Attachment G: Laboratory Testing Techniques

[redacted]

Sincerely,

William J. Neumann

William J. Neumann
Vice President
[redacted]

[redacted]

[redacted]

REVIEWED BY
QUALITY ASSURANCE
INITIAL [redacted] DATE 11-17-2022

[redacted]

Certified by: William J Neumann Date: February 23, 2023

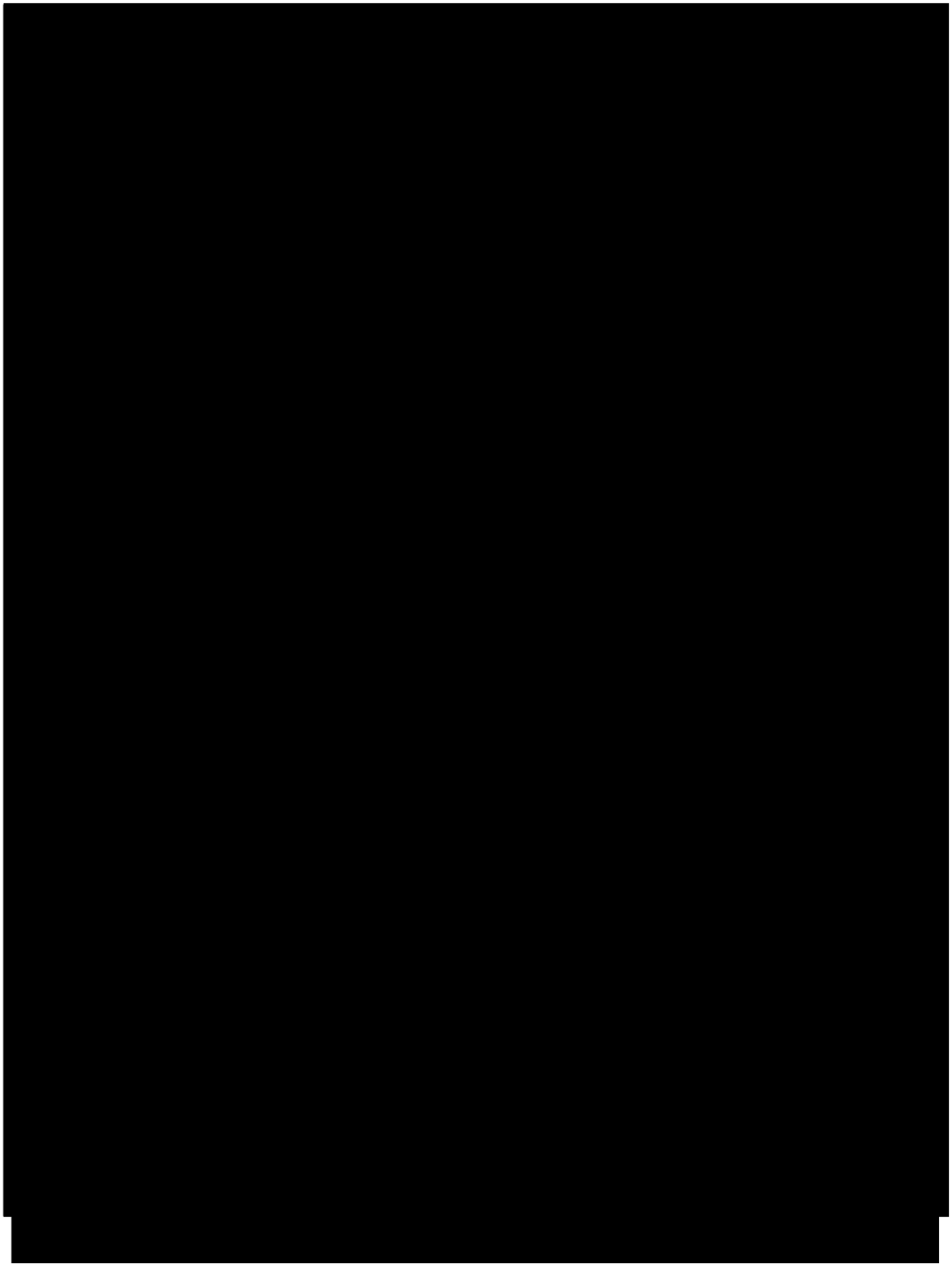
William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

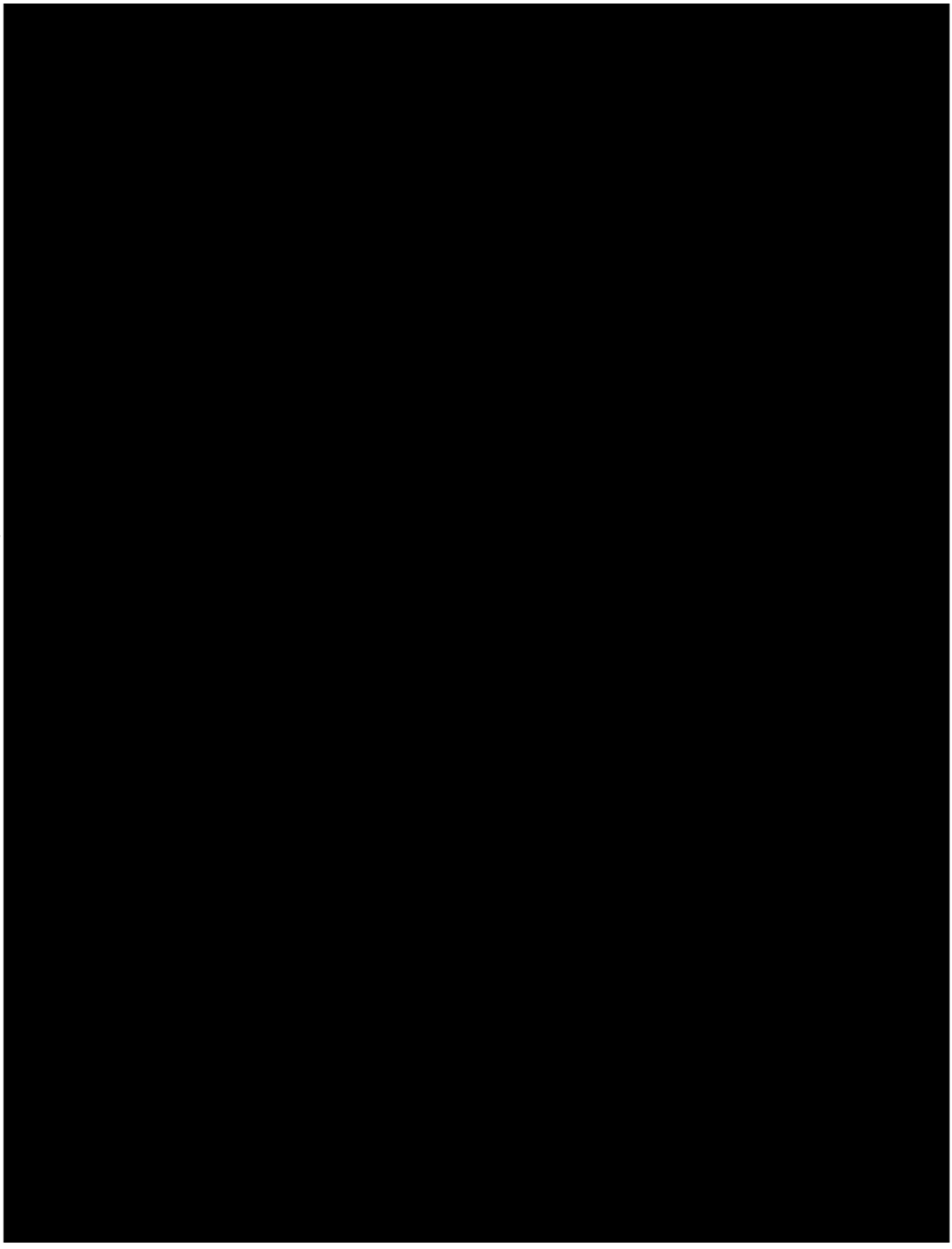
[redacted]

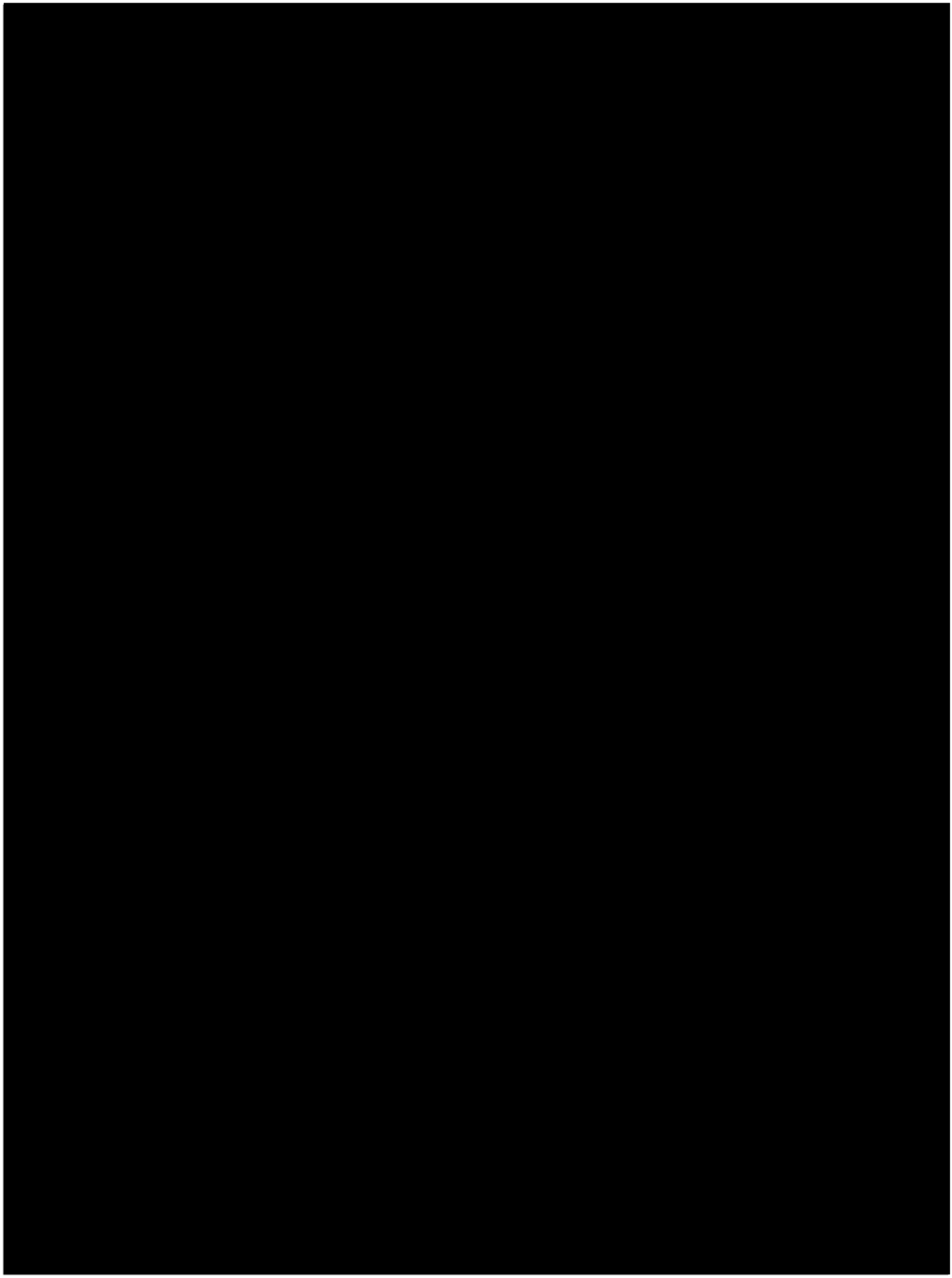
[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs







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Sincerely,

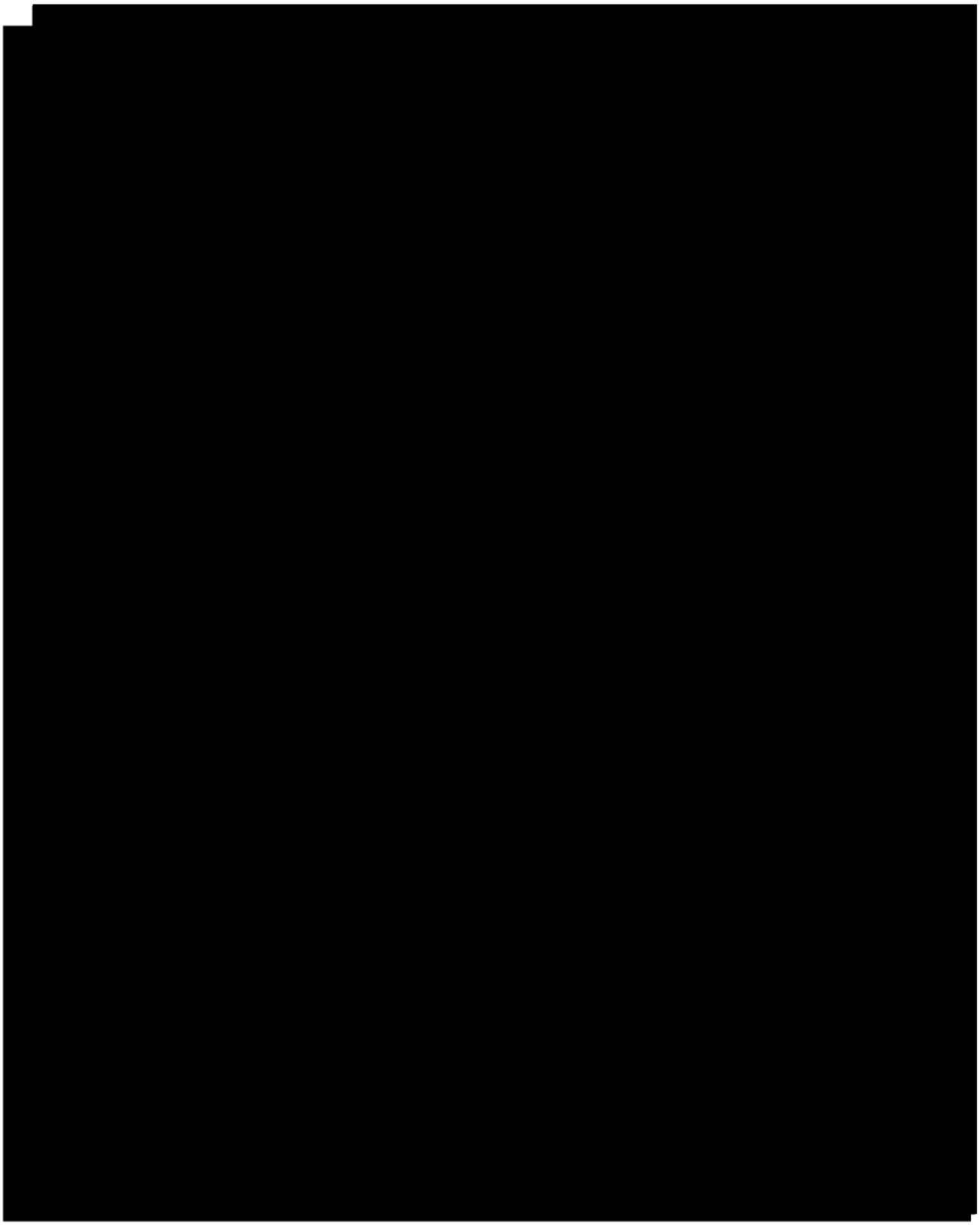
William J. Neumann

William J. Neumann
Vice President
QA & Regulatory Affairs

[redacted]

[redacted]

[redacted]



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Sincerely,

William J. Neumann
Vice President
QA & Regulatory Affairs
[redacted]

[redacted]

[redacted]

U.S. FOOD & DRUG ADMINISTRATION

One Montvale Avenue, 4th Floor
Stoneham, MA 02180-3500
Phone Number: 781-587-7500 -
Fax Number: 781-587-7556
NWE-DO Weather Line: 781-587-7600

03/20/2018

Melvin Weiss, Chairman of the Board of Directors
Consumer Product Testing Co. Inc.
70 New Dutch Ln
Fairfield, NJ 07004-2514, US

[redacted]

Sincerely,

Maya M. Davis
Compliance Officer
maya.davis@fda.hhs.gov
(860) 240-4289 ex. 25

Digitally signed by Maya M. Davis -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Maya M. Davis -S, 0.9.2342.19200300.100.1.1=2000361096
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[redacted]

FDA Establishment Inspection Report (EIR)

[redacted]

February 2 – 4, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331- 4900
FAX: (973) 331- 4969

March 31, 2016

Mr. William Neumann
V. P. Quality Assurance and Regulatory Affairs
[redacted]

Louise Miranda
U.S. Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, New Jersey 07054
Telephone: 973-331-4903

Sincerely,

Lisa Harlan
Supervisory Consumer Safety Officer

[redacted]

[redacted]

[redacted]

Mr. William Neumann
V.P. Quality Assurance and Regulatory Affairs
[redacted]

[redacted]

[redacted]

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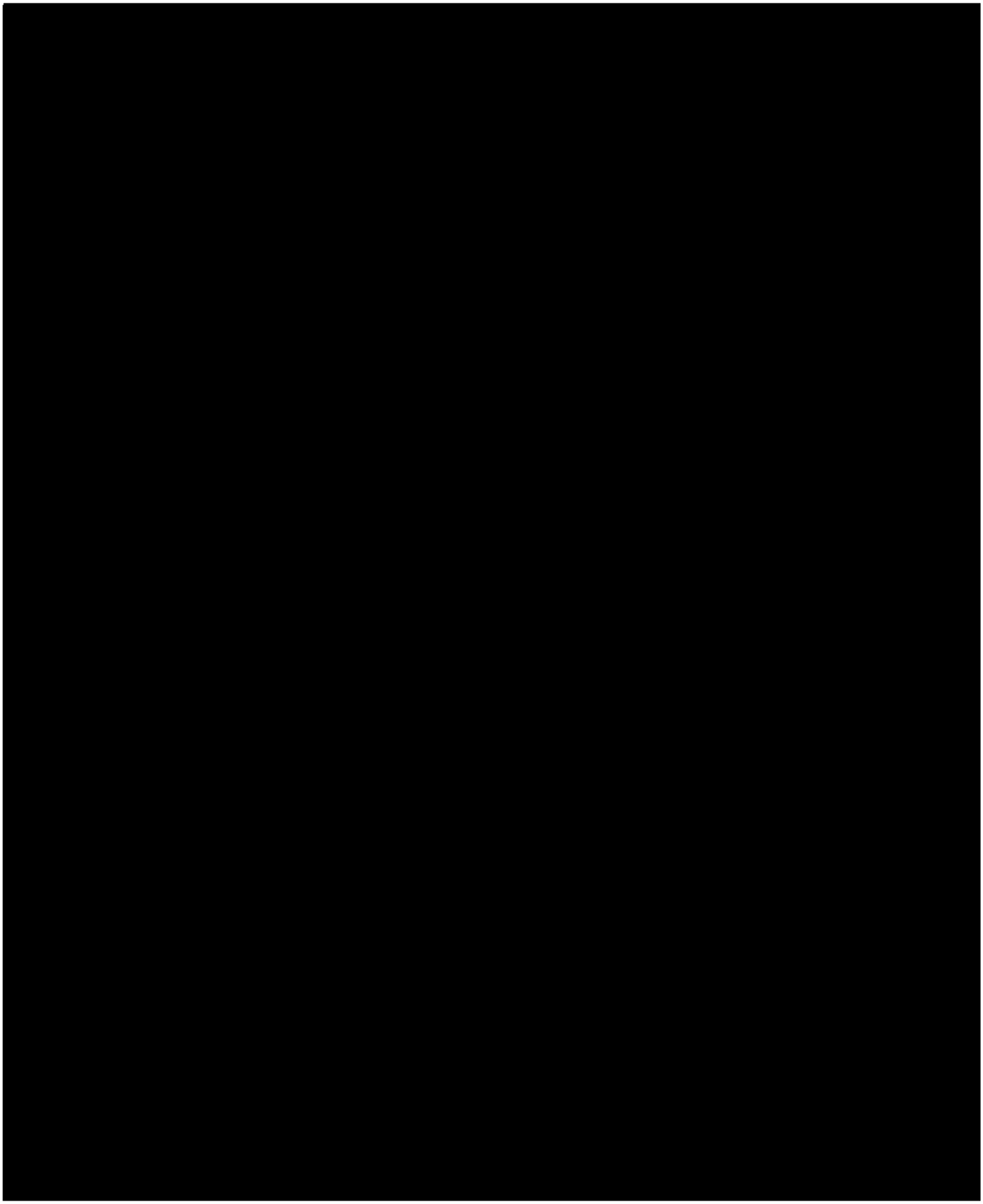

