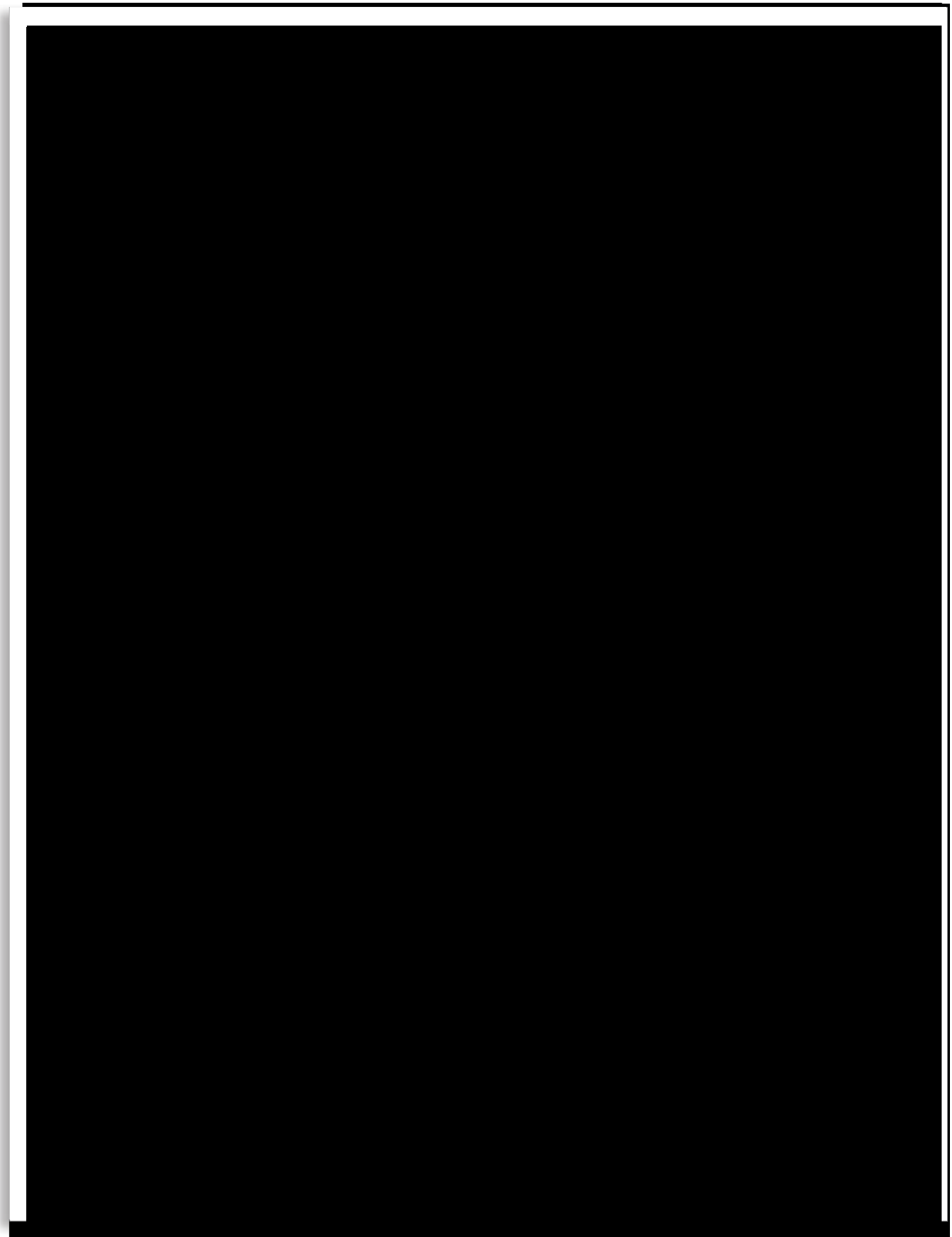

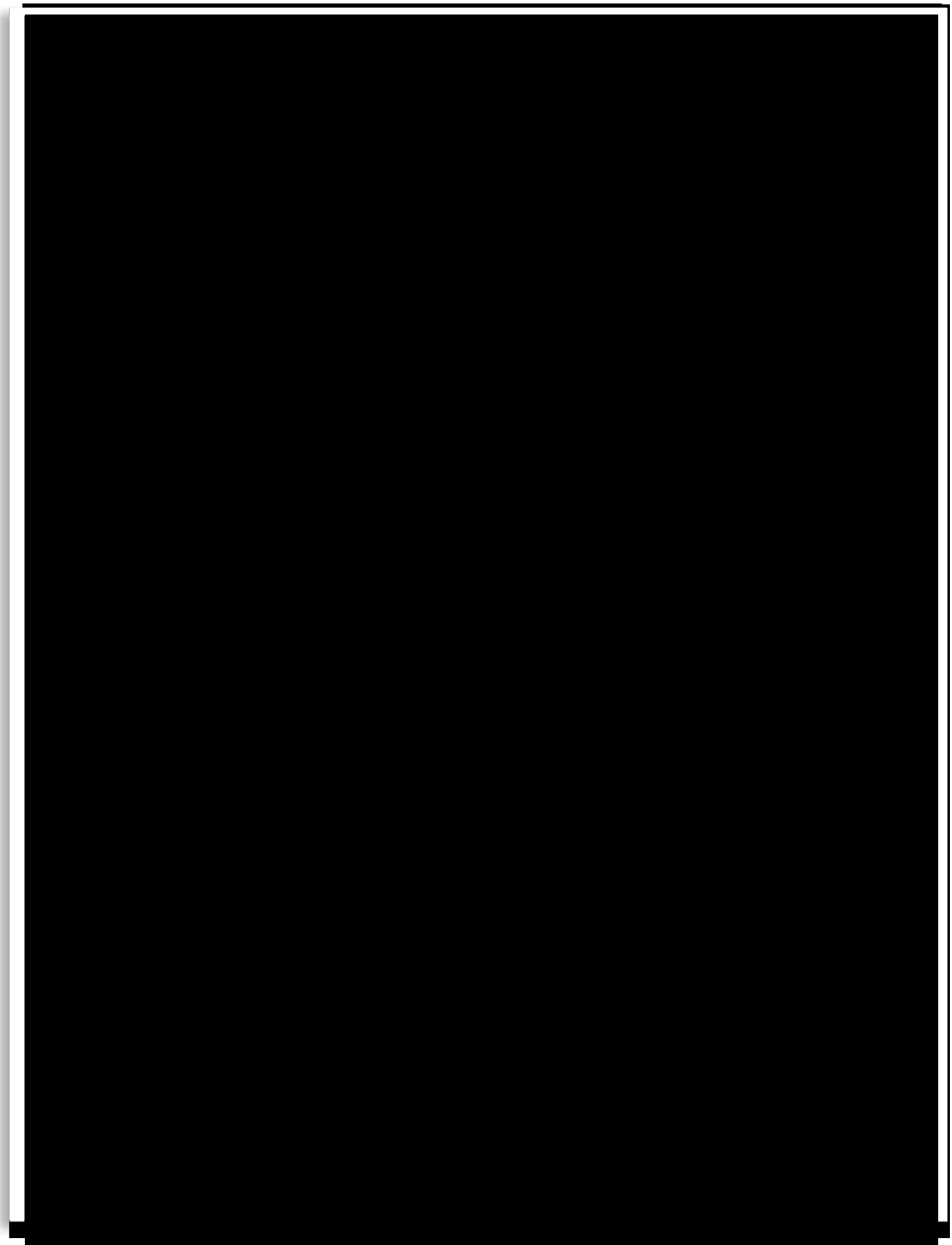

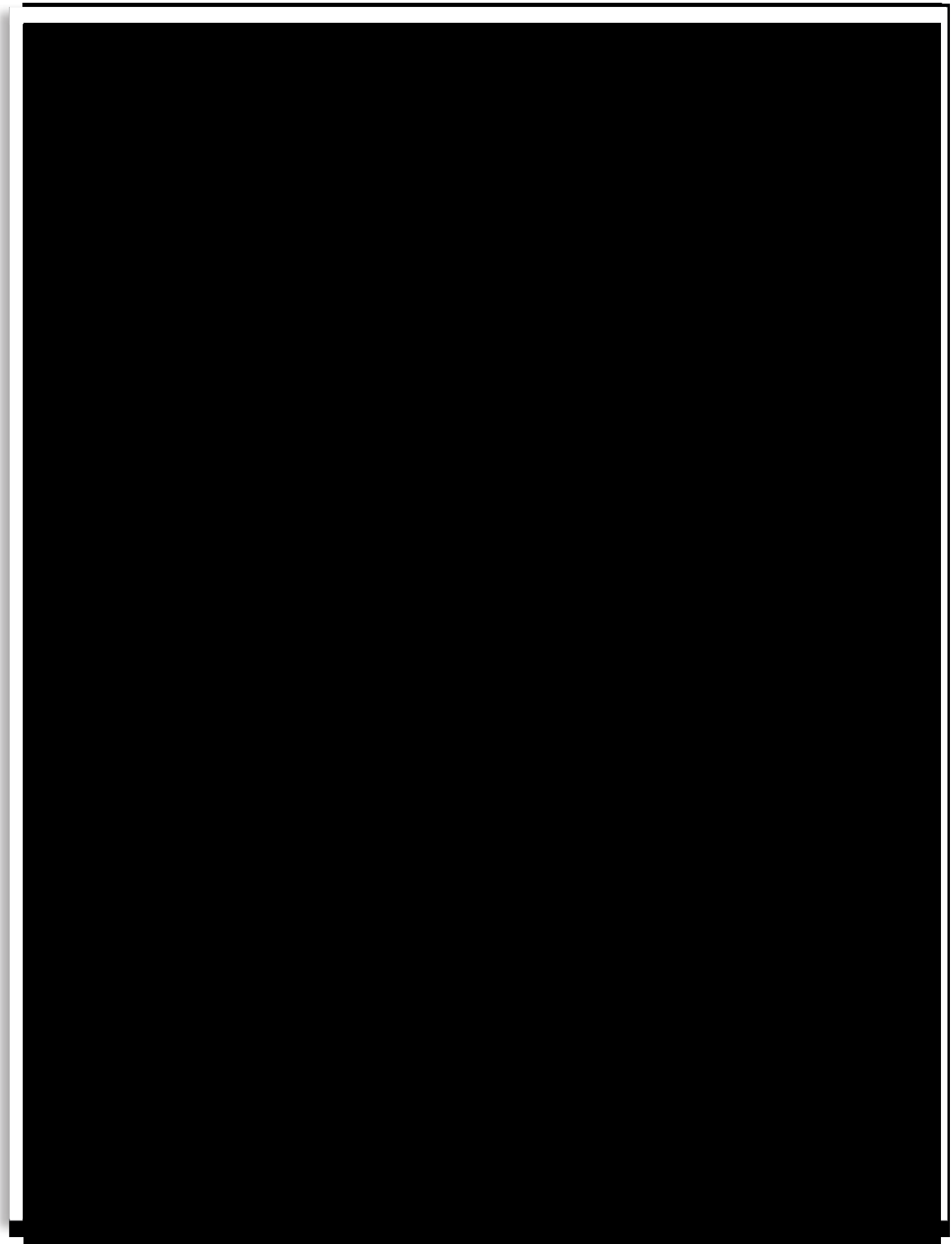

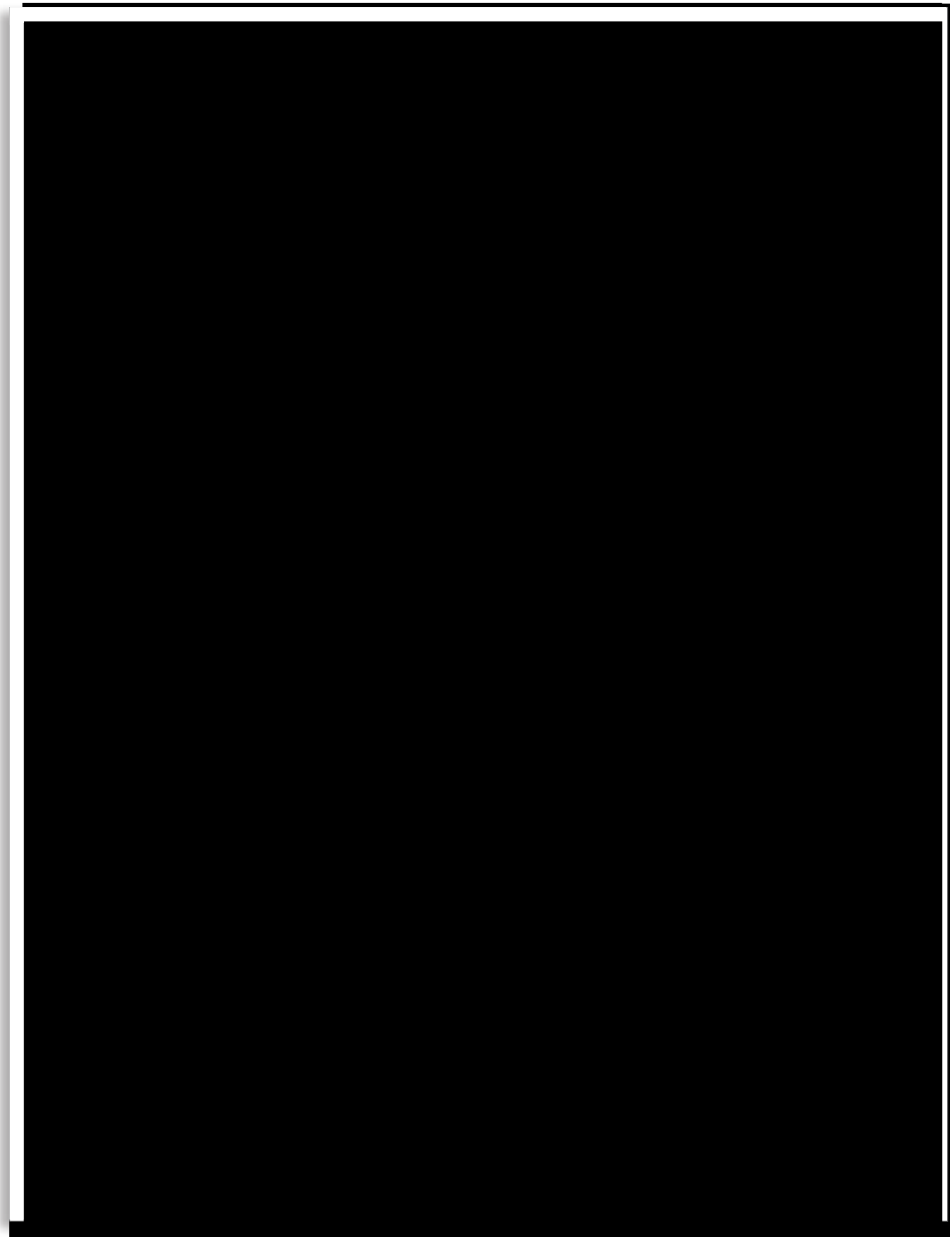

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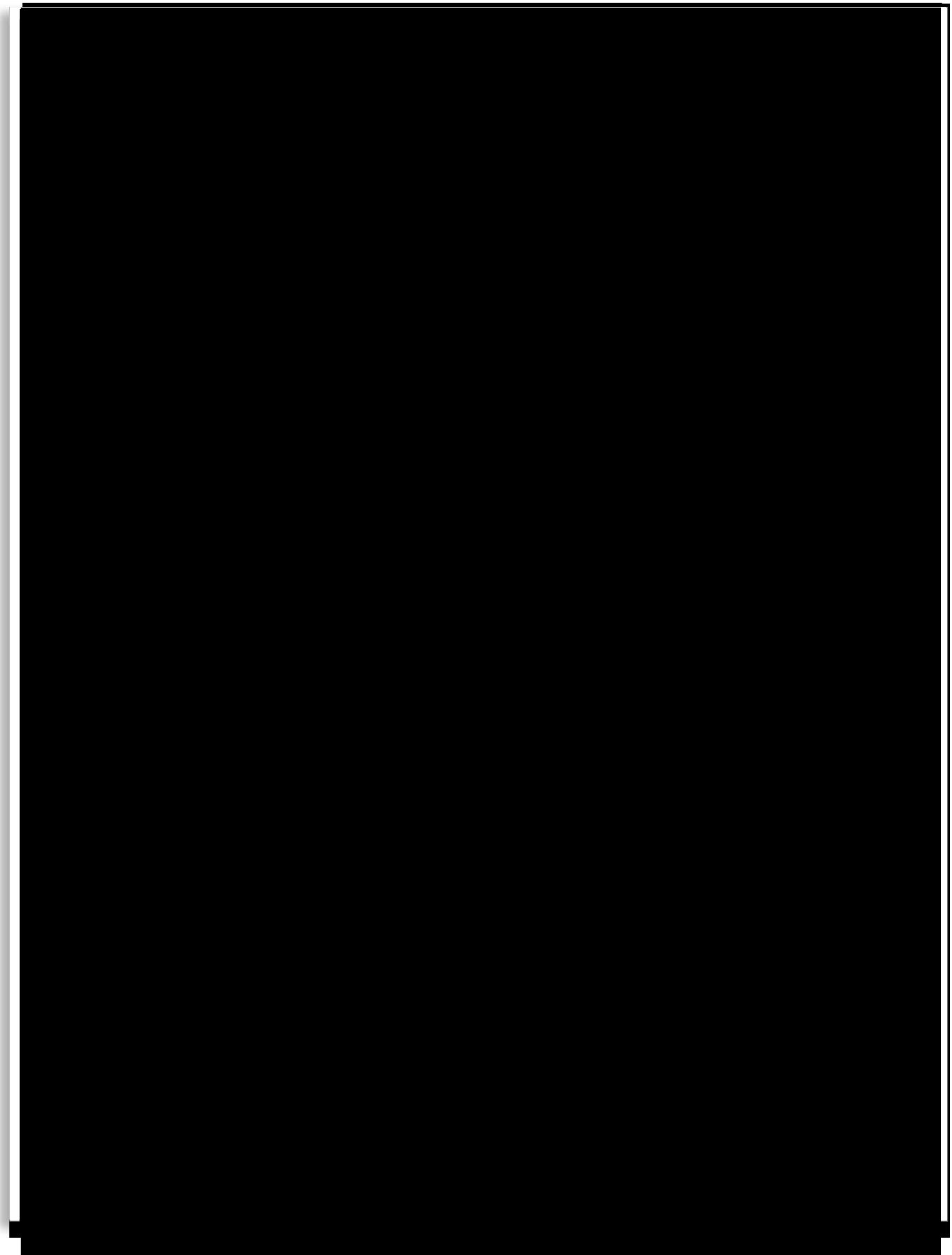

