
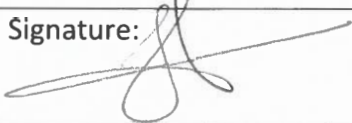
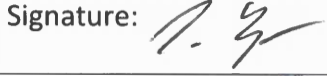



Attachment I : Compliance Plan

 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 1 of 16

Issued by: Quality Assurance	Copy No.:
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Prepared by: Operations Administrative Coordinator	Signature: 	Date: Aug 10, 2022
Reviewed by: Department Management	Signature: 	Date: 10-AUG-2022
Approved by: QA Management	Signature: 	Date: aug 10. 2022

1.0 Purpose

- 1.1 To define a procedure for monitoring temperature in the warehouse area at Methapharm Inc. (Methapharm) and during shipment to ensure that required storage conditions are maintained.
- 1.2 To define instructions for retrieving and reviewing data from the temperature monitoring devices and system at Methapharm.
- 1.3 To define the calibration and maintenance procedures of the temperature monitoring devices at Methapharm.

2.0 Scope

- 2.1 This procedure applies to all Active Pharmaceutical Ingredients (API), drug products, and medical devices imported, distributed and/or warehoused by Methapharm including professional samples, commercial product and product used for clinical trials. Hereinafter collectively referred to as 'Goods' or 'Products'.
- 2.2 This procedure applies to all temperature monitoring devices, including, but not limited to, xTag2 Sensors and xTag Displays used for the monitoring of temperature in areas where active pharmaceutical ingredients (API), drug products, and medical devices are stored at Methapharm.
- 2.3 Products must be transported, handled and stored in a manner that mitigates the risk of exposure to temperatures outside labelled storage conditions; potentially impacting the safety, quality and effectiveness of the product.

 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 2 of 16

2.4 Temperature excursions outside of labelled storage conditions, may be acceptable provided stability data and scientific/technical justification exist demonstrating that product quality is not affected during the time period of the excursion.

2.5 For API, drug products, and medical devices which are distributed by Methapharm, but which are received and stored at a third-party logistics provider (3PL), the 3PL will follow their own internal procedures for temperature monitoring during storage and transportation. In addition, the 3PL is bound by the conditions of the Quality Agreement in place between the two companies regarding the temperature monitoring of Methapharm products during storage and transportation and the reporting of temperature excursions.

3.0 Responsibility

3.1 It is the responsibility of all Methapharm employees involved in warehouse activities to read, understand and follow this procedure.


3.2 It is the responsibility of the Operations Department to ensure all data loggers used in the warehouse are calibrated and used within their calibration period, and for managing records generated from the data loggers.

4.0 References and Related SOPs

GUI-0069 – Guidelines for environmental control of drugs during storage and transportation
QS-013 - Receiving Goods
QS-015 – Deviations and Non-conformances
QS-020 – Record Retention Requirements
QS-039 – Vendor Management

5.0 Forms/Attachments

Attachment QS-004-1 – Data Logger Locations in Warehouse
Form QS-004-2 – Maintenance Log
Form QS-004-3 - Annual Calibration Log – Warehouse Temperature Monitoring Devices
Attachment QS-004-4 – List of Calibrated Data Loggers
Form QS-004-5 – Evaluation Questionnaire

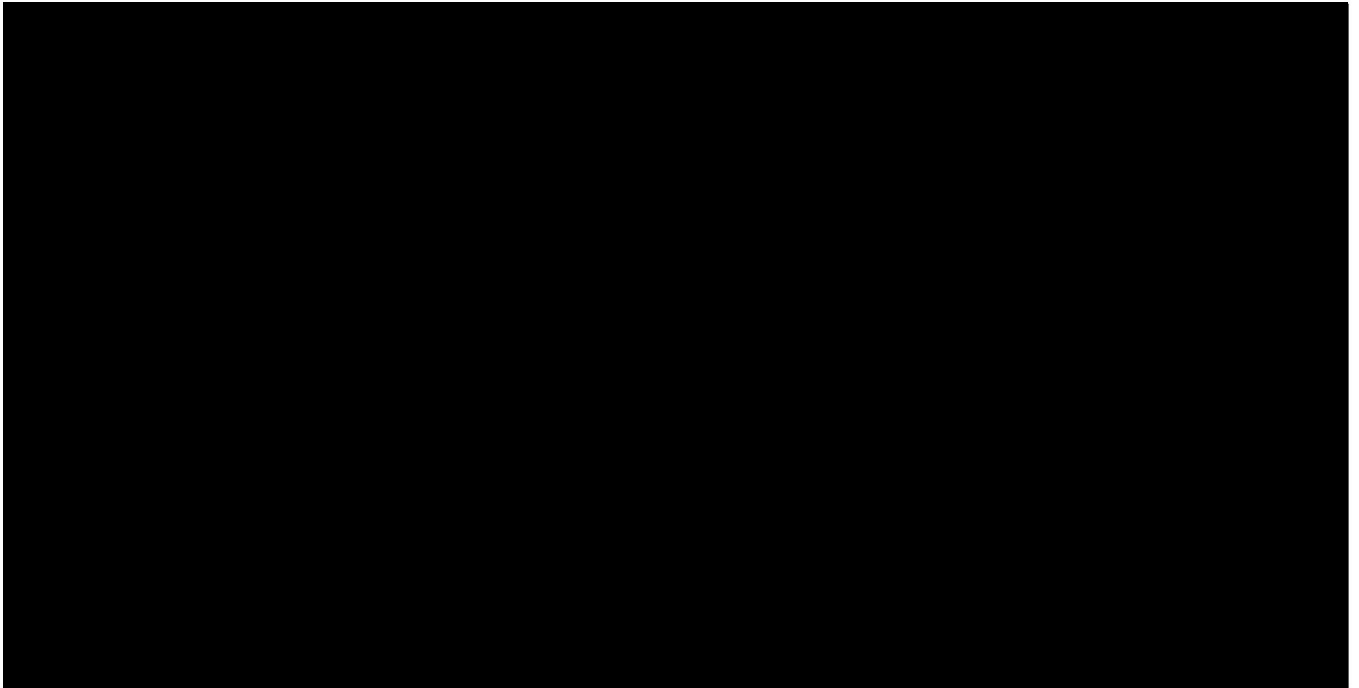
 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 3 1 2022	SOP Number: QS-004.005
		Page 3 of 16

6.0 Definitions


- 6.1 Mirador™ Express Software and Web Portal: A web-based application for 24/7, real-time monitoring of temperature by Cryopak Validation Technologies (CVT). xTag Sensors are installed in the warehouse to measure temperature and transfer this information via xTag Display to the Mirador Express Server. TCP/IP protocol is used for communication between xTag Displays and the Mirador Express Server. The Mirador Server is a remote hosted solution (SaaS). The Web Portal is the main interface that shows the sensor (xTag Sensor) locations and real-time temperature readings received from sensors.
- 6.2 Temperature Data Logger or Temperature Sensor: A device that continuously measures the temperature of an area. Note that Data Logger and Sensor are used interchangeably within this SOP.
- 6.3 Temperature Excursion: A variance outside of the labelled storage condition of a product or outside of the 'normal' operating conditions of the warehouse. A temperature excursion can occur during storage and/or transportation.