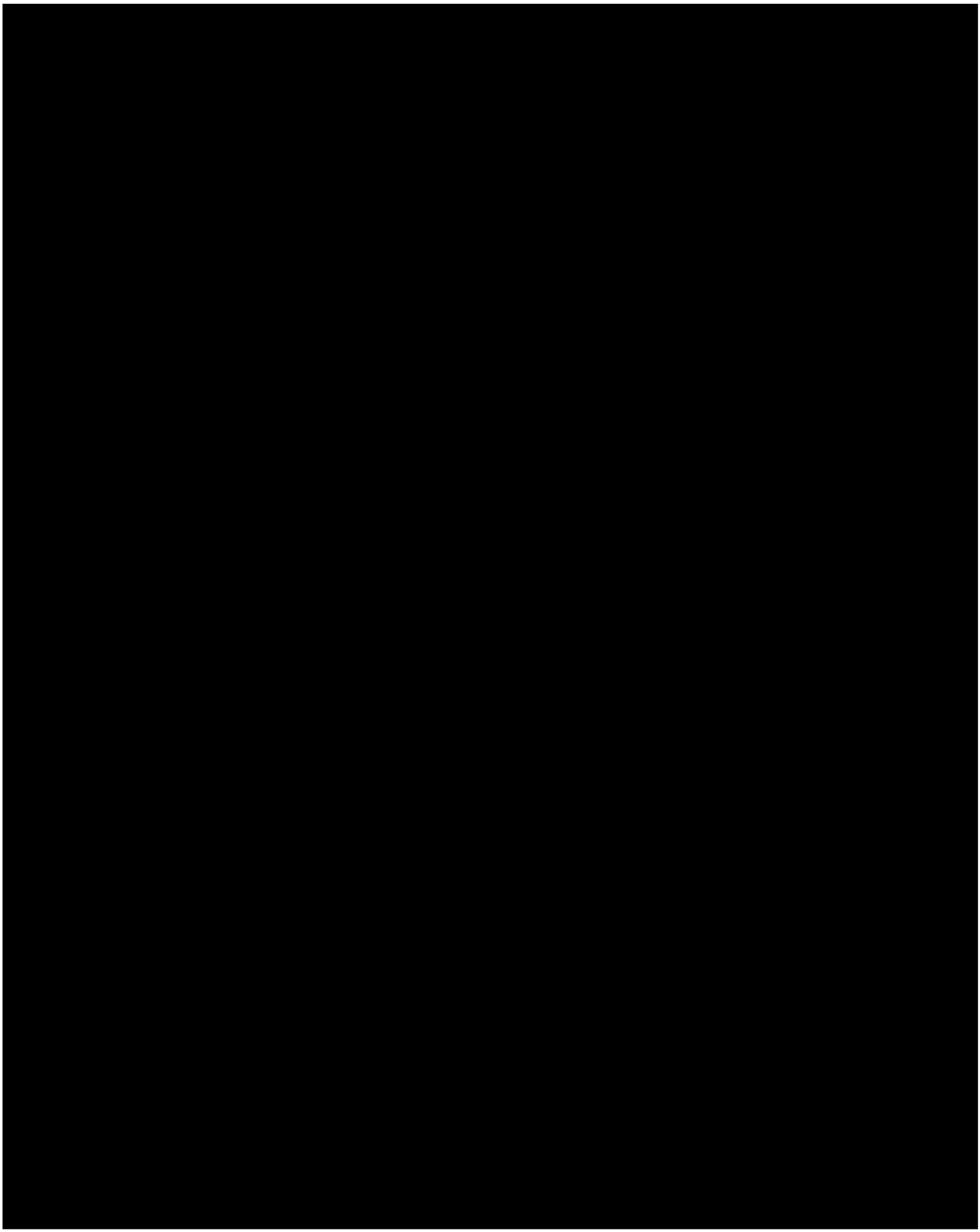

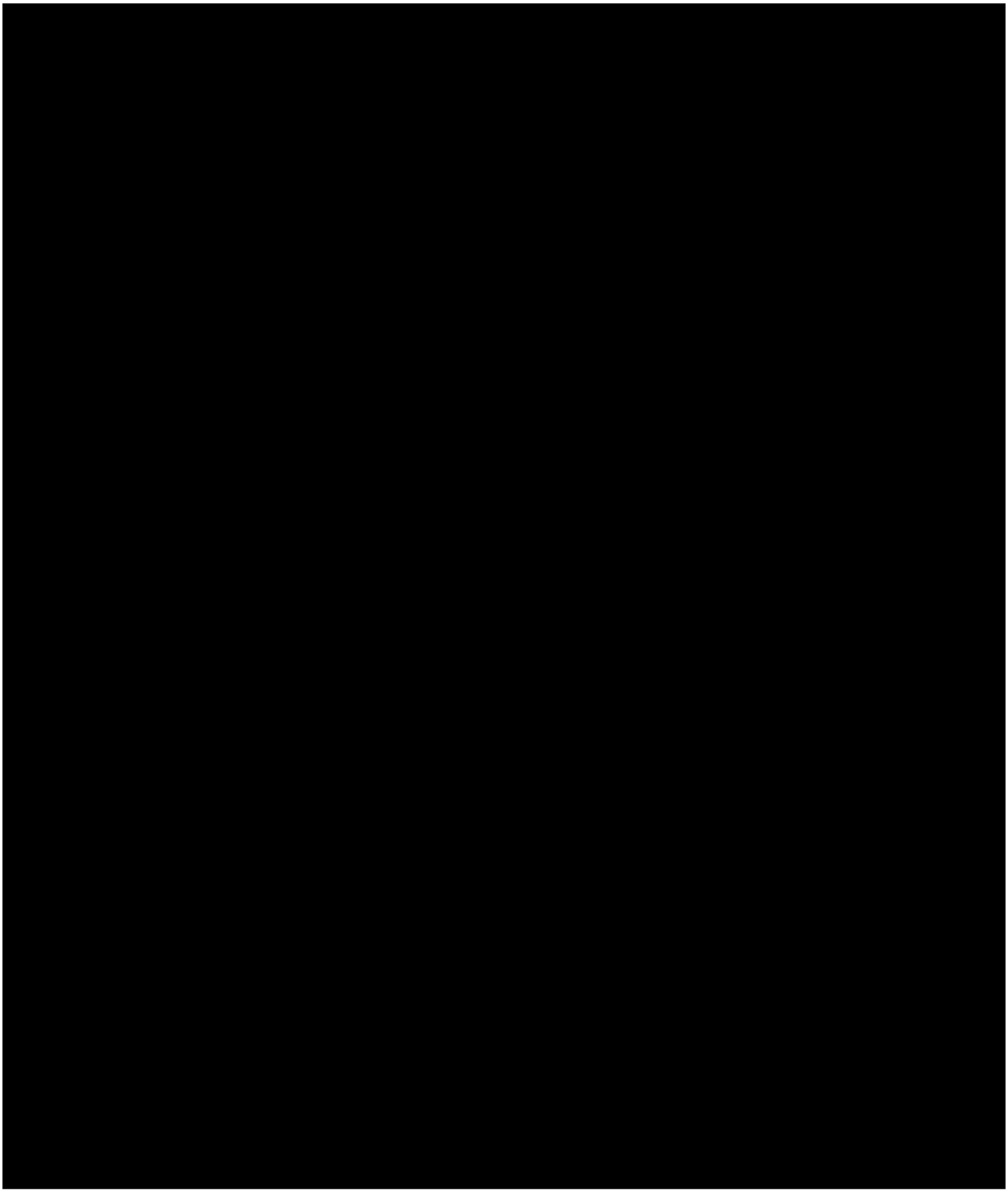

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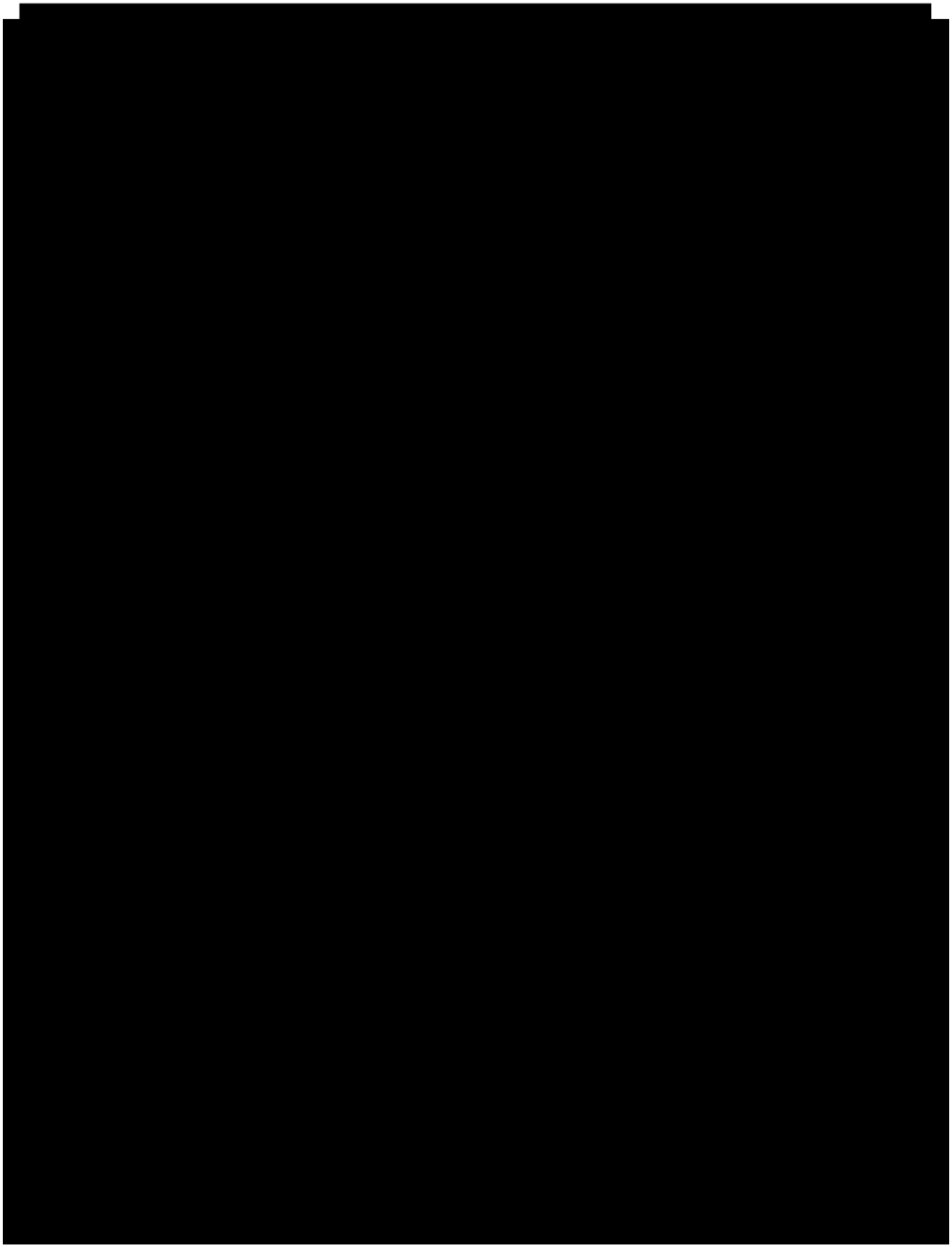
X Peter R Lenahan

Peter R Lenahan
Investigator
Signed by: Peter R. Lenahan -S



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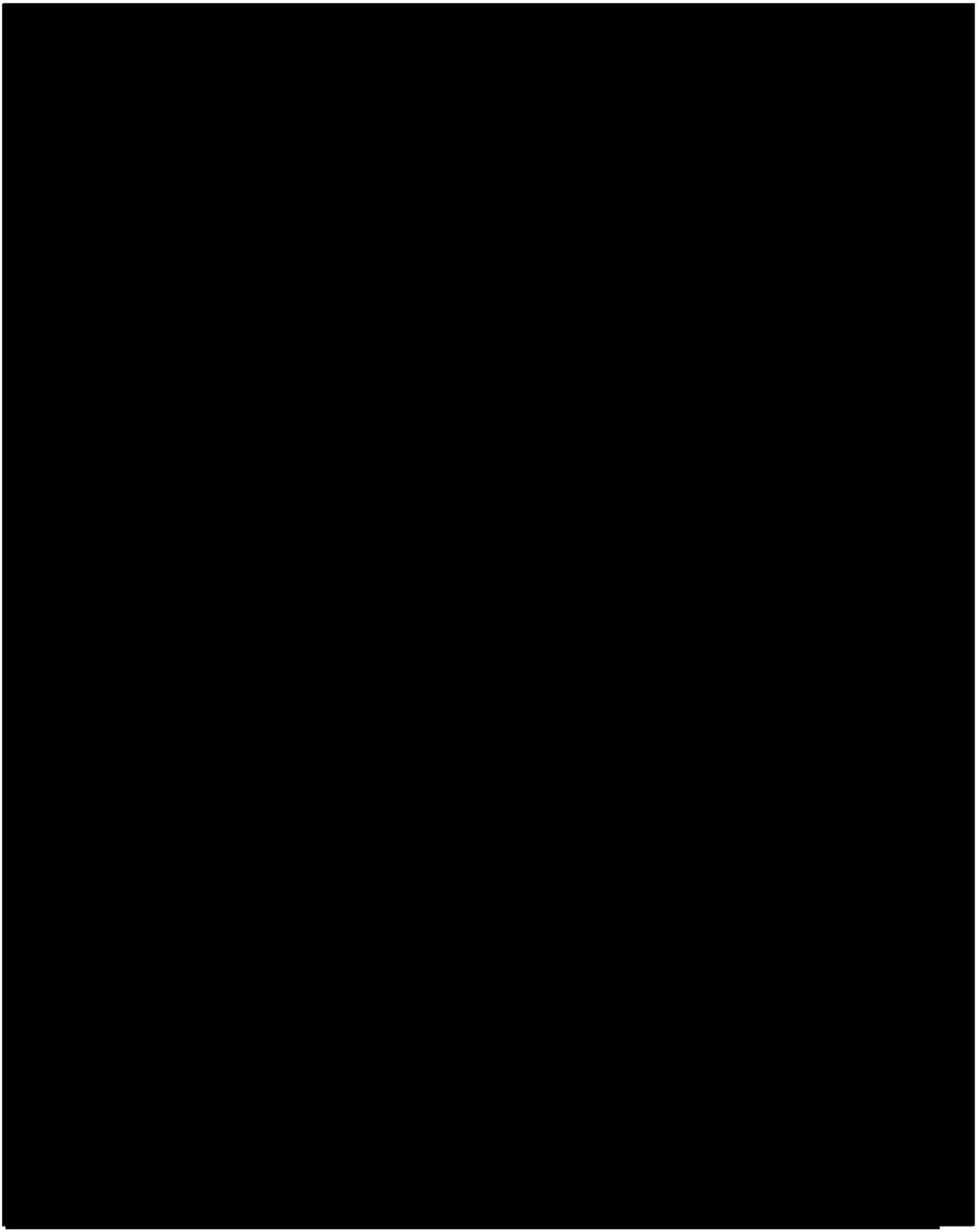

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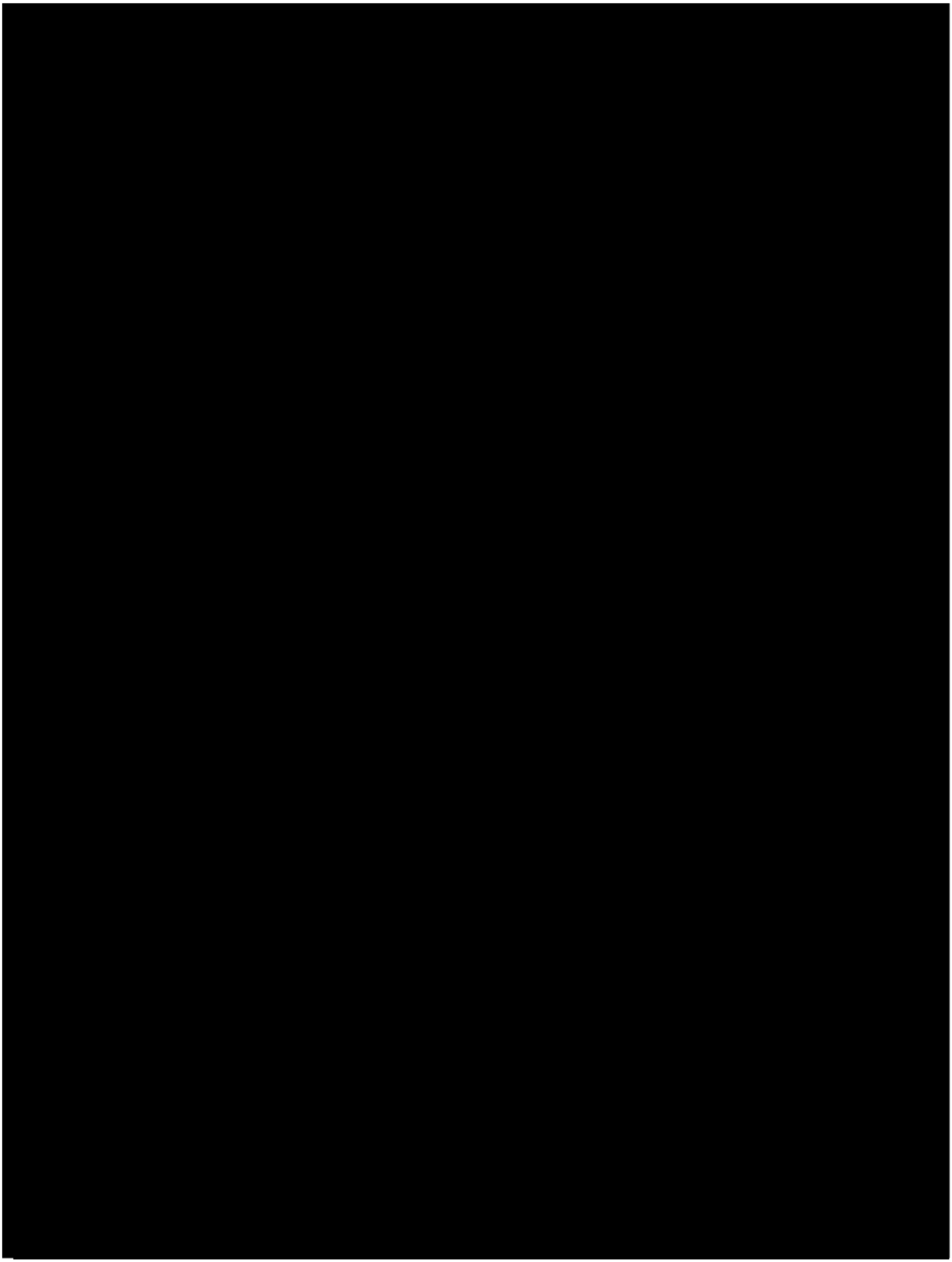

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[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]

[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]

[redacted]

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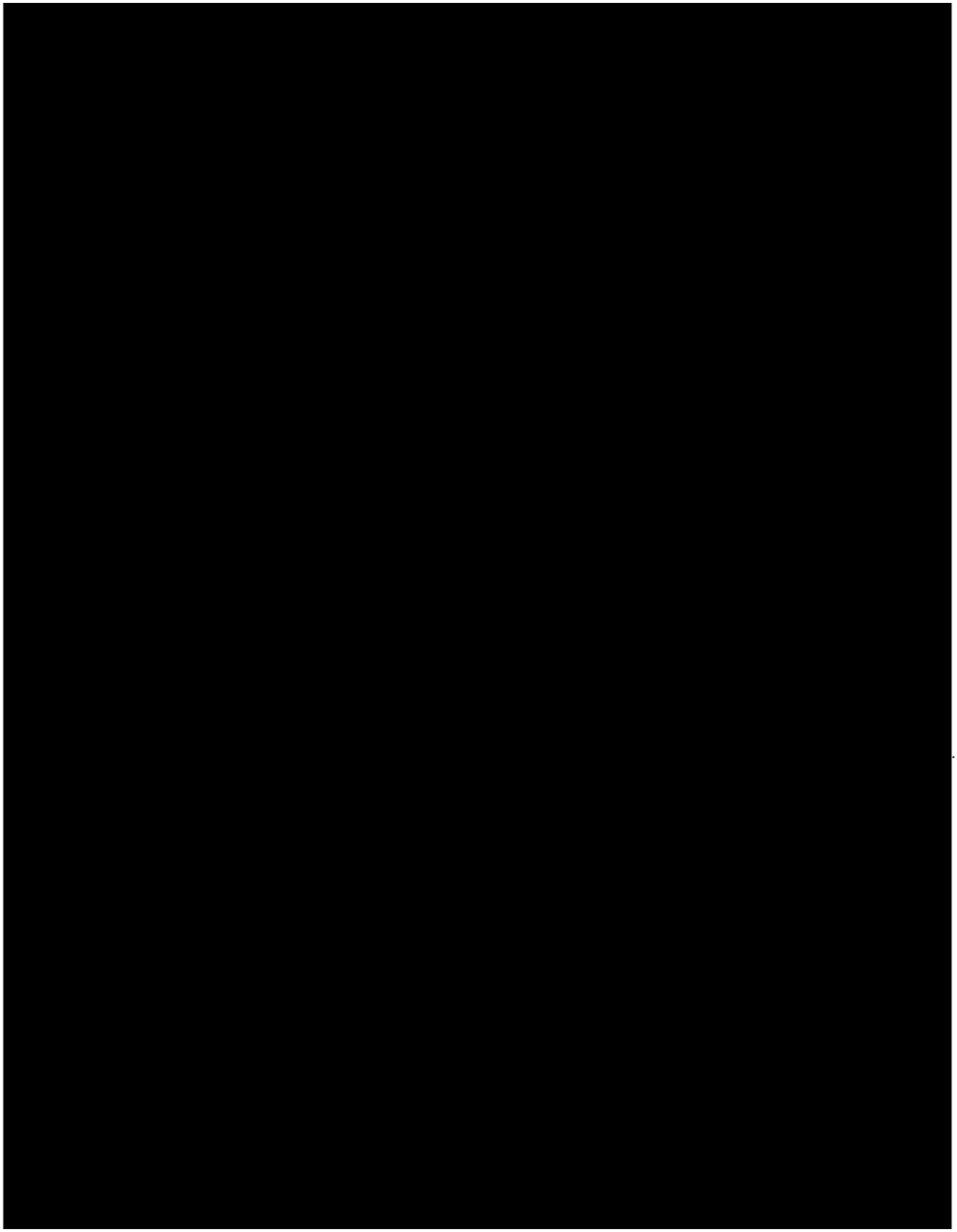
William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]



[redacted]

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]

QUALITY AGREEMENT

Between

Life Science Logistics, LLC
3100 Olympus Blvd., Suite 100
Dallas, TX 75019

[redacted]

William J Neumann — 03 JAN 2022

William J. Neumann
Vice President of QA & Regulatory Affairs

[redacted]

Bozie Madison — 03 JAN 2022

Bozie Madison
Associate Director of Regulatory Affairs and Compliance
Life Science Logistics

1 SCOPE

1.1 The purpose of this Quality Agreement is to confirm responsibilities of LSL and SUPPLIER with respect to receiving, handling, storing and testing laboratory samples for LSL. These responsibilities are outlined in the following sections.

