

# Manufacturing Facility Review

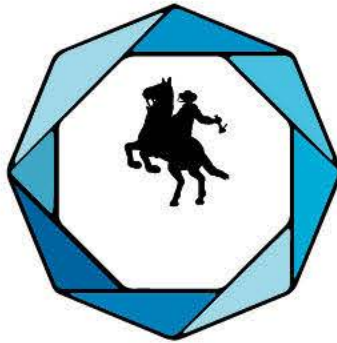


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# EXECUTIVE SUMMARY

8th Revolution would like to thank the management at [REDACTED] for the opportunity to audit and report on the infrastructure and processes within the manufacturing department at [REDACTED]

Based on our observations, audit, and analysis, we conclude the manufacturing and materials department at [REDACTED] "Needs Improvement." This indicates that a combination of weaknesses in the system of control and minor non-compliances with the controls in places is such as to place service objectives at risk.

Our report is structured as follows:

- In the first section titled "Mock cGMP Audit Results," we provide our observations related to the common good manufacturing practice (cGMP) audit checklist.
- In the next section titled "Current State of Manufacturing Department at [REDACTED]" we provide our observations related to the procedures and processes being implemented and followed at [REDACTED]
- In the next section titled "Proposed State of Manufacturing Department at [REDACTED] House," we provide proposed changes for the [REDACTED] team to consider and implement.
- In the next section titled "Intellectual Property," we provide our professional opinion on opportunities in extraction and post processing.
- In the final section "Implementation Plan," we provide a project plan with approximate timeline and sequence of implementation of the identified improvement opportunities.

As per our audit, the top three 'Positives' for the Manufacturing Department at [REDACTED] are as follows:

1. Passion for producing high quality cannabis derivative products.
2. Company culture.
3. Operator experience.

We observed the following top three areas of 'Improvement' for the Manufacturing Department at [REDACTED] as follows:

1. Facility Design and equipment Layout
2. Material flow
3. Correct post processing equipment for crystallization



# INTRODUCTION

## Objective

The overall project consists of establishing [REDACTED] live resin extraction and postproduction. These efforts will produce a unique and precisely defined system that can be operated at multiple locations while maintaining quality, consistency, and reliability [REDACTED] will be portable, scalable, modular, automated, and economical.

The first phase of the project consisted of a manufacturing audit conducted through an onsite visit during the week of [REDACTED]. Observations of the manufacturing process and facility consisted of reviewing all current standard operating procedures, working hands-on with technicians at each individual process, and conversations with management to understand material flow.

The purpose of the audit is to provide an independent and objective view regarding the manufacturing and material processing at [REDACTED].

This report presents the third-party review findings with observations and best practice recommendations, where there may be opportunities for improvement.

## Scope of Engagement

The scope of work for the first phase of the project was for 8th Revolution to provide an engineer and process audit of [REDACTED]. The audit consisted of observing the current extraction, purging, post-processing, and fulfillment operations.

The goal of observing these processes was to

- Identify gaps in the current standard operating procedures (SOPs), determining unique intellectual property (equipment configurations, materials management, work processes, instrumentation, workflow management), highlighting opportunities within the current process for improved controls, automation, equipment modifications, efficiencies, and workflow.
- Evaluate the quality control management program currently in place and provide input in addition to suggestions on potential missing quality control procedures.
- Evaluate the environment and quality management program for strengths and weaknesses.

This report serves as a comprehensive report summarizing the onsite evaluation and providing strategic recommendations.

## Approach for the Engagement

The approach of the engagement is as follows:

- A detailed understanding of the process was obtained by interviewing the process operators, employees, and owners based on a comprehensive checklist covering the process and subprocesses of the manufacturing department.
- Copies of system documents were requested and reviewed to familiarize and understand the completeness of the departmental processes. Onsite visit was conducted during the week of [REDACTED] to review the performance of the department and infrastructure.
- Key risks and controls were identified and documented based on process understanding, site surveys, and interviews conducted.
- Detailed examination of key documents related to the process and subprocesses was conducted based on the identified risks
- The observations and recommendations in this report are based upon reviewing the documents and infrastructure, performing site inspection, auditor's previous experience in manufacturing facilities, best practices and benchmarks, including documentation provided by [REDACTED] personnel, and discussions with the process owners and senior management.

## Acknowledgement

We would like to take this opportunity to thank the management and staff at [REDACTED] for their cooperation and assistance during the first phase of this project. We are committed to offering your team excellent service and look forward to building a long and value-added relationship with [REDACTED]

## Limitations

This third-party audit procedures rely on information and representations made available to 8th Revolution by the process owners and key individuals associated with the processes. Our third-party audit procedures is comprised of inquiries, observations, and limited tests of transactions on a sample basis, covering the detailed assessment objectives.

Any misrepresentation intentional or otherwise may affect the results and recommendations of this report.



# Mock cGMP Audit Results

8th Revolution performed a 5-section mock audit based on a checklist from the code of Federal Regulations, Title 21, Part 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, current as of 4/1/2018), Subpart B – Current Good Manufacturing Practice. The results from the mock audit were aggregated into the following scoring matrix.

Section	Excellent (5)	Very Good (4)	Good (3)	Acceptable (2)	Sub Standard (1)	Non Existent (0)	Not Surveyed (N/A)	Score	Max Score	Percent
Grounds										
Plant Construction and Design										
Sanitary Facilities and Controls										
Equipment and Utensils										
Process and Controls										
Total										

Table 1. Summarization of Process Facility Audit

Rating	
0 – 168	This score is classified as must “Must Improve.” A score which falls within this range needs immediate attention of management to initiate radical actions.
169 – 285	This score is classified as "Good to Improve." A score which falls within this range requires immediate efforts from the company/department while taking into considerations financial impact for the organization.
285 – 335	This score is classified as "Stable." A score in this range is an observation for the management to consider opportunities for continuous improvement.

We elaborate on each section in detail below. The complete checklist has been attached to this document as an addendum.

## Grounds - [REDACTED]

This section covers potential inspection activities of the manufacturing facility property and neighboring properties.

### Observations

- The grounds are well maintained for most of the property. The dirt parking lot could be a source of contamination for the extraction department.

## Plant Construction and Design - [REDACTED]

This section covers the overall design of the manufacturing plant addressing aspects that could be a source of contamination for the finished products.

### Observations

- The manufacturing process is currently exposed to the outdoors which has an inherent risk of contamination.

## Sanitary Facilities and Controls - [REDACTED]

This section covers the water supply, plumbing design, and disposal systems to ensure they are of adequate standards for manufacturing finished goods.

### Observations

- Facilities were well maintained and easy to access.

## Equipment and Utensils [REDACTED]

This section covers the design of the manufacturing equipment, environment, and tools used to create the finished product.

### Observations

- Some manufacturing areas have limited space and are poorly designed. For example, having to use a step ladder as a standard feature should be avoided or built into the system. Additionally, more temperature measurement points would provide additional quality control.

## Process and Controls [REDACTED]

This section covers the overall techniques, raw materials, storage guidelines, and manufacturing operations implemented to create the finished products.

### Observations

- More measurement points must be the primary focus to increase process control. To control the process, the first step is understanding parameters dictating the results, which current requires additional measurements.









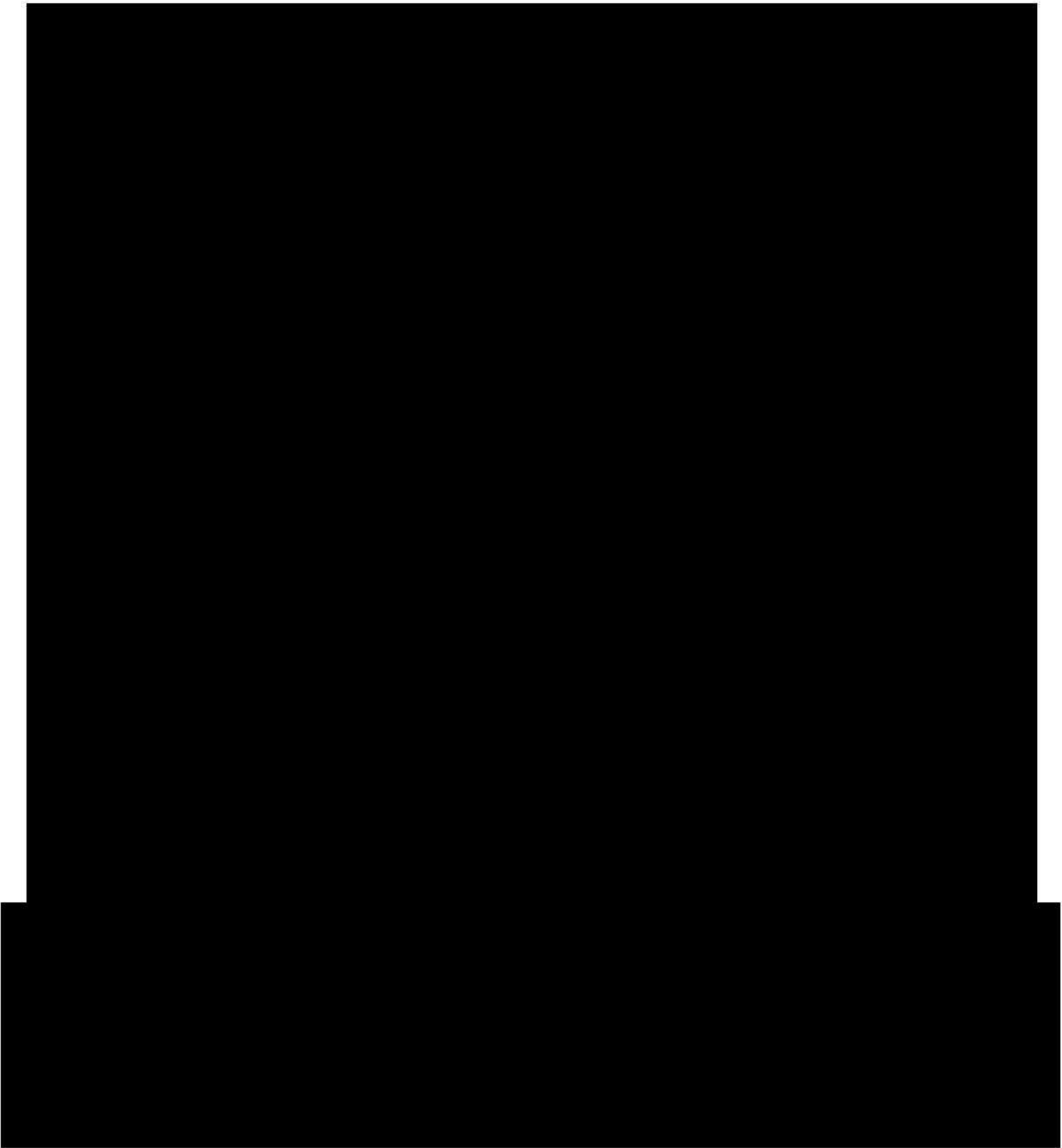
# Current State of Manufacturing at [REDACTED]

8th Revolution began its onsite facility evaluation by performing a walk-through and understanding of the current processes at [REDACTED]. We reviewed the process flow within the manufacturing operations at [REDACTED]. Below, we have summarized our understanding of the current manufacturing plant, procedures, and processes. To aid in this understanding, we have also included a flow diagram provided by the [REDACTED].



## LEGEND

-  = Existing building, Climate controlled HVAC
-  = -18°C (0°F) Freezer, outdoors
-  = Shipping Container, outdoors
-  = -40°C (-40°F) ultra low Freezer, outdoors
-  = Covered area, outdoors
-  = C1D1 certified area, outdoors

