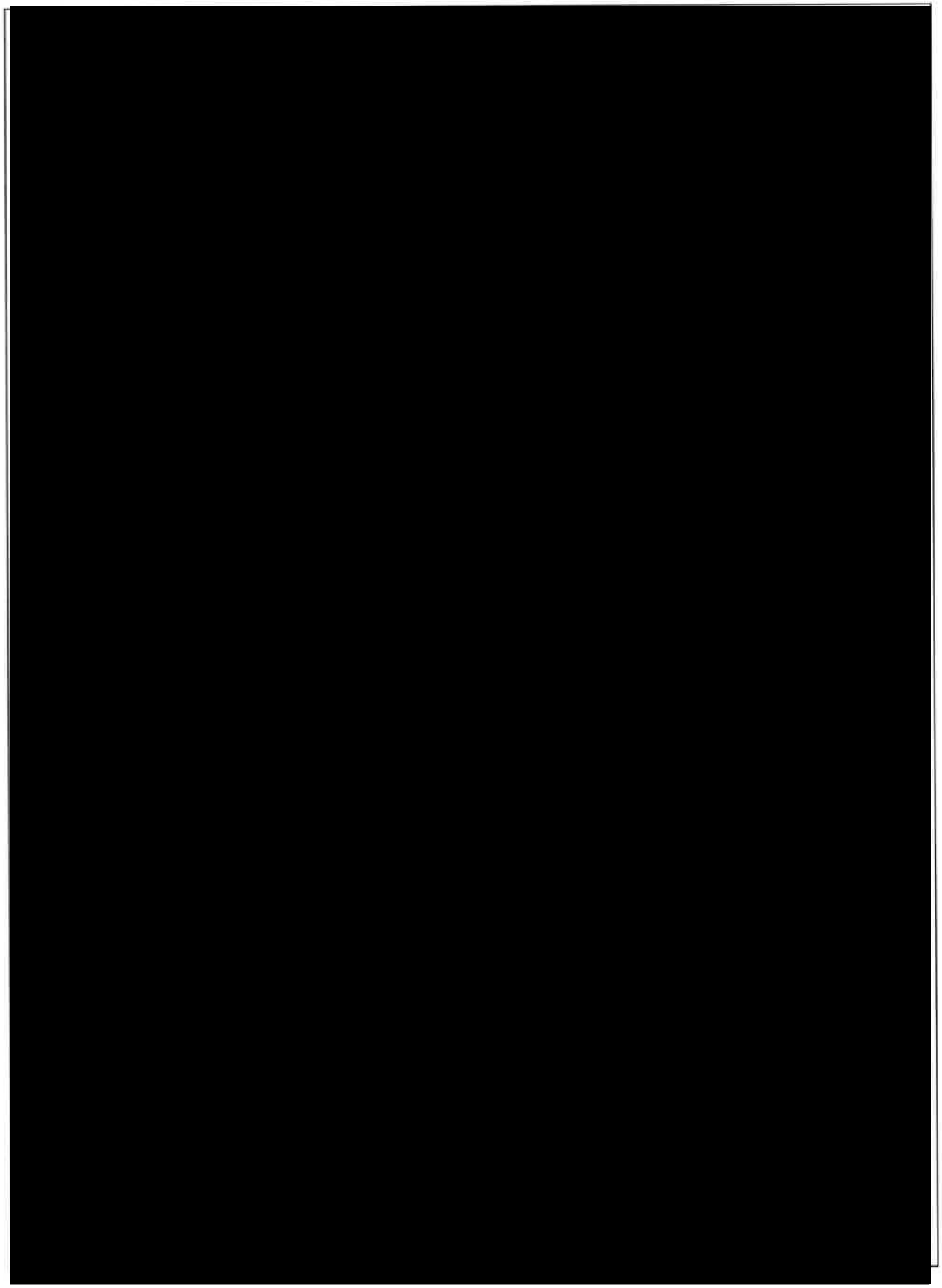


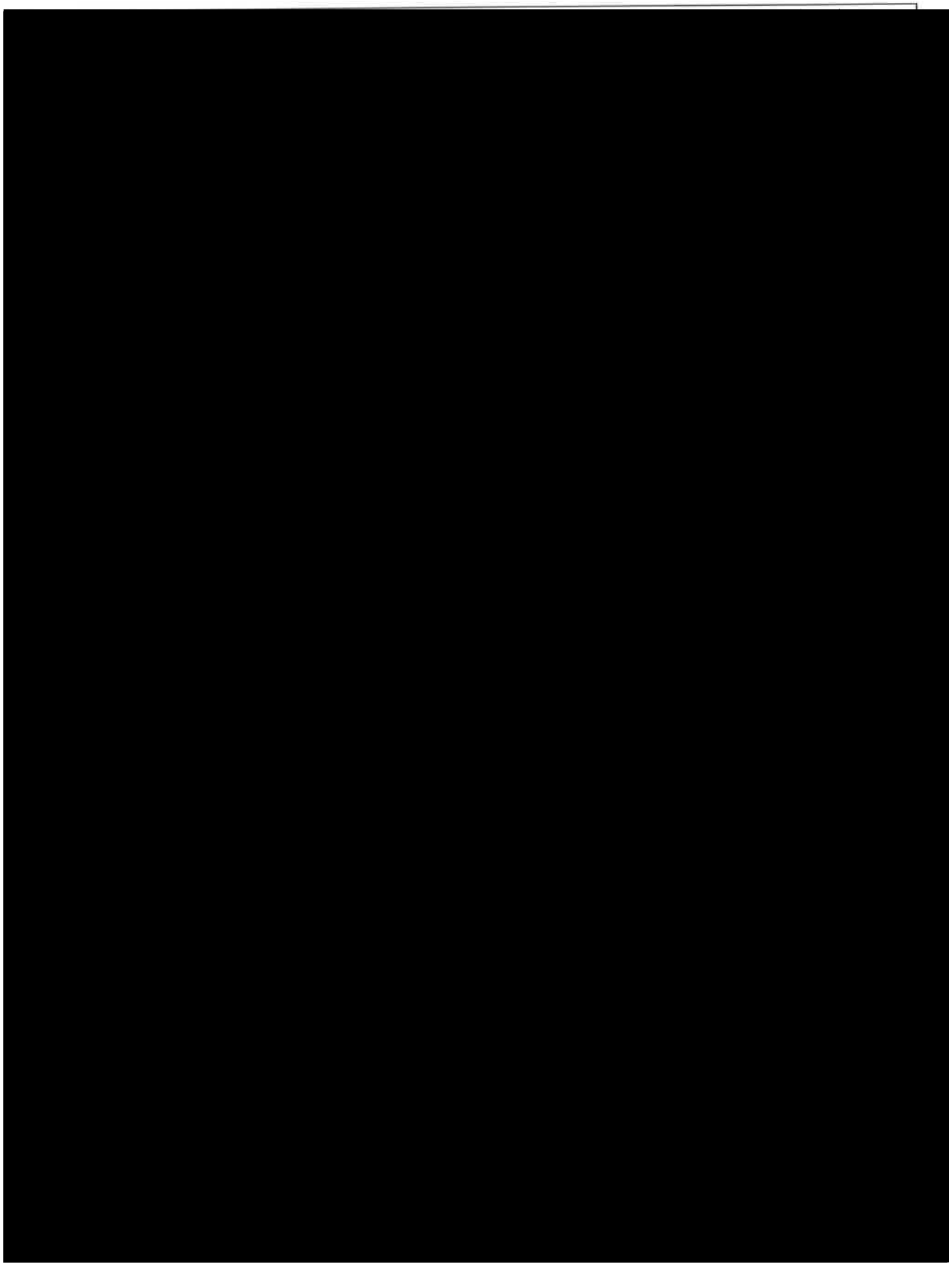


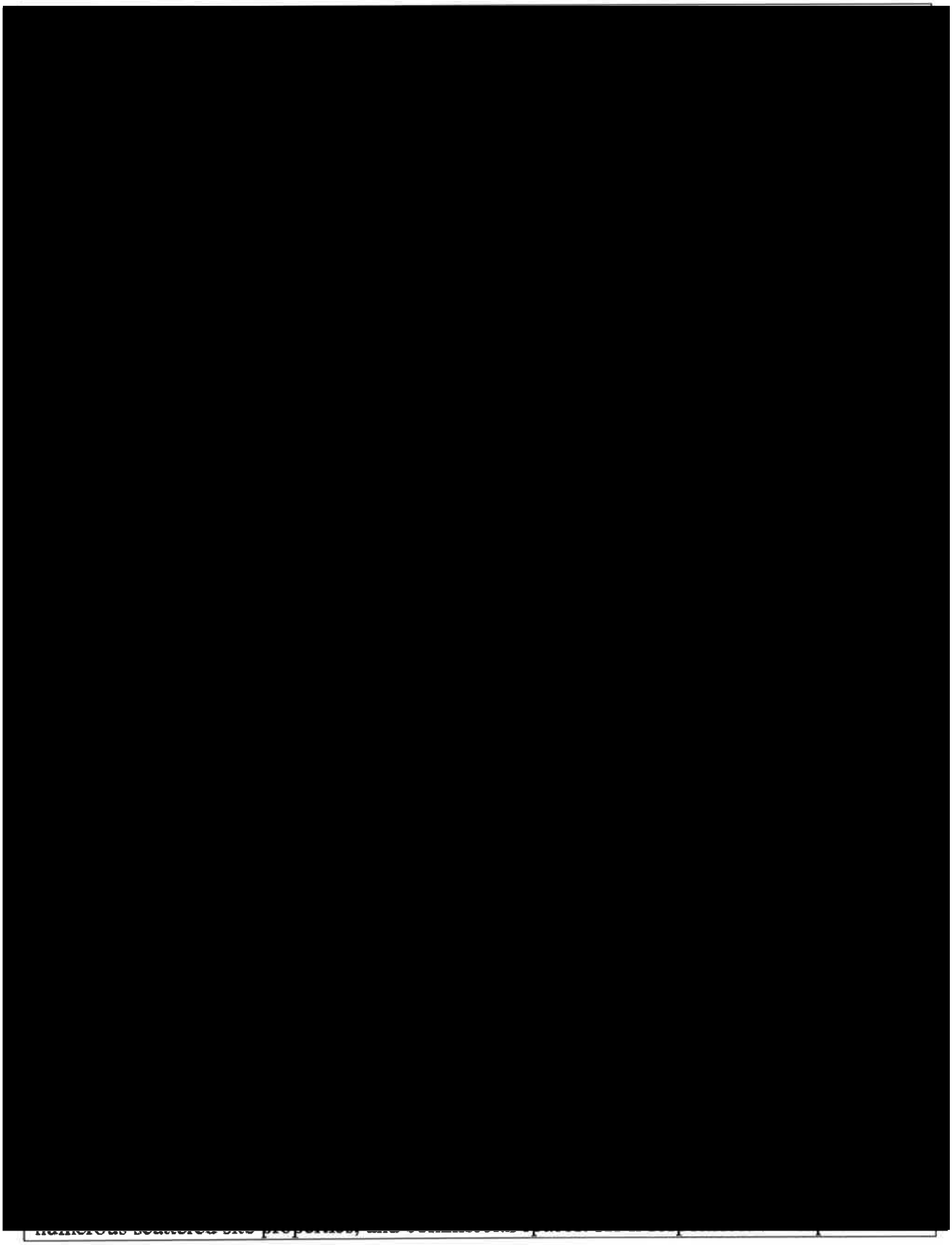


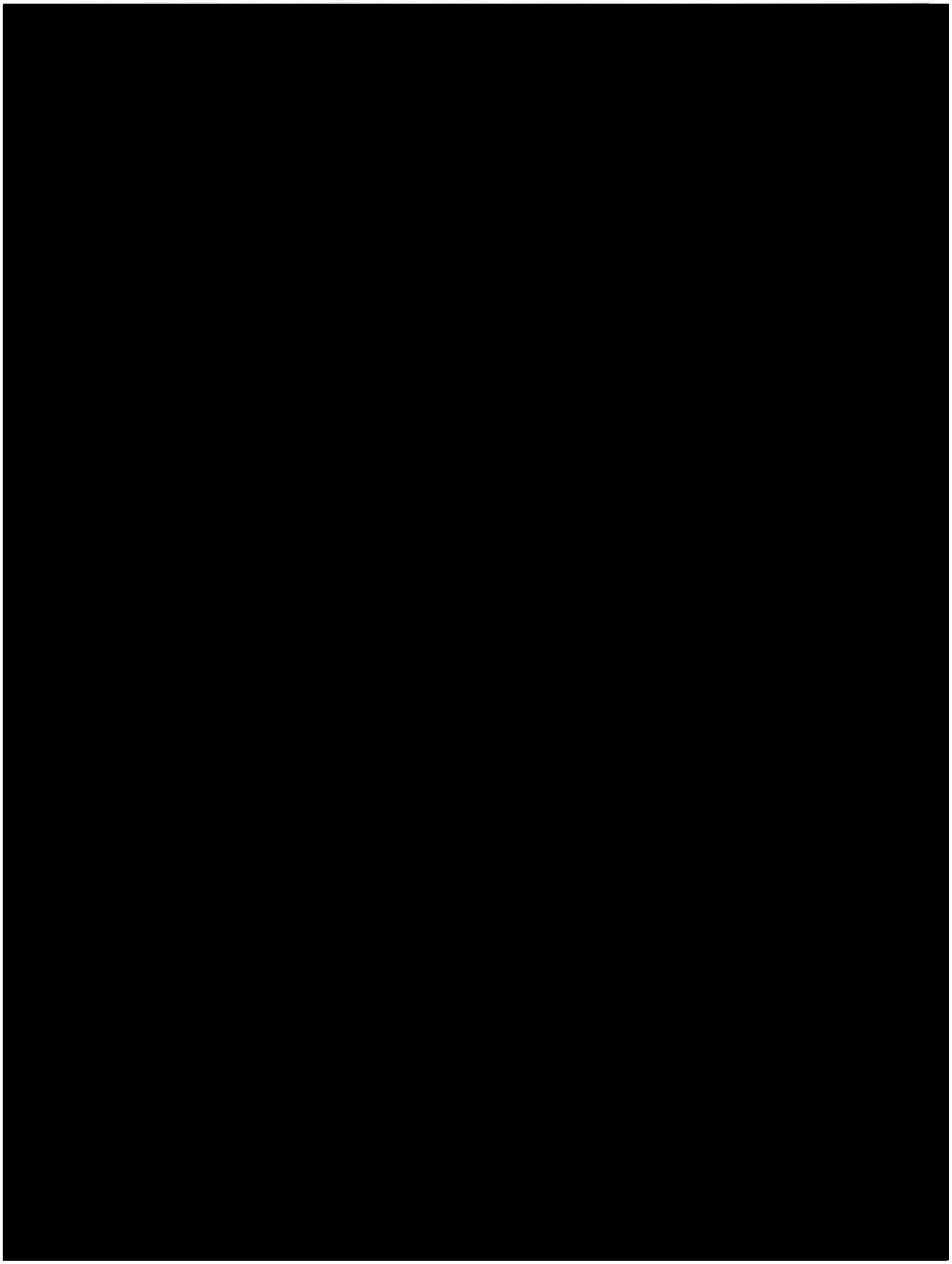


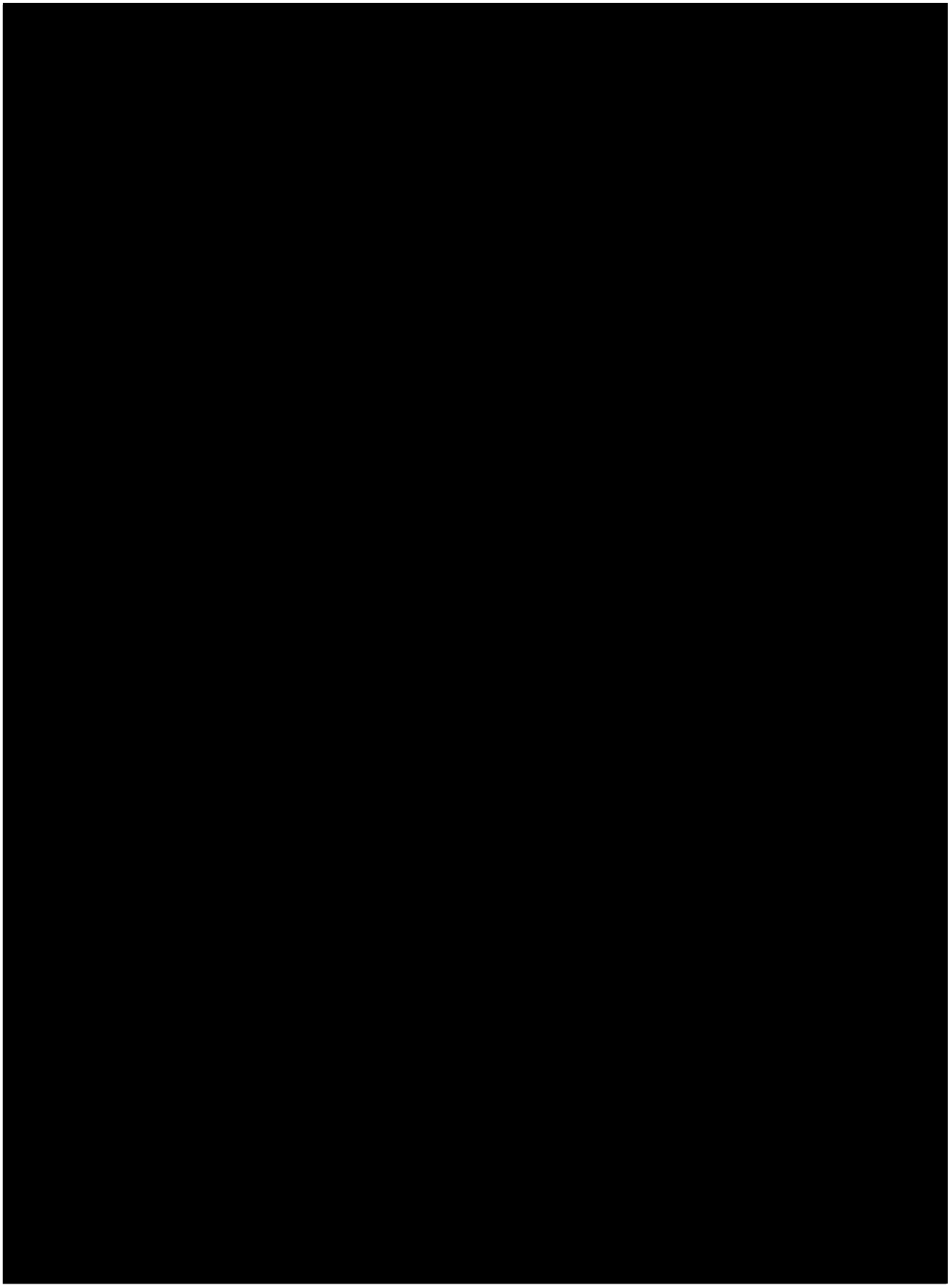




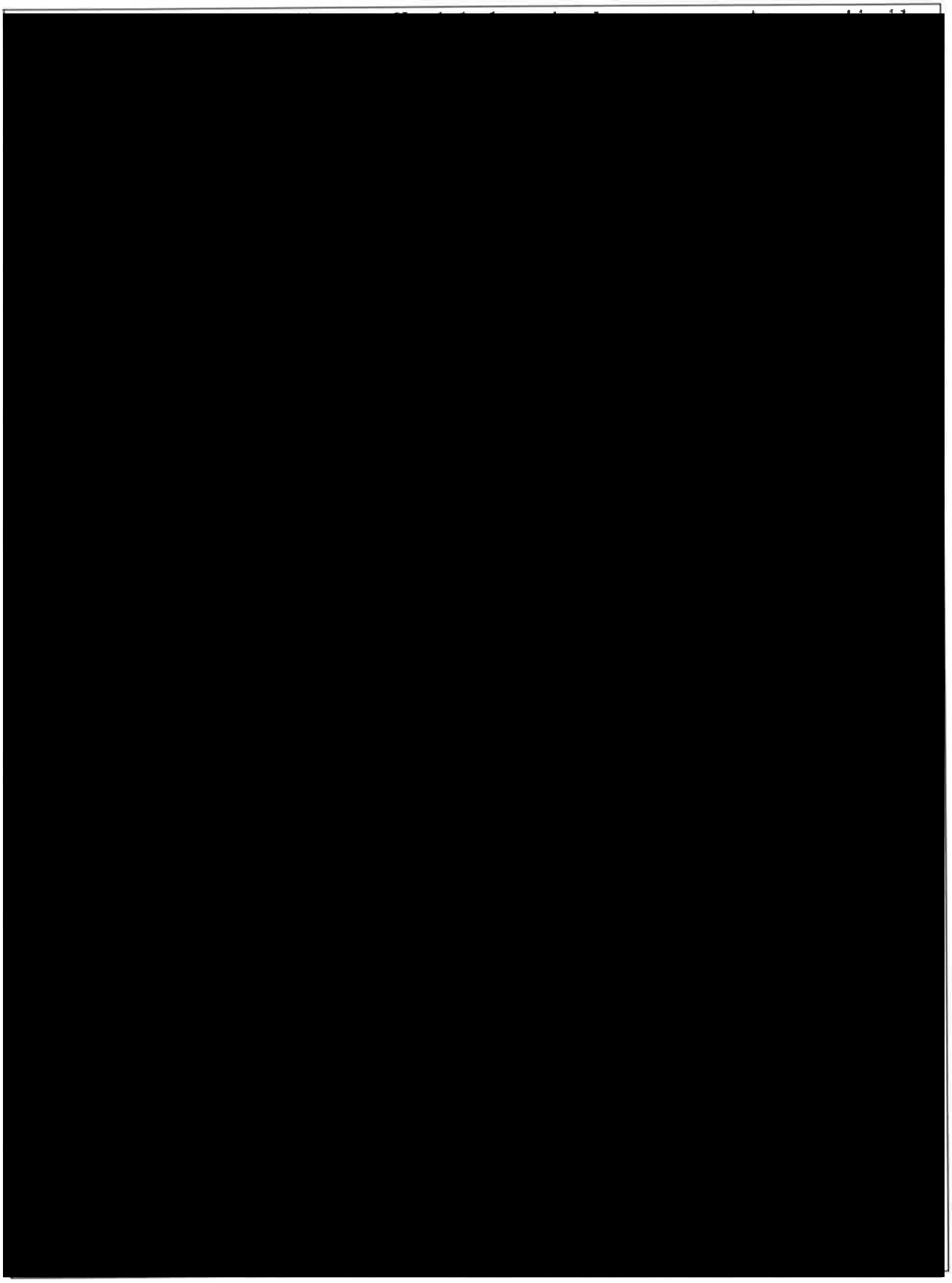








Clinical Director of Product Lineup, Robin Katcoff



[redacted]

b. certify adequate capitalization and attach relevant documentation *

(b) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 20% of the Business and Economic subsection. Maximum length 6 pages.]

See attached documentation.

c. a detailed plan evidencing how the processor will enforce the alcohol and drug free workplace policy. *

(c) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 10% of the Business and Economic subsection. Maximum length 1,575 words.]

The Company will ensure that a detailed plan evidencing how the alcohol and drug free workplace policy will be addressed through the development of standard operating procedure. The Company's Processing Supervisor responsible for regular training the Company's Processor Agents on the drug and alcohol-free workplace policy, as well as enforcement.

All Processor Agents will be trained in the signs of and protocols to follow if they suspect a

co-worker is under the influence, which includes sharing their observations and concerns with their direct supervisors. The standard operating procedure will detail the appropriate response to enforce the alcohol and drug free workplace policy and handle reports of suspected violations of this policy. Every employee will receive training from the Processor Supervisor and/or outside specialists in identifying signs of alcohol or drug abuse.

As detailed in the Company's standard operating procedure, it is the Processing Supervisor's responsibility to:

- Properly train Processor Agents on the alcohol-and-drug-free workplace policy
- Observe Processor Agent performance
- Investigate reports of dangerous practices
- Document negative changes and problems in performance
- Clearly state consequences of policy violations

Drug Screening
Enforcement of the alcohol and drug free workplace policy begins with the applicant screening process. Before hiring a Processor Agent, a drug screen will be performed as required by the Commission as a condition of employment. The Company will contract with a laboratory certified by SAMHSA and the State of Maryland, such as the Laboratory Corporation of America, to perform secure, pre-employment urine screening. The Company will refuse employment to any individual who fails a drug test. The applicant may reapply after one year, must successfully pass a pre-employment drug test, and will be on a probationary period.

A Processor Agent who tries to dilute the specimen, refuses to be screened or tested, or substitutes the specimen with that of another person will be subject to the same consequences of a positive test. A sample that shows signs of substitution or adulteration will be declared positive. A refusal to participate in testing will result in a positive result and be subject to either not being hired or, if currently employed, the same disciplinary action and referrals as a confirmed positive test.

The Processing Supervisor will secure from each Processor Agent hired a signed document stating that that they will adhere to the State's alcohol and drug free workplace policy. The signed document will be kept in the Processor Agent's file. All records will be stored and maintained throughout a Processor Agent's tenure.

The Company will conduct drug and/or alcohol testing under any of the following circumstances:

- Before Employment Start Date: Every potential Processor Agent will be tested for drug use prior to the start of their employment duties and contract. Should a potential Processor Agent's testing result in drug use (without a doctor's prescription and/or explanation), the individual will not be given the position with the Company and/or further review will be conducted.
- Testing Randomly: Processor Agents may be selected at random for testing at any time determined by the Company.

- After-Incident Testing: Any Processor Agent involved with an Company investigation including accidents, may be asked to be tested for alcohol or drug usage in the workplace.
- For-Cause Testing: The Company may ask a Processor Agent to submit to a drug and/or alcohol test at any time the Company believes that the Processor Agent may be under the influence in the workplace.

Processor Agent Training

To further ensure that the detailed plan evidencing how the processing facility will enforce the alcohol and drug free workplace policy, the Company will lead an educational program on the regulations and laws, health risks of alcohol and drug abuse, and the safety and productivity hazards of drug and alcohol use in the workplace for all employees. New Processor Agents will be required to participate in this educational program before being permitted to work, and all Processor Agents will complete a re-training in the program at least once a year. Updates to the educational program will occur at least once per year and as needed. The Processing Supervisor will oversee any changes to the educational awareness training.

The Company's alcohol and drug-free workplace policies will be reviewed with particular attention to the following policies:

- Abusing/using alcohol or drugs while on the premises, committing a controlled dangerous substance offense, or committing an alcohol or drug related driving offense are strictly prohibited during work hours and shall be cause for immediate dismissal.
- Working under the influence of alcohol or a controlled substance is prohibited.
- Any Processor Agent whose abilities are impaired, or is unable to perform his or her duties due to consumption or abuse of alcohol or a controlled substance will not be permitted to work.
- Any Processor Agent convicted of an illegal drug-related offense must notify the Company within five calendar days of the conviction, and
- Violation of the alcohol and drug-free policy will result in appropriate disciplinary action including, but not limited to:

    - Termination
    - Suspension
    - Mandatory or voluntary attendance of drug treatment programs, rehabilitation or Processor Agent assistance programs
    - Notification of the necessary authorities if appropriate
    - Processor Agents will be notified that entering the Company's property constitutes consent to searches and inspections. If an individual is suspected of violating the drug-free workplace policy, he or she may be asked to submit to a search or inspection at any time. Searches can be conducted of pockets and clothing, lockers, desks and workstations.

This policy will apply to anyone representing the Company and/or conducting business with the Company, and therefore will be in effect during normal working hours, on the premises of

the processing, and/or during Company-sponsored events.

Educational Efforts
Written notification of the Company's alcohol and drug free workplace policy will be published in the Processor Agent manual, covering the following points:

- The unlawful manufacture, distribution, dispensing, possession, or use of drugs, and the abuse of drugs or alcohol is prohibited in the Company's workplace.
- Working under the influence of drugs or alcohol is strictly prohibited.
- Processor Agents must notify the Processing Supervisor of any criminal drug or alcohol abuse conviction for an offense occurring in the workplace not later than five days after a conviction.
- Processor Agents must notify the Processing Supervisor of any arrest for an alleged controlled dangerous substance offense on the Processor Agent's next scheduled workday, or within one week, whichever is earlier.
- Specific actions that will be taken against Processor Agents for violation of these regulations include possible termination.
- Referrals to substance abuse treatment resource aggregators such as the National Council on Alcoholism and Drug Dependence of Maryland (NCADD-Maryland) and AMHSA's Substance Abuse Treatment Facility Locator may be made.

In addition, the Company will:

- Communicate information about the health risks of alcohol and drug use through the Company's websites and health and wellness initiatives in the workplace
- Incorporate substance abuse information in workplace wellness strategies, such as learning about good nutrition, exercise, stress reduction methods, and the like
- Ensure that Company wellness programs, Processor Agent Assistance Programs and Work/Life programs provide education, screening and follow-up services for Processor Agents' drug and alcohol problems
- Respect Processor Agents' privacy
- Reserve the right to require a Processor Agent to satisfactorily participate in a bona fide drug or alcohol abuse assistance or rehabilitation program
- Encourage any Processor Agents suffering from substance abuse to seek assistance
- Notify the appropriate authorities of any suspicious activity involving the unlawful use, manufacture, distribution, delivery or possession of illicit drugs or alcohol occurring on the Company's premises

To support Processor Agents, the Company's alcohol-and-drug-free workplace policy will encourage Processor Agents to utilize the services of qualified professionals in the community to assess the seriousness of suspected drug or alcohol problems and identify appropriate sources of help.