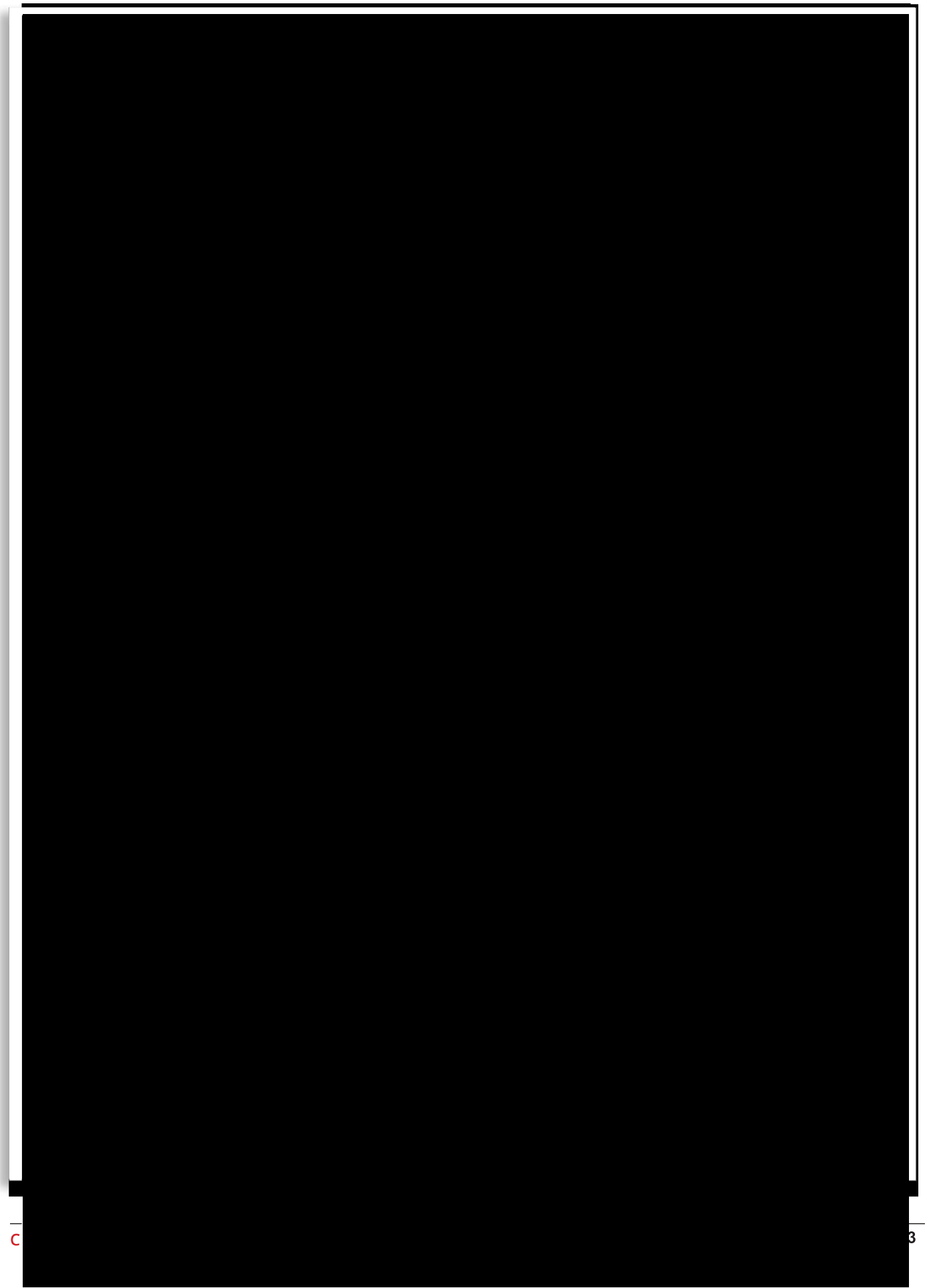

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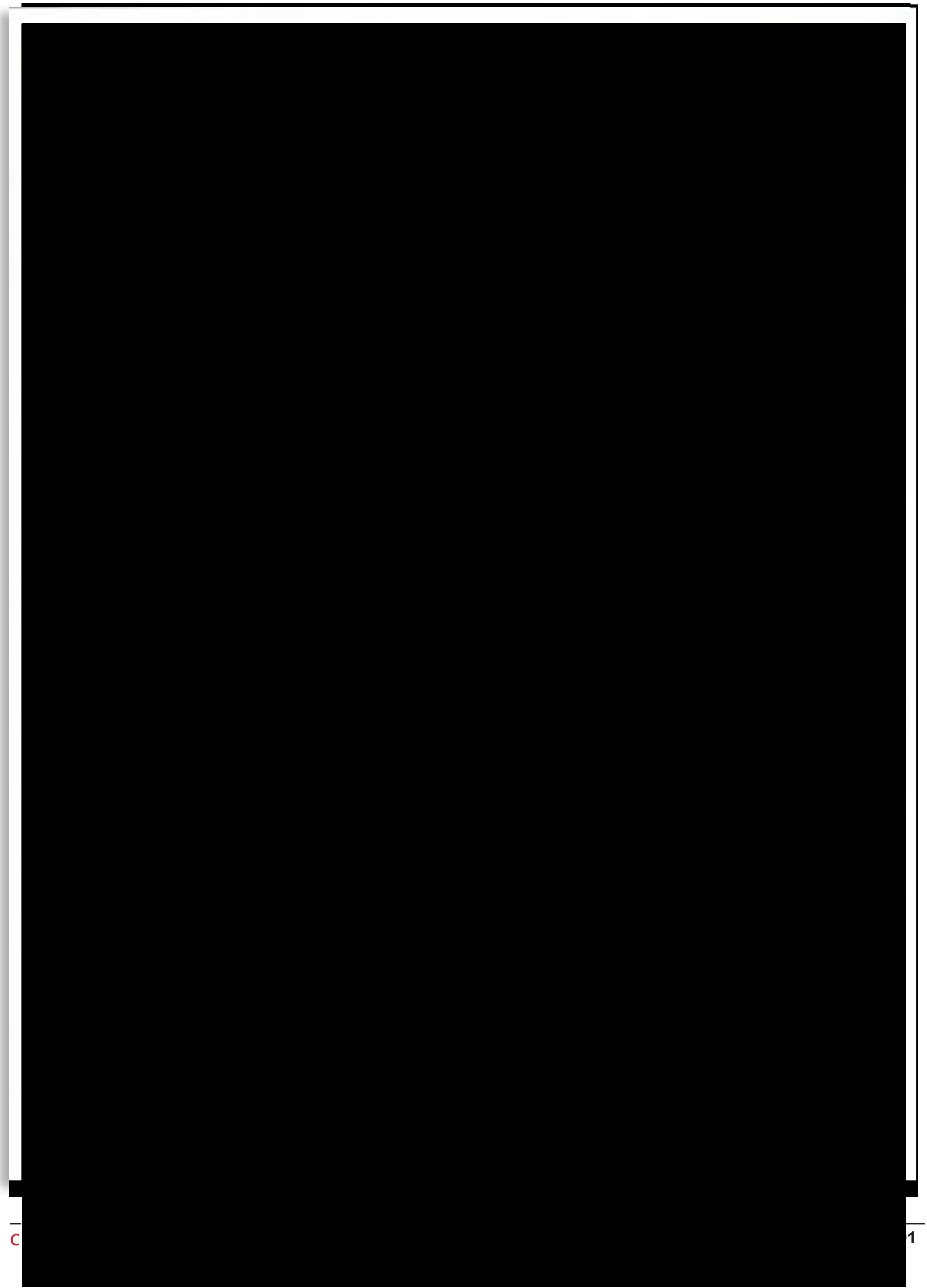

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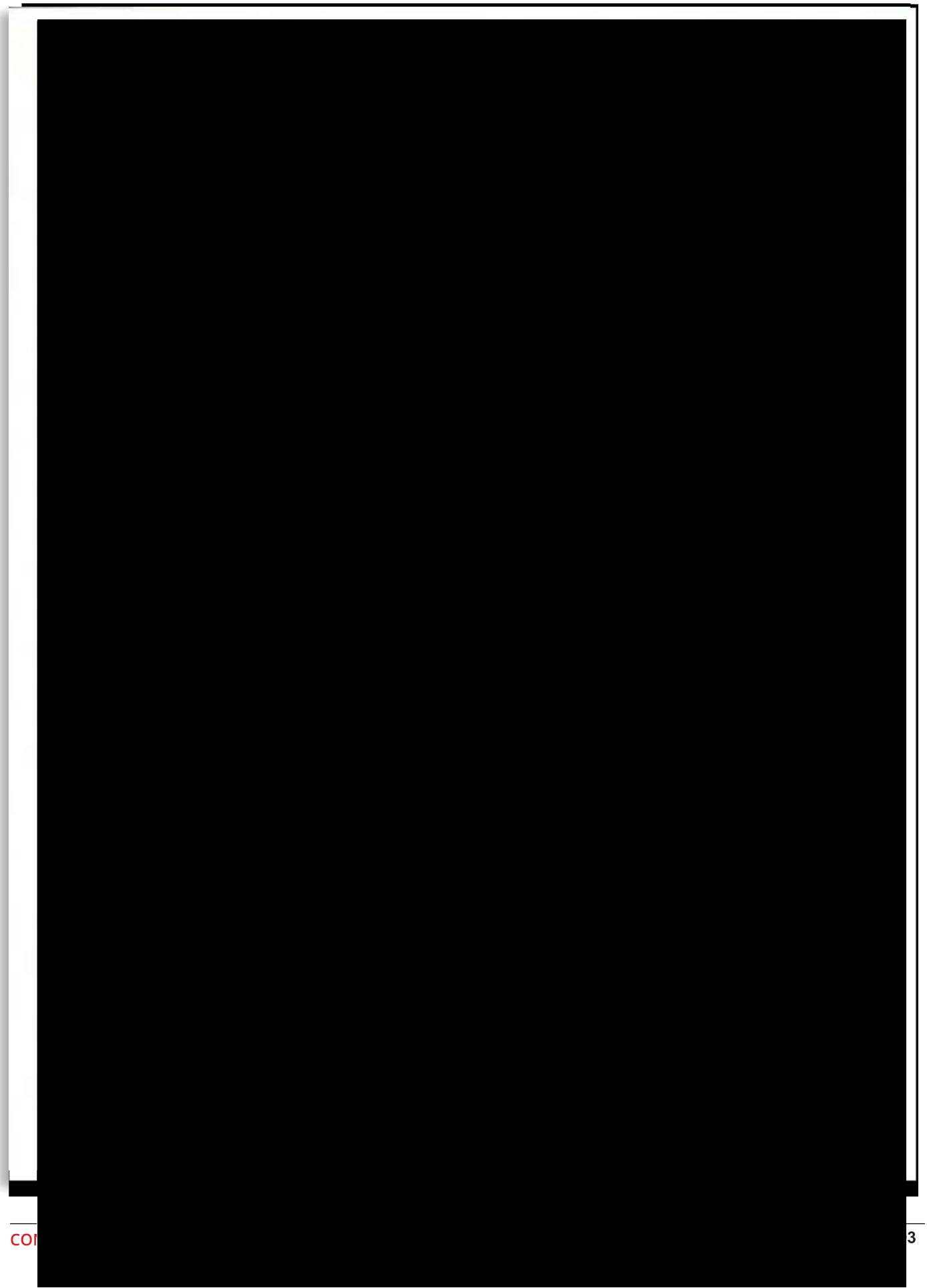