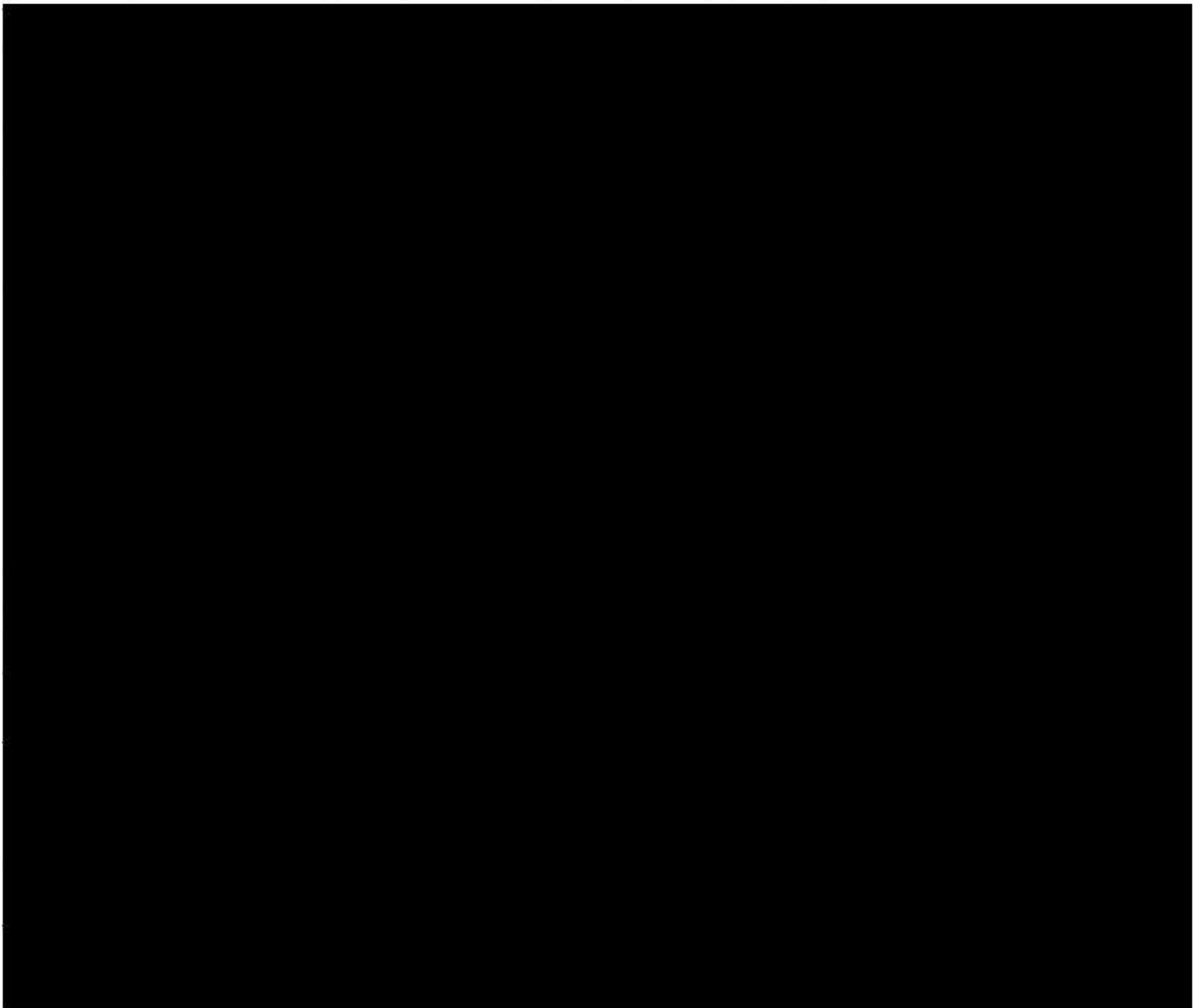




# Extraction Department

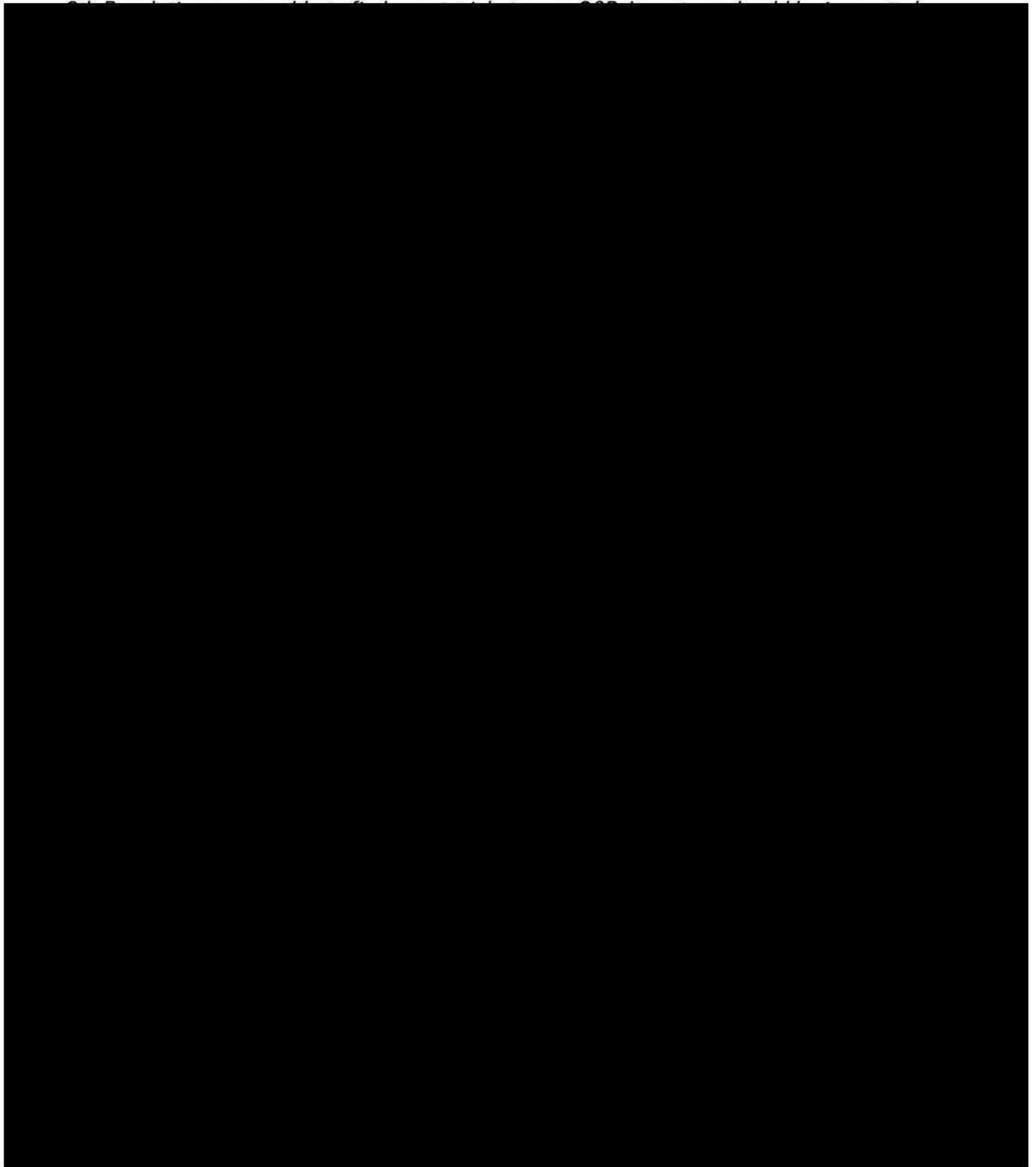


## Material Storage



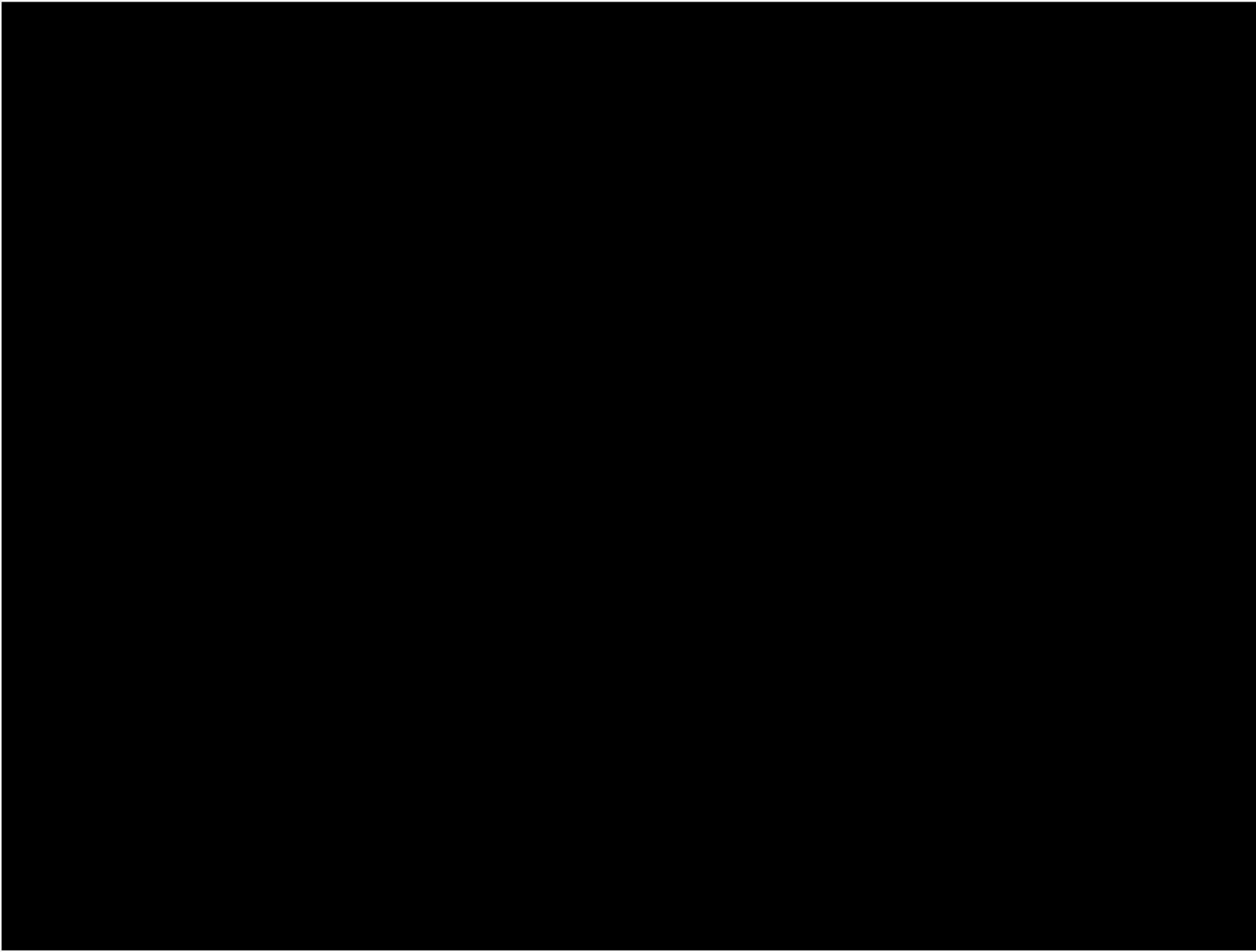


## Observations

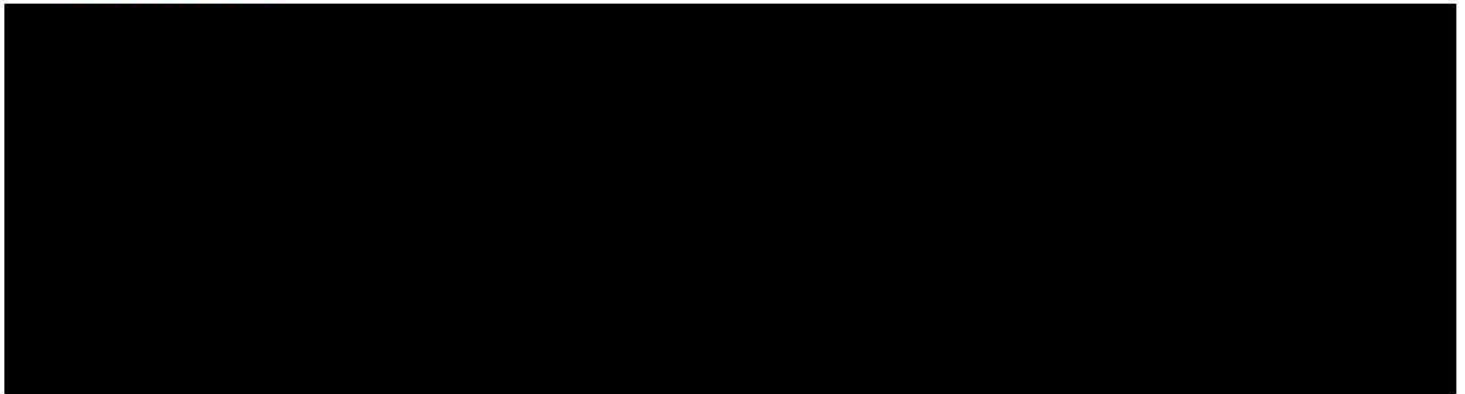




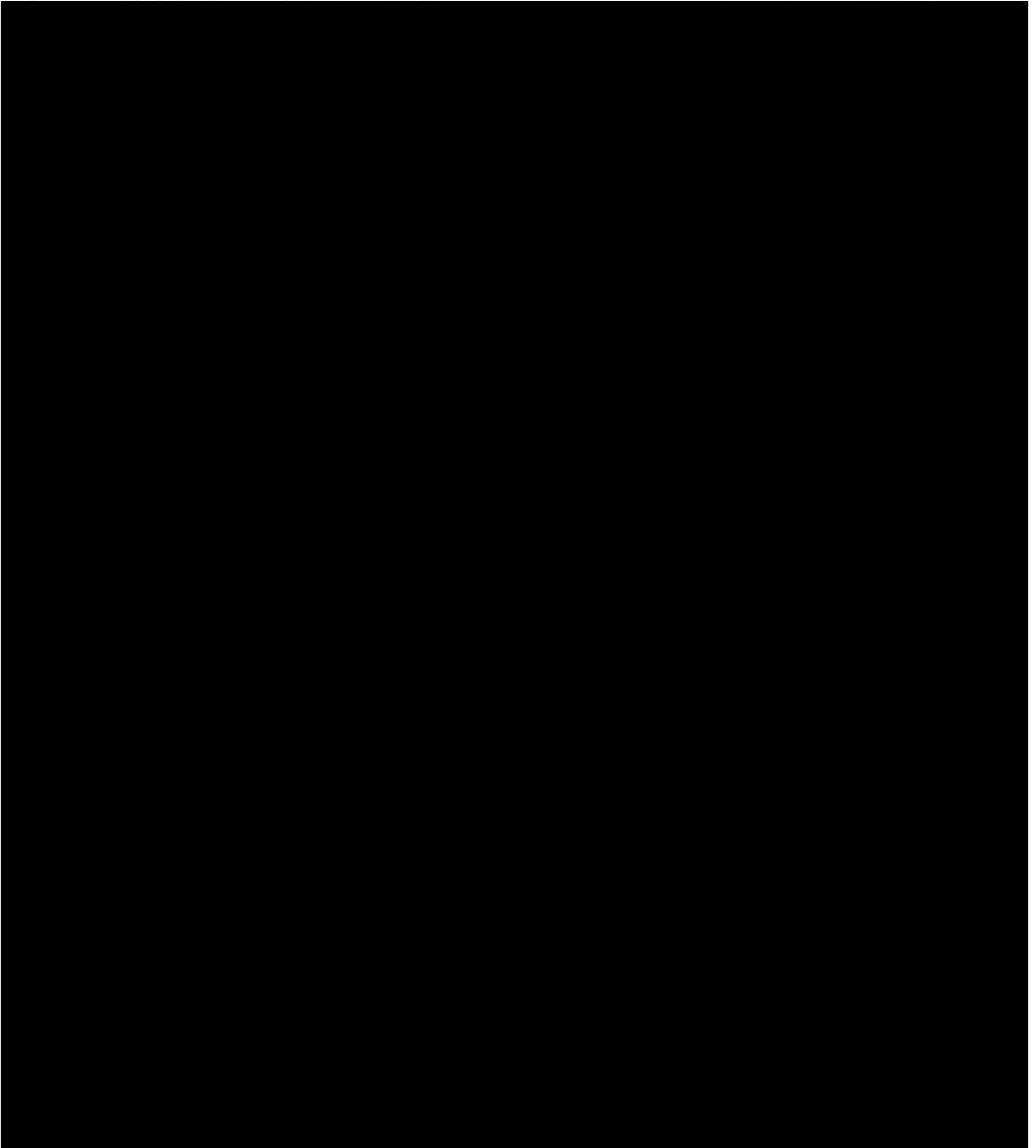
## Material Preparation

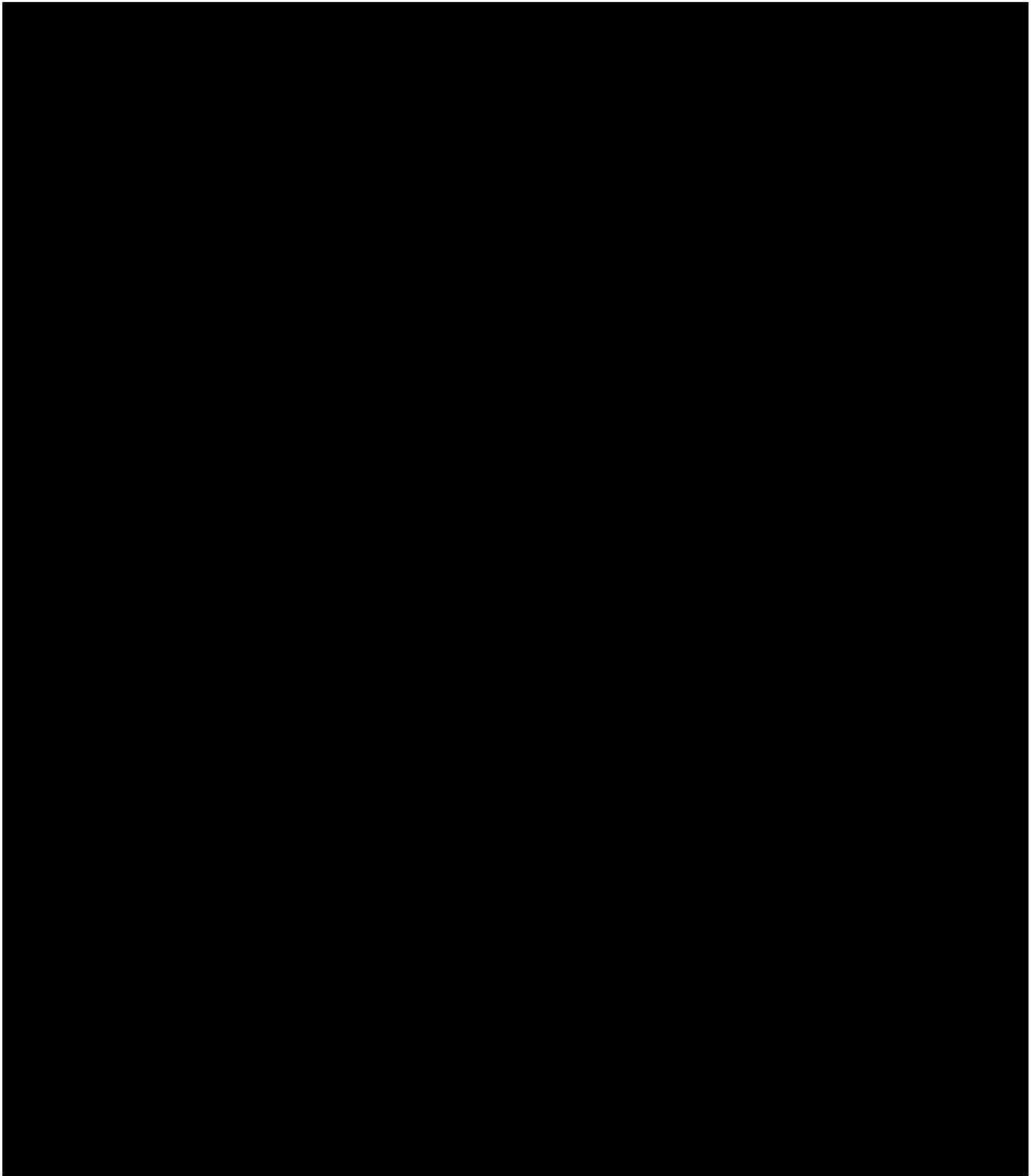