1.2 The Agreement shall be effective as of the date of last signature above. This Agreement will be reviewed as necessary to ensure that the roles and responsibilities reflect current practice and can be modified as needed with the written approval of both parties.

1.3 SUPPLIER commits to be compliant with applicable sections of the current Good Manufacturing Practices (cGMP) for Finished Pharmaceuticals as published in 21 CFR Parts 210 and 211 and applicable ICH guidelines.

2 FACILITIES AND PERSONNEL

2.1 SUPPLIER shall ensure that its facilities and equipment are clean and properly maintained.

2.2 SUPPLIER shall provide adequate number of qualified trained technical staff for carrying out receiving, handling, storage, testing and reporting functions.

2.3 SUPPLIER shall ensure that only qualified trained staff is employed in all cGMP and quality-related operations and that SUPPLIER will conduct regular training of all key personnel including temporary staff according to the site training procedures necessary for cGMP and ICH compliance.

2.4 SUPPLIER shall maintain training records for such personnel and shall make them available during an audit by LSL or authorized Regulatory Authorities.

2.5 The responsibilities and procedures applicable to the SUPPLIER's Quality Unit shall be in writing and shall be followed.

2.6 Training in cGMP shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.

2.7 SUPPLIER shall qualify and calibrate all instruments and equipment per cGMP requirements.

2.8 SUPPLIER shall be responsible for qualifying its critical vendors and any sub-contractors utilized for the testing of LSL samples.

3 MATERIALS

[redacted]

4 DOCUMENTATION

[redacted]

5 CHANGE CONTROL

[redacted]

6 DEVIATIONS

[redacted]

7 ANALYSIS

[redacted]

8 SPECIFICATIONS AND TEST METHODS

[redacted]

9 QUALITY INVESTIGATIONS: OUT-OF SPECIFICATION (OOS) TEST RESULTS

[redacted]

10 REGULATORY AUTHORITY INSPECTIONS

[redacted]

11 QUALITY AUDITS

[redacted]

12 QUALITY AUDIT CLOSE-OUT

[redacted]

13 CONTROL AND DISPOSAL OF SAMPLES

[redacted]

14 HEALTH, SAFETY, AND ENVIRONMENTAL PROTECTION

[redacted]

[redacted]

Sincerely,

William J. Neumann

William J. Neumann
Vice President
[redacted]

[redacted]

[redacted]

[redacted]

REVIEWED BY
QUALITY ASSURANCE
INITIAL [redacted] DATE 11-17-2022

[redacted]

[redacted]

Certified by: William J Neumann Date: February 23, 2023

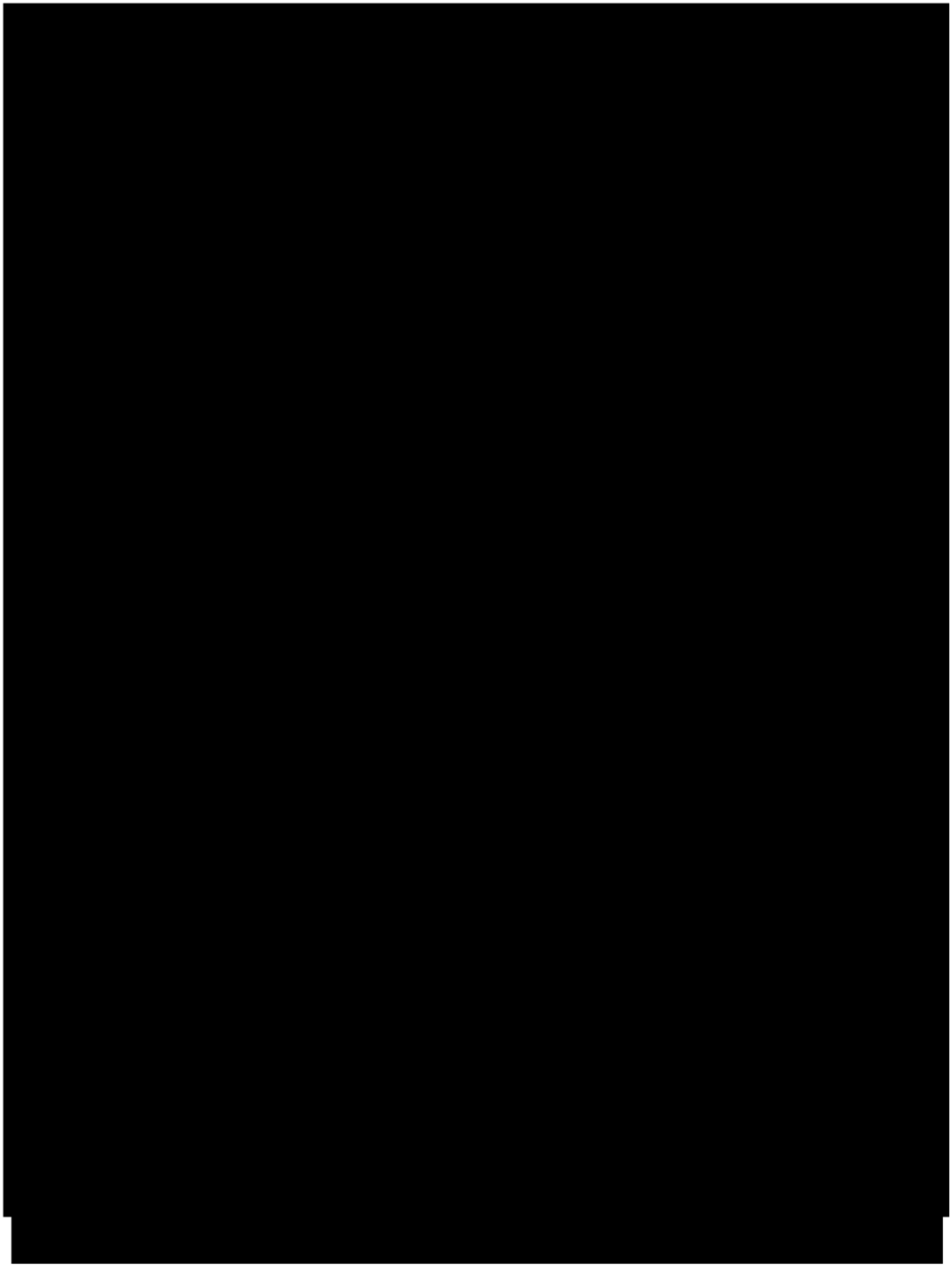
William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

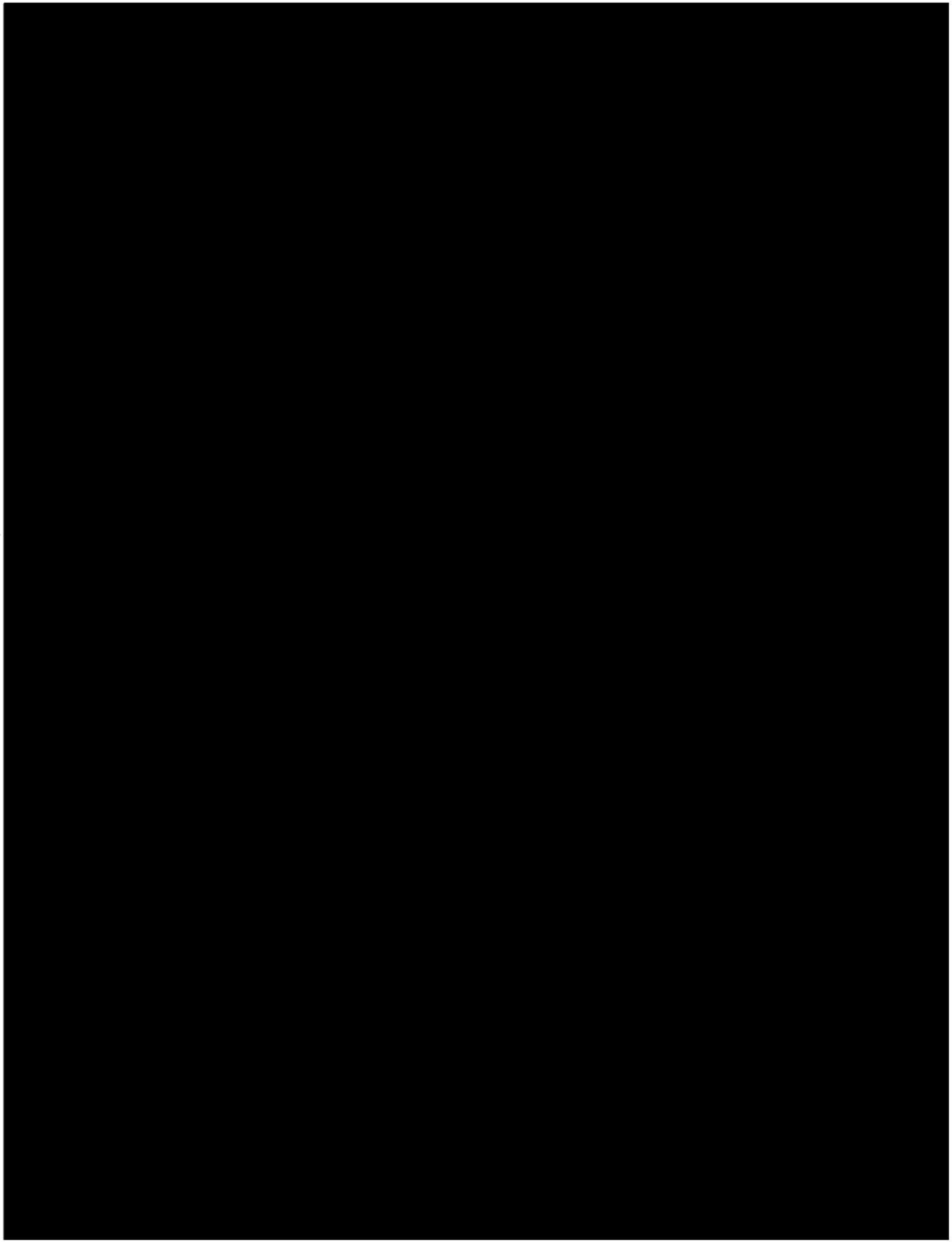
[redacted]

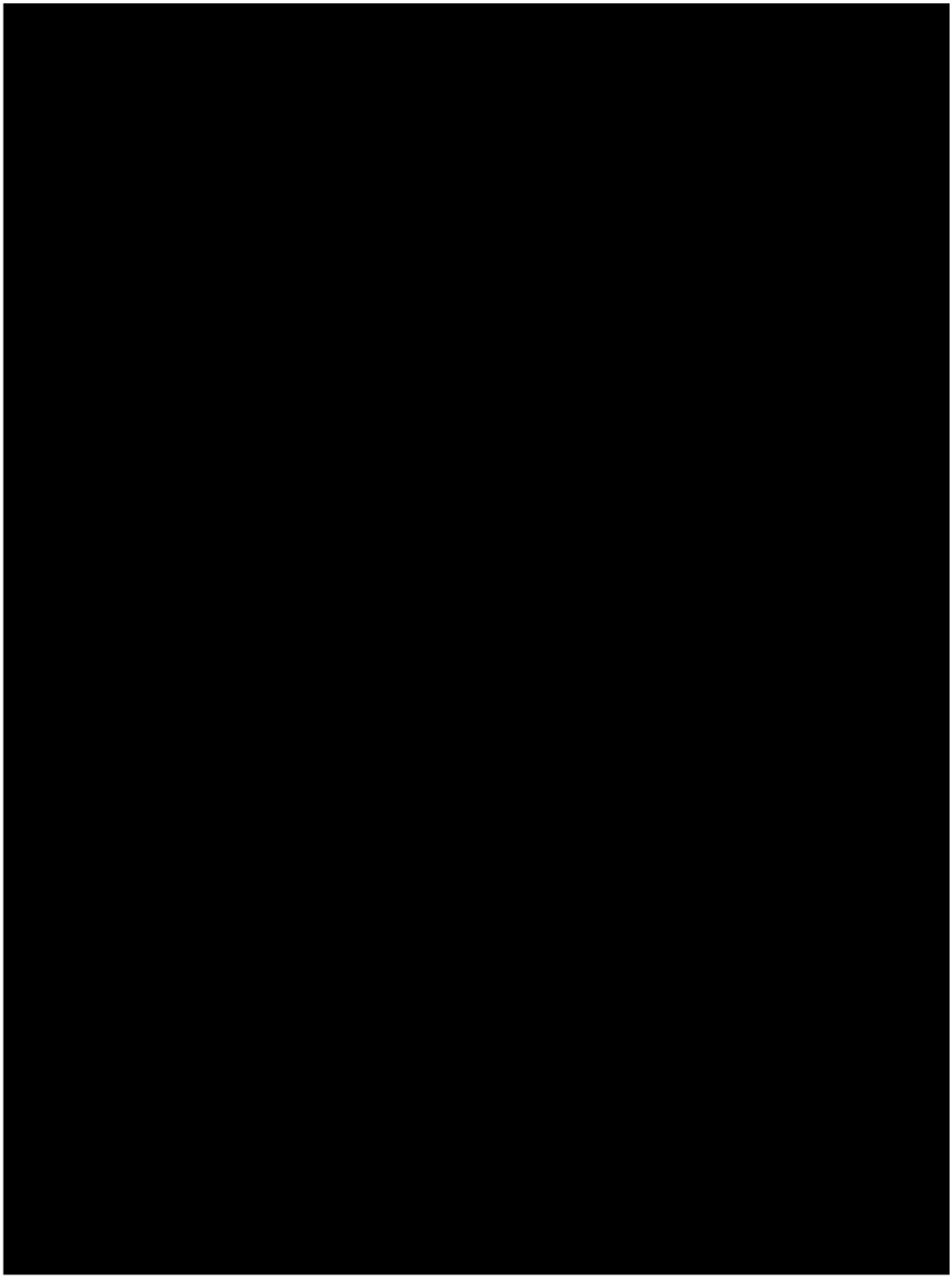
[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs







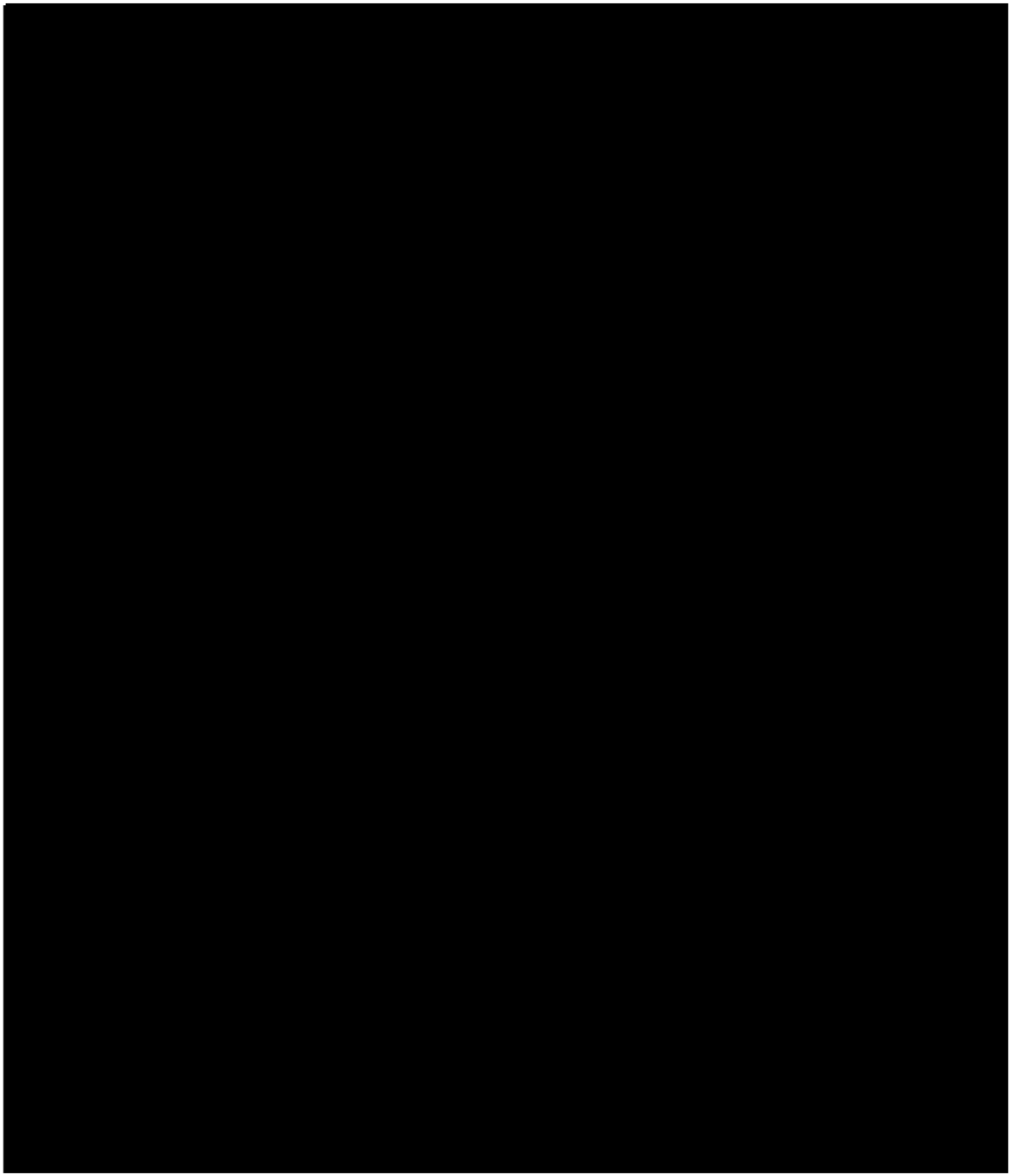
[redacted]

Sincerely,

William J. Neumann

William J. Neumann
Vice President
QA & Regulatory Affairs

[redacted]



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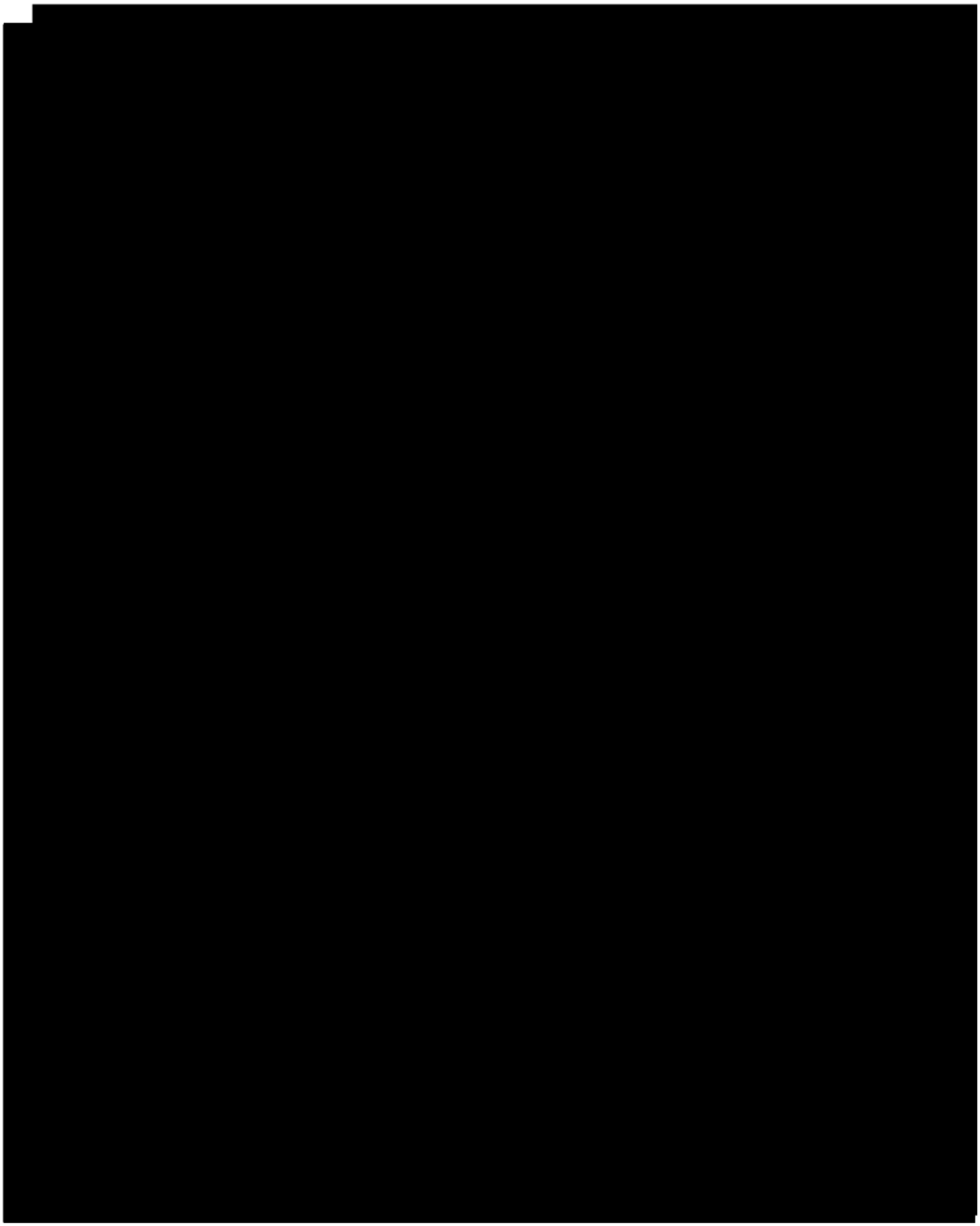

[redacted]

Sincerely,

William J. Neumann
Vice President
QA & Regulatory Affairs
[redacted]

[redacted]