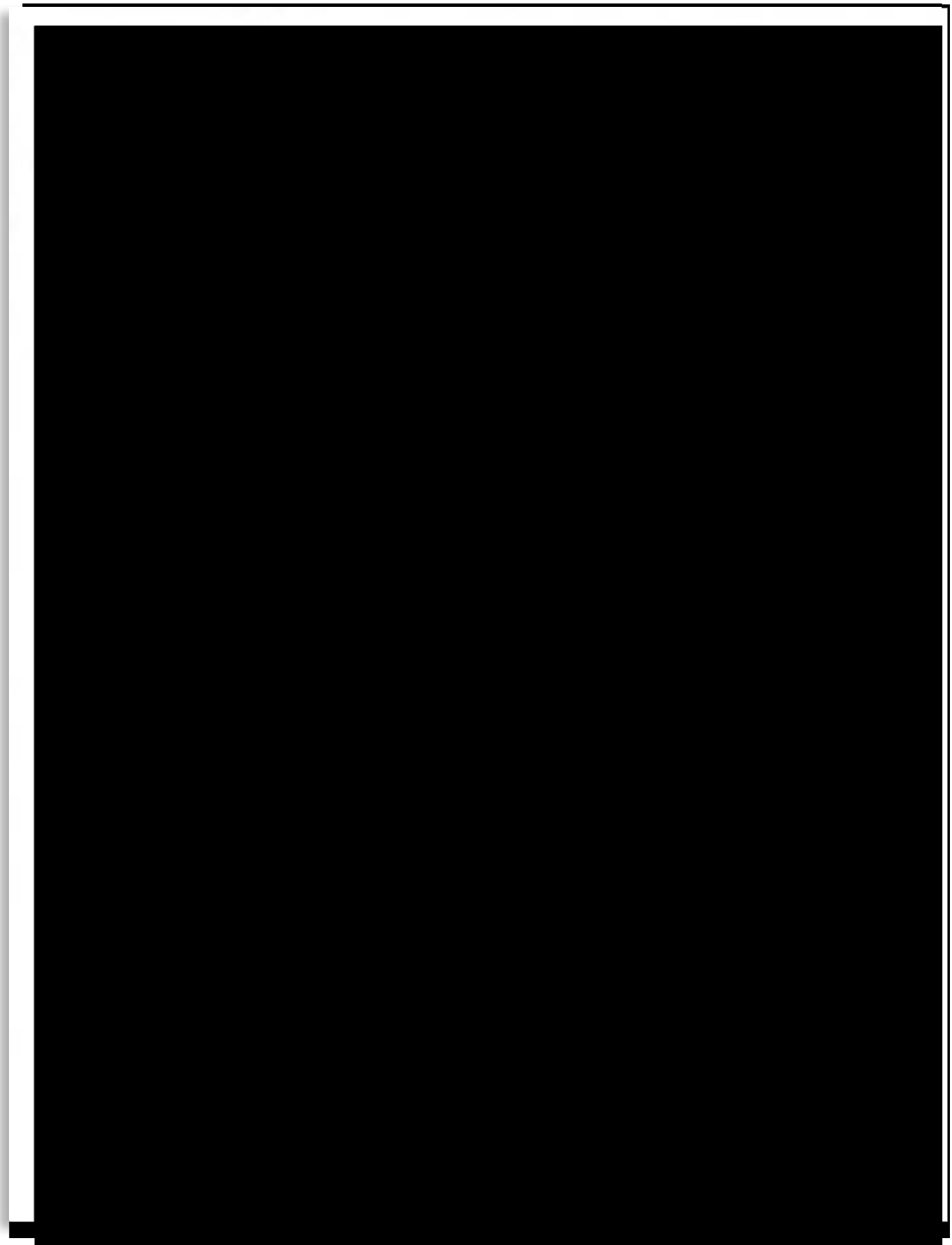

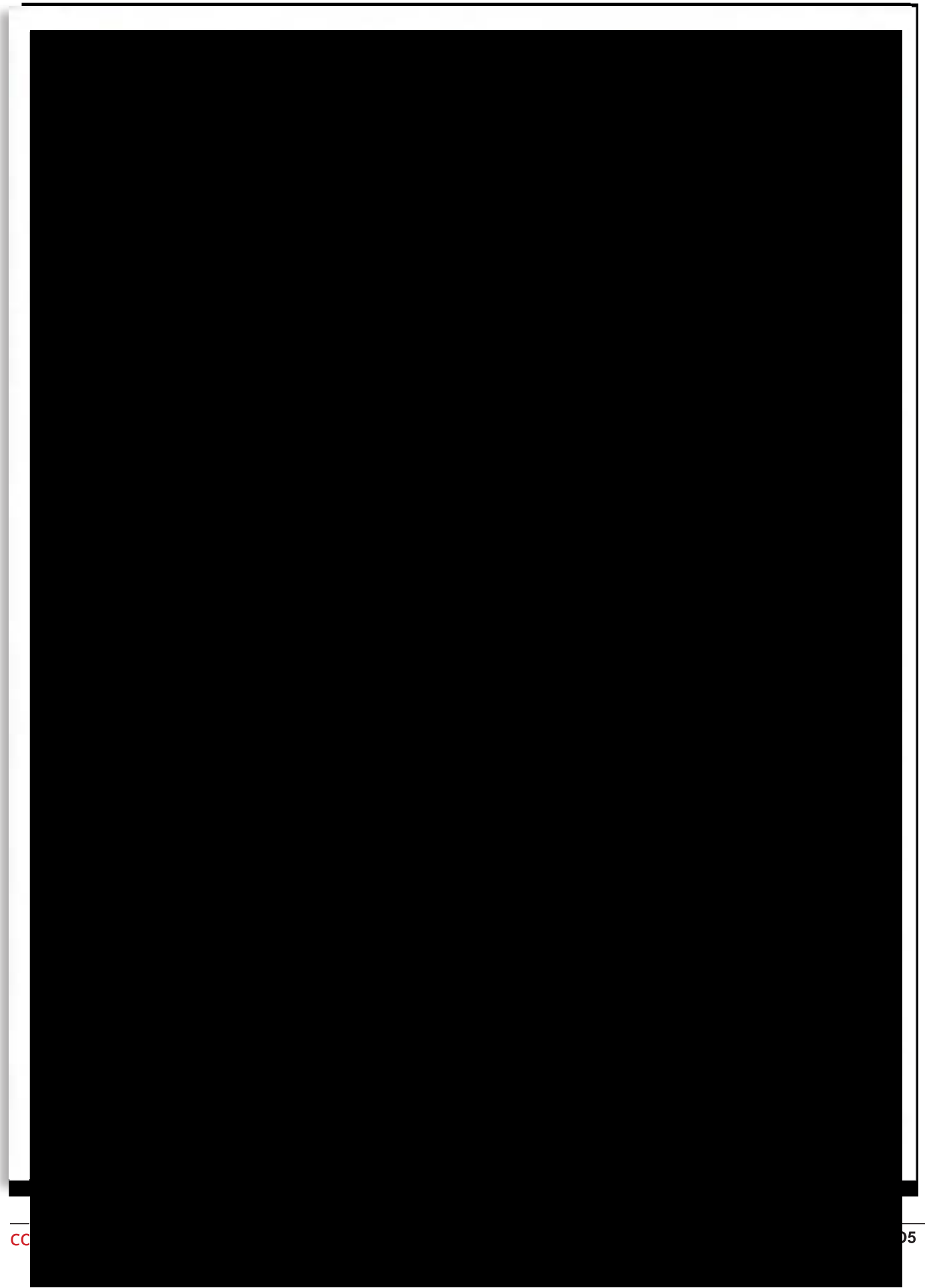

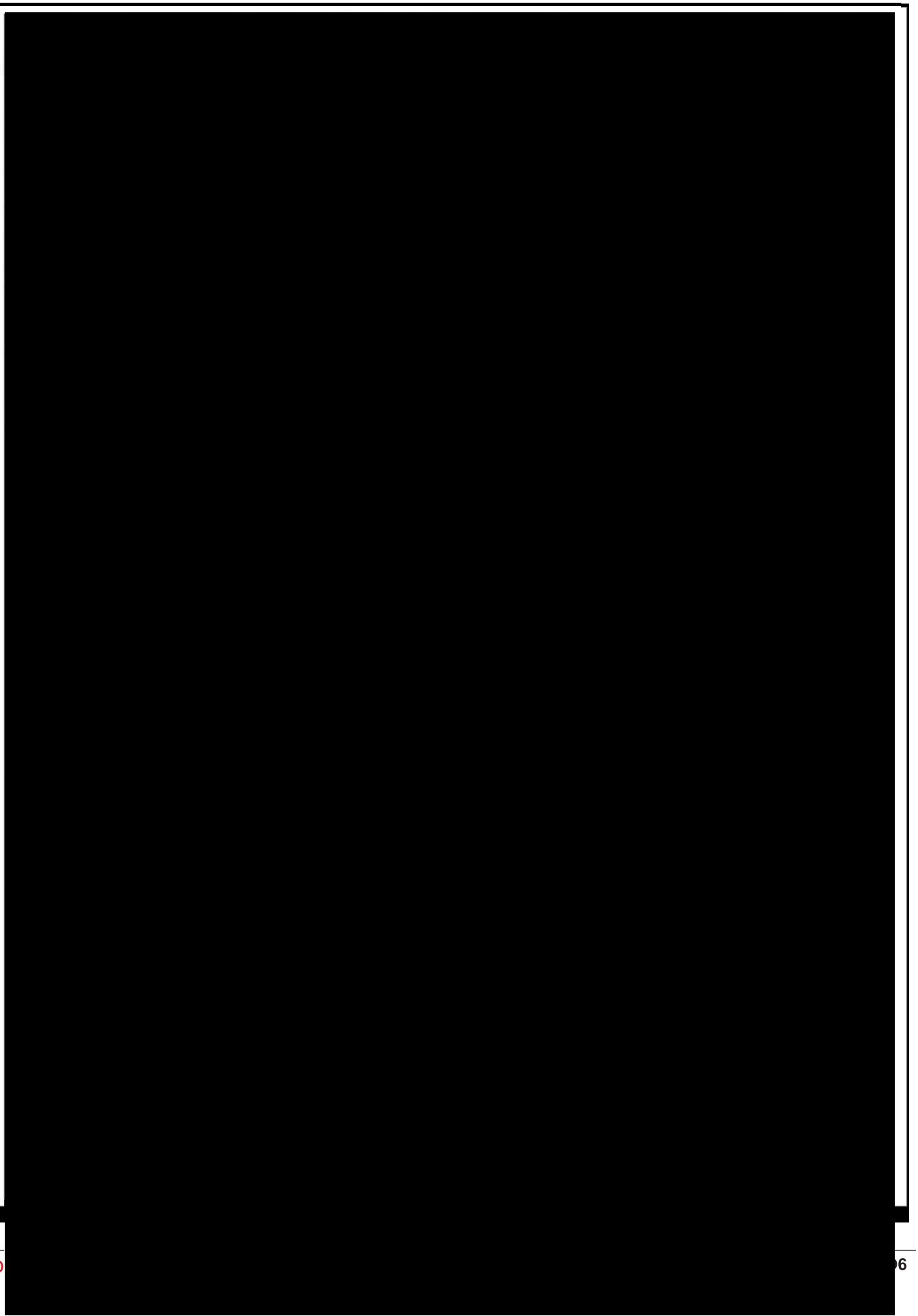

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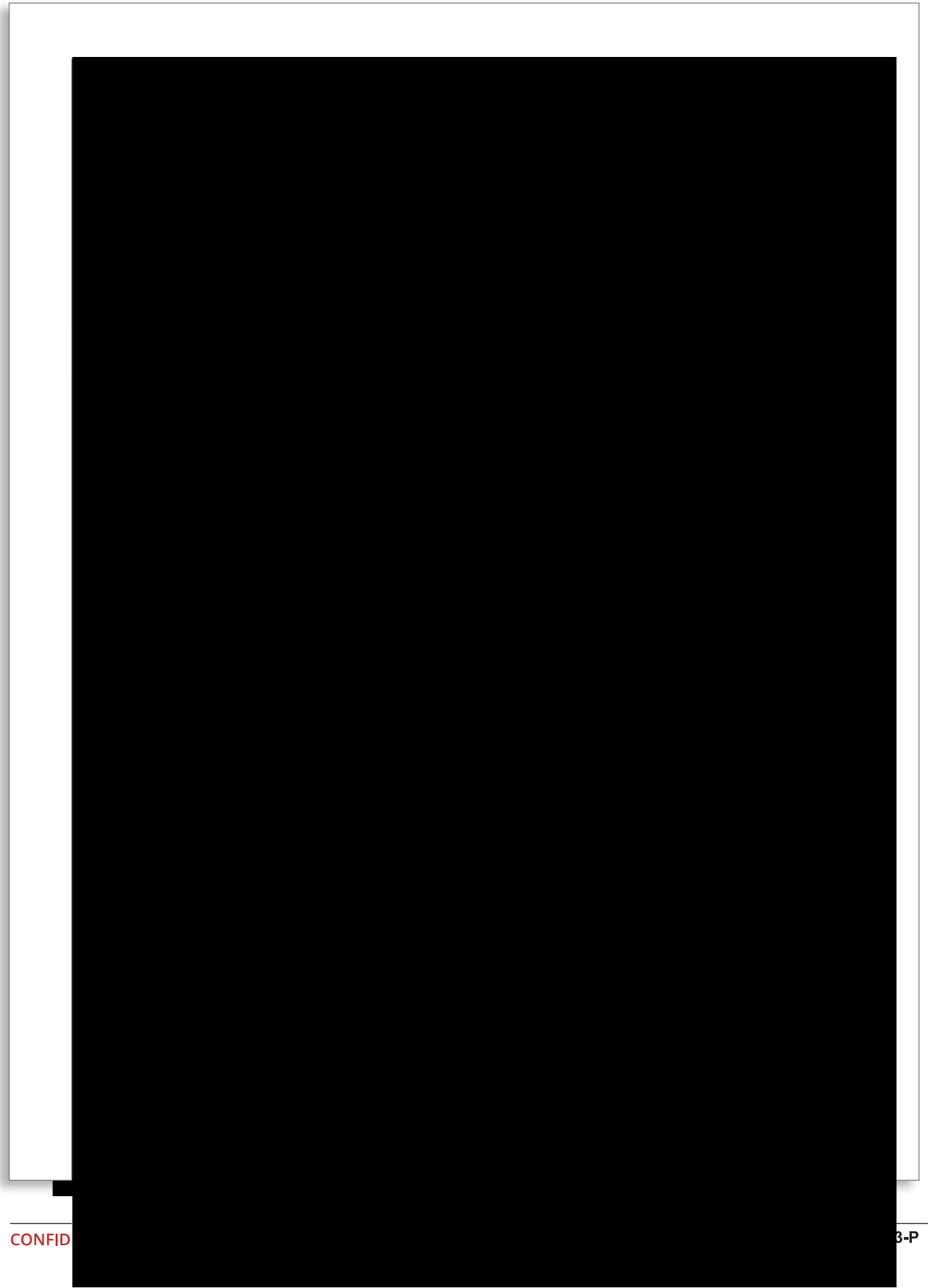

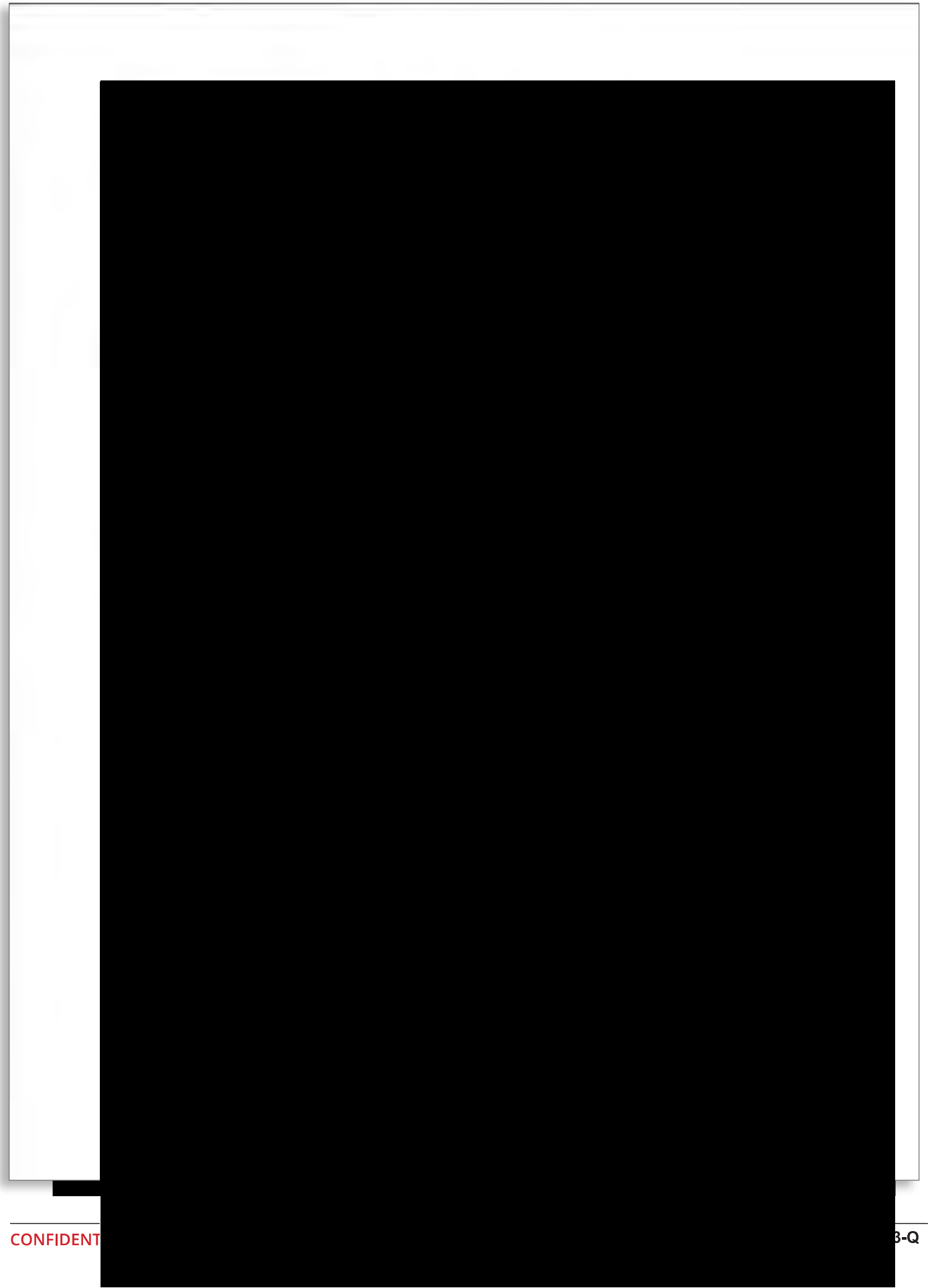

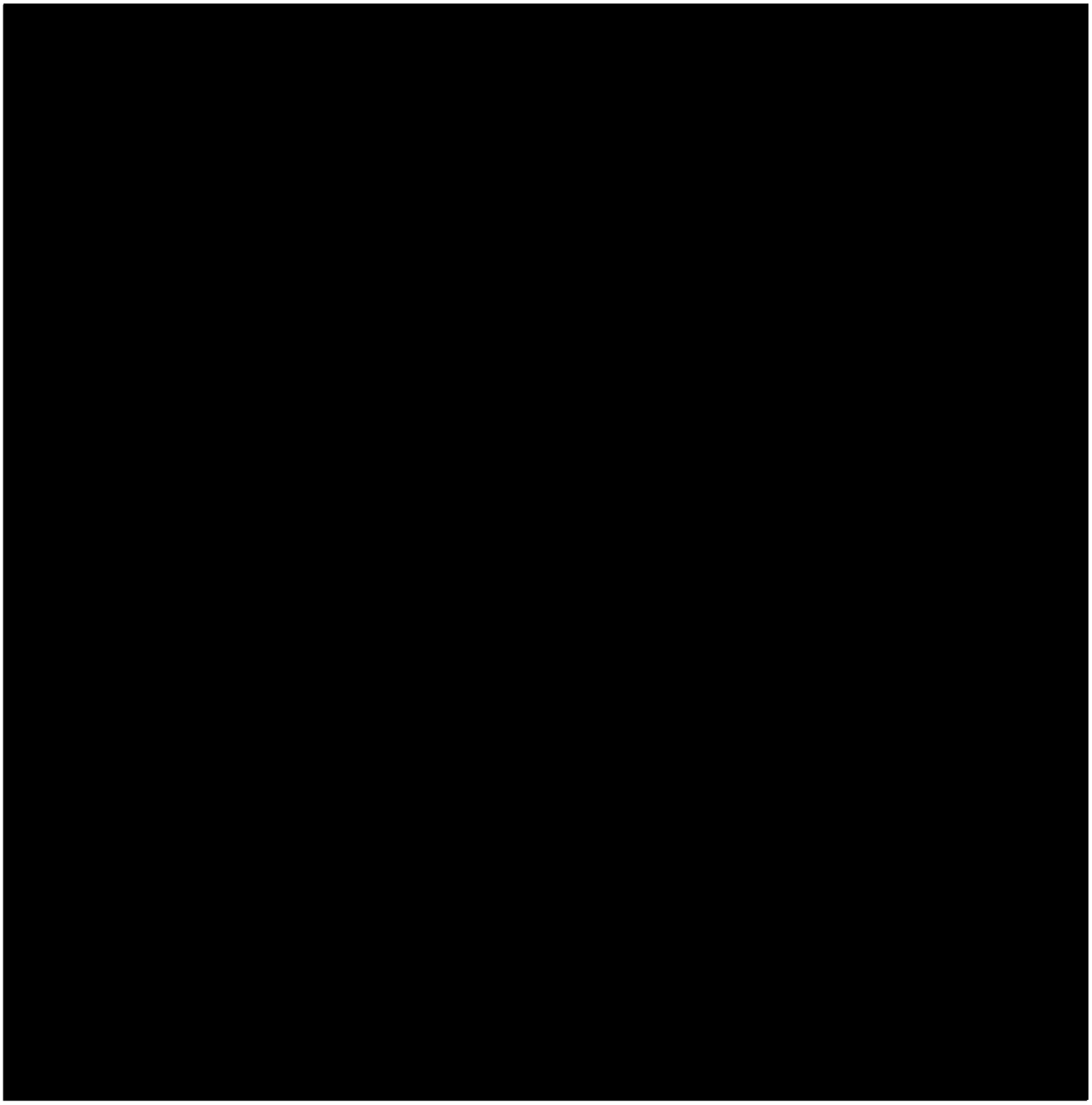

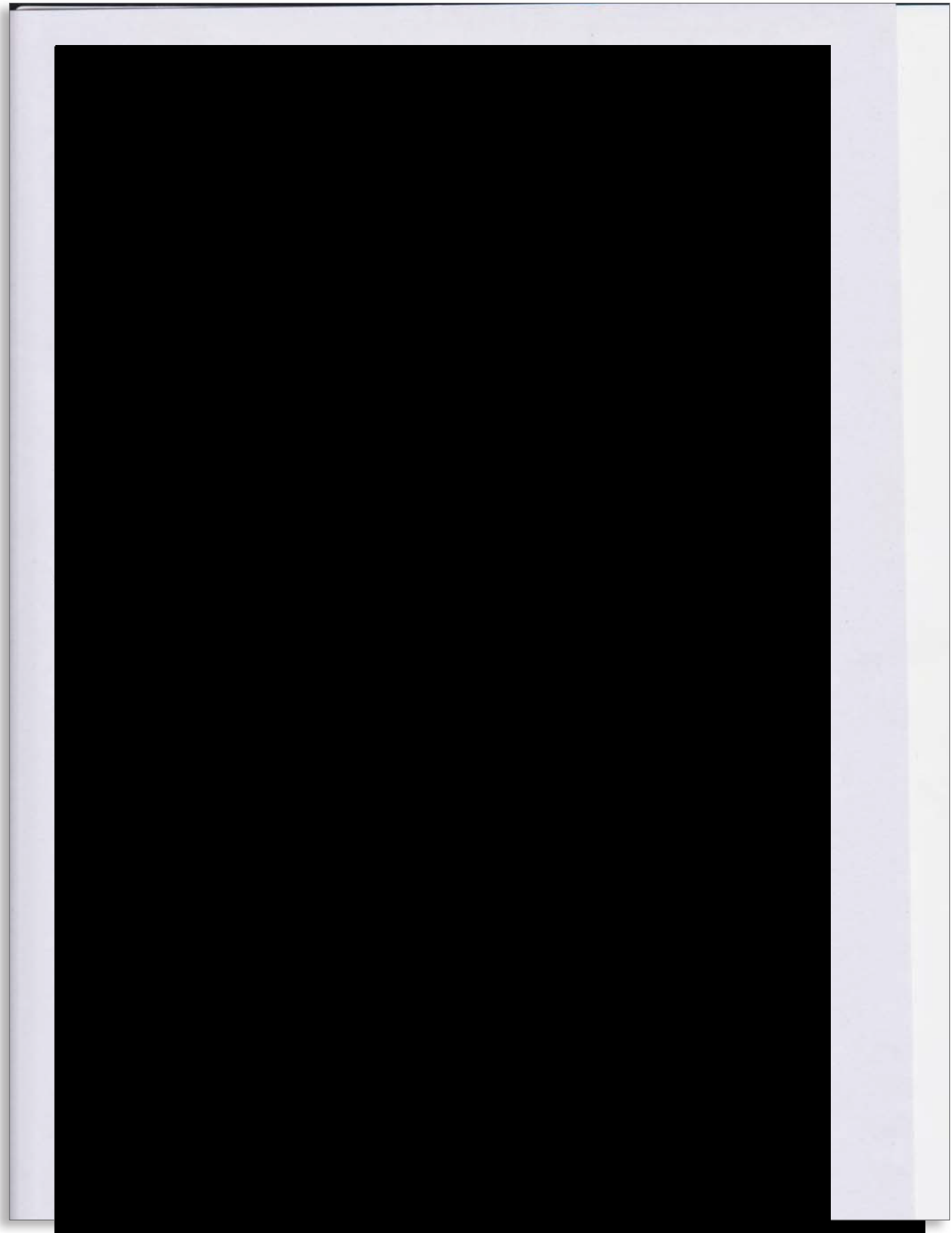

Response to Criterion 6

"Background Checks"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

CONTENTS

ATTACHMENTS

6-A: Endnotes
6-B: Compliance Checklist

Criterion 6 Language

Ability to comply with criminal background check requirements pursuant to this chapter and sections 329D-7, 329D-12, and 846-2.7, HRS; Response shall be no longer than three (3) pages.