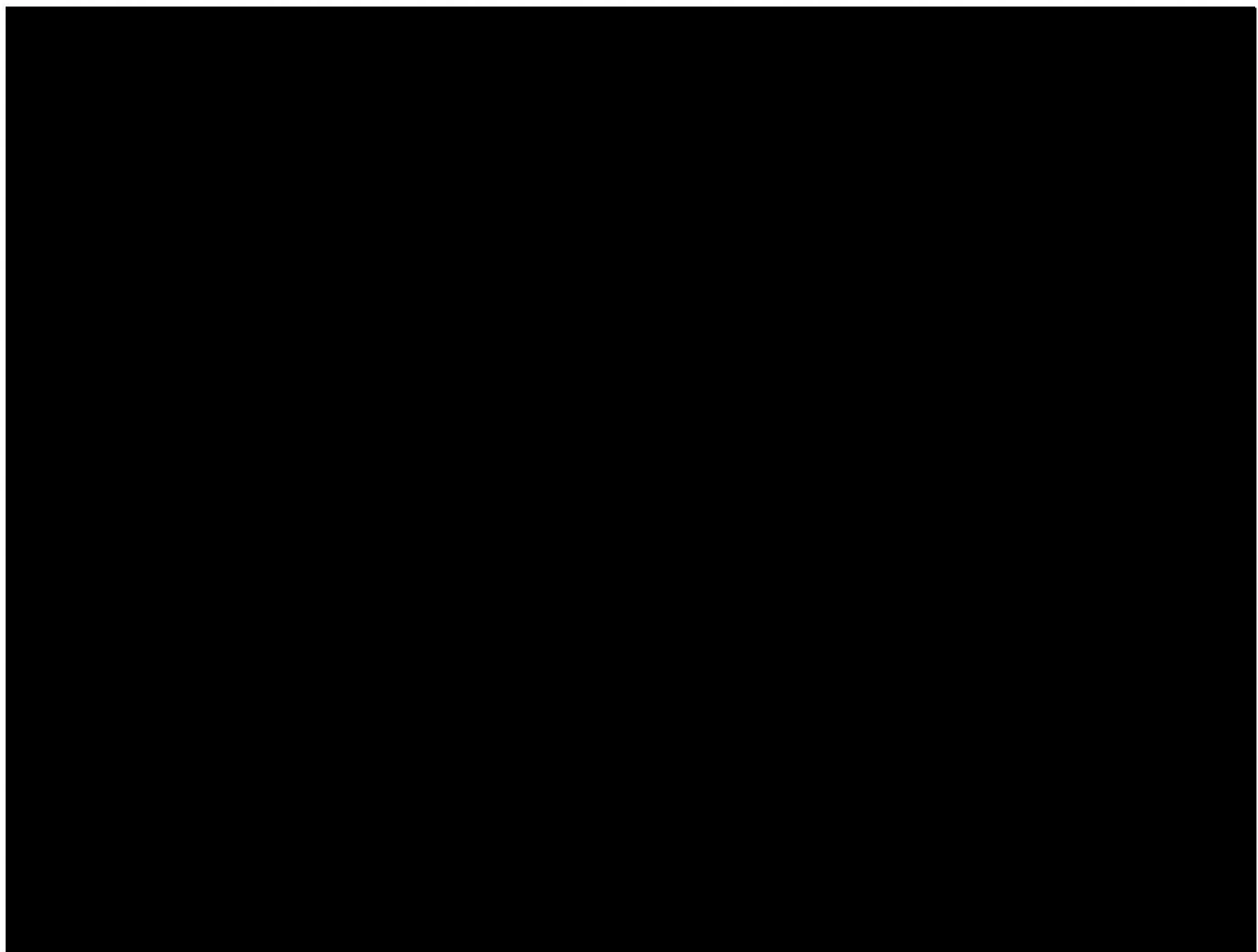
7.0 Procedure

7.1 Daily Monitoring of Temperature in the Warehouse

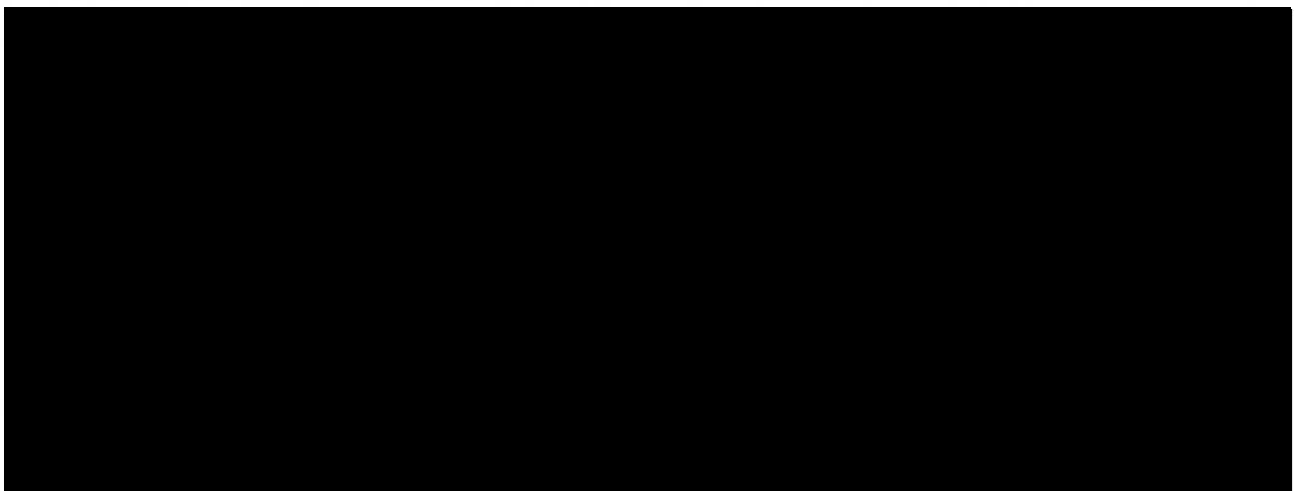


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 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 3 1 2022	SOP Number: QS-004.005
		Page 4 of 16

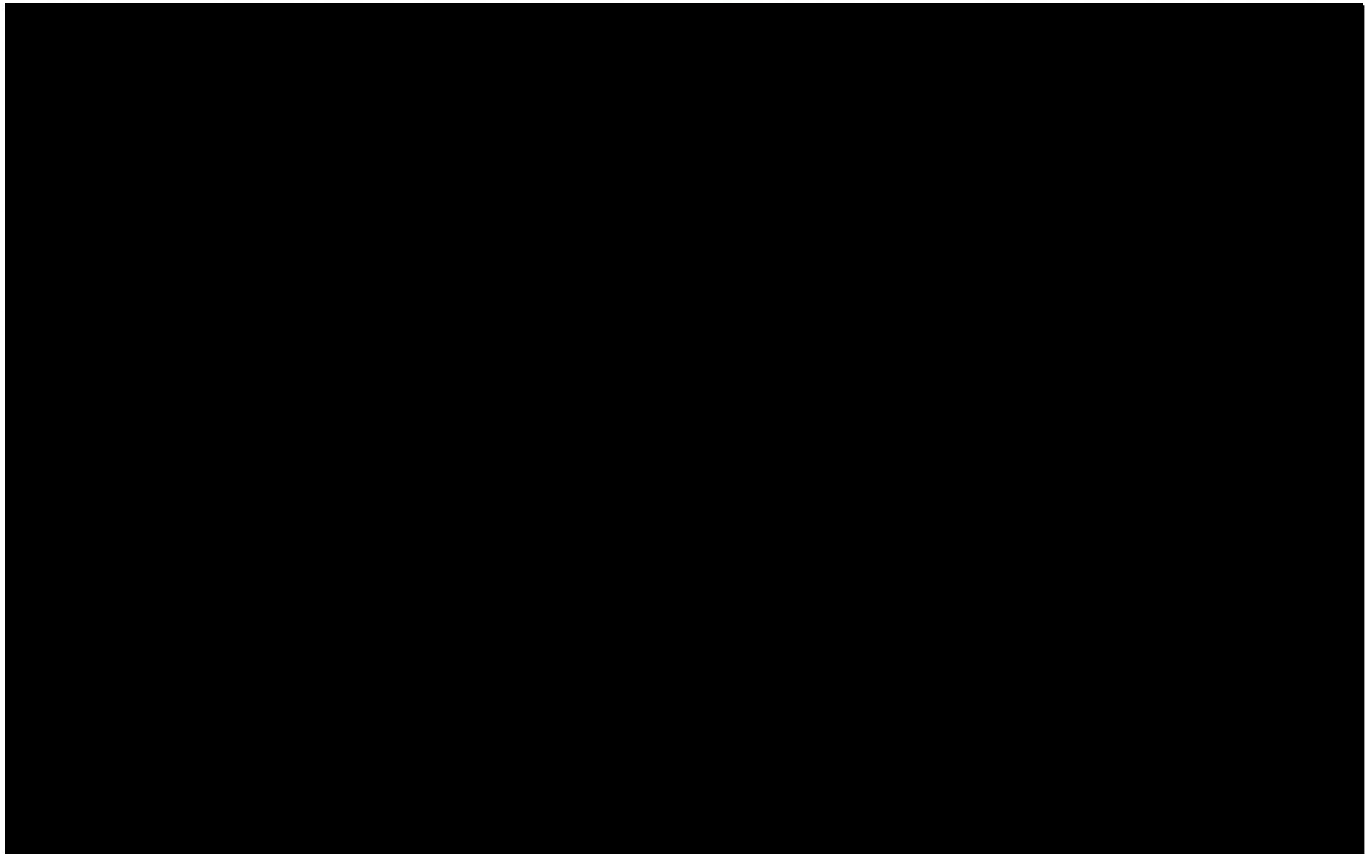


7.2 xTag2 Sensors and xTag Display

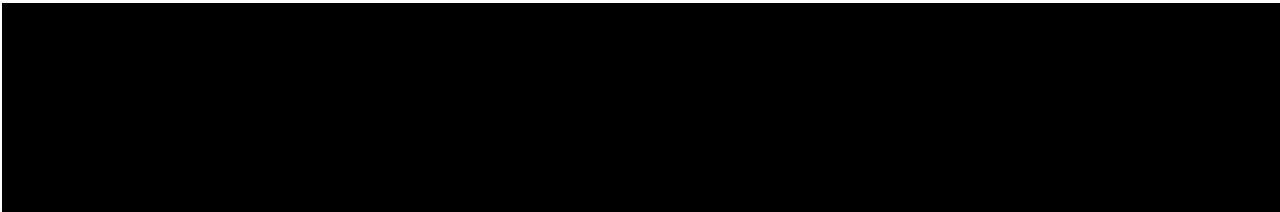


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 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 3 1 2022	SOP Number: QS-004.005 Page 5 of 16



7.3 Mirador Express Software



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Standard Operating Procedure

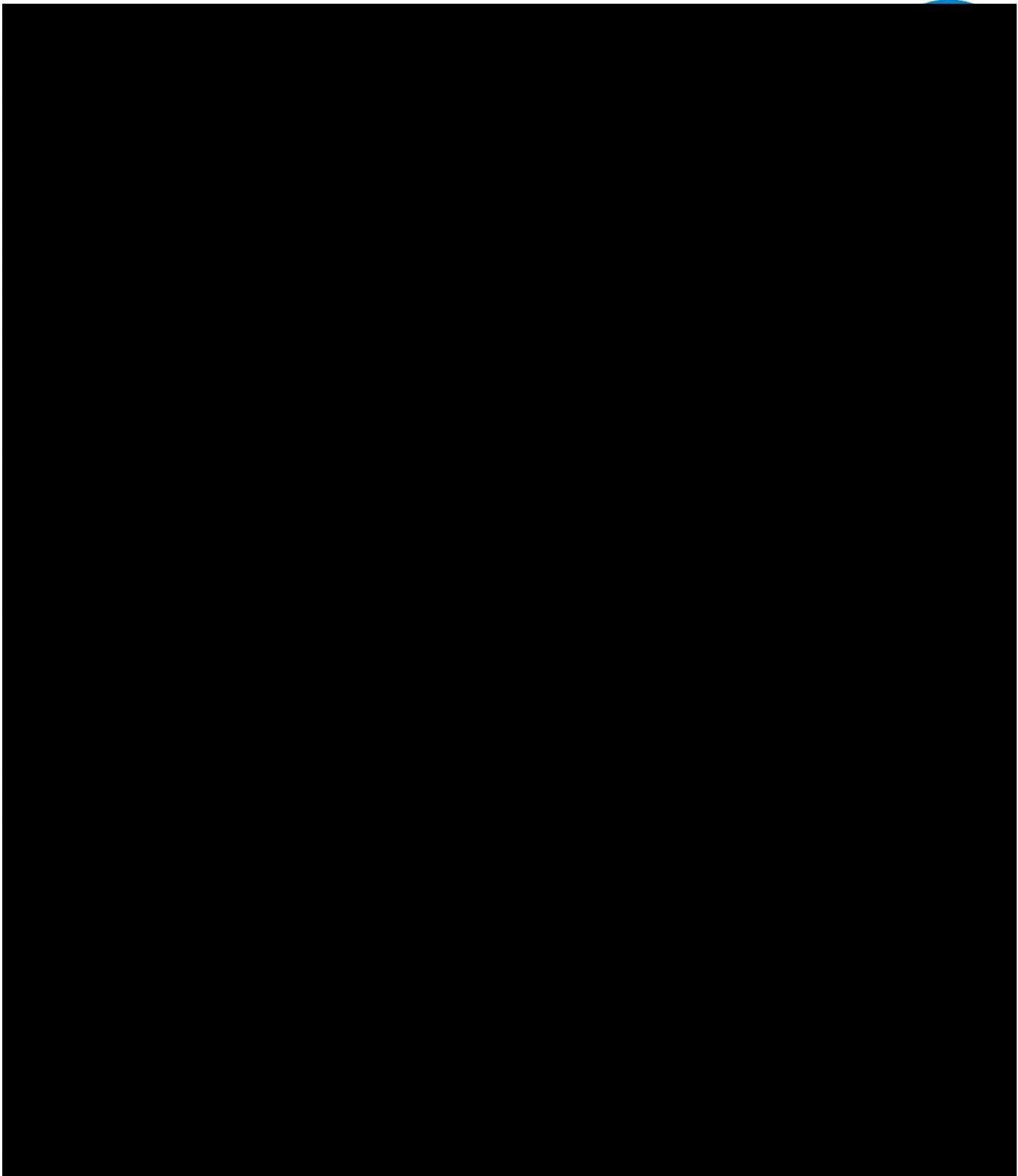
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**Temperature Monitoring
During Storage and
Transportation**