## Observations



## Hydrocarbon Extraction Process



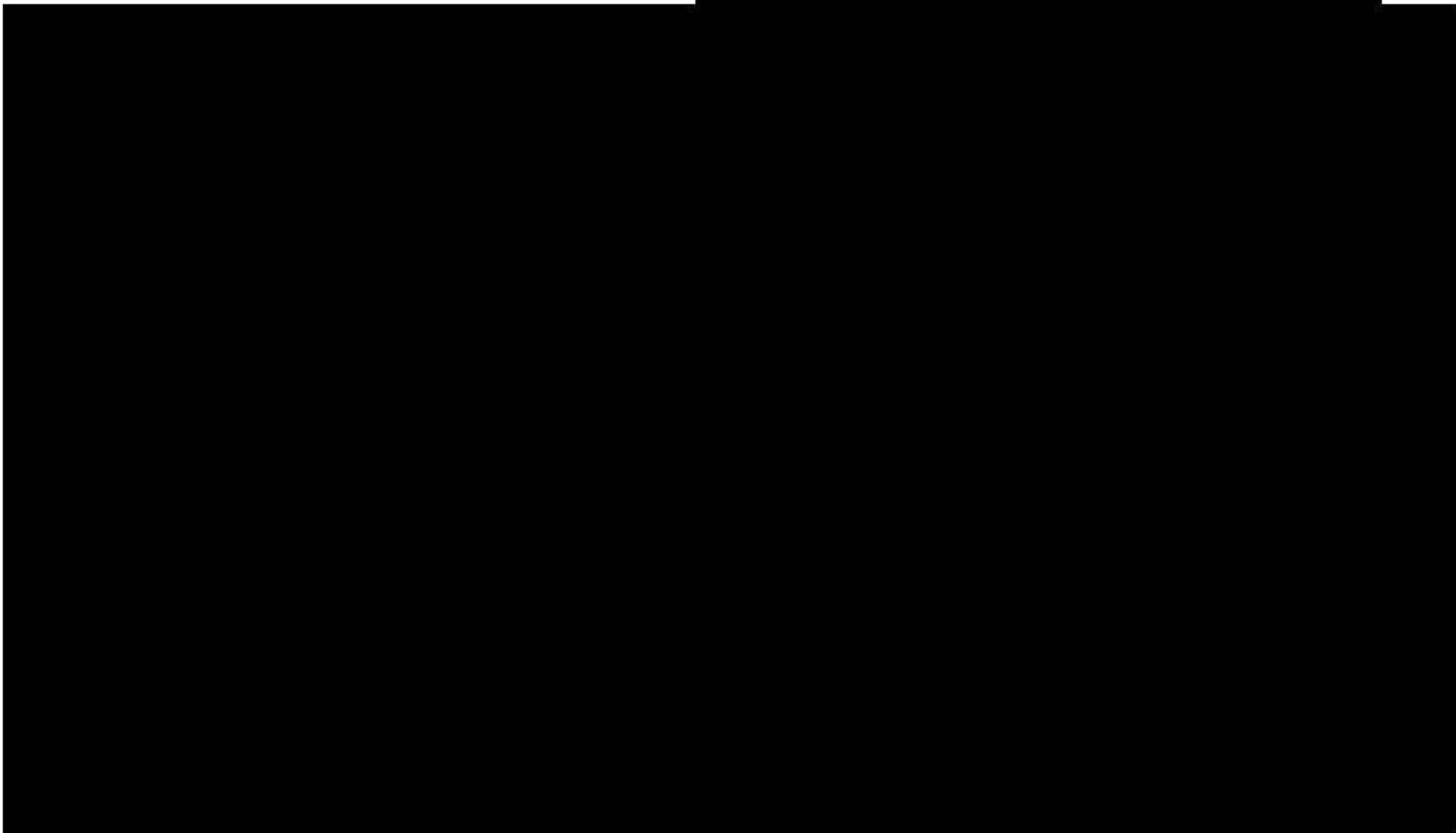


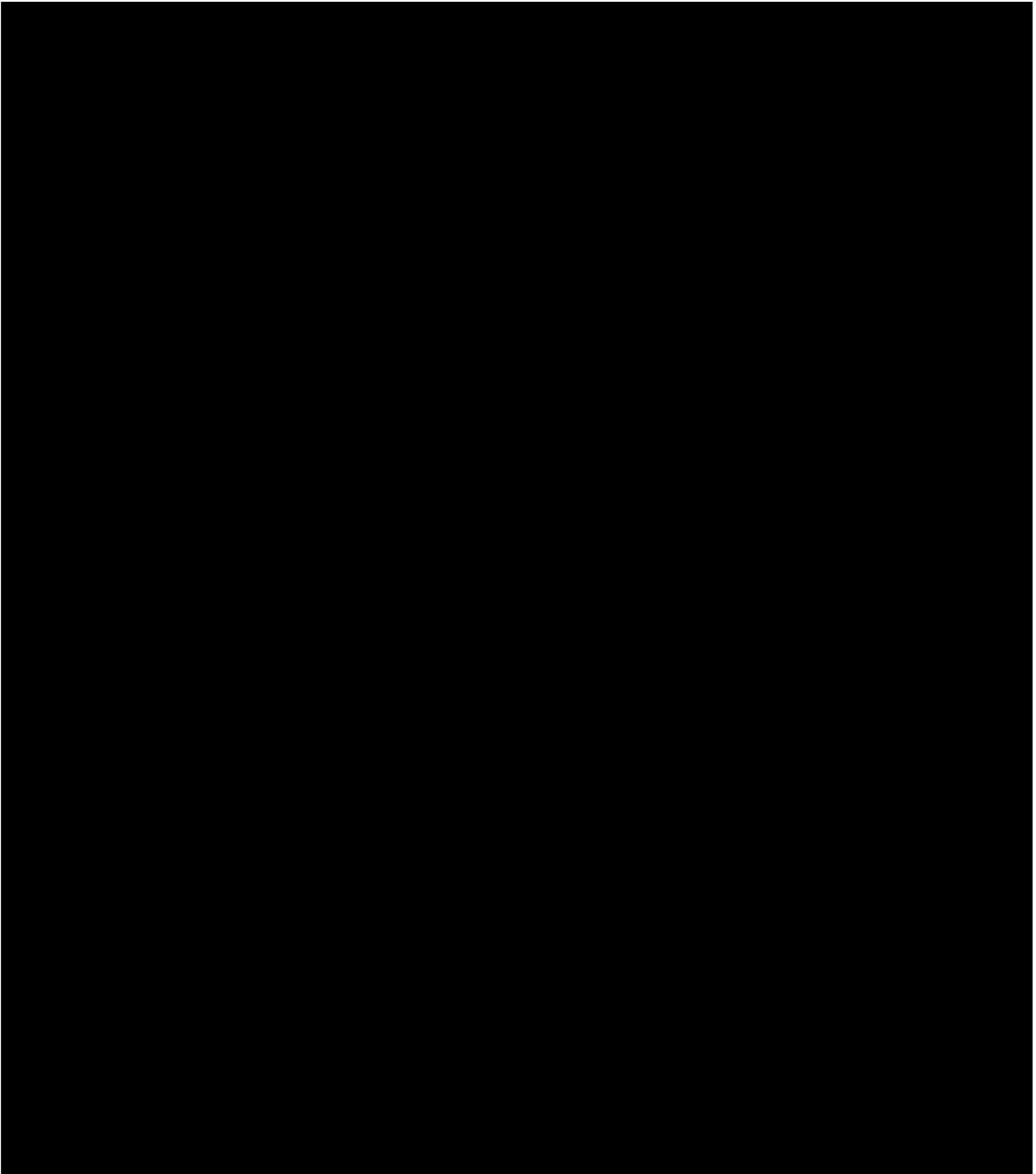


## Observations



Variable	Value	Source
Mass of cannabis used in extraction		
THCA concentration in cannabis (potency)		
Mass of <i>n</i> -butane used in extraction		
Molar mass of THCA		
Density of <i>n</i> -butane		