We at Launiupoko Farm with our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") have the ability to meet and exceed the criminal background check requirements of HAR 11-850 and HRS 329D-12, as demonstrated in this Response. Endnotes throughout the text show compliance with relevant cited HAR and HRS sections (Hawai'i Administrative Rules and Hawai'i Revised Statutes), and are listed separately as **Attachment 6-A** and in Compliance Checklist form as **Attachment 6-B**.

We hold ourselves to a high standard. To ensure full legal compliance and the reputable and responsible character of our dispensary, we will require background checks for all of our employees, subcontractors and their employees, and prospective employees.[1] These standards and background checks will apply to all individuals, not just new hires, and will be re-conducted at least annually for all required persons[2] and more frequently at management's discretion.[3]

Persons Requiring a Criminal Background Check

We will require a criminal background check as outlined below any time one of the following positions is filled or changes: all officers, directors, shareholders with at least 25% ownership interest or more, members, and managers of an entity applicant or licensee; any employee of a dispensary; any subcontractor of a dispensary; all officers, directors, shareholders with at least 25% ownership interest or more, members, and managers of a subcontracted production center or retail dispensing location; each employee of a subcontracted production center or retail dispensing location; any person permitted to enter or remain in dispensary facilities pursuant to sections 329D-6, 329D-15, and 329D-16, HRS; and agents of any of the above persons.[4] This will include all of our consultants, including all of our expert consultants from JATAC.[5]

Criminal Background Check Policies and Procedures

Every person in, or applying for, any of these positions will sign a written consent form to undergo a criminal background check.[6] We will pay all applicable processing fees for conducting the background check.[7] Further, once any individual is placed in any of these positions, they will sign a written consent form to undergo a repeat of this background check at any time during their association with us.

▶ FBI AND STATE CRIMINAL BACKGROUND CHECKS

The criminal background check will include the submission of fingerprints to the Federal Bureau of Investigation for a national criminal background check and to the Hawai'i Criminal Justice Data Center for a state criminal background check that will include non-conviction data.[8] Any individual required to undergo a criminal background check will submit the following information to the requesting agency or qualified entity: consent to obtain the applicant, employee, or volunteer's fingerprints, consent to conduct the criminal history record check, and consent to participate in the Rap Back program; identifying information required by the Federal Bureau of Investigation, such as the applicant, employee, or volunteer's name, date of birth, height, weight, eye color, hair color, gender, race, and place of birth; and a statement indicating whether the applicant, employee, or volunteer has ever been convicted of a crime and, if so, the particulars of the conviction.[9]

▶ E-CRIM REPORTS

Additionally, all of our employees will agree to provide a recent E-Crim report upon request of the dispensary and to report all arrests or convictions to the dispensary when they occur. We will require E-Crim reports to be run on an at least annual basis and will report any arrest or conviction of an employee to the Department immediately on being informed of it.[10]

▶ EMPLOYMENT SCREENING SERVICES

Beyond this background check, we will obtain permission from all employees to provide their information to a third party employee screening service such as Employment Screening Services. This permission will include the ability to run reports through the screening service, which will include residence history and felony and misdemeanor conviction records.

Disqualifying Factors in Criminal Background Checks

These criminal background checks will be run both to ensure that individuals meet the high standards to which we hold our employees and affiliates, and to ensure that no individual is given a position if they have a disqualifying factor in their criminal background check. Disqualifying factors include: any felony conviction;[11] a conviction related to use, possession, or distribution of drugs or intoxicating compounds; a conviction for a crime involving violence; a conviction for a crime involving a firearm; a conviction for a crime involving theft, or business or commercial fraud; or any other background history that the department finds would pose a risk to the health, safety, or welfare of the public or a qualifying patient, considering the nature of the offense, the time elapsed since the offense occurred, and evidence of rehabilitation.[12] If an individual has a disqualifying factor revealed by their background check, the individual shall be prohibited from joining us in any capacity.[13] If we have any reason to believe that an individual in any of the above positions has a new disqualifying factor, we will demand a current E-Crim report and run a report with the third party screening service. If an arrest or conviction has occurred, even if not for one of the crimes listed above, we will immediately inform the Department.

1. HRS 329D-7(8)
2. HRS §329D-12, HAR §11-850-17(a)
3. HRS §329D-12,HAR §11-850-17(d)
4. HRS §329D-12, HAR §11-850-17(a),
5. HAR §11-850-51(A)(3)(A)
6. HRS §329D-12, HAR §11-850-17(c)
7. HRS §329D-12, HAR §11-850-17(c)
8. HRS 846-2.7(a)
9. HRS 846-2.7(a), 846-2.7(d)
10. HRS §329D-12, HAR §11-850-17(d)
11. HRS §329D-12, HAR 11-850-16,
12. HRS §329D-12, HAR §11-850-17(b)1-6
13. HRS §329D-12, HAR §11-850-17(b)

HAR COMPLIANCE CHECKLIST

CRITERION 6 "Background Checks"

Ability to comply with criminal background check requirements pursuant to this chapter and sections 329D-7, 329D-12, and 846-2.7, HRS;

Response shall be no longer than three (3) pages.

Relevant HAR sections	Endnote Number
HAR §11-850-17(a)	2, 4
HAR §11-850-17(b)	11, 12
HAR §11-850-17(c)	5, 6
HAR §11-850-17(d)	3

Response to Criterion 8

"Patient Confidentiality"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

CONTENTS

ATTACHMENTS

8-A: Endnotes

8-B: Compliance Checklist

8-C: BioTrackTHC Supporting Documents

8-D: State Dispensary Software RFP Excerpts

8-E: Patient Focused Certification Information

Criterion 8 Language

Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products; Response shall be no longer than three (3) pages.

We at Launiupoko Farm with our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") have the ability to maintain confidentiality of patients medical conditions, health statuses, and purchases, as demonstrated in this Response. Endnotes throughout the text show compliance with relevant cited HAR and HRS sections (Hawai'i Administrative Rules and Hawai'i Revised Statutes), and are listed separately as **Attachment 8-A** and in Compliance Checklist form as **Attachment 8-B**.

BioTrackTHC Will Ensure Confidentiality of Information and Purchases

Launiupoko Farm will maintain patient confidentiality through: a) the use of BioTrackTHC, our integrated seed-to-sale inventory management software, b) established policies and procedures, and c) appropriate training and supervision of all employees who have direct patient contact or have any access to sensitive data (See **Attachment 8-C**: BioTrackTHC supporting documents).

BioTrackTHC provides industry standard Secure Socket Layer (SSL) encryption technology ensuring a secure operating experience, and it supports remote access that is fully secure and founded on current industry standards of strong authentication, encryption and HIPAA compliance. Further, the connection to BioTrackTHC is encrypted end-to-end, leaving no point in the network path unencrypted. Storing all qualified patient information within the BioTrackTHC system ensures that all such data, including personally identifying information, is confidential as required by law. We will use BioTrackTHC to track all patient and caregiver purchases so that the amounts, time, date, and individuals involved with all purchases will also be stored in an encrypted and confidential system.

Little or No Access to Information Will Ensure Confidentiality of Qualifying Patients' Medical Conditions and Health Statuses

Our dedication to patient confidentiality begins with minimizing the information that qualified patients and caregivers will be required to provide us and that we will maintain. We will verify the validity of patients' Registry Identification Cards directly with the Department of Health (DOH) software tracking system (See **Attachment 8-D**: State Dispensary Software RFP Excerpts).[1] Thus we will have no need for any verifying patient records from any doctor. We at Launiupoko Farm Dispensary are not doctors, and we do not diagnose, prescribe, or give any medical advice, or keep any medical records. All of our customers have their own doctors who keep their own records. The only information that we will have regarding medical condition and health status is that an individual patient is a qualified, registered patient and that their Registry Identification Card is valid according to the Department. We will not have access to any information regarding medical condition and health status held by the DOH. We will store qualified patient and caregiver verification information within BioTrackTHC to safeguard any personal identifying information and to keep it confidential from public disclosure.[2]

▶ INDEPENDENT PROVIDERS OF ALTERNATIVE HEALTH SERVICES

In the event that independent providers of alternative health and wellness services at our dispensary have information regarding a qualifying patient's medical condition or health status, each provider will be responsible for the security of such information. A written agreement between Launiupoko Farm and such independent providers will require them to comply with all laws and regulations, especially those pertaining to the confidentiality of patient information.

Policies, Procedures, and Training Will Ensure Confidentiality

Limiting and safely storing the information that we obtain and maintain with BioTrackTHC ensures the confidentiality of qualified patient and caregiver information, but we will also implement policies, procedures, and training that addresses this requirement. All of our employees will undergo Patient Focused Certification training, which includes compliance and best practice instruction by the Cannabis Training Institute (see **Attachment 8-E**: Patient Focused Certification Information).

All employees who work one-on-one with patients regarding the selection of medicine will receive additional training regarding best practices for interactions with patients and will sign an agreement stating that all patient conversations will be kept confidential.

Photography and Video Recording Prohibited in Dispensary Facility

To prevent any invasion of privacy or confidentiality by photography or video recording, we will implement policy and training, as well as post physical signs, that prohibit photography or video recording inside a dispensary facility. The only individuals who will be permitted to photograph or record videos inside facilities are the dispensary licensee, the Department, law enforcement personnel, or persons approved in writing by the Department.[3]

1. REQUEST FOR PROPOSALS No. RFP-15-HTH-OHCA FOR MEDICAL MARIJUANA DISPENSARIES COMPUTER SOFTWARE TRACKING SYSTEM, pg 4, License Requirement 1, but see pg. 36, Exhibit B – Specifications, Functional Requirements, Point of Sale Sub-Section. http://health.hawaii.gov/medicalmarijuana/wp-content/blogs.dir/93/files/2015/11/DOH-S2S-RFP-111915.pdf
2. HAR §11-850-40(a)
3. HAR §11-850-40(b)

HAR COMPLIANCE CHECKLIST

CRITERION 8 "Patient Confidentiality"

Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

Response shall be no longer than three (3) pages.

Relevant HAR sections	Endnote Number
HAR §11-850-40(a)	2
HAR §11-850-40(b)	3

BioTrackTHC™
The Only Seed to Sale Solution

[redacted]

1/12/2015

Reference: BioTrackTHC Support Document and Letter of Intent
Lau Niu Poko

Dear James,

BioTrackTHC provides effective cutting -edge technology solutions for the emerging legal marijuana industry. Solutions that not only prevent product theft, but assist business owners in running their cultivation, processing, packaging, and retail operations more profitably and more legally compliant. Furthermore, this is all done without leaving sensitive business and consumer data vulnerable in the cloud. Specifically, BioTrackTHC is the industry's only true seed--to--sale software system with enterprise resource planning, complete inventory tracking, point--of--sale, marketing, financial reporting and regulatory compliance features. Subsequently, because it is a server -based system with advanced security features, customers can rest assured that no one,- not even the BioTrackTHC team,- can access their business or consumer information without their permission.

This document confirms BioTrackTHC's intentions to enter into a formal agreement with Lau Niu Poko to provide software solutions guaranteed to meet published Hawaii Department of Health reporting, regulation, and compliance guidelines for cannabis production facilities in the event that an authorized license is obtained.

Thank you for your consideration of BioTrackTHC. We are eager to assist you in your efforts to acquire a license and look forward to entering into a software solution agreement with you upon receipt of that license.

Best Regards,

Moe Afaneh
Chief Operating Officer

[redacted]

BioTrackTHC™ The Only Seed to Sale Solution

Hawaii HB 321

(A) Secure inventory tracking and control;
(B) Protecting confidential customer information;

(1) Ability to comply with the requirements in this chapter and chapters 329 and 3290, HRS, for inventory tracking, security, and sales limits for qualifying patients;

(1) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

(2) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 3290-7 and 3290-8, HRS;

(3) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;

(4) A plan for secure disposal or destruction of marijuana and manufactured marijuana products;

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

(a) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

(b) A dispensary licensee shall not accept any marijuana or manufactured marijuana products from any other dispensary.

[redacted]

NO pre-rolls, no samples, no paraphernalia

§11-850-35 Employee records

(a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked.

The Time Clock function within BioTrackTHC records the date and time that every employee clocks into and out of the system. A manager can be granted the permission within the system to modify the clock in/out times for an employee in the event of an error or someone forgetting to clock out.

§11-850-36 Transport

(a) A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.

(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.

(c) Each time marijuana and manufactured marijuana products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system. A dispensary licensee shall only transport marijuana or manufactured marijuana products that are listed on the manifest. A dispensary licensee shall transport marijuana or manufactured marijuana products in secured containers . The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.

(b) Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.

[redacted]

(c) The designated employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest.

(d) The dispensary licensee shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion.

(e) A dispensary licensee shall not transport marijuana or manufactured marijuana products:

(1) Off site to qualifying patients or to primary caregivers;
(2) To another county or another island within the same county; or
(3) To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.

(b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-38 Reports.

(a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

(b) Reports shall include but not be limited to:
1. Records of entry and exit for all individuals who entered a dispensary facility;

2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
3. Amounts by category of marijuana and manufactured marijuana products sold;
4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
5. A summary financial statement;
6. Laboratory results of all tests conducted;
7. Description of any breach or halt in its security system and tracking system; and
8. Any other information requested by the department.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-39 Audits

(a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
(b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
(c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit Icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).

§11-850-41 Record retention.

(a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:
(1) Inventory tracking including transport of marijuana and manufactured marijuana products;

(2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
(3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
(4) Logs of entry and exit for dispensary facilities; and
(5) Employee records.

(b) A dispensary licensee shall retain for a minimum of one year all security recordings.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

§11-850-42 Allowed quantities for dispensing.

(a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days .

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.

§11-850-43 Disposal or destruction.

(a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the

cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.

(b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.

(c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.

§11-850-61 Tracking requirements

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable . The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Marijuana.

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

§11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

§11-850-74 Equivalent weights for manufactured marijuana products.

(a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.

(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

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[redacted]

BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamper-evident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

LABORATORY CERTIFICATION, TESTING, AND STANDARDS

§11-850-81 Laboratory testing required.

A dispensary licensee shall not ' dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

§11-850-85 Laboratory standards and testing

(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.

(a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

(1) The chemical profile of the batch for the following compounds:
- (A) 9 (delta 9) - Tetrahydrocannabinol (THC)
- (B) Tetrahydrocannabinol Acid (THCA)
- (C) Cannabidiol (CBD)
- (D) Cannabidiolic Acid (CBDA)
- (E) Cannabigerol (CBG)
- (F) Cannabinol (CBN)

(2) The presence of the following contaminants, which shall not exceed the following levels:

(A) Heavy metals:
- (i) Arsenic 10.0 ppm
- (ii) Lead 6.0 ppm
- (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm

[redacted]

(B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm

(C) Solvents:

(i) Butanes 800 ppm

(ii) Heptanes 500 ppm (iii) Benzene** 1 ppm

(iv) Toluene** 1 ppm (v) Hexane** 10 ppm

(vi) Total Xylenes (m,o,p-xylene) 1 ppm

** Contaminants in solvents

(D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(E) Moisture content of plant material <15%

(F) Microbiological impurities, including but not limited to:

1. Total Viable Aerobic Bacteria:
   a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
   b. C02 and Solvent Based Extracts: 104 CFU/g
2. Total Yeast and Mold:

(a) Unprocessed and Processed Materials: 104 CFU/g

(b) C02 and Solvent Based Extracts: 103 CFU/g

(iii) Total Coliforms:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(iv) Bile-tolerant Gram Negative Bacteria:

(a) Unprocessed and Processed Materials: 103 CFU/g

(b) C02 and Solvent Based Extracts: 102 CFU/g

(v) *E. coli* (pathogenic strains) and *Salmonella spp.:* Not detected in 1 g

(vi) *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger :* <1 CFU/g;

(vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and

(3) Additional testing requested at the discretion of the department.

The above information can all be generated within BioTrackTHC and reflected on the label for each product.

(d) The certified laboratory may retest or reanalyze ,the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.

(e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.

(f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:

1. The time and date the sample was obtained;
2. A description of the sample, including the amount;
3. What tests were conducted on each sample;
4. The results of the tests including the certificate of analysis; and
5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
6. and shall make all the records available to the department upon request.

(g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.

(h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.

(i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.

(j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon

receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore, every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.

All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.

BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.

§11-850-92 Packaging and labeling for retail sale.

(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

(1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:

(A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;

(B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;

(2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;

(3) The batch number and date of packaging;

(4) Includes a computer tracking inventory identification number barcode generated by tracking software;
(5) Date of harvest or manufacture and "Use by date";
(6) Instructions for use;
(7) The phrases "For medical use only" and "Not for resale or transfer to another person";
(8) The following warnings:
(A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
(B) "This product has intoxicating effects and may be habit forming";
(C) "Smoking is hazardous to your health";
(D) "There may be health risks associated with consumption of this product";
(E) "This product is not reconunended for use by women who are pregnant or breast feeding";
(F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
(6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
(9) The name of the laboratory that performed the testing;
provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
(c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

BioTrackTHC™'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.


BioTrackTHC™
The Only Seed to Sale Solution

[redacted]

Hawaii Medical Marijuana Dispensary License Application Support Document

The format of the application asks for one's education, knowledge and experience with the sections outlined below, among others. The information contained within this document is to be used to assist an applicant with answering the questions that fall within the scope of the capabilities of BioTrackTHC; i.e. inventory tracking, sales limits, labeling, etc.

No guarantees or warranties, either expressed or implied, are associated with this document.

I) Secure inventory tracking and control

All authentication is encrypted via industry standard SSL and hardware is managed and maintained internally. As with any system involving patient data, security is a top priority at BioTrackTHC. Each BioTrackTHC client utilizes the latest Secure Socket Layer (SSL) encryption technology to ensure a secure operating experience. All technology supporting remote access to the BioTrackTHC based solution can be described as fully secure and founded on current industry standards of strong authentication, encryption and HIPAA Compliance. Regardless of network connection type being wired/wireless or commercial/government ISP, the connection state is always encrypted end-to-end from browser to web server using Secure Socket Layer (SSL). Database connections are also encrypted via standard authentication + SSL. At no point in the network path will data be unencrypted.

(4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;

(1) A protocol for admitting qualifying patients or primary caregivers with valid government issued photo identification and medical marijuana registration cards issued pursuant to chapter 329, HRS, prior to allowing them access to the secured room for sales;

This is the responsibility of the licensee.

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;

[redacted]

[redacted]

SUBCHAPTER 5
TRACKING REQUIREMENTS

§11-850-61 Tracking requirements.

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

The BioTrackTHC system is comprised of several components; all of which are designed to seamlessly integrate with one another. Recognized as the industry leader in seed-to-sale tracking, the BioTrackTHC producer, processor and retail tracking components are completely interoperable with one another. Whether the tracking requirements include plants, trimmings, waste, conversion, dispensing or anything in between; the BioTrackTHC system, in concert with its unique inventory typing system, can currently track anything the industry allows by law.