Effective Date: **AUG 3 1 2022**


Section: Operations

SOP Number: QS-004.005

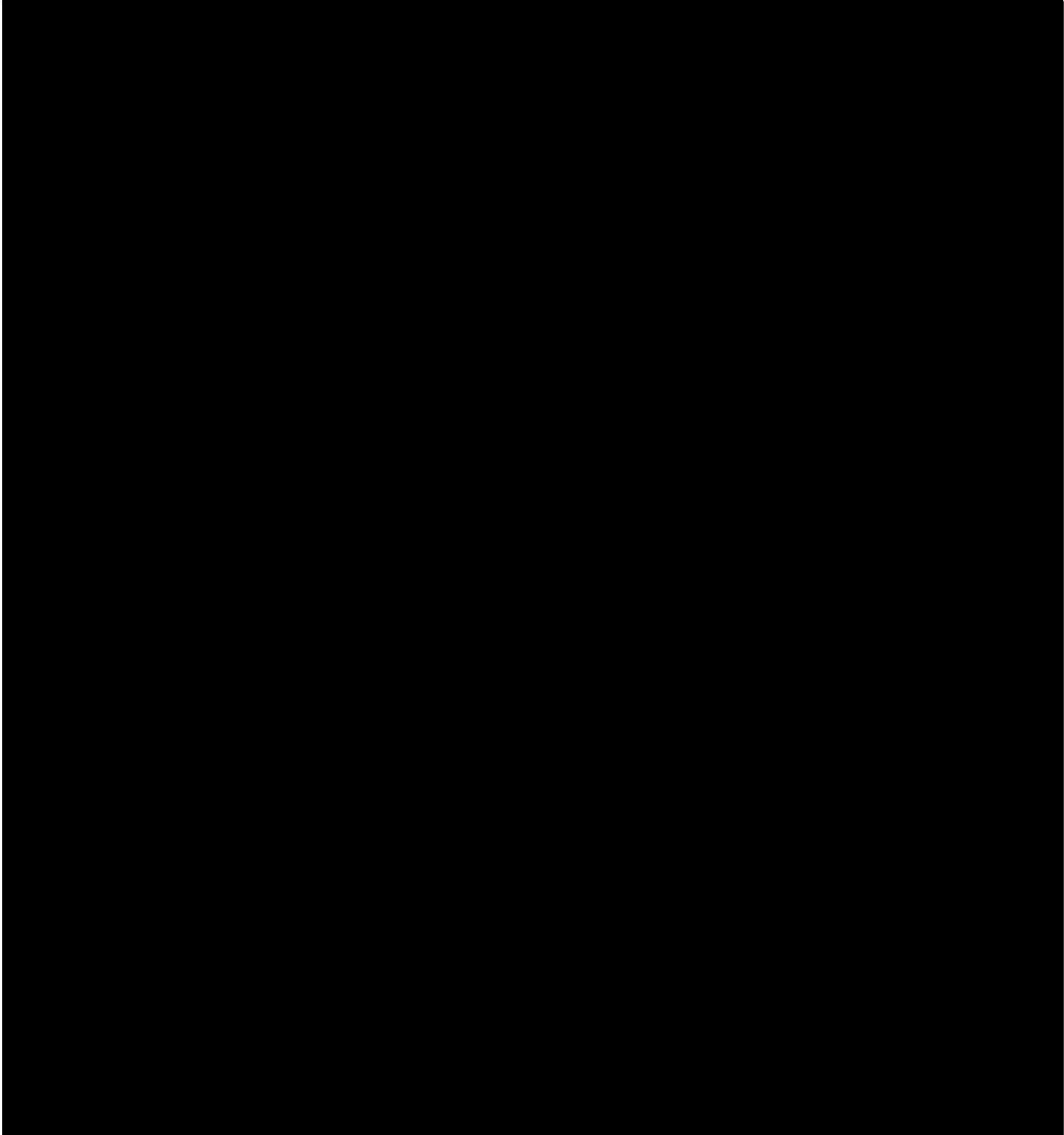
Page **6** of **16**




Confidential Trade Secrets

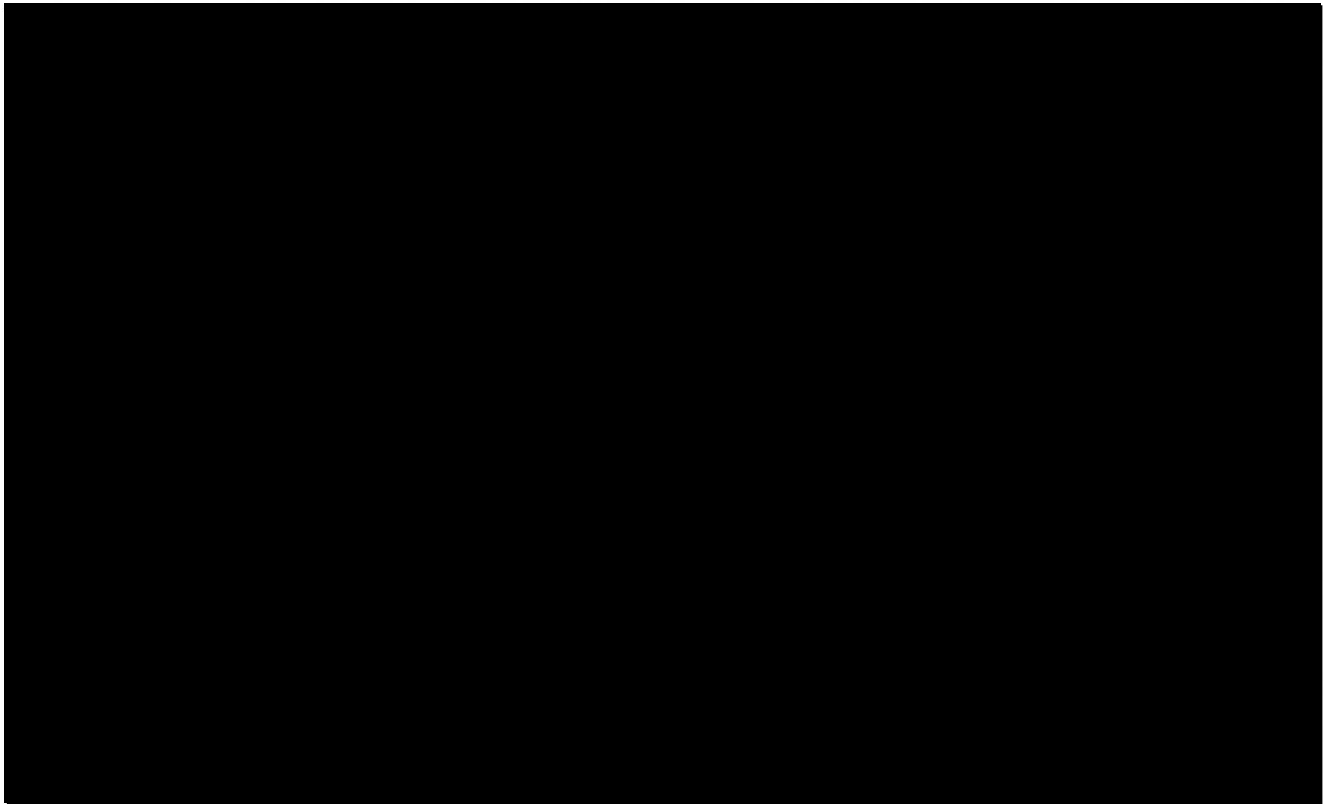
 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
		SOP Number: QS-004.005
	Effective Date: AUG 3 1 2022	Page 7 of 16

7.3.4 How to Run a Report in the Web Portal

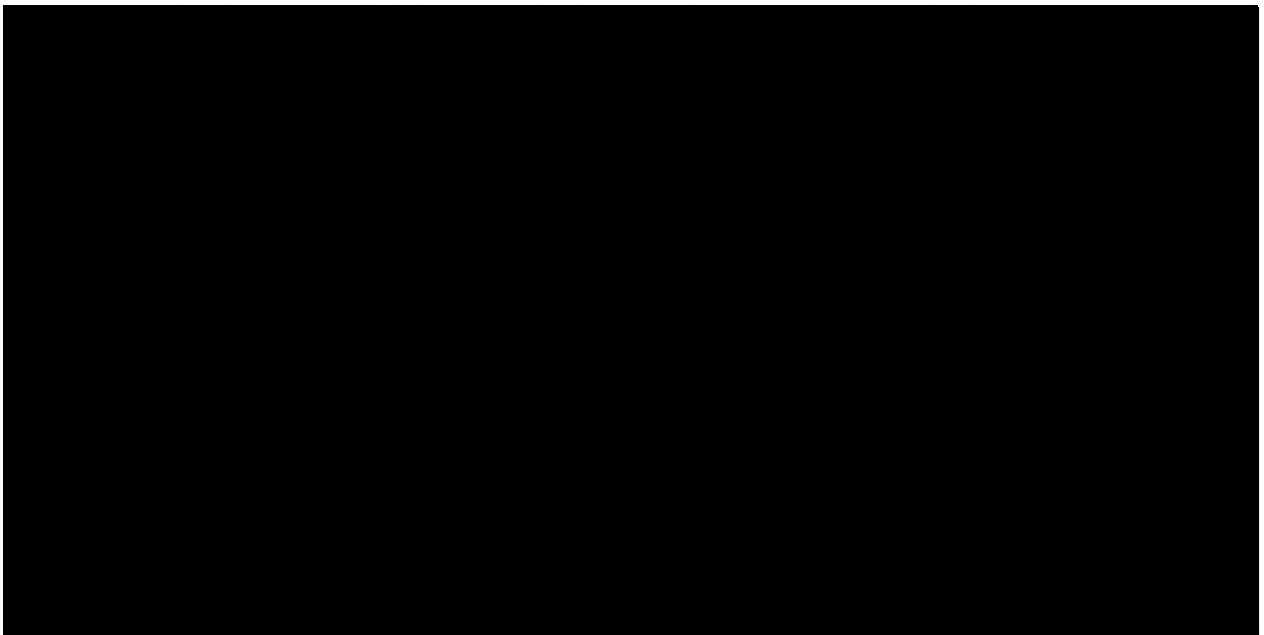


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 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 8 of 16



7.4 Alarms from Mirador Express Software



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Standard Operating Procedure

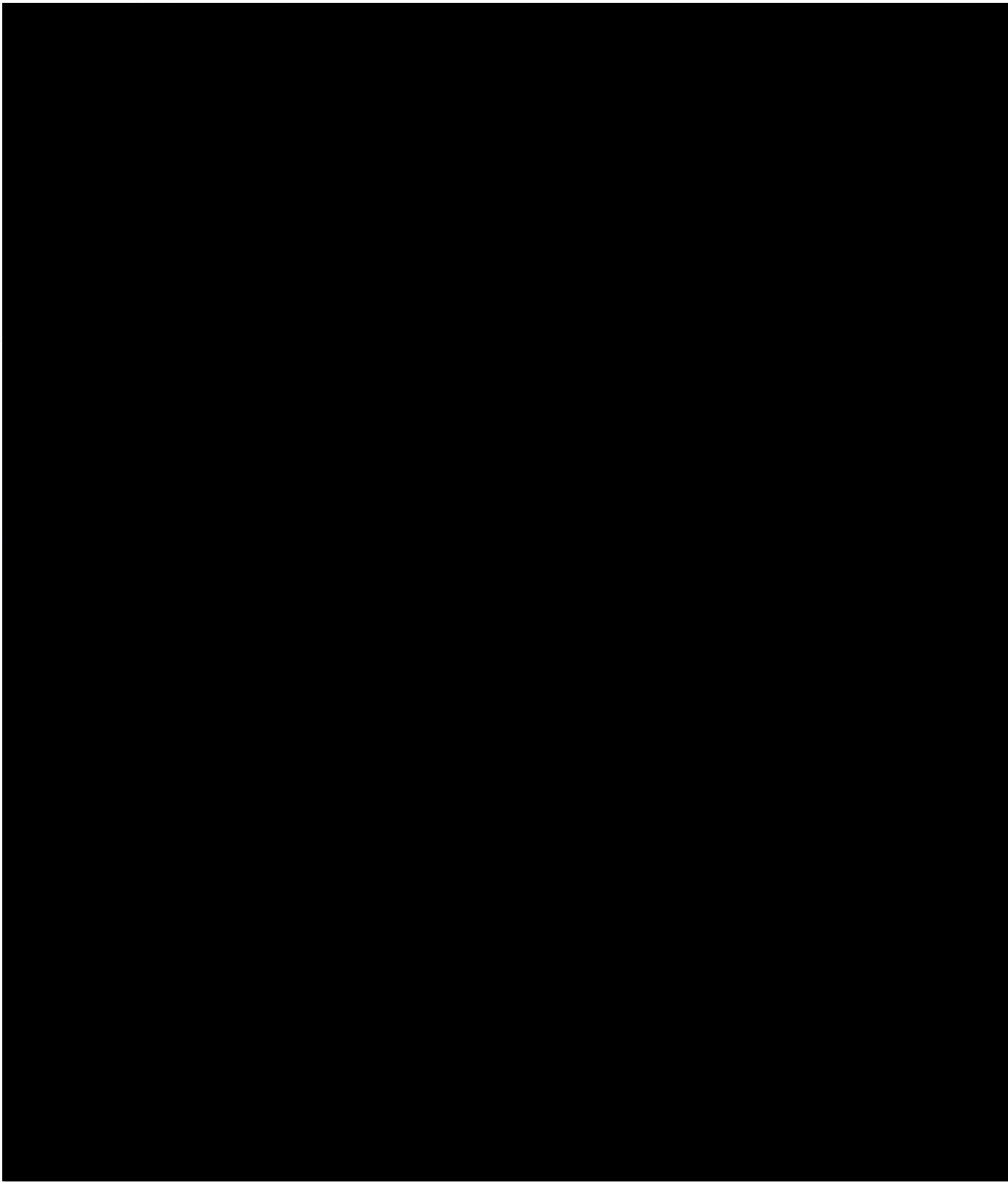
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**Temperature Monitoring
During Storage and
Transportation**