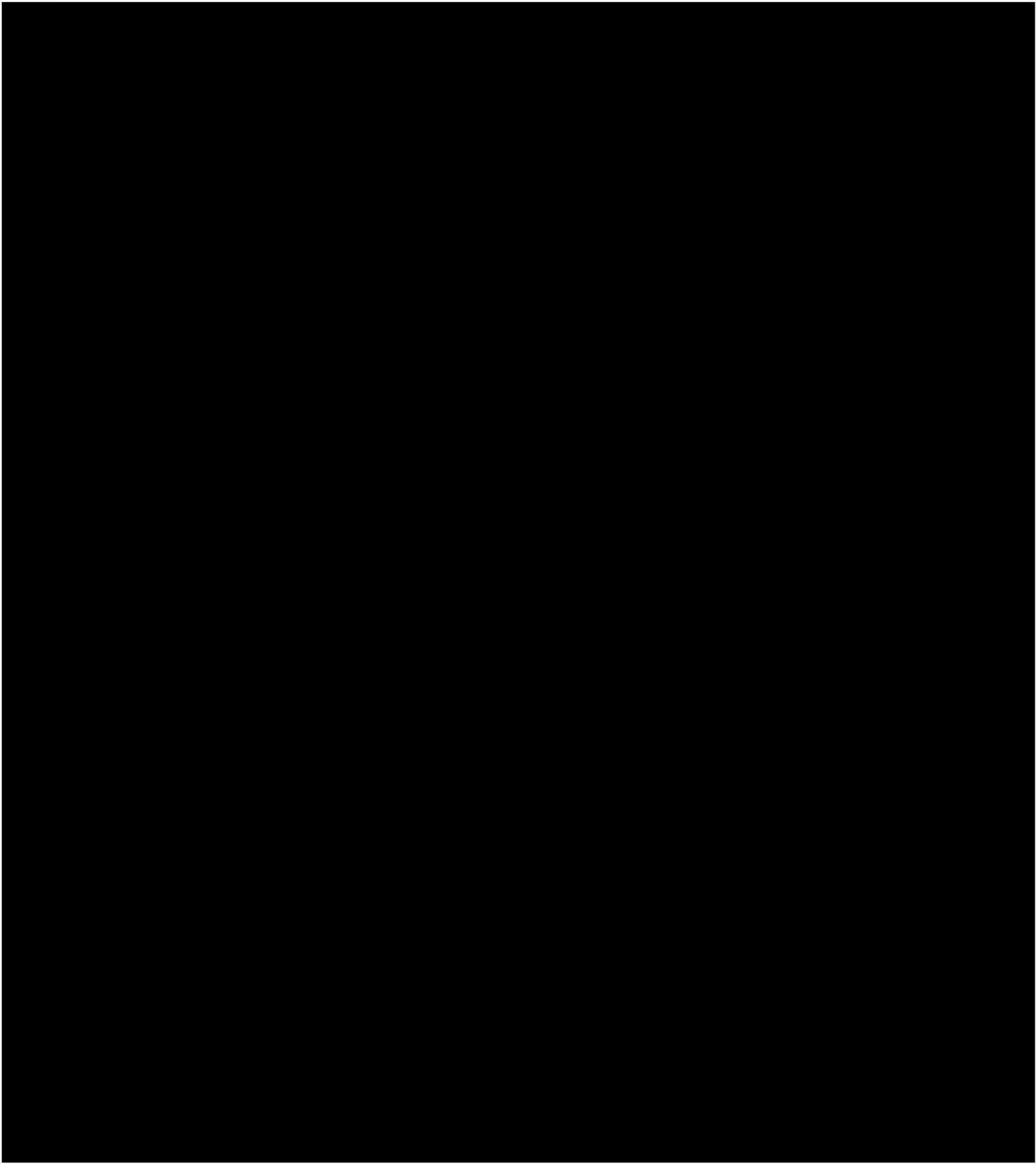




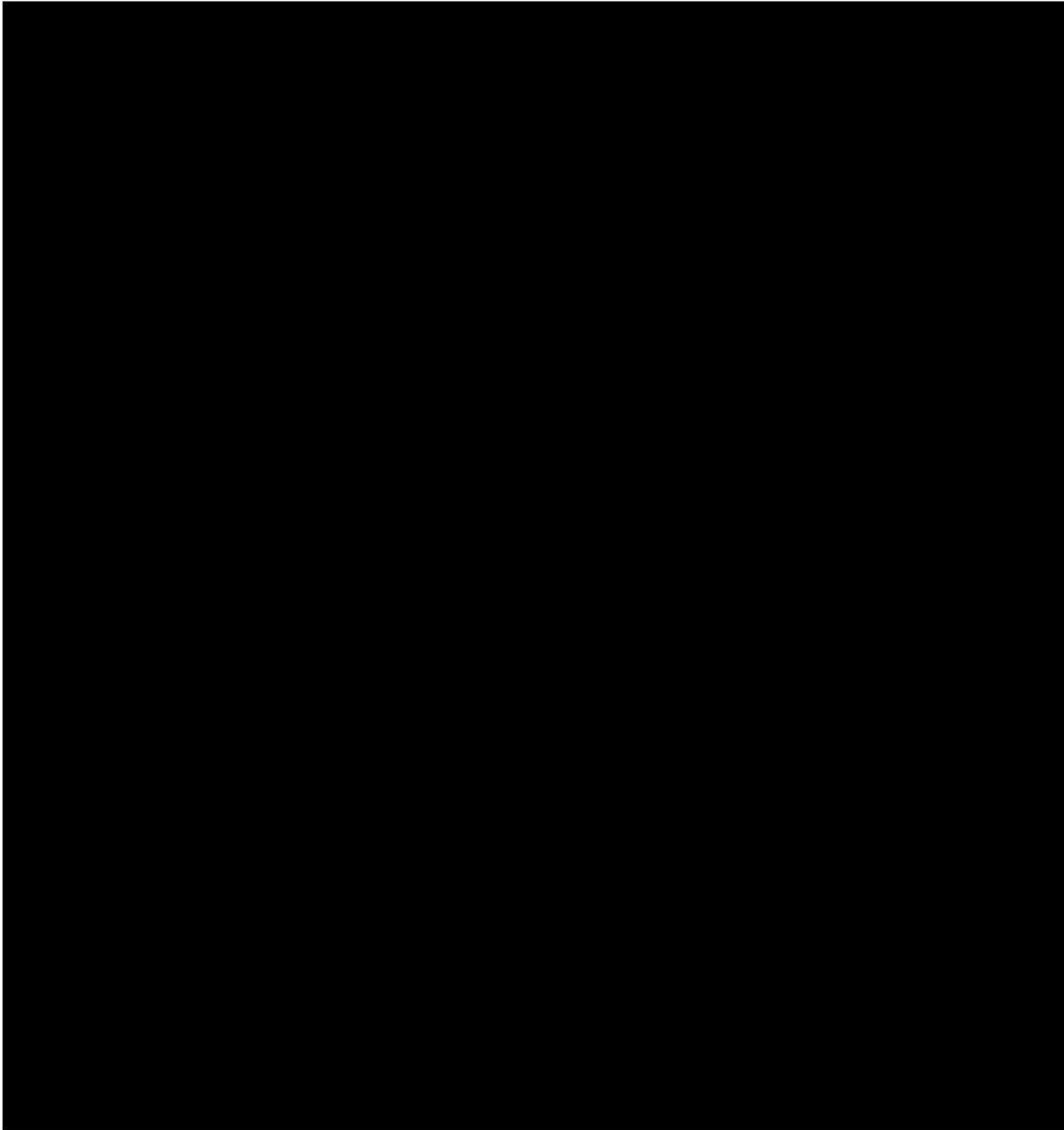
## Material Flow Through Extraction Department