Consequences of Violating the Company's Alcohol and Drug-Free Workplace Policy
Following a violation of the alcohol and drug-free workplace policy, standard operating

procedure allow the Processing Supervisor to offer the violating Processor Agent an opportunity for rehabilitation. In such cases, the Processor Agent must sign and abide by the terms set forth in a Return-to-Work Agreement as a condition of continued employment. The Return-to-Work Agreement will include statements that the Processor Agent agrees to such as the following:

- To comply with all Company policies and procedures
- To abstain from the use of alcohol and/or other drugs except when recommended by a physician who has been informed of the Processor Agent's difficulty with substance abuse
- To pay for all costs of treatment and monitoring not covered by the Processor Agent's insurance plan
- To submit to unannounced follow-up drug testing for a period of five years

Any Processor Agent who tests positive for a second time on any drug screen, or who has violated his/her Return-to-Work agreement, will be immediately terminated.

Through the careful drafting, implementation, and enforcement of standard operating procedure, mandatory training, drug testing protocols, and staff support, the Company shall assure that the a detailed plan evidencing how the processing will enforce the alcohol and drug free workplace policy is addressed.

3. Please describe how the Applicant will address the additional factors to:

a. certify Maryland residency among the owners and investors and attach relevant documentation, *

(a) [Reference 10.62.19.04 of the regulations. Graded Yes or No. Weighted 20% of the Additional Factors subsection. Maximum length 1 pages.]

See attached documentation.

b. certify that the Applicant is not in arrears regarding any tax obligation in Maryland and in any other jurisdictions and attach relevant documentation, *

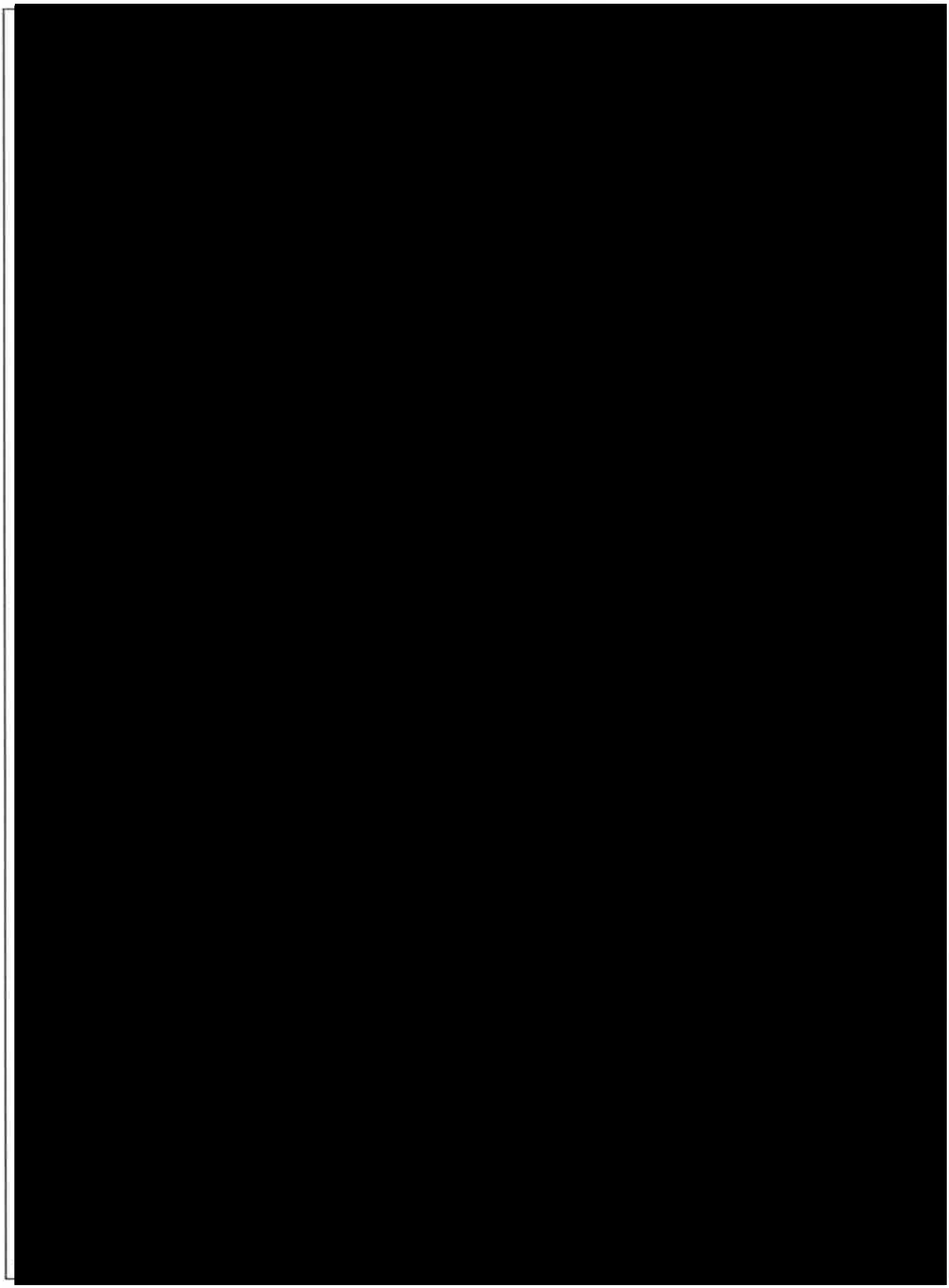
(b) [Reference 10.62.19.04 of the regulations. Graded Yes or No. Weighted 30% of the Additional Factors subsection. Maximum length 1.5 pages.]

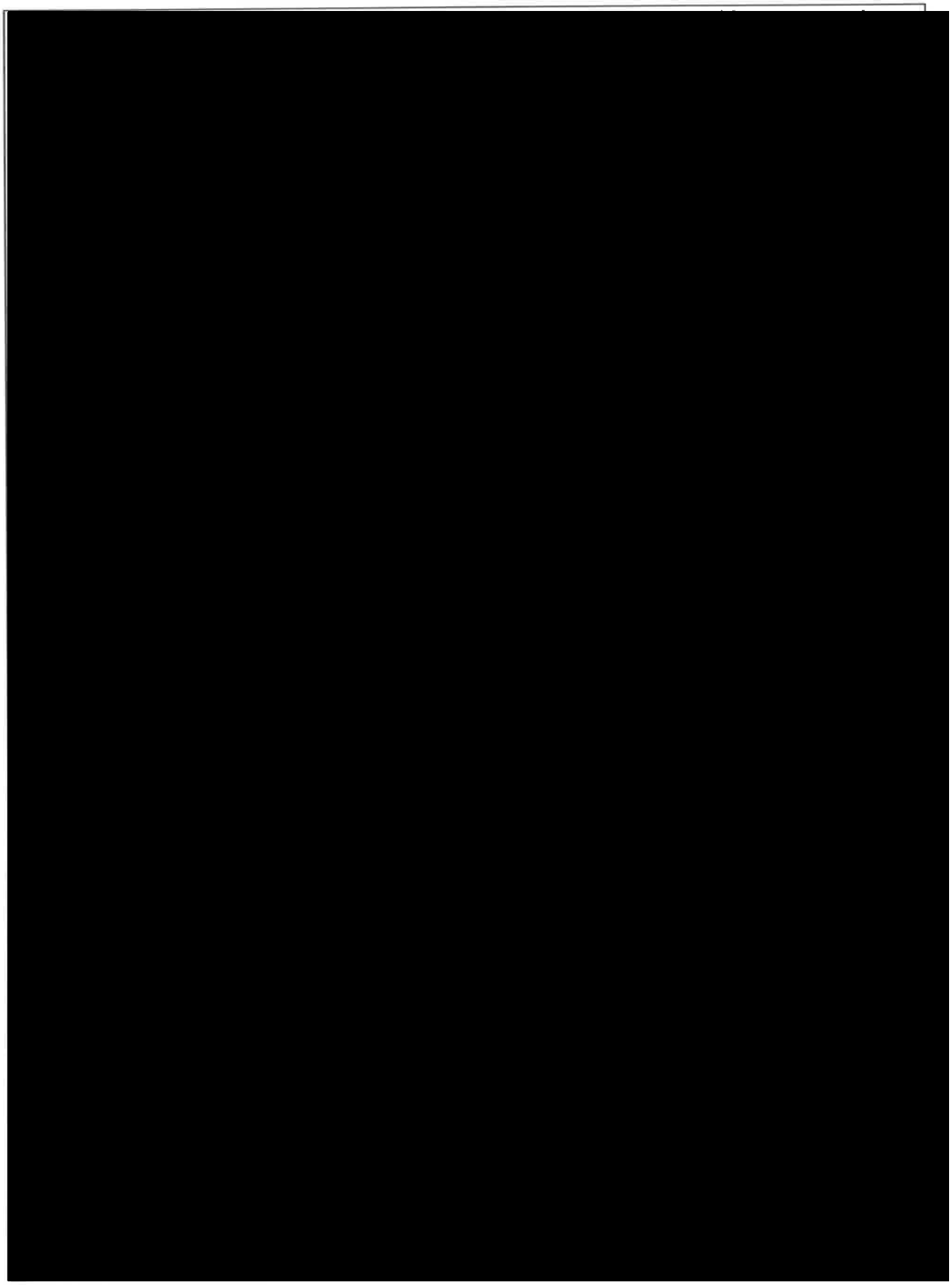
See attached documentation.

c. a list of proposed medical cannabis extracts and medical cannabis-infused products proposed to be produced with proposed cannabinoid profiles, including (i) varieties with high cannabidiol content and (ii) whether the product has any demonstrated success in alleviating symptoms of specific diseases or conditions. *

i) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 49.5% of the Additional Factors subsection. Maximum length 1,125 words.]

ii) [Reference 10.62.19.04 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Additional Factors subsection. Maximum length 115 words.]





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10.62.19.05

4. Please describe how the Applicant will address the stipulation that the Commission may deny issuing a pre-approval of a license if, for any individual identified in the Application specified in COMAR 10.6219.02B(1) and (2) of this chapter, the payment of taxes due in any jurisdiction is in arrears. *

[Reference 10.62.19.05 of the regulations. Graded Yes or No. Weighted 5% of the Business and Economic subsection. Maximum length 780 words.]

[redacted]

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10.62.20.07

5. Please describe how the Applicant will train all Processor Agents on Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the processor agent's responsibilities. *

[Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Business and Economic subsection. Maximum length 780 words.]

The Applicant will establish and implement a training program for all Processor Agents, which will cover Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the processor agent's responsibilities. The Company will require that its dispensary Agents undergo the appropriate training to cover compliance with State laws, and legal culpability, safety, and security regarding Federal laws. In addition, the training will cover compliance with Federal laws pertaining to employment, discrimination, OSHA, and related regulations. This training will be completed before the processor agent can work independently upon initial employment and annually thereafter. Each Processor Agent will complete an exam on the materials presented and completion will be documented. The training materials and attendance records will be retained for five years and made available for inspection.

Each Processor Agent will receive the following training:

Maryland State Specific Compliance Training
Maryland State-Specific Compliance Training is designed to give all Processor Agents a comprehensive foundation of knowledge, ensuring they know the compliance expectations of local and State government and regulatory agencies.

State and Local Laws
Medical cannabis facilities are regulated by both state and local laws. During this training, participants will get to know their local and state medical cannabis laws and how those laws apply to them as medical cannabis facility staff, as well as to the patients they will be serving.

This training provides a broad regulatory overview, necessary to maintain compliance, in all disciplines of the medical cannabis industry. Because compliance may be subject to both State and local oversight, this training discusses the specifics of both local and State regulatory provisions.

In order to remain informed on the latest information regarding medical cannabis on the local, state, and federal levels, the Processor Supervisor will join the Maryland Cannabis Industry

Association, whose mission is to "promote the growth of a responsible and legitimate cannabis industry and to work for a favorable social, economic, and legal environment for that industry to thrive in Maryland."

Occupational Safety and Health Administration (OSHA)
An effective occupational safety and health training program can result in fewer injuries and illnesses, better morale and lower workers' compensation insurance premiums, among other benefits. The Applicant is committed to providing its employees every opportunity to increase their knowledge and better understand their rights and responsibilities as Agents. Onsite OSHA training will be performed at regular intervals. Each new Agent will be ensured to have completed onboarding training before beginning work at the Applicant's premises.

Operational Training
To ensure that each Processor Agent is trained and educated to perform their duties in accordance with current best industry practices, the Applicant will, as part of standard operating procedure, provide training materials to Processor Agents on-site in both hard copy and in electronic form.

These materials will include but are not limited to:

Processing

Based on the AHPA Recommendations to Regulators for Processing Operations, this training is designed to provide attendees the skills necessary to implement good processing practices. This course also explores best practices and safe handling procedures for operations that provide processing of medical cannabis products.

Manufacturing, Labeling and Holding

This training is designed to provide Processor Agents with the tools necessary to comply with General Manufacturing Practices including general personnel responsibility and safety, physical condition of the Applicant's premises and surrounding grounds, manufacturing controls including packaging, holding and labeling controls, cannabis material acquisition, inventory and recordkeeping, fielding and documenting complaint, product returns, product safety recalls, and adverse event reporting.

In service and third-party training will keep employees up to date with the latest medical cannabis and related industry information and advancements. Local advocacy and educational organizations will be engaged to provide employees with skills and education needed to safely and effectively perform their job duties and to keep informed of any substantive changes to this rapidly growing industry.

- Americans for Safe Access
- Students for a Sensible Drug Policy
- Know Your Rights Training through the ACLU of Maryland
- LEAP
- CASA
- Labor Network for Sustainability

In addition to the above listed topics, annual refresher training will include elements of issues, deviation or examples of inconsistencies or irregularities with the above requirements. Focus will be drawn on identifying the problems (what worked and what did not), what the corrective measures were and, where appropriate, what could have been done better and how to prevent a recurrence.

6. Please describe how the Applicant will train all Processor Agents on standard operating procedure. *

[Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 10% of the Business and Economic subsection. Maximum length 1,575 words.]

New hires will undergo a training course designed to transfer all critical knowledge, including standard operating procedure, but also a complete understanding of the responsibilities and risks associated with each job function in the organization. In addition, because the Applicant will hire all processor Agents based on their scientific and technical understanding, product knowledge, process knowledge, and/or risk assessment abilities, the Applicant will include in this training period an opportunity for the new hires to provide input into the standard operating procedure.

Basic knowledge for all processor Agents will include:

- Processor Agents will be trained to understand and follow standard operating procedure for all the methods, equipment, solvents, and gases used when processing medical cannabis concentrates and medical cannabis-infused products. Every SOP will be designed following FDA, GLP, GMP and OSHA guidelines and regulations to warrant the safety of all employees, the appropriate performance of all processes, and the quality of the final products.
- Processor Agents will be trained on procedures to ensure absolute sanitary conditions in areas that have been designated for packaging and handling, including all equipment utensils, and accessories used during the packaging process.
- Processor Agents will receive appropriate training to follow OSHA protocols for the handling and storage of each individual chemical, solvent and/or gas involved in processing medical cannabis concentrates and medical cannabis-infused products.
- Processor Agents will be properly trained to operate, calibrate, troubleshoot and housekeep each piece of equipment required to perform their individual tasks. Equipment placement within the facility will comply with OSHA guidelines and regulations.
- Processor Agents will be encouraged to participate in a whistleblower program in order to prevent substance diversion and sanitary infractions.

The Processor Supervisor will maintain accurate records of each processor agent's training, whether provided by the Applicant or by a third party, and will include any evaluation of in-house training alongside the attendance records. All processor Agents will attend mandatory bi-annual refresher training sessions on the standard operating procedure, in addition to required additional coursework to extend and maintain their skills and knowledge of regulatory compliance issues. Ongoing training will address the policies, processes, procedures, and written instructions related to operational activities, products, the quality

system, and SOPs.

Job specific training requirements will be conducted to ensure each employee is familiar with their role and can demonstrate competency before being allowed to work independently. This will include but not be limited to the following areas:

- Organizational structure, including management, the quality unit and operations
- Where SOPs are located and how to access and use them in the course of their workday.
- How equipment functions
- How to log data
- Sanitation and cleaning procedures
- Personal hygiene requirements
- Waste management practices
- Quality control practices
- Documentation requirements and practices
- Emergency procedures
- GMP principles training on a regular basis
- Skills or Competency training
- SOPs, Test Methods, and Master Batch Records

Every Processor Agent will be trained initially and retrained annually on the facilities Chemical Hygiene Plan and Hazard Communication Plan. This will ensure each licensed Processor Agent knows how to access material Safety Data Sheets, how to interpret their content, how to label and to take precaution when using hazardous materials. Safe handling and storage of hazardous materials will be addressed with each agent.

Training with Management of Equipment and Critical Process Utilities
The Applicant will train its staff to follow the "V Model" principles for qualification of major critical items of equipment or critical process utilities. The V model requires development of user, functional and design specifications, which are used for design qualification. Qualification of equipment, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), shall be documented in pre-approved protocols and reports.

Routine Monitoring, Maintenance, Calibration and Control of Equipment
Processor Agents manufacturing medical cannabis finished products will receive training on critical equipment and process utilities that shall be monitored and controlled during use according to the approved written procedures and schedules for preventive maintenance.

Personal Protective Equipment (PPE)
All Processor Agents will be trained on how to use Personal Protective Equipment to protect workers from chemical exposure.

- Respiratory protection – disposable, cartridge, air-line, half or full face.
- Eye protection – spectacles/goggles, shields, visors.
- Hearing protection – ear muffs and plugs.
- Hand protection – gloves and barrier creams.

- Foot protection – shoes/boots.
- Head protection – helmets, caps, hoods, hats.
- Protection from falls – harness and fall arrest devices.
- Skin protection – hats, sunburn cream, long sleeved clothes.
- Other personal protective equipment – protective clothing for cryogenic work or environments with high temperatures.

Facility Records and Materials

The Applicant will train all Processor Agents on the use of the BioTrackTHC inventory control system for records and materials that are generated by the Processing Facility, and may be specific to one or more studies performed at the facility/site. Such records and materials will be inspected for the reconstruction of a study and for the general assessment of the continuing compliance of a test facility with Principles of GLP. In the case of detecting a potential discrepancy or diversion of any medical cannabis or medical cannabis finished products, all Processor Agents will be trained on how to detect such activity using the perpetual inventory control system. Training will be performed for Processor Agents on procedures for maintaining facility records and all training materials will be retained.

Medical Emergency Training

All Processor Agents, management level staff, and security personnel will be trained in American Red Cross–certified adult and pediatric first aid, cardiopulmonary resuscitation (CPR), and the use of an Automated External Defibrillator (AED), either on-site or off-site. Applicant will sponsor a first aid, CPR and AED class for all employees before opening, and if other Agents are hired, they will be sent for off-site training and required to present a certificate of completion before starting work.

The Applicant will implement training plans to all Processor Agents in case of emergencies, for but not limited to the following procedures:

- Processor Agents to immediately call 911 during a medical emergency for help (if required), and immediately notify Processor Agents for Security through designated communication devices.
- Processor Agents will be trained to take no action that would jeopardize the safety of personnel or visitors.
- Processor Agents will be trained to perform CPR if necessary.
- Processor Agents will be trained to use an AED if necessary.
- Processor Agents will be trained to know where all first-aid kits are located within the Processing Facility.
- Processor Agents will be trained on how to treat minor chemical-related injuries and understand the full inventory of the chemicals used at the Processing Facility
- Processor Agents will be trained to retain as much physical evidence and visual descriptions of the incident involved with the medical emergency for post investigational purposes with law enforcement or medical emergency personnel.
- Processor Agents will be required to perform annual drills on medical emergency response protocols and procedures

Fire Safety Plans and Training

The Applicant will create standard operating procedure and training manuals to train Processor Agents on fire safety. Prior to opening the facility, the Applicant will work with the local fire department and police to discuss fire safety plans associated with the Processing Facility. All Processor Agents will be trained to quickly assess the situation to determine if it is safe to treat the fire by use of a fire extinguisher or is evacuation or partial facility evacuation necessary.

The Applicant will provide training materials to all Processor Supervisors who will be in command in the event of a Fire to make the determination on how to contain and control the fire, whether an evacuation will be necessary, and how to contact and respond to emergency personnel. All Processor Agents will be trained to extinguish the fire while also securing the facility and materials from contamination. Standard operating procedure, retraining of Processor Agents (if necessary), and company policies will be updated accordingly based on the information in the investigation.

In the event a fire is not dealt with locally, the Processor Agents and personnel will be trained to evacuate the premises securing as many critical areas as safely achievable. Emergency services will be called and the Agents and personnel will wait outside the building for the fire department to evaluate the situation and give the all clear to reenter. Both of these events will be reported to management and a thorough investigation will take place to determine how the fire started, what damage occurred, and what remediation measures will be necessary. Standard operating procedure, retraining of Processor Agents (if necessary), and company policies will be updated accordingly based on the information in the investigation.

Chemical Spill Plans and Training

All Processor Agents will be appropriately trained on spill response in the event of a chemical spill inside the Processing Facility. Every agent is responsible for participating in spill response activities.

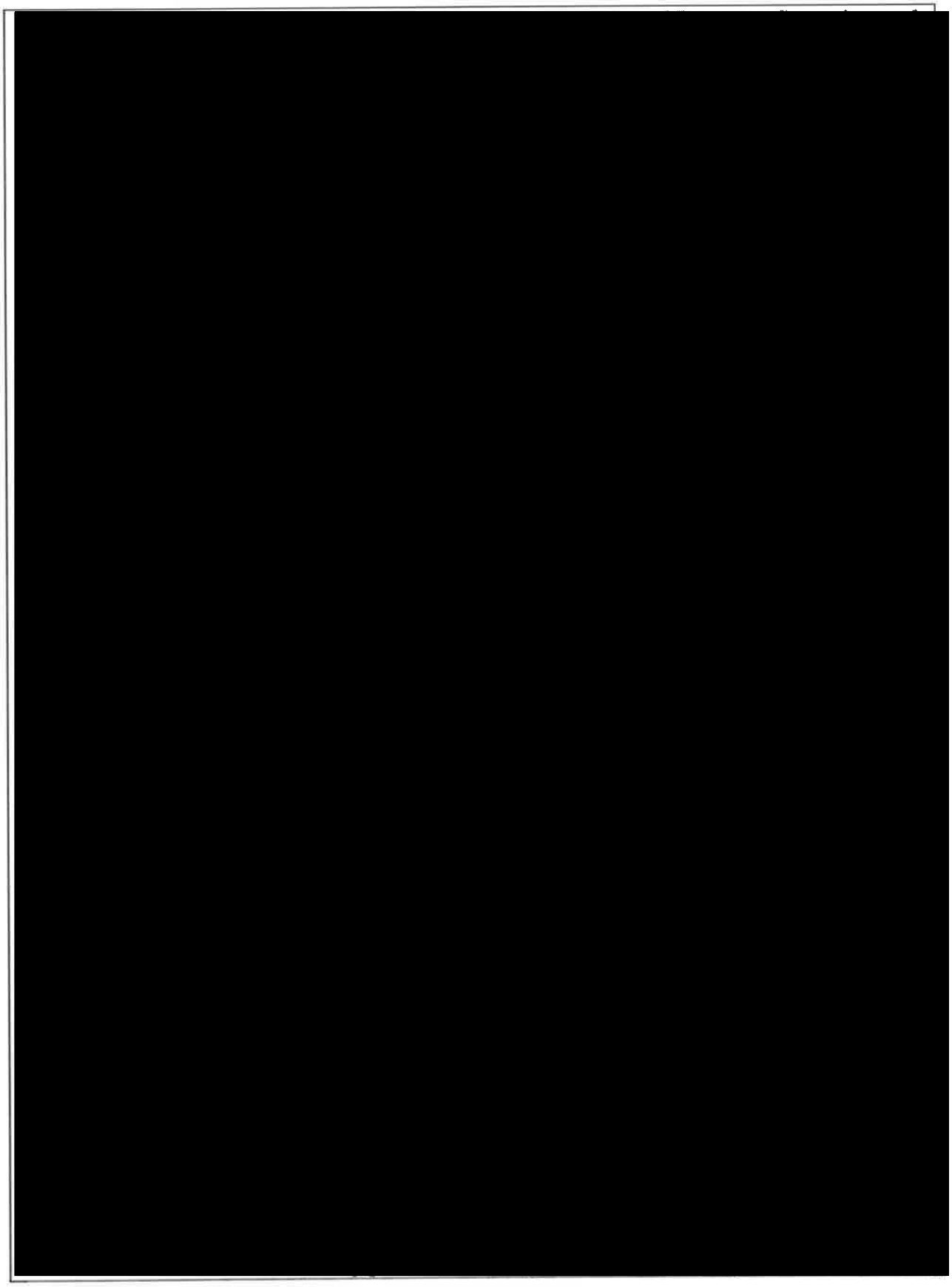
General Spill Cleanup Procedures

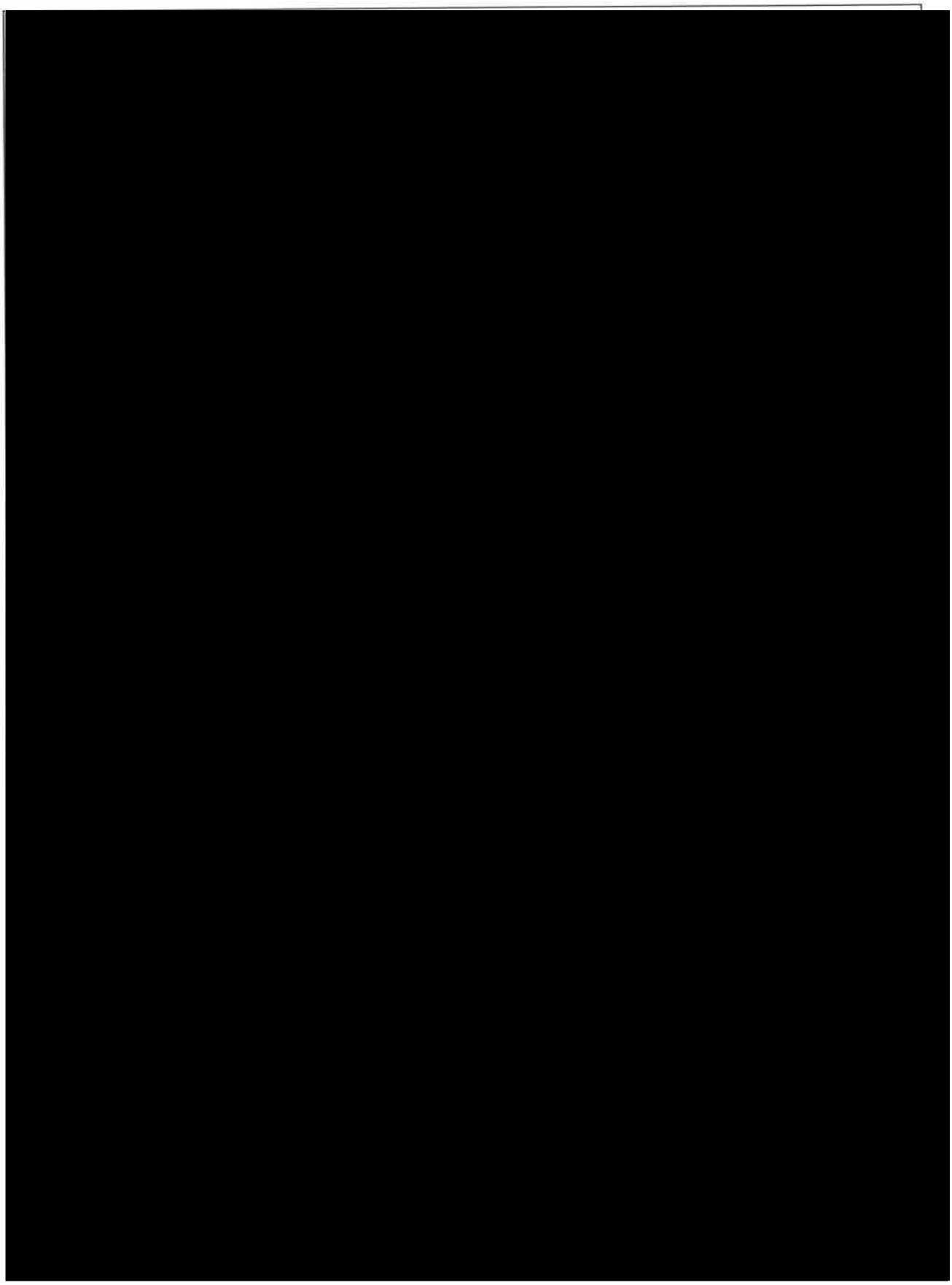
In the event of a chemical spill, Agents will be trained to evacuate the lab and immediately notify the Processing Supervisor. Immediate evacuation of the lab is followed by evaluation by appropriate Agent(s) and the UPD will be notified if there is a possibility of an acute respiratory hazard or if assistance is needed to clean up the spill. If anyone is injured or suffers from contamination, UPD is immediately notified and decontamination measures undertaken.