[redacted]

U.S. FOOD & DRUG ADMINISTRATION

One Montvale Avenue, 4th Floor
Stoneham, MA 02180-3500
Phone Number: 781-587-7500 -
Fax Number: 781-587-7556
NWE-DO Weather Line: 781-587-7600

03/20/2018

Melvin Weiss, Chairman of the Board of Directors
Consumer Product Testing Co. Inc.
70 New Dutch Ln
Fairfield, NJ 07004-2514, US

[redacted]

Sincerely,

Maya M. Davis
Compliance Officer
maya.davis@fda.hhs.gov
(860) 240-4289 ex. 25

Digitally signed by Maya M. Davis -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Maya M. Davis -S, 0.9.2342.19200300.100.1.1=2000361096
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FDA Establishment Inspection Report (EIR)

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February 2 – 4, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331- 4900
FAX: (973) 331- 4969

March 31, 2016

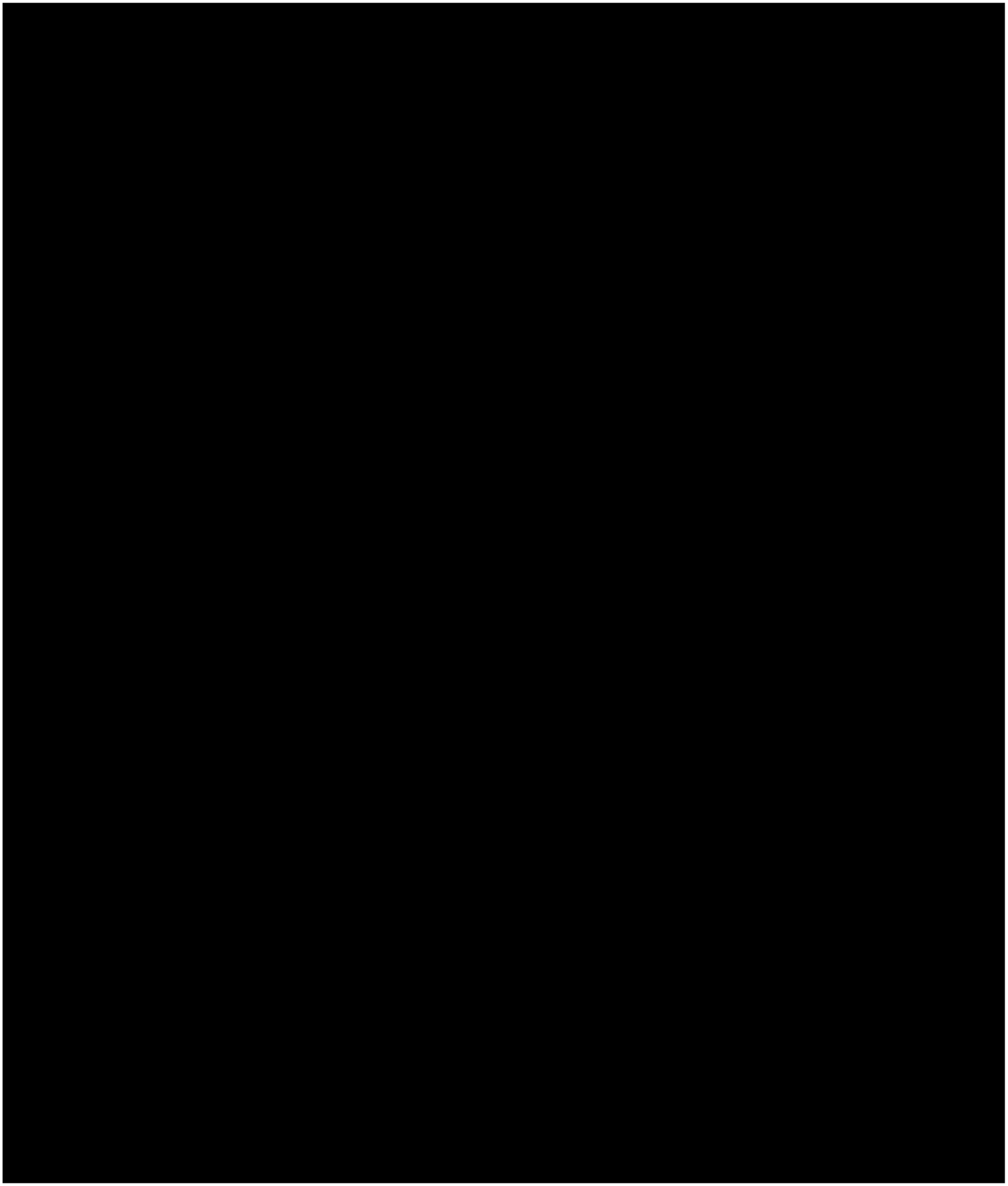
Mr. William Neumann
V. P. Quality Assurance and Regulatory Affairs
[redacted]

Louise Miranda
U.S. Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, New Jersey 07054
Telephone: 973-331-4903

Sincerely,

Lisa Harlan
Supervisory Consumer Safety Officer

[redacted]



[redacted]

Mr. William Neumann
V.P. Quality Assurance and Regulatory Affairs
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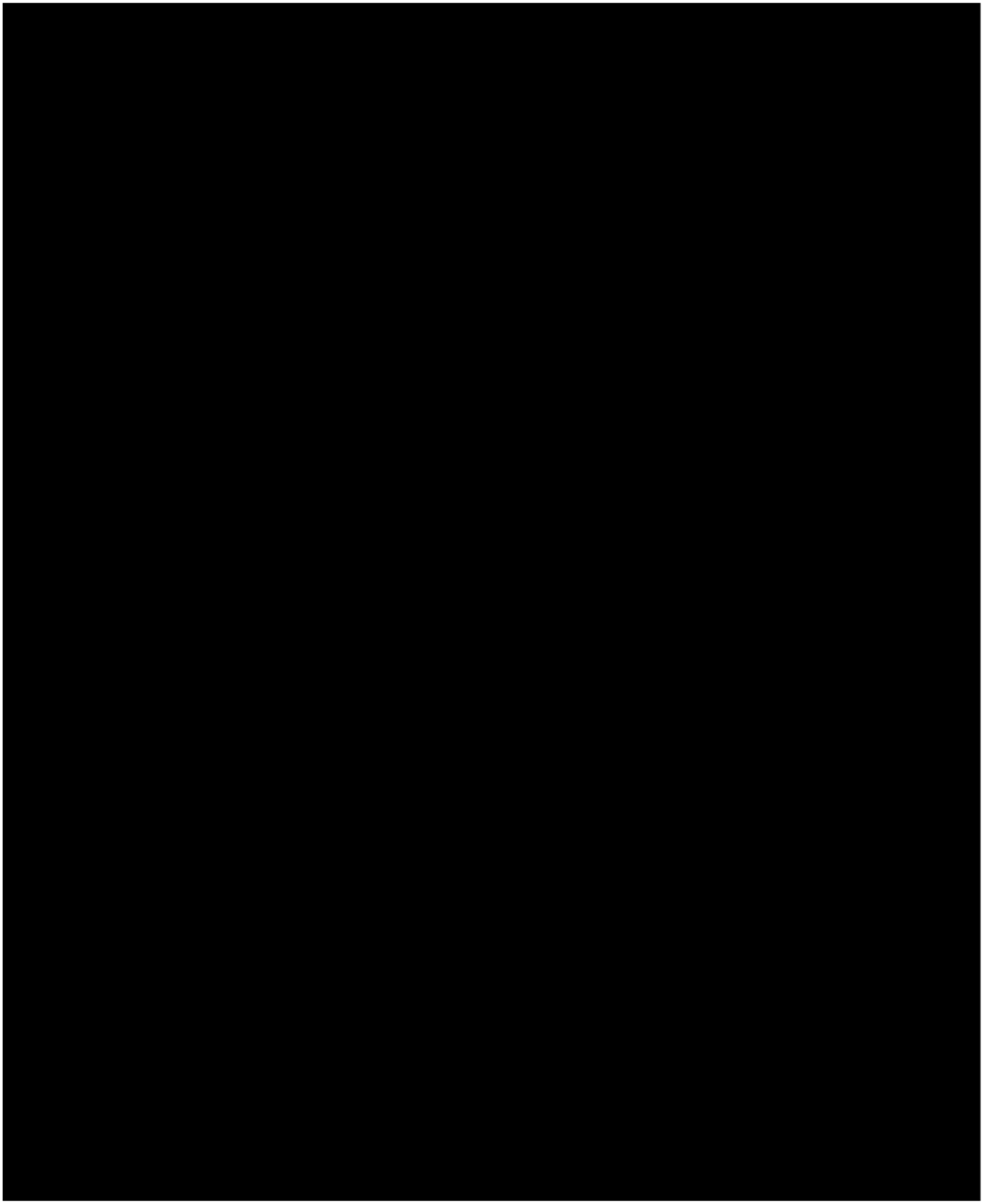

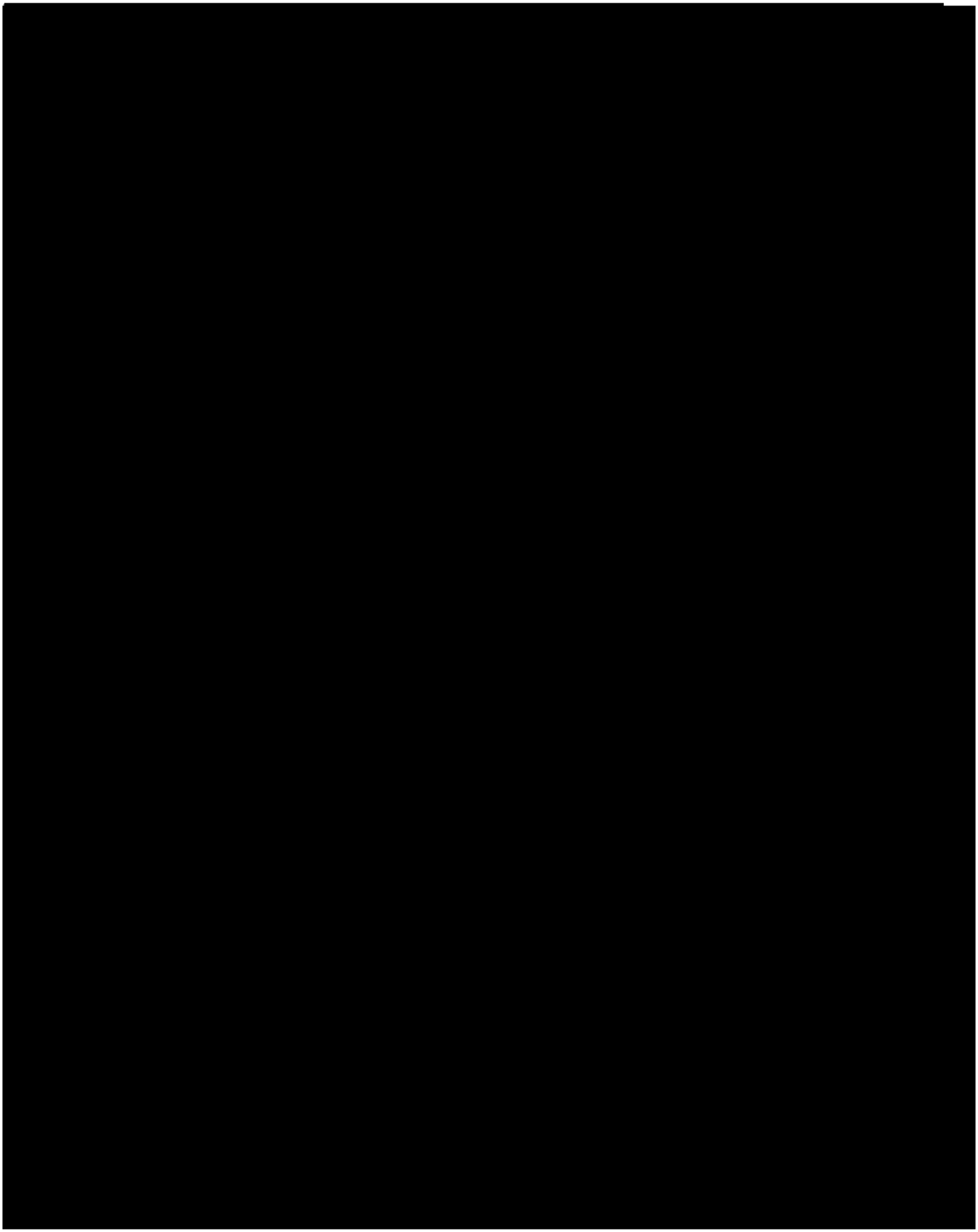

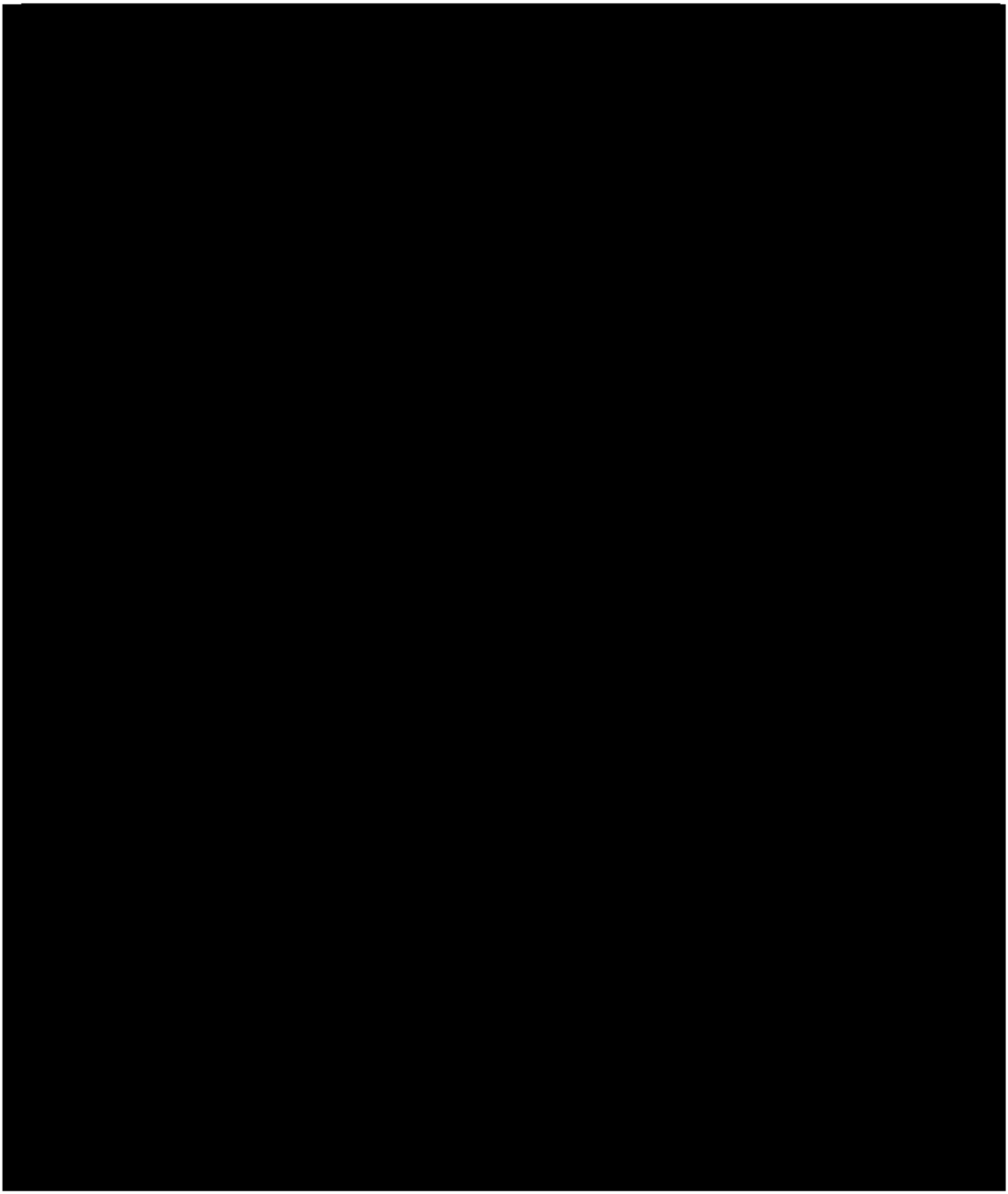

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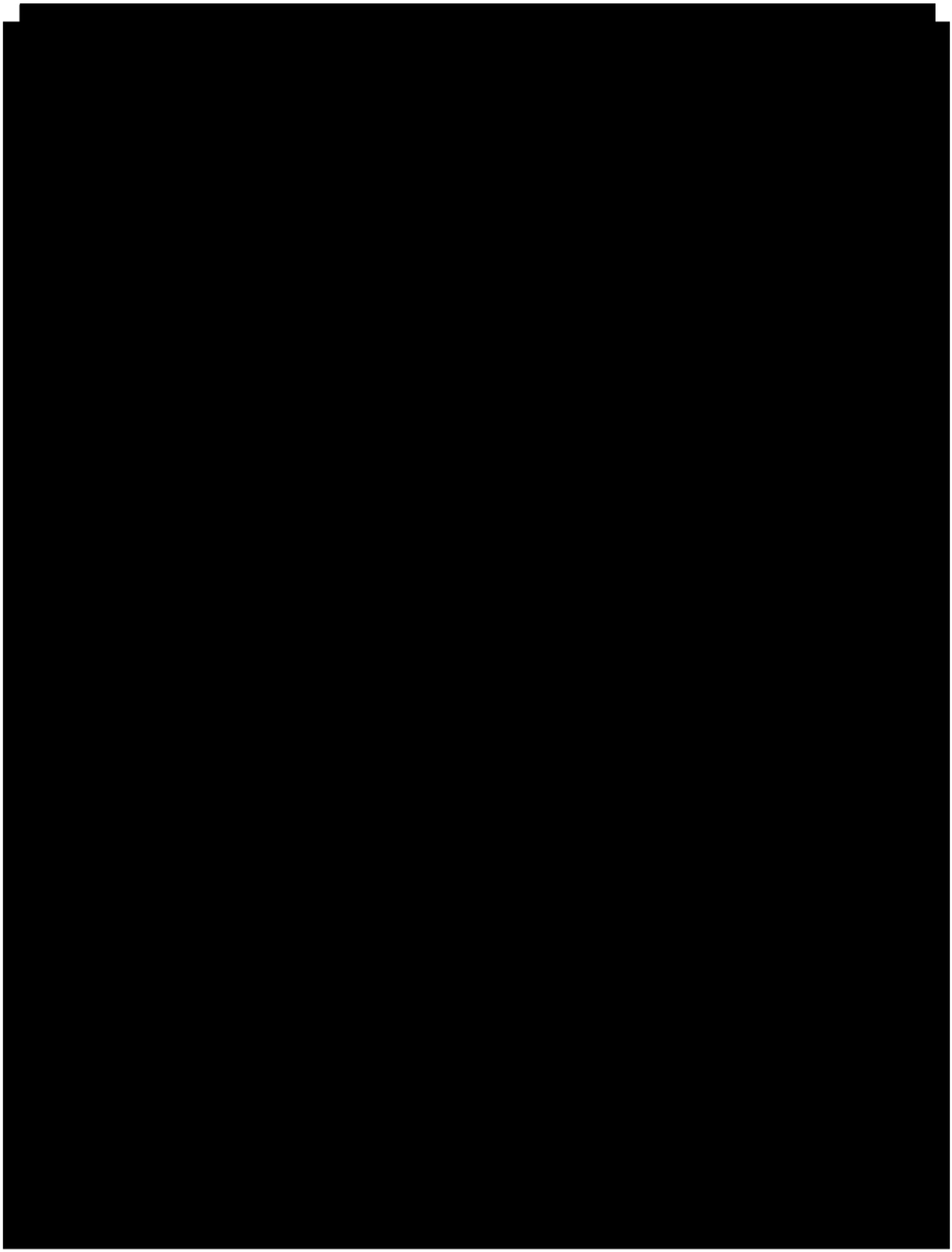
X Peter R Lenahan