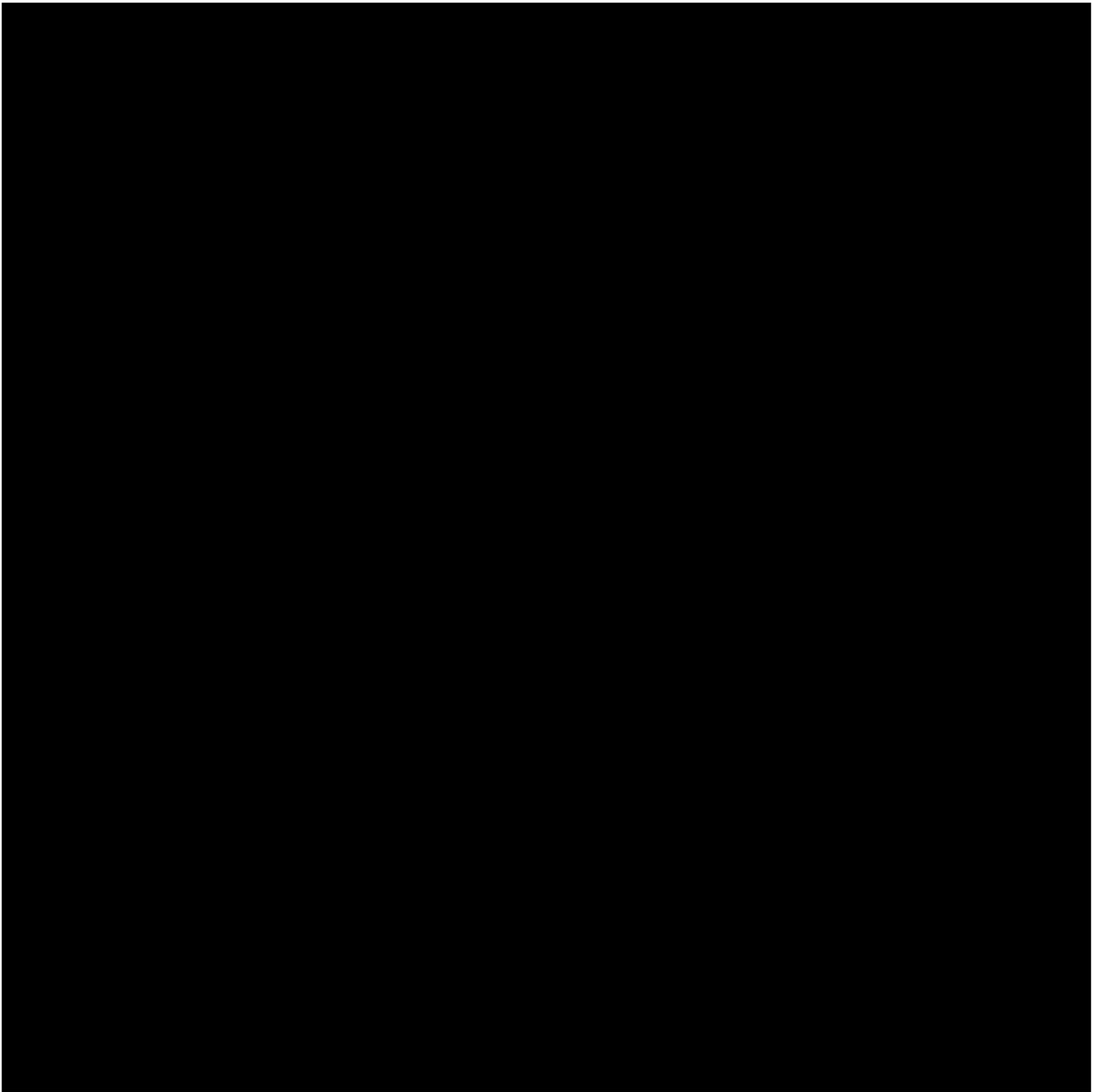






## Quality Management Program

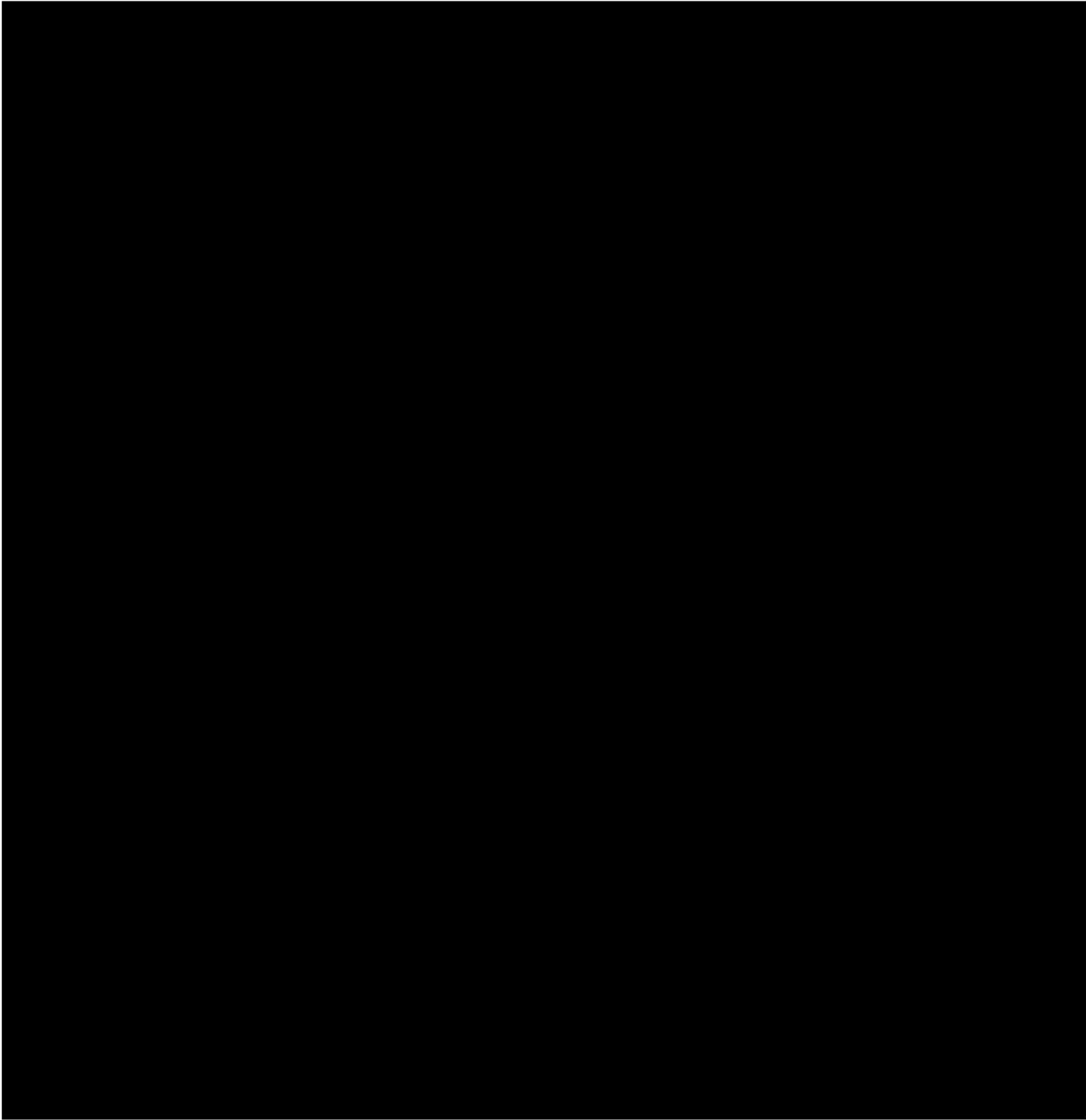






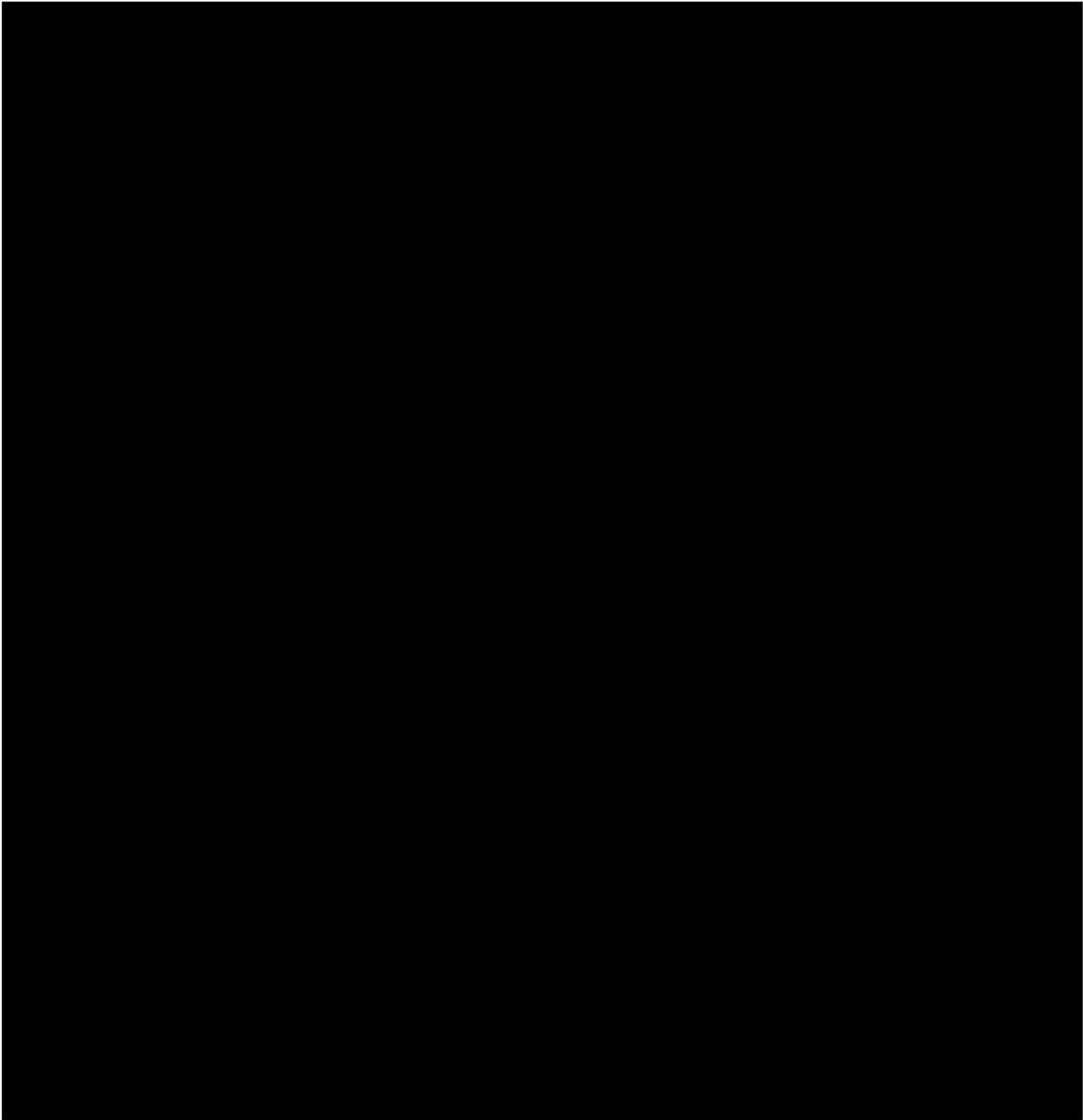


## Maintenance



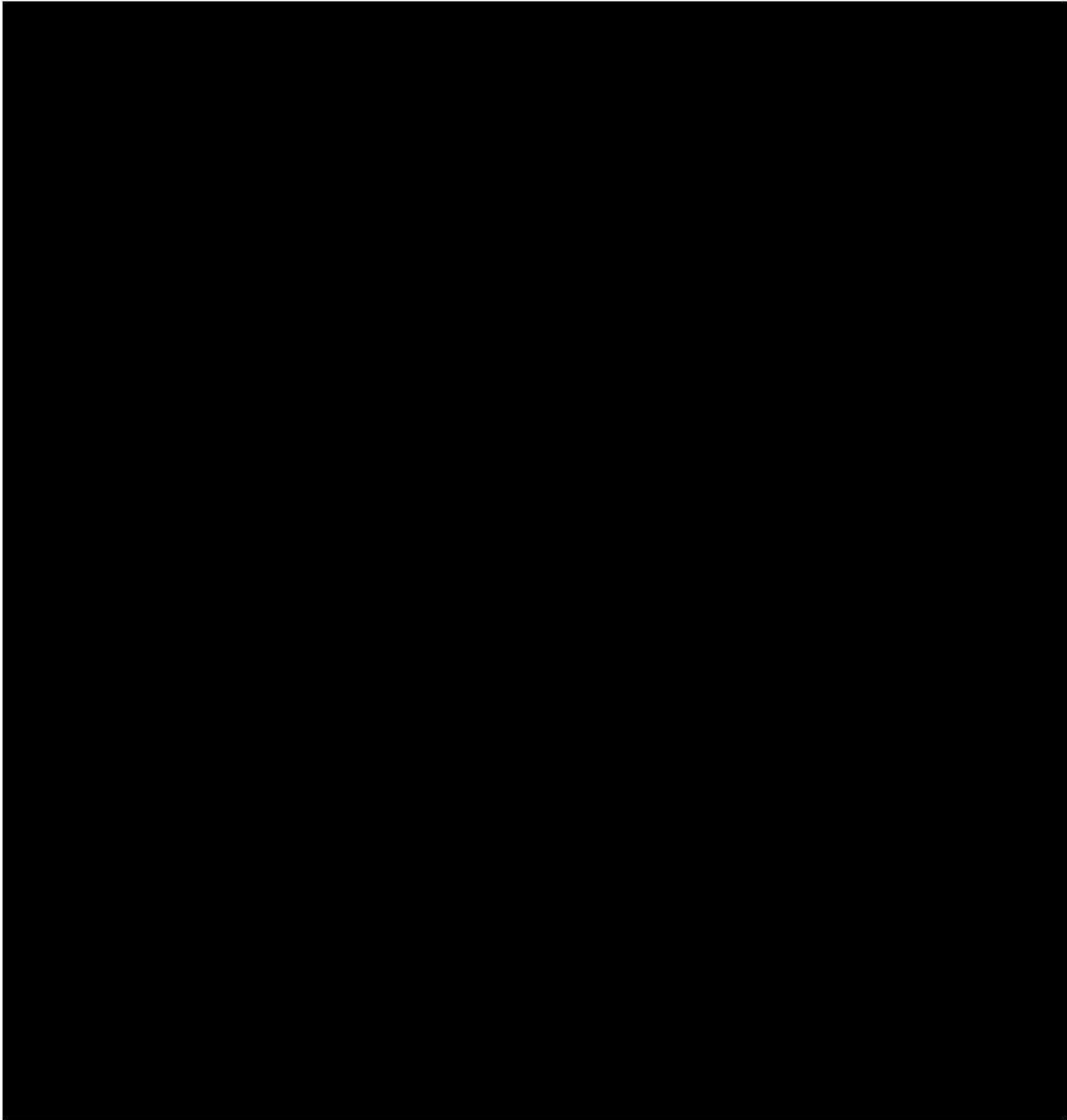


## Observations





## Safety



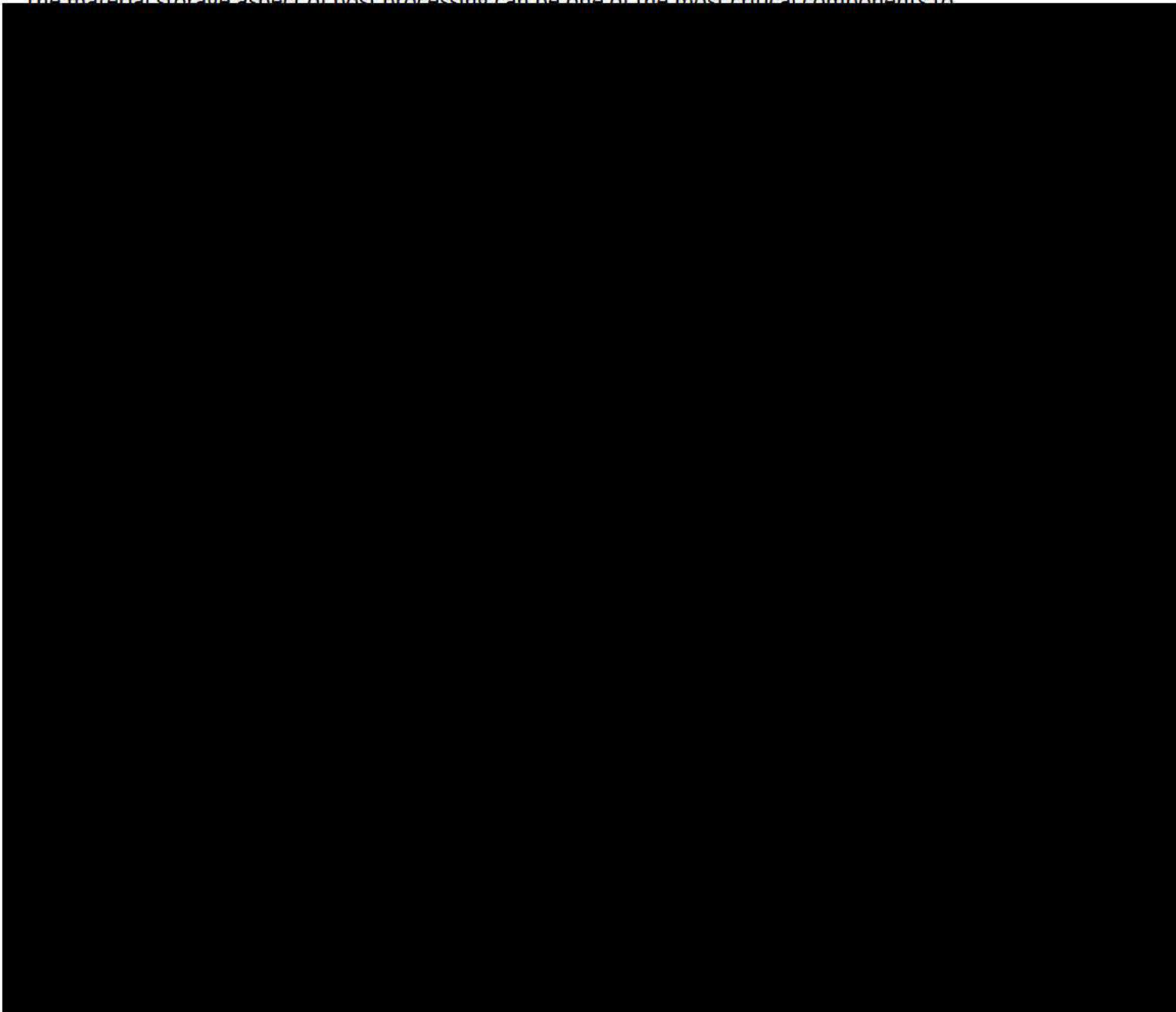


# Post Processing Department



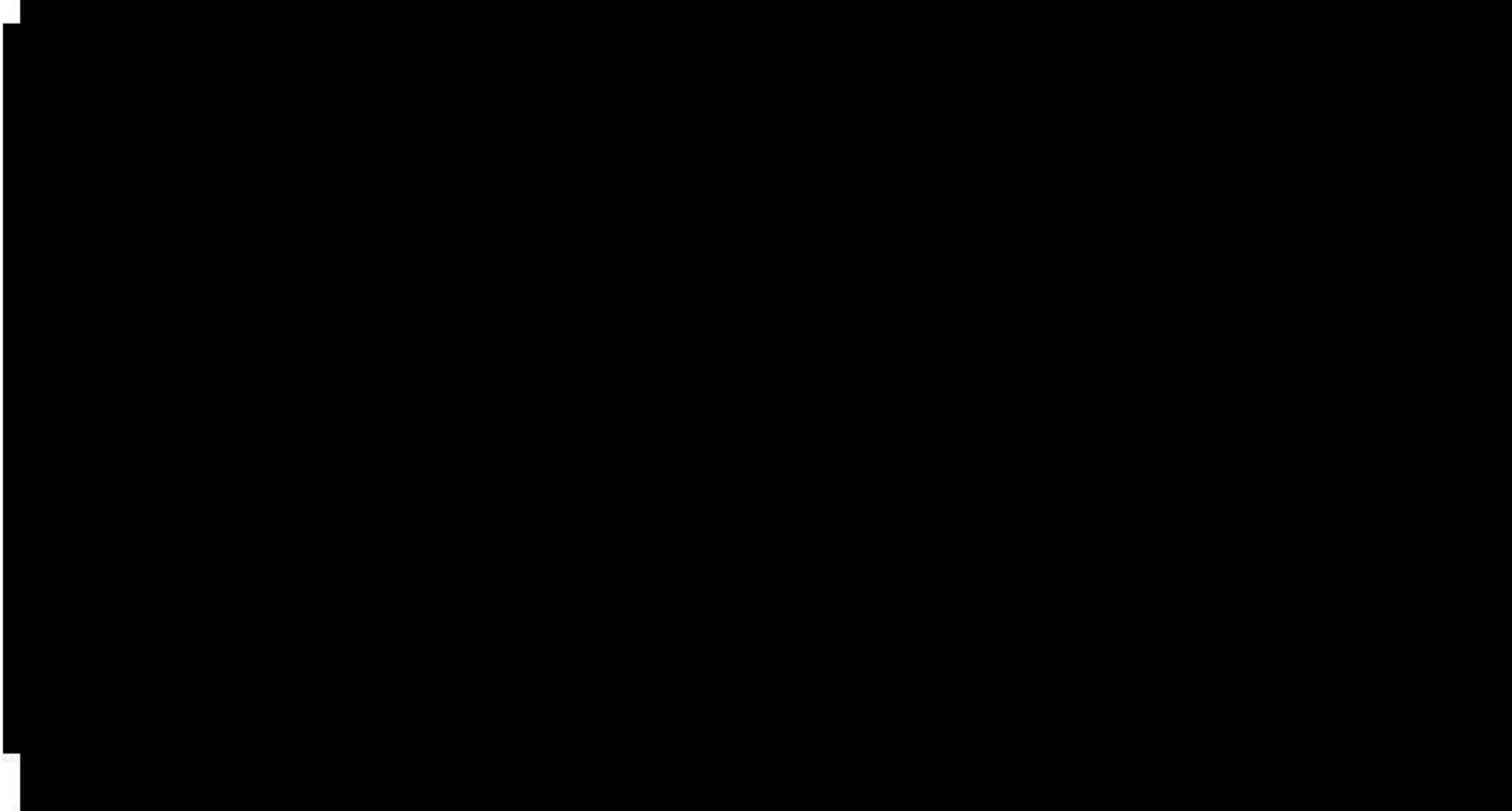
## Material Storage

The material storage aspect of post processing can be one of the most critical components to