7. Please describe how the Applicant will train all Processor Agents on detection and prevention of diversion of medical cannabis. *

[Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 17% of the Safety and Security subsection. Maximum length 1,530 words.]

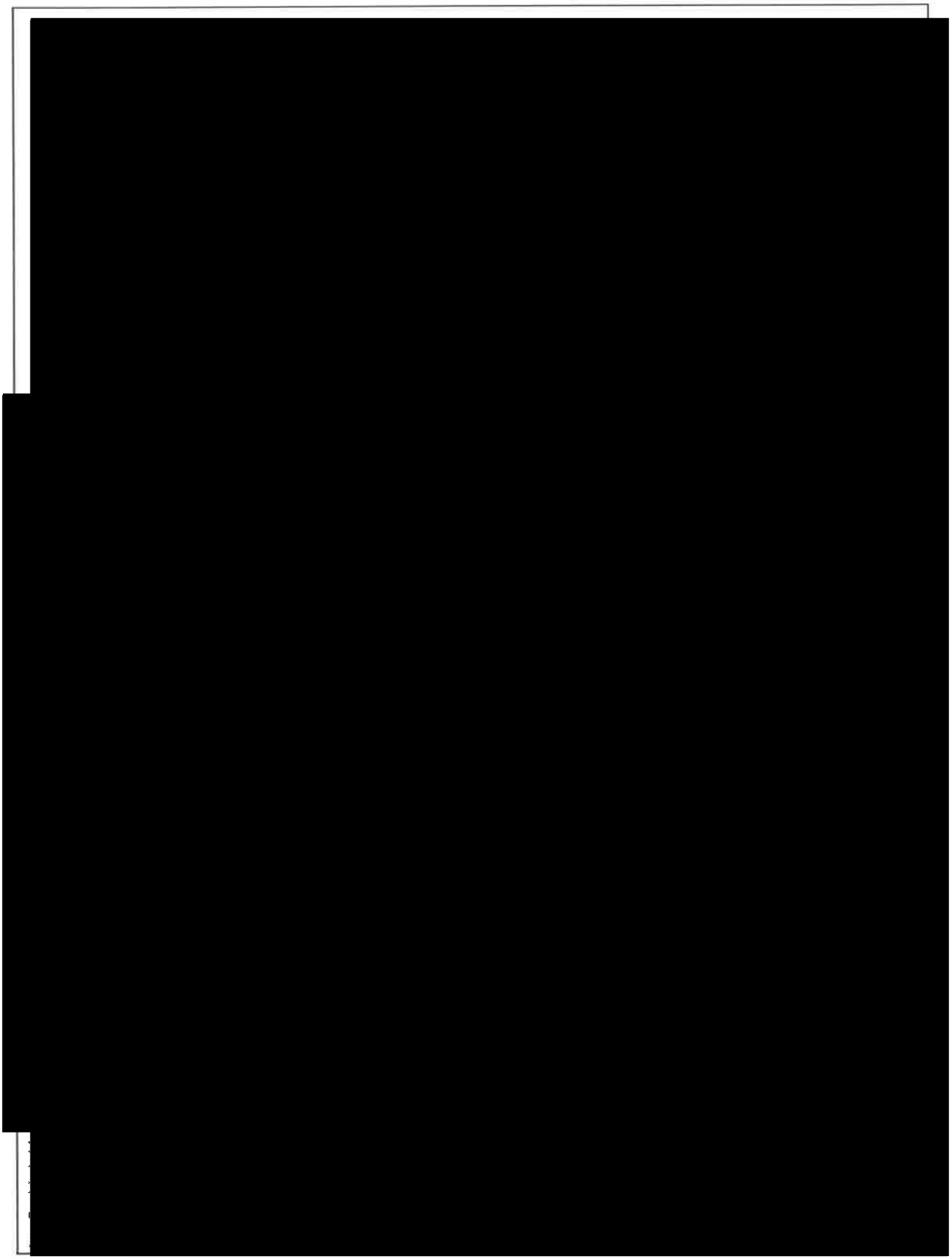
[redacted]

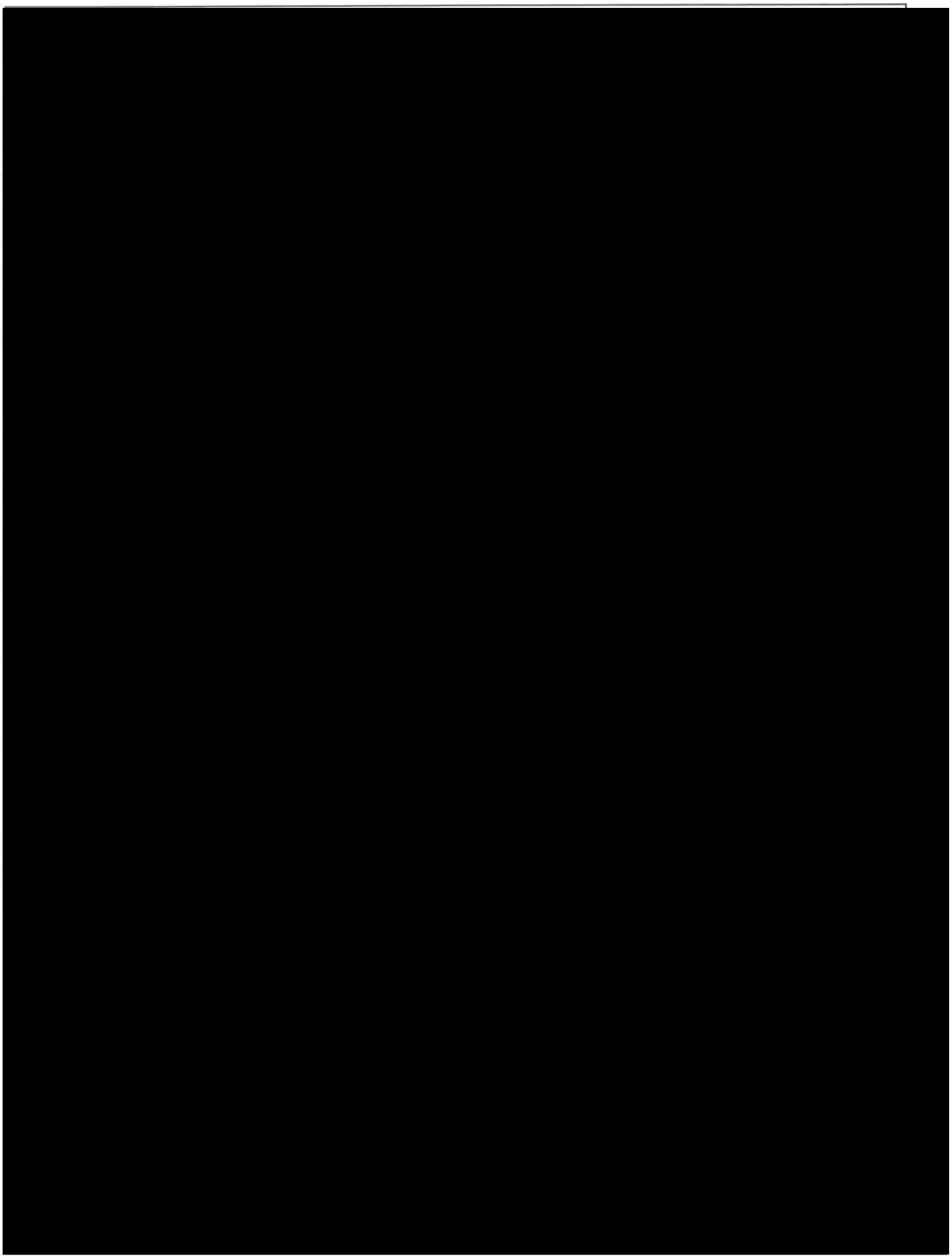


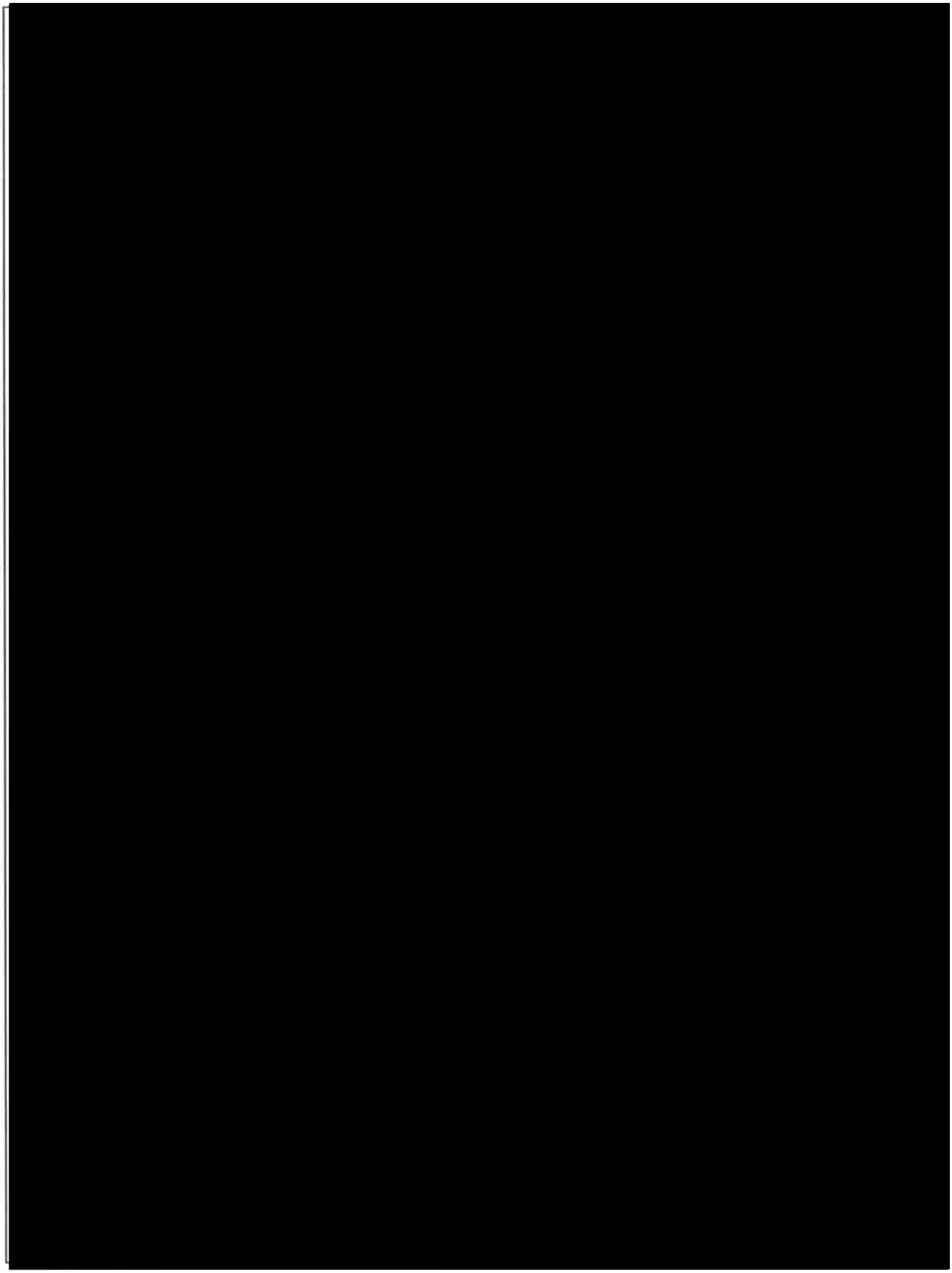


8. Please describe how the Applicant will train all Processor Agents on security procedures. *

[Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 17% of the Safety and Security subsection. Maximum length 1,530 words.]







9. Please describe how the Applicant will train all Processor Agents on safety procedures, including responding to (1) a medical emergency, (2) a fire, (3) a chemical spill, and (4) a threatening event including an armed robbery, an invasion, a burglary, or any other criminal incident. *

(1) [Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Safety and Security. Maximum length 450 words.]
(2) [Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Safety and Security subsection. Maximum length 450 words.]
(3) [Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Safety and Security subsection. Maximum length 450 words.]
(4) [Reference 10.62.20.07 of the regulations. Graded 0 to 5 scoring. Weighted 10% of the Safety and Security subsection. Maximum length 900 words.]

1. Medical Emergency Training

All Processor Agents, management level staff, and security personnel will be trained in American Red Cross–certified adult and pediatric first aid, cardiopulmonary resuscitation (CPR), and using an Automated External Defibrillator (AED), either on-site or off-site, sponsored by the Applicant. Applicant will sponsor a first aid, CPR and AED class for all employees before opening, and if other Agents are hired, they will be sent for off-site training and required to present a certificate of completion before starting work.

All personnel will be trained by the Processor Agent for Security to use the first-aid kits and automatic electronic defibrillators on site, the locations of kits and devices, and the protocol to be followed regarding notifying security, management, and local emergency response authorities of a medical emergency on site. First-aid and medical emergency information will be printed in a prominent place in the employee manual. After tending to the injured, emphasis will be on maintaining security during a medical emergency.

The Applicant will create training plans to prepare all Processor Agents for dealing with medical emergencies. This will include but not limited to the following procedures:

- During a serious medical emergency, Processor Agents are to immediately call 911 and

immediately notify Processor Agents for Security through designated communication devices.

- Processor Agents will be trained to take no action that would jeopardize the safety of personnel or visitors.
- Processor Agents will be trained to perform CPR if necessary.
- Processor Agents will be trained to use an AED if necessary.
- Processor Agents will be trained to know where all first-aid kits are located within the Processing Facility.
- Processor Agents will be trained on how to treat minor chemical-related injuries and understand the full inventory of the chemicals used at the Processing Facility
- Processor Agents will be trained to retain as much physical evidence and visual descriptions of the incident involved with the medical emergency for post investigational purposes with law enforcement or medical emergency personnel.
- Processor Agents will be required to perform annual drills on medical emergency response protocols and procedures

2. Fire Safety Plans and Training

The Applicant will create standard operating procedure and fire safety training manuals for Processor Agents. Prior to opening the facility, the Applicant will work with the local fire department and police to discuss fire safety plans associated with the Processing Facility. The Applicant will present the building construction plans, emergency response plans, and proposed containment procedures. The Applicant understands that due to the nature of the Processing Facility, it is critical the local fire department fully understands where to use water to contain fires due to potential chemical fire reactions.

In the event of a fire at the Processing Facility, all Processor Agents will be trained to quickly assess the situation to determine if it is safe to treat the fire with a fire extinguisher or is evacuation or partial facility evacuation necessary. The Applicant will provide training materials to all Processor Supervisors who will be in command in the event of a fire to make the necessary determinations, whether an evacuation will be necessary, and how to contact and respond to emergency personnel.

Locally Treated Fire Training Procedures

In the event the fire that can be treated locally, all Processor Agents will be trained to extinguish the fire while also securing the facility and materials from contamination. Once the fire has been extinguished, equipment, the facility and in-process materials will need to be evaluated for smoke damage or other contaminations. A reconciliation strategy and plan will be implemented to investigate when and how the fire started and how much damage was created from the fire. Standard operating procedure, retraining of Processor Agents (if necessary), and company policies will be updated accordingly based on the information in the investigation.

Fire Emergency Services Training Procedures

In the event a fire is not treated locally, the Processor Agents will evacuate the premises securing as many critical areas as safely achievable. Emergency services will be called and the Agents will wait outside the building for the fire department to evaluate the situation and give

the all clear to reenter. Both of these events will be reported to management and a thorough investigation will take place to determine how the fire started, what damage occurred, and what remediation measures will be necessary. Standard operating procedure, retraining of Processor Agents (if necessary), and company policies will be updated accordingly based on the outcome of the investigation.

3. Chemical Spill Plans and Training
All Processor Agents and personnel will be appropriately trained on spill response in the event of a chemical spill inside the Processing Facility. Every Agent is responsible for participating in spill response activities. A fully stocked spill kit will be maintained in the Processing Facility. Areas with high spill risk will be stocked with a mobile spill kit for immediate mitigation.

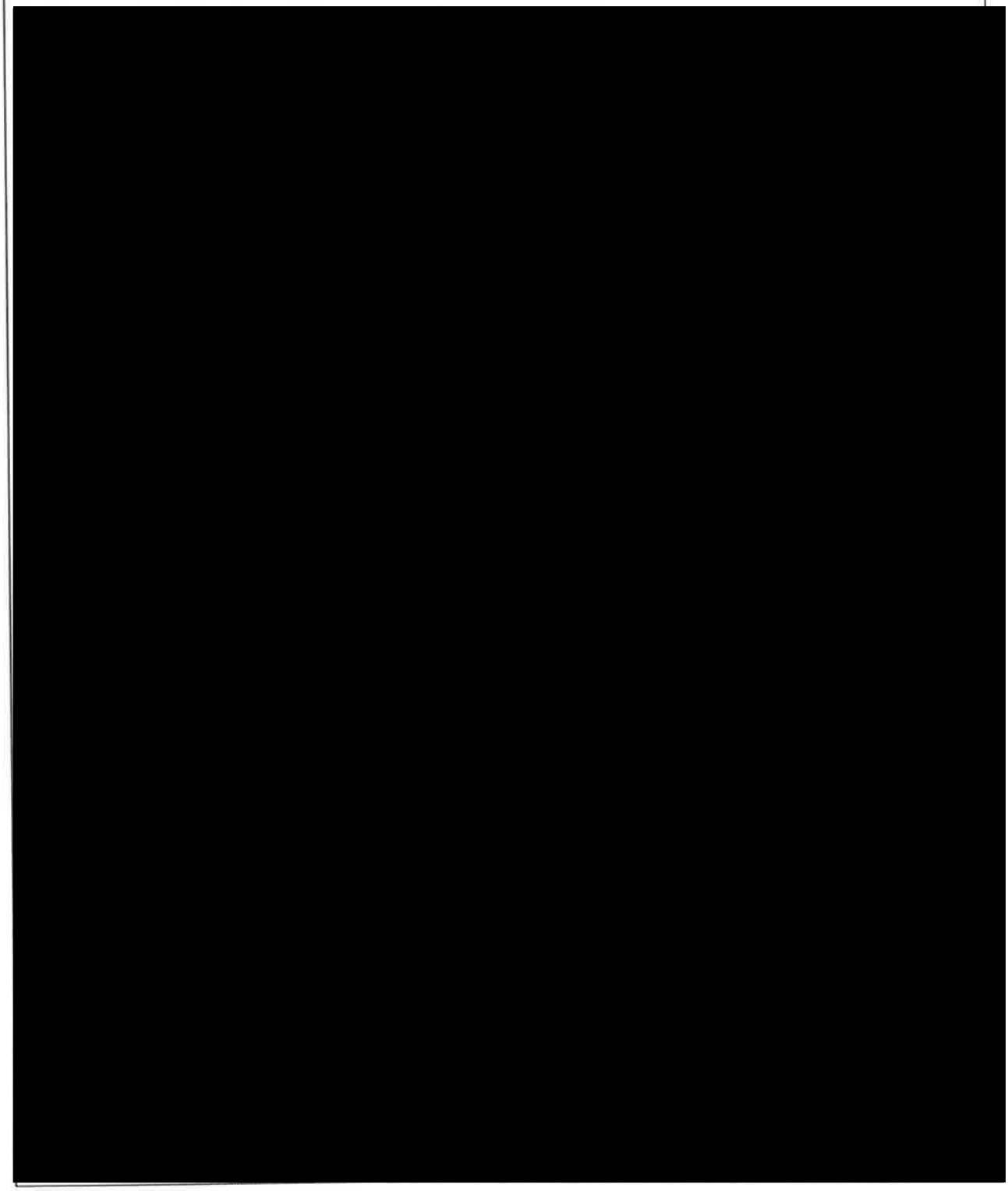
Ethanol
The Applicant will be using Ethanol in its botanical extraction procedures. Ethanol will be utilized for many purposes as a solvent used for botanical extraction. In the event of an ethanol spill, all employees in the immediate area will be notified of the spill. One or more Agents will clean it up with absorbent material and move the liquid to the center of the spill. Processor Agents will ensure there is no ignition source to ignite the vapor. Saturated rags or towels will be collected in a plastic bag and contained. Once the spill has been dried, the area is wiped down with water or other water based cleaner. Ethanol-soaked absorbent materials must be allowed to evaporate in a well-ventilated area before being disposed of in accordance with the standard operating procedure.

General Spill Cleanup Procedures
In the event of a chemical spill, Processor Agents will be trained, knowledgeable and equipped to handle the incident. Processor Agents will be trained to never proceed to clean up a spill if the hazards associated with the chemical are unknown or if they are unsure of how to clean up the spill. If anyone is injured or contaminated, Processor Agents will immediately notify UPD and begin decontamination measures or first aid, if trained. All tools used in the clean-up will be decontaminated (plastic scoop, tongs, etc.). All gross contamination will be removed with a wet paper towel and the contaminated paper towels will be disposed of as hazardous waste. Tools will be rinsed off with copious amounts of water. All gloves used will be disposed of as hazardous waste. Tools will be dried off and place back into the spill kit along with the splash goggles.

Personal Protective Equipment (PPE)
To avoid chemical exposure in the laboratory, Processor Agents will be trained to operate and be responsible for:

- Respiratory protection – disposable, cartridge, air-line, half or full face.
- Eye protection – spectacles/goggles, shields, visors.
- Hearing protection – headphones and plugs.
- Hand protection – gloves and barrier creams.
- Foot protection – shoes/boots.
- Head protection – helmets, caps, hoods, hats.

- Protection from falls – harness and fall arrest devices.
- Skin protection – hats, sunburn cream, long sleeved clothes.
- Other personal protective equipment – protective clothing for cryogenic work or environments with high temperatures.



[redacted]

10. Please describe how the Applicant will retain training materials and attendance records and make the training materials available for inspection by the Commission. *

[Reference 10.62.20.07 of the regulations. Graded Yes or No. Weighted 5% of the Business and Economic subsection. Maximum length 780 words.]

The Applicant will retain training materials and attendance records and make the training materials available for the inspection by the Commission by either providing tamper-evident hard copies from a secure and segregated room, or tamper-evident and secure, searchable digital copies.

Each training session provided by the Company will include copies of all materials and a list of trainers and attendees. Each attendant's employment file will mirror this information. Both sets of files will document the purpose and content of the session or examination, the time, date, and any notes or scores. These records will be reviewed by the Processor Supervisor within a week of the training session.

For any training provided by a third-party organization or consultant, the Processor Supervisor will take steps to ensure that comparable records can be produced. The Processor Supervisor will be informed in advance of all such trainings, and will arrange to receive attendance from the trainer. Prior to the training session, the Processor Supervisor will request that the trainer provide a copy of the materials for inspection by the Commission.

Training records will include all records of all Processor Agents, the level of training attained, the classes attended, and the training materials for each training course. If a certificate, or continuing education credits are achieved, all such records will be included and submitted to the Commission. A Processing Supervisor will gather all records to be submitted and will be responsible for submitting records in either format to the Commission for further review, inspection, or analysis. Training and attendance will be documented and retained for 5 years for the Commission's review following electronic data storage standard operating procedure.

10.62.21.03

11. Please describe how the Applicant will construct the premises to prevent unauthorized entry. *

[Reference 10.62.21.03 of the regulations. Graded 0 to 5 scoring. Weighted 3% of the Safety and Security

[redacted]

10.62.21.04

12. Please describe how the Applicant will design and install lighting fixtures to ensure proper surveillance. *

[Reference 10.62.21.04 of the regulations. Graded 0 to 5 scoring. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

[redacted]

10.62.21.05

13. Please describe how the Applicant will maintain a security alarm system that covers all perimeter entry points and windows at the premises. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 3.5% of the Safety and Security subsection. Maximum length 315 words.]

[redacted]

14. Please describe how the Applicant will assure that the security alarm system is continuously monitored. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

[redacted]

15. Please describe how the Applicant will assure that the security alarm system is capable of detecting smoke and fire. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

16. Please describe how the Applicant will assure that the security alarm system is capable of detecting power loss. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

17. Please describe how the security alarm system will include panic alarm devices mounted at convenient, readily-accessible locations through the licensed premises. *

[Reference 10.62.21.05 of the regulations. Graded 0 to 5 scoring. Weighted 3.5% of the Safety and Security subsection. Maximum length 315 words.]

The Applicant has engaged a qualified local security company to install panic alarm devices mounted at convenient, readily accessible locations throughout the licensed premises. The locations of these devices will be informed by the security company's best practices, as well as the Applicant's medical cannabis industry advisors, who will advise on where the main areas of risk are. The alarms will be discreetly camouflaged to enable use without detection in all areas of the public zone, including:

- Administration Office Rooms
- Reception desk
- Personnel lunchrooms
- Female and Male locker Rooms
- Security Office
- Delivery/Receiving Area Room

Panic alarm devices will also be installed in Processing and Manufacturing Rooms such as:

- Lead Processor Agents offices

- Chemical Extractions Laboratory
- Packaging and Labeling Room
- Secure Room
- Delivery/Receiving Area Room

Each location will be identified to all Processor Agents during initial training, and reiterated at six-month safety and security training reviews. The Secure Room will have a panic button inside the safe for the medical cannabis finished products inventory. The Processor Agent for Security, in coordination with the third-party local security Applicant, will perform periodic maintenance and procedures to ensure each panic alarm device functions correctly. On-hand replacement parts will be stored to ensure any prompt problem resolution, and equipment replacement will be performed to reduce recurring issues to ensure the safety of all Processor Agents and Processing Facility.

18. Please describe how a second, independent alarm system will be used to protect the location where records are stored on-site. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security

[redacted]

19. Please describe how a second, independent alarm system will be used to protect the location where records are stored off-site. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

20. Please describe how a second, independent alarm system will be used to protect any room that holds medical cannabis. *

[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

21. Please describe how the security alarm system will remain operational until the premises of the Licensee no longer have any medical cannabis on the premises. *
[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

22. Please describe how all security alarm systems will be equipped with auxiliary power sufficient to maintain operation for at least 48 hours. *
[Reference 10.62.21.05 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

10.62.21.06

23. Please describe how the Applicant will maintain a motion activated video surveillance recording system at all premises that records all activity in images of high quality and high resolution capable of clearly revealing facial detail. *
[Reference 10.62.21.06 of the regulations. Graded 0 to 5 scoring. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

[redacted]

24. Please describe how the Applicant will maintain a motion activated video surveillance recording system at all premises that operates 24-hours a day, 365 days a year without interruption. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

25. Please describe how the Applicant will maintain a motion activated video surveillance recording system at all premises that provides a date and time stamp for every recorded frame. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

26. Please describe how the Applicant will post appropriate notices advising visitors of the video surveillance. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

27. Please describe how the Applicant will assure that a surveillance camera shall be located and operated to capture activity at each exit from the premises.*

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

28. Please describe how the Applicant will assure that a surveillance camera shall capture activity at each entrance to an area where medical cannabis is processed, tested, packaged, and stored. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

29. Please describe how a recording of all images captured by each surveillance camera will be kept at the licensed premises. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 0.5% of the Safety and Security subsection. Maximum length 70 words.]

[redacted]

30. Please describe how a recording of all images captured by each surveillance camera will be kept at an off-site location. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 0.5% of the Safety and Security subsection. Maximum length 70 words.]

[redacted]

31. Please describe how recordings of security video surveillance will be accessed-limited. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1.5% of the Safety and Security subsection. Maximum length 135 words.]

[redacted]

32. Please describe how recordings of security video surveillance will be secured by a security alarm system that is independent of the main premises security alarm system. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security

[redacted]

33. Please describe how recordings of security video surveillance will be in a format that can be easily accessed for investigational purposes. *

[Reference 10.62.21.06 of the regulations. Graded 0 to 5 scoring. Weighted 1% of the Safety and Security

[redacted]

34. Please describe how recordings of security video surveillance will be retained for a minimum of 30 calendar days. *

[Reference 10.62.21.06 of the regulations. Graded Yes or No. Weighted 0.5% of the Safety and Security subsection. Maximum length 70 words.]

[redacted]

10.62.21.07

35. Please describe how, when a visitor is admitted to a non-public area of the premises of a Licensee, a registered processor agent will log the visitor in and out. *

[Reference 10.62.21.07 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

36. Please describe how, when a visitor is admitted to a non-public area of the premises of a Licensee, a registered processor agent will retain with the log a photocopy of the visitor' s government issued identification. *

[Reference 10.62.21.07 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security subsection. Maximum length 90 words.]

[redacted]

37. Please describe how, when a visitor is admitted to a non-public area of the premises of a Licensee, a registered processor agent will continuously visually supervise the visitor while on the premises. *

[Reference 10.62.21.07 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Safety and Security subsection. Maximum length 180 words.]