Peter R Lenahan
Investigator
Signed by: Peter R. Lenahan -S



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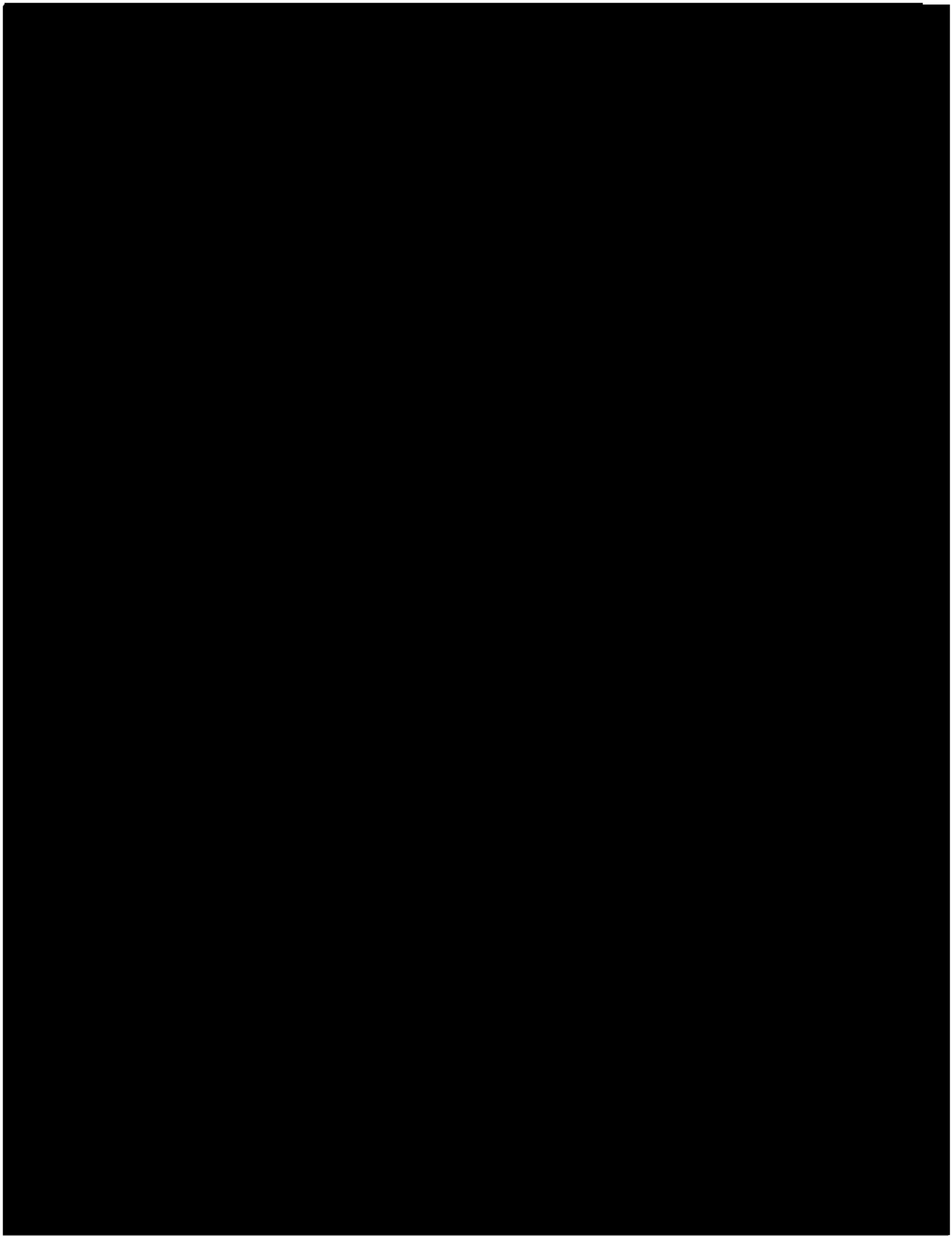
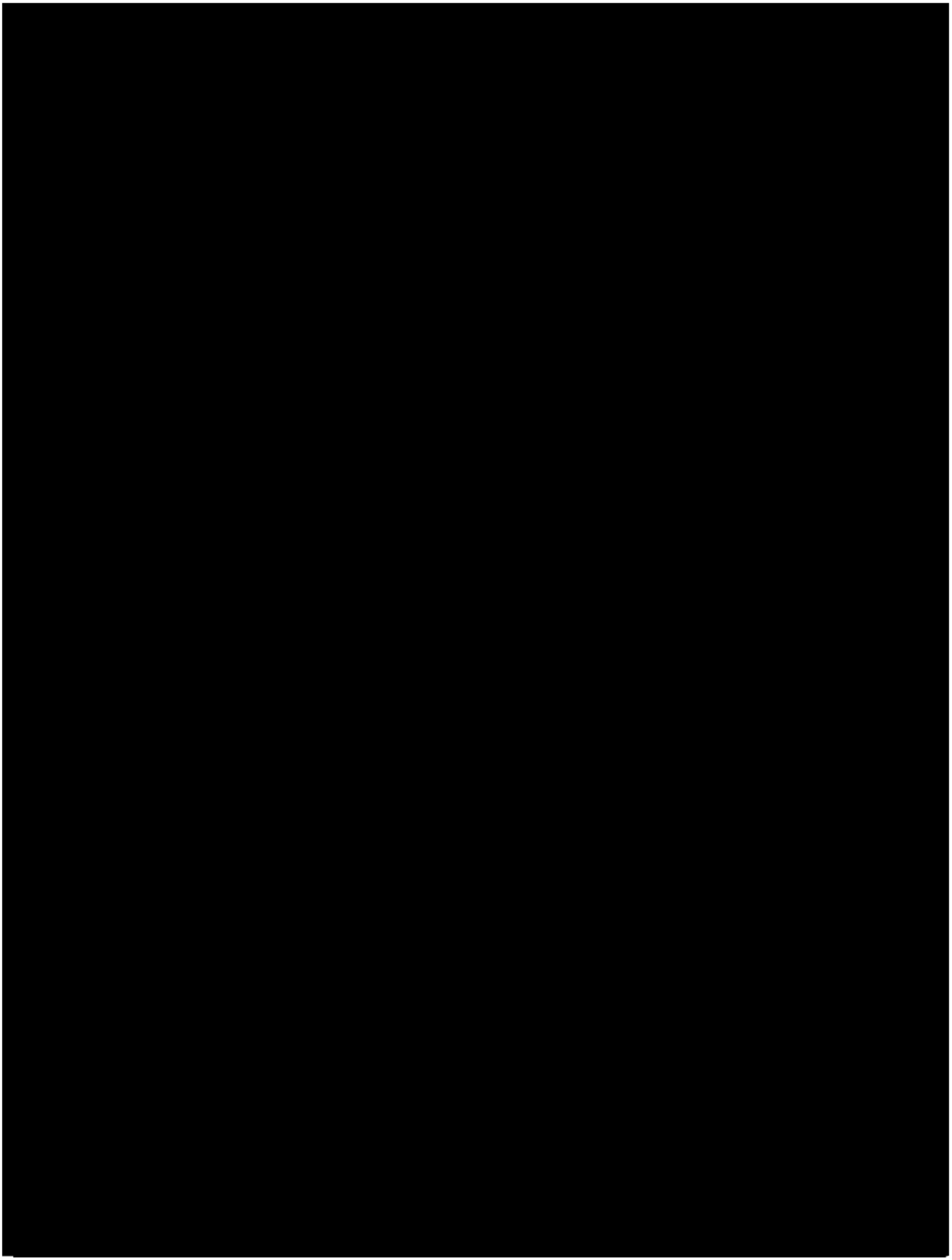




[redacted]

[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]

[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

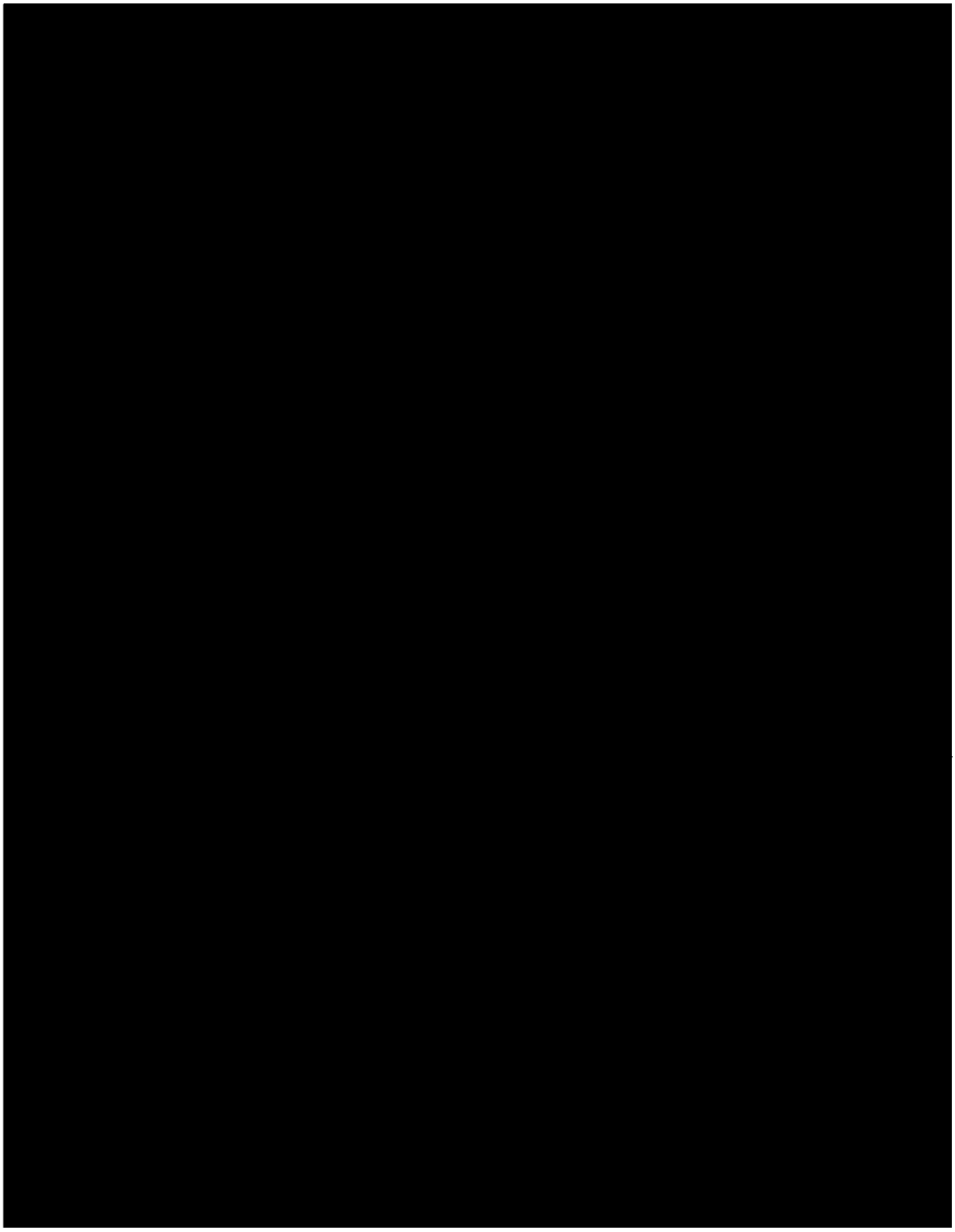
[redacted]

[redacted]

Certified by: William J Neumann Date: February 23, 2023

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]



[redacted]

William J. Neumann
Vice President
Quality Assurance & Regulatory Affairs

[redacted]

[redacted]

15 Dec 22

Norman Cyr
Manager of Quality Assurance

[redacted]

Exempt from disclosure pursuant to Section 119.0715, F.S.

[redacted]

[redacted]

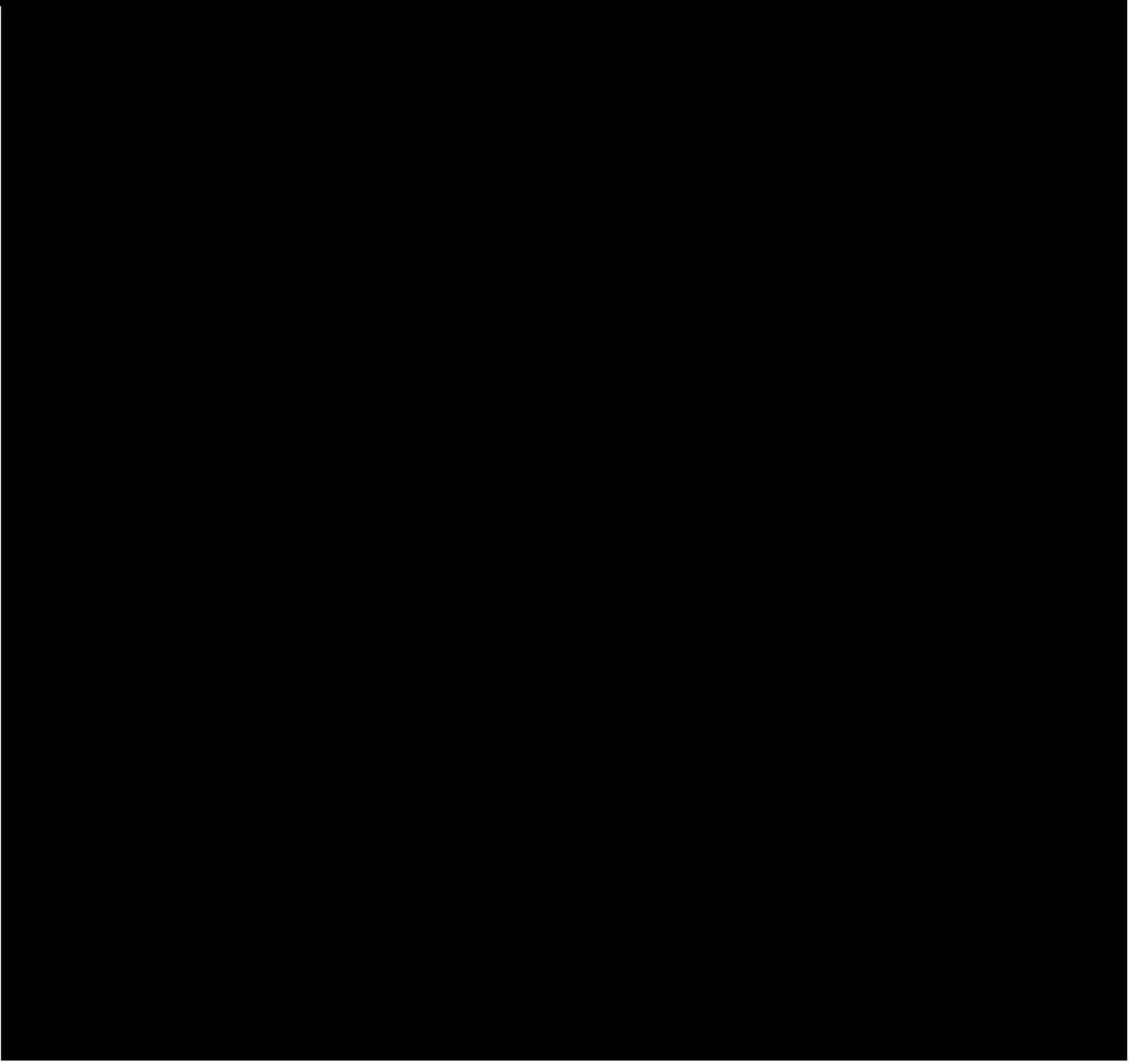
15Dec22

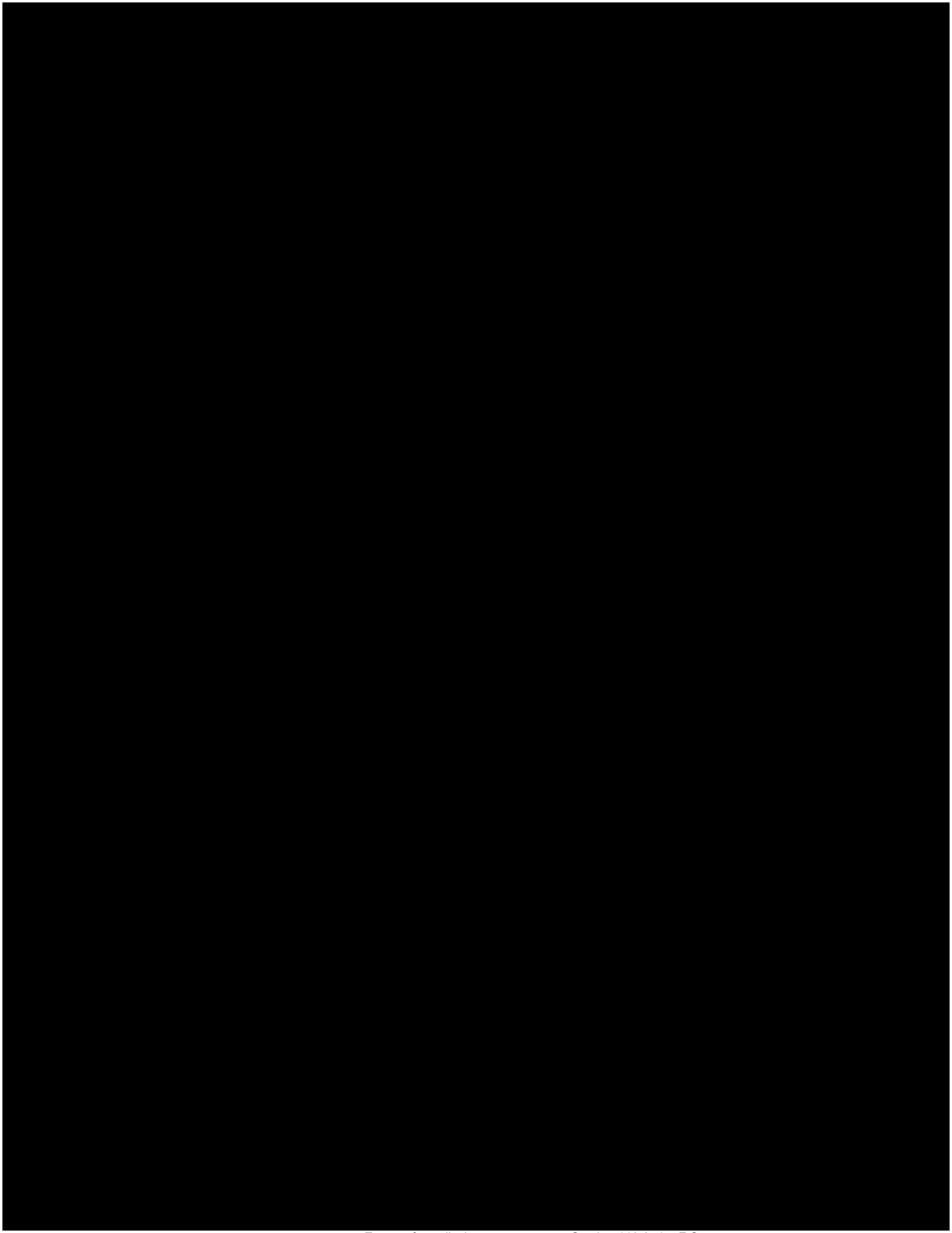
Norman Cyr
Manager of Quality Assurance

[redacted]

Exempt from disclosure pursuant to Section 119.0715, F.S.

[redacted]





[redacted]

15 Dec 22

Norman Cyr
Manager of Quality Assurance

[redacted]

Exempt from disclosure pursuant to Section 119.0715, F.S.

[redacted]

[redacted]

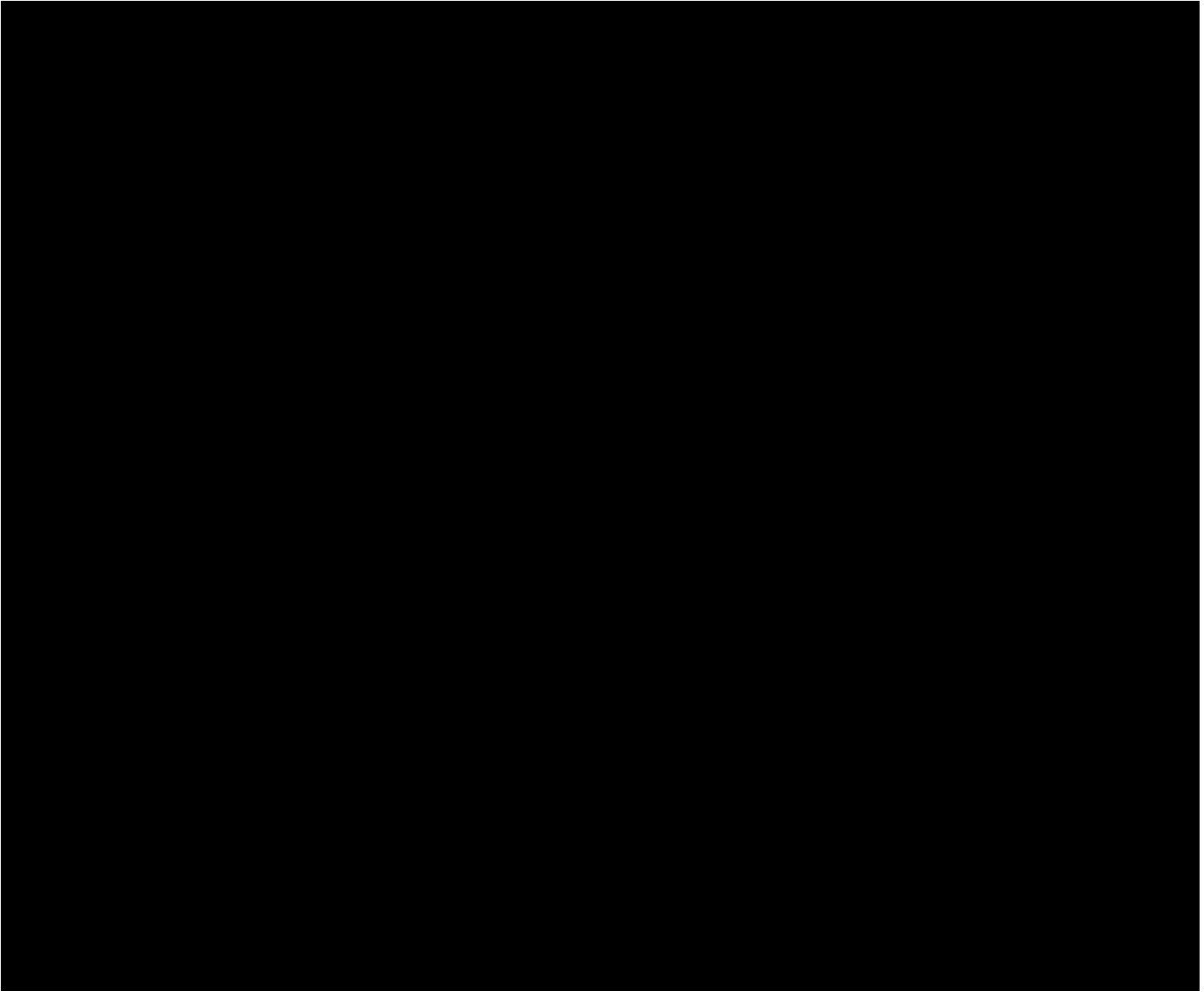
15Dec22

Norman Cyr
Manager of Quality Assurance

[redacted]

Exempt from disclosure pursuant to Section 119.0715, F.S.

[redacted]



Quality Agreement for cGMP Testing Services

Between

LifeScience Logistics
3100 Olympus Blvd, Suite 100
Dallas, TX 75019
And

[redacted]

Approvals

Signature: _____ Date: 14 Dec 21

Norman Cyr, Associate Manager, Quality Assurance

[redacted]

Signature: _____ Date: 30 NOV 2021

Bozie Madison, Associate Director of
Regulatory Affairs and Compliance
LifeScience Logistics

[redacted]

Contents

[redacted]

1.0 Objective:

1.1 The Purpose of this Quality Agreement is to establish, clarify, and communicate quality expectations related to cGMP testing.