The BioTrackTHC System issues a globally unique, non-repeating 16-digit identification number to each plant. At every stage in the product lifecycle where something needs to be differentiated, the System issues a new "child" identifier (e.g., separating flower from stems during the harvest process, separating edible batches that are going to different dispensaries, the creation of new clones or seeds from a mother plant, etc…). The System issues the identifier to prevent accidental or intentional identifier duplication by the user, and the 16-digit identifier ensure scalability and longevity—the System could generate 1,000,000 identification numbers per second and it would not run out of unique identifiers for over 317 years.

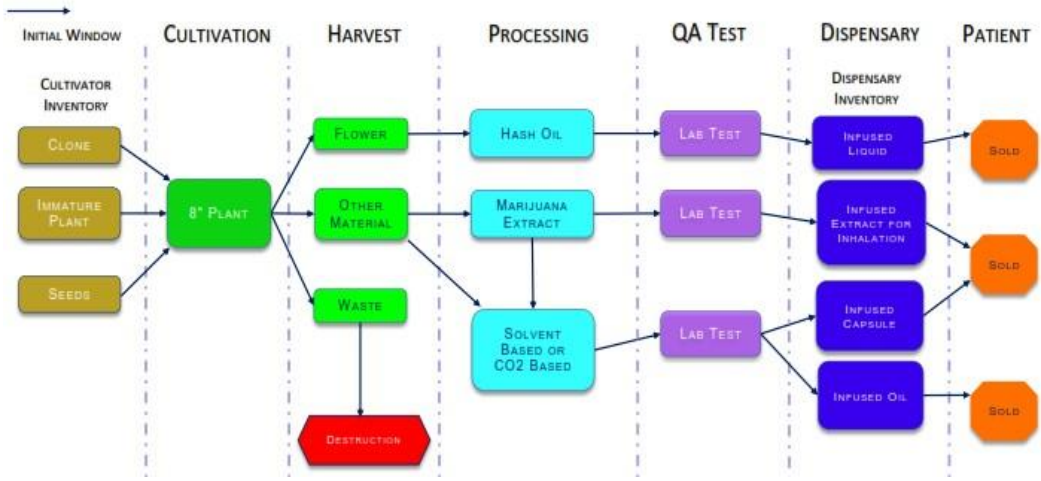
Every identifier is associated with a quantity that is measured in either discrete units or a weight depending on the item's classification; for example, plants, seeds, and infused edibles are measured in discrete units, whereas, bulk flower and stems are measured in continuous weight. This creates an unbroken audit chain. Select any identification number and both the State and the registered organization can backwards-trace the medical cannabis product's lineage all the way

[redacted]

back to the plant from which it came, and also forwards-trace every gram to where it is still in inventory, where it has been dispensed, to whom it was dispensed, and where it was destroyed.

As an example, if 100 grams were harvested from plant 98765: in this case, 2 grams were consumed by the testing laboratory, 8 grams were dispensed to patient Smith, 15 grams were dispensed to patient Jones, 55 grams are still in inventory, and 20 grams have been destroyed.

Laboratory testing is built-in and tied directly into the inventory typing system. This allows for very complex or very simple rules on what needs to be tested, what the testing requirements are, the pass/fail limits, etc. This testing paradigm provides a model for ensuring that only properly tested product may be sold to a patient. The system's integrated features can be setup to prevent the sale or transfer of product that has not passed state mandated laboratory tests, if necessary.

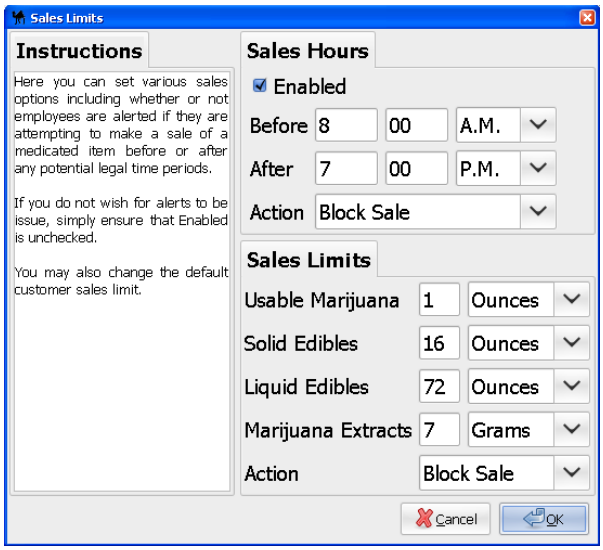


(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

Within "Sales Limits" a BioTrackTHC user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any Department defined limits. As the system will be recording every transaction, this data can be

parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

In the event that a patient has exceeded their purchasing limit; the retail dispensing location will be notified within the Tracking System that the patient has exceeded their sales limit; in response, the System will issue a stop purchase alert. The System does not allow for a retail dispensing location to transact with a patient that has exceeded their pre-defined sales limit.



(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

BioTrackTHC is the winner apparent to the state contract for Hawaii's computer software tracking system for the medical marijuana dispensary system based on and in compliance with Chapter 329D HRS. BioTrackTHC's commercial software provides seamless data exchange integration between a licensee and the state's marijuana tracking system. There will be integration via the application program interface (API) between the registered organization's BioTrackTHC enterprise system and the state interface utilized by the Hawaii DOH. This will

allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by Hawaii DOH.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

In the event of a loss of internet access, BioTrackTHC has the ability to operate in Offline mode. While operating in Offline mode a facility may continue to process sales with an on-site server, even if the internet connectivity goes down. When service is restored, all changes made in Offline mode will be updated and synced within the system.

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

BioTrackTHC provides record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Confidentiality of a patient's medical information is the responsibility of the licensee and their staff.

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products

Labels for medical marijuana and medical marijuana products will be labeled using only black lettering on a white background with no pictures or graphics[i] and will include:

a) Net weight in ounces and equivalent physical weight of the marijuana used to produce the product.
b) The concentration of tetrahydrocannabinol or tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol; as well as the name of the laboratory that performed the testing
c) The dispensary licensee's license number and the name of the production center
d) The batch number and date of packaging
e) A computer tracking inventory identification number barcode generated by tracking software.
f) Date of harvest or manufacture and Use By Date
g) Instructions for use
h) The phrases: "For medical use only"; "Not for resale or transfer to another person"; "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated

with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; and a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable)

BioTrackTHC's label creation tool enables licensees to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

The following list contains the fields already integrated into BioTrackTHC. Should the State desire additional fields, BioTrackTHC will create and implement those fields per request.

- Custom Text Fields
- Images
- Lines
- Additives
- Barcode
- Batch #
- Custom Batch #
- Customer MMJ #
- Customer Name
- Date
- Date and time
- Employee Name
- Employee License #
- Grow License #
- Harvest Date
- Inventory Grade
- License #
- MITS ID
- Package Date
- Package Weight
- Plant Birthdate
- Product Expiration
- Product Ingredients
- Product Name

- Strain
- Strain Type
- Testing Date
- Testing Lab
- Usable Weight
- Weight
- Test Results
  - All Available
  - CBC
  - CBD
  - CBD-A
  - CBG
  - CBN
  - D8-THC
  - D9-THC
  - D9-THC-A
  - H2O
  - Heavy Metals
  - Mold
  - Mildew
  - Total THC
  - Total Cannabinoids

(11) A plan for secure disposal of marijuana and manufactured marijuana products;

The BioTrackTHC MMJ Tracking System tracks and reports on all disposal of marijuana and marijuana products within a licensed facility. The System allows for the adjustment of inventory quantities as the result of both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes, and inventory audits) and external factors (such as theft and seizure by law enforcement). Data related to disposal information may include, but is not limited to: the amount disposed, reasons for disposal, day/time, identity of the employee(s) conducting the disposal, and manner of disposal in addition to all product-related data such as inventory classification, etc.

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

After a testing laboratory has entered sample test results into the System, the licensee retrieves the testing laboratory results and the System applies those results to the original lot from which

[redacted]

the sample came. Only if the inventory item has a status of "Passed QA" can it be placed on a manifest. A registered organization user cannot, under any circumstance, place an item on transportation manifest if that item requires testing and does not have a "Passed QA" status (e.g. not yet tested or failed testing).

[redacted]

EXCEPRTS FROM:

Hawaii Department of Health

RELEASE DATE: Friday, November 19, 2015

REQUEST FOR PROPOSALS

No. RFP-15-HTH-OHCA

FOR

MEDICAL MARIJUANA DISPENSARIES COMPUTER SOFTWARE TRACKING SYSTEM

STATE OF HAWAII

DEPARTMENT OF HEALTH

OFFICE OF HEALTH CARE ASSURANCE

To be submitted to the Hawaii Department of Health no later than:

FRIDAY, DECEMBER 4, 2015 at 4:30 PM, Hawaii Standard Time

IN THE DEPARTMENT OF HEALTH

OFFICE OF HEALTH CARE ASSURANCE,

601 KAMOKILA BOULEVARD, ROOM 337

KAPOLEI, HAWAII 96707

ATTN: DISPENSARIES SOFTWARE

Keith R. Ridley
Chief, Office of Health Care Assurance
Hawaii Department of Health

SECTION TWO

BACKGROUND AND SCOPE OR WORK

2.1 PROJECT OVERVIEW AND HISTORY

Background. The mission of the department is to protect and improve the health and environment for all people in Hawaii.

In July 2015, the State of Hawaii enacted Act 241, "Relating to Medical Marijuana," which established a licensing system for medical marijuana dispensaries to be implemented by the department. Act 241 became Chapter 329D, Hawaii Revised Statutes (HRS).

A total of eight licenses shall be awarded. Each dispensary license permits up to two production centers that shall be limited to no more than three thousand marijuana plants each, and up to two retail dispensing locations. Retail dispensing locations shall not be at the same location as the dispensary licensee's production centers. Three licenses shall be issued for the city and county of Honolulu, two dispensary licenses each shall be issued for the county of Hawaii and the county of Maui, and one dispensary license shall be issued for the county of Kauai.

Each dispensary licensee may commence dispensing medical marijuana and manufactured marijuana products to qualifying patients or primary caregivers no earlier than July 15, 2016, with approval by the department, in accordance with Chapter 329D, HRS.

Project Overview. Chapter 329D, HRS, requires the department to establish, maintain, and control a computer software tracking system that shall have real time, twenty-four hour access to the data of all dispensaries. At a minimum, the department shall have access to data relating to:

1. The total amount of marijuana in possession of all dispensaries from either seed or immature plant state, including all plants that are derived from cuttings or cloning, until the marijuana, marijuana plants, or manufactured marijuana product is sold or destroyed;
2. The total amount of manufactured marijuana product inventory, including the equivalent physical weight of marijuana that is used to manufacture manufactured marijuana products, purchased by a qualifying patient and primary caregiver from all retail dispensing locations in the State in any fifteen day period;
3. The amount of unused organic material produced by each plant at harvest; and
4. The transport of marijuana and manufactured marijuana products between production centers and retail dispensing locations, including tracking identification issued by the tracking system, the identity of the person transporting the marijuana or manufactured marijuana products, and the means of transport including the make, model, and vehicle identification number of the vehicle used for transport.

The department intends to operate a web-based software system that will be used by state employees for the collection and reporting of seed-to-sale tracking information described above and in Exhibit B. Licensees are expected to provide or make available data to the State's computer software tracking directly, through application program interface (API), data interchange service tool, or by means of a process and technology

acceptable to the Department of Health.

Project Environment. Licenses will be issued by the Department of Health, Office of Health Care Assurance, which performs all state licensing activities on healthcare facilities, agencies and organizations in Hawaii.

While Chapter 329D, HRS, makes the licensed production and distribution of marijuana legal under state law, marijuana remains illegal in under federal law. Additionally, unlicensed commercial production and distribution of marijuana remains illegal in Hawaii. A dispensary shall not transport marijuana or manufactured marijuana products to another county or another island or properties owned or occupied by the federal government.

Other public and private entities may be required to have access to the department's MMJ Tracking system such as law enforcement or laboratories.

The scope of this RFP will not include hardware equipment such as computer, bar code or other scanners, label printers, and point-of-sale devices such as weighing scales, flatbed scanners, cash drawers and receipt printers that will be used by the licensees.

Licensees are also required to purchase, operate, and maintain a computer software tracking system that shall:

1. Interface and have data interchange capability with the department's computer software tracking system including the state's patient registry system to verify a person's status as a qualifying patient or caregiver of a qualifying patient;
2. Allow each licensed dispensary's production center to submit to the department data in real time, by automatic identification and data capture, all marijuana, marijuana plants, and manufactured marijuana product inventory in possession of that dispensary from either seed or immature plant state, including all plants that are derived from cuttings or cloning, until the marijuana or manufactured marijuana product is sold or destroyed;
3. Allow the licensed dispensary's retail dispensing location to submit data to the department in real time for the total amount of marijuana and manufactured marijuana product purchased by a qualifying patient and primary caregiver from the dispensary's retail dispensing locations in the State in any fifteen day period; provided that the software tracking system shall impose an automatic stopper in real time, which cannot be overridden, on any further purchases of marijuana or manufactured marijuana products, if the maximum allowable amount of marijuana has already been purchased for the applicable fifteen day period; provided further that additional purchases shall not be permitted until the next applicable period.

2.2 SCOPE OF WORK

2.2.1 Executive Summary: Offeror to provide a concise summary of the products and services proposed.

provide this information to State users in a single, easily accessible report by licensees and overall summary at the state level.			
The ability to generate a receipt, in real time, at the point of sale and maintain the copy of the receipt and the sale transaction for at least six years.			
The ability for the registered organization to capture and report a reason for not dispensing to a patient.			
Point of Sale Sub-Section			
The ability to integrate with external data sources, in real time, to verify the validity of the patient's Registry ID Card.			
The ability to automatically enforce state and patient sales limits across all licensed dispensaries regardless of which licensed dispensary the MMJ or manufactured MMJ products were purchased.			
The ability to track product returns to the dispensing facility or registered organization, including reason for return and fate of returned product.			
The ability to generate a unique serial number for each dispensing transaction.			
Include a certification and testing program to ensure that licensees can correctly use the web service interface to submit data to the system.			
Any additional information from Offeror to describe how the proposal meets the requirements of this section ("Functional Requirements"). A separate document, clearly labeled and appended to this Exhibit may be used.			

Security Requirements

Mandatory Qualification	Met/Not Met	Available Y/N?	Est. Cost
Must have a user-based security model that allows licensees to only view data collected for that individual licensee.			
Must also allow department staff or designees to view data for all Marijuana Licensees based on specified search criteria.			
Any additional information from Offeror to describe how the proposal meets the			

Why PFC?

Patient Focused Certification (PFC) is a non-profit, third-party certification for the medical cannabis industry offered by Americans for Safe Access (ASA). ASA has been fighting for the rights of patients and for safe and legal access to medical cannabis for over decade. As an independent organization, we are able to work with regulators, industry, healthcare professionals and patients to set industry standards nationwide.

PFC is the only certification based on the new quality standards for medical cannabis products and businesses issued by the American Herbal Products Association and the American Herbal Pharmacopoeia. The program was established to help medical cannabis businesses ensure the production of quality products & services while giving patients, caregivers, healthcare providers, and regulators a way to easily identify them.

Where Do I Find PFC Certified Companies & Products?

Visit: patientfocusedcertification.org/companies

Companies participating in the PFC program can be found on our website above. If there is not a company near you, take this brochure to your local provider and ask them to enroll!

1806 Vernon St. NW - Washington, DC 20009
202.857.4272 - pfc@safeaccessnow.org
www.patientfocusedcertification.org

ASA PFC

PATIENT FOCUSED CERTIFICATION

a project of Americans for Safe Access Foundation

Look for
the PFC Seal

Choose Your
Medicine
with Confidence

What does the PFC Seal tell you?

When you see the PFC seal at a distribution center or on a product label, it tells you that the quality of products and services has been verified through the rigorous Patient Focused Certification Program.

Patient Focused Certification means:

- Company staff are well trained
- Products and services have been tested for contaminates
- Products and services meet legal requirements as well as AHPA and AHP standards
- Companies have recall protocols in place

How does PFC provide Certification?

PFC works with companies who voluntarily participate in the program and agree to adhere to local laws, AHPA and AHP standards. We verify their companies through a comprehensive evaluation process.

Our auditors:

- Perform thorough audits of the facilities.
- Test products in PFC certified laboratories.
- Conduct at least one surprise audit a year to ensure PFC standards are upheld.
- Maintain a consumer complaint database and follow up with the company for any needed corrective action.
- Only allow the PFC seal to be used on products that meet the PFC criteria.

Safety & Quality Assurance

More than one-third of the US population lives in states with medical cannabis laws, & over one million Americans are legally using medical cannabis under the care of a physician.

While many states and localities have created regulations to govern the location, size, & taxati of these businesses , they do not, for the most part, address the quality and safety of the prod ucts being sold.

Patients have the right to know how their medicine has been produced, that is free of contaminates & should be confident that the medicine they are receiving has been handled with the highest quality standards. They can now look fo the PFC seal to help them determine which proc ucts to purchase.

PFC is available to all companies cultivating, manufacturing or distributing medical cannabis products, as well as to laboratories providing analytic services to these companies. PFC includ employee training, compliance inspections, pro uct testing, ongoing monitoring, and an indepen dent complaint process for customers.

Companies certified by PFC are demonstrating a commitment to safety and quality.

Response to Criterion 9

"Laboratory Testing Plan"

Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

CONTENTS

ATTACHMENTS

Criterion 9 Language

Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 329D-7 and 329D-8, HRS; Response shall be no longer than three (3) pages.

We at Launiupoko Farm with our dedicated team of expert consultants from James Anthony Technical Assistance Consulting ("JATAC," and both collectively, "we") have the ability to comply with all requirements for certified laboratory testing of marijuana and manufactured marijuana products. Endnotes throughout the text show compliance with relevant cited HAR and HRS sections (Hawai'i Administrative Rules and Hawai'i Revised Statutes), and are listed separately as **Attachment 9-A** and in Compliance Checklist form as **Attachment 9-B**.

Patient safety is paramount to the success of Launiupoko Farm. To that end, we have created a framework of procedures and policies to ensure that at all times, the medical marijuana that we distribute is free from harmful contaminants, complies with mandated Quality Assurance/Quality Control (QA/QC) testing and is held to a safety standard in excess of the tolerance thresholds defined in HAR §11-850-85(c). The importance of preventative technique cannot be overstated, as it is the most critical factor contributing to the successful cultivation and distribution of safe non-contaminated marijuana.