[redacted]

38. Please describe how, when a visitor is admitted to a non-public area of the premises of a Licensee, a registered processor agent will ensure that the visitor does not touch any plant or medical cannabis. *

[Reference 10.62.21.07 of the regulations. Graded 0 to 5 scoring. Weighted 1% of the Safety and Security

[redacted]

39. Please describe how the Applicant will maintain a log of all visitors to non-public areas for 2 years. *

[Reference 10.62.21.07 of the regulations. Graded Yes or No. Weighted 1% of the Safety and Security

[redacted]

[redacted]

10.62.22.02

40. Please describe how the Applicant will train each registered processor agent in the standard operating procedure and retain attendance records. *

[Reference 10.62.22.02 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Business and Economic subsection. Maximum length 780 words.]

New hires will undergo a training course designed to transfer all critical knowledge, including standard operating procedure, but also a complete understanding of the responsibilities and risks associated with each job function in the organization. In addition, because the Applicant will hire all processor Agents based on their scientific and technical understanding, product knowledge, process knowledge, and/or risk assessment abilities, the Applicant will include in this training period an opportunity for the new hires to provide input into the standard operating procedure.

- Processor Agents will be trained individually to understand and follow standard operating procedure for all the methods, equipment, solvents, and gases used when processing medical cannabis concentrates and medical cannabis-infused products. Every SOP will be designed following FDA, GLP, GMP and OSHA guidelines and regulations to warrant the safety of all employees, the appropriate performance of all processes, and the quality of the final products.
- Processor Agents will be trained individually to ensure absolute sanitary conditions in areas that have been designated for packaging and handling, including all equipment utensils, and accessories used during the packaging process.
- Processor Agents will individually receive appropriate training to follow OSHA protocols for the handling and storage of each individual chemical, solvent and/or gas involved in processing medical cannabis concentrates and medical cannabis-infused products.
- Processor Agents will individually be properly trained to operate, calibrate, troubleshoot and housekeep each piece of equipment required to perform their individual tasks. Equipment placement within the facility will comply with OSHA guidelines and regulations.
- Processor Agents will individually be encouraged to participate in a whistleblower program in order to prevent substance diversion and sanitary infractions.

The Applicant will retain training materials and attendance records and make the training materials available for the inspection by the Commission by either providing tamper-evident hard copies from a secure and segregated room, or tamper-evident and secure, searchable digital copies.

Each training session provided by the Company will include copies of all materials and a list of trainers and attendees. Each attendant's employment file will mirror this information. Both sets of files will document the purpose and content of the session or examination, the time, date, and any notes or scores. These records will be reviewed by the Processor Supervisor within a week of the training session.

Job specific training requirements will be conducted to ensure each employee is familiar with their role and can demonstrate competency before being allowed to work independently. This will include but is not limited to the following areas:

- Organizational structure, including management, the quality unit and operations
- Where SOPs are located and how to access and use them in the course of their workday.
- How equipment functions (theory and operation)
- How to log data
- Sanitation and cleaning procedures
- Personal hygiene requirements
- Waste management practices
- Quality control practices
- Documentation requirements and practices
- Emergency procedures
- GMP principles training on a regular basis
- Skills or Competency training
- SOPs, Test Methods, and Master Batch Records

Every Processor Agent will be individually trained initially and retrained annually on the facilities Chemical Hygiene Plan and Hazard Communication plan. This will ensure each licensed Processor Agent knows how to access material Safety Data Sheets, how to interpret their content, know how to label and take precaution when using hazardous materials. For any training provided by a third-party organization or consultant, the Processor Supervisor will take steps to ensure that comparable records can be produced. The Processor Supervisor will be informed in advance of all such trainings, and will arrange to receive attendance from the trainer. Prior to the training session, the Processor Supervisor will request that the trainer provide a copy of the materials for inspection by the Commission.

Training records will include all records of all Processor Agents, the level of training attained, the classes attended, and the training materials for each training course. If a certificate, or

continuing education credits are achieved, all such records will be included and submitted to the Commission. A Processing Supervisor will gather all records to be submitted and will be responsible for submitting records in either format to the Commission for further review, inspection, or analysis.

Training and attendance will be documented and retained for 5 years for the Commission's review following electronic data storage standard operating procedure.

41. Please describe how the Applicant will assure that a copy of the standard operating procedure will be readily available on site for inspection by the Commission. *
[Reference 10.62.22.02 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will ensure that a copy of all standard operating procedure and Applicant policies will be readily available on-site in both print and electronic form. All information and data related to the written standard operating procedure will be updated as the company grows. The data will be recorded and stored in the perpetual inventory control system, and can be printed or sent electronically to the Commission for inspection.

10.62.22.03

42. Please describe how the Applicant will not acquire medical cannabis from an individual or entity in Maryland other than a Licensee. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will not acquire medical cannabis from an individual or entity in Maryland other than a Licensee. Upon pre-approval, the Applicant understands that it is a licensed Processor and subject to all regulations as set forth in COMAR 10.62.22.03. The Applicant will only acquire medical cannabis raw material from licensed Growers within the state of Maryland to produce medical cannabis finished products to distribute to licensed Dispensaries.

43. Please describe how the Applicant will not acquire medical cannabis from outside Maryland unless authorized by the Commission. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will not acquire medical cannabis from outside of Maryland unless authorized by the Commission. Upon pre-approval, the Applicant understands that it is a licensed Processor and therefore subject to all regulations as set forth in COMAR 10.62.22.03. The Applicant will only acquire medical cannabis raw material from licensed Growers within the state of Maryland to produce medical cannabis finished products to distribute to licensed Dispensaries.

44. Please describe how the Applicant will not transport medical cannabis to any place outside of Maryland. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will not transport medical cannabis or medical cannabis finished products outside the state of Maryland. The Applicant will have tight control over its Processor Agents and staff; the Company's managers and consultants will give instructions and training on remaining compliant with state and local regulations.

45. Please describe how the receiving Applicant will detail in the standard operating procedure the steps set forth in 10.62.22.03 (C), (D) and(H), and a shipping Licensee shall detail in its standard operating procedure the steps set forth in 10.62.22.03 (C)—(H), to assure the integrity of the shipment of products containing cannabis. *

[Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant shall, as set forth in COMAR 10.62.22.03, assure the integrity of the shipment of products containing medical cannabis. The Applicant shall create and detail in its standard operating procedure, that upon arrival of a medical cannabis transport vehicle, the Transportation Agent shall notify an appropriate Processor Agent to continue the chain of custody of the shipment of products containing cannabis. After notifying an appropriate Processor Agent of the Transportation Agent's arrival, the Processor Agent will:

- Log into the electronic manifest;
- Take custody of a shipment of products containing cannabis;
- Confirm the transportation agent is carrying appropriate identification;

The Processor Agent will then instruct the Transportation Agent to drive into the secure loading dock area which will be locked at all times during the delivery transaction. As the shipment of products is received, they are placed into a quarantine area. The Processor Agent places a red tag on each received product, clearly labeling the products as being quarantined. The Processor Agent will then conduct a physical inspection on each product to ensure that:

- All products are secure, undamaged, and appropriately labeled
- All products are the correct products in terms of quantity and quality, and correspond with the correct purchase order number, shipment information, transportation agent information, and date of delivery information within the perpetual inventory control system
- The shipment of products meet all requirements for the order and receipt of materials to ensure the integrity of the package
- Products are released from quarantine

If the integrity of the shipment of products is compromised, the Processor Agent will notify a Processor Supervisor to inform him of the discrepancy. The Transportation Agent will also notify their supervisor. A discrepancy will either warrant a rectification or non-rectification. The result information is recorded into the perpetual inventory control system and a potential investigation into the discrepancy will proceed to resolve the discrepancy.

46. Please describe how the receiving Applicant will detail in the standard operating procedure the steps set forth in 10.62.22.03 (C), (D) and(H), and a shipping Licensee shall

detail in its standard operating procedure the steps set forth in 10.62.22.03 (C)—(H), to assure the integrity of the electronic manifest and inventory control system. *
[Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will create standard operating procedure and detail the steps set forth in 10.62.28.03 §(C)-(H) to assure the integrity of the electronic manifest and inventory control system. The Applicant will only accept deliveries that have been scheduled and pre-approved by the Processor Supervisor —no unsolicited products will be accepted. The Processor Supervisor and Processor Agent in charge of handling the delivery will be responsible for handling all shipments to the Processing Facility and will adhere to the Applicant's mandatory standard operating procedure regarding the receipt of all medical cannabis products.

When a medical cannabis transport vehicle arrives, the Processor Agent and Processor Agent for Security will verify the transportation agent's identification and evaluate the delivered medical cannabis packages in the quarantine area of the receiving loading dock. The package's shipping Licensee bar code will be scanned into the perpetual inventory control system, allowing the Agents to confirm that each package's electronic manifest is correctly labeled and verified so that the contents of the shipment correlate with data obtained from the perpetual inventory control system.

If the Processor Agent uncovers a discrepancy in the shipment where the electronic manifest does not correspond with the data in the perpetual inventory control system, the Processor Agent will notify a Processor Supervisor to notify the Transportation Agent's supervisor.

47. **Please describe how the receiving Applicant will detail in the standard operating procedure the steps set forth in 10.62.22.03 (C), (D), and (H) and a shipping Licensee shall detail in its standard operating procedure the steps set forth in 10.62.22.03 (C)—(H), to assure the quality of the products in the shipment. ***
[Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant, pursuant to 10.62.22.03(C) - (H), will create standard operating procedure to assure the quality of the products in the shipment. When checking packages being received by a shipping licensee, the Processor Agent will place all packages in custody into the quarantine area for a quality control check before being admitted into the facility. The Processor Agent will perform the quality control check to assure the quality of the products in the shipment and input the following information into the perpetual inventory control system:

- The proprietary or established name or names of the product;
- The strength and dosage form of the product; (if applicable)
- The unique corresponding shipping barcode number of the product;
- The package size;
- The number of packages;
- The lot number of the package;
- The date and time of the transaction;
- Physical inspection of the packages to ensure they are secure, undamaged, and appropriately labeled

- The date of the shipment, if more than 24 hours after the date of the transaction;
- The business name and address of the person from whom ownership is being transferred;
- The signature or identification number of the Transportation Agent who delivers the shipment as set forth by COMAR 10.62.22.03(C) - (H);

48. Please describe how the Applicant will assure that, upon arrival of a medical cannabis transport vehicle, the transportation agent will notify an appropriate registered processor agent to continue the chain of custody of the shipment of products containing cannabis. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Operational subsection. Maximum length 135 words.]

The Applicant will assure that, upon arrival of a medical cannabis transport vehicle, the Transportation Agent will notify an appropriate Processor Agent to continue the chain of custody of the shipment of products containing cannabis through first placing a phone call to the facility indicating that there will be a scheduled delivery. The Transportation Agent will schedule an appointment to make a delivery to the facility, which will then be verified by the Lead Processor Agent. Upon arrival at the Processor Facility with the medical cannabis transport vehicle, the Transportation Agent will check-in with the receptionist to notify an appropriate Processor Agent to continue the chain of custody for a shipment of products. The Transportation Agent will enter the Public Zone of the facility to verify the Transportation Agents identification and electronic manifest.

49. Please describe how the Applicant will assure that an agent of the receiving Licensee will log into the electronic manifest. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure the Registered Processor Supervisor receiving the shipment will log into the electronic manifest all documentation, data and related records and materials in a timely manner and this process will be verified by the Registered Processor Security Agent who will be present and is responsible for the retention and integrity of the documentation, data, and related records and materials until they are accepted into the archive.

50. Please describe how the Applicant will assure that an agent of the receiving Licensee will take custody of a shipment of products containing cannabis. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure the Agent of the receiving Licensee will take custody of a shipment of products containing cannabis upon receiving and verifying the identification of the Transportation Agent with the shipment of products, and logging into the electronic manifest to verify the shipment.

51. Please describe how the Applicant will assure that an agent of the receiving Licensee will confirm that (1) the transportation agent is carrying appropriate identification; (2) the package is secure, undamaged, and appropriately labeled; (3) each package in the shipment is labeled as described in the electronic manifest; (4) the contents of the shipment are as described in the electronic manifest. *

(1) [Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]
(2) [Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]
(3) [Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]
(4) [Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

1. The Applicant will assure that the receiving Licensee will confirm the transportation agent is carrying appropriate identification when the receiving Licensee receives the shipment and proper identification proves that the transportation agent's driver's license matches the individual present and the individual is verified by the receiving Licensee's Supervising Agent, who will revise the electronic manifest, which will electronically notify the Applicant of the status update and securely archive records.

2. The Applicant will assure that the receiving Licensee will confirm the package of medical cannabis and medical cannabis products is secure, undamaged, and appropriately labeled, by the receiving Licensee's Supervising Agent, who will assure the quality of the package and revise the electronic manifest, which will electronically notify the Applicant of the status update and securely archive records electronically and off-site, in a secure, searchable cloud-based computing system.

3. The Applicant will assure that the receiving Licensee will confirm each package of medical cannabis and medical cannabis products in the shipment are labeled as described in the electronic manifest, by the receiving Licensee's Supervising Agent, who will assure the quality of the label of each package in the shipment matches the electronic manifest in the shipment and revise the electronic manifest, which will electronically notify the Applicant.

4. The Applicant will assure that the receiving Licensee will confirm the contents of the shipment are as described in the electronic manifest by the receiving Licensee's Supervising Agent, who will assure the quality of the contents of each package in the shipment and revise the electronic manifest. This will electronically notify the Applicant, and electronically archive records off-site in a secure, searchable cloud-based computing system.

52. Please describe how the Applicant will assure that an agent of the receiving Licensee will record the confirmations of the electronic manifest. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

The Applicant, to assure that an agent of the receiving Licensee will record the confirmations of the electronic manifest immediately and provide a copy of the electronic manifest for the shipment to the shipping licensee, will detail in the standard operating procedure the steps set forth in §§C, D and H of COMAR 10.62.22.03.

53. Please describe how the Applicant will assure that an agent of the receiving Licensee will obtain in the electronic manifest the signature or identification number of the transportation agent who delivers the shipment. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant, to assure that an agent of the receiving Licensee will obtain in the electronic manifest the signature or identification number of the transportation agent who delivers the shipment, will detail in the standard operating procedure the steps set forth in §§C, D and H of COMAR 10.62.22.03. The transportation agent will provide the completed electronic manifest to the Applicant.

54. Please describe how the Applicant will assure that an agent of the receiving Licensee will record in the electronic manifest the date and time the receiving agent takes custody of the shipment. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

The Applicant will a create standard operating procedure to assure that an agent of the receiving Licensee will record the date and time of the shipment into the electronic manifest after the receiving Licensee logs into the electronic manifest, verifies the Transportation Agent, physically inspects the shipment of products, confirms the shipment, and obtains the signature of the Transportation Agent.

55. Please describe how the Applicant will assure that an agent of the receiving Licensee will enter the products containing cannabis into the inventory control system. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure that an agent of the receiving Licensee will enter the products containing medical cannabis into the inventory control system by detailing in the standard operating procedure the steps set forth in §§C, D and H of COMAR 10.62.22.03. The receiving Licensee will describe and record medical cannabis products into the electronic manifest as part of the standard operating procedure.

56. Please describe how the Applicant will assure that an agent of the receiving Licensee will segregate the items in the shipment from the inventory until the item can be inspected. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure that an agent of the receiving Licensee will segregate the items in the shipment from the inventory until the item can be inspected as set forth in §§C, D and H of COMAR 10.62.22.03. The receiving Licensee will take custody of the shipment and place the shipment into the quarantine area and segregate the items in the shipment before being admitted into the Processing Facility.

57. Please describe how the Applicant will assure that an agent of the receiving Licensee will inspect each item to ensure that the packaging of each item is undamaged, accurate, and complete. *

[Reference 10.62.22.03 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will create standard operating procedure to assure that an agent of the receiving Licensee will inspect each item to ensure that the packaging of each item is undamaged, accurate, and complete as set forth in §§C, D and H of COMAR 10.62.22.03

When the Applicant receives a shipment and the Transportation Agent is verified, a receiving Licensee and a Processor Supervisor will verify that each item shipped is recorded in the electronic manifest. The shipped items are placed into a quarantine area and labeled with a quarantine tag and segregated for visual inspection to determine if the items are secure, properly labeled, undamaged, and its contents match the electronic manifest. The physical inspection will require a log into the electronic manifest to describe the details of the shipment. Processor Agents will perform the following:

- All receipt of materials will be delivered to the labeled quarantine area □
- No material is received unless its shipping documentation matches the corresponding purchase order in the perpetual inventory control system
- All materials received are issued a unique Quarantine Number
- A list of all receipt of materials will be recorded in the receiving shipment logbook. □
- The following information is recorded in the electronic manifest by the designated Processor Agent and confirmed:
    - Quarantine # □
    - Product Description
    - Condition of shipment
    - Name □
    - Date □
    - Source Name □
    - Item #□
    - Quantities
    - Transportation Agent ID □
    - Purchase Order Number □
    - Individual and total quantity
    - Registered Transportation Agent signature □
    - Vendor signature

Upon clearance through quarantine procedure, two agent signatures will be needed to complete the change in chain of custody to accurately reflect compliance. The transportation

agent will provide the completed electronic manifest to the receiving Licensee.

58. Please describe how the Applicant will assure that an agent of the receiving Licensee will, upon determining that the item passes inspection, release the item into the stock. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

The Applicant will create standard operating procedure to assure that an agent of the receiving Licensee will, upon determining that the item passes inspection, release the item into the stock, as per the steps set forth in §§C, D and H of COMAR 10.62.22.03. Upon passing the quarantine check and receiving the electronic manifest from the Transportation Agent, the receiving Licensee takes custody of the shipment and admits it into the facility.

59. Please describe how the Applicant will assure that the transportation agent will provide a copy of the electronic manifest for the shipment to the receiving Licensee. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure that the transportation agent will provide a copy of the electronic manifest for the shipment to the receiving Licensee as per the steps set forth in §§C, D and H of COMAR 10.62.22.03. The Transportation Agent will electronically sign the manifest and release it to the receiving Licensee. The Licensee will sign the same electronic manifest to close the transaction before logging off the perpetual inventory control system.

60. Please describe the Applicant will assure that the transportation agent will provide the completed electronic manifest to the shipping Licensee. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure that the upon delivering a shipment that a Transportation Agent will follow steps in COMAR 10.62.22.03 (d) 1-10, ensuring the shipping Licensee takes custody of the shipment. Upon determining the shipment passes inspection and the items are released into stock, the Transportation Agent will provide a copy of the completed electronic manifest to the shipping Licensee.

61. Please describe how the Applicant will assure that the shipping Licensee will retain the electronic manifest for the shipment for 5 years. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

The Applicant will assure that upon delivering a shipment or receiving a shipment, a shipping Licensee will retain a completed electronic manifest of every transaction for 5 years. The electronic manifest will record this information into the perpetual inventory control system, which retains data and stores the information on site and off site for referencing purposes and make these records available for inspection.

62. Please describe how the Applicant will assure that a discrepancy between the electronic manifest and the shipment, identified by either a transportation agent or a receiving agent, will be reported by each agent to each agent's supervisor. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will assure that if there is a discrepancy between the electronic manifest and the shipment, identified by either a registered Transportation Agent or a Processor Agent receiving shipment, the discrepancy **will be reported by each agent to each agent's supervisor**. If a discrepancy is discovered by the receiving Processor Agent, the agent will notify a Processor Supervisor who will then immediately notify the licensed Transportation Agent Supervisor for further review. If the Transportation Agent discovers the discrepancy, that agent will notify their supervisor and then ask to speak with the receiving Processor Supervisor to discuss the discrepancy and proceed towards a rectification.

The Applicant will not accept any shipment unless the details of the shipment match the description of the order in the electronic manifest. Details of a discrepancy can include but are not limited to:

- Purchase order number does not match the order of the shipment
- Shipment identification number does not match the order of the shipment
- Physical contents of the shipment are not correct
- Packages are damaged, inaccurate, incomplete, or mislabeled
- Transportation Agent cannot furnish proper identification

Upon finding a discrepancy and after notifying each agent's supervisor of a discrepancy, the discrepancy (if possible) can be rectified and the accepting Processor Supervisor will record this information into the electronic manifest. If the discrepancy is rectified, the receiving Licensee will take custody of the shipment.

63. Please describe how the Applicant will assure that, if a discrepancy can be immediately rectified, the accepting processor supervisor will record the rectification in the electronic manifest. *

[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will assure through its standard operating procedure that if there is a discrepancy between the electronic manifest and the shipment, identified by either a registered Transportation Agent or a Processor Agent receiving shipment, the discrepancy will be reported by each agent to each agent's supervisor. Once the receiving Processor Supervisor is made aware of the discrepancy, a rectification process will be performed to see if there can be a resolution to the shipment being cleared through quarantine. The Processor Supervisor will perform the following steps:

- Notify the Transportation Agent Supervisor about the discrepancy
- Perform a line item check in the electronic manifest to the corresponding shipment
- Thoroughly and physically check all packages to ensure they are secure, undamaged, and appropriately labeled
- Search and investigate where the discrepancy is in the shipment and why

- Notify the Transportation Agent Supervisor of the investigation

If a discrepancy can be rectified and the shipment is accepted, the accepting Processor Supervisor will record this information into the electronic manifest as part of the Applicant's standard operating procedure when accepting shipments that require a rectification.

64. Please describe how the Applicant will assure that a discrepancy that cannot be immediately rectified will be reported to the Commission by the receiving Licensee within 24 hours of the observation of the discrepancy and an investigation of the discrepancy shall be initiated by the shipping Licensee. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will assure through its standard operating procedure that if a discrepancy cannot be immediately rectified between a Processor Supervisor and/or a Transportation Agent Supervisor during a shipment, **the receiving Licensee will file a report with the Commission within 24 hours of the observation of the discrepancy**. After filing the report whether by phone or electronically, an investigation will take place on the discrepancy to discover the original cause of the discrepancy by the shipping Licensee. The shipping Licensee will begin to investigate through methods of comparison with the shipment and the electronic manifest and record any deviations from the original shipment information recorded in the electronic manifest. The shipping Licensee will perform the following steps:

- Perform a line item check in the electronic manifest to the corresponding shipment
- Thoroughly and physically check all packages to ensure they are secure, undamaged, and appropriately labeled
- Verify that the contents in the shipment are as described in the electronic manifest, and note if there is a discrepancy in the contents. i.e. product name, quantity, quality, expiration date, shipping barcode number, etc.
- Compile a report of the attributes of the discrepancy to be used in the preliminary and final report

Within seven business days, a preliminary report will be compiled of the discrepancy and will be submitted to the Commission for review. Within 30 business days, a final report of the conclusion of the investigation will be submitted to the Commission for a final review.

65. Please describe how the Applicant will assure that the shipping Licensee will submit to the Commission a preliminary report of an investigation of a discrepancy within 7 business days of the observation of the discrepancy. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will assure through its standard operating procedure that the shipping Licensee **will submit to the Commission a preliminary report of an investigation of a discrepancy within 7 business days** of the observation of the discrepancy. Upon the observation of the discrepancy and after following steps of notifying agent supervisors of both the Transportation Agent and the shipping Licensee of the discrepancy, the receiving Licensee will file a report

with the Commission immediately or within 24 hours of the observation of the discrepancy. After filing the report whether by phone or electronically, an investigation will take place on the discrepancy to discover the original cause of the discrepancy by the shipping Licensee. The shipping Licensee will begin to investigate through methods of comparison with the shipment and the electronic manifest and record any deviations from the original shipment information the electronic manifest. The shipping Licensee will perform the following steps:

- Perform a line item check in the electronic manifest to the corresponding shipment
- Thoroughly and physically check all packages to ensure they are secure, undamaged, and appropriately labeled
- Verify that the contents in the shipment are as described in the electronic manifest, and note if there is a discrepancy in the contents. i.e. product name, quantity, quality, expiration date, shipping barcode number, etc.
- Compile a report of the attributes of the discrepancy to be used in the preliminary and final report

After the preliminary investigation, the shipping Licensee will have compiled and completed information involved with the discrepancy to file the preliminary report that will be submitted to the Commission for review within 7 business days.

66. Please describe how the Applicant will assure that the shipping Licensee will submit to the Commission a final report of the investigation within 30 business days. *
[Reference 10.62.22.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will assure through its standard operating procedure that the shipping Licensee will submit to the Commission a final report of an investigation of a discrepancy within 30 business days of the observation of the discrepancy. Upon the observation of the discrepancy and after following steps of notifying agent supervisors of both the Transportation Agent and the shipping Licensee of the discrepancy, the receiving Licensee will file a report with the Commission immediately or within 24 hours of the observation of the discrepancy. After filing the report whether by phone or electronically, an investigation will take place on the discrepancy to discover the original cause of the discrepancy by the shipping Licensee. The shipping Licensee will begin to investigate through methods of comparison with the shipment and the electronic manifest and record any deviations from the original shipment information the electronic manifest. The shipping Licensee will perform the following steps:

- Perform a line item check in the electronic manifest to the corresponding shipment
- Thoroughly and physically check all packages to ensure they are secure, undamaged, and appropriately labeled
- Verify that the contents in the shipment are as described in the electronic manifest, and note if there is a discrepancy in the shipment i.e. product name, quantity, quality, expiration date, shipping barcode number, etc.
- Compile a report of the attributes of the discrepancy to be used in the preliminary and final report

After the preliminary investigation, the shipping Licensee will have compiled and completed

information involved with the discrepancy to file the preliminary report and submitted to the Commission for review within 7 business days. The shipping Licensee will continue to investigate the discrepancy to gather as much information on the discrepancy as possible. The shipping Licensee will keep the investigation open until it is closed, or continues up to a 30-day period. **On or before the 30-day period from the observation of the discrepancy, a shipping Licensee will submit a final report on the discrepancy to the Commission.**

10.62.22.04

67. Please describe how an Applicant's standard operating procedure will provide for maintaining the cleanliness of any building or equipment used to store or display medical cannabis. *

[Reference 10.62.22.04 of the regulations. Graded 0 to 5 scoring. Weighted 4% of the Operational subsection. Maximum length 540 words.]

The Applicant will establish, maintain and follow standard sanitation procedures for all buildings and equipment used to store medical cannabis and document these procedures as part of its standard operating procedure. The Processor Supervisor will ensure all employees involved are trained to properly clean assigned equipment and document the process. In compliance with FDA and GMP requirements, one or more Processor Supervisor's will be assigned to supervise overall sanitation. The Applicant will adopt sanitation procedures from the AHP monograph. Each of these supervisors will be qualified by education, training, or experience to develop and supervise sanitation procedures.

The Processor Supervisor will assign specific personnel for the cleaning of all production equipment and oversee the proper performance of cleaning and sanitation standard operating procedure to ensure sanitary production equipment, The Applicant will maintain standard operating procedure addressing written procedures to be implemented for the cleaning of equipment, including utensils, used in the manufacture, processing, packing or holding of all products. These written procedures, schedules, and logbooks will include:

- Assignment of responsibility for cleaning equipment □
- Controlling airborne contamination; □
- Using sanitary handling procedures; □
- Using safe water in all operations;
- Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated ingredients in processing operations; □□
- Storing packaging materials, in-process medical cannabis raw material, and medical cannabis finished products appropriately to prevent contamination and adulteration; □
- Preventing cross-contamination and mix-ups between contaminated or adulterated medical cannabis raw material or medical cannabis finished products and non-tainted medical cannabis; □
- Washing or cleaning containers and packaging components that contain contaminants;
- Using effective measures to protect marijuana products against adulteration by other foreign materials when at risk due to processing equipment or instruments
- A description in sufficient detail of the methods and materials used for cleaning and the methods of disassembling and reassembling equipment to ensure proper cleaning □
- Measures for the protection of clean equipment from contamination prior to use □

- Required inspection of equipment for cleanliness immediately before use □
- Based upon the individual equipment design, the following sequence of cleaning operations will be performed upon the completion of each batch of product.
- If applicable, a reduced written disassemble and cleaning procedure may be utilized between sequential batches of the identical product brand, strength, and dosage form.
- Upon the completion of a manufacturing or packaging operation, equipment will be disassembled and all moveable parts removed so that the equipment can be properly cleaned.
- All exterior surfaces will be sanitized and the interior cleaned with an approved detergent mixed with water and then rinsed thoroughly with tap water.
- Finally, all surfaces that come in contact with components will be sanitized with denatured alcohol and allowed to air dry. □
- Upon completion, the employee will fill in the cleaning log and inform their immediate supervisor the equipment is ready for inspection.

An audit or check will be performed on the equipment cleaning and its documentation on a random basis several times a week. These reviews will include an inspection of the actual equipment cleanliness and the accuracy of all cleaning documentation. All cleaning records required by this procedure will be retained for at least five (5) years after distribution of the last batch of product manufactured, processed or packaged utilizing that equipment.