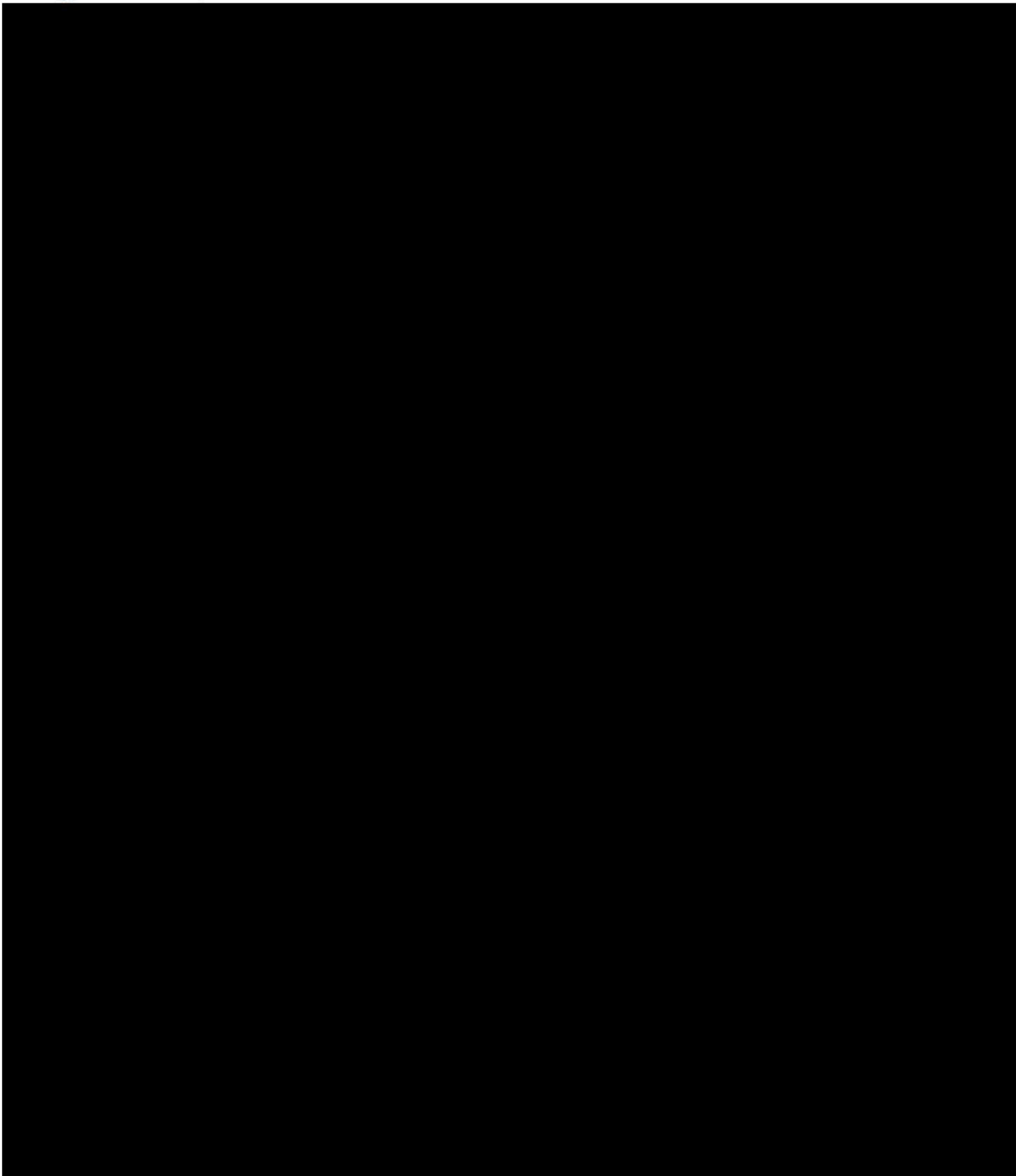


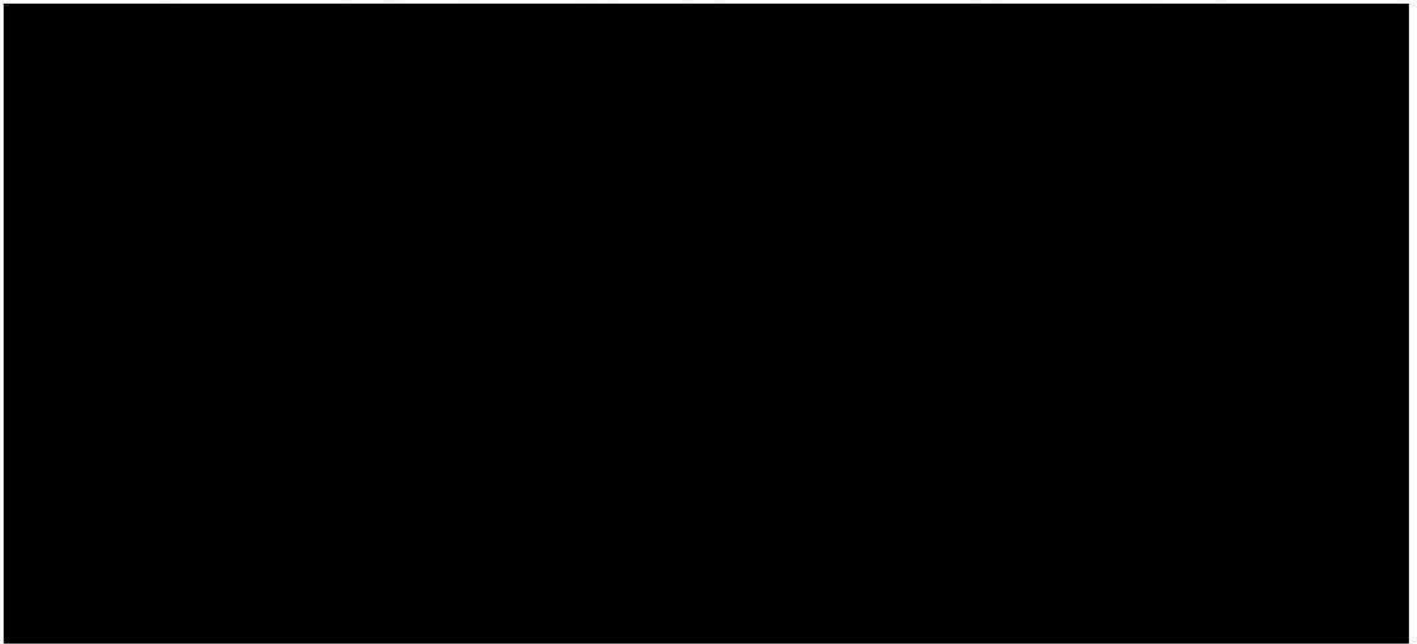
## Observations



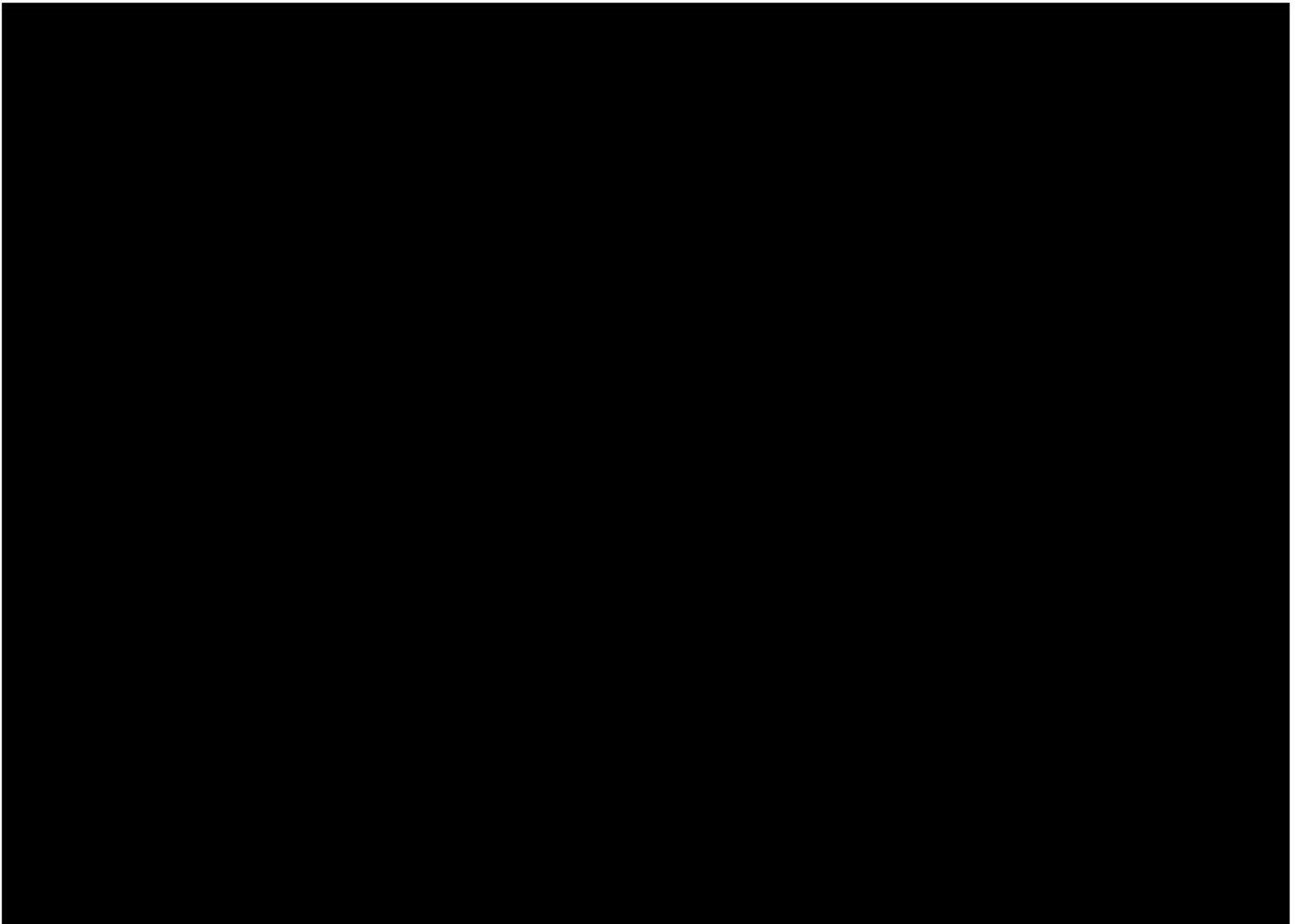
## Material Flow and Product Differentiation