1.2 The Agreement shall be effective as of the date of the last signature above. This Agreement shall remain in effect until cancelled with written notice by either party.

1.3 In the event a conflict arises between the Quality Agreement and Signed Quotation, the terms in this Quality Agreement shall prevail with respect to quality matter, and the terms of the Signed Quotation shall prevail with respect to all other matters.

2.0 Regulatory Requirements:

2.1 [redacted] shall perform testing in compliance with U.S. Current Good Manufacturing Practices (cGMP) 21 CFR Parts 11, 210 & 211, ISO 17025:2017, accepted industry practices, and/or applicable USP guidelines. Testing activities will be fully documented in such a way to provide traceability, and will be stored in the archives of [redacted]

3.0 Scope:

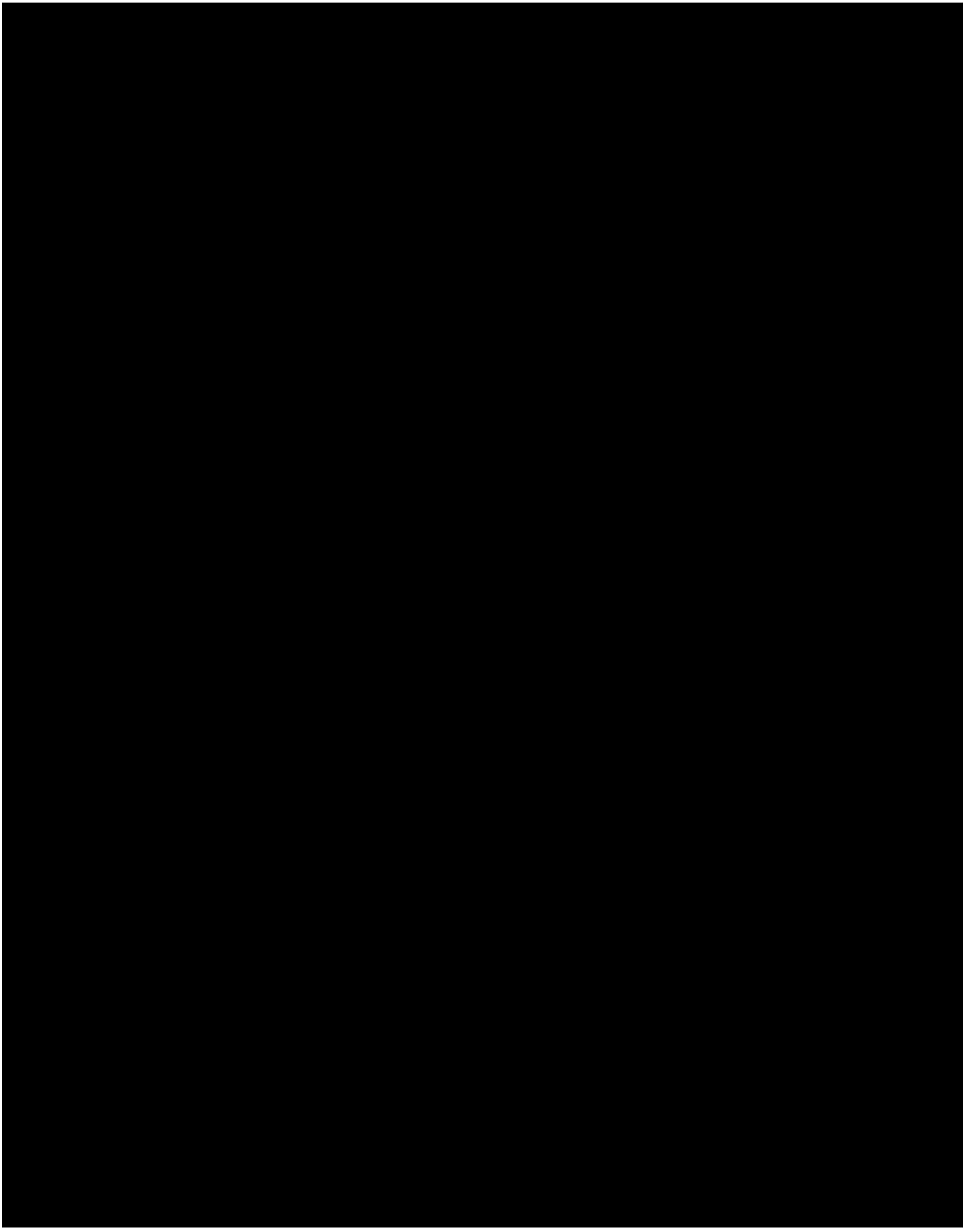
3.1 This Quality Agreement is between **LifeScience Logistics**, hereafter referred to as "Client", and [redacted]

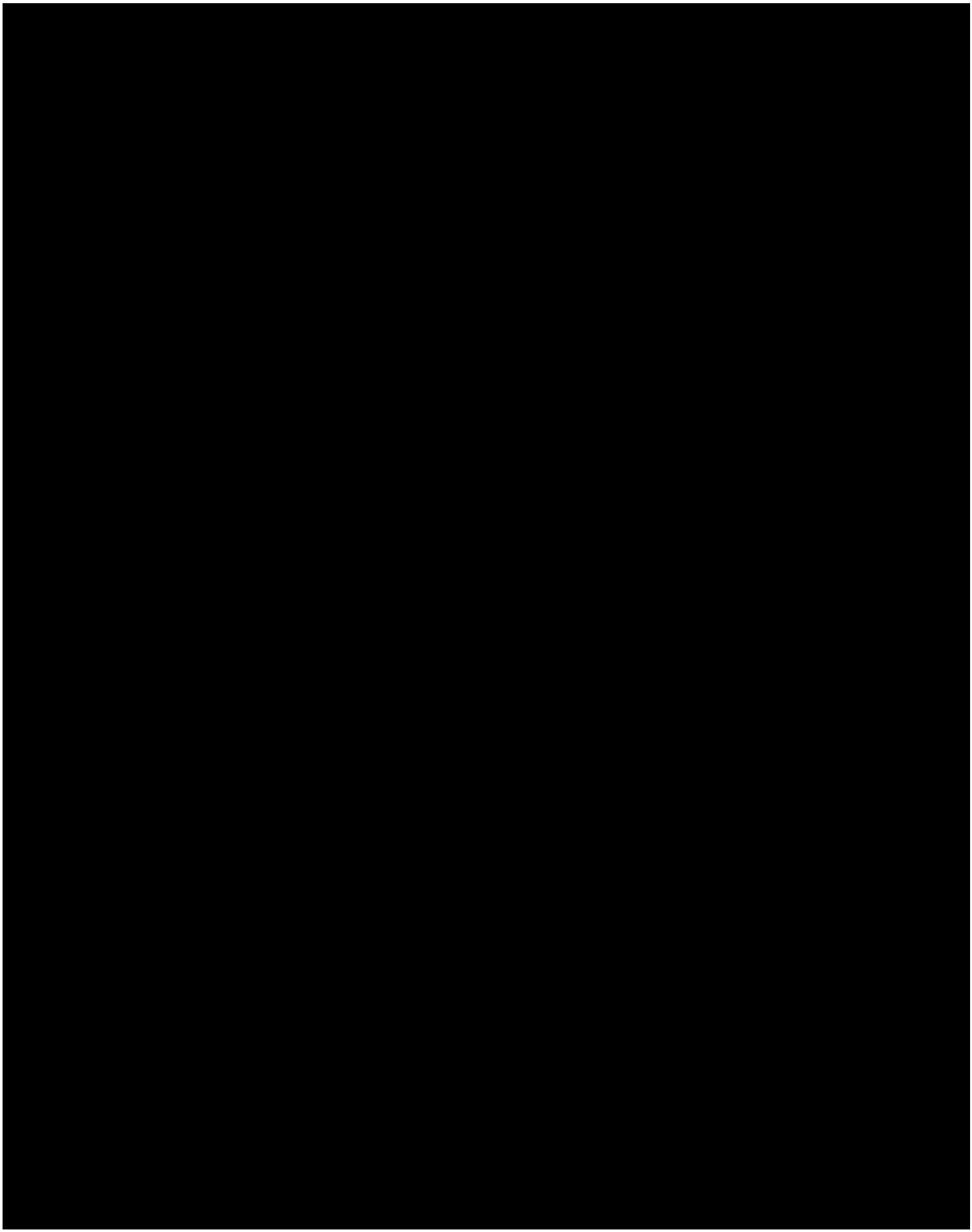
3.2 This agreement shall apply exclusively to samples submitted for testing that must be tested in compliance with cGMP guidelines.

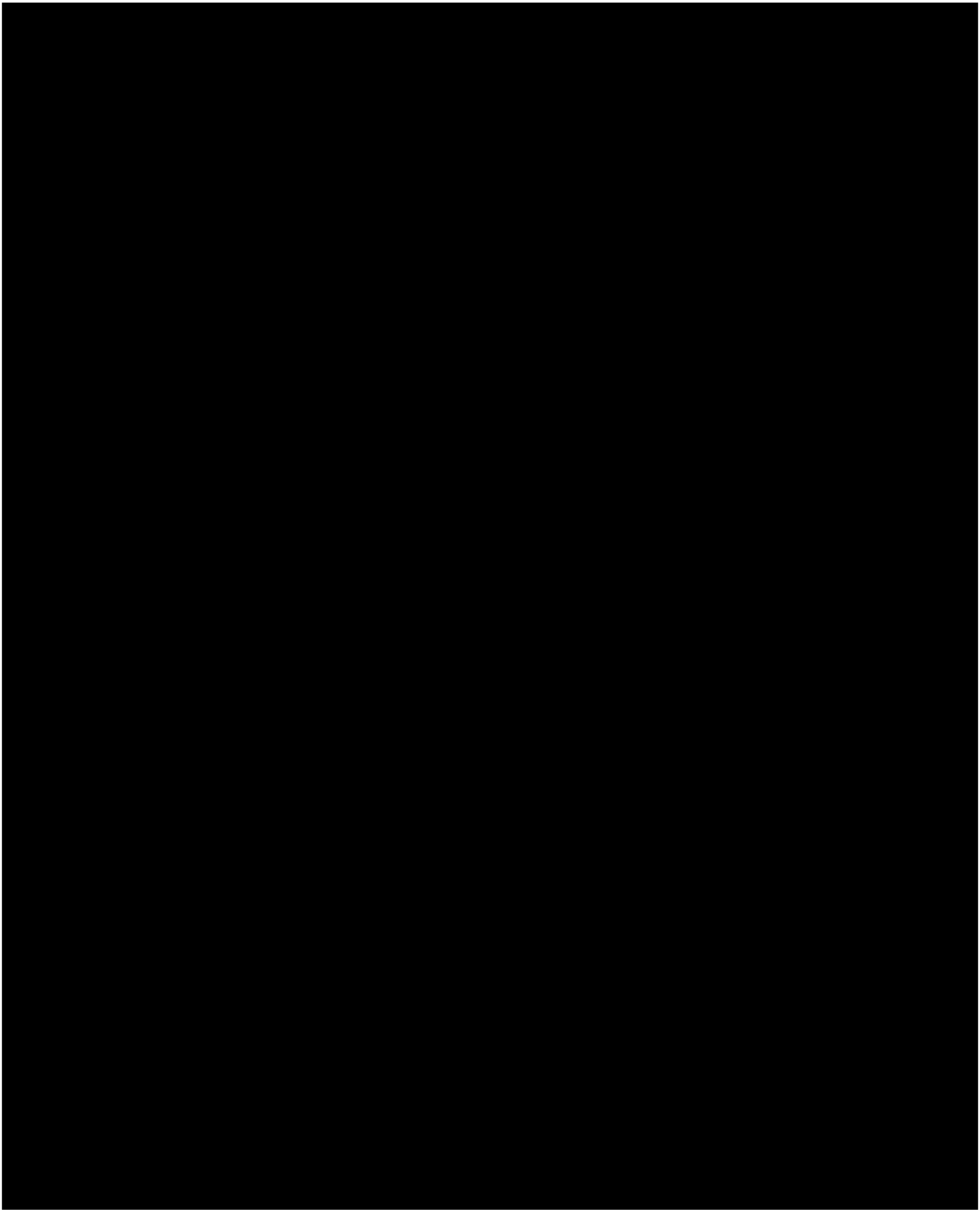
3.3 It is the responsibility of the Client to inform [redacted], utilizing the [redacted] sample submission form, and by contacting [redacted] Business Development group, if the requested testing is to be conducted per cGMP guidelines. When samples are submitted to [redacted] and designated as cGMP, and a quote is in place that indicates cGMP testing requirements, then the testing will be conducted under cGMP conditions.

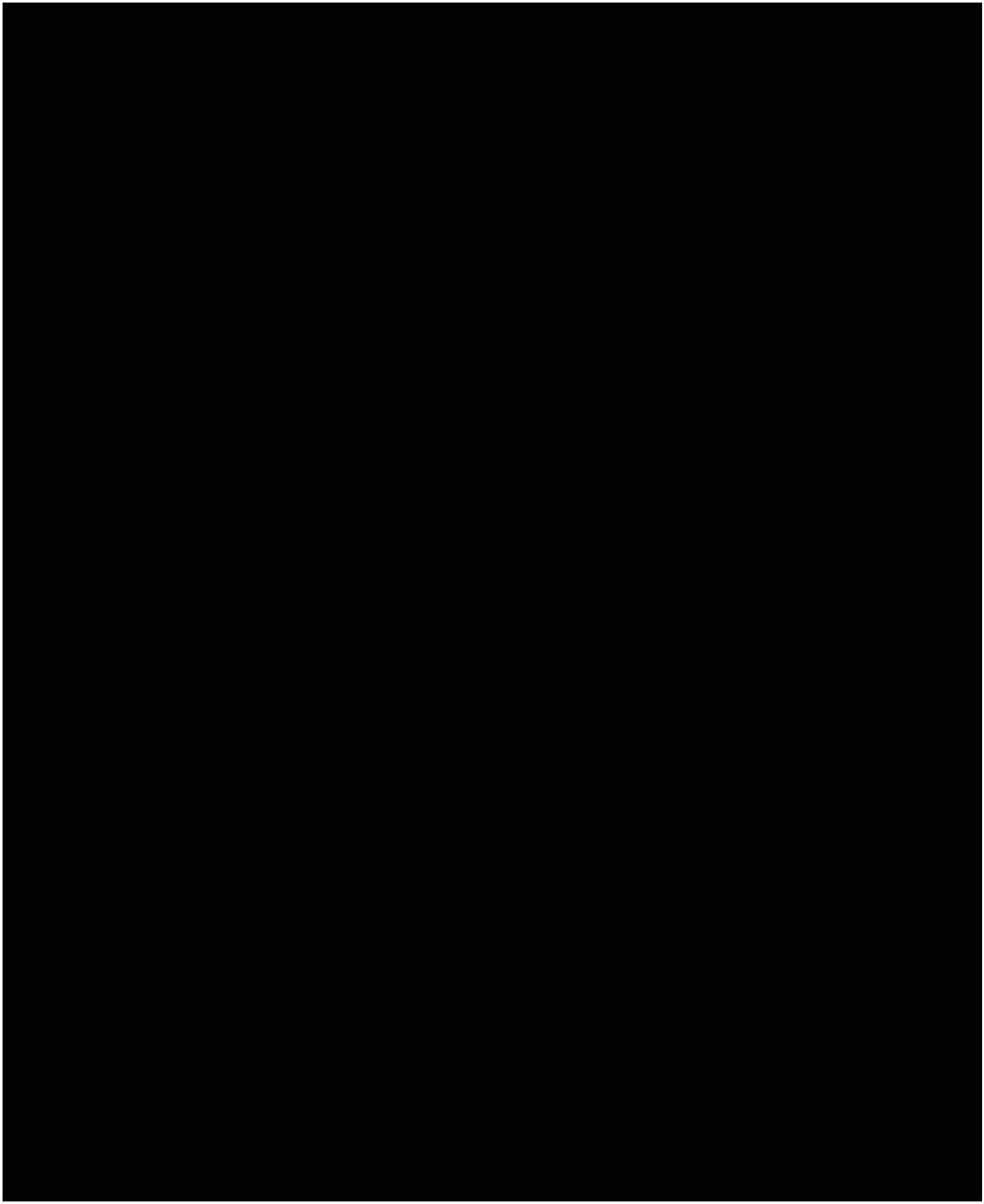
4.0 Responsibilities:

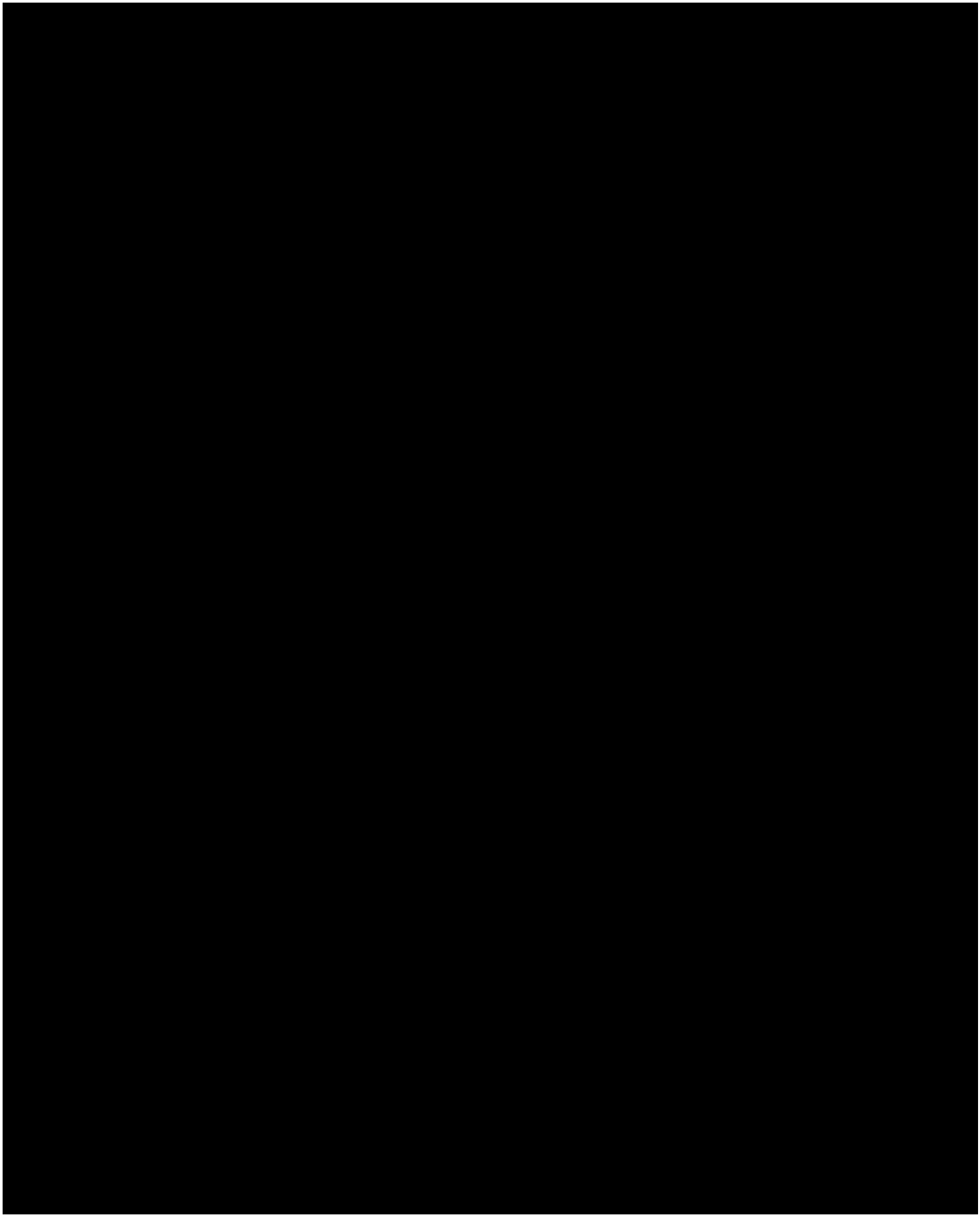
[redacted]