Quality Assurance Testing With Steep Hill Labs

We will not dispense any marijuana or manufactured marijuana products (MMPs) until each batch of each product has been tested for all required compounds[1] by a state accredited quality assurance laboratory[2] that has been certified by the Department.[3] We have are contracting with Steep Hill Labs, http://steephill.com, a world leading expert on marijuana safety and quality assurance to establish best quality assurance practices at its facilities while testing each batch in a statistically representative manner.[4] Upon licensing, we will conduct internal studies to validate a sampling methodology, but in general will follow the sampling principals laid out in **Attachment 2-C**: Sampling Marijuana for Analytical Purposes, which was created by Steep Hill Labs for Washington State to address questions and issues related to proper QA/QC sampling.[5]

▶ STEEP HILL LABS PARTNERSHIP WITH SPECTRA ANALYTICAL

Due to uncertainty as to whether a state accredited testing facility will emerge in the Hawai'i marketplace, Launiupoko Farm has reached out to Steep Hill Labs to suggest a relationship with a pre-existing laboratory onHawai'i. This partnership ensures that high quality marijuana testing will be available to meet the contamination and purity thresholds required under HAR §11-850-85(c)(1) and HAR §11-850-85(c)(2). [redacted] marijuana testing license. Steep Hill has validated methodology for all the categories of testing required under state law and will be providing protocols, oversight, and guidance to Spectra Analytical for a swift implementation of a comprehensive testing program. Steep Hill has agreed to make its protocols and methodologies available for confidential review by the Department of Health (DOH). In the event that [redacted] a license, Launiupoko Farm will contract with the highest quality available state accredited provider of testing services.

▶ CONTINUOUS REVIEW AND MONITORING

We will actively test our products with a state accredited testing facility and will issue a Certificate of Analysis[6] for all compounds and contaminants required by the Department and listed in **Attachment 9-D**: Steep Hill Labs Compounds and Contaminants List. All sampling will be redundant, with duplicate samples stored in a secure and tamper-proof container for retesting at the request of the DOH.[7] We will work proactively with our state accredited laboratory to implement a process of continual improvement and oversight of its facilities, including a continuous review of all QA/QC procedures. This process of continual self-betterment is the key to ensuring the safest medicine for patients, and it is our first line of defense in maintaining a safe marijuana supply. To the extent required by the circumstances, we will install systems to actively monitor and control any type of contamination that may prove to uniquely affect our facilities as a result of climate or

other localized factors specific to Hawai'i. These may include in-house microbiological contamination monitoring, real time potency and moisture monitoring, or other systems designed to maintain a process analytical type approach to QC/QC in a marijuana facility.

▶ SECURE STORAGE AND DESTRUCTION OF NONCONFORMING BATCHES

Throughout the QA/QC process, we will follow a strict chain of custody and utilize tamper proof, secure containers. Batches will be quarantined in secure storage[8] until such time as a laboratory certificate of analysis is made available and a release order is issued by the DOH. All portions of non-conforming batches will be destroyed.[9] The status of all batches will be maintained both in our BioTrackTHC inventory management software system and the state tracking system (see **Attachment 9-E**: BioTrackTHC Support Document). With DOH approval, and if it is determined that the public health would not be adversely affected, we may from time to time request a single retest for a failed batch.[10] [redacted]

▶ ISO-9001 ACCREDITATION

In depth record keeping is important to the effective oversight and management of an internal QA/QC plan. Upon licensure, Launiupoko Farm will pursue ISO:9001 accreditation, which will become a core component of our quality management system and which will harmonize the record keeping process with the state accredited testing laboratory. The state laboratory will almost certainly be pursuing ISO:17025 accreditation on a parallel path. As such, for a period of five years, in depth testing records including the certificate of analysis for each batch,[12] will be kept at our facilities and at the state accredited testing facility, and will be readily available for inspection should the DOH request them.[13]

1. HRS 329D-7(8)
2. HRS §329D-12, HAR §11-850-17(a)
3. HRS §329D-12,HAR §11-850-17(d)
4. HRS §329D-12, HAR §11-850-17(a),
5. HAR §11-850-51(A)(3)(A)
6. HRS §329D-12, HAR §11-850-17(c)
7. HRS §329D-12, HAR §11-850-17(c)
8. HRS 846-2.7(a)
9. HRS 846-2.7(a), 846-2.7(d)
10. HRS §329D-12, HAR §11-850-17(d)
11. HRS §329D-12, HAR 11-850-16,
12. HRS §329D-12, HAR §11-850-17(b)1-6
13. HRS §329D-12, HAR §11-850-17(b)

HAR COMPLIANCE CHECKLIST

CRITERION 9 "Laboratory Testing Plan"

Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 329D-7 and 329D-8, HRS;

Response shall be no longer than three (3) pages.

Relevant HAR sections	Endnote Number
HAR §11-850-81(a)	3
HAR §11-850-81(a)(1)	2
HAR §11-850-85(a)	4,7
HAR §11-850-85(b)	5
HAR §11-850-85(c)	6
HAR §11-850-85(d)	10
HAR §11-850-85(e)	11
HAR §11-850-85(f)	13
HAR §11-850-85(g)	1
HAR §11-850-85(h)	12
HAR §11-850-85(i)	9
HAR §11-850-85(j)	8

[redacted]

Sampling Cannabis for Analytical Purposes

[redacted]

[redacted]

[redacted]

Table of Contents

Overview

This paper discusses the practice and regulatory implications of sampling cannabis for potency and purity tests. It proceeds in three parts: first, by discussing proper procedures by which a small, representative test sample can be taken from a larger lot of cannabis; second, by discussing the natural levels of heterogeneity in the cannabis plant; and finally, by discussing the cost burdens of different sampling regulations, including the size of a lot.

Initiative 502 established a program for chemically testing regulated cannabis, in order to protect consumers from unhealthy product and inform them of a product's potency and purity. Such a program will require a policy on sampling methodology. Sampling is an integral aspect of cannabis testing, and if done dishonestly or improperly, it may skew the results of an otherwise reliable testing process. Of particular regulatory importance is to prohibit producers or testers from manipulating sampling procedures in order to exaggerate a product's reported potency or purity, and consequent retail value. Another important decision is the appropriate size of the sampling lot. Both of these policy decisions are important in order to establish a high standard for industry practice and to prevent intentional manipulation of results.

In the regulations proposed by the WSLCB on July 3rd, 2013, the unit of usable cannabis from which a sample is pulled is referred to as a lot. A lot of flower must come from one or more plants of the same strain and weigh no more than five pounds[WAC 314-55-010(9)]. The unit of extract or infused cannabis product from which a testing sample is pulled is referred to as a "batch." A grower's yield or harvest, typically pulled from a set of plants of the same strain grown under the same conditions, is broken up into lots, and those lots are submitted for testing. It can be assumed that growers will create lots as large as they are allowed, and that they will want to lose as little product to testing as possible and minimize their testing costs.

In determining a requisite sampling lot size, the Washington State Liquor Control Board (WSLCB) faces an inherent trade-off between accuracy (or representativeness) in testing results and regulatory cost. On one hand, a larger lot size eases the burden on the cannabis industry by requiring fewer tests, since each lot must be individually divided into a sample and run through the required tests. Moreover, since sampled material cannot be sold, a larger lot size decreases the dead loss of unsellable cannabis. On the other hand, if there is a large amount of variation within an individual lot, a sample from within that lot might have drastically different properties than another part of that lot. This is the problem introduced by the heterogeneity of cannabis, in part because grinding the product into a homogenous mixture decreases its retail value, and in part because of the biological properties of the plant.

Cannabis plants exhibit heterogeneity in two regards: across different parts within the same plant and across different plants within the same strain. Cannabis plants have been subject to decades (if not centuries) of intense domestication, both through breeding and cloning, creating a wide variety of strains each with their own biological peculiarities. Through a combination of conventional wisdom among growers and scientific studies, we

know that some strains can be cloned with higher levels of similarity than others. This characteristic would reduce the level of variety from one plant to another, provided both are members of the same strain. Another type of heterogeneity, intra-plant, is important to sampling procedures. This paper will review the mixed literature on levels of heterogeneity in cannabis plants and identify policies appropriate to deal with those levels of natural heterogeneity.

As the I-502 market develops, and more growers demonstrate their capacities to produce and reproduce strains with consistent cannabinoid profiles, the WSLCB may consider developing a varietal registry of different cannabis strains. Such a registry could establish expected potency levels and variances for particular strains. This information could be used both to verify the accuracy of a particular test result and to distinguish those varieties with the most severe levels of variance. A possible cost-saving measure would be to allow larger lot sizes or more relaxed testing regulations for those strains known to exhibit lower levels of variation. Such research could also facilitate the distinction between one strain and another, as defined in WAC 34-55-102(10) of the CR-102 for cannabis producer licenses and requirements.

This paper makes two assumptions about the procedures of testing laboratories. First, we assume a high degree of competence from laboratories, and of the accuracy, robustness, and reproducibility of their methodologies. It is imperative that any laboratory providing testing be able to demonstrate at least 95% accuracy of the testing methodology by passing a blind proficiency test of random samples. Second, it is assumed that a chain-of-custody plan will be followed, such that no contamination will be introduced in the lab. Sterile handling in a biosafety hood (Class II, Type A bio-safety cabinet) is necessary for testing for microbiological contamination. Each facility should have a sample processing room and secure storage room. At the point of sample reception, a log should note the time of arrival, the recipient, the sender, and the lot and, when applicable, the batch number (USDA 2013).

Sampling of Raw Plant Material

Sampling

Sampling is the selection of a subset within a whole, in order to estimate characteristics of the whole. In the case of cannabis, this is harder than it may appear at first blush. First, cannabis naturally varies in chemical potency, both within a single plant and between one plant and another (and between strains); secondly, cannabis is commonly marketed as intact flower buds. For this reason, cannabis cannot be homogenized without permanently damaging the un-sampled product. Alcoholic beverages, for instance, do not face this second problem. Even if a company's brewing or distilling process produces some vats with 6% alcohol and others with 7% alcohol, simply mixing the two vats together can standardize the product. Similarly, tobacco is generally baled, and cores are taken for quality analysis without damage to the bulk material. Performing the same procedure with cannabis would require grinding the entire crop into small bits, thereby reducing its aesthetic appeal and retail value. Since the heterogeneity in cannabis potency cannot easily be mixed away, this puts the onus on other ways for verifying that a sample is representative of its whole.

Since the psychoactive chemicals of cannabis are unevenly and non-randomly distributed throughout the plant, there exists an opportunity for producers to manipulate the sampling process in order to produce a sample that exaggerates their crops' potency. THC content is commonly regarded to vary from the top to the bottom of the plant, or by the proximity to the light source. In the case of outdoor production, it is widely believed that flowers from the bottom of a plant receive less sunlight than those at the top of the plant; this is also purported to be true for indoor production, but the effect might be mitigated by carefully placing high-intensity lamps so that they shine more uniformly on all flowers in the plant. In either case, flowers that receive less exposure to light are likely to have lower cannabinoid and terpenoid content. Since a cannabis producer is typically aware which parts of the plant are most well lit, he often knows where to find the most potent flowers from the cannabis plant – typically, those at the top. Potentially, this represents a crucial information asymmetry between the producer and the testing agency. A producer may manipulate his crop's potency ratings by deliberately selecting his plant's most potent flowers and submitting them to the testing agency as representative of the entire plant's (or crop's) inflorescence.

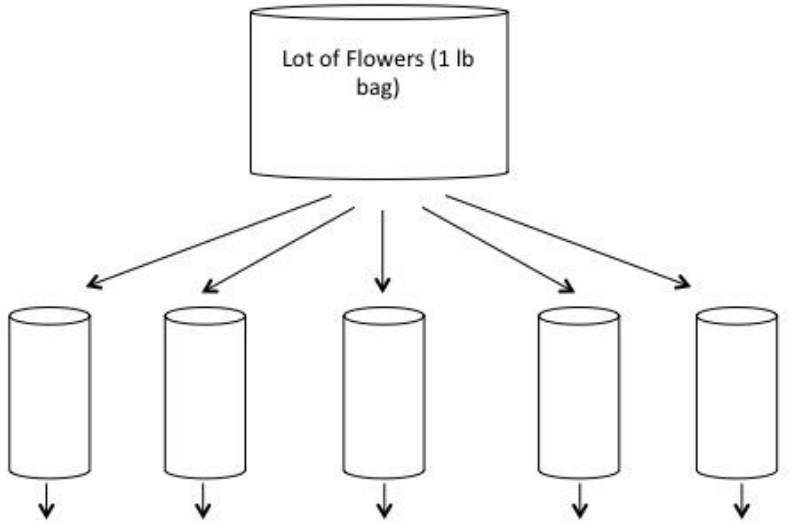
There are several options to address this vulnerability, depending in part on whether samples are taken at the time of harvest or only after the harvest is dried. If samples are taken at the time of harvest, cannabis should be gathered in groups according to their exposure to light. This could be achieved by adhering to height standards (such as one sample taken at x feet and another at y feet) or distance in lumens away from the light source. These samples would need to be cured or dried prior to analysis. In this case, a trained field inspector (as recommended by the USDA-Animal and Plant Inspection Service Plant Protection and Quarantine APHIS-PPQ) could sample at the time of harvest, selecting flowering tops taken from different parts of the plant. Health Canada has prescribed a procedure for industrial hemp that could be adapted to this purpose (Canada 2008). If plants were trellised, then a height variable would not be necessary. Each plant to be sampled needs to be readily accessible from all sides of the plant, and in its original growing location. Official samples should be brought to the testing location by the inspector.

Another option is to allow producers to lot cannabis according to their own methods, but then have testing agencies select a random sample from within those lots. In this case, growers would first dry and lot their own harvests. The agencies would then randomly sample the lots using established methodologies. In this scenario, growers might choose to lot their harvest based on flower size, light exposure, or other strategic considerations. If a lot is smaller than two kg or under the five lb. lot definition, then whatever is 20% of the lot can be used for sampling, as long as the final sample taken for cannabinoid analysis is at least 2.5 g. The rest of the plant material can be returned to the grower (except for additional material needed for microbiological testing) when performed on a separate sample. Allowing growers to perform their own semi-quantitative testing at this level could represent a cost savings to the grower. A semi-quantitative methodology might be high performance thin layer chromatography or infrared technology.

In either case, it is important that growers cannot knowingly provide testing agencies with samples that are unrepresentative of the lot. In the first case, this is accomplished by

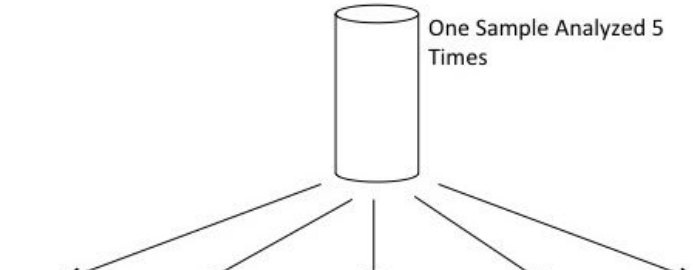
preventing growers from being able to select the sample; in the second case, this is accomplished by sampling from a larger lot than is normal. Regardless of the sampling protocol, any laboratory or method used must demonstrate precision (Figure 1), intra-assay accuracy (Figure 2), and reproducibility over time (Figure 3). These data were generated and compiled using cannabis samples in California as part of an internal single-lab validation methodology by Integrated Analytical Systems, a bio-analytical company in Berkeley, California

Figure 1: Method Precision



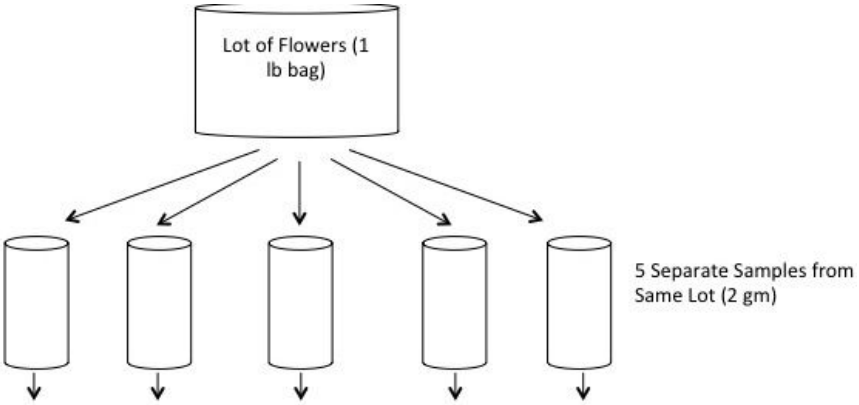
Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Relative Variability
7.59% THC	8.44% THC	7.85% THC	8.32% THC	7.59% THC	***±5.1%***

Figure 2: Method Accuracy



Analysis 1	Analysis 2	Analysis 3	Analysis 4	Analysis 5	Relative Variability
7.81%	8.06%	8.02%	7.88%	7.91%	±2.3%

Figure 3: Method Reproducibility Over Time



Day of Analysis	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Day 1	9.11% THC	8.42% THC	8.62% THC	8.01% THC	8.56% THC	
Day 60	9.03% THC	8.62% THC	8.40% THC	7.73% THC	8.69% THC	
Difference	0.9%	2.4%	2.7%	3.5%	1.5%	±2.2%

Sample preparation for useable cannabis

Established methodologies exist for preparing a sample of useable cannabis for testing. These methods vary slightly based on the intent of the test (e.g. detecting pesticides, or potency, or microbiotics). However, for the most part a simple and common protocol should be used for this process.

Selecting the sample

Cannabis inflorescence (fruiting tops or flowers) or "trim" is sampled when performing testing for potency and/or microbiotics. The "fan leaves" of the plant are used for pesticide testing. Broad leaf should be collected from each plant in the lot. This sampling could be done at another time prior to harvest.

A test specimen will be comprised of inflorescence taken from a lot of plants, and a representative sample of 10 grams per kilogram (or 2% of the total lot) or trim from the flowers (10 grams per kilogram or 2%). A "lot" of plants can be distinguished by count, by lumens, or defined by the space receiving approximately the same conditions with regard to light, moisture, nutrition, CO_2 and temperature recommended to be 20 plants (Mechtler et al. 2004).

Homogenization of the raw sample

The plant sample must be made homogeneous for test results to be representative. Homogenization requires the sample be broken down to a form that can be mixed effectively, comparable to the process of turning wheat into flour.

First, the sample should be ground to a size of around 0.5 cm in size and thoroughly mixed. There is some disagreement about grinding a sample because trichomes can be lost in the process, but without grinding a sample cannot be as homogeneous. To minimize the leaching of resins, grinders made of silanized glass or stainless steel are recommended over wood and plastic. Regardless of the material, every element of the grinder must be thoroughly cleaned with solvent rinses between samples.

Once grinding is completed, the next step is quartering. Quartering ensures that every part of the sample is sufficiently mixed to have an equal chance of being selected for testing. The ground sample is gathered into an even and square-shaped heap. Next, it is divided diagonally into four equal parts. The two opposite parts are then taken and carefully mixed. This portion is now placed in another square shape and divided diagonally. Two opposite parts are taken and carefully mixed. This 2.5-gram sample can be used for the analysis of cannabinoids, terpenoids, or other phytochemicals.