68. Please describe how an Applicant will have a standard operating procedure to maintain the medical cannabis free from contamination. *

[Reference 10.62.22.04 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

In order to maintain the medical cannabis free of contamination, Processor Agents will be required to comply with the Applicant's standard operating procedure. All Processor Agents will be trained to ensure absolute sanitary conditions in areas that have been designated for extraction of medical cannabis and packaging and handling, including all equipment, utensils, and accessories used during the packaging process. The Applicant's standard operating procedure have been designed to meet or exceed the high sanitary standards of the Maryland Food Service Facilities Regulations pertaining to the handling of food-grade products:

- All Agents involved with the handling and packaging of medical cannabis will wear proper lab coats, latex gloves, and hairnets.
- Personnel will also be required to wash hands and exposed areas of the arm before beginning work, before and between glove use, and after using a toilet facility.
- Gloves will be replaced after each pound of medical marijuana has been packaged, or, when beginning to package a different variety or shipment of product (to prevent cross-contamination), and, as by required by FSFR, every two-hours. (Food Service Facility Regulation: 1.01.01.16)
- Prior to entering the packaging room, Packaging Agents must report to the Processing Supervisor or Packaging Supervisor any illness or personal health condition that might compromise the cleanliness or quality of the medical cannabis the Processor Agent might handle.
- A sanitation log will be maintained with records retained for five years.

The Applicant's employee handbook will include a stipulation for Processor Agents that allows them to call-in sick without penalty on an unlimited basis. This will prevent any contamination from reaching any medical cannabis product or medical cannabis patients.

The Applicant will also maintain a separate, covered stainless steel covered bin in the secure room for storing medical cannabis for disposal. This bin will be completely sanitized inside and out, limiting opportunities for cross-contamination, and only be opened in rooms where no other medical cannabis products are exposed to the air. The outside of this bin and the room where it is opened will be sanitized immediately after the bin is re-closed.

69. Please describe how an Applicant will have a standard operating procedure to require a processor agent to report any personal health condition that might compromise the cleanliness or quality of the medical cannabis the processor agent might handle. *
[Reference 10.62.22.04 of the regulations. Graded Yes or No. Weighted 2% of the Production Control subsection. Maximum length 135 words.]

All Processor Agents will be explicitly trained to report to their direct supervisor, or, if unavailable, to the Processing Supervisor, any personal health condition that might compromise the cleanliness or quality of the medical cannabis that the Processor Agent handles.

The Applicant will include a Personal Health, Hygiene, and Cleanliness handout in the employee handbook that will describe all of the symptoms and health conditions that may compromise the cleanliness or quality of any medical cannabis handled by a Processor Agent. Each Processor Agent will be asked to sign a document that acknowledges the handout per the Applicant's standard operating procedure.

Employees will also be trained, as per the Applicant standard operating procedure, to report any fellow agent that is demonstrating any of the symptoms or conditions identified in the Personal Health, Hygiene, and Cleanliness handout directly to the Processing Supervisor.

70. Please describe how an Applicant's standard operating procedure will provide for disposal and segregated storage of any medical cannabis that is outdated, damaged, deteriorated, misbranded, or adulterated. *
[Reference 10.62.22.04 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Production Control subsection. Maximum length 135 words.]

[redacted]

[redacted]

71. Please describe how an Applicant's standard operating procedure will provide for disposal and segregated storage of any medical cannabis whose containers or packages have been improperly or accidentally opened. *

[Reference 10.62.22.04 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Production Control

[redacted]

10.62.22.05

72. Please describe how an Applicant's standard operating procedure will provide for maintaining the sanitation of equipment that comes into contact with medical cannabis. *

[Reference 10.62.22.05 of the regulations. Graded 0 to 5 scoring. Weighted 4% of the Operational subsection. Maximum length 540 words.]

The Applicant will ensure as a standard operating procedure, that the licensed premises, all personnel, and equipment used within the Processing Facility for the preparation, packaging, storage, infusion, or sale of medical marijuana is maintained in clean and sanitary conditions. The Applicant will acquire necessary supplies for facility cleaning and sanitation and other facility uses that are not directly incorporated into a medical marijuana product, shall be inspected visually for their correct label identification. All buildings and facilities equipment shall be maintained in a clean sanitary condition, free of infestation by rodents, birds, insects and other vermin.

A Registered Processor Supervisor shall ensure all Processor agents in the facility:

- Clean hands and exposed portions of arms in a hand washing sink and wear gloves and change gloves as often as needed;
  - Before preparing medical marijuana including working, with equipment and utensils;
  - During preparation, as often as necessary to avoid contamination and to prevent cross-contamination when changing tasks;
  - After handling soiled equipment or utensils;

- After using the toilet room;

All trays, buckets, other receptacles, racks, tables, shelves, other utensils, or the machinery used in moving, handling, cutting, mixing, grinding, packaging, or other processes are cleaned daily.

If working directly with the preparation of medical marijuana or the infusion of marijuana into non-edible products, Processor Agents will:

- Wear protective apparel such as coats, aprons, gowns, or gloves to prevent contamination.
- Report to the Processing Supervisor any health condition experienced by the Processor Agent that may adversely affect the safety or quality of any medical marijuana with which the Processor Agent may come into contact.

If the Processing Supervisor determines that a Processor Agent has a health condition that may adversely affect the safety or quality of the medical marijuana, they are prohibited from direct contact with any medical marijuana or equipment or materials for processing medical marijuana until it's been determined that the Processor Agent's health condition will not adversely affect the medical marijuana.

The sanitation management of each facility and equipment shall be maintained in a current written document or protocol, applicable to either contractors or Processor Agents assigning responsibility for the site cleaning and sanitation. The log forms with date, time and name of each Processor agent will be maintained in a binder and signed off in real time as cleaning activities occur.

These documents shall describe in sufficient detail:

- Cleaning schedules, methods, equipment and materials to be used in cleaning the facility and equipment. Logs documenting these activities are performed according to their required schedule and specific tasks. Written procedures shall be maintained to ensure consistent quality and frequency.
- Any rodenticides, insecticides, fungicides, fumigating Agents and sanitizing Agents shall be used in accordance with the Federal Insecticide, Fungicide and Rodenticide Act. Adequate records documenting the frequency and methods utilized for these activities shall be maintained using the standard operating procedure's protocol of signing off in a binder at the time of the cleaning.

The Applicant understands the importance of good clean hygiene practices and utilizing of all standard precautions and procedures to ensure safe handling in receiving, processing and packaging of all medical cannabis products. All hygiene practices outlined will assist in maintaining the sanitation of equipment that comes into contact with medical cannabis.

73. Please describe how the Applicant will ensure that automatic, mechanical, or electronic equipment is routinely calibrated and periodically check to ensure proper performance. *

[Reference 10.62.22.05 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will ensure through its standard operating procedures that critical and essential equipment is routinely calibrated and periodically checked according to the manufacturer's specifications to ensure proper performance.

- Balances will be serviced and calibrated annually by the manufacturer or a designated representative. Pre-operational checks will be completed each day the balance is used. Results of the checks will be documented and recorded.
- HPLC will use preventative maintenance that is performed annually by the manufacturer or a designated third-party maintenance organization. This maintenance will be documented. Each day prior to use a system suitability test will be performed to ensure operations are within the specification of the monograph. Additionally, a visual inspection of the equipment will be conducted on valves, seals, pistons for general wear. Annually the instrument will be calibrated against the appropriate monographs on interest with reference sources from the US Pharmacopeia and/or American Herbal Pharmacopeia.
- Extraction systems and subsystems will be visually inspected each day prior to use to ensure fittings, tubing, seals, gauges and electronic components are in working order. Service and performance checks will be performed by the manufacture or a designated third-party maintenance organization.
- Laminar airflow hoods and biosafety cabinets will be certified every 6 months by a licensed third-party vendor.
- Facility HVAC air balance and pressure gauges will be evaluated annually by a licensed third-party vendor.
- Additional equipment and instruments will also be routinely checked for proper performance.

Calibration records, service logs and daily operational check records will be maintained for each item for a period of 5 years for inspection by the Commission.

74. Please describe how the Applicant will ensure that any scale, balance, or other measurement device is routinely calibrated and periodically check to ensure accuracy. *

[Reference 10.62.22.05 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will only utilize scales, balance and weights and other measurement for the manufacturing, processing, packaging or holding cannabis product within the facility. The Applicant will ensure any scales, weights and balance or other measurement will be routinely calibrated, inspected or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections will be maintained. The Processor Agent performing scale calibration tests and adjustments will revise log indicating the date and time, in chronological order.

Scales, balance and weights shall be maintained and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, quality, or purity of the medical cannabis product beyond established specifications. It will be the responsibility of the Processor Supervisor to oversee the safe operation of equipment utilized by the Processor Agents and ensure compliance with the standard operating procedure.

Written protocols shall be established for the maintenance of scale weights and measures used in the manufacture, processing, packing or holding of all cannabis products. Written procedures will include maintenance schedules and sanitizing schedules. A description in sufficient detail of the scales, weights and measures equipment and materials used in the calibration operations. All weights and measures will be uniquely identified and have a dedicated equipment maintenance log.

Written records of the calibration maintenance (except for routine in-process adjustments) will include the date, time, and identification of the previous product and lot number processed with that equipment. If and when discrepancies arise, all products that were processed between calibration periods in question will be evaluated for accuracy by the Processor Supervisor.

75. Please describe how the Applicant will maintain an accurate log recording the cleaning of equipment. *

[Reference 10.62.22.05 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will as a standard operating procedure record and maintain in an accurate log, the date, time, and name of the Processor Agent. Written procedures will describe in sufficient detail: Cleaning schedules, methods, equipment and materials to be used in cleaning the facility and equipment. Accurate records documenting these activities are performed according to their schedule and written procedures will be maintained to ensure consistent accuracy of information.

76. Please describe how the Applicant will maintain an accurate log recording the maintenance of equipment. *

[Reference 10.62.22.05 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will as a standard operating procedure maintain an accurate log recording equipment maintenance. This log will be maintained in a current written document, applicable to either contractors or Processor Agents assigned responsibility for the equipment maintenance and repair. Processor Agent will log the name, date, and time the maintenance took place. These documents will describe in detail: schedules, methods, equipment, and materials used in maintaining processing equipment.

77. Please describe how the Applicant will maintain an accurate log recording the calibration of equipment. *

[Reference 10.62.22.05 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will as a standard operating procedure, maintain accurate records of the calibration of equipment, applicable to either contractors or Applicant employees assigning responsibility for the calibration of equipment or repair. The records will include date, time, and name of the Processor Agent and will be maintained in a binder and as each activity occurs, it will be logged and signed off on.

10.62.22.06

78. Please describe how an Applicant will submit to the Commission at the end of the month following each calendar quarter a list of the products and the products' specifications that the Licensee offered for distribution in the previous calendar quarter. *

[Reference 10.62.22.06 of the regulations. Graded Yes or No. Weighted 1% of the Operational subsection. Maximum length 70 words.]

At the end of the month following each calendar quarter, the Applicant will submit to the Commission, a list of the products and the product specifications that were offered for distribution in the previous calendar quarter. Using the perpetual inventory control software system, a query to the database will generate inventory lists that can be easily managed and readily available to the Commission on a quarterly basis for review.

10.62.23.02

79. Please describe how the Applicant will require that any person involved in processing medical cannabis concentrates and medical cannabis-infused products is (1) appropriately trained in accordance to their job description to safely operate and maintain the system used for processing and attendance records are retained, (2) has direct access to applicable material safety sheets and labels, and (3) follows OSHA protocols for handling and storage of all chemicals. *

(1) [Reference 10.62.23.02 of the regulations. Graded 0 to 5 scoring. Weighted 10% of the Operational subsection. Maximum length 1,350 words.]
(2) [Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]
(3) [Reference 10.62.23.02 of the regulations. Graded 0 to 5 scoring. Weighted 5% of the Operational subsection. Maximum length 675 words.]

1. The Applicant will create standard operating procedure for a quality training system concerned with the organizational process and the conditions under which operational, occupational, and environmental safety studies shall be planned, performed, monitored, recorded, archived and reported. The Applicant commits to training each person involved with the processing of medical cannabis that will include:

a. Job specific (at the task level) training requirements will be conducted to ensure each Processor Agent is familiar with their role and can demonstrate competency before being allowed to work independently. This will include but not limited to the following areas:

- Organizational structure, including management, the quality unit and operations
- Where SOPs are located and how to access and use them in the course of their

workday.

- How equipment functions (theory and operation)
- How to log data
- Sanitation and cleaning procedures
- Personal hygiene requirements
- Waste management practices
- Quality control practices
- Documentation requirements and practices
- Emergency procedures
- GMP principles training on a regular basis
- Skills or Competency training
- SOPs, Test Methods, and Master Batch Records

b. Every employee will be trained initially and retrained annually on the facilities Chemical Hygiene Plan and Hazard Communication plan. This will ensure each employee knows how to access material Safety Data Sheets, how to interpret their content, and how to label and take precautions when using hazardous materials.

c. In addition to the required hazard communication training safe handling and storage of hazardous materials will be addressed with each employee. This will include the location and proper use of flammable storage cabinets for the storage of ethanol and handling compressed gases.

Training with Management of Equipment and Critical Process Utilities
Manufacturing and QC equipment and process utilities are uniquely identified during installation. The Applicant will train its staff to follow the "V Model" principles for qualification of major critical items of equipment or critical process utilities. The V model requires development of user, functional and design specifications, which are used for design qualification. Qualification of equipment, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), shall be documented in pre-approved protocols and reports.

Routine Monitoring, Maintenance, Calibration and Control of Equipment
Processor Agents manufacturing medical cannabis finished products will receive training on critical equipment and process utilities that shall be monitored and controlled during use according to the approved written procedures and schedules for preventive maintenance. Critical equipment and utilities, shall be tagged and removed from use when under repair maintenance and shall not be used until cleared by the authorized personnel. The Applicant shall:

- Provide training materials to written standard operating procedure for startup, operation, shutdown, cleaning, calibration and maintenance of all critical equipment and utilities.
- Maintain equipment and utilities history logs shall be maintained for all critical items.
- Calibrate all critical measuring devices/instruments at defined intervals to a written schedule, if necessary using qualified contract calibration laboratories. Regular checks on the ongoing accuracy and performance of measuring devices shall be conducted.

Water and Clean Steam System Control and Monitoring
The purified water system will be regularly monitored according to a written sampling and testing program under the control of the laboratory. Written procedures and training for sampling, testing and reporting results. Action and alert limits will be established and documented.

HVAC Systems – Maintenance and Monitoring
The HVAC systems servicing all GMP cleanrooms shall be regularly maintained to a written schedule. Records of maintenance shall be retained. Routine monitoring shall include daily recording and periodic trending of clean room pressure differentials, at least quarterly cleaning of pre-filters, quarterly inspection of Air Handling Units, at least annual certification of HEPA filters and routine environmental monitoring programs.

Quality Assurance Management
Before producing medical cannabis concentrates and medical cannabis-infused products, the Applicant will develop standard operating procedure, good manufacturing practices (GMP), and a training plan aimed at improving performance and safety, and will require that any person involved in processing medical cannabis concentrates and medical cannabis-infused products is appropriately trained in accordance with the following policies:

- Only qualified personnel will perform operations understanding fully the responsibilities and risks associated each job function in the organization.
- Clearly defined appropriate qualifications for each position will be maintained to ensure that individuals are assigned appropriate responsibilities.
- Employees will be hired based on their scientific and technical understanding, product knowledge, process knowledge, and/or risk assessment abilities.
- Continued training will be provided to ensure that employees remain proficient in their operational functions and in their understanding of the standards set forth by Good Laboratory Practices.
- Ongoing training will address the policies, processes, procedures, and written instructions related to operational activities, products, the quality system, and standard operating procedure.
- The Quality Assurance Supervisor will be responsible for maintaining accurate records of each employee's relevant qualifications including in-house training and attendance records.
- The Quality Assurance Supervisor will be exercise oversight of the organization's practices and procedures and who has documented training and experience in quality assurance and quality control procedures.
- There will be an adequate number of qualified personnel to perform and supervise the processing, manufacture, testing, packing, holding, or shipping of each product.
- The Applicant will have on staff at least one individual with a minimum of 10 years' experience in good laboratory practices (GLP), Good Manufacturing Practices (GMP), and Good Clinical Practice (GCP).
- In compliance with FDA and GMP requirements, one or more qualified personnel will

be assigned to supervise overall sanitation and each of these supervisors will be qualified by education, training, or experience to develop and supervise sanitation procedures

- Only personnel authorized by supervisory personnel will enter those areas of the buildings and facilities designated as a limited-access area. Records will be maintained identifying those areas individuals are authorized to enter.
- Consultants advising on the manufacture, processing, packing, holding, or shipping of medical marijuana products will have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained.
- Records will be maintained with the name, address, and qualifications of any consultants and the type of service they provide.

Processor Agents will be provided with information and training relevant to the hazards of the chemicals present in their laboratory. The training will be provided at the time of initial hiring and assignment to the laboratory and prior to assignments involving new exposure situations. All Processor Agents involved with operations of the Processing Facility will be trained on the following:

- The full text content of the OSHA Laboratory standard and its appendices
- The location and availability of the Chemical Hygiene Plan
- Permissible exposure limits (PELs) for OSHA regulated substances, or recommended exposure levels for other hazardous chemicals where there is no applicable standard
- Signs and symptoms associated with exposure to hazardous chemicals in the laboratory
- The location and availability of reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals in the laboratory, including, but not limited to, MSDSs.
- Methods and observations used to detect the presence or release of a hazardous chemical. These may include employer monitoring, continuous monitoring devices, and familiarity with the appearance and odor of the chemicals
- The physical and health hazards of chemicals in the laboratory work area
- The measures that workers can take to protect themselves from these hazards, including protective equipment, appropriate work practices, and emergency procedures

<u>Medical Cannabis Specific Training</u>
The Applicant will create a quality training system based on standard operating procedure to educate methodologies, studies, tests, and research for cannabis education training. This will include:

- Identification of cannabis strain varieties for targeted therapy
- Understanding the cultivation of cannabis to educate Licensed Growers for creating cannabis raw material and higher or patient targeted qualities of the material
- Variations of medical cannabis products and how to produce them
- Medical cannabis concentrate recipes and formulations
- Equipment and Technology for producing medical cannabis finished products
- Data sharing with Licensed Dispensaries for targeted therapeutic patient services and medical cannabis finished products

Safe operations of the Processing Facility will be maintained and attendance will be documented and retained for 5 years for the Commission's review.

2. The Applicant will develop standard operating procedure, good manufacturing practices, and a training plan to ensure that any employee involved in processing medical cannabis concentrates and medical cannabis-infused products receives appropriate safety training and signs the correspondent standard operating procedure for each individual chemical. The Applicant will enforce that Material Safety Data Sheets (MSDS) for all chemicals used in the facility are organized in a binder, accessible to all Processor Agents and employees, and placed in multiple locations (e.g. cabinet doors, walls). Processor Agents will be trained to be able to interpret MSDS and labels to identify:

- Chemical name.
- Common name and synonyms.
- Chemical Abstracts Service (CAS) number and other unique identifiers.
- Impurities and stabilizing additives, which are also classified and which contribute to the classification of the chemical.
- The hazard classification of the chemical (e.g., flammable liquid, category).
- Signal word.
- Hazard statement(s).
- Pictograms (the pictograms or hazard symbols may be presented as graphical reproductions of the symbols in black and white or be a description of the name of the symbol (e.g., skull and crossbones, flame).
- Precautionary statement(s).
- Description of any hazards not otherwise classified.
- Name, address, phone number of the manufacturer, importer, or other responsible party, and emergency phone number.
- Recommended use of the chemical (e.g., a brief description of what it actually does, such as flame retardant) and any restrictions on use (including recommendations given by the supplier).

3. The Applicant will develop standard operating procedure, good manufacturing practices, and a training plan that will require employees involved in processing medical cannabis concentrates and medical cannabis-infused products to follow OSHA protocols for handling and storage of all chemicals. This will include:

- Precautions for safe handling, including recommendations for handling incompatible chemicals, minimizing the release of the chemical into the environment, and providing advice on general hygiene practices (e.g., eating, drinking, and smoking in work areas is prohibited).
- Recommendations on the conditions for safe storage, including any incompatibilities. Provide advice on specific storage requirements (e.g., ventilation requirements)
- Necessary first-aid instructions by relevant routes of exposure (inhalation, skin and eye contact, and ingestion).
- Description of the most important symptoms or effects, and any symptoms that are acute or delayed and recommendations for immediate medical care and special

treatment needed, when necessary.

- Recommendations of suitable extinguishing equipment, and information about extinguishing equipment that is not appropriate for a particular situation.
- Advice on specific hazards that develop from the chemical during the fire, such as any hazardous combustion products created when the chemical burns.
- Recommendations on the appropriate response to spills, leaks, or releases, including containment and cleanup practices to prevent or minimize exposure to people, properties, or the environment.
- Use of personal precautions (such as removal of ignition sources or providing sufficient ventilation) and protective equipment to prevent the contamination of skin, eyes, and clothing.
- Emergency procedures, including instructions for evacuations, consulting experts when needed, and appropriate protective clothing.
- Methods and materials used for containment (e.g., covering the drains and capping procedures).
- Cleanup procedures (e.g., appropriate techniques for neutralization, decontamination, cleaning or vacuuming; adsorbent materials; and/or equipment required for containment/clean up)
- OSHA Permissible Exposure Limits (PELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.
- Appropriate engineering controls (e.g., use local exhaust ventilation, or use only in an enclosed system).
- Recommendations for personal protective measures to prevent illness or injury from exposure to chemicals, such as personal protective equipment (PPE) (e.g., appropriate types of eye, face, skin or respiratory protection needed based on hazards and potential exposure).
- Any special requirements for PPE, protective clothing or respirators (e.g., type of glove material, such as PVC or nitrile rubber gloves; and breakthrough time of the glove material).

PPE specific training

To ensure the greatest possible protection for Processor Agents in the workplace, the cooperative efforts of both the Applicant and Processor Agents will help in establishing and maintaining a safe and healthful work environment. The Applicant will be responsible for:

- Performing a "hazard assessment" of the workplace to identify and control physical and health hazards.
- Identifying and providing appropriate PPE for employees.
- Training employees in the use and care of the PPE.
- Maintaining PPE, including replacing worn or damaged PPE.
- Periodically reviewing, updating and evaluating the effectiveness of the PPE program.

Storage of Chemicals

The Applicant will ensure that stored materials will not create a hazard for employees.

The Applicant will make workers aware of such factors as the materials' height and weight, how accessible the stored materials are to the user, and the condition of the containers where the materials are being stored when stacking and piling materials. To prevent creating hazards when storing materials, the standard operating procedure will address the following:

- Keep storage areas free from accumulated materials that cause tripping, fires, or explosions, or that may contribute to the harboring of rats and other pests;
- Place stored materials inside buildings that are under construction and at least 6 feet from hoistways, or inside floor openings and at least 10 feet away from exterior walls;
- Place stored materials outside of buildings that have necessary security equipment and perimeter fencing
- Processor Agents will consider all options such as placing bound material on racks, and secure it by stacking, blocking, or interlocking to prevent it from sliding, falling, or collapsing.

80. Please describe how the Applicant will assign a unique lot number to each lot of medical cannabis concentrate of medical cannabis-infused product. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

[redacted]

The Applicant will retain the records of production and distribution of each lot and of daily checklists to maintain uniformity from lot to lot through the use of a perpetual inventory control system, in a secured, segregated room with limited access control. The Company will retain production and distribution logs in a cloud-based secured-access control system in accordance with state and federal laws.

The Applicant will maintain, independent of the inventory control, a searchable, secure, tamper-evident record of the distribution of all products and transactions that contains the name and address of the recipient, the quantity delivered, and the name, strength, batch number and lot number of the distributed product. The Applicant will retain a record of test methods and test results for each lot. The Company will maintain a duplicate set of all records at a secure, offsite location, for a period of 5 years.

Samples will remain in the segregated and secure inventory control room until retesting or destruction. Labels will be printed and securely placed on each packaged product that includes lot number and expiration date.

81. Please describe how the Applicant will carry out a validation process on the first 10 lots of any new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 9% of the Operational subsection. Maximum length 1,215 words.]

Before any batch from a new process is commercially distributed for use by a qualified patient, the Applicant will carry out a validation process on the first 10 lots of all new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process. This assurance will be obtained from objective information and data from in-house analysis assuring consistent production of a final product that meets attributes relating to identity, strength, quality, purity, and potency.

Process Performance Qualification

For each new product, the Applicant will generate a standard operating procedure that specifies the manufacturing conditions, controls, testing, and expected outcomes and will discuss the following elements in the production log and revise such perpetual inventory control systems for the following:

- The manufacturing conditions, including operating parameters, processing limits, and component (raw material) inputs.
- The data to be collected (presence of hazardous contaminants, cannabinoid profile) and when and how it will be evaluated (plant material, concentrate, infused product).
- Tests to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.
- The sampling plan, including sampling points, number of samples, and the frequency of sampling for each unit operation and attribute.The number of samples should be adequate to provide sufficient statistical confidence of quality both within a batch and between batches. The confidence level selected can be based on risk analysis as it relates to the particular attribute under examination.
- The Processor Supervisor will ensure that the sampling of the first 10 lots of any new medical cannabis concentrate and medical cannabis-infused product will be more extensive than what will be typical during routine production.

The Processor Supervisor will follow standard operating procedure to ensure that the criteria and process performance indicators that allow for a science- and risk-based decision about the ability of the process remain consistent producing quality products consistently. The Applicant will retain results ensuring in all formats, including digital, separately and securely, on- and off-site, and that the criteria include:

- A description of the statistical methods to be used in analyzing all collected data (e.g., statistical metrics defining both intra-batch and inter-batch variability).
- Provision for addressing deviations from expected conditions and handling of nonconforming data. Data should not be excluded without a documented, science-based justification.

- Design of facilities and the qualification of utilities and equipment, personnel training and qualification, and verification of material sources (components and container/closures), if not previously accomplished.
- Status of the validation of analytical methods used in measuring the process, in-process materials, and the product.

Continued Process Verification

The Applicant will provide continual assurance that the process remains in a state of control (the validated state) during commercial manufacture by establishing an ongoing program for detecting unplanned departures from the process, collecting and analyzing product and process data that relate to product quality.

- Production data should be collected to evaluate process stability and capability, and should guard against overreaction to individual events as well as against failure to detect unintended process variability.
- Adherence to the CGMP requirements and Good Laboratory Practices set forth by the World Health Organization, specifically, the collection and evaluation of information and data about the performance of the process, will allow the detection of undesired process variability.
- Variation can also be detected by the timely assessment of defect complaints, out-of specification findings, process deviation reports, process yield variations, batch records, incoming raw material records, and adverse event reports.
- Appropriately trained Processor Agents and Processor Supervisor Agents will be encouraged to provide feedback on process performance.
- Data gathered during this stage might suggest ways to improve and/or optimize the process by altering some aspect of the process or product, such as the operating conditions (ranges and set-points), process controls, component, or in-process material characteristics.
- The Applicant will ensure that the maintenance of the facility, utilities, and equipment is another important aspect of the process ensuring control, and the proper cleaning protocols established and set forth are followed correctly for each new batch or lot.
- Once established, the qualification status must be maintained through routine monitoring, maintenance, and calibration procedures and schedules.
- Documentation at each stage of the process validation lifecycle is essential for effective communication.

In-House Analytical Methodology

At every sampling step, the Applicant will ensure that the product will be tested for safety (presence of hazardous solvents, heavy metals, bacterial or fungal infection) and potency (cannabinoid and terpenoid profile) by Liquid Chromatography, as set forth by the Applicant standard operating procedure, following the Good Laboratory Practices guidelines. The Applicant, Processor Supervisor Agent, and Processor Agent knowledge will depend on accurate and precise measuring techniques used to test and examine the quality of raw plant starting material, in-process materials, finished concentrates and cannabis-infused products.

Although validated analytical methods are not necessarily required during product- and process-development activities or when used in characterization studies, analytical methods

will be scientifically sound to provide specific, sensitive, and accurate insight and information, to be used both internally by the Applicant and externally, when applicable, and provide results for the Applicant and the Commission, or an authorized agent or agency, if requested, that are reliable. The Applicant will verify the data necessary to provide the qualified assurances of proper equipment function for laboratory experiments. The Processor Supervisor Agent will ensure that all procedures for analytical method and equipment maintenance, documentation practices, and calibration practices supporting process-development efforts are to be documented or described.

All necessary records, including certificate of analysis, material purchase order sheets, Processor Agents and Processor Supervisors involved in changes to chain of custody, will be securely stored in a segregated room, and digitally mirrored off-site in a searchable and secured database for a minimum of five years, or two years after the presumed expiration date, whichever comes later.

The Applicant will create standard operating procedure and policies to ensure that all manufactured products pass quality control testing and meet the appropriate standards of the Consumer Product Safety Division. For Quality Assurance, the following elements of a quality system are selected for special emphasis due to their significant effect on product integrity and safety:

It is imperative that consumer products be inspected and tested prior to distribution in order to verify their conformance to established requirements. When a product includes components or subassemblies that are not accessible for inspection and testing, inspection and testing will be undertaken, as applicable, before such items are inaccessibly assembled into parent units. The Applicant will create standard operating procedure and train Processor Agents and personnel to conduct meaningful, objective and uniform inspections and tests.