Effective Date: **AUG 3 1 2022**

Section: Operations

SOP Number: QS-004.005

Page **9** of **16**



Confidential Trade Secrets



Standard Operating Procedure

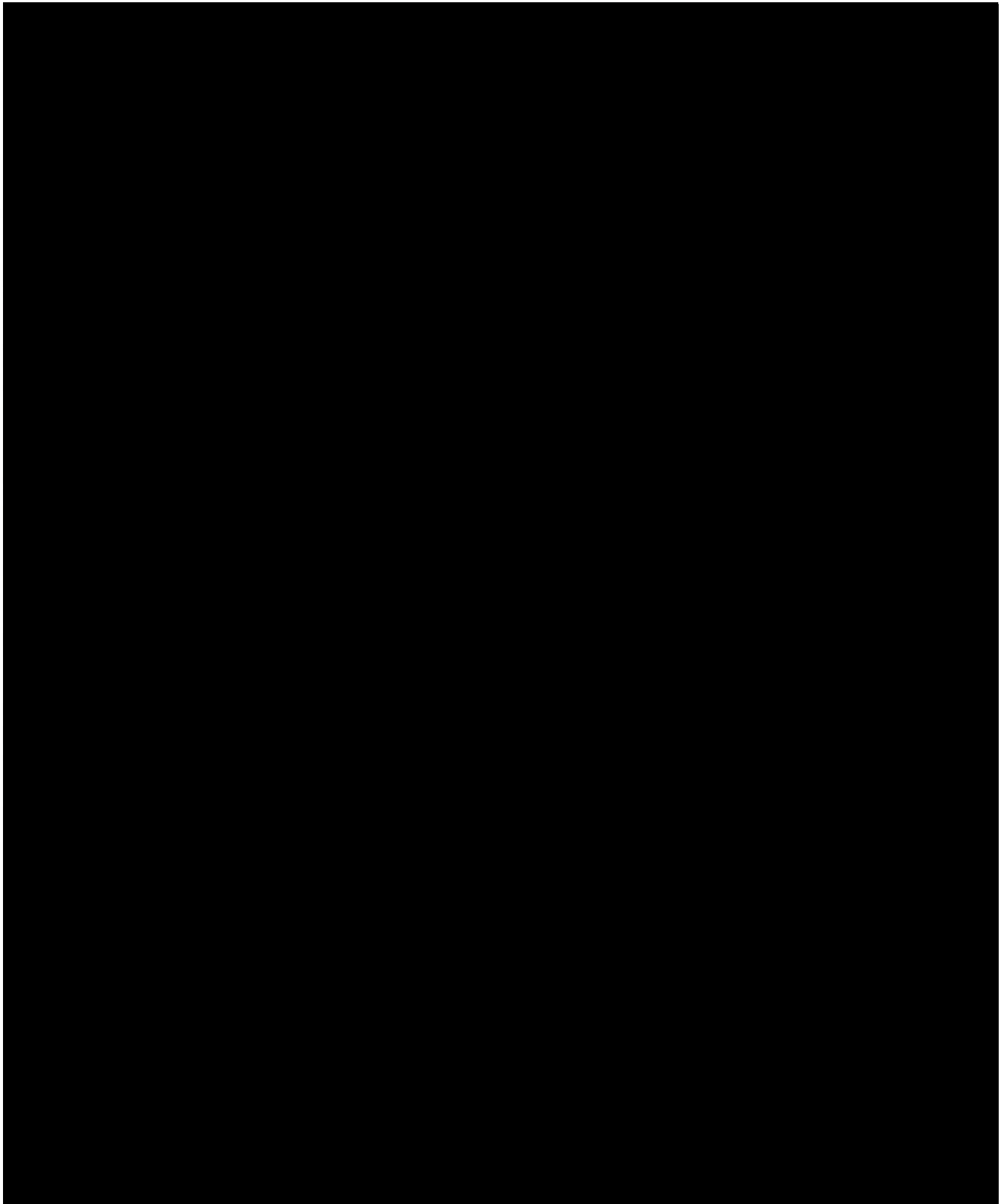
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**Temperature Monitoring
During Storage and
Transportation**

Effective Date: **AUG 31 2022**

Section: Operations

SOP Number: QS-004.005

Page **10** of **16**



Confidential Trade Secrets



Standard Operating Procedure

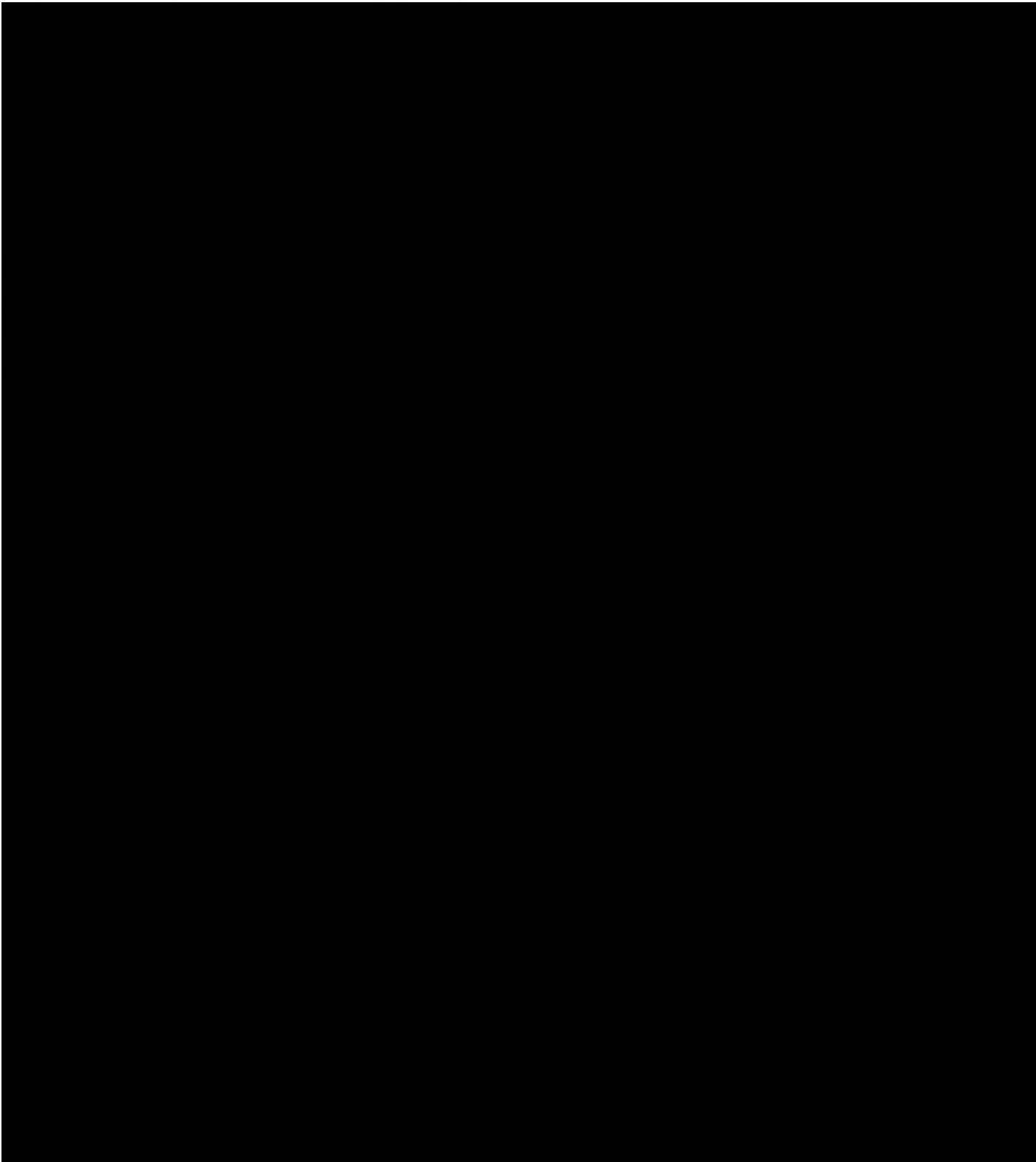
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**Temperature Monitoring
During Storage and
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Effective Date: AUG 31 2022