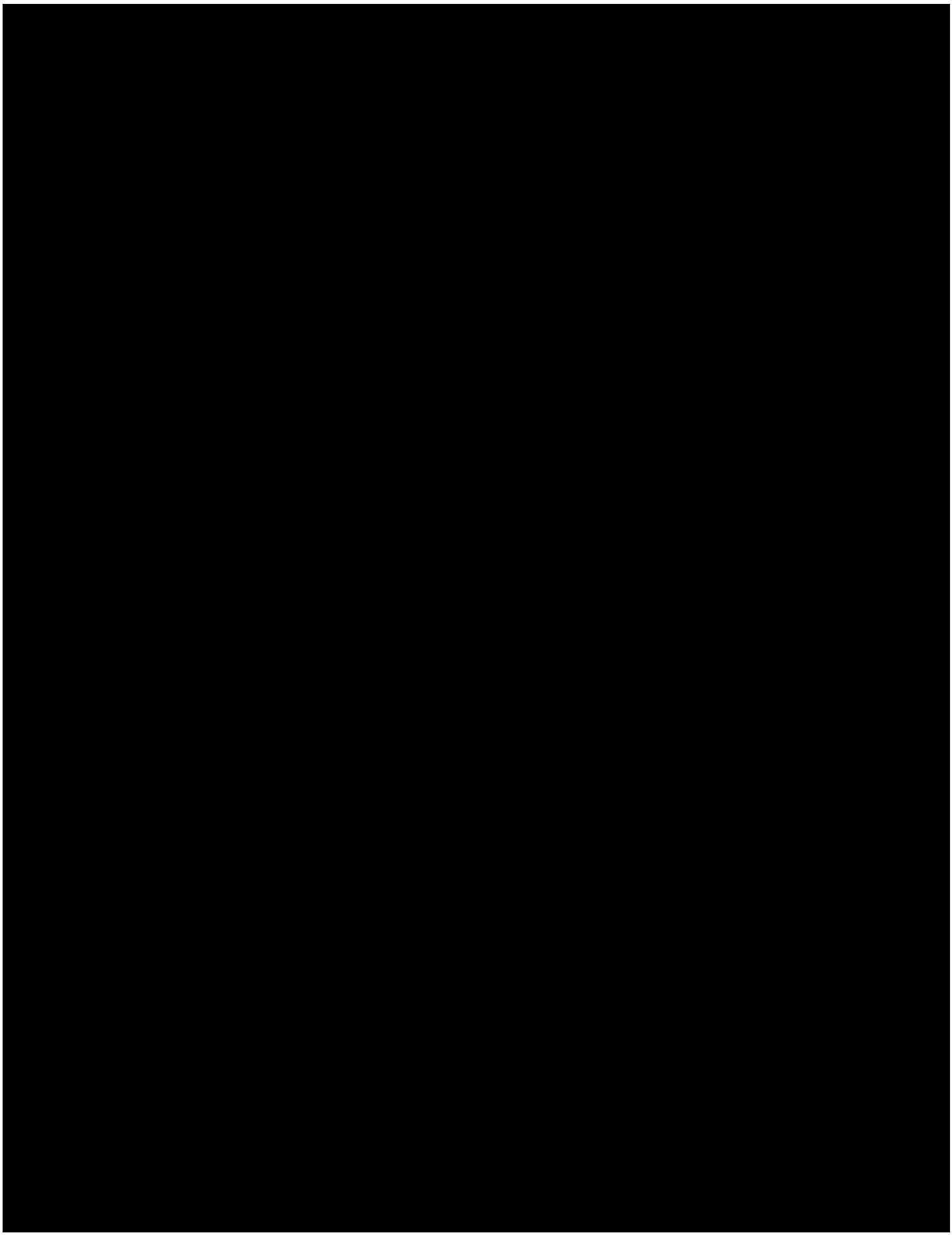


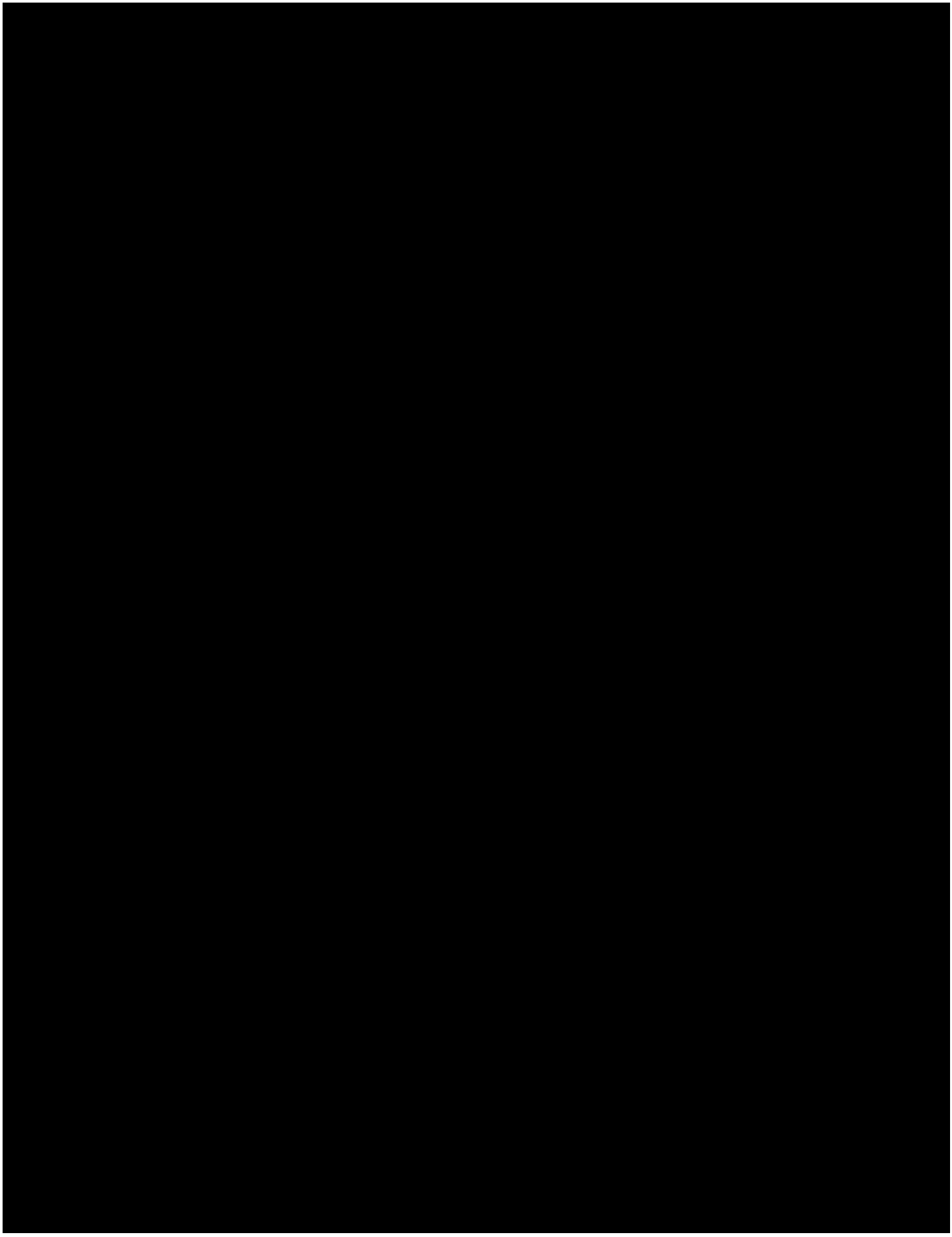


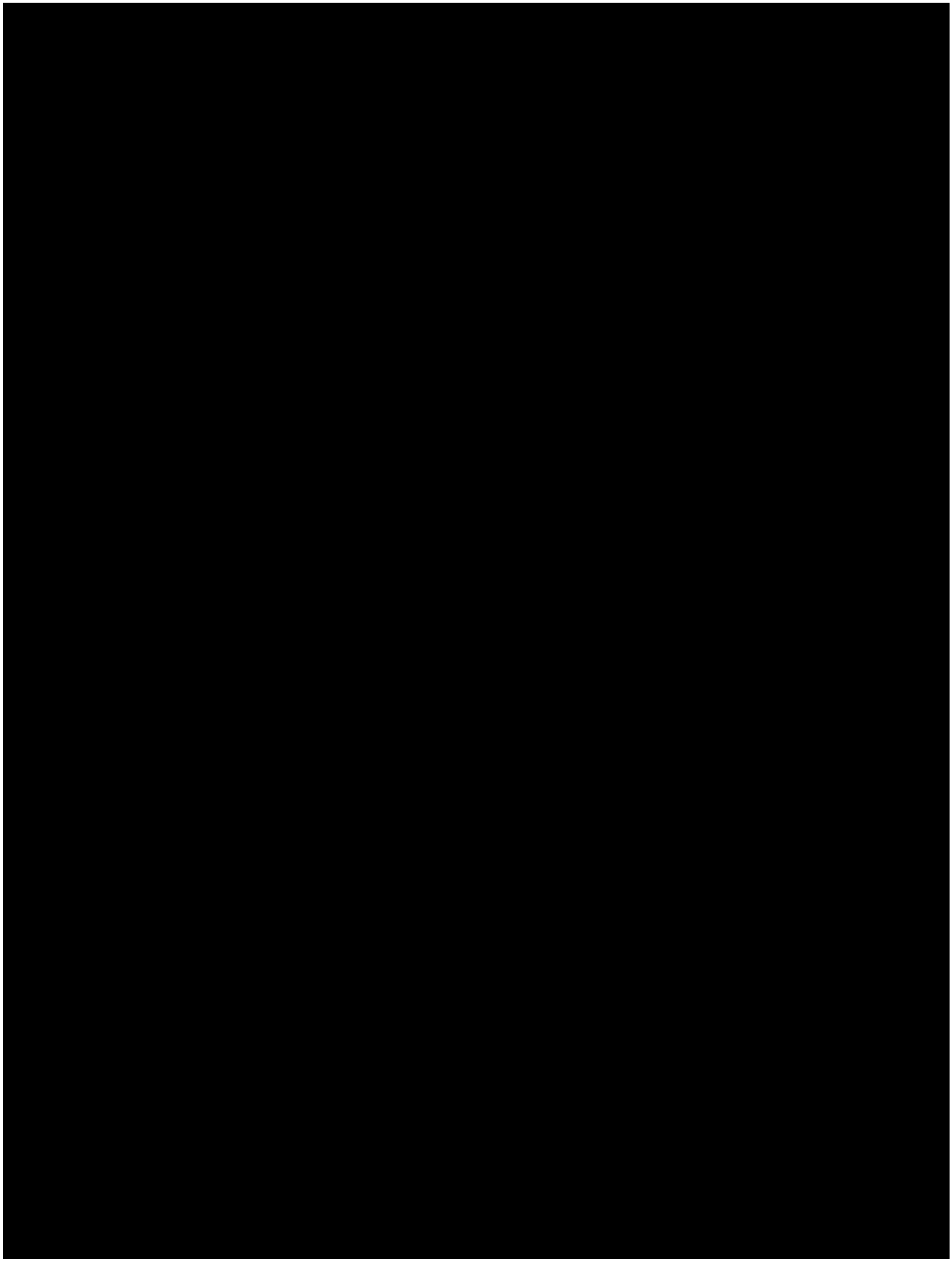












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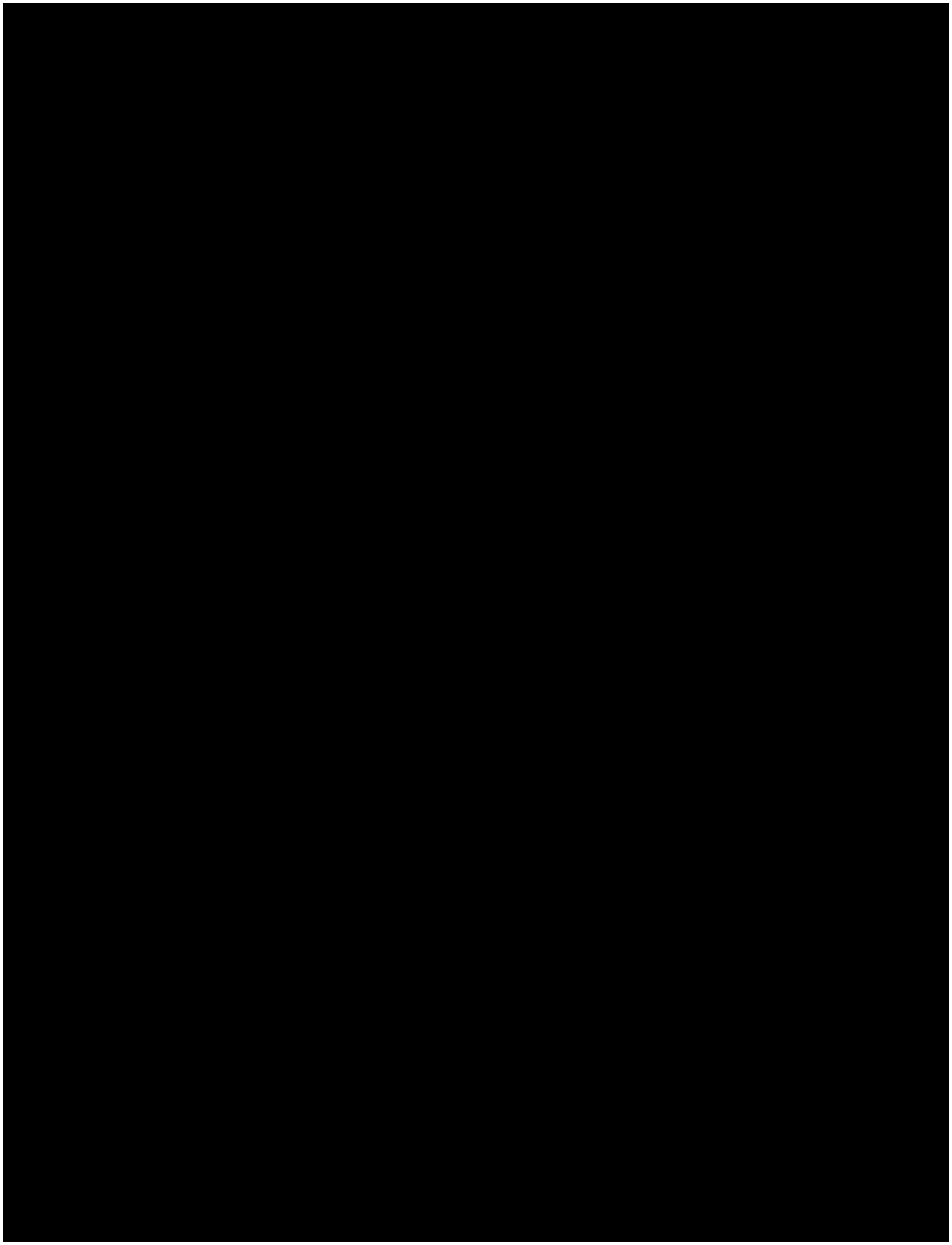

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5.0 Appendices

5.1 Appendix 1: Contact and Responsibilities

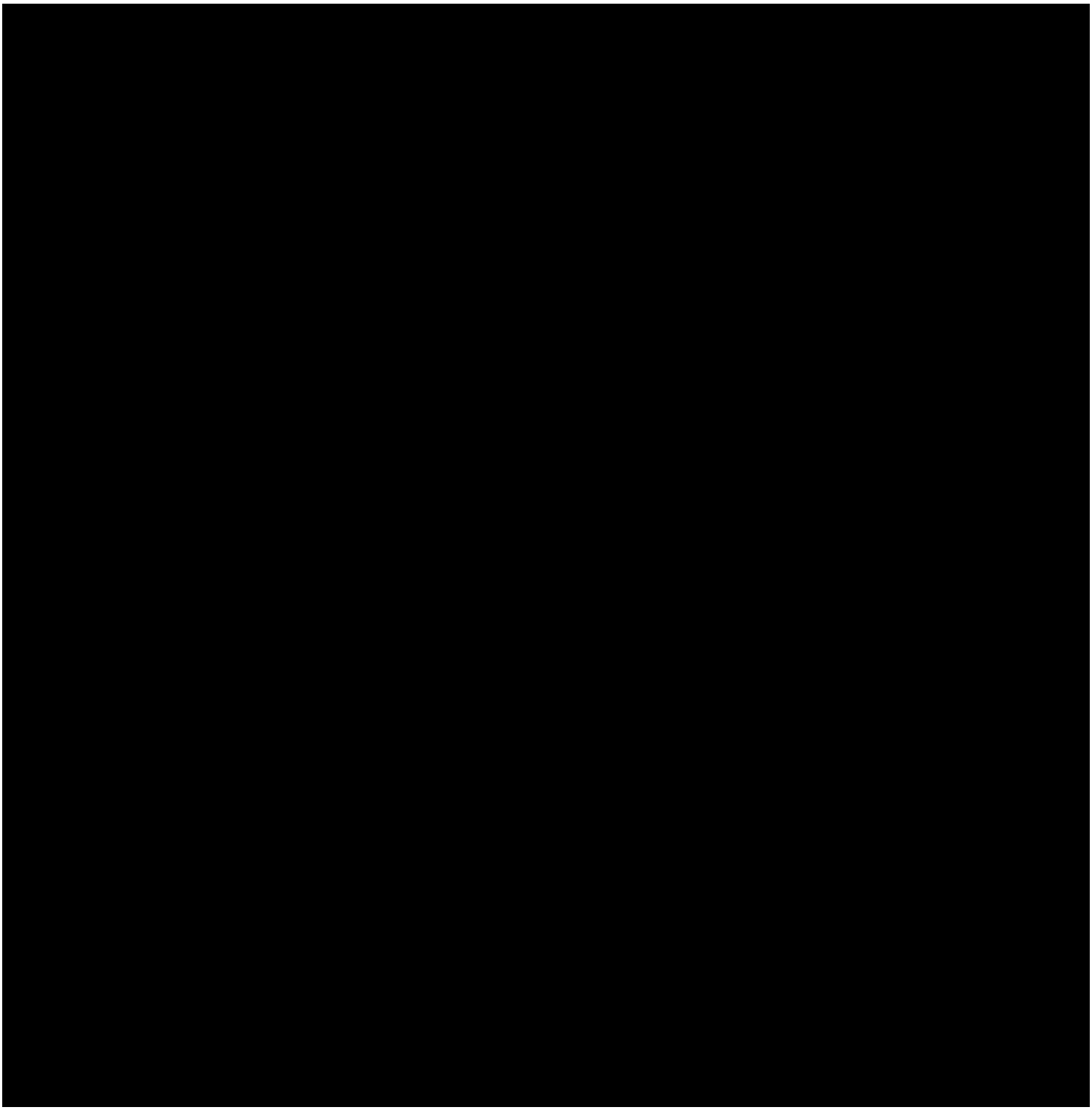
5.2 Appendix 2: Third Party Contractors

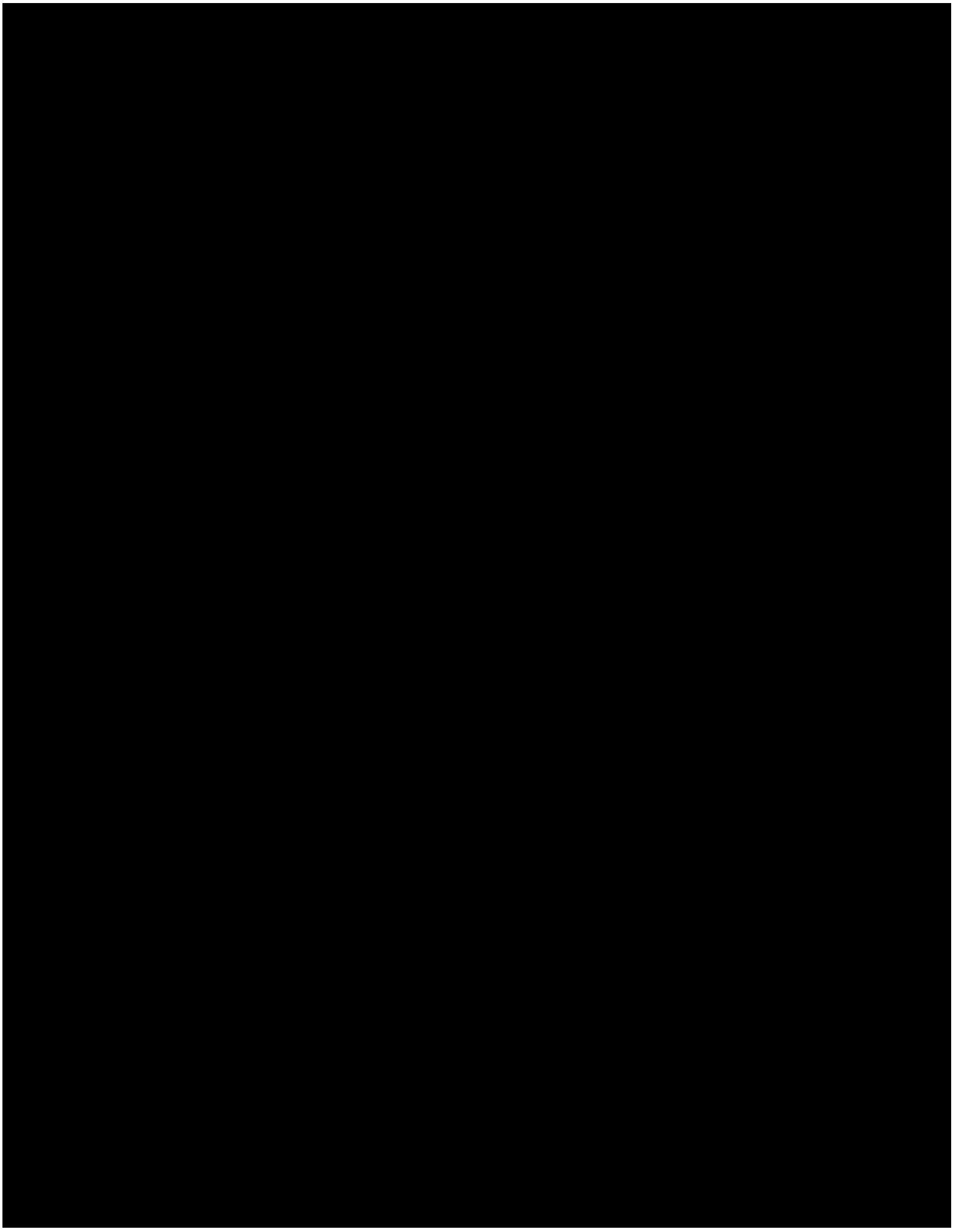
6.0 References:

5.1 21 CFR Parts 11, 210 & 211

7.0 History:

Date	Revision	Changes
DDMMMYYYY	.00	New document





LifeScience Logistics			
Title:	Prescription Drug Process Overview		
Number:	SOP 7001	**Rev. Date:**	12 MAY 2021
Rev. Level:	000	**Page:**	1 of 5

1.0 PURPOSE

The purpose of this procedure is to define the process for the purchasing, processing, and distributing of Prescription drugs within LifeScience Logistics.

2.0 SCOPE

The total lifecycle of prescription drugs is applicable to the scope of this document.