Except for critical characteristics or when pertinent standards require the inspection and testing of each unit of product, the Applicant may use statistical techniques for inspection, testing, calibration, process control, and technical auditing. Sampling procedures will be in accordance with standard sampling tables, including related procedural precautions. If the Applicant designs alternative sampling plans, documentation of the statistical characteristics and procedural details of such plans will be recorded.

Some material fails to conform to established requirements in manufacturing operations. Such non-conforming material is a potential hazard to safety because it can be easily and inadvertently assembled into end products. Therefore, the Applicant will require that all non-conforming material be clearly labeled and segregated to ensure this material does not make it into the end product.

82. Please describe how the Applicant will establish a standard operating procedure for the methods, equipment, solvents, and gases when processing medical cannabis concentrates and medical cannabis-infused products. *
[Reference 10.62.23.02 of the regulations. Graded 0 to 5 scoring. Weighted 14.5% of the Operational subsection. Maximum length 1,960 words.]

The Applicant will establish standard operating procedure for all the methods, equipment, solvents, and gases used when processing medical cannabis concentrates and medical cannabis-infused products. Every standard operating procedure will be designed following FDA, GLP, GMP and OSHA guidelines and regulations to warrant the safety of all employees, the appropriate performance of all processes, and the quality of the final products.

Methods

Standard procedures of operation will be developed to describe every procedure involved in the manufacturing of medical cannabis concentrates and cannabis-infused products. Standard operating procedure will include but will not be limited to:

- Title (e.g. Preparation of raw plant material for extraction)
- Unique standard operating procedure code that identifies it
- Starting date from which the standard operating procedure is effective
- Name of the person/entity who wrote it
- Name of the person/entity who approved it
- Description of the purpose/policy
- Description of the employees involved and their individual responsibilities
- Stepwise description of the procedure
- Appropriate record keeping

The methods described will include but not be limited to:

- Preparation of raw plant material for extraction
- Extraction
- Post-extraction processing of cannabis oil/concentrate
- In-house and independent testing of the final product to ensure consistent safety and potency
- In-house testing of intermediate step samplings to ensure process validation
- Manufacturing of cannabis concentrates (e.g. wax, shatter, oil, vape liquid, etc.)
- Manufacturing of cannabis-infused products (e.g. soft gels, film strips, controlled-release tablets, etc.)
- Distribution of released cannabis-infused products
- Quarantine and disposal of unusable or contaminated product
- Product stability testing and expiration dating
- Quality assurance product review and release
- Investigation of cannabis-infused product complaints, adverse effects and recalls
- Record keeping and compliance reporting

Equipment

Standard procedure of operation will be developed to ensure the appropriate use and maintenance of the equipment involved in the manufacturing of cannabis concentrates and cannabis-infused products. Equipment will be used according to manufacturer instructions and specification sheets and operator manuals will be available to employees at all times. Employees will be properly trained to operate, calibrate, troubleshoot and housekeep each piece of equipment they need to use to perform their individual tasks. Equipment placement

within the facility will comply with OSHA guidelines and regulations. Equipment will include but will not be limited to:

- Personal protection equipment (PPE, e.g. gloves, lab coats, goggles, respirators)
- Laboratory grade glassware (e.g. flasks, dishes, funnels) and tools (e.g. scissors, tweezers, spatulas).
- Scientific scales of appropriate range
- Mechanical grinders
- Scientific ovens/stoves
- Vacuum ovens
- Supercritical fluid extraction systems
- Rotary evaporators
- Fume hoods
- Vacuum pumps and cold traps
- Heating mantles and baths
- Refrigerators and freezers
- In-house analytical system (e.g. LCMS, UV, FTIR)

Solvents

Standard procedure of operation will be developed to ensure the appropriate handling, storage and disposal of solvents involved in the manufacturing of cannabis concentrates and cannabis-infused products. Solvents will be of analytical grade (min 99% purity) and free of traces of hazardous solvents such as benzene. Safety data sheets will be clearly displayed and available to employees at all times. Employees will be properly trained to handle, store, identify and dispose of any solvent needed to perform their individual tasks. Solvent storage and disposal will comply with OSHA guidelines and regulations. Solvents will include but will not be limited to:

- Anhydrous Ethanol
- 2-Propanol
- HPLC-grade water
- HPLC-grade methanol
- HPLC-grade Acetonitrile
- Acetone

Solvents used on the manufacturing of cannabis concentrates and cannabis-infused products will be reclaimed by vacuum distillation when possible. Solvents used for cleaning or analytical purposes will be reclaimed or stored and disposed according to OSHA guidelines and regulations

Gases

Standard procedure of operation will be developed to ensure the appropriate handling, storage and tank disposal of gases involved in the manufacturing of cannabis concentrates and cannabis-infused products. Safety data sheets will be clearly displayed available to employees at all times. Employees will be properly trained to handle, store, identify and dispose of any gas needed to perform their individual tasks. Gas tank storage, placement and disposal will comply with OSHA guidelines and regulations. Gases will include but will not be limited to:

- Carbon dioxide (CO_2)
- Nitrogen (N_2)
- Compressed filtered air

Extraction of cannabis oil from raw plant material using gases (e.g. CO_2, butane) will be performed in a "closed loop" process to prevent release of flammable or hazardous gases. Closed loop systems will include a reclamation pump and tank. Gases used for purging, drying or analytical purposes (nitrogen and compressed filtered air) will not be reclaimed.

Before any batch from a new process is commercially distributed for use by a qualified patient, the Applicant will have gained a high degree of assurance in the performance of the manufacturing process such that it will consistently produce a final product that meets those attributes relating to identity, strength, quality, purity, and potency. This assurance will be obtained from objective information and data from in-house analysis (see below).

Process Performance Qualification

For each new product, the Applicant will generate a standard operating procedure that specifies the manufacturing conditions, controls, testing, and expected outcomes and will discuss the following elements in the production log and revise such perpetual inventory control systems for the following:

- The manufacturing conditions, including operating parameters, processing limits, and component (raw material) inputs.
- The data to be collected (presence of hazardous contaminants, cannabinoid profile) and when and how it will be evaluated (plant material, concentrate, infused product).
- Tests to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.
- The sampling plan, including sampling points, number of samples, and the frequency of sampling for each unit operation and attribute.
- The number of samples should be adequate to provide sufficient statistical confidence of quality both within a batch and between batches. The confidence level selected can be based on risk analysis as it relates to the particular attribute under examination.
- **The Processor Supervisor Agent will ensure that the sampling of the first 10 lots of any new medical cannabis concentrate and medical cannabis-infused product will be more extensive than what will be typical during routine production.**

The Processor Supervisor Agent will follow standard operating procedure to ensure that the criteria and process performance indicators that allow for a science- and risk-based decision about the ability of the process remain consistent and produce quality products consistently. The Applicant will retain results ensuring in all formats, including digital, separately and securely, on- and off-site, and that the criteria include:

- A description of the statistical methods to be used in analyzing all collected data (e.g., statistical metrics defining both intra-batch and inter-batch variability).
- Provision for addressing deviations from expected conditions and handling of

nonconforming data. Data should not be excluded from further without a documented, science-based justification.

- Design of facilities and the qualification of utilities and equipment, personnel training and qualification, and verification of material sources (components and container/closures), if not previously accomplished.
- Status of the validation of analytical methods used in measuring the process, in-process materials, and the product.

Continued Process Verification

The Applicant will provide continual assurance that the process remains in a state of control (the validated state) during commercial manufacture by establishing an ongoing program for detecting unplanned departures from the process and collect and analyze product and process data that relate to product quality.

- Production data should be collected to evaluate process stability and capability, and should guard against overreaction to individual events as well as against failure to detect unintended process variability.
- Adherence to the CGMP requirements and Good Laboratory Practices set forth by the World Health Organization, specifically, the collection and evaluation of information and data about the performance of the process, will allow the detection of undesired process variability.
- Variation can also be detected by the timely assessment of defect complaints, out-of specification findings, process deviation reports, process yield variations, batch records, incoming raw material records, and adverse event reports.
- Appropriately trained Processor Agents and Processor Supervisor Agents will be encouraged to provide feedback on process performance.
- Data gathered during this stage might suggest ways to improve and/or optimize the process by altering some aspect of the process or product, such as the operating conditions (ranges and set-points), process controls, component, or in-process material characteristics.
- The Applicant will ensure that the maintenance of the facility, utilities, and equipment is another important aspect of ensuring that the process remains in control, and the proper cleaning protocols established and set forth are followed correctly for each new batch or lot.
- Once established, the qualification status must be maintained through routine monitoring, maintenance, and calibration procedures and schedules.
- Documentation at each stage of the process validation lifecycle is essential for effective communication.

In-House Analytical Methodology

At every sampling step, the Applicant will ensure that the product will be tested for safety (presence of hazardous solvents, heavy metals, bacterial or fungal infection) and potency (cannabinoid and terpenoid profile) by Liquid Chromatography, as set forth by the Applicant standard operating procedure, following the Good Laboratory Practices guidelines. The Applicant, Processor Supervisor Agent, and Processor Agent knowledge will depend on accurate and precise measuring techniques used to test and examine the quality of raw plant starting material, in-process materials, and finished concentrates and cannabis-infused products.

Although validated analytical methods are not necessarily required during product- and process-development activities or when used in characterization studies, analytical methods will be scientifically sound to provide specific, sensitive, and accurate insight and information, to be used both internally by the Applicant and externally, when applicable, and provide results for the Applicant and the Commission, or an authorized agent or agency, if requested, that are reliable. The Applicant will verify the data necessary to provide the qualified assurances of proper equipment function for laboratory experiments. The Processor Supervisor Agent will ensure that all procedures for analytical method and equipment maintenance, documentation practices, and calibration practices supporting process-development efforts are to be documented or described.

All necessary records, including certificate of analysis, material purchase order sheets, Processor Agents and Processor Supervisor Agents involved in changes to chain of custody, will be securely stored in a segregated room, and digitally mirrored off-site in a searchable and secured database for a minimum of five years, or two years after the presumed expiration date, whichever comes later.

The Applicant will create standard operating procedure and policies to ensure that all manufactured products pass quality control testing and meet the appropriate standards of the Consumer Product Safety Division. For Quality Assurance, the following elements of a quality system are selected for special emphasis due to their significant effect on product integrity and safety:

It is imperative that consumer products be inspected and tested prior to distribution in order to verify their conformance to established requirements. When a product includes components or subassemblies that are not accessible for inspection and testing, inspection and testing will be undertaken, as applicable, before such items are inaccessibly assembled into parent units. The Applicant will create standard operating procedure and train Processor Agents and personnel to conduct meaningful, objective and uniform inspections and tests.

Except for critical characteristics or when pertinent standards require the inspection and testing of each unit of product, the Applicant may use statistical techniques for inspection, testing, calibration, process control, and technical auditing. Sampling procedures will be in accordance with standard sampling tables, including related procedural precautions. If the Applicant designs alternative sampling plans, documentation of the statistical characteristics and procedural details of such plans will be recorded.

In most manufacturing operations some material fails to conform to established requirements. Such non-conforming material is a potential hazard to safety because it can be easily and inadvertently assembled into end products. Therefore, the Applicant will require that all non-conforming material be clearly labeled and segregated to ensure this material does not make it into the end product.

83. Please describe how, if the Applicant uses a solvent-based extraction method, the solvents will be at least 99 percent pure. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant plans to use carbon dioxide gas extraction exclusively. If the Applicant were to use a solvent-based extraction method, **the Applicant will assure the solvents will be at least 99 percent pure.** These will be handled and stored following manufacturer instructions, MSDS specifications, and OSHA guidelines and regulations and Good Laboratory Practices. The Applicant will use solvents in a closed-loop extraction system designed to recover the solvents. At such a time as the Applicant decides to use solvent based processing, the Applicant will develop appropriate relationships with industrial suppliers and ensure the purity of the solvents.

84. If the Applicant uses solvent extraction, please describe how the standard operating procedure of an Applicant will require the use of solvents in a professional grade, closed-loop extraction system designed to recover the solvents. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant plans to use carbon dioxide gas extraction exclusively. If the Applicant were to use a solvent-based extraction method, the Applicant will assure the solvents will be at least 99 percent pure. These will be handled and stored following manufacturer instructions, MSDS specifications, and OSHA guidelines and regulations and Good Laboratory Practices.

85. Please describe how, if the Applicant uses solvent extraction, the standard operating procedure of an Applicant will require work in a spark-free environment with proper ventilation. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 5% of the Operational subsection. Maximum length 675 words.]

The Applicant will NOT require a spark-free environment due to the methodology of extractions and solvents used being CO2, a non-flammable gas. In the future if the Applicant decides to use solvents that require a spark-free environment, the Applicant will create a standard operating procedure establishing the additional precautions to be taken in cases when liquid solvents and gases are capable of producing a flammable atmosphere under the conditions of use. These safety measures exclude smoking, open flames, arcs and spark-producing equipment from the area. Appropriate ventilation will be enforced to provide or maintain oxygen, to dilute or remove contaminants such as carbon dioxide and other toxic or explosive gases and to cool spaces, making them more comfortable for all employees while performing their assigned duties.

Fume hoods and other ventilation devices will be used to avoid exposure to airborne substances and to prevent their escape into the working atmosphere. Laboratory chemical hoods are the most important components used to protect laboratory personnel from exposure to hazardous chemicals. Therefore, the standard operating procedure will include the following practices for hoods and ventilation systems:

Chemical hoods

- Toxic or corrosive chemicals that require vented storage should be stored in vented

cabinets instead of in a chemical hood.

- Chemical waste will not be disposed of by evaporation in a chemical hood.
- Keep chemical hood areas clean and free of debris at all times.
- Solid objects and materials, such as paper, should be prevented from entering the exhaust ducts as they can reduce the airflow.
- Chemical hoods should be maintained, monitored and routinely tested for proper performance.

Ventilation system

- Heating and cooling should be adequate for the comfort of workers and operation of equipment.
- A negative pressure differential will exist between the amount of air exhausted from the laboratory and the amount supplied to the laboratory to prevent uncontrolled chemical vapors from leaving the laboratory.
- Local exhaust ventilation devices will be appropriate to the materials and operations in the laboratory.
- The air in the laboratory will be continuously replaced so that concentrations of odoriferous or toxic substances do not increase during the workday.
- Laboratory air will not be recirculated but exhausted directly outdoors.
- Air pressure will be negative with respect to the rest of the building. Local capture equipment and systems should be designed only by an experienced engineer or industrial hygienist.
- Ventilation systems will be inspected and maintained on a regular basis. There will be no areas where air remains static or areas that have unusually high airflow velocities.

Before work begins, all employees will be provided with proper training that includes how to use the ventilation equipment, how to ensure that it is functioning properly, the consequences of improper use, what to do in the event of a system failure or power outage, special considerations, and the importance of signage and postings.

86. Please describe how, if the Applicant uses solvent extraction, the standard operating procedure of an Applicant will require following all applicable OSHA regulations, and local fire, safety, and building codes in the processing and storages of the solvents. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant plans to use carbon dioxide gas extraction exclusively. **The Applicant will follow all applicable OSHA regulations, and local fire, safety, and building codes in the processing and storages of any solvents.** If the Applicant decides to use solvent based processing that is flammable, the Applicant will hire knowledgeable personnel who will advise on the appropriate standard operating procedure and potential changes to the facility.

The Application will adhere to the following guidelines for the processing and storage of chemicals:

- Solvents will not be stored in the chemical hood, on the floor, in areas of egress, on the

bench top, or in areas near heat or in direct sunlight.

- Laboratory-grade, flammable-rated refrigerators and will be used to store sealed chemical containers of flammable liquids that require cool storage.
- Flammable solvents will be stored in a spark-free environment and in approved flammable-liquid containers and storage cabinets.
- Grounding and bonding will be used to prevent static charge buildups when dispensing solvents.
- Chemical storage and handling rooms will be controlled-access areas with proper ventilation, appropriate signage, diked floors, and fire suppression systems.
- Each waste type will be stored in a compatible container pending transfer or disposal.
- Waste containers will be clearly labeled and kept sealed when not in use.
- Non-explosive electrical systems, grounding and bonding between floors and containers, and non-sparking conductive floors and containers will be used in the central waste accumulation area.
- Fire suppression systems, specialized ventilation systems, and dikes will be installed in the central waste accumulation area.
- Chemicals, reAgents, and solutions will be labeled to indicate identity, expiry date and specific storage instructions.

87. Please describe how, if the Applicant uses carbon dioxide gas extraction, the standard operating procedure will require every vessel be rated to a minimum of 900 pounds per square inch. If using propane, the vessel should be rated to a minimum of 600 pounds per square inch. If using butane, the vessel should be rated to a minimum of 200 pounds per square inch. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 4% of the Operational subsection. Maximum length 540 words.]

The Applicant anticipates using carbon dioxide gas extraction exclusively. The Applicant's standard operating procedure will specifically require every carbon dioxide vessel to be rated to a minimum of 900 pounds per square inch (psi). The Applicant has selected an extraction machine that exceeds these requirements, which will be the SFE Bio-Botanical extraction system from Waters. The machine has vessels rated to pressures up to 8700 psi. If the Applicant were to use propane and/or butane gas extraction for the manufacturing of different cannabis concentrates and cannabis infused-products, the standard operating procedure would require every vessel be rated to a minimum of 600 psi in the case of propane and 200 psi in the case of butane. The Applicant's standard operating procedure also stipulate the use of professional grade gases in a closed-loop system, following all applicable OSHA regulations, and local fire, safety and building codes.

According to OSHA's Laboratory standard, a "compressed gas" (1) is a gas or mixture of gases in a container having an absolute pressure exceeding 40 pounds per square inch (psi) at 70°F (21.1°C); or (2) is a gas or mixture of gases having an absolute pressure exceeding 104 psi at 130°F (54.4°C) regardless of the pressure at 70°F (21.1°C); or (3) is a liquid having a vapor pressure exceeding 40 psi at 100°F (37.8°C) as determined by ASTM (American Society for Testing and Materials) D-323-72, [29 CFR 1910. 1450(c)(1)-(3)].

The Processor Supervisor will ensure that compressed gases are supplied either through fixed piped gas systems or individual cylinders of gases. The Applicant will include compressed gases in their inventory of chemicals in their Chemical Hygiene Plan. Compressed gases contained in cylinders vary in chemical properties, ranging from inert and harmless to toxic and explosive. The high pressure of the gases constitutes a serious hazard in the event that gas cylinders sustain physical damage and/or are exposed to high temperatures. Leaking inert gases (e.g., nitrogen) can quickly displace air in a large area creating an oxygen-deficient atmosphere; toxic gases can poison the air; and flammable or reactive gases can lead to fire and exploding cylinders.

The Applicant will store, handle, and use compressed gases in accordance with OSHA's Compressed Gases standard (29 CFR 1910.101) and Pamphlet P-1-1965 from the Compressed Gas Association.

- All cylinders whether empty or full must be stored upright.
- Cylinders should never be dropped or allowed to strike each other with force.
- Cylinders will only be transported with protective caps in place and will not be rolled or dragged.

88. Please describe how, if the Applicant uses carbon dioxide gas extraction, the standard operating procedure will follow all applicable OSHA regulations, and local fire, safety, and building codes. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will create standard operating procedure to ensure that when using carbon dioxide gas for botanical extractions, all Processor Agents will follow all applicable OSHA regulations for local fire, safety, and building codes. These standards will include but are not limited to the following:

- Inspection of compressed gas cylinders. Each employer shall determine that compressed gas cylinders under his control are in a safe condition to the extent that this can be determined by visual inspection. Visual and other inspections shall be conducted as prescribed in the Hazardous Materials Regulations of the Department of Transportation (49 CFR parts 171-179 and 14 CFR part 103). Where those regulations are not applicable, visual and other inspections shall be conducted in accordance with Compressed Gas Association Pamphlets C-6-1968 and C-8-1962, which is incorporated by reference as specified in Sec. 1910.6.
- The in-plant handling, storage, and utilization of all compressed gases in cylinders, portable tanks, rail tankcars, or motor vehicle cargo tanks shall be in accordance with Compressed Gas Association Pamphlet P-1-1965, which is incorporated by reference as specified in Sec. 1910.6.
- Compressed gas cylinders, portable tanks, and cargo tanks shall have pressure relief devices installed and maintained in accordance with Compressed Gas Association Pamphlets S-1.1-1963 and 1965 addenda and S-1.2-1963.
- The Applicant will be knowledgeable about OSHA's Portable Fire Extinguishers standard, 29 CFR 1910.157, and train Processor Agents to be aware of the different fire

extinguisher types and how to use them, including the placement, maintenance, and testing of portable fire extinguishers including Class B fire risk.

89. Please describe how, if the Applicant uses carbon dioxide gas extraction, the standard operating procedure will use carbon dioxide that is at least 99 percent pure. *

[Reference 10.62.23.02 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will be using carbon dioxide gas extraction to create medical cannabis finished products and will create a standard operating procedure that will ensure the carbon dioxide is 99% pure. The Applicant will select a specialty gas supplier that will be required, per the Applicant's standard operating procedure, to supply a certificate of analysis before any carbon dioxide cylinders are purchased. The certificate of analysis will include the following information:

- Description of the synonym formula
- Gas data such as molecular weight and density
- Specific volume
- Safety information and shipping information
- Gas grade will be research purity and parts per million specifications of elements such as:
  - Carbon Monoxide < 0.2 ppm
  - Hydrogen < 1 ppm
  - Nitrogen < 5 ppm
  - Oxygen < 2 ppm
  - Water < 2 ppm
  - THC as Methane < 4 ppm

The Applicant will ensure that each carbon dioxide cylinder to be purchased will be at least 99.999% pure to utilize for botanical extractions. The Applicant will receive the certificate of analysis from the specialty gas supplier and confirm that the carbon dioxide purity requirement is met.

10.62.23.03

90. Please describe how, upon successful completion of a validation process, the Applicant will use an independent testing laboratory that has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement. *

[Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 5% of the Production Control subsection. Maximum length 340 words.]

The Applicant will provide continual assurance that the process remains in a state of control (the validated state) during commercial manufacture by establishing an ongoing program for detecting unplanned departures from the process and collect and analyze product

and process data that relate to product quality. This Applicant will utilize this procedure in order to validate the medical cannabis product.

Upon successful completion of the validation process of the medical cannabis products, the Applicant will carefully select an independent testing laboratory that has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement. The Applicant will require the laboratory to have an agent obtain samples according to a statistically valid sampling method for each lot to analyze the samples according to the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP), or a scientifically valid methodology that is equal or superior to that of the AHP monograph.

The selected lab will be on a basis of whether the lab is state-certified, incorporates the correct testing procedures with the correct equipment, and has the qualified credentials to test medical cannabis equal or superior to the AHP monograph. No independent testing laboratory may handle, test, or analyze cannabis products unless the independent testing laboratory has been registered by the Commission and is independent from all other persons and entities involved in the medical cannabis industry. The laboratory will be required to issue a certificate of analysis for each test, with supporting data, and report whether the chemical profile conforms to a variety of cannabinoids and terpenes, and that the presence of contaminants does not exceed the levels as required by the FDA.

91. Please describe how, upon successful completion of a validation process, the Applicant will use an independent testing laboratory to have an agent of the independent testing laboratory obtain samples according to a statistically valid sampling method for each lot. *

[Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 2.5% of the Production Control subsection. Maximum length 170 words.]

The Processing Supervisor will ensure that an agent of the independent testing laboratory will obtain and prepare samples according to a statistically valid sampling method for each lot, according to the most current version of the Cannabis Inflorescence Monograph published by the American Herbal Pharmacopeia (AHP), or a scientifically valid methodology that is equal or superior to that of the AHP monograph. Crosby and Patel's *General Principles of Good Sampling Practice* will be followed.

Several samples will be taken from various parts of each lot, and their results compared. If not within acceptable standards for precision, the following will be re-evaluated:

- Is the sample is representative and homogeneous
- Is the testing method used based on sound scientific principles and has it been shown to be robust and reliable for the sample type
- Are the instruments used calibrated property
- Is the person carrying out the analysis is qualified and properly trained, and
- Is the integrity of the calculation used to arrive at the result is correct and statistically

sound.

92. Please describe how, upon successful completion of a validation process, the Applicant will use an independent testing laboratory to analyze the samples according to (1) the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP) or (2) a scientifically valid methodology that is equal or superior to that of the AHP monograph. *

(1) [Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]
(2) [Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

1. The independent testing laboratory chosen by the Applicant will be required to be well versed in the current version of the AHP cannabis inflorescence monograph, as will be the Processing Supervisor. The lab will be required to use Gas Chromatography (GC) or High Performance Liquid Chromatography (HPLC), following the AHP protocols for sample preparation, decarboxylation, reagent preparation, chromatographic conditions, standards solution stability, and sample application.

2. If a methodology other than one described in the AHP monograph is to be used, the Processing Supervisor and an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, such as the American Association for Laboratory Accreditation (A2LA) will evaluate the scientific validity of the method to ensure that it is equal or superior to that of the AHP monograph.

93. Please describe how, upon successful completion of a validation process, the Applicant will use an independent testing laboratory that, in the event of a test result which falls out of specification, will follow their standard operating procedure to confirm or refute the original result. *

[Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

If a test result falls out of specification, the laboratory will follow their standard operating procedure to confirm or refute the original result. If the Applicant receives results that do not meet specifications, the Applicant will rework or reprocess the batch to be retested by the independent testing laboratory to ensure all required specifications are met, issue a certificate of analysis, and destroy the remains of the sample after analysis.

94. Please describe how, upon successful completion of a validation process, the Applicant will use an independent testing laboratory to destroy the remains of the sample of medical cannabis after analysis is completed. *

[Reference 10.62.23.03 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]

Under the terms of all agreements made with independent testing laboratories, the Applicant will require those laboratories to destroy the remains of any sample of medical cannabis after analysis is completed through incineration or other appropriate method to render it unusable. The Processor Supervisor will record the destruction of the sample by the laboratory into the inventory control system.

10.62.23.04

95. Please describe how the Applicant will assure that an independent testing laboratory will issue a certificate of analysis for each lot, with supporting data, to report whether or not the lot conforms to the specifications for the lot of the following compounds: Δ9-Tetrahydrocannabinol (THC), Tetrahydrocannabinolic Acid (THCA), Cannabidiol (CBD), Cannabidiolic Acid (CBDA), the terpenes described in the most recent version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP), Cannabigerol (CBG), and Cannabinol (CBN). *

[Reference 10.62.23.04 of the regulations. Graded Yes or No. Weighted 10% of the Production Control subsection. Maximum length 675 words.]

The Applicant will use only accredited independent testing laboratories that issue a certificate of analysis for each batch, with supporting data, to report whether the chemical profile of the batch conforms to a variety of cannabinoids and terpenes, and that the presence of contaminants does not exceed the levels as required by the AHP monograph.

The Processing Supervisor will discuss the need for certificates of analysis and supporting data for each batch tested with the laboratory as a condition of their contract, and will inspect the certificates that are issued to be sure that the following compounds are quantified and that the data supports the concentrated calculated:

(a) Delta9-Tetrahydrocannabinol (THC);
(b) Tetrahydrocannabinolic Acid (THCA);
(c) Cannabidiol (CBD);
(d) Cannabidiolic Acid (CBDA);
(e) The terpenes described in the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
(f) Cannabigerol (CBG); and
(g) Cannabinol (CBN)

If a test result falls out of specification, the laboratory shall confirm or refute the original result. If the Applicant receives results that do not meet specifications, the Processor Supervisor will rework or reprocess the batch. The batch will be retested by the independent testing laboratory to ensure that all required specifications are met, issue a certificate of analysis, and destroy the remains of the sample after analysis is completed.

Samples from batches of all medical cannabis will be placed into a long-term room temperature stability program to confirm and eventually extend any expiration date previously assigned utilizing accelerated stability data. At least one sample batch per year of all distributed packaged medical cannabis products shall be placed into a long-term room temperature stability program at an approved independent testing laboratory. The shelf-life

of all products will be independently validated by ongoing stability testing. Product shelf life specifications will include all required storage conditions including storage at the licensed facilities once sealed, during transport, and with the patient or qualified caregiver.

All stability results shall be promptly evaluated upon completion of each testing interval. Results will be tabulated as part of this evaluation and reviewed for adverse trends. Stability failures shall be promptly investigated. This written investigation including any necessary corrective actions shall be reviewed by the Processor Supervisor Agent and approved by the Applicant and all necessary adjustments of the standard operating procedure will be updated and implemented.

Appropriate stability studies may be dropped from this stability program based upon the deletion of products from the marketplace, revisions in product formula and packaging, or other justifiable reasons as determined by the Company or the Commission. All medical cannabis distributed will be stable for a minimum of 60 days after being opened as specified in the label directions and storage conditions of light, temperature, and humidity. All stability protocols, reports and associated testing results required by this procedure shall be retained for at least five years after completion of the last testing interval for that product.