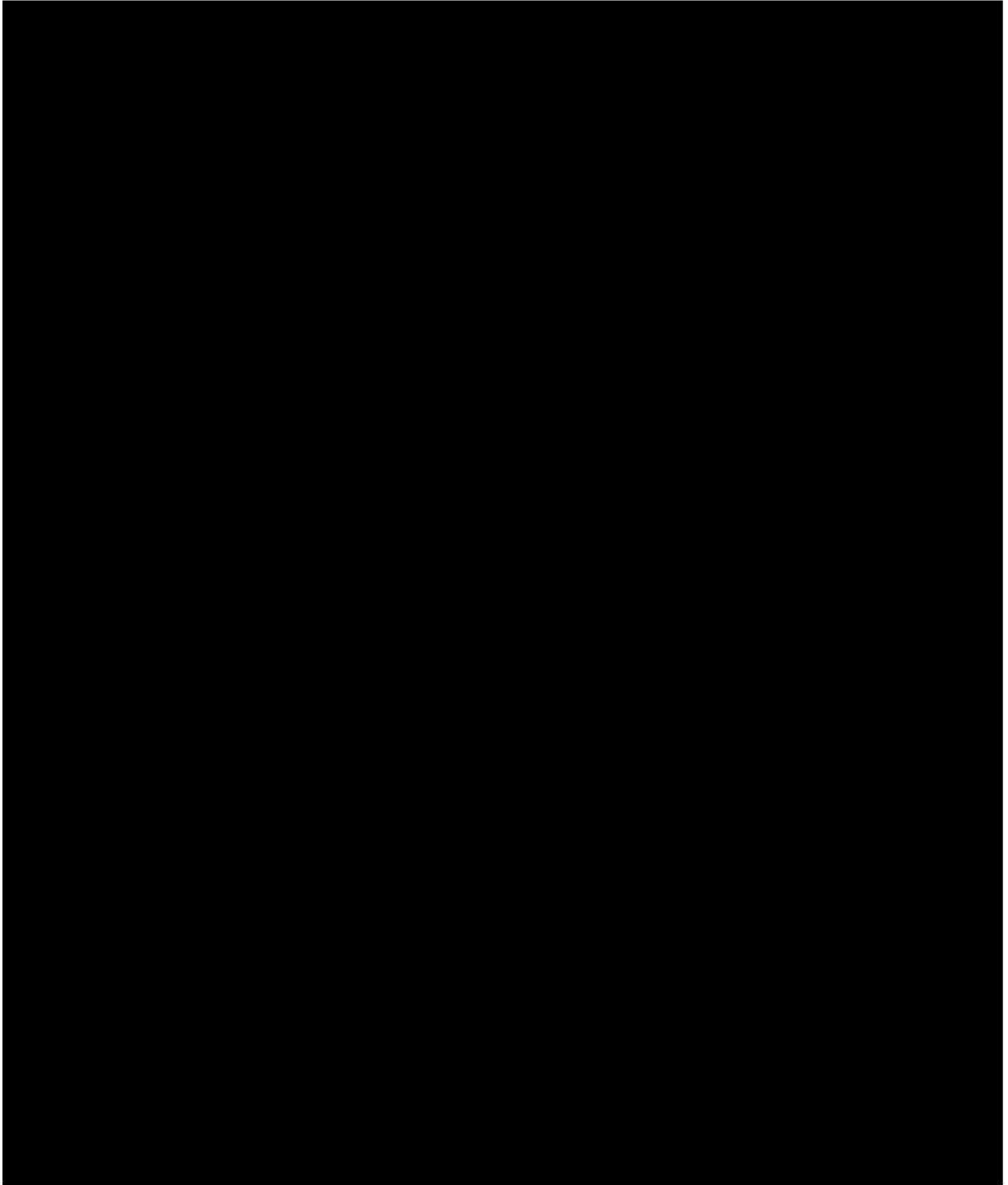


### *Observations*



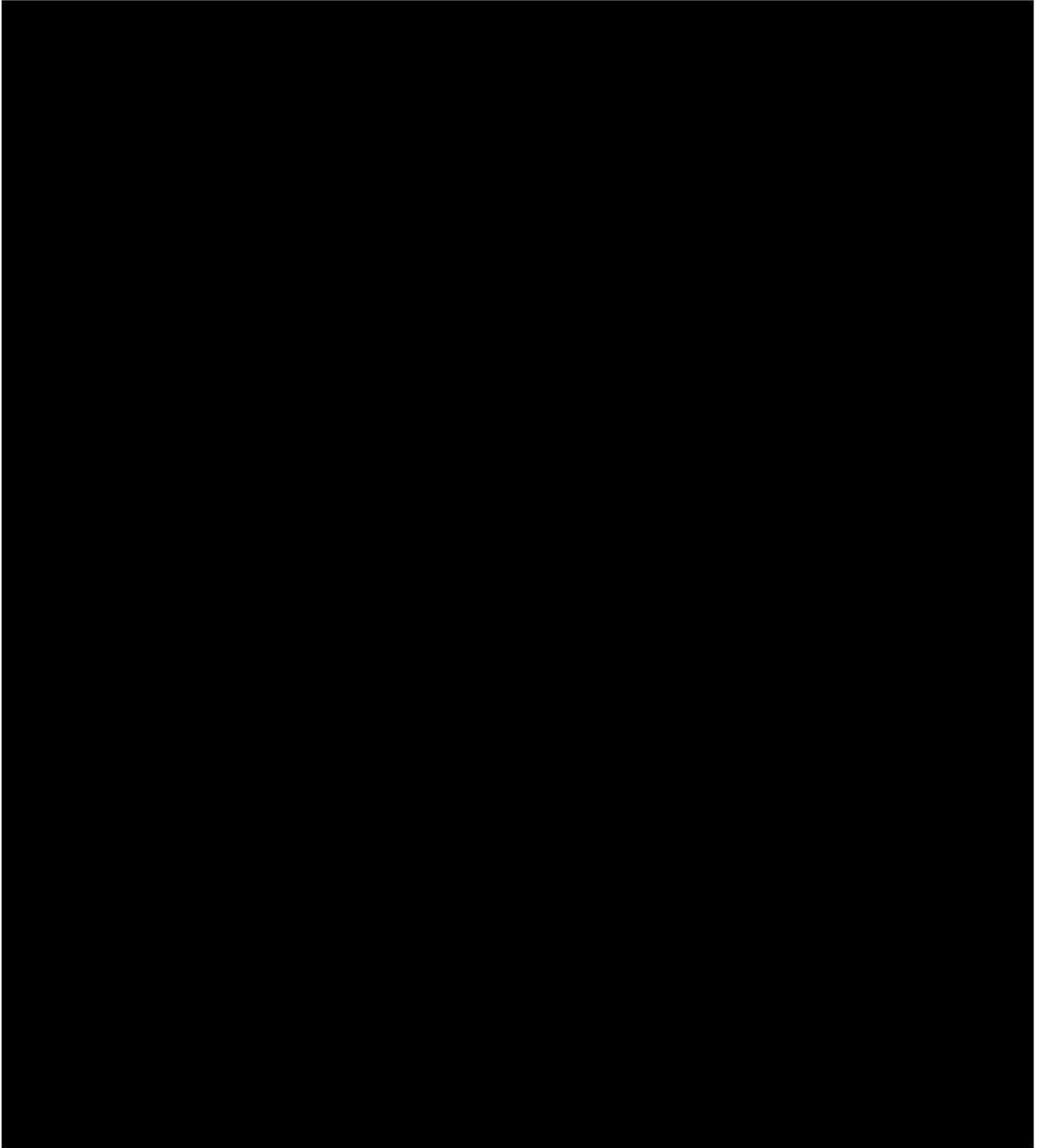


## Equipment and Tools

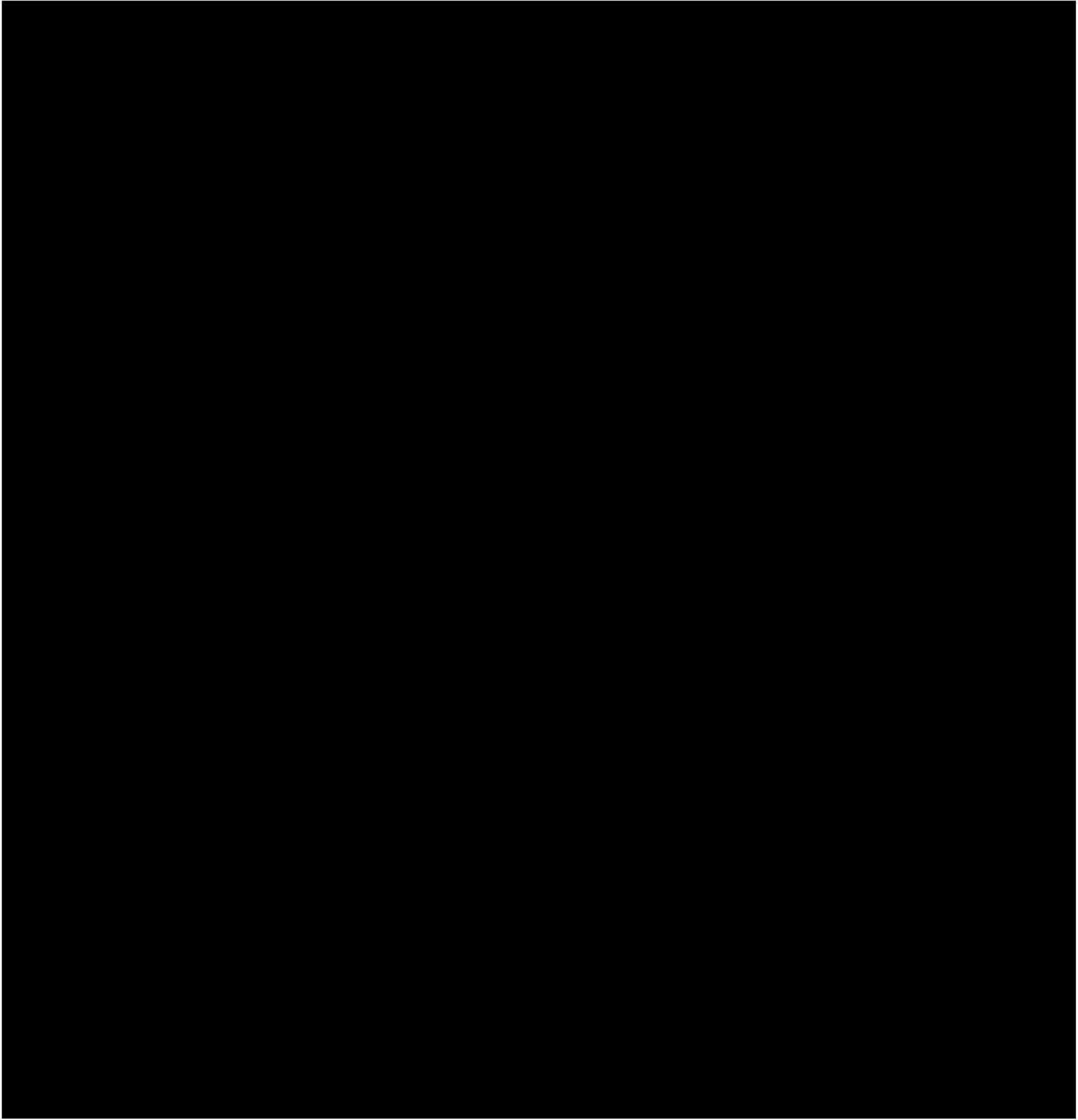




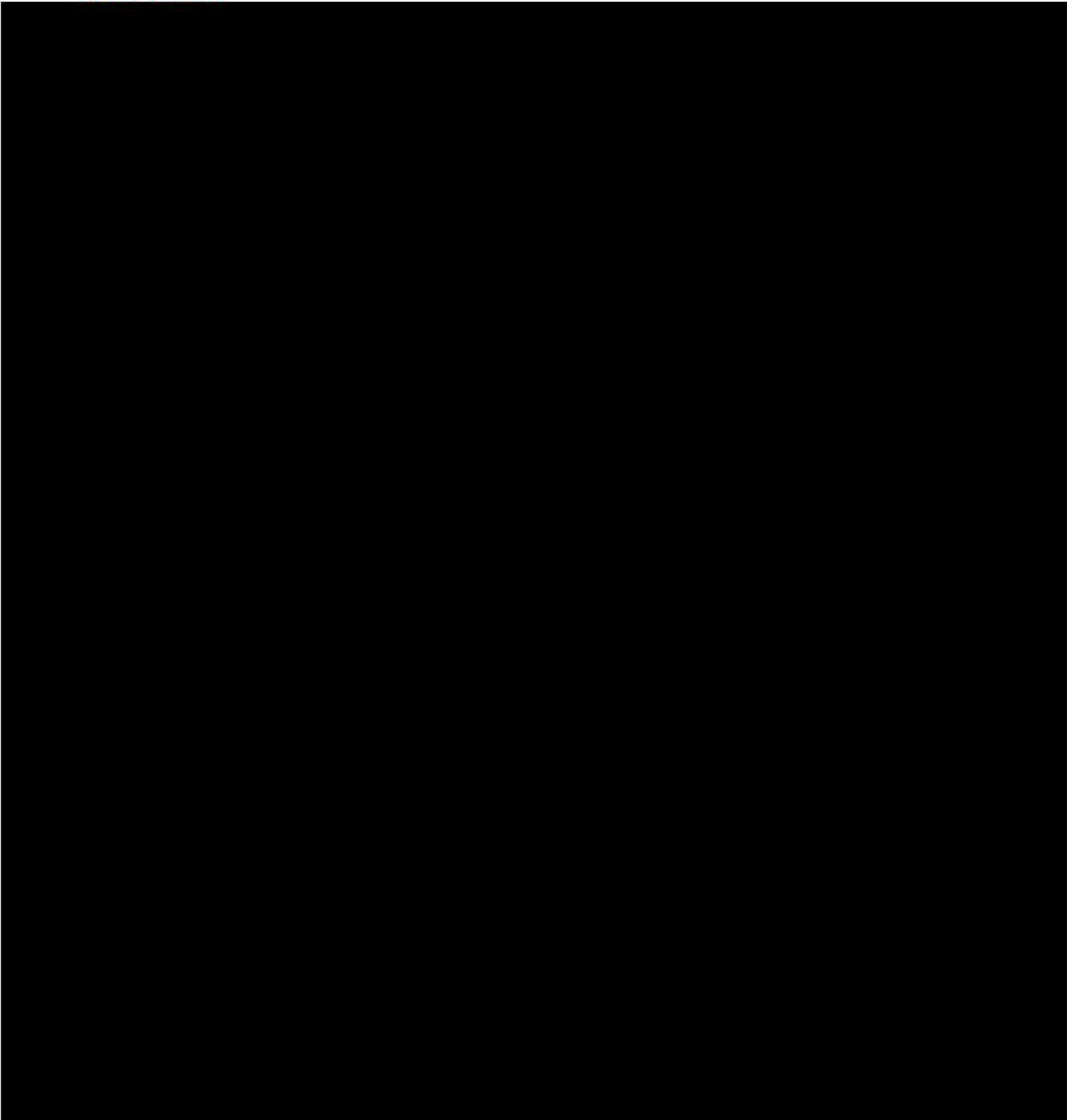
## Observations



## Quality Management Program

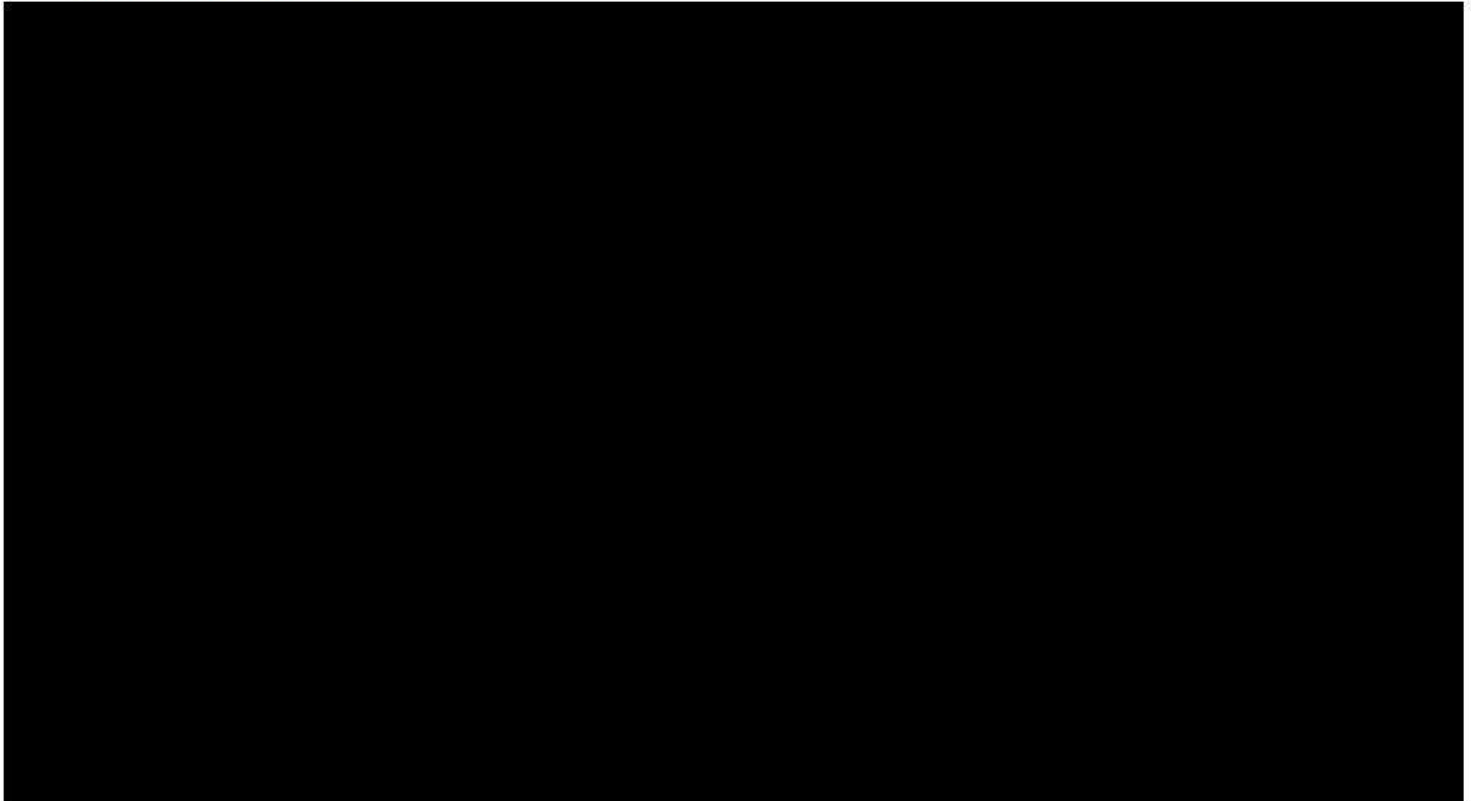


## Observations

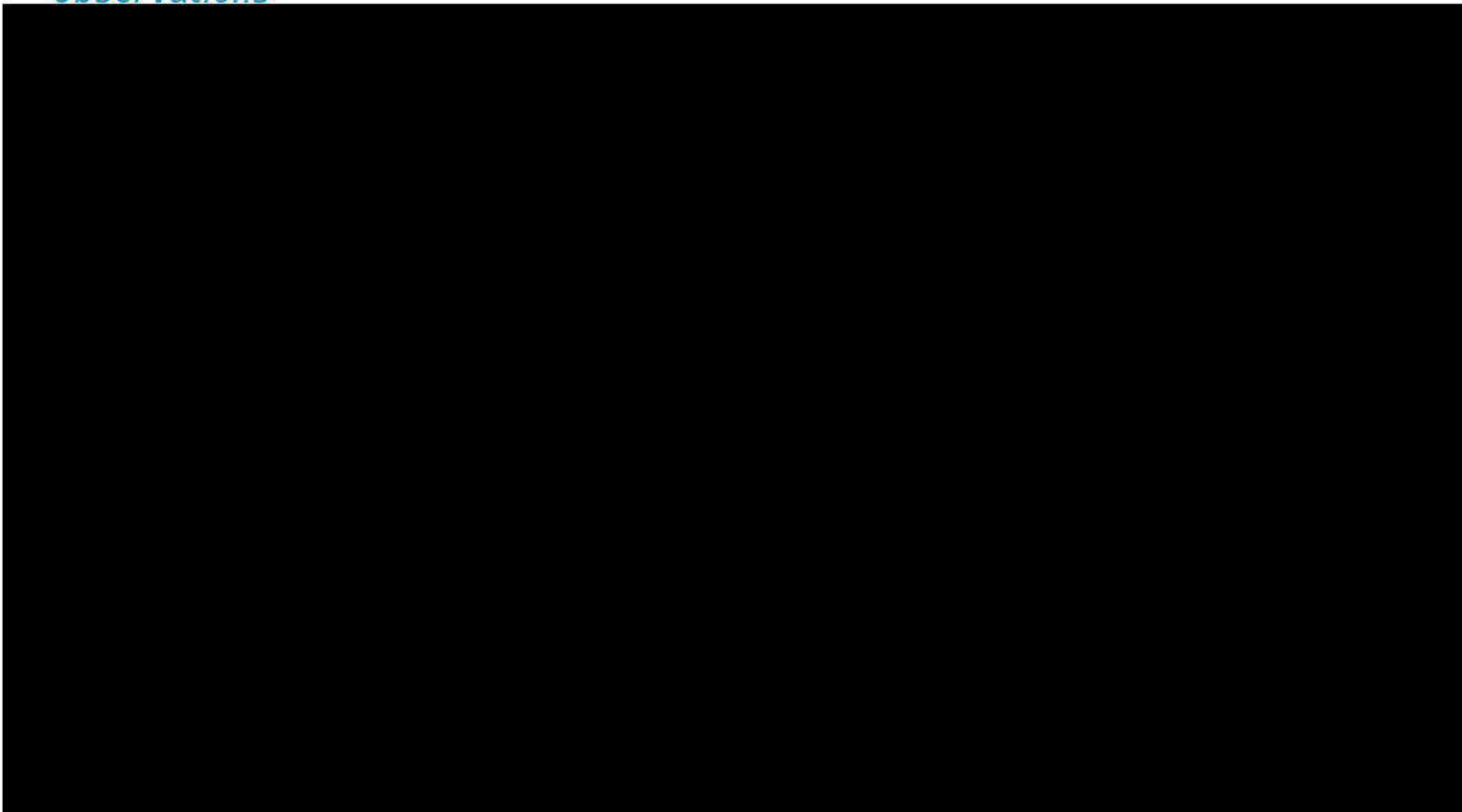