This procedure applies to all LSL facilities participating in the Section 804 Importation Program.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
SOP 1351	Deviation/CAPA – RX
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
WI 600.02	Prescription Drug Item Setup
WI 600.05	Prescription Drug Receiving
WI 600.06	Prescription Drug Hold and Release
WI 600.07	Prescription Drug Initial Sampling and Laboratory Testing
WI 600.08	Prescription Drug Relabeling Requirements and Process
WI 600.10	Prescription Drug Pick/Pack/Ship
WI 600.27	Prescription Drug Vendor Returns and Quarantine Shipping

4.0 DEFINITIONS

N/A	N/A

5.0 ABBREVIATIONS/ACRONYMS

CEO	Chief Executive Officer
CFR	Code of Federal Regulation
CQCU	Corporate Quality Control Unit
DIN	Drug Identification Number
LSL	LifeScience Logistics
QA	Quality Assurance
QR	Quarantine Receipt
NDC	National Drug Code
SOP	Standard Operating Procedure
WI	Work Instruction

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Functional Owner	Ensure training requirements by position are updated in MQ1 to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision guidelines.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly reports any problems or deviations from the procedure to your Supervisor or designee.

7.0 [redacted]

[redacted]

Initial Sampling and Laboratory Testing

[redacted]

[redacted]

Re-Labeling

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from the CEO/Principal and/or VP of Quality and Compliance prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

10.0 TRAINING RECORD

[redacted]

1.0 PURPOSE

The purpose of this procedure is to define the processes required to receive, sample, and test drug product received under the State Drug Importation Program, also known as the Section 804 Importation Program. The Drug Products referenced in this procedure will be imported from Canada and meet the requirements as set forth under section 804 of the Federal Food, Drug and Cosmetic Act.

2.0 SCOPE

This procedure applies to all LSL facilities where SDIP Drug Products are received, processed and distributed.

All non-SDIP products are out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 804	Section 804 Importation Program
21 CFR 820	Quality Systems Regulations
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
SOP 1351	Deviation/CAPA – RX
WI 600.05	Prescription Drug Receiving
WI 600.06	Prescription Drug Hold and Release
WI 600.07.01	DIN Product Sampling and Approval Form
WI 600.08	Prescription Drug Relabeling Requirements and Process
WI 600.10	Prescription Drug Pick/Pack/Ship

4.0 DEFINITIONS

Component	Any ingredient or material intended for use in the manufacture of a drug product
Drug Product	A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients.
Nonconformance	A result that does not meet predetermined criteria.

5.0 ABBREVIATIONS/ACRONYMS

CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
LSL	LifeScience Logistics
QA	Quality Assurance

QR	Quarantine Receipt
SDIP	State Drug Importation Program
SIP	Section 804 Importation Program
SOP	Standard Operating Procedure
WI	Work Instruction

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Functional Owner	Ensure training requirements by position are updated in MQ1 to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision guidelines..
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly reports any problems or deviations from the procedure to your Supervisor or designee.

7.0 PROCEDURE

[redacted]

Part I: Sampling

[redacted]

PART II: TESTING

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

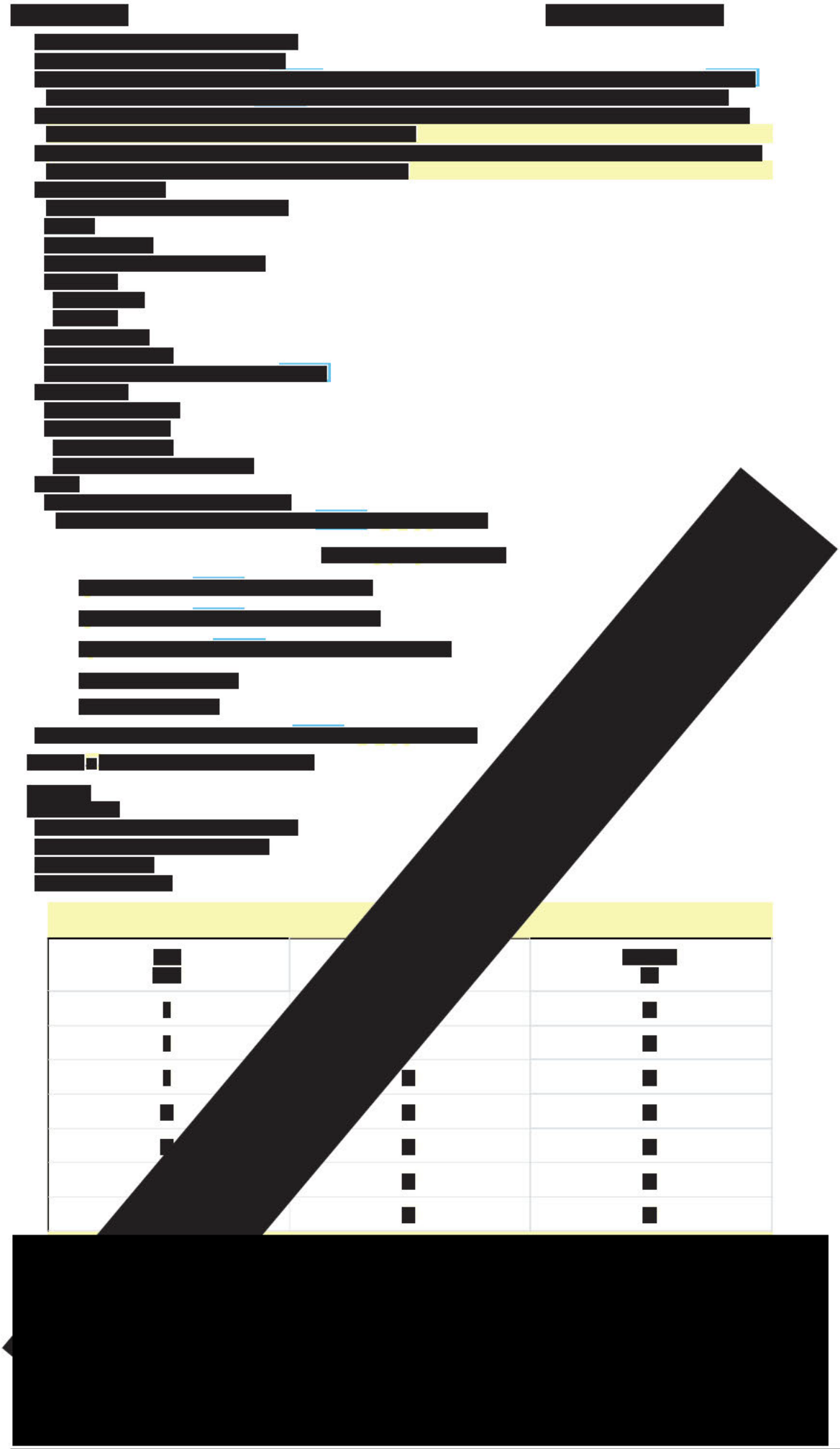
8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from the CEO/Principal and/or Director of Quality and Regulatory Affairs prior to reproduction or transmission in any form.

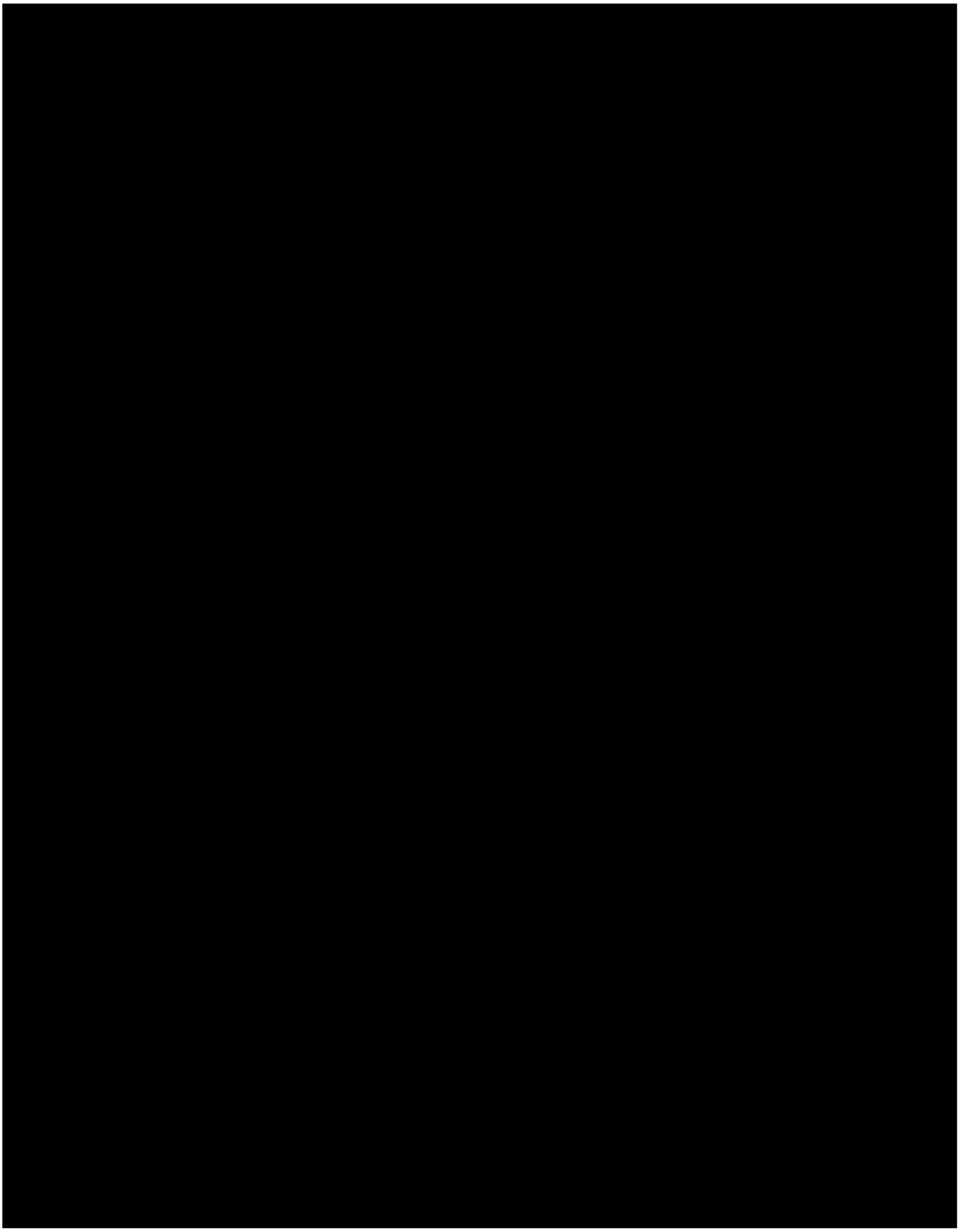
9.0 REVISION HISTORY

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

10.0 TRAINING RECORD

[redacted]





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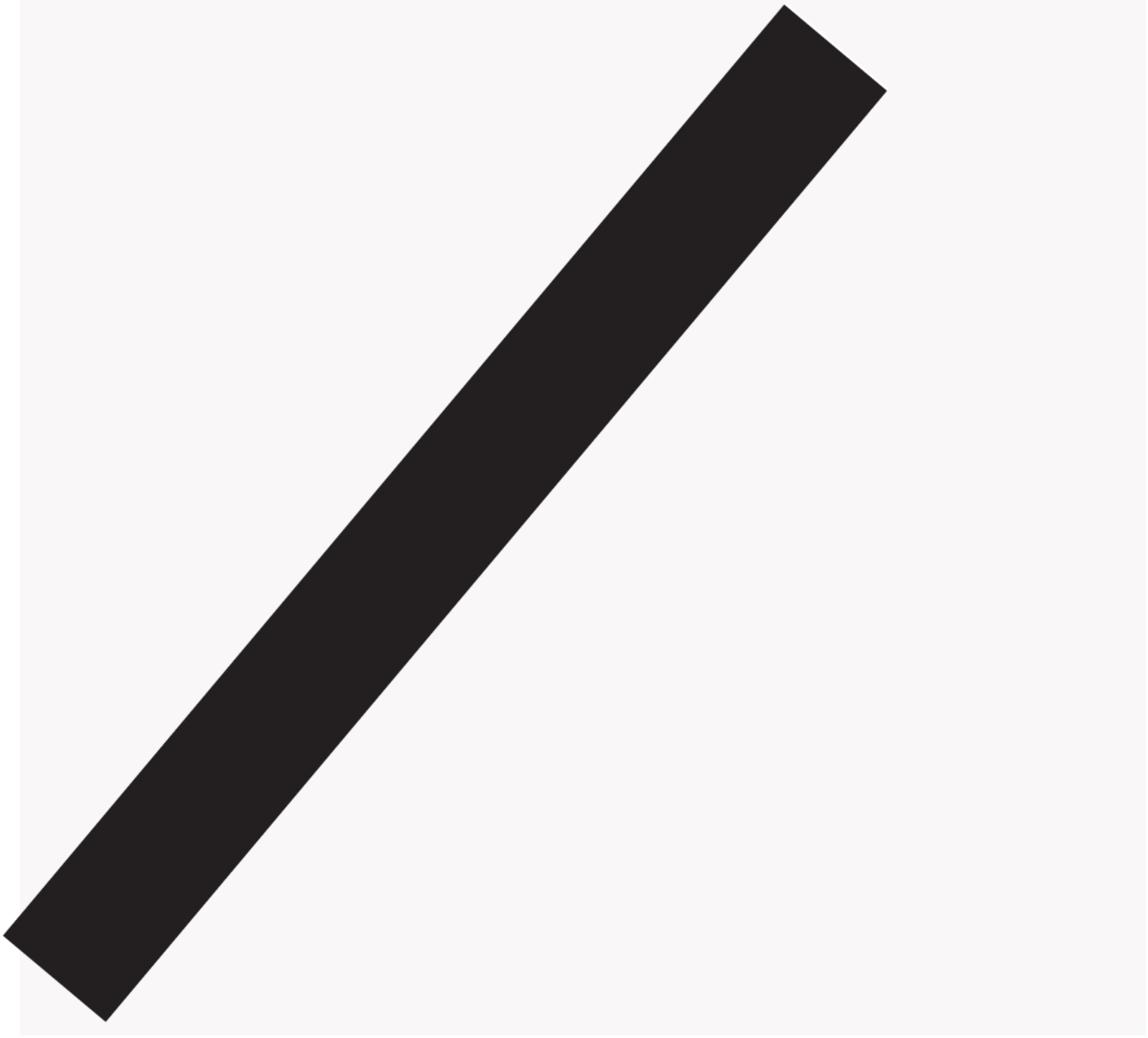

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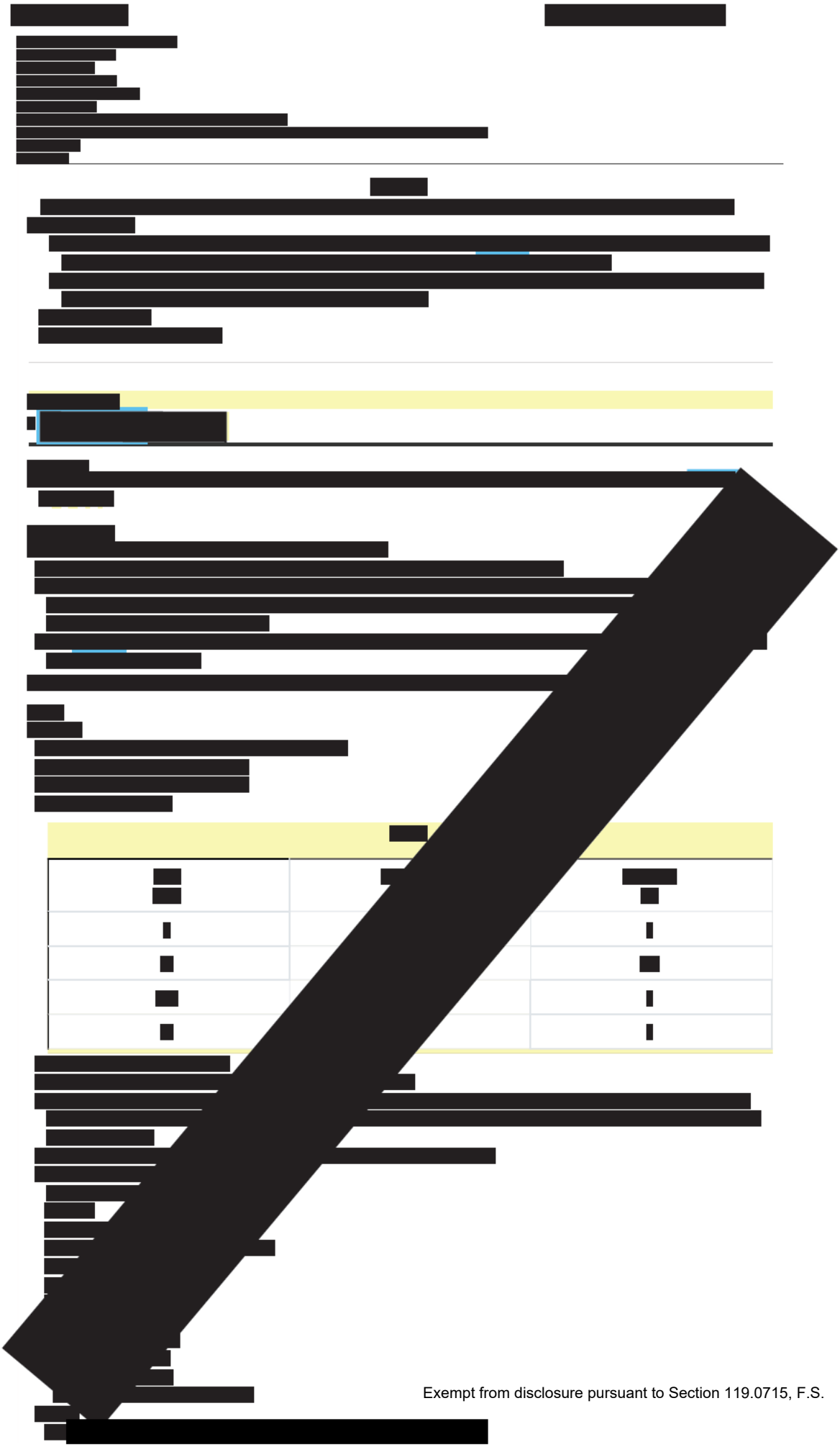
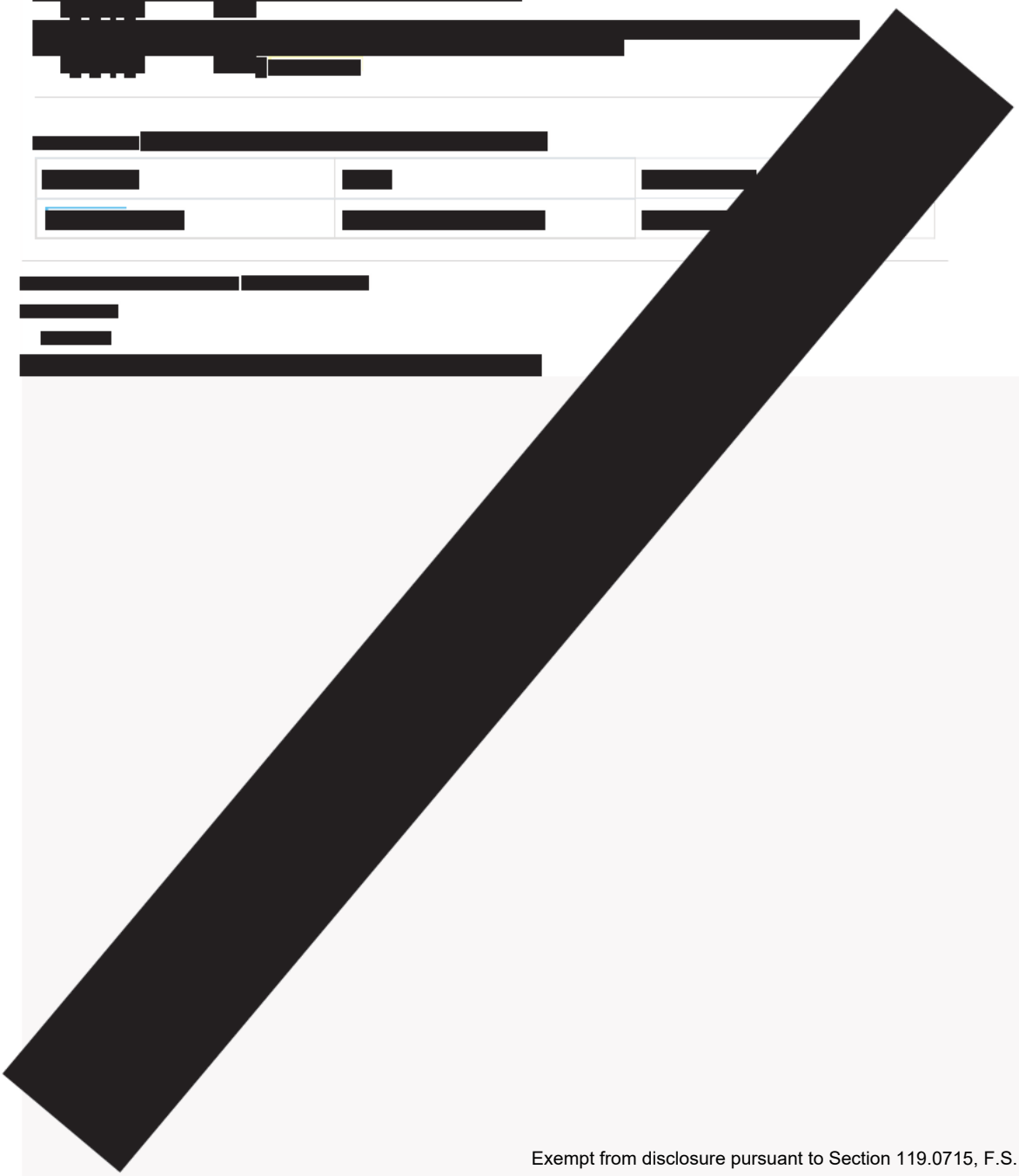


Exempt from disclosure pursuant to Section 119.0715, F.S.



Exempt from disclosure pursuant to Section 119.0715, F.S.