Section: Operations

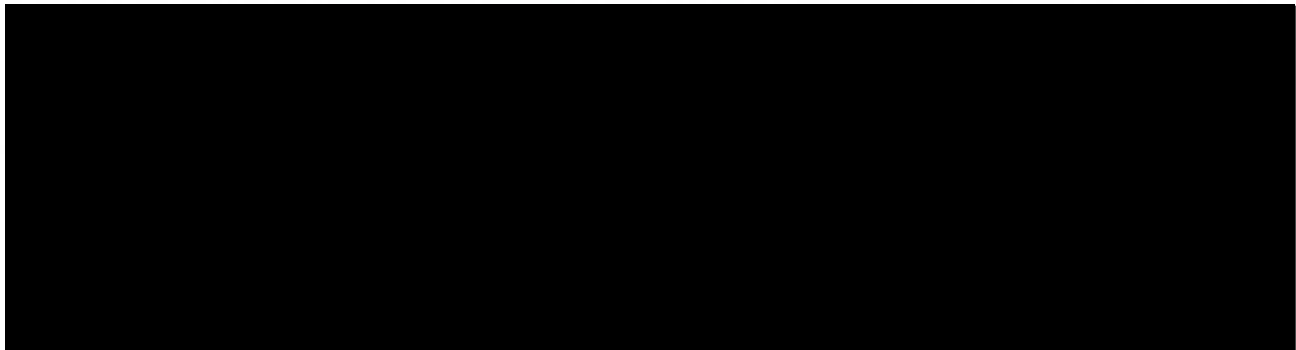
SOP Number: QS-004.005

Page **11** of **16**

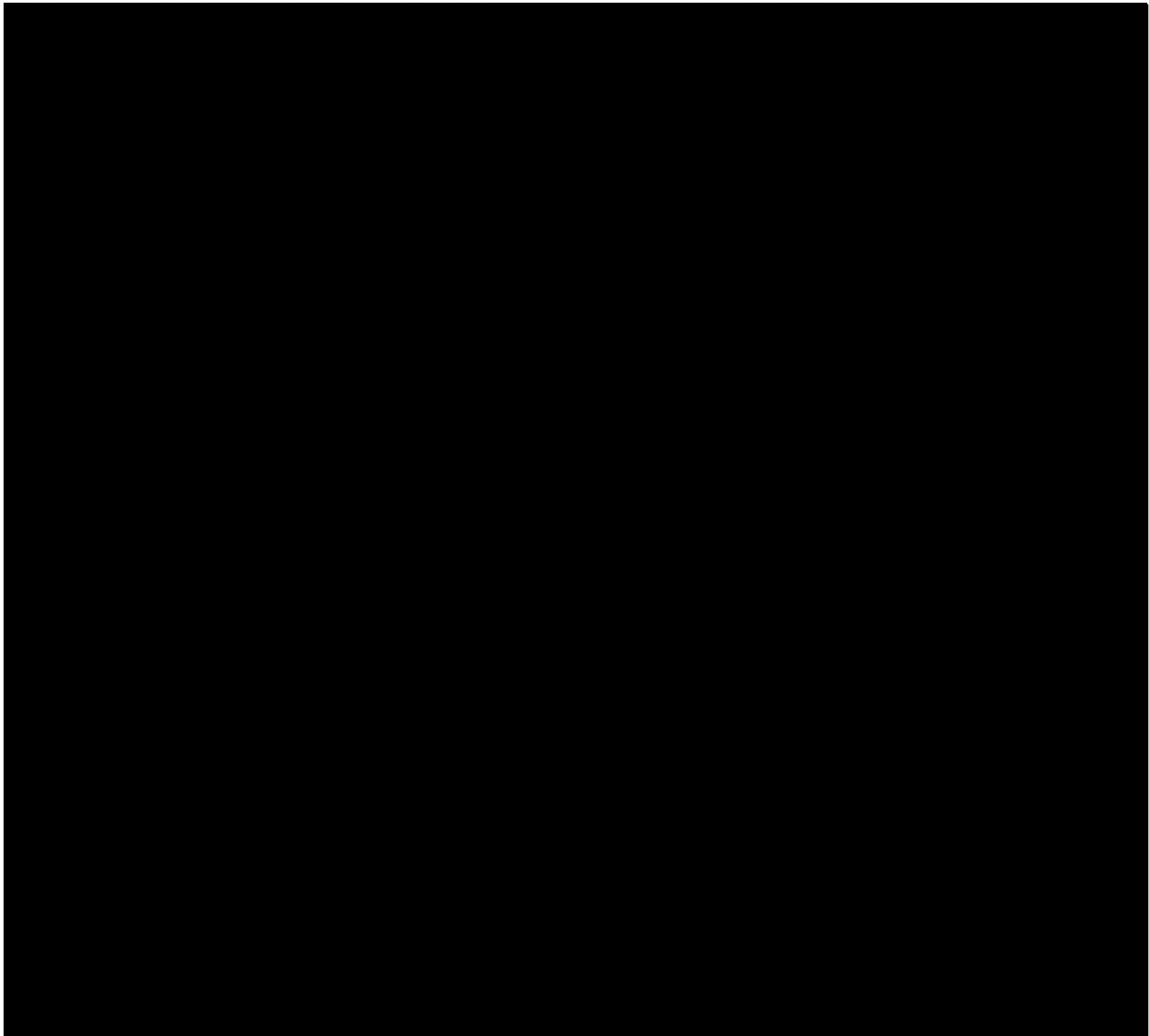


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 Standard Operating Procedure	Title: Temperature Monitoring During Storage and Transportation	Section: Operations
	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 12 of 16



7.5 Calibration and Maintenance of Data Loggers and IR Thermometer



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Standard Operating Procedure

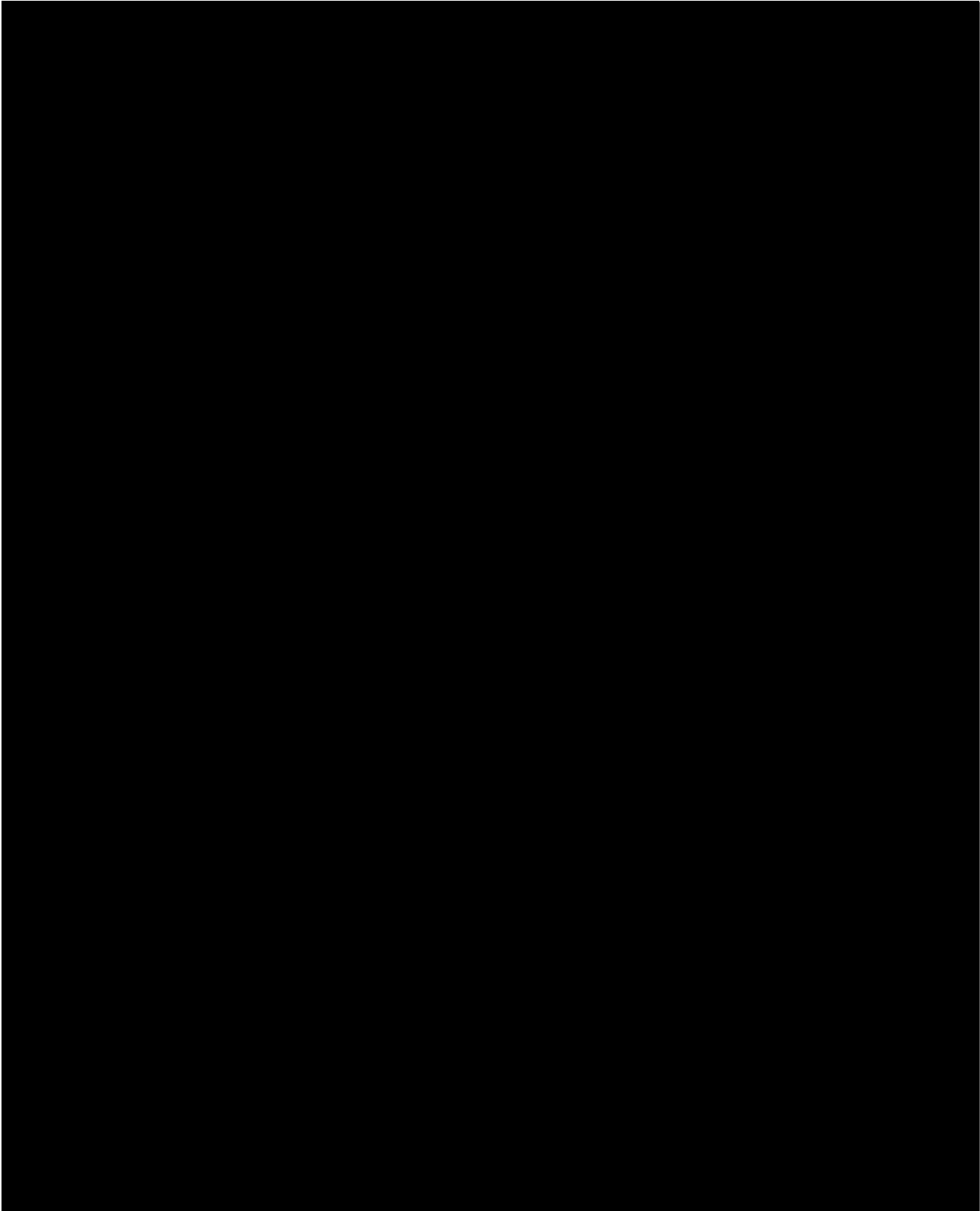
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**Temperature Monitoring
During Storage and
Transportation**

Effective Date: **AUG 3 1 2022**


Section: Operations

SOP Number: QS-004.005

Page **13** of **16**

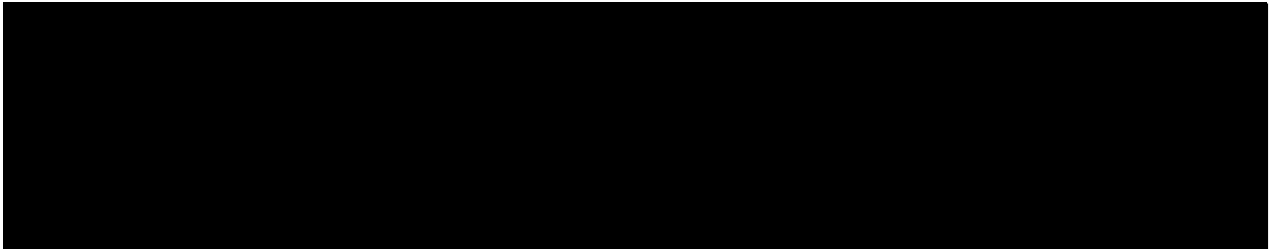


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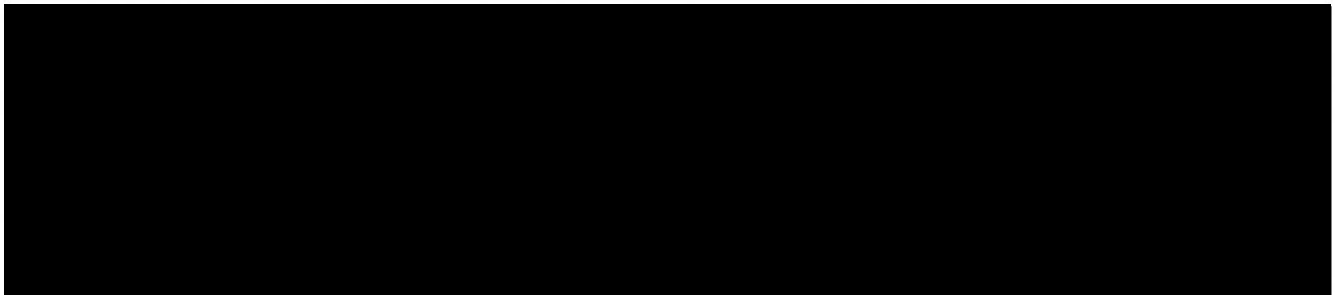
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	Effective Date: AUG 3 1 2022	SOP Number: QS-004.005
		Page 14 of 16