The remainder of the sample can be used for microbiological testing. Sampling methods could be further refined and validated through a series of experiments that the WSLCB should conduct to determine the relative variance of different sampling methodologies for cannabis crops. This data can then be made available to the entire industry, and may serve to refine the regulatory process.

Obtaining a representative sample for analysis

A two-gram sample of flower or trim should allow for a confidence of approximately 12% relative variability (or five grams for a relative error of approximately 5%; see Table 1 and Figure 4). In developing the laboratory protocol, a five-gram representative sample is needed for the least variability. However, as the data below reflect, 2.5 grams would allow for an acceptable variation across a single sample. Analytical performance standards for hemp are described in Table 2 (Canada 2008).

Table 1

Sample Weight	Variability
1 gram	±9.9%
*2 grams**	*±5.1%*
3 grams	±4.3%
5 grams	±1.5%

* recommended weight to submit for testing

Figure 4

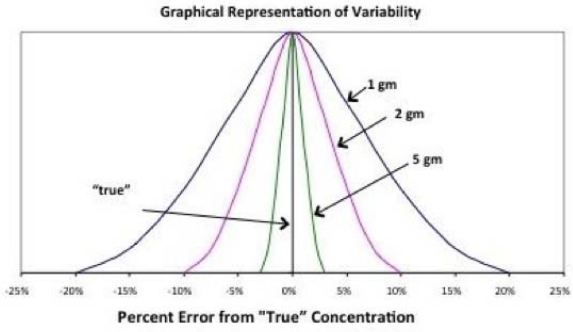


Table 2: Analytical performance standards for hemp, and parameters for THC analysis: the limit of detection (LOD), limit of quantification (LOQ), and acceptable linear range for reference standards. These values may be adopted and required of labs that want to be certified to test cannabis in Washington State.

Parameters	Concentration of THC in industrial help, other than its derivatives or products containing those derivatives	Concentration of THC in derivatives of industrial hemp, or products containing those derivatives

Minimum limit of detection	0.1% (w/w)	4.0 µg/g
Minimum limit of quantification	0.1% (w/w)	4.0 µg/g
Intra-assay precision	C.V. (coefficient of variation) ≤ 10% at 0.3% (n=8)	C.V. (coefficient of variation) ≤ 10% at 10.0 µg/g (n=8)
Linear range	$r^2 \leq 0.98$ in the range of 0.1% to 1.0% (w/w)	$r^2 \leq 0.98$ in the range of 4.0 µg/g to 30.0 µg/g (w/w)

Sample preparation for extracts and cannabis-infused products

The global market for botanical and plant-derived drugs is expected to increase from $19.5 billion in 2008 to $32.9 billion in 2013. Finished products made from medicinal and aromatic plants are increasingly prescribed and bought over the counter. An extract is obtained as a solution by treating plants (or parts of them) with a solvent, which can then be further concentrated through evaporation, distillation, or some other process (WHO 2004). Liquids intended for oral consumption should be uniform, and finished products need to be handled in clean facilities and assayed for residual solvent and/or labeled with final ethanol or glycerol concentration. Mixed batches can be used for solvent extraction and a homogeneous sample needs to be submitted for final analytical determination of active ingredients. An herbal drug product may be a solid extract, a soft extract (partially evaporated), or a liquid extract (1:1).

Selecting the Sample

The sampling unit is a batch of extract (there may be more than one per lot) including tinctures and fatty oils of herbal materials. Extract lots are produced either by extraction, fractionation, purification, concentration, or other physical or biological processes. The final volume is the lot size, while "individual units" are the containers of product eventually sold from this lot. Extractions are preparations made by steeping or heating herbal materials in alcohol, glycerin and/or honey, or in other materials (WHO 2007). The size of the sampling unit should be scaled to be representative of the size of the lot of extract, and the sample size will determine an acceptable quality level. Resins and solid extracts should be sampled by weight, and liquids by volume.

Testing agencies should adequately homogenize each batch and take representative samples from three separate areas of the container (WHO 1998). The amount of the representative sample may be determined by the volume of the batch, again extracting a predetermined percent of the total volume. In the case of resinous material, it may need to be warmed on a heater/stirring device. This is now a "pooled" sample.

Homogenization of the pooled sample

Homogenization of the sample should occur by stirring or vortexing and may require heating of the sample. After homogenization, the sample should be quartered.

The process of quartering samples of a finished product is similar to quartering samples of dried flower. A sample is placed in a single container, and then divided into four equal volumes. Two parts are then combined and vortexed. This portion is now divided in half. Two opposite parts are taken and mixed. This representative sample can be used for the analytics of cannabinoids, terpenoids, or other phytochemicals.

The remainder of the sample can be used for microbiological or residuals testing. Sampling methods should be further refined and validated through a series of experiments that the WSLCB could conduct to determine the relative variance of different sampling methodologies for cannabis derived products. These data can then be made available to the entire industry, and provide guidance for the regulatory process.

Acceptance Sampling

Acceptance sampling could prove a viable alternative to the sampling methods described above. Acceptance sampling was originally applied by the U.S. military for the testing of bullets during World War II. If every bullet were to be tested in advance, no bullets would be left to ship. If, on the other hand, none were tested, malfunctions were likely to occur in the field of battle (Bheda 2010). Acceptable Quality Level (AQL) is a statistical measurement of the maximum number of defective goods considered acceptable in a particular sample size. If the AQL is not reached for a particular sampling of goods, manufacturers will review the various parameters in the production process to determine the areas causing the defects.

The AQL will vary from product to product. For example, medical products are more likely to have a more stringent AQL because defective products can result in serious health risks. Companies have to weigh the added cost associated with the stringent testing and potentially higher spoilage due to a lower defect acceptance with the potential cost of a product recall. Industry AQL charts could provide WSLCB with AQL protocol for botanical products made from cannabis extracts.

The lot size, on the y-axis, is based on how many individual units will be on the market from a particular lot. Unit size is not defined by the chart, but by individual manufacturers. For instance, a CO_2 cartridge manufacturer's unit would be a single cartridge, a baker's unit may be an individual cookie, and a farmer's unit might be a gram or an ounce. The AQL (the x axis) is the level of acceptance for the number of units that fall outside of quality parameters (how many). The numbers within the body of the chart are sample sizes. When working with a lot size of 2500 units at a 0.065% AQL, one would want a sample size of 200 units from each lot to ensure this level of confidence. As the AQL is reduced, confidence increases in the probability of units meeting quality parameters. Following our example, a 2500 unit lot with an AQL of 0.065% (with zero units falling out of specs in a sample of 200) has a statistical probability of producing two defective units. By contrast, a lot of 2500 units with an AQL of 1% (with zero units falling out of specs in a sample of 42) has a statistical probability of producing 25 defective units.

In order to implement this strategy for cannabis products, it would be necessary to convert what is currently a continuous variable (% concentration) to a discrete binary variable. Setting a threshold for acceptable quality or concentration of product would accomplish this.

Acceptance sampling protocol for the cannabis industry could take many forms. The practice is easily applied to products with obvious definitions of a unit, such as extracts or edibles because their contents have been homogenized. It will not be as clear how appropriate acceptance sampling could be for raw flower until more is understood about the heterogeneity of the crop. Theoretically a lot of flower would be broken up into predetermined units of sale and a certain number of those units selected for testing. Qualifications to deem a unit defective could be a certain level of contaminants or a cannabinoid profile that is too different from the goal for that strain.

Varietal Registration and State-led Research Efforts

For obvious historical reasons, the science and practice of cannabis cultivation and testing are not as well established or well documented as in other fields. Cannabis production and testing has historically been performed in secrecy, and private companies have been reluctant to construct and share large databases. This lack of shared knowledge constrains both the cannabis industry and regulators. Establishing an informational database or a center for research would deliver some benefit to the State of Washington, if it were to decide to spearhead such an effort.

One model of a shared informational database is a germplasm bank or a varietal registration, also known as a chemotaxonomic classification system and an associated seed repository, intended to illuminate the characteristics of different cannabis strains. Registration could occur upon a grower's demonstrated ability to reproduce a strain with a high degree of homogeneity. Such a strain could then, in effect, be trademarked without ownership rights and registered with the State as a "varietal." This public database could be useful to both entrepreneurs in the private sector and regulators in the public sector. Over time, if a strain's ability to retain phenotype is relatively strong, regulators may opt to relax testing requirements for a certain varietal, defraying testing costs in the long term. This registration could also help regulators to distinguish between different strains ("…a pure breed or hybrid variety of Cannabis reflecting similar or identical combinations of properties such as appearance, taste, color, smell, cannabinoid profile, and potency"). The issue of chemical fingerprinting is further discussed in the BOTEC paper, "1c. Testing for Psychoactives."

More ambitiously, Washington could also opt to establish a research center within an existing state laboratory. Such a program could investigate many different aspects of the cannabis plant, including product consistency, identifying new varietals, fingerprinting cultivars, participating in the development of medically relevant strains, and determining whether there actually are ailment- or symptom-specific components. Such an effort could contribute to arguments to designate Washington as a "Protected Geographical Indication" or a "Protected Designation of Origin." To date, such research has been blocked by federal regulations, although it is often taken for granted in other areas of agriculture.

However, Washington might pay all the costs of such an effort and reap only a small portion of the benefits. Although Washington, along with Colorado, has recently become a major player in the cannabis industry, this celebrity status might not last. Other states might legalize as soon as 2014 or 2016 – notably California – and they may do so with more business-friendly regulations, not to mention warmer and drier climates. Initiative 502 may have given Washington's cannabis industry a head start, but other states will soon join the race. Leading a research effort might help Washington maintain that head start, but should not be expected to guarantee Washington's spot as an industry leader in the long term.

Heterogeneity

In this section we review studies concerned with the heterogeneity of cannabis across growing conditions and varietal strains. Cannabis is an inherently variable plant, with strong genetic and environmental contributions to variance in quality (Zamengo et al. 2013). In the interest of having products in the marketplace that are as predictable as possible (but still appropriately labeled), research and a list of needs should be required.

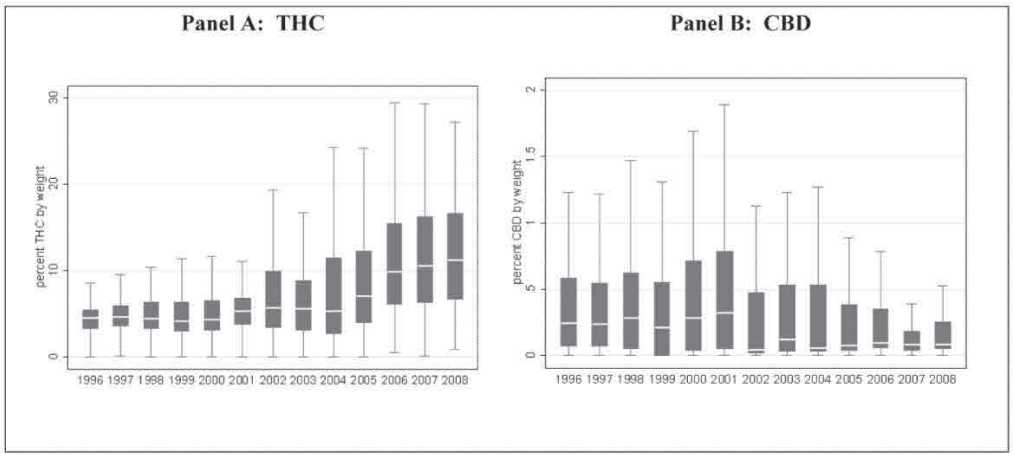
The contents of a lot should be as homogeneous as possible. Gathering lots using the criteria described—products of the same strain, flowers from consistent areas of the plant, similar bud size, etc.—relies largely on growing techniques that have been commonly accepted, but hardly corroborated by scientific protocol. This lack of information reveals vulnerability in sample testing. How effective could testing be if we cannot put forth an acceptable range of its representativeness? Under the regulations put forth by the WSLCB, a lot must consist of flower taken from plants of the same strain. However, there is little literature to tell us that plants of the same strain grown under identical conditions can be assumed homogenous, or to what extent they differ. To know how representative a sample is, we must know the extent of heterogeneity occurring in cannabis plants when grown in identical conditions.

There is a compelling need to learn much more about how growing conditions affect the phenotype and chemotype of the cannabis plant. To set forth a range of acceptable variation in a product, it is important to understand the extent of natural variation. Industry consensus is that the quality and quantity of light will affect THC production. Increasing lumens, particularly of specific wavelengths, may potentially increase THC production, but studies that suggest that cannabinoid content is more controlled by genetics (Fournier et al 1987) than by other factors such as the quality or quantity of light a plant receives. Because cannabinoids are secondary metabolites (chemicals produced by the plant in response to stress), some suggest that light "stress" could increase their production. However, these secondary metabolites may have unknown roles and are not fully understood. There are many other variations in growing techniques, such as addition of CO_2 to the growing environment, nutrient mixtures, soil mixtures, humidity levels, pH balance of the soil, hydroponics, and water administration, that will dictate plant metabolism.

The genetic profile of cannabis has changed over the last several decades, as evidenced by analysis of cannabinoids in seized samples (Burgdorf et al. 2011; Mehmedic et al. 2010)

[See Figure 5]. This change in genetic stock is reflected in the relative changes in total THC content and also the ratio of THC to CBD.

Figure 5: Variability in THC/CBD in seized crops over time. Median, 25th and 75th percentiles of cannabis seized in California for 4,561 plants from 1998 to 2006.



Typical Heterogeneity

Cannabis is an inherently variable plant, with strong genetic and environmental contributions to variance in quality factors. Given the interest in ensuring products in the marketplace are of known content and appropriately labeled, there is a need for research into the determinants of plant characteristics.

An analysis of hemp samples in Germany, Poland, France, and Hungary was undertaken to estimate the sample size needed for "routine control tasks" (Mechtler et al. 2004). One study found no association between plant size and THC content. They also found great consistency in hemp crops over years and consistent "intra-plant" levels of THC with as many as 30 samples from a single plant.

However, another study concluded that a varietally homogeneous hemp field might contain a significant number of plants behaving irregularly with respect to THC values. Further, the number of plants sampled for routine analysis was fixed by European Union (EU) regulations at 50 plants (regulation number (VO (EG) 1177/2000).

Few publications have explored this topic with regards to regulated indoor growth of cannabis. Growers often cultivate what is known as a genet: a "clonal colony" in which all of the individuals (ramets) have originated vegetatively from a single ancestor. One advantage of indoor production is an enhanced ability to carefully control soil nutrients and light, factors that can contribute greatly to variations in growth, biomass, morphology, and physiology of clones (Wang et al. 2012). Under these conditions, producers can provide

consistent treatment from one plant to another, and often to different parts of the same plant (for instance by the uniform position of lights). However, it is unknown what effect these conditions have on reducing the variance in plant chemotypes, or their psychoactive chemical content. For instance, two different plants cloned from the same "mother" might grow differently even if they are exposed to the exact same conditions. It may be in Washington State's interest to commission or encourage such experiments, perhaps as part of a larger effort to form a varietal registry.

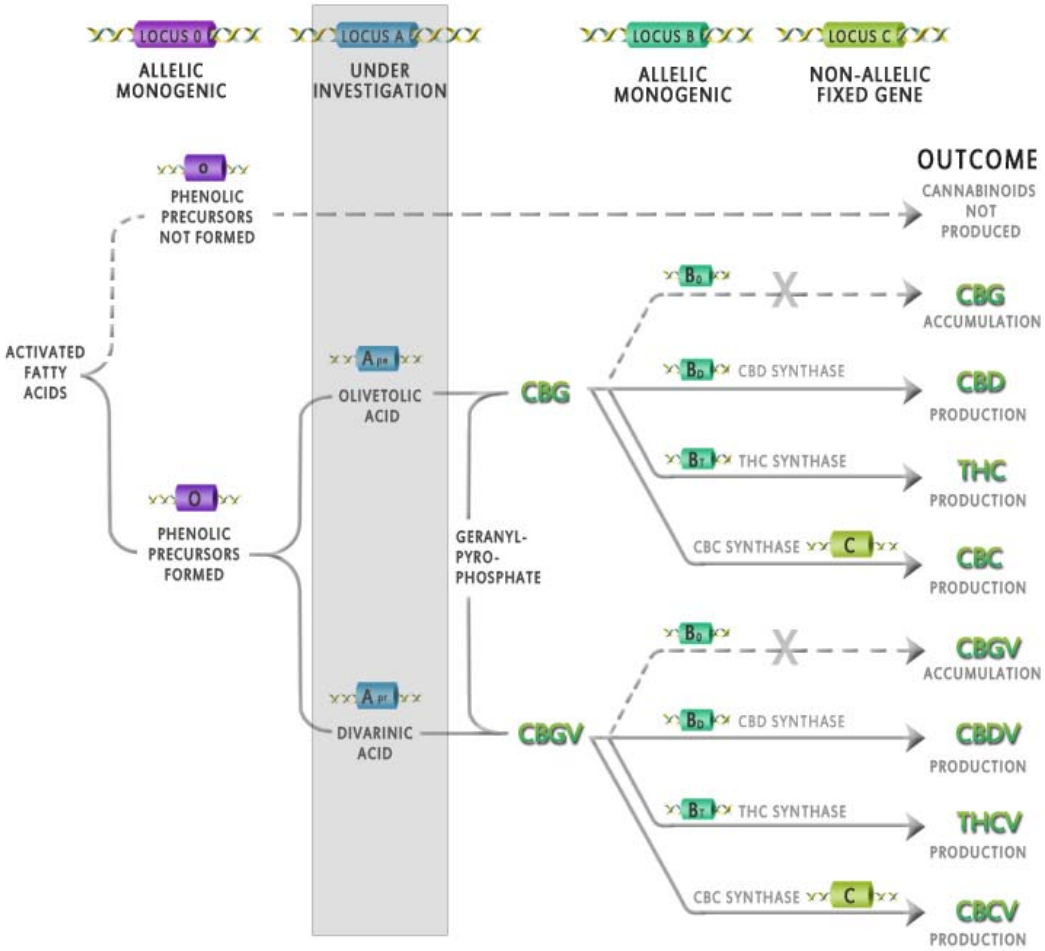
Heterogeneity across strains

Small and Beckstead (1973) were the first to survey cannabis accessions for cannabinoid variability. The University of Mississippi concluded that, phenotypically, cannabis might be a single species that has not stabilized and has many variations (Doorenbos et al. 1971). The researchers prepared fields and planted seed from several varieties, noting that environment and climate, not heredity, are the most important determinants of cannabinoid content. They also found a great deal of inter-plant variability in THC content, and report an interesting anecdote.