The Processor Supervisor Agent will revise the perpetual inventory control system to prepare the tested product for the next stage after quarantine and maintain all records, including digital, in a secure and separate storage area, and cloud-based server space with searchable log. The production log for each sample will include, but not limited to:

- Certificate of analysis and all procedures,
- Processor Agent's initial and/or signature;
- Processor Supervisor Agent;
- Maintenance logs for equipment used;
- Transportation Licensee and agent information relevant to product transportation; and
- Relevant information of independent testing laboratory Licensee

96. Please describe how the Applicant will assure that an independent testing laboratory will issue a certificate of analysis for each lot, with supporting data, to report that the presence of the following contaminants do not exceed levels as required by the AHP monograph: any residual solvent or processing chemicals; foreign material such as hair, insects, or any similar or related adulterant; any microbiological impurity, including total aerobic microbial count (TAMC), total yeast mold count (TYMC), *P. aeruginosa*, *Aspergillus spp.*, *S. aureus*, *Aflatoxin B1, B2, G1,* and *G2,* and *Ochratoxin A.*; and whether the batch is within specification for odor and appearance. Please also describe how residual levels of volatile organic compounds (VOCs) will be below the specifications as set by the United States Pharmacopeia (USP Chapter 467). *
[Reference 10.62.23.04 of the regulations. Graded Yes or No. Weighted 10% of the Production Control subsection. Maximum length 675 words.]

The Applicant will use an independent testing laboratory that has adopted a standard operating procedure to test medical cannabis and is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition

Arrangement. No independent testing laboratory may handle, test, or analyze cannabis or cannabis products unless the independent testing laboratory has been registered by the Commission, is independent from all other persons and entities involved in the medical cannabis industry, is accredited by an accreditation body or has a provisional registration from the Commission, and has established standard operating procedure that provide for adequate chain of custody controls for samples transferred to the independent testing laboratory for handling, storing, testing, and destroying.

An independent testing laboratory will issue a certificate of analysis for each lot, with supporting data, to report that the presence of the following contaminants do not exceed the levels as required by the AHP monograph:

(a) Any residual solvent or processing chemicals;
(b) Foreign material such as hair, insects, or any similar or related adulterant;
(c) Any microbiological impurity, including:
(i) Total aerobic microbial count (TAMC);
(ii) Total yeast mold count (TYMC);
(iii) P. aeruginosa;
(iv) Aspergillus spp.;
(v) S. aureus;
(vi) Aflatoxin B1, B2, G1, and G2; and
(vii) Ochratoxin A

An independent testing laboratory will issue a certificate of analysis for each lot, with supporting data, to report that residual levels of volatile organic compounds (VOCs) shall be below the specifications as set by the United States Pharmacoepeia (USP Chapter 467).

An independent testing laboratory will issue a certificate of analysis for each lot, with supporting data, to report whether the batch is within specification for odor and appearance. If a test result falls out of specification, the laboratory shall confirm or refute the original result. If the Applicant receives results that do not meet specifications, the Processor Supervisor will rework or reprocess the batch. The batch will be retested by the independent testing laboratory to ensure that all required specifications are met, issue a certificate of analysis, and destroy the remains of the sample after analysis is completed.

Samples from batches of all medical cannabis will be placed into a long-term room temperature stability program to confirm and eventually extend any expiration date previously assigned utilizing accelerated stability data. At least one sample batch per year of all distributed packaged medical marijuana products shall be placed into a long-term room temperature stability program at an approved independent testing laboratory. The shelf-life of medical cannabis will be independently validated by ongoing stability testing. Product shelf life specifications will include all required storage conditions including storage at the licensed facilities once sealed, during transport, and with the patient or qualified caregiver.

All stability results shall be promptly evaluated upon completion of each testing interval. Results will be tabulated as part of this evaluation and reviewed for adverse trends. Stability failures shall be promptly investigated. This written investigation including any necessary

corrective actions shall be reviewed by the Processor Supervisor and approved by the Applicant and all necessary adjustments of the standard operating procedure will be updated and implemented.

Appropriate stability studies may be dropped from this stability program based upon the deletion of products from the marketplace, revisions in product formula and packaging or other justifiable reasons as determined by the Company, or the Commission. All medical cannabis and medical cannabis products will be distributed will be stable for a minimum of 60 days after being opened as specified in the label directions and storage conditions of light, temperature and humidity. All stability protocols, reports and associated testing results required by this procedure shall be retained for at least five years after completion of the last testing interval for that product.

The Processor Supervisor will revise the perpetual inventory control system to prepare the tested product for the next stage after quarantine and maintain all records, including digital, in a secure and separate storage area, and cloud-based server space with searchable log.

10.62.23.05

97. Please describe how, if an Applicant/Licensee, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the Applicant/Licensee could assign an expiration date to the lot. *

[Reference 10.62.23.05 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will, upon review of the certificate of analysis determines the lot meets the specification for the product, the Applicant could assign an expiration date to the lot by recording this information into the perpetual inventory control system. The Applicant will routinely evaluate the stability of its cannabinoid concentrates and packaged medical cannabis finished products utilizing appropriate testing measures.

The stability of each lot in each dosage form and packaging format of distributed medical cannabis product shall be confirmed by testing at a licensed independent testing laboratory. This laboratory will have standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the international Laboratory accreditation Cooperation (ILAC) Mutual recognition Arrangement. Testing will be done using statistically valid sampling methods for each lot. Samples will be analyzed according to the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP). Testing will ensure each medical cannabis finished product will be packaged in such a manner to meet optimal conditions throughout their labeled shelf life.

If the Processor Supervisor, upon review of the certificate of analysis by the independent testing laboratory, determines that a lot meets the specification for the product, the agent will assign an expiration date to the lot, revise lot status in the perpetual inventory system, and prepare the product for release into distribution.

No finished medical cannabis product will leave the premises or be released for distribution until all proper testing and reporting has been confirmed and all status updates are recorded in the perpetual inventory system.

98. Please describe how, if an Applicant/Licensee, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the Applicant/Licensee could release the lot for distribution. *

[Reference 10.62.23.05 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

Upon receipt of the certificate of analysis from the independent testing laboratory, the Processor Supervisor will examine the analysis for each lot, with supporting data, to report whether the chemical profile of each lot conforms to the specifications of the lot for the following compounds:

- Cannabidiol
- Cannabidiol Acid
- Cannabidiolic Acid
- Cannabigerol
- Cannabinol
- Tetrahydrocannabinol
- Terpenes described in the most current version of the cannabis influorescense monograph published by the American Herbal Pharmacopeia
- D9-THC (Delta-9 Tetrahydrocannabinol)
- D8-THC (Delta-9 Tetrahydrocannabinol)
- THCA (Tetrahydocannabivarin Acid)
- THCVA(Tetrahydrocannabivarin – Acid)
- CBC(Cannabichromene)
- CBDV(Cannabidivarin)
- CBDVA(Cannabidivarin - Acid)
- CBG(Cannabigerol)
- CBGA(Cannabigerol – Acid)
- CBGV(Cannabigerovarin)
- CBNV(Cannabinovarin)

The Applicant shall confirm the presence of any residual solvents, contaminants, or any foreign matter such as hair, insects, or similar adulterants does not exceed the levels as required by the AHP monograph. The amount of residual levels of any volatile organic compounds will also be examined for compliance with the specifications set by the United States Pharmacoepia.

<u>Microbiological Impurities</u>

The certificate of analysis will confirm that each batch is checked for the following:

- Total aerobic microbial count

- Total yeast mold count
- P. Aeruginisa
- Aspergillus spp
- S. aureus
- Aflatoxin B1, B2, G1 and G2
- Ochratoxin A

A thorough inspection will be performed at the premises. All medical cannabis will be examined for any irregularities in odor or appearance such as pest damage, mold, mildew, spidermites. Upon determination that the product meets all required specifications, it will be released into distribution and logged into the perpetual inventory control system.

99. Please describe how, if an Applicant/Licensee, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the Applicant/Licensee could revise the status of the lot in the inventory control. *

[Reference 10.62.23.05 of the regulations. Graded Yes or No. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Processor Supervisor or Processor Agent will assign an expiration date to the lot by entering into the perpetual inventory control system the length of time after final packaging during which the medical cannabis is fit for its intended use when stored and used according to its labeling. As the receiving Licensee, the Processor Agent for Product Procurement will, upon determining each item has passed inspection, change the product's status in the BioTrackTHC inventory control system from "uninspected products not to be distributed" to " ready for distribution." The Product Procurement agent will then move the products from the Uninspected Products section of the secure room to the "READY FOR DISTRIBUTION" section.

- All packaged medical marijuana products at the manufacturing facility will be stored under quarantine until the completion of all laboratory testing and properly released by Quality Assurance for distribution.
- Upon its approval for distribution, all packaged medical marijuana products will be securely and separately stored under appropriate environmental conditions consistent with its shelf life specifications and labeling.
- The oldest lot of an approved product with shortest expiration dating will be distributed.
- A distribution history for each lot of medical marijuana product including the brand name, strength, dosage form, receiving site, date and quantity shipped shall be maintained to facilitate its recall, if necessary.
- The perpetual inventory control system will begin allowing the release of products after successful certificate of analysis only after the Processor Supervisor has revised quarantine batch and "ready for distribution" label has been applied.

100. Please describe how, if an Applicant/Licensee receives test results that the lot does not meet specifications, the Applicant/Licensee could rework or reprocess the lot according to their standard operating procedure. *

[Reference 10.62.23.05 of the regulations. Graded 0 to 5 scoring. Weighted 2% of the Operational subsection. Maximum length 270 words.]

The Applicant will create standard operating procedure that state that if the lot receives test results that do not conform to the appropriate standards or specifications, the Applicant will reworked or reprocess back into the manufacturing process and repeat a crystallization step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process. Possible issues and remedies shall include:

- Active pharmaceutical ingredients, cannabinoids, terpenes, and other content intermediates that do not conform the specifications should be subjected to reprocessing or reworking.
- Perform an investigation before deciding the reprocessing of a batch.
- Based on the nature of the problem or reasons for failure QA, will recommend the Process Development Lab to generate the procedure for reprocessing.
- Quality Assurance department will review the Reprocessing procedure.
- Based on the reprocessing procedure, Process Development lab and production department should prepare the Batch Production Control Record, which will be approved by Quality Assurance for implementation.
- Process Development lab and Quality Assurance will monitor the yield and quality of the batch taken for Reprocessing.
- Allot a batch number to the reprocessed as per the Batch numbering system SOP.
- If the batch complies with the specifications then samples will be retained for stability studies.
- After the completion of 3 months of stability studies, the approved reprocessed batch is released.
- Reprocessed material shall not be distributed to the regulatory market.
- If the batch is not approved after reprocessing or rework, details will be forwarded to the Process Development lab for further action and reprocessing.
- If Process Development lab is unable to develop a procedure for reprocessing then the material will be destroyed by incineration.

101. Please describe how the reworked or reprocessed lot will be resampled and retested by the independent testing laboratory to meet all required specifications. *

[Reference 10.62.23.05 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will create a standard operating procedure to ensure that all reworked or reprocessed lots will be resampled and retested by the third party independent testing laboratory. Sampling and testing of each lot of medical cannabis finished products shall be conducted with a statistically significant number samples and with acceptable methodologies to assure all lots are adequately assessed for consistent cannabinoid profiles and contaminants.

102. Please describe how the Applicant will retain every certificate of analysis. *
[Reference 10.62.23.05 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

An independent testing laboratory will issue a certificate of analysis for each batch, with supporting data, to report whether the profile of the batch conforms to a variety of cannabinoids and terpenes, and that the presence of contaminants does not exceed the levels as required by the AHP monograph. The Applicant will retain every certificate of analysis through a perpetual inventory control system that digitally stores this information for referencing.

10.62.23.06

103. Please describe how the Applicant will provide a sample from each released lot to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to (1) ensure product potency and purity and (2) provide support for expiration dating. *
(1) [Reference 10.62.23.06 of the regulations. Graded Yes or No. Weighted 2.5% of the Production Control subsection. Maximum length 170 words.]
(2) [Reference 10.62.23.06 of the regulations. Graded Yes or No. Weighted 2.5% of the Production Control subsection. Maximum length 170 words.]

1. The Processor Supervisor will hold medical cannabis in a secure, segregated storage area until released for distribution. The Processor Agent will provide a retained sample from each released lot to an independent testing laboratory sufficient to perform stability testing at 6-month intervals **to ensure product potency and purity**, and provide support for expiration dating. The Applicant will retain every certificate of analysis.

2. The Processor Supervisor will hold medical cannabis in a secure, segregated storage area until released for distribution. The Company will provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to ensure product potency and purity, and **provide support for expiration dating**. The Applicant will retain every certificate of analysis.

104. Please describe how the Applicant will retain a sample from each released lot (1) sufficient to provide for follow-up testing if necessary, and will (2) properly store the sample for 1 year past the date of expiration of the lot. *
(1) [Reference 10.62.23.06 of the regulations. Graded Yes or No. Weighted 1% of the Production Control subsection. Maximum length 70 words.]
(2) [Reference 10.62.23.06 of the regulations. Graded Yes or No. Weighted 0.5% of the Production Control subsection. Maximum length 70 words.]

1. The Applicant will retain a sample from each lot released to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to ensure product potency and purity, and provide support for expiration dating. The retained sample will also be used for any follow-up testing, if necessary, within the time period before the

expiration date, or for a potential recall of medical cannabis finished products.

2. The Applicant will retain a sample from each lot released to an independent testing laboratory in a secure, segregated temperature-controlled storage area for one year past the expiration date of the lot. The Applicant will retain every certificate of analysis from each corresponding lot to ensure accuracy of the properly stored lot, and the area will be labeled as containing samples to be retained until the proper date.

10.62.23.07

105. Please describe how the Applicant will submit to the Commission within 30 days following the end of a quarter a list of the products and the products' specifications that the Applicant offered for distribution in the quarter. *

[Reference 10.62.23.07 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

Accurate labeling of each individual medical cannabis finished product and entry into the BioTrackTHC inventory control system will ensure that all products and their specifications can be generated for review and submission to all interested parties. The Processing Supervisor shall generate and submit to the Commission within 30 days following the end of a quarter a list of the products and its specifications that the Applicant offered for distribution in the quarter.

10.62.24.01

106. Please describe how all items will be individually processed at the original point of processing. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Processor Supervisor will create standard operating procedure to ensure that once a medical cannabis product is ready to be packaged. Processor Agents will securely package each individual product in a Packaging and Labeling Room within the Processing Facility. A Processor Supervisor will enter each packaged finished product's data and identifying information into the perpetual inventory control system. The finished product is labeled and stored within the Secure Room.

107. Please describe how a package of medical cannabis finished product will be plain. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Processor Supervisor will ensure all packages of medical cannabis finished products will be in packaging that is plain in physical appearance. The Applicant will select plain packaging options suited to the amount of product it will hold that is equal or superior to CRREO, and is approved by CPSC and EPA under ASTM D3475-08, Type XIA classification. The packaging will not have any cartoons, color schemes, images, or graphics.

108. Please describe how a package of medical cannabis finished product will be opaque. *
[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Processor Supervisor will ensure all packages of medical cannabis finished products will be in opaque packaging. The Applicant will select opaque packaging options suited to the amount of product it will hold that is equal or superior to CRREO, and is approved by CPSC and EPA under ASTM D3475-08, Type XIA classification. The package will not bear any indication of its contents by the physical appearance of the package.

109. Please describe how a package of medical cannabis finished product will be tamper-evident, and if applicable or appropriate, child-resistant. *
[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant has secured compliant packaging vendors to ensure that each individual package of medical cannabis finished product will be constructed of materials that will be tamper-evident, each package has a design that enhances product and patient safety, and each package possesses child-resistant properties that conform to CFR 1700.15 of the Poison Prevention Packaging Standards set forth by the Consumer Product Safety Commission.

110. Please describe how a package of medical cannabis finished product will bear a finished-product lot number and expiration date. *
[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will ensure that each package of medical cannabis finished product will bear a clear label that will list a finished product lot number, expiration date of the product, and printed on the primary label on the package. The label will have a text font of no less than 1/16th of an inch and not obstruct other required labels on the package.

111. Please describe how a package of medical cannabis finished product will bear a clear warning that (1) the contents may be lawfully consumed only by a qualifying patient named on an attached label; (2) it is illegal for any person to possess or consume the contents of the package other than the qualifying patient; and (3) it is illegal to transfer the package or contents to any person other than a transfer by a caregiver to a qualifying patient. *
(1) [Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]
(2) [Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]
(3) [Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

1. The Applicant will ensure that each package of medical cannabis finished product will bear a clear label that will list a warning, "The contents of this package may be lawfully consumed only by (Name of Patient)." The label will have a text font of no less than 1/16th of an inch, will be isolated from other labels on the package, and not obstruct other required labels on the package.

2. The Applicant will ensure that each package of medical cannabis finished product bear a clear label that will list a warning, "It is illegal to consume the contents of this package other than the qualifying patient." The label will have a text font of no less than 1/16th of an inch, will be isolated from other labels on the package, and not obstruct other required labels on the package.

3. The Applicant will ensure that each package of medical cannabis finished product bear a clear label that lists a warning, "It is illegal to transfer the package or contents to any person other than a transfer by a caregiver to a qualifying patient." The label will have a text font of 1/16th of an inch, is isolated from and will not obstruct other require labels on the package.

112. Please describe how a package of medical cannabis finished product will bear a clear warning to keep the package and its contents away from children other than a qualifying patient. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will ensure that each package of medical cannabis finished product will bear a clear and conspicuous label that will list a warning, "Keep contents away from children unless they are qualifying patients." The label will have a text font of no less than 1/16th of an inch, will be isolated from other labels on the package, and not obstruct other required labels on the package.

113. Please describe how a package of medical cannabis finished product will bear the Maryland Poison Control Center emergency telephone number. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will ensure that each package of medical cannabis finished product will bear a clear and conspicuous label that will list the Maryland Poison Control Center emergency telephone number to ensure patient safety. The label will state, "Maryland Poison Control Center" with the address and 24 hour telephone number for contact information in the event a patient has an adverse reaction to a medical cannabis finished product.

114. Please describe how a package of medical cannabis finished product will bear the name of the Licensee that packaged the medical cannabis finished product and the telephone number of the Licensee for reporting an adverse patient event. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will ensure, through its standard operating procedure, that each package containing a medical cannabis finished product will bear the name and telephone number of the Licensee who packaged the product located on the label. In the case of an adverse event, a patient can retrieve this information from the label to promptly report the complaint to the Licensee from which the medical cannabis finished product originated.

115. Please describe how a package of medical cannabis finished product will bear any allergen warning required by law. *

[Reference 10.62.24.01 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant may manufacture medical cannabis products with potential allergens. The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires appropriate labeling of products by placing the word "Contains" followed by the allergen on the label.
If any ingredients in these products are recognized under the guidelines by FALCPA to be potential allergens, the package of the medical cannabis finished product will bear appropriate allergen warnings to notify the patient.

116. Please describe how a package of medical cannabis finished product will bear a listing of the non-medical cannabis ingredients. *

[Reference 10.62.24.01 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant may manufacture medical cannabis finished products that have a variety of potential non-medical cannabis ingredients. The Processor Agent for Packaging and Labeling will create a detailed list of all non-medical cannabis ingredients used in the production of the medical cannabis finished product, and properly include the list in the labeling of the product to ensure that a patient can identify those ingredients if necessary.

117. Please describe how a package of medical cannabis finished product will bear an itemization, including weight, of all cannabinoid and terpene ingredients specified for the product, and the concentrates of any cannabinoid of less than one percent will be printed with a leading zero before the decimal point. *

[Reference 10.62.24.01 of the regulations. Graded 0 to 5 scoring. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will receive a laboratory certificate of analysis that includes all cannabinoid and terpene ingredients specified for the medical cannabis product. The product is weighed, and the laboratory and weight information will be included on the labeling of the product. In cases where medical cannabis finished products contain cannabinoid compounds of less than one percent, this will be indicated by printing a leading zero before the decimal point.

118. Please describe how a package of medical cannabis finished product will leave space for a licensed dispensary to attach a personalized label for the qualifying patient. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will affix a variety of labels to a package of medical cannabis finished product. Any labeling text will be unobstructed and conspicuous. Each package that will be shipped to a licensed dispensary will retain enough space on its external wrapping so that Dispensary Agents can affix a personalized label specific for each qualifying patient and without obstructing the existing labeling on the package.

119. Please describe how the Applicant will assure that a package of medical cannabis finished product does not bear any resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially available candy, snack, baked good, or beverage. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will assure that a package of medical cannabis finished product does not bear any resemblance of any commercially available candy, snack, baked good, or beverage. The Applicant has identified and will use a compliant packaging manufacturer whose products are plain, opaque, and generic in form. The packaging shall bear no resemblance to any trademark or characteristic that would resemble candy, snack, baked good, or beverage.

120. Please describe how the Applicant will assure that a package of medical cannabis finished product does not bear any statement, artwork, or design that could be reasonably mislead any person to believe that the package contains anything other than a medical cannabis finished product. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will assure that all packaging of medical cannabis finished products will be in a plain, opaque, and in a package that is clearly labeled with its content information. The Applicant will not produce or allow for the release of any packaging that bears statements, artwork or any designs that may mislead a person or a medical cannabis patient to believe the package contains anything but medical cannabis.

121. Please describe how the Applicant will assure that a package of medical cannabis finished product does not bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county, or municipality or any agency thereof. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will assure that each package of medical cannabis finished product does not bear any seal, flag, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed by any state, county, or municipality. The Applicant has identified and will use a compliant packaging manufacturer whose products are plain, opaque, generic in form, and only use required and appropriate labels.

122. Please describe how the Applicant will assure that a package of medical cannabis finished product does not bear any cartoon, color scheme, image, graphic, or feature that might make the package attractive to children. *

[Reference 10.62.24.01 of the regulations. Graded Yes or No. Weighted 0.5% of the Operational subsection. Maximum length 70 words.]

The Applicant will assure that each medical cannabis finished product will be in plain and opaque packaging, and will in no way bear any cartoon, color scheme, image, graphic, or feature that might make the package attractive to children. The Applicant has selected and will use a compliant packaging manufacturer whose packaging products are plain, opaque, generic in form, and only use required and appropriate labels.

END OF DOCUMENT

Portfolio Holdings

[redacted]

D'ORAZIO & ASSOCIATES, INC.
7600 Leesburg Pike, Suite 460 East
Falls Church, Virginia 22043
Phone: (703) 269-3100
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Jeremy L. Meek, CFP® E-mail: jlm@dorazioadvisors.com

October 30, 2015

Maryland Medical Marijuana Commission
4201 Patterson Avenue
Baltimore, MD 21215

RE: Adequate Capitalization

[redacted]

Sincerely,

Joseph A. D'Orazio
President

Question 3a: Certifying Maryland residency on the part of owners and/or investors. Owner

STATE OF MARYLAND
Department of Assessments and Taxation

I, HEIDI DUDDERAR OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES , OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT FGM PROCESSING, LLC , REGISTERED OCTOBER 20, 2015, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF MARYLAND, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS OCTOBER 23, 2015.

Heidi Dudderar
Associate Director

301 West Preston Street, Baltimore, Maryland 21201
Telephone Balto. Metro (410) 767-1340 / Outside Balto. Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice
Fax (410) 333-7097

crbink

R0009864735

Turner, Leins & Gold, LLC

Certified Public Accountants and Business Consultants

108 Center Street, North, 2nd Floor
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(703) 242-6500
Facsimile (703) 242-1600

51 Monroe Place, Suite 1900
Rockville, Maryland 20850-2429
(301) 340-6300
Facsimile (301) 340-7168

November 4, 2015

RE: Jessica White
SS# XXX-XX-9173
221 Solway Rd
Timonium MD 21093

To whom it may concern:

[redacted]

Sincerely,

J. Paul Johnson, Jr., CPA, CFP®, CGMA

November 2, 2015

Maryland Medical Marijuana Commission
4201 Patterson Avenue
Baltimore, MD 21215

RE: No Taxes in Arrears

To the Maryland Medical Marijuana Commission:

I, Joseph A. D'Orazio, being a Certified Professional Accountant in the Commonwealth of Pennsylvania, certify that James Manchisi has been my client for the past 9 years and, during that time, he has timely filed his federal and state income tax returns. Mr. Manchisi is not in arrears with respect to his income taxes in any jurisdiction.

If you have any questions or require additional information feel free to contact me.

Sincerely,

Joseph A. D'Orazio

October 29, 2015

To the Maryland Medical Marijuana Commission,

[redacted]

H&R BLOCK

THEODORE L.
BRYANT

MASTER TAX ADVISOR
ENROLLED AGENT

MLK Plaza
3655 Page Blvd
Saint Louis, MO 63113
Office: 314.652.1080
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theodore.bryant@tax.hrblock.com

AVAILABLE YEAR-ROUND
HRBLOCK.COM

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Facsimile (703) 242-1600

51 Monroe Place, Suite 1900
Rockville, Maryland 20850-2429
(301) 340-6300
Facsimile (301) 340-7168

November 4, 2015

RE: Jessica White
SS# XXX-XX-9173
221 Solway Rd
Timonium MD 21093

To whom it may concern:

[redacted]

November 2, 2015

Maryland Medical Marijuana Commission
4201 Patterson Avenue
Baltimore, MD 21215

RE: No Taxes in Arrears

To the Maryland Medical Marijuana Commission:

[redacted]

Sincerely,

Joseph A. D'Orazio
President

October 29, 2015

[redacted]

H&R BLOCK

THEODORE L.
BRYANT

MASTER TAX ADVISOR
ENROLLED AGENT

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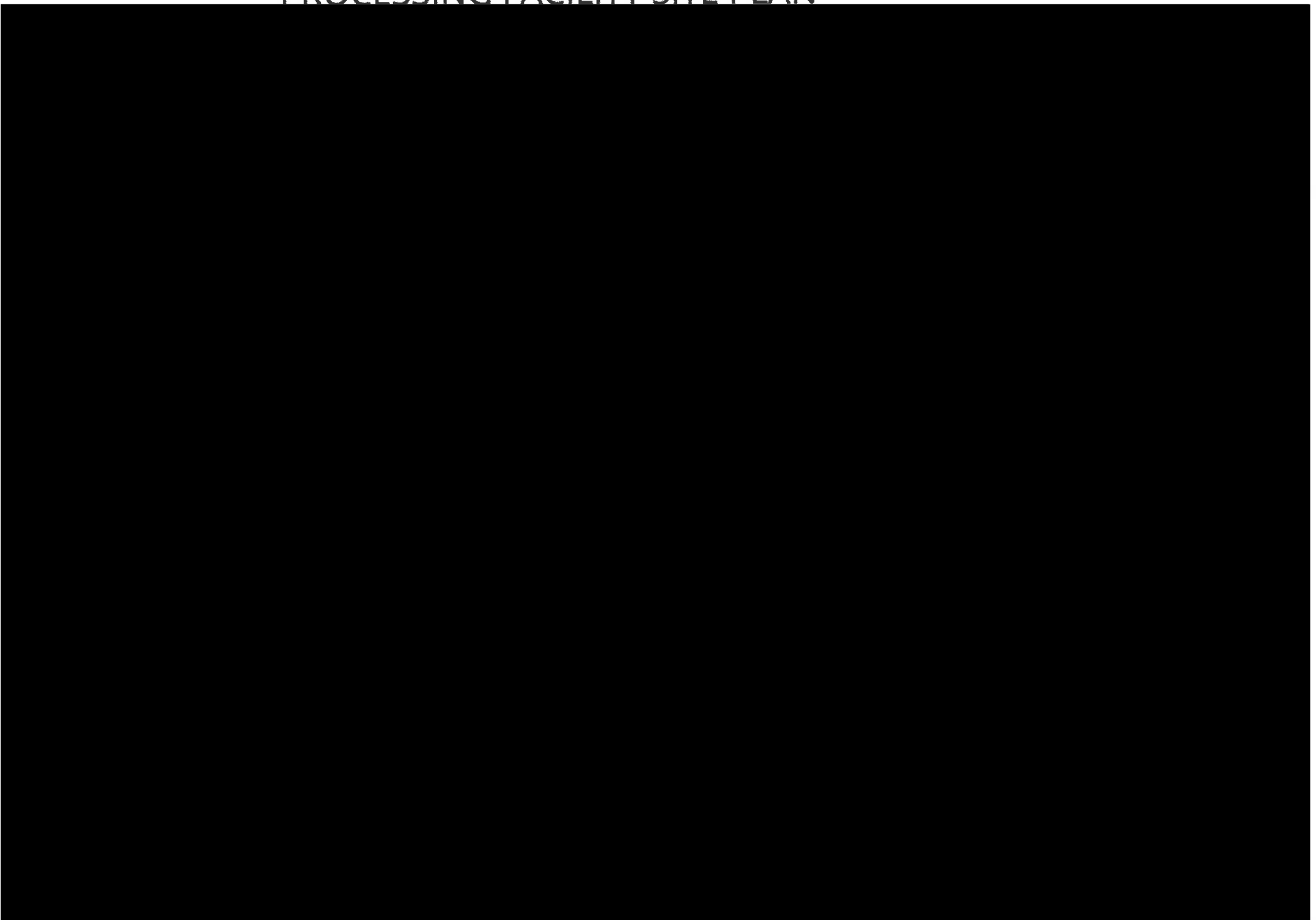
AVAILABLE YEAR-ROUND
HRBLOCK.COM

OPE[illegible]IONS ZONE
PUBLIC ZONE

PROCESSING FACILITY SITE PLAN



Orthodox Union

UNION OF ORTHODOX JEWISH CONGREGATIONS OF AMERICA • איחוד קהילות האורתודוקסים באמריקה
ELEVEN BROADWAY / NEW YORK, NY 10004 / 212-613-8241 / FAX: 212-613-0752 / WWW.OUKOSHER.ORG

בס"ד

November 5, 2015

To Whom It May Concern:

The Orthodox Union provides kosher certification services and is the owner of the famous Ⓤ kosher certification mark.