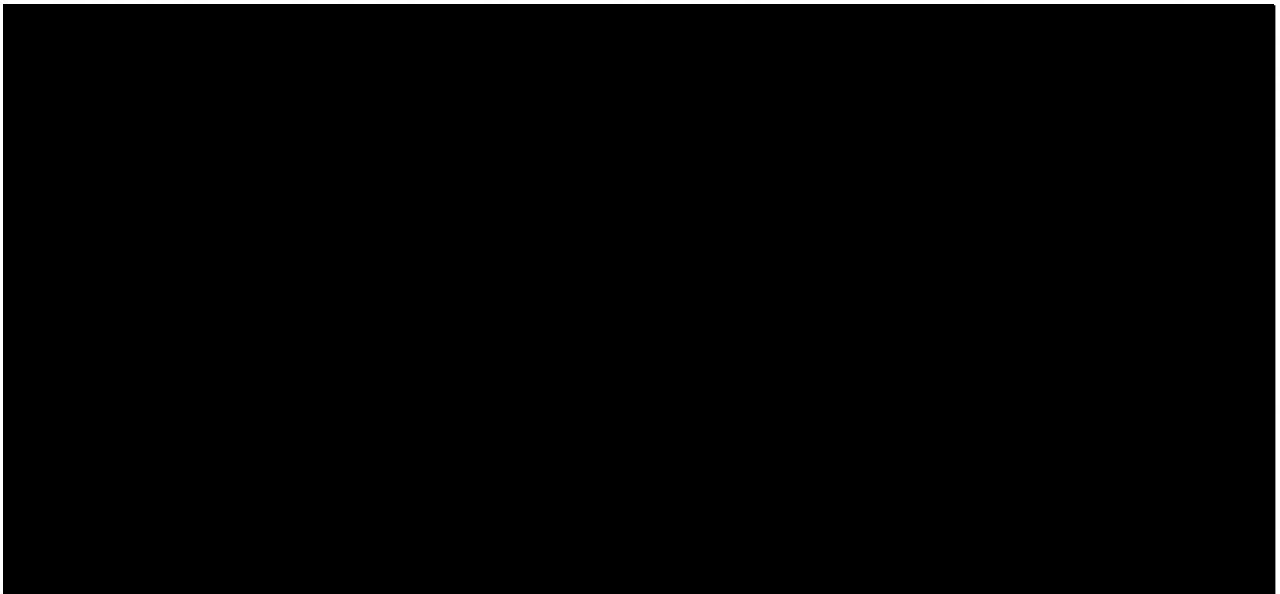
7.6 While the Data Loggers are out for Calibration




7.7 Challenging the Data Loggers Alarms

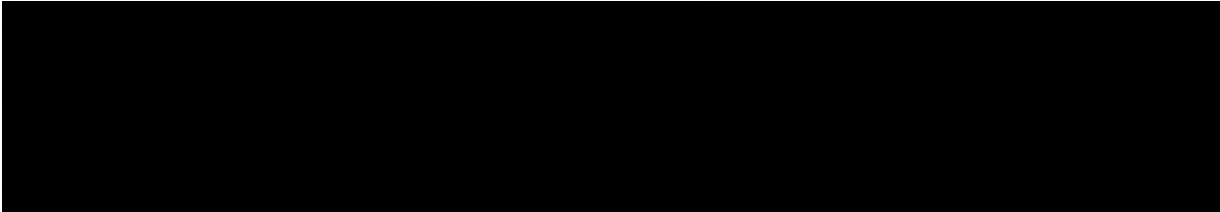


7.8 Temperature Monitoring During Transportation

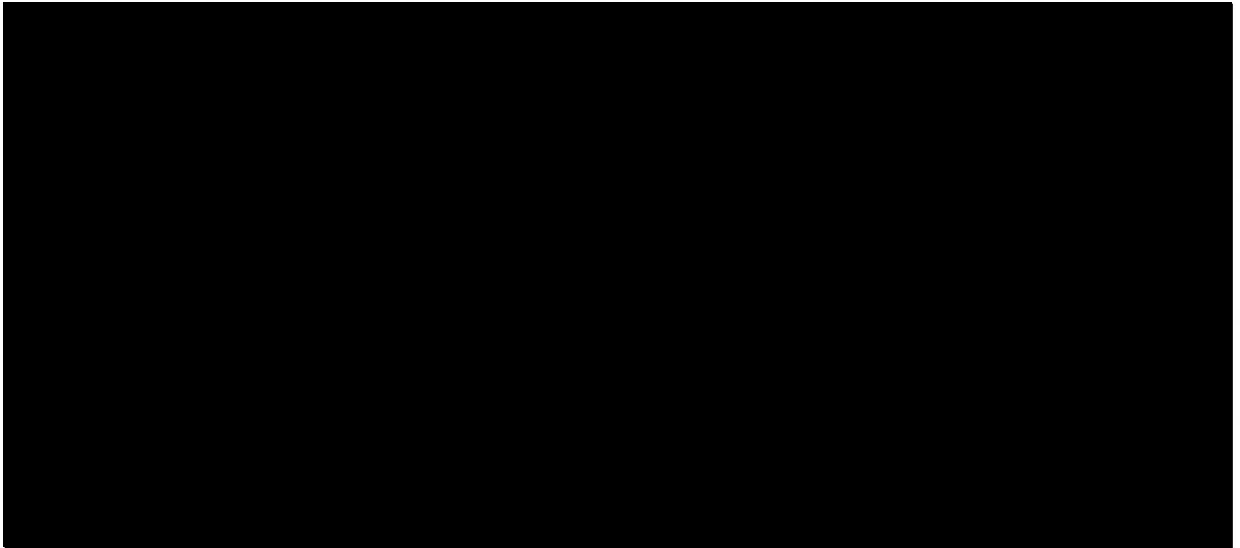


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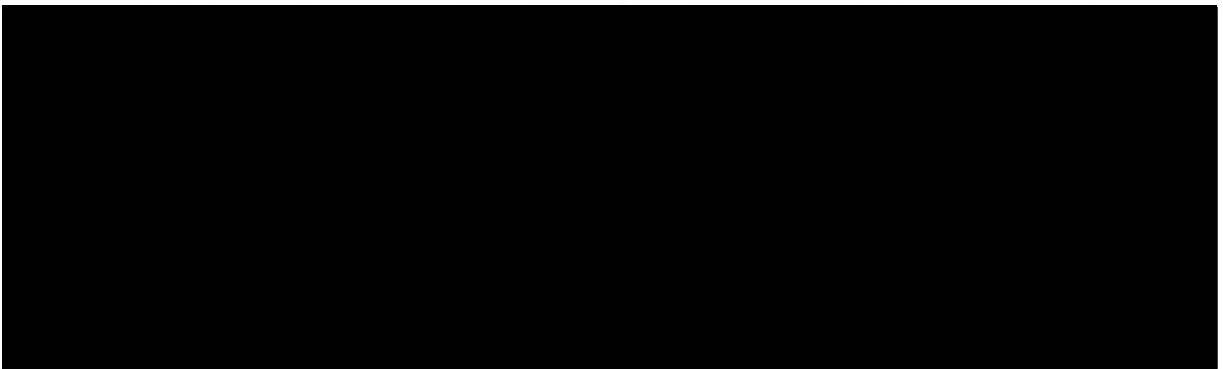
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	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 15 of 16