## Maintenance

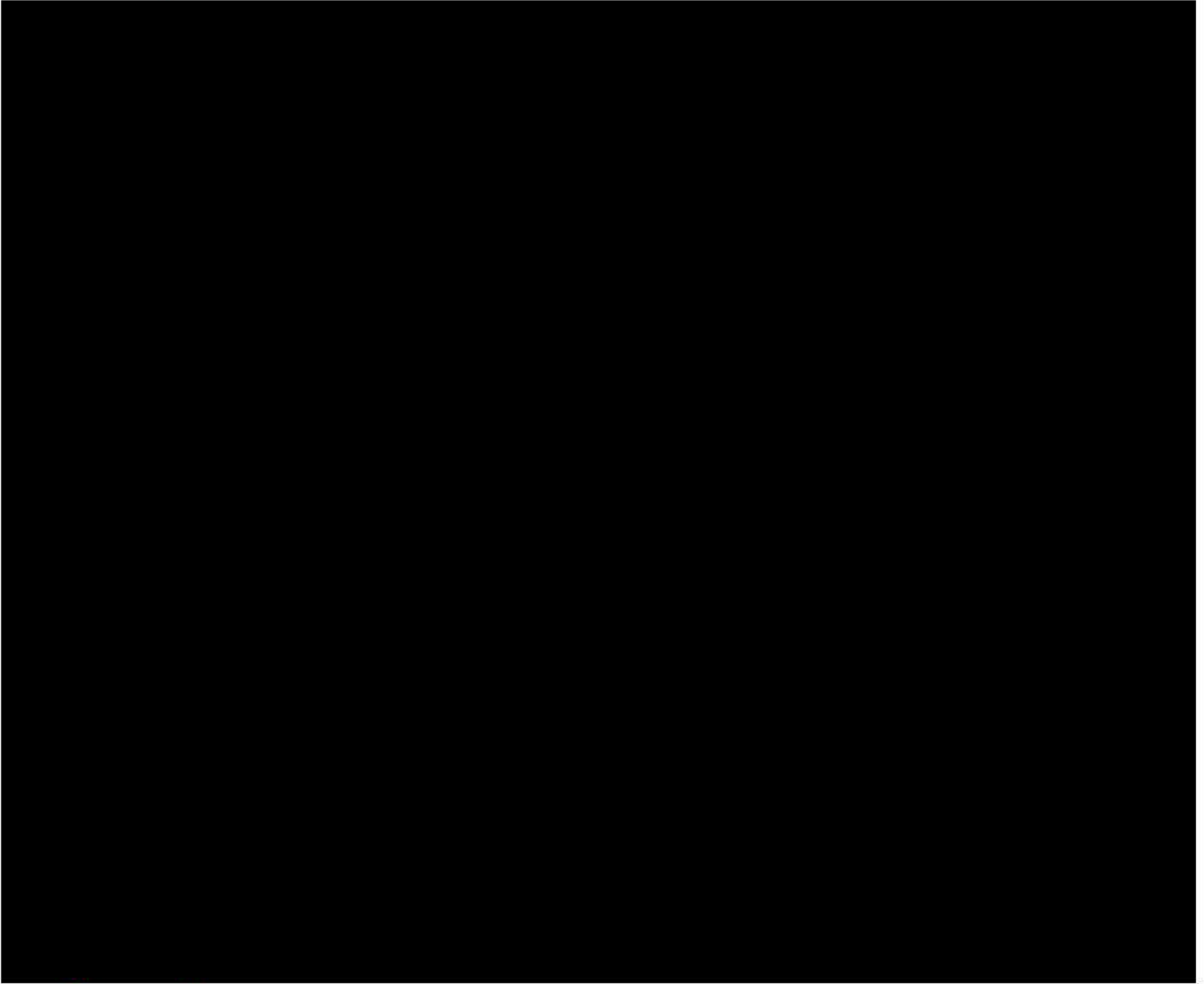


## Observations

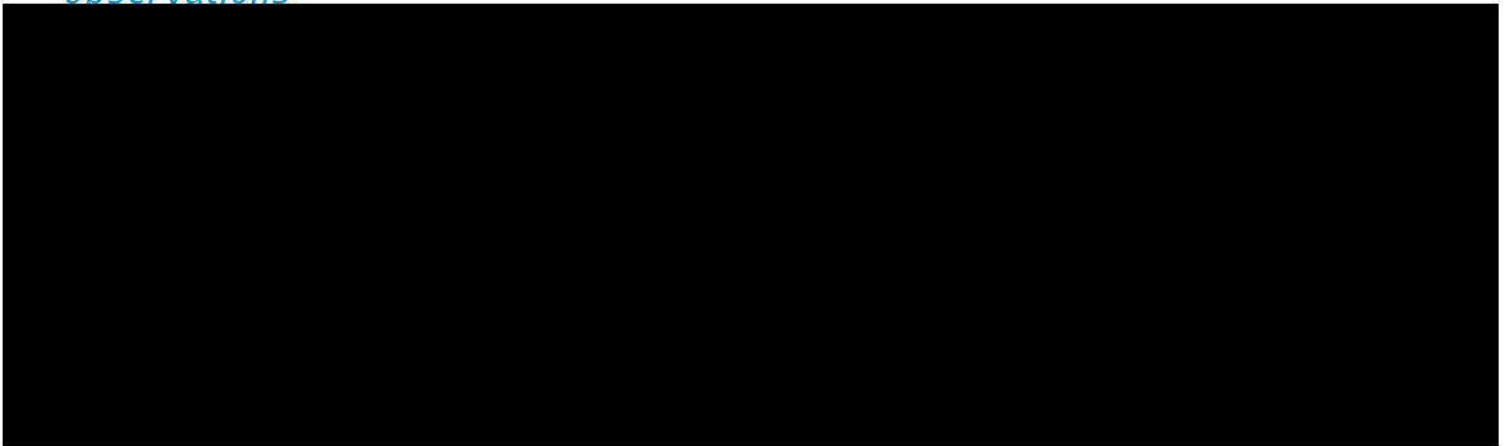




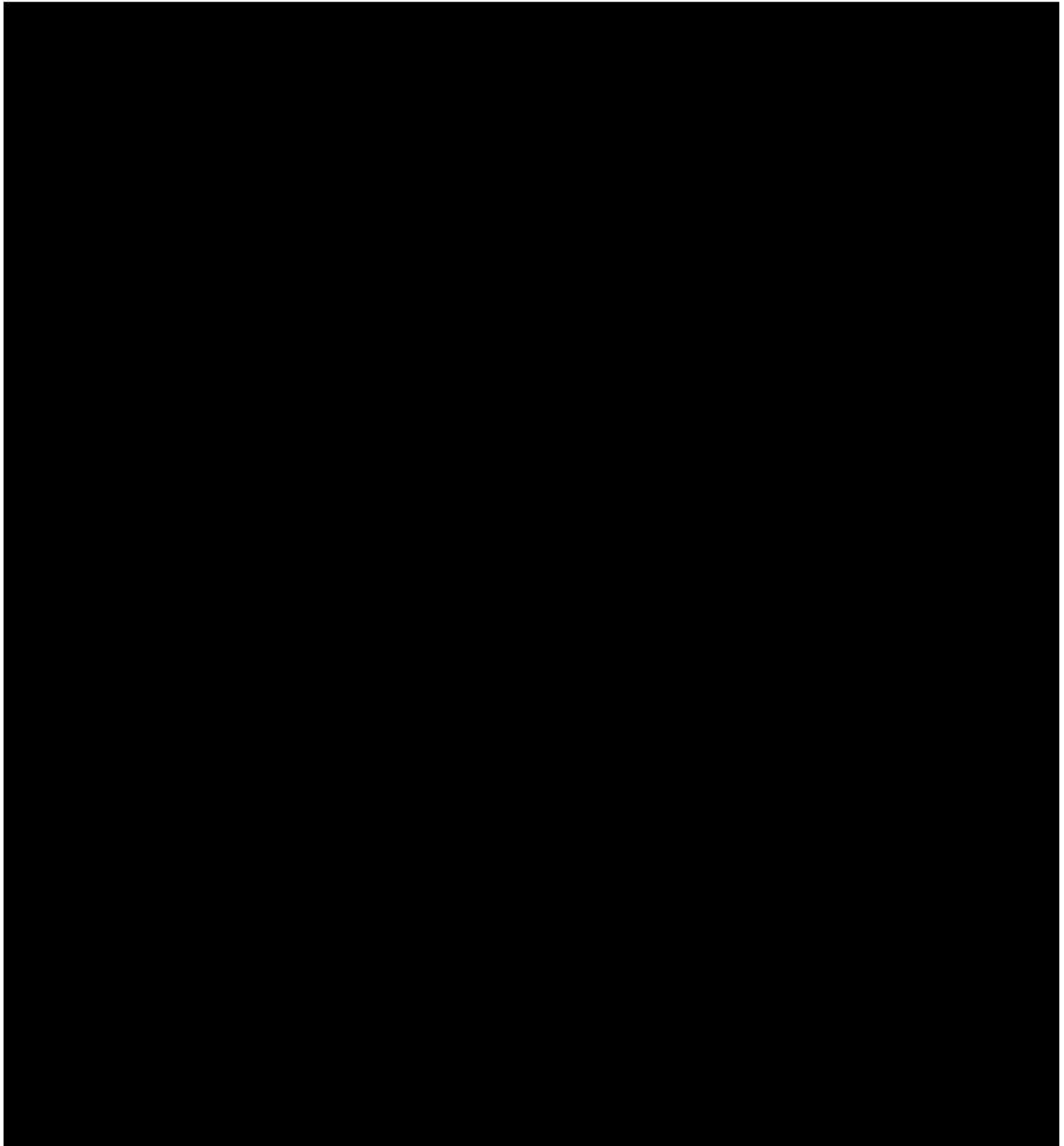
## Safety



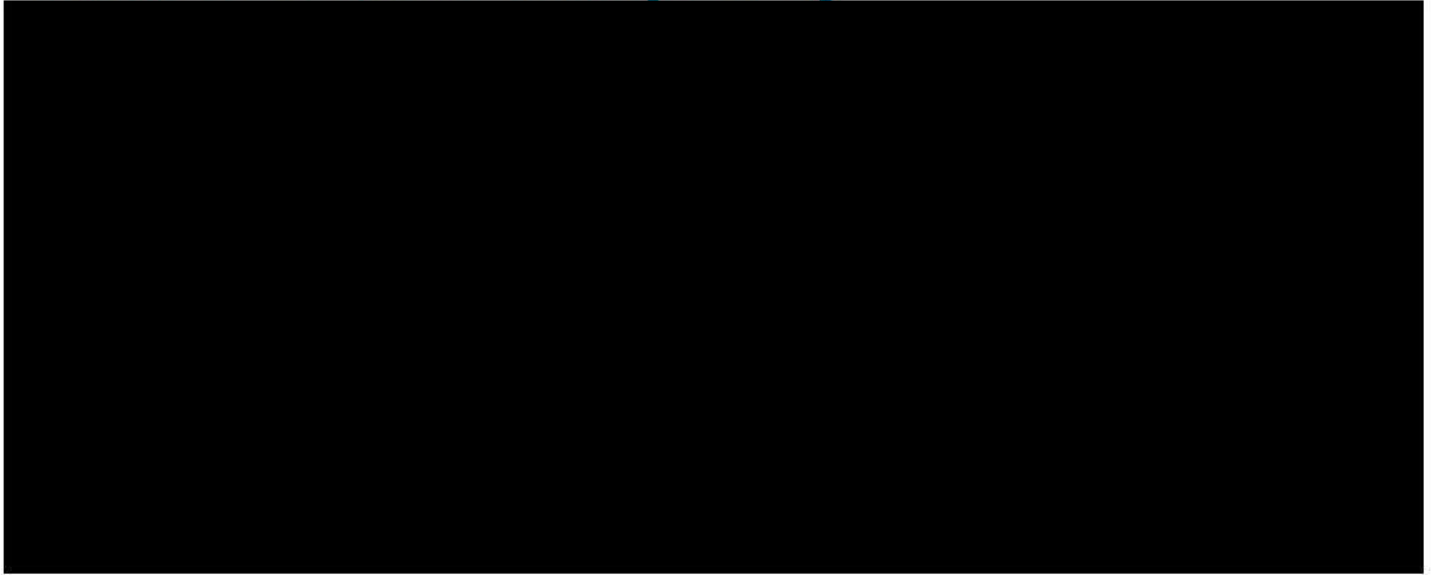
## Observations



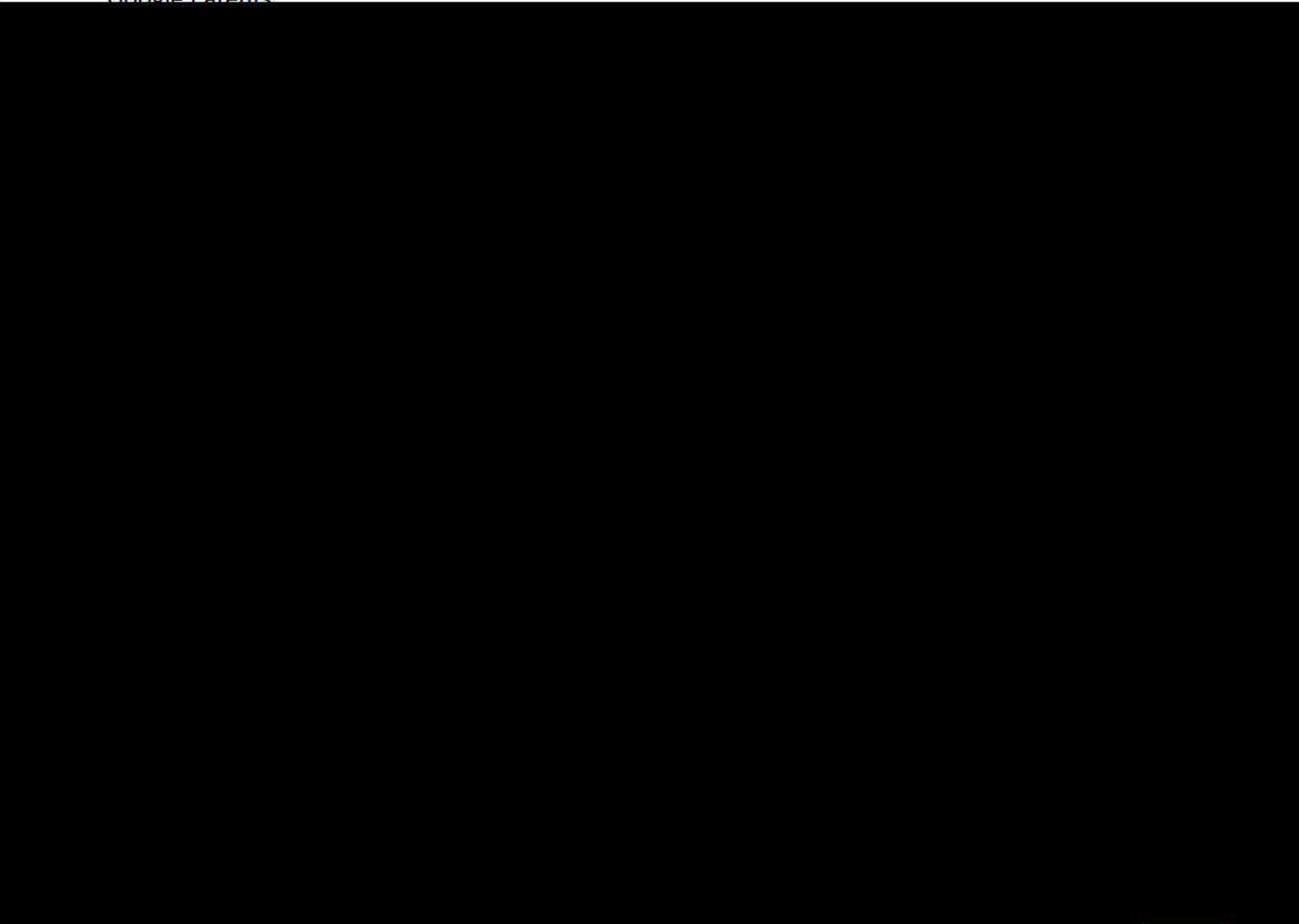
# Standard Operating Procedures



# Intellectual Property



Google Patents:





## Research and Development