This letter confirms that **FGM Processing LLC** recently submitted an application to the Orthodox Union in order to obtain kosher certification. As of the date of this letter, the Orthodox Union has not yet entered into a certification agreement with FGM Processing LLC; however, the parties are currently working toward that goal.

Please note that until FGM Processing LLC and the Orthodox Union enter into a certification agreement, the products sold by FGM Processing LLC are not certified by the Orthodox Union and the Ⓤ mark may not be used on such products until the certification agreement is in effect. When the parties will enter into a certification agreement, FGM Processing LLC will have a Letter of Kosher Certification issued by the Orthodox Union evidencing the certified status of the products listed therein.

Sincerely,
UNION OF ORTHODOX JEWISH
CONGREGATIONS OF AMERICA

Debbie Kaufman

Debbie Kaufman
Kosher Certification
New Company Department

- A detailed plan evidencing how the processor will distribute to dispensaries;
- A list of proposed medical cannabis extracts and medical cannabis-infused products to be produced with proposed cannabinoid profiles, including:
    - Varieties with high cannabidiol content;
    - Whether the product has any demonstrated success in alleviating symptoms of specific diseases or conditions.

SECTION U: Affirmation Section

The Applicant understands the following:

	Yes	No
1. The burden of proving an Applicant's qualifications rests on the party applying for the license.	☒	☐
2. The Commission may deny an Application that contains a misstatement, omission, misrepresentation, or untruth.	☒	☐
3. An Application shall be complete in every material detail.	☒	☐
4. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an Application.	☒	☐
5. The party applying for the license shall provide requested additional information by the close of business of the 14th business day after the request has been received by the Applicant.	☒	☐
6. If the party applying for the license does not provide the requested information within 14 business days, the Commission may consider the Application to be suspended.	☒	☐
7. The Commission intends to award the licenses to the best Applications that most efficiently and effectively ensure public safety and safe access to medical cannabis and medical cannabis-infused products.	☒	☐
8. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted Applications. The Applications shall be ranked based on weighted criteria.	☒	☐
9. The party applying for the license will provide an amended Application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an	☒	☐

	Yes	No
interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.		
10. For each individual identified in the Application specified in Regulation .02B(1) and (2) of this chapter, an Applicant will provide to the Director of the Central Repository:		
a. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each processor agent and investor identified in the Application; and	☒	☐
b. A request that the individual's state and national criminal history record information be forwarded to the Commission.	☒	☐
11. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the Application:		
a. The criminal history record information or background information demonstrate an absence of good moral character; or	☒	☐
b. The payment of taxes due in any jurisdiction is in arrears.	☒	☐
12. The Commission may rescind pre-approval of a processor license if the processor is not operational within 1 year of pre-approval.	☒	☐
13. The Commission may issue a processor license on a determination that:		
a. The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;	☒	☐
b. All inspections are passed and all of the Applicant's operations conform to the specifications of the applicable regulations;	☒	☐
a. The proposed premises:		
i. Are under the legal control of the Applicant;	☒	☐
ii. Comply with all zoning and planning requirements; and	☒	☐

	Yes	No
iii. Conform to the specifications of the Application as pre-approved pursuant to the applicable regulations; and	☒	☐
iv. The first year's license fee specified in COMAR 10.62.35 has been paid.	☒	☐
14. The Commission may deny transfer of an interest in a license if, for any proposed transferee:		
a. The criminal history record information or the background investigation demonstrate an absence of good moral character; or	☒	☐
b. The payment of taxes due in any jurisdiction is in arrears.	☒	☐
15. The Commission, after review of the criminal history record information, may disqualify any prospective registered processor agent from registration for an absence of good moral character or if the payment of taxes in any jurisdiction is in arrears.	☒	☐
16. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.	☒	☐

Please review and answer the following:

	Yes	No
1. The party applying for the processor license irrevocably gives consent to the Commission and persons authorized by the Commission to:		
a. Verify all information provided in the Application documents; and	☒	☐
b. Conduct a background investigation of the individual(s).	☒	☐
2. The party applying for the processor license waives any contractual, statutory, or common law obligation of confidentiality and authorizes any government agency in any jurisdiction to release to and provide access to the Commission of any and all information the Applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the Applicant.	☒	☐

	Yes	No
3. The party applying for the processor license releases all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the Applicant's capacity to manage a licensed processor facility and the Applicant's good moral character.	☒	☐
4. All processor agents affiliated with this Application are 21 years old or older at the time of Application.	☒	☐
5. All of the processor agents affiliated with this Application have never been convicted of a felony drug offense	☒	☐

An Applicant Shall Commit to the Following:

	Yes	No
1. All processor agents will be 21 years or older.	☒	☐
2. The party applying for the license commits to having any and all processor agents registered with the Commission before the agent may volunteer or work for a Licensee.	☒	☐
3. The party applying for the license commits to registering a processor agent by submitting to the Commission:		
a. The name, address, date of birth and Social Security Number of a processor agent;	☒	☐
b. Documentation of the submission of fingerprints of the processor agent to the Central Registry; and	☒	☐
c. The request for the criminal history record information of the processor agent to be forwarded to the Commission.	☒	☐
4. The Applicant will not register a prospective processor agent if the prospective processor agent has ever been convicted of a felony drug offense.	☒	☐
5. The party applying for the license will provide an amended Application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity,	☒	☐

	Yes	No
even after a license is issued.		
6. For each individual identified in the Application the processor agent commits to requiring any prospective medical cannabis processor agent register with the Commission before the Applicant will employ the agent or permit the agent to volunteer for the Applicant.	☒	☐
7. If an Applicant is issued a pre-approval for a license the party applying for the license commits to submitting to the Commission, as part of its Application:		
a. An audited financial statement for the Applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the Applicant; and	☒	☐
b. Payment of the stage 2 Application fee specified in COMAR 10.62.35.	☒	☐
8. The party applying for the license commits to having no interest of 5 percent or more of a license issued pursuant to this chapter assignable or transferable unless:		
a. The Commission has received notice in a manner determined by the Commission of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;	☒	☐
b. The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;	☒	☐
c. The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and	☒	☐
d. The transferee has paid the required fee specified in COMAR 10.62.35.	☒	☐
9. The party applying for the license acknowledges that a Licensee is eligible to apply to renew a license every 2 years.	☒	☐
10. The party applying for the license acknowledges that ninety days before the expiration of a license, the Commission will notify the Licensee of the:		

	Yes	No
a. Date on which the license expires;	☒	☐
b. Process and the fee required to renew the license; and	☒	☐
c. Consequences of a failure to renew the license.	☒	☐
11. The party applying for the license acknowledges that at least 30 business days before a license expires a Licensee shall submit:		
a. The renewal Application as provided by the Commission;	☒	☐
b. Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more;	☒	☐
c. To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and	☒	☐
d. Payment of the fee specified in COMAR 10.62.35.	☒	☐
12. The party applying for the license acknowledges that the Commission shall renew a license that meets the requirements for renewal as stated in COMAR 10.62.19.08(C).	☒	☐
13. The party applying for the license acknowledges that the Commission shall issue to each registered processor agent an identification card that shall include a photograph of the face of the registered processor agent taken no more than 6 months before the date of the Application.	☒	☐
14. At all times at the premises of a Licensee, every processor agent shall visibly wear the identification card issued to the registered processor agent by the Commission.	☒	☐
15. The party applying for the license commits to renewing the identification card every 2 years.	☒	☐
16. If a registered processor agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the Licensee commits to:		
a. Reporting the loss, destruction or theft to a the Commission;	☒	☐

	Yes	No
b. Applying for a replacement card; and	☒	☐
c. Paying a replacement card fee specified in COMAR 10.62.35.	☒	☐
17. As soon as possible upon termination of a registered processor agent's association with a Licensee, the Licensee commits to:		
a. Take custody of the terminated registered processor agent's identification card;	☒	☐
b. Obtain any keys or other entry devices from the terminated registered processor agent; and	☒	☐
c. Ensure the terminated registered processor agent can no longer gain access to the premises of the Licensee.	☒	☐
18. Within 1 business day of the termination of a registered processor agent's association with a Licensee, the Licensee commits to:		
a. Notify the Commission:		
i. Of the termination and the circumstances of a termination;	☒	☐
ii. Whether the terminated registered processor agent has returned the agent's identification card; and	☒	☐
iii. Initiate delivery of the terminated registered processor agent's identification card to the Commission.	☒	☐
19. The party applying for the license acknowledges that the Commission will revoke an identification card of a processor agent upon receiving notification that a processor agent is no longer associated with a Licensee.	☒	☐
20. The party applying for the license acknowledges that if a registered processor agent does not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.	☒	☐
21. The party applying for the license acknowledges that the Licensee shall require a prospective processor agent to submit to a drug screen before commencement of association.	☒	☐
a. The party applying for the license acknowledges that the drug	☒	☐

	Yes	No
screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.		
b. In addition to the drugs to be screened in accordance with the procedures set forth in COMAR 17.09.04-.08, the screen shall include any other drugs as required by the Commission.	☒	☐
22. The party applying for the license acknowledges that unless medically justified, a prospective processor agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.	☒	☐
23. The party applying for the license acknowledges that a registered processor agent shall retain training materials and attendance records and make the training materials available for inspection.	☒	☐
24. The party applying for the license acknowledges that a registered processor agent shall declare in writing that the registered processor agent will adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.	☒	☐
25. The party applying for the license acknowledges that the Licensee will retain the declaration in the registered processor agent's personnel record.	☒	☐
26. The party applying for the license commits to notifying the Commission that the Licensee has verified that no registered processor agent has been convicted of a felony drug offense, every year, on a date determined by the Commission.	☒	☐
27. The party applying for the license commits to locating the premises of a Licensee within Maryland.	☒	☐
28. The party applying for the license commits to conspicuously displaying the processor license at the location where the Licensee is authorized to operate.	☒	☐
29. The party applying for the license commits conforming the premises and operations to all local zoning and planning requirements.	☒	☐
30. The party applying for the license commits to notifying the Commission before any major renovation or modification is undertaken.	☒	☐
31. The party applying for the license acknowledges that if the Commission		

	Yes	No
does not renew a license due to a failed inspection or an inadequate Application for renewal, the Licensee may apply for reinstatement by:		
a. Submitting a plan to correct the deficiencies noted during an inspection; and	☒	☐
b. Amending the Application for renewal.	☒	☐
32. The party applying for the license acknowledges that the Commission may decline to renew a license if:		
a. The plan to correct deficiencies identified in an inspection is deficient;	☒	☐
b. The amended Application for renewal is deficient; or	☒	☐
c. The Licensee has repeatedly failed inspections.	☒	☐
33. The party applying for the license acknowledges that a Licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:		
a. Shall cease operations at all premises; and	☒	☐
b. May not process medical cannabis.	☒	☐
34. The party applying for the license acknowledges that a license may be reinstated upon:		
a. Payment of the reinstatement fee specified in COMAR 10.62.35; and	☒	☐
b. Submission of a reinstatement Application approved by the Commission.	☒	☐
35. The party applying for the license may apply to change the location of the Licensee's operation.	☒	☐
36. The party applying for the license, to change the location of the Licensee's operation, must submit an Application to the Commission along with the fee specified in COMAR 10.62.35.	☒	☐
37. The party applying for the license, to change the location of the Licensee's	☒	☐

	Yes	No
operation, may not begin processing medical cannabis at a new location until all inspections have been passed.		
38. The party applying for the license commits to providing the Commission or law enforcement agency for just cause with any recording of security video surveillance as requested.	☒	☐

The undersigned attests that the Applicant organization will adhere to the statutory/regulatory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

James Manchisi — 10/29/2015

Signature — Date

James Manchisi

Printed Name

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION- INVESTOR/PROCESSOR AGENT

Investor/Agent:
(Investor/Agent's Name) GREG McNeal-Smith

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Signature of Applicant

11-04-15
Date

Printed Name of Applicant GREG McNeal-Smith

CA NOTARY ACKNOWLEDGMENT ATTACHED

NOTARY

The undersigned, a Notary Public in and for the County of _____, in the State of _____, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This _____ day of _____, 20___, and to which witness my hand and seal.

_____
Notary Public

_____
Printed Name

Stamp or Seal

CA NOTARY ACKNOWLEDGMENT ATTACHED

My Commission Expires: _____, 20____

California All-Purpose Acknowledgment

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Sonoma

On 11/4 *, 2015,*
before me, Julie A Gwin, Notary Public, personally appeared

** Gregory McNeal-Smith **

Who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under penalty of perjury under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

JULIE A. GWIN
COMM. # 2007673
NOTARY PUBLIC - CALIFORNIA
SONOMA COUNTY
MY COMM. EXPIRES MAR. 14, 2017

Signature of Notary Public
Julie A Gwin
COMMISSION EXP 3-14-17

(Seal)

Attached to Document Auth for Release of Info *Pages* 30a
Investor/processor Agent

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: DANIEL WATNICK
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Signature of Applicant

11/2/15
Date

DANIEL WATNICK
Printed Name of Applicant

NOTARY

The undersigned, a Notary Public in and for the County of Essex, in the State of Massachusetts, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 2 day of November, 2015, and to which witness my hand and seal.

Denise LeBlanc
Notary Public

Denise LeBlanc
Printed Name

DENISE LeBLANC
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
My Comm. Expires Jan. 26, 2018

Stamp or Seal

My Commission Expires: January 26, 2018

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent:
(Investor/Agent's Name) Lynne M. Schlosser

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Lynne M Schlosser
Signature of Applicant

11/4/15
Date

Lynne M. Schlosser
Printed Name of Applicant

NOTARY

The undersigned, a Notary Public in and for the County of St. Louis, in the State of Missouri, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 4th day of November, 2015, and to which witness my hand and seal.

Erica A. Stelfox
Notary Public

Erica A. Stelfox
Printed Name

ERICA A. STELFOX
Notary Public, Notary Seal
State of Missouri
St. Louis County
Commission # 15634073
My Commission Expires March 19, 2019

Stamp or Seal

My Commission Expires: March 19th, 2019

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: Robert P. Greene
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis Processor (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Robert P. Greene
Signature of Applicant

11/02/2015
Date

Robert P. Greene
Printed Name of Applicant

NOTARY

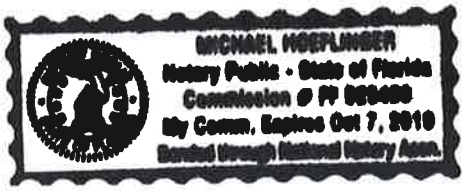
The undersigned, a Notary Public in and for the County of MIAMI-DADE, in the State of FLORIDA, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 2nd day of NOVEMBER, 2015, and to which witness my hand and seal.

Notary Public

MICHAEL HOEFLINGER

Printed Name



Stamp or Seal

My Commission Expires: OCTOBER 7, 2019

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION- INVESTOR/PROCESSOR AGENT

Investor/Agent:
(Investor/Agent's Name) Lysa Regits

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Lysa Regits
Signature of Applicant

11/2/15
Date

Lysa Regits
Printed Name of Applicant

NOTARY

The undersigned, a Notary Public in and for the County of Baltimore, in the State of Maryland, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 2 day of November, 20 15 and to which witness my hand and seal.

Nichole Shields
Notary Public

Nichole Shields
Printed Name

NICHOLE SHIELDS
Notary Public
Baltimore County
Maryland
My Commission Expires Nov 20, 2018

Stamp or Seal

My Commission Expires: Nov 20, 2018, 20 18

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: James Manchisi
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland. Processor

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

James Manchisi
Signature of Applicant

10/29/2015
Date

James Manchisi
Printed Name of Applicant

NOTARY

The undersigned, a Notary Public in and for the County of FAIRFAX, in the State of VIRGINIA, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 30th day of OCTOBER, 2015, and to which witness my hand and seal.

Notary Public

CAROL INUKAI-SMITH
Printed Name

Stamp or Seal

My Commission Expires: 4-30, 2017

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
None			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

James Manchisi — 10/29/2015

Name- Signature — Date

James Manchisi

Name- Printed

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: BRIAN FOX
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Brian Fox
Signature of Applicant

10/26/15
Date

Printed Name of Applicant BRIAN FOX

NOTARY

The undersigned, a Notary Public in and for the County of St. Louis, in the State of Missouri, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 26th day of October, 2015, and to which witness my hand and seal.

Erica A. Stelfox
Notary Public

Erica A. Stelfox
Printed Name

ERICA A. STELFOX
Notary Public, Notary Seal
State of Missouri
St. Louis County
Commission # 15634073
My Commission Expires March 19, 2019

Stamp or Seal

My Commission Expires: March 19, 2019

FORM 2

AUTHORIZATION FOR RELEASE OF INFORMATION-BUSINESS ENTITY

Business Entity Name: FGM Processing, LLC
Name of Person Completing Form: James Manchisi
(Authorized Representative)

James Manchisi is an Authorized Representative, empowered by the Business Entity to execute this form on its behalf.

FGM Processing,LLC is an Applicant for a Medical Cannabis Processor (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about the Business Entity. The Business Entity irrevocably gives its consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of the Business Entity; and (3) to have access to any and all information that the Business Entity has provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about the Business Entity.

By executing this Authorization, the Business Entity authorizes any of the following entities to release to the Commission any and all information about the Business Entity that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, the Business Entity expressly waives, releases, discharges and forever holds harmless and agrees to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

James Manchisi — 10/29/2015

Signature of Authorized Representative — Date

James Manchisi

Printed Name of Authorized Representative

NOTARY

The undersigned, a Notary Public in and for the County of FAIRFAX, in the State of VIRGINIA, certifies that the above named individual, as an Authorized Representative of FGM PROCESSING, LLC, appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 30th day of OCTOBER, 2015, and to which witness my hand and seal.

Notary Public

CAROL INUKAI-SMITH
Printed Name

Stamp or Seal

My Commission Expires: 4-30, 2017

FORM 3

Trade Secret & Financial Data Notification

FGM Processing, LLC is an Applicant for a Medical Cannabis Processor License. understands that the Commission is an entity of the State of Maryland and any documents or data that is submitted to the State of Maryland may be disclosed by the State pursuant to a Maryland Public Information Act ("MPIA") Request.

While the MPIA permits certain exclusions from disclosure, James Manchisi understands the State makes no guarantees or promises that such data will not be disclosed. has reviewed the MPIA, as it is available online at http://www.lexisnexis.com/hottopics/mdcode. James Manchisi understands that other helpful resources may be found at www.oag.state.md.us/Opengov.

James Manchisi understands that the documents or data it provides is to the State of Maryland may not be confidential, or if confidential, may or may not be disclosed pursuant to a MPIA request.

James Manchisi — 10/29/2015

Signature of Person or Authorized Representative — Date

James Manchisi

Printed Name

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
IL. Dept of Financial Professional Regulation	Dispensary	Terra Herbal Health LLC	DISP 000001

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Brian Fox — 10/26/15

Name- Signature — Date

Name- Printed

BRIAN FOX

FORM 1

AUTHORIZATION FOR RELEASE OF INFORMATION-INVESTOR/PROCESSOR AGENT

Investor/Agent: Jessica L White
(Investor/Agent's Name)

I am an investor or an agent applying for a Medical Cannabis (Grower/Processor/Dispensary) License in the State of Maryland.

The Maryland Medical Cannabis Commission ("Commission") is required by law to conduct an investigation of an Applicant for a Medical Cannabis Dispensary License. That investigation requires the Commission to collect and evaluate information about me. I irrevocably give consent to the Commission, the Maryland State Police, and persons authorized by the Commission to: (1) verify all information provided in the license Application documents; (2) conduct a background investigation of me; and (3) to have access to any and all information that I have provided to any other jurisdiction seeking a similar license in that jurisdiction, as well as information obtained by that other jurisdiction during the course of any investigation that it may have conducted about me.

By executing this Authorization, I authorize any of the following entities to release to the Commission any and all information about me that the Commission requests: any local, State or Federal unit; any commercial or business enterprise; any non-profit entity; any individual; or any other public or private entity. The requested information may be released in written, verbal, electronic, or any other form.

With respect to any claims or liability arising from the release of the requested information to the Commission, I expressly waive, release, discharge and forever hold harmless and agree to indemnify, the unit, entity, or individual that releases the information to the Commission under the authority of this Authorization.

A photo, facsimile, or electronic copy of this signed and dated Authorization shall be equally as effective as an original.

Jessica L. White
Signature of Applicant

10/28/15
Date

Printed Name of Applicant Jessica White

NOTARY

The undersigned, a Notary Public in and for the County of Baltimore, in the State of Maryland, certifies that the above named individual appeared in person, and before me, either known to me or satisfactorily proved to be individual whose name subscribed to the within instrument and signed the Authorization and Notification.

This 28th day of October, 2015, and to which witness my hand and seal.

Notary Public

KARLA HERMOSA

Printed Name

KARLA HERMOSA
Notary Public
Baltimore County
Maryland
My Commission Expires Aug. 6, 2016

Stamp or Seal

My Commission Expires: Aug. 06, 2016

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
none			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Jessica White
Name- Signature

11·6·15
Date

Name- Printed Jessica White

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
None			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Name- Signature Gregory McNeal-Smith Date 11-04-15

Name- Printed Gregory McNeal-Smith

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
NONE			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Name- Signature

11/2/15
Date

DANIEL WATNICK
Name- Printed

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
none			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Lynne M Schlosser
Name- Signature

11/4/15
Date

Lynne M. Schlosser
Name- Printed

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
IL Dept of Financial and Professional Regulation	Dispensary	Terra Herbal Health, LLC	DISP000001

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Name- Signature

11/02/2015
Date

Robert P. Greene
Name- Printed

FORM 4

Regulatory Agency Form

BUSINESS INTEREST IDENTIFICATION & AUTHORIZATION FORM

I/We, the undersigned Applicant, hereby state(s) as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of Cannabis in any form, in the following States or jurisdiction and corresponding agency or authority:

State & Name of Agency	Type of License	Name of License	License or Registration #
none			

I/We hereby specifically grant the Maryland Department of Health & Mental Hygiene permission to contact the above listed States or jurisdiction and their licensing agency or authority to confirm the information contained in the Application for a dispensary license. I/We hereby specifically grant permission to the above listed States or jurisdiction and their licensing agency or authority to release to the Maryland Department of Health & Mental Hygiene any and all information relating to the Application, licensure or authorization to produce or otherwise deal in the distribution of Cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the Application, license or authorization; and
b. A copy of documentation so indicating; or
c. A statement that the Applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the Applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the Applicant organization to the statutory requirements.

Lysa Regits
Name- Signature

11/2/15
Date

Lysa Regits
Name- Printed

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☒	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☒	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☒
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☒	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☒
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☒	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☒
8. If you are employed by the State, please state the name, agency and position.		
9. I acknowledge that I fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and Any activity regarding cannabis that does not comply with Maryland law or regulations is a violation of State law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges.	Yes ☒	No ☐
10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☒	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☒	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☒	No ☐

Dated this 4th day of November, 2015.

Jessica White
Signature of Owner/ Managing Director

Jessica White
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 4th day of November, 2015.

(SEAL)

Notary Public

Expires 8/9/2017

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☒	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☒	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☒
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☒	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☒
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☒	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☒
8. If you are employed by the State, please state the name, agency and position.		
9. I acknowledge that I fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and Any activity regarding cannabis that does not comply with Maryland law or regulations is a violation of State law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges.	Yes ☒	No ☐
10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☒	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☒	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☒	No ☐

Dated this 26th day of October, 2015.

Signature of Owner/ Managing Director

Brian Fox
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 26th day of October, 2015.

(SEAL)
ERICA A. STELFOX
Notary Public, Notary Seal
State of Missouri
St. Louis County
Commission # 15634073
My Commission Expires March 19, 2019

Notary Public

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☒	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☒	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☒
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☒	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☒
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☒	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☒
8. If you are employed by the State, please state the name, agency and position.		
9. I acknowledge that I fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and Any activity regarding cannabis that does not comply with Maryland law or regulations is a violation of State law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges.	Yes ☒	No ☐
10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☒	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☒	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☒	No ☐

Dated this 29th day of October, 2015.

James Manchisi

Signature of Owner/ Managing Director

James Manchisi

Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 30th day of October, 2015.

(SEAL)

Notary Public

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☒	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☒	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☒
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☒	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☒
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☒	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☒
8. If you are employed by the State, please state the name, agency and position.		
9. I acknowledge that I fully understand that: Cannabis is a Schedule I controlled substance under the Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Manufacture, distribution, cultivation, processing, possession, or possession with intent to distribute a Schedule I controlled substance, or conspiring or attempting to do so, are offenses subject to harsh penalties under federal law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges; and Any activity regarding cannabis that does not comply with Maryland law or regulations is a violation of State law and could result in arrest, prosecution, conviction, incarceration, fine, seizure of property, and loss of licenses or other privileges.	Yes ☒	No ☐
10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☒	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☒	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☒	No ☐

Dated this 2 day of NOV, 20 15.

Lysa Regits
Signature of Owner/ Managing Director

Lysa Regits
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 2 day of NOV, 20 15.

NICHOLE SHIELDS
Notary Public
Baltimore County
Maryland
My Commission Expires Nov 20, 2018
(SEAL)

Nicole Shields
Notary Public

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☑	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☑	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☑
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☑	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☑
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☑	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☑
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10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☑	No ☐
11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☑	No ☐
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Dated this 4th day of November, 2015.

Lynne M. Schlosser
Signature of Owner/ Managing Director

Lynne M. Schlosser
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 4th day of November, 2015.

(SEAL)
ERICA A. STELFOX
Notary Public, Notary Seal
State of Missouri
St. Louis County
Commission # 15634073
My Commission Expires March 19, 2019

Erica A. Stelfox
Notary Public

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☑	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☑	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☑
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☑	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☑
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☑	No ☐

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10. I certify that I have not been charged with or have been convicted of a felony offense which is reflective of an absence of good moral character.	Yes ☑	No ☐
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12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☑	No ☐

Dated this 2 day of November, 2015.

Signature of Owner/ Managing Director

DANIEL WATNICK
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this 2 day of November, 2015.

(SEAL)

DENISE LeBLANC
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
My Comm. Expires Jan. 26, 2018

Notary Public

FORM 5

Investors, Agents, Owners & Managing Director Certification Statement Form

1. I certify that any Cannabis business entity or its equivalent in which I hold or have held an interest, has not had the registration or license, suspended, revoked, placed on probationary status or subject to any disciplinary action. If no, provide an explanation.	Yes ☑	No ☐
2. I certify that no business or non-profit entity on whose board of directors I have served has been convicted of a crime, fined, censured or had any registration or authorization to do business revoked or suspended, or been the subject of an administrative or judicial proceedings challenging the entity's proper operation under law. If no, please explain and refer to case or news reports.	Yes ☑	No ☐
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide an explanation.	Yes ☐	No ☑
4. I certify that I am not delinquent on the filing of State or Federal taxes. If delinquent, provide an explanation.	Yes ☑	No ☐
5. If you have held a medical Cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminate) by any State? If yes, provide a brief explanation.	Yes ☐	No ☑
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Maryland or other State. If no, provide a brief explanation.	Yes ☑	No ☐

7. Are you employed by the State of Maryland? If no, skip next question.	Yes ☐	No ☑
8. If you are employed by the State, please state the name, agency and position.		
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11. I certify my acknowledgement that Application Fees are non-refundable.	Yes ☑	No ☐
12. I acknowledge that in filing an Application for a license and receiving a date and time stamped receipt, the following: a. The Commission is vested with broad discretion to select the Applicants to be awarded a License; and b. The Commission's decisions in selecting the Applicants shall be final.	Yes ☑	No ☐

Dated this 4th day of November, 2015.

Signature of Owner/ Managing Director

Greg McHeff-Smith
Printed Name of Owner/ Managing Director

Sworn to and subscribed before me on this _____day of _____, 20_____.

(SEAL)

_____
Notary Public

CA NOTARY JURAT ATTACHED 37a

California Jurat

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Sonoma

Subscribed and sworn to (or affirmed) before me, Julie A Gwin, Notary Public,

on this 4 day of November 2015, by

**Gregory McNeal-Smith **

proved to me on the basis of satisfactory evidence to be the person(s) who

appeared before me.

JULIE A. GWIN
COMM. # 2007673
NOTARY PUBLIC - CALIFORNIA
SONOMA COUNTY
MY COMM. EXPIRES MAR. 14, 2017

Signature _____

Julie A Gwin, Notary Public (seal)

COMMISSION EXP 3-14-2017

Attached to Document Forms, Investors, Agents Page 37 OF ____

Owners & Managing Mem