A cannabis plant alleged to have been grown in a closet with a tungsten light bulb was delivered to their facility. The authors described it as leggy, with greenish-yellow leaves, and yet the cannabis harvested analyzed for Δ^9-THC at 6.8%, CBD: 0.26%, CBN: 0.28%. At this time, 6.8% THC was well above any of the outdoor plants with regard to THC production. In other words, this neglected specimen was remarkably successful at producing psychoactive cannabinoids, even though it may have been exposed to inferior soil and lighting conditions. This observation is instructive with regard to visible and ultraviolet lighting in indoor growing facilities. Clearly, a "stressed" plant produced a relatively greater amount of THC than any of the other varieties cultivated outdoors. While this report gave some information on heterogeneity across strains, unlike more contemporary farmers the researchers were not growing clones from a single plant.

In 2003, GW Pharmaceutical published a paper in *Genetics* which stated: "there is little doubt that environmental factors have a strong influence in modulating the amount of cannabinoids present in the different parts of the plants at different growth stages." However, they report that cannabinoid profiles in general are under strong genetic control (the THC to CBD ratio, specifically) and that plants typically demonstrate high degrees of polymorphisms (or spontaneous genetic mutations) - up to 80% measured in fiber-type plants - which can account for variability (de Meijer et al. 2003). For plants that were double inbred clones (S_2's: female lines with "pure fixed" chemotype), major cannabinoids ranged from between 84-98% of total cannabinoid fractions.

Figure 5: GW Pharmaceuticals shows how cannabinoid content is under genetic control and uses genetic manipulation to precisely control cannabinoid production.



Below, we compiled THC content data taken from the website of a Seattle-based medical cannabis facility. We randomly chose several strains: "Blue Dream" (n=20), "Blueberry" (n=8), "Jack Herer" (n=9) and "Harlequin" (n=9) for purposes of resale. Figure 6 shows THC concentration by weight, and summary statistics are given in Table 3. Assuming that the samples were tested accurately, these strains appear to have different rates of variability. The data, though very limited, suggest an approximate 25-30% variability in Blue Dream, 25% for Blueberry, 60% for Jack Herer, and 40% for Harlequin. (Due to a small sample size, these figures might not accurately represent characteristics of these strains in the larger market.)

Table 3: Statistics on Δ^9-THC content for four commercial *Cannabis* varieties, from the *Analytical 360* website, a medical cannabis laboratory in Seattle. The sampling and testing

methodology is unreported. Data in this table summarizes the data presented in Figure 6. These data do not necessarily represent typical characteristics of these strains.

	Blue Dream	Blueberry	Jack Herer	Harlequin
Number of observations	21	8	9	9
Minimum	6.560	10.05	5.130	3.710
25% Percentile	14.05	13.16	14.56	4.385
Median	17.05	15.36	16.11	4.930
75% Percentile	18.20	17.47	16.87	5.670
Maximum	21.61	20.67	17.91	7.110
Mean	15.99	15.27	14.80	5.069
Std. Deviation	3.657	3.206	3.816	1.015
Std. Error	0.7980	1.134	1.272	0.3385

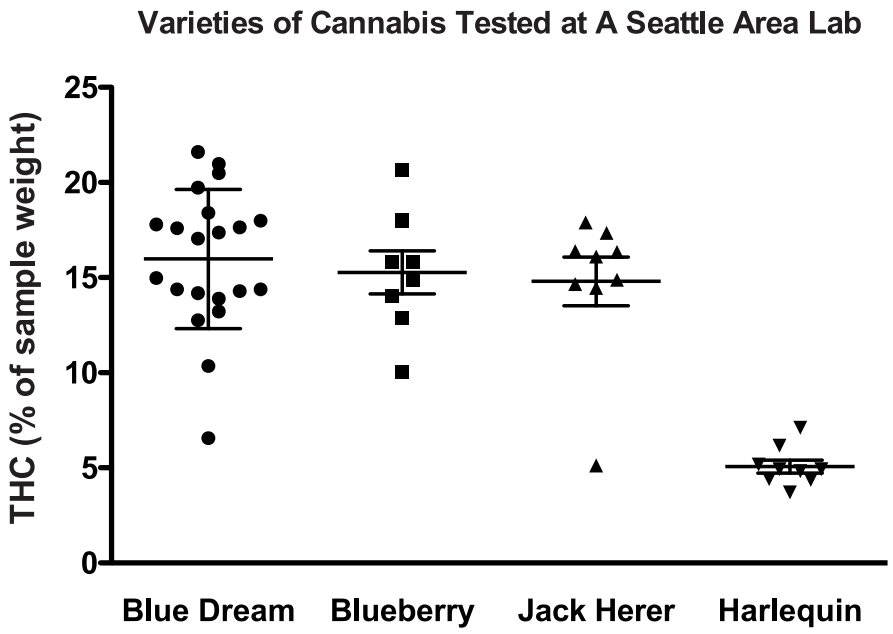


Figure 6: A graphical representation of the individual data from Table 3, showing the mean and the standard deviation across randomly chosen strains.

These data suggest that there is significant variation in THC potency within some strains but not others. There are also some cases of irregularity or outliers in each strain set. These data provide information on the lack of homogeneity across a strain. In some cases, there may be an error of categorization: a sample of Harlequin might have been mislabeled as Blue Dream. There may also be a significant genetic drift or disparity within the genotype of cannabis considered to be a single variety. Further, it is unknown whether there is similar variability in the terpenoid profile, which also contributes to the user experience.

Heterogeneity across production methods

The cultivation of cannabis has accelerated over the last 25 years, and is grown all over the world for a variety of uses and in a variety of ways. Globally, these operations can be grouped into three categories: historic/traditional production, cultivation in the developing world for the developing world, and production in the developed world—primarily outdoor but increasingly indoor operations (Decorte et al. 2011). The increased demand for cannabis since the 1960s has provided economic incentives for optimization of growing conditions for the highest yield and maximum potency. Given the range of approaches, it may be difficult to distinguish good from bad growing, but there is no doubt that plants are highly environmentally adaptable and that just like the market and the growers, there is a

lot of heterogeneity. Even when conditions are intended to be identical, there will still be variation across a crop.

Cropping methods and breeding strategies also affect the potency of cannabis (Burgdorf et al. 2011; Pijlman et al. 2005). Over the last four decades, the concentration of THC and other cannabinoids has increased, which baffled Mehmedic and coworkers as they found the "potencies inconceivable" and attributed their high measurements to "scientific and statistical shortcomings" (Mehmedic et al. 2010). There is little doubt that the potency increase is associated with both genetic selection and increasing sophistication of horticultural practices, including lighting, fertilization, addition of carbon dioxide, control of light intensity and photoperiod, temperature control, watering, balancing the pH of the soil, hydroponic growing, "supercropping", plant spacing and trellising, and growing media (Chandra et al. 2008).

UV lighting as a factor in THC content

Ultraviolet radiation plays a role in enhancing THC levels in cannabis. Lydon et al. (1987) showed that THC content could be increased with UV-B irradiation (280-320 nm). However, indoor growing facilities currently favor high-pressure sodium lamps (emitting at around 546-620 nm) and metal halide lights (400-700nm). Seven varieties of cannabis were seeded and grown under conditions common to commercial practice to determine whether the level of electrical power is a useful estimate for final yield, and to determine whether the observation of increased potency could be attributed to lighting regimes (Potter & Duncombe 2012). Conditions were controlled with regard to day length, temperature, and CO_2 level. Zones of light with regard to electrical power consumption were varied and kept at a constant distance from the plant canopy as they grew for eight weeks. Flowers were then harvested, dried, and analyzed. Flower to leaf ratio significantly increased as a function of electrical power with an average yield of 470g/m^2. The authors did not report a significant difference in THC content based on this sodium lighting intensity however, and suggest that the increase in THC is based more on the breeding (genetics).

Table 4: The effect of light power density on Δ^9-THC potency.

Electrical Power Per Unit Area W/m^2	Variety							
	Early Pearl	G1	Wappa	White Berry	Super Skunk	Hindu Kush	White Widow	Mean*
270	9.54	10.49	19.28	11.04	18.89	12.22	17.78	14.46
400	9.43	11.07	19.05	10.45	19.37	12.72	17.53	14.38
600	9.54	11.36	17.77	11.02	19.08	13.26	17.43	14.49

*There was no observed increase in mean potency—linear regression, $p > 0.05$.
THC, $\triangle^9$-tetrahydrocannabinol.

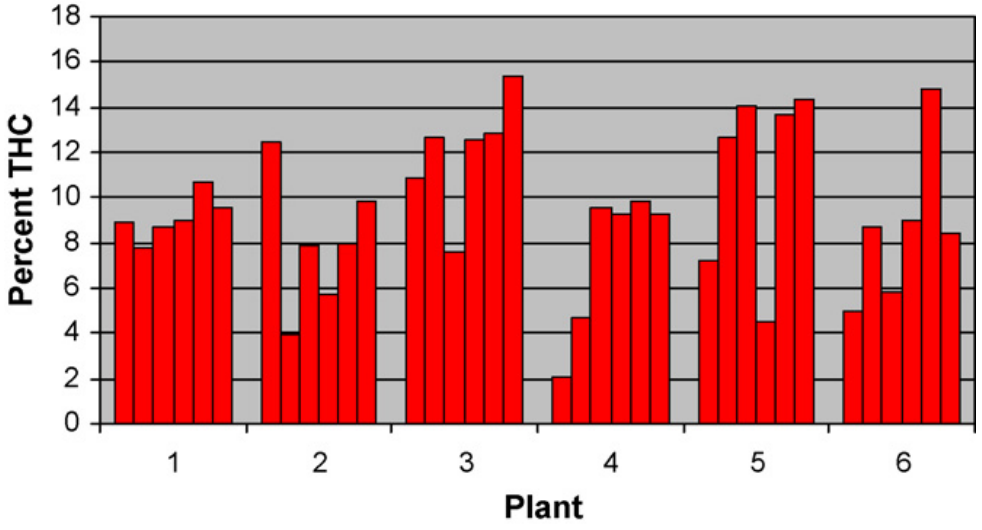
Indoor growers often use a variety of lighting sources (including metal halide and LED) that provide greater spectrum of lighting, and measure lumens (not wattage) to predict vegetative growth. Whether and how specific wavelengths and intensities factor in THC

potency remains unknown. These are much needed experiments that could benefit the industry by maximizing product consistency and quality control.

Degrees of plant/crop heterogeneity

Indoor cultivation offers an advantage to the grower by allowing greater control over plant environment, and gives the ability to grow continuously without seasonal limitation. The setups vary widely with regard to sophistication. Typically, larger scale operations require higher levels of sophistication. It is assumed that more sophisticated operations are better able to regulate growth. However, variables such as nighttime temperature (if using outdoor ventilation), moisture and nutrient supply (if not automated), and equipment failures (fans, heaters, and coolers) can all contribute to outcome variability. In order to ascertain variability in yield and potency for criminal sentencing purposes in New Zealand, an initial study of crops of six plants in each of three "grows" were cultivated under controlled, indoor hydroponic conditions (Knight et al. 2010). Since environmental and nutritional factors were controlled, the study found that plant variety had a major influence on THC levels. A much wider study would be required to determine whether there is considerable variation in THC levels in a subspecies. Variability was determined by the authors to be due to flowers not all being at an equal stage of ripeness, and they recommend multiple analyses. A limitation of the study with regards to results from "grow 2" and "grow 3" were that they encountered serious problems, e.g., nutrient burn and spider mites, yet also found considerable variation both inter- and intra-plant. Individual data for the figure below was not provided, so the actual relative variability amongst this set of six clones is unknown (Figure 7).

Figure 7: THC results for six random samples from each plant in Grow 2, (clones) of the Knight study.



Overall, it can be assumed than even when growing the same variety under the same conditions there may be a substantial degree of cannabinoid variability. Based on the limited data available, it is best to label cannabis potency as a range - not a definite value, - for a given variety. Many laboratories currently report potency to two decimal points, allowing the consumer to misperceive precision for accuracy. This practice is misleading, and misrepresents the accuracy of testing protocols. Typically, that amount of specificity is warranted when results are based on multiple samples (n=3 in research). For single samples, decimal points should be dropped when reporting test results even if a lab has demonstrated a high degree of proficiency, as the inter and intra-plant variability warrant reporting potency in a range. Based on these data, a suggested range that may be reliable is around 2%. As the skill level of growers is refined, and with experimental data demonstrating a lower relative variation, this could be reduced to 1%. A state-sanctioned laboratory to conduct such experiments is needed.

Tensions in Testing Procedures

Many of the sampling policies described in this paper have significant implications on the price of testing. (To be clear, by price of testing we mean the costs levied on the producer, processor, and testing laboratory, as a result of specific policies regarding sampling methodology.) Since these regulations pertain only to the I-502 market, and not to the medical or black markets, minimizing the cost burden of testing and sampling-related policies is important to strengthening I-502's ability to complete with these markets on price. Moreover, and for the same reason, even the most relaxed and least imposing testing and sampling policies discussed in this document will represent a cost increase over the current levels of testing expenditure as enjoyed even recently by the medical and gray markets. (However, these quality assurance regulations may also produce value, if consumers are willing to pay higher prices for cannabis with these assurances of potency and purity.)

The definition of a lot may have to evolve over time as the economy of scale evolves with the market. If it is projected that only large producers will be able to remain in the marketplace, then lot sizes will become much larger than what the existing framework may allow.

The suggested amount for a lot of plant material is not more than five pounds, based upon the approximate flower yield from an indoor grow facility using tables, or a 25 foot greenhouse row with mature plants spaced six feet apart (average yield estimated at 500 grams of flower per plant; Potter et al. 2012). The size of the greenhouse or area in which a particular variety is grown should determine what makes up the lot. A lot can be part of a larger unit that is a complete harvest. For instance, a harvest may include one lot or ten lots.

The decision on a maximum lot size entails a specific trade-off between cost and representativeness of the sample. As allowed lot sizes increase, producers and processors may separate products into a lesser number of individual lots, and testing laboratories may run fewer tests. Depending on required lot sizes, and based on the estimates of lot sizes in this document, a producer who produces a ton of plant material a year might have to pay as

much as $65,000 a year for the required testing (excluding the possibility of bulk discounts). This would represent approximately 4% of gross income. (See Table 5).

Another option to reduce the cost burden of these policies would be to allow growers to access semi-quantitative methods for potency results, and provide this along with pesticide testing data as part of the grower's certificate of analysis. Then, producer-processors would absorb some of the costs for quantitative potency and microbiology testing of product that will be distributed for retail sale. For instance, HPTLC or infrared (IR) can be used to estimate potency and help growers conduct their own experiments with growing methodologies and harvest times. A semi-quantitative result can qualify for a certificate of analysis for the producer/processor. At the next stage of packaging and finishing the product, the quantitative analysis could occur (HPLC, GC).

Finally, we might expect some decrease in the cost of testing as the volume of demand for testing increases. For instance, a common blood test for total cholesterol has a retail price of five dollars in California, yet preparing a blood sample is more time-consuming and expensive than preparing a cannabis sample. One important factor that distinguished the cholesterol test from the cannabis test is the volume of sales activity to the vendor. As demand for testing increases, testing companies will be able to make more efficient use of capital and overhead, and thus costs for testing may sink across the board.

Financial Feasibility for Raw Plant Material

Twenty grams per kilogram from the producer equates to a net loss of an estimated 60 dollars in sales for the grower, or about 1% of the total lot price. With large-scale growing facilities, a 2% sample represents a cost of about $100, and at this time with the grower performing all of the required tests, another $200. $300 per kilo of plant material over a year, if producing a ton would cost the grower about $125,000 a year. If the lot size is increased to 5kg, costs would be reduced, but it will be necessary for laboratories to decrease the cost of running the test by improving high-throughput procedures. Estimates are provided in Table 5.

Table 5: Comparing the cost of testing cannabis flowers with respect to size of the grow facility.

Lot (Kilos per year)	# of 2 kilo batches	Sample cost per lot (@$3 per gram)	Test Cost per batch	Cost per harvest	Cost per Year
15.6	7.8	$468	$1560	$8,112	$64,896
9.36	4.68	$280	$1,216	$4,864	$38,937
4.68	2.34	$140	$608	$2,432	$19,468
2.34	1.17	$70	$304	$1,216	$9,734

The above table calculates cost for a producer with eight harvests a year (twice-annual production for each of four varieties, operating at different scales of production. Each test that must be carried out has two cost components: price of testing and value of the destroyed sample. The price of each individual test (including cannabinoids, pesticides, heavy metals, and microbiology) is assumed to be $50. Each test requires homogenizing 20 grams of product; in the testing process, seven grams are rendered unusable and the remainder may be returned to the producer in a homogenized state. The table assumes that the value of each gram of cannabis to the producer is $3 per gram, and that homogenized cannabis loses half of its value. (By these calculations, each test costs the producer a combined $40.50 in inventory.) Based on these numbers, the total cost of testing is 4% of the total potential gross receipts at $3 per gram.

Financial Feasibility for Extracts and Infused Products

It is more difficult to project costs of sampling extracts or cannabis-infused products. These are currently being produced in a variety of ways, from very expensive supercritical CO_2 extraction to simple tincturing with ethanol. Moreover, extractions are performed on widely different scales, from quart jar operations in home kitchens to larger lots in professional facilities. The amount of starting material and volume produced will vary greatly across these methods. Retail price also varies based on the cost of the materials involved in producing the product. A great deal more research should be done to determine representative sample sizes and cost projections for testing these products. More concentrated resins may need a smaller representative sample than a more dilute tincture. As discussed earlier, a representative sample from a lot may be 2% of the total or an AQL protocol can be developed that is based on lot size. Without knowing the exact costs of producing the various types of products, it is difficult to estimate the testing costs and feasibility.

A pound of raw material may yield about 50 g of a semi-solid extract using CO_2 extraction. For a tincture using glycerine or ethanol extract, the starting material will dictate the size of the lot. Standard statistical sampling was described in the sampling section.

Conclusion

There are many factors that can affect the cannabinoid profile and potency of cannabis. Controlling for the stain or genetic make up of a plant is often considered the most effective way to ensure a homogeneous crop. Though the WSLCB regulations require that a lot of cannabis be of the same strain, in this paper we have seen that other factors such as lighting quality and nutrients may play a major role in the potency of the plant. Informing the consumer about the strain of cannabis they are purchasing may not give them as much information about the psychoactive content of the product as could be hoped. Continuous testing of harvests is required to truly inform the customer.

Just like any other industry, standardized statistical sampling methods for the Washington cannabis industry are needed to ensure customer safety and to support a supply chain to produce products of unrivaled standards, purity, and quality. Cannabis is a highly variable

crop, and lot size must be small enough to recognize the unique makeup of a particular harvest. The extent of variability in cannabis is not infinite and at a certain point there are diminishing returns of reducing lot size. Required methods for gathering lots and retrieving samples must attempt to reduce variability and any opportunity for the results to be manipulated while at once keeping down the cost of testing.

The various methodologies and constraints of sampling methodologies have been explained herein. It is expected that some of these may change with the development of technology and the dissemination of knowledge across industry. The future trajectory of these developments has an element of unknowability, and there may come a time when they may merit a separate response from regulating agencies. In the meantime, additional research may be productive to the mission of ensuring the quality, consistency, and accurate labeling of cannabis products.

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