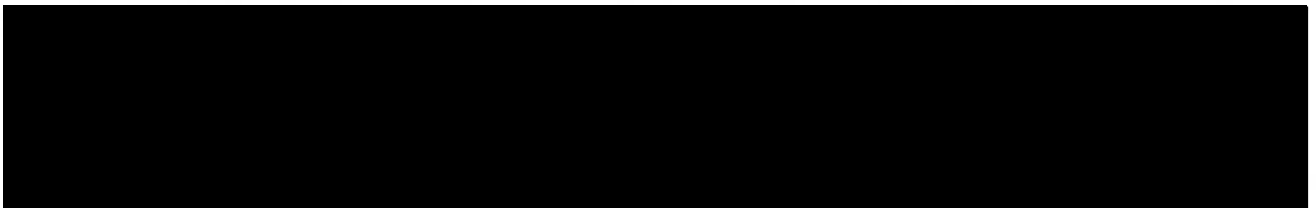
7.9 Reporting Deviations




7.10 Thirty Party Logistics Provider (3PL)



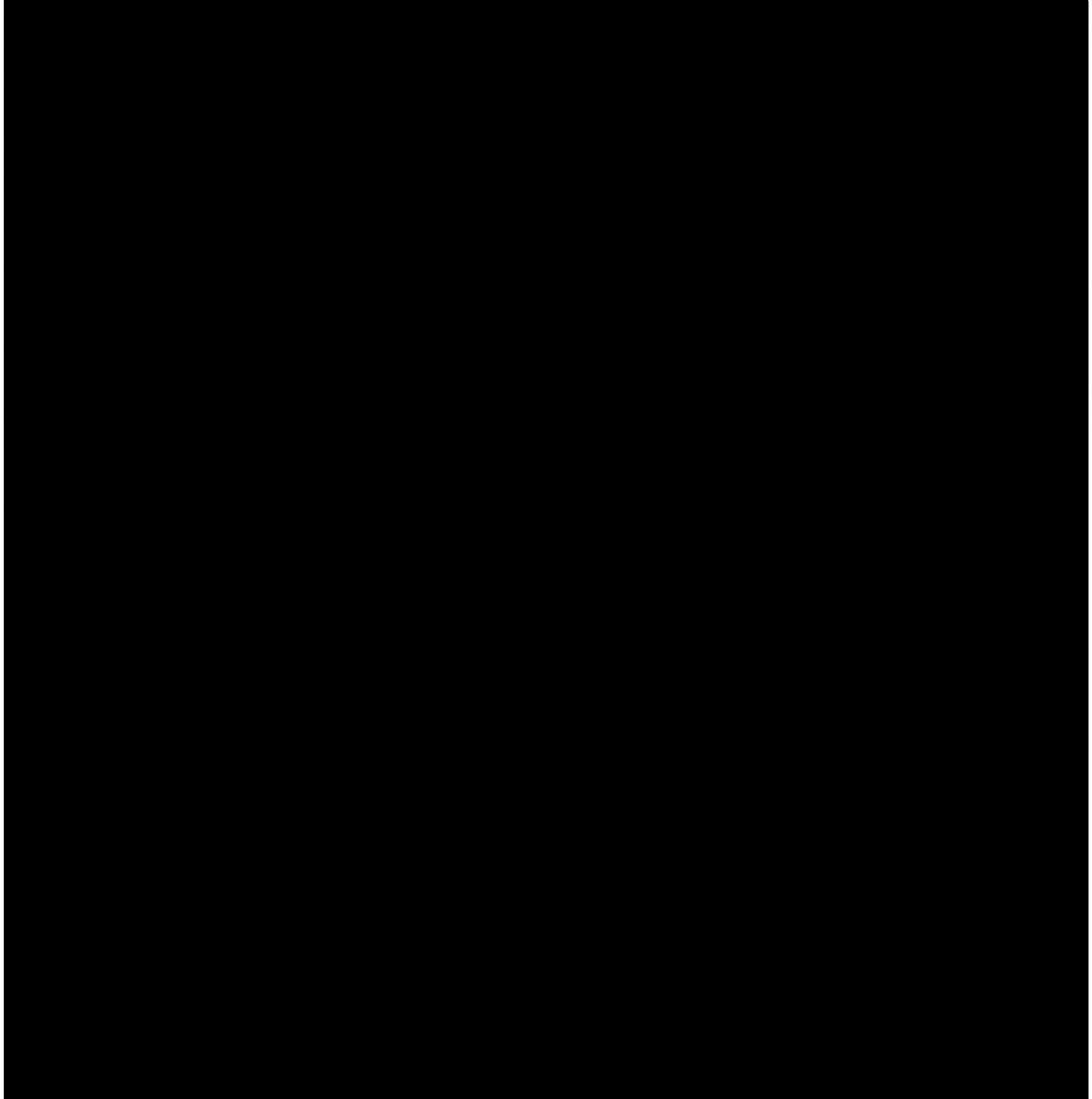
8.0 Records







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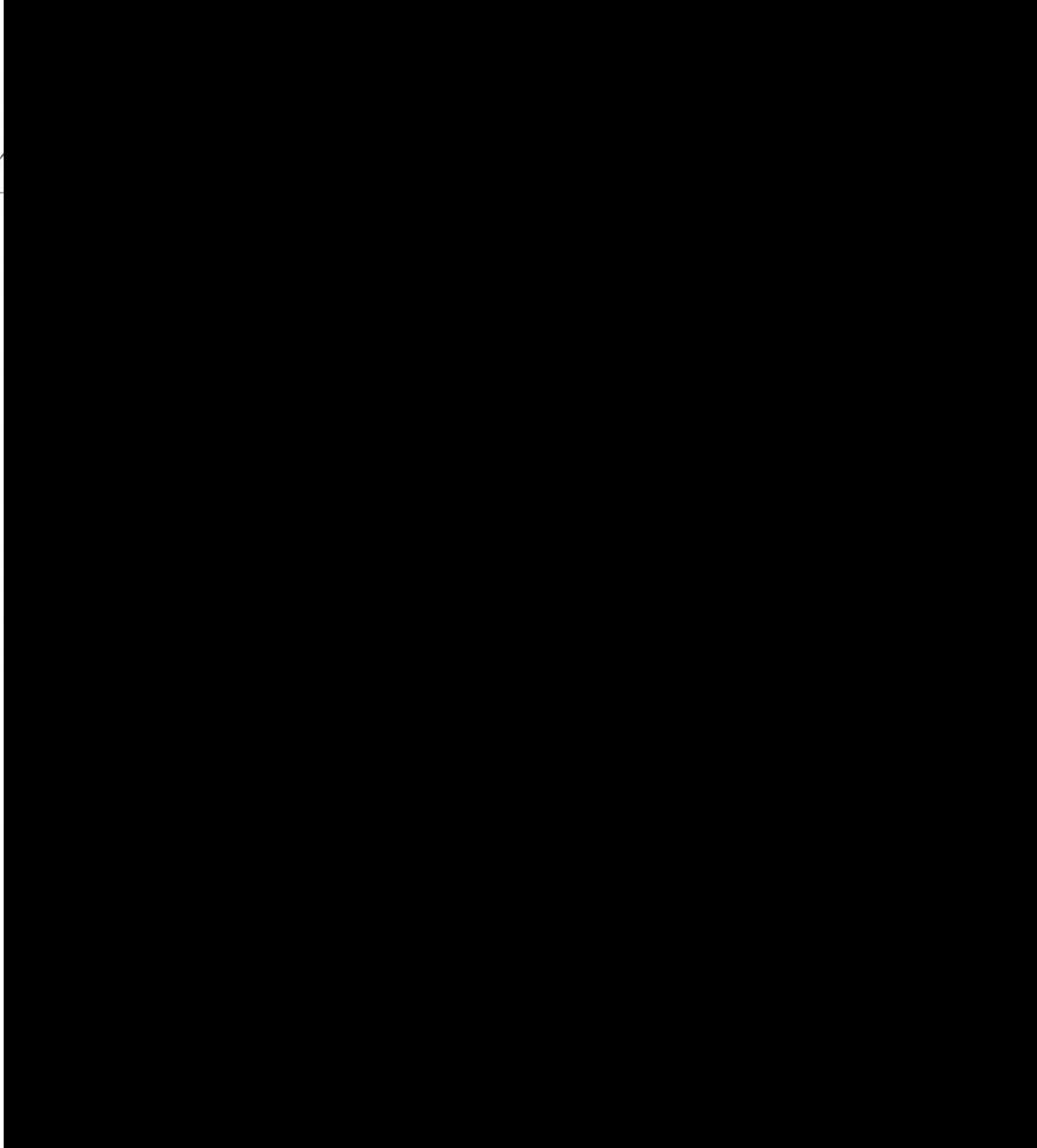
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	Effective Date: AUG 31 2022	SOP Number: QS-004.005
		Page 16 of 16

9.0 Revision History



Confidential Trade Secrets

	Title: Data Logger Locations in Warehouse	Attachment QS-004-1.005
	Effective Date: AUG 31 2022	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Aug 10, 2022	Date: 10-AUG-2022	Date: aug 10. 2022



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



Title: **Maintenance Log**

Form QS-004-2.005

Effective Date: **AUG 3 1 2022**

Page **1** of **1**

Prepared By: 

Reviewed By: 

Approved By: 

Date:

AUG. 10, 2022

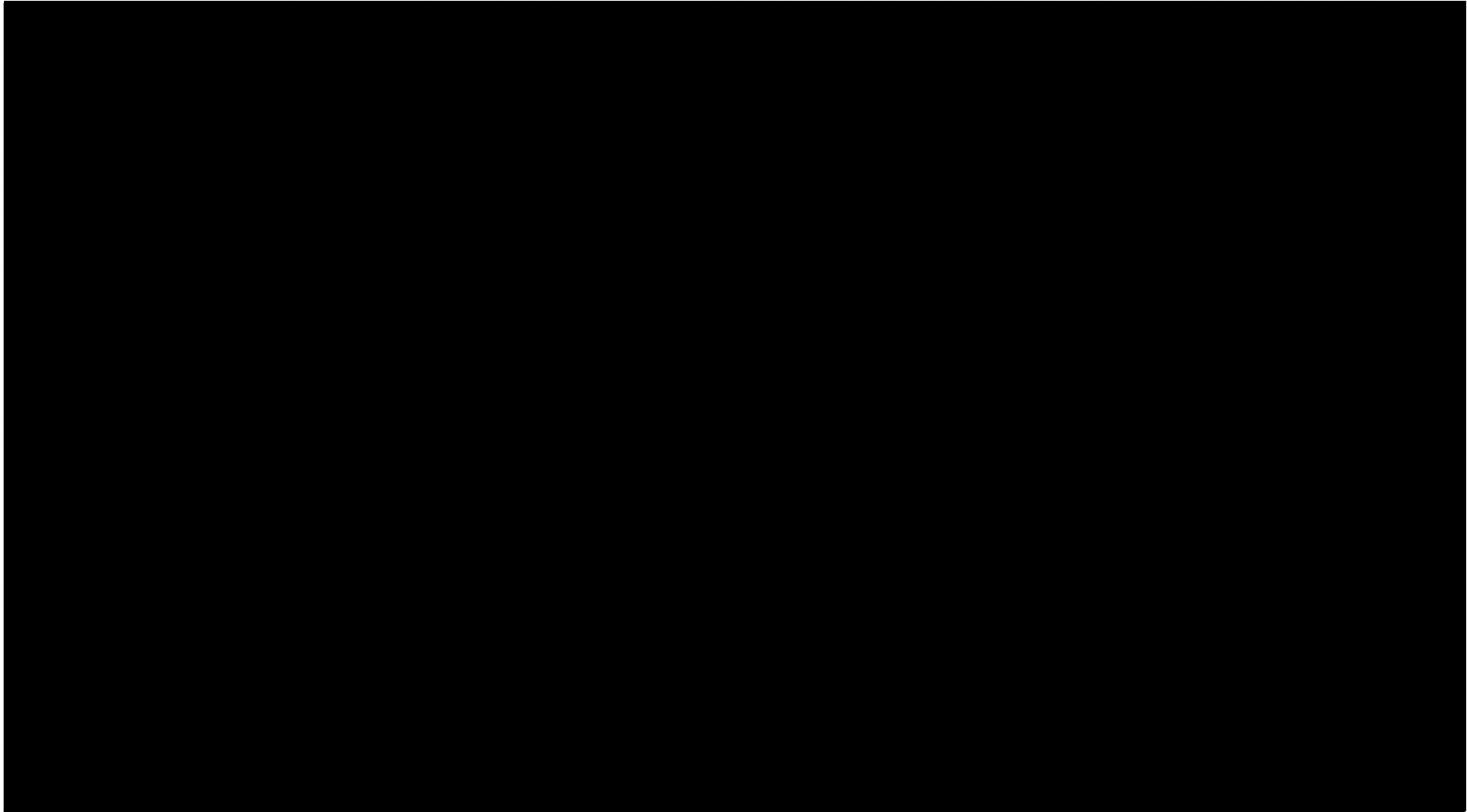
Date:

10 - AUG - 2022

Date:

aug 10. 2022

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Title: Annual Calibration Log -
Warehouse Temperature
Monitoring Devices

Form QS-004-3.005

Effective Date: AUG 3 1 2022

Page 1 of 1

Prepared By:

Reviewed By:

Approved By:

Date:

AUG. 10, 2022

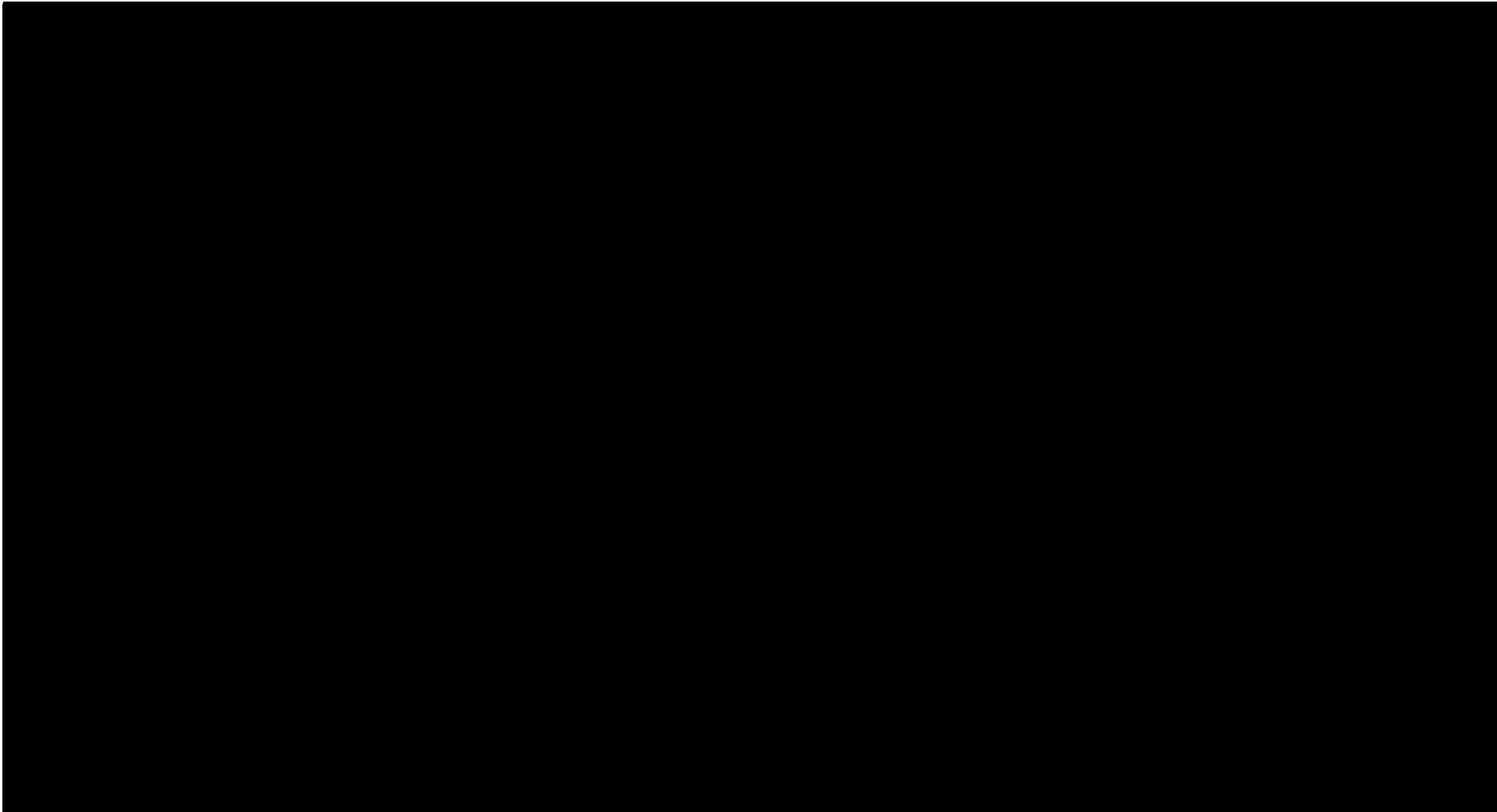
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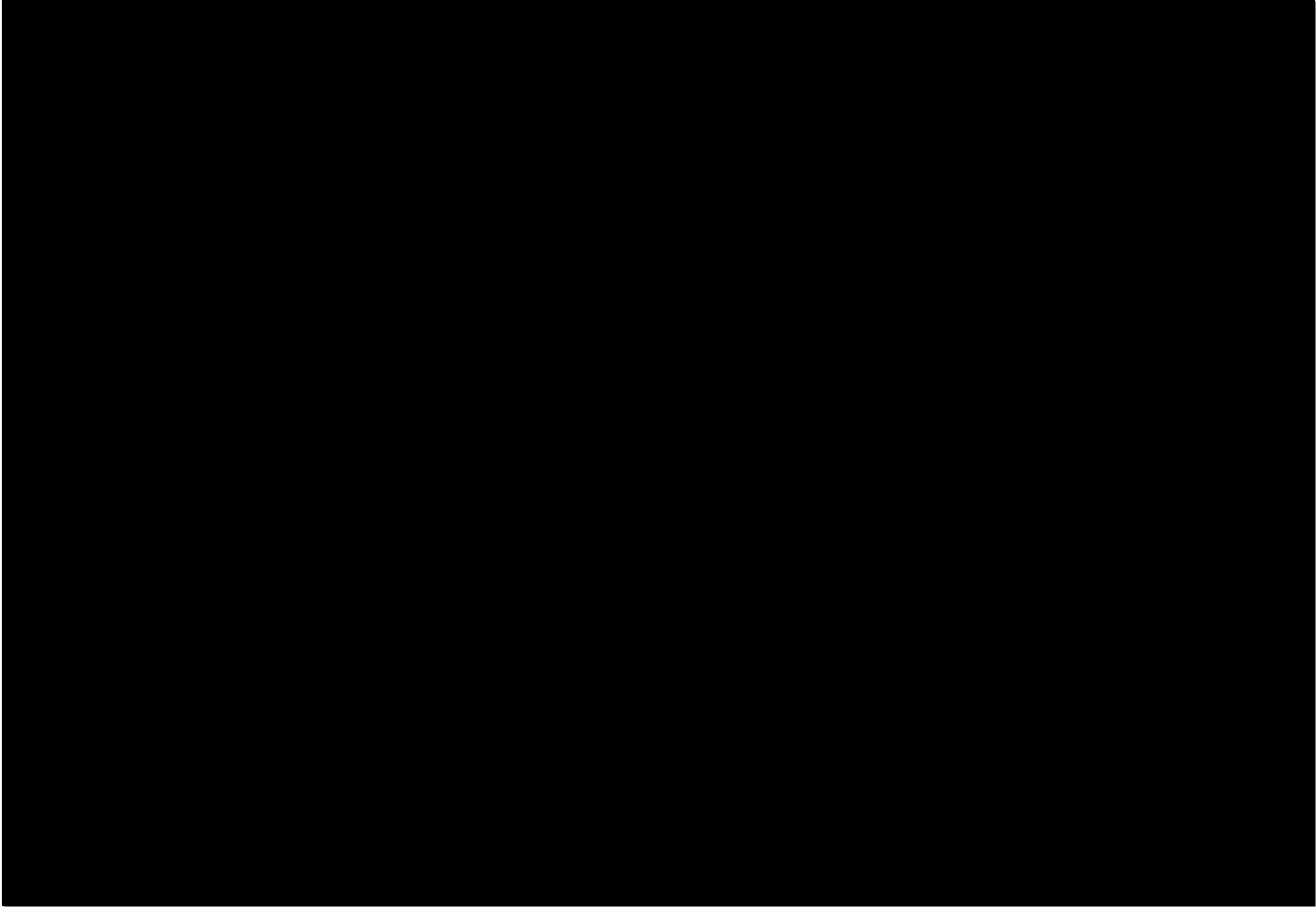
Date:

aug 10. 2022


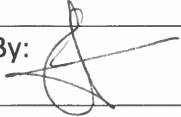
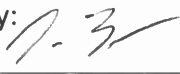

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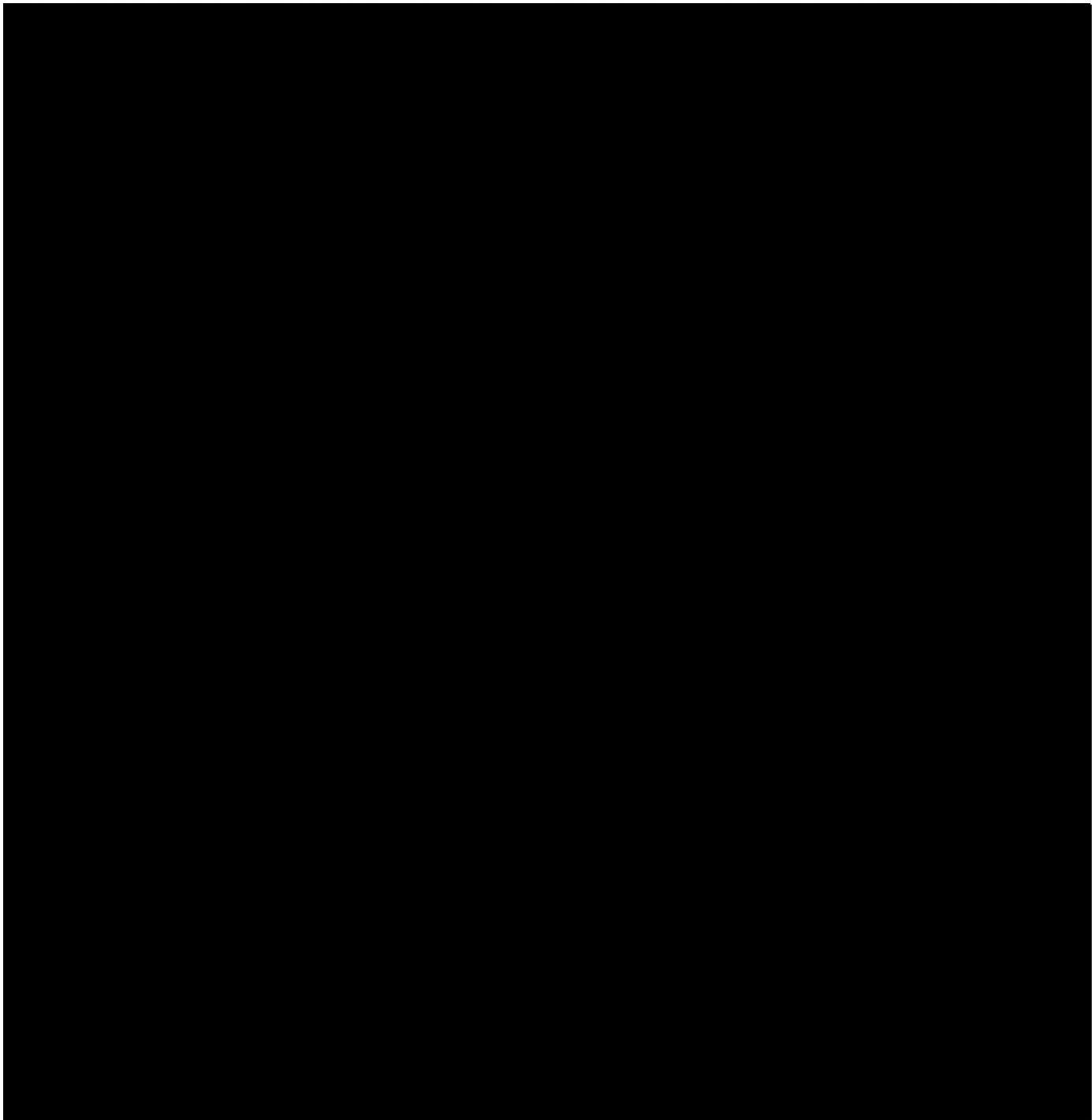


	Title: List of Calibrated Data Loggers	Attachment QS-004-4.005
	Effective Date: AUG 31 2022	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Aug. 10. 2022	Date: 10-AUG-2022	Date: Aug 10. 2022




Confidential Trade Secrets

	Title: Evaluation Questionnaire	Attachment QS-004-5.005
	Effective Date: AUG 31 2022	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Aug. 10 / 2022 .	Date: 10 - AUG - 2022	Date: aug 10. 2022



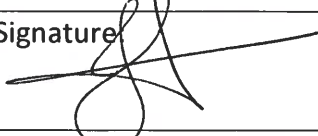


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Exempt from disclosure pursuant to Section 119.0715, F.S.

 Standard Operating Procedure	Title:	Section: Operations
	Sanitation	SOP Number: QS-005.005
	Effective Date: OCT 14 2021	Page 1 of 5

Issued by: Quality Assurance	Copy No.: Electronic Copy
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Note: Not a controlled copy unless the above space is completed in red ink or text.

Prepared by: Operations Administrative Coordinator	Signature: 	Date: Sept. 27/2021
Reviewed by: Department Management	Signature: 	Date: Sept 27, 2021
Approved by: QA Management	Signature: 	Date: Sept 28, 2021

1.0 Purpose

To provide a procedure for the regular sanitation and maintenance of the Methapharm Inc. (Methapharm) Warehouse.

2.0 Scope

- 2.1 This procedure covers the sanitation activities regularly performed by Operations Personnel and Contract Janitorial staff in the warehouse where active pharmaceutical ingredients (API), drug products and/or medical devices are stored.
- 2.2 For any API, drug products and medical devices which are imported, distributed and/or wholesaled by Methapharm, but which are received and stored at a third-party logistics provider (3PL), the 3PL will follow their own internal procedures for sanitation activities.


3.0 Responsibility

- 3.1 It is the responsibility of Operations Personnel and Contract Janitorial staff who have access to the warehouse, to read, understand, and follow this procedure. All activities controlled under this procedure must be documented and verified.
- 3.2 Methapharm QA is responsible for reviewing, signing, and dating completed Sanitation and Floor Washing Logs.

4.0 References and Related SOPs

HPFBI Good Manufacturing Practices (GMP) Guidelines – C.02.007
FDA 21 CFR 211.56
QS-020 – Record Control and Retention

Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Operations
	Sanitation	SOP Number: QS-005.005
	Effective Date: OCT 14 2021	Page 2 of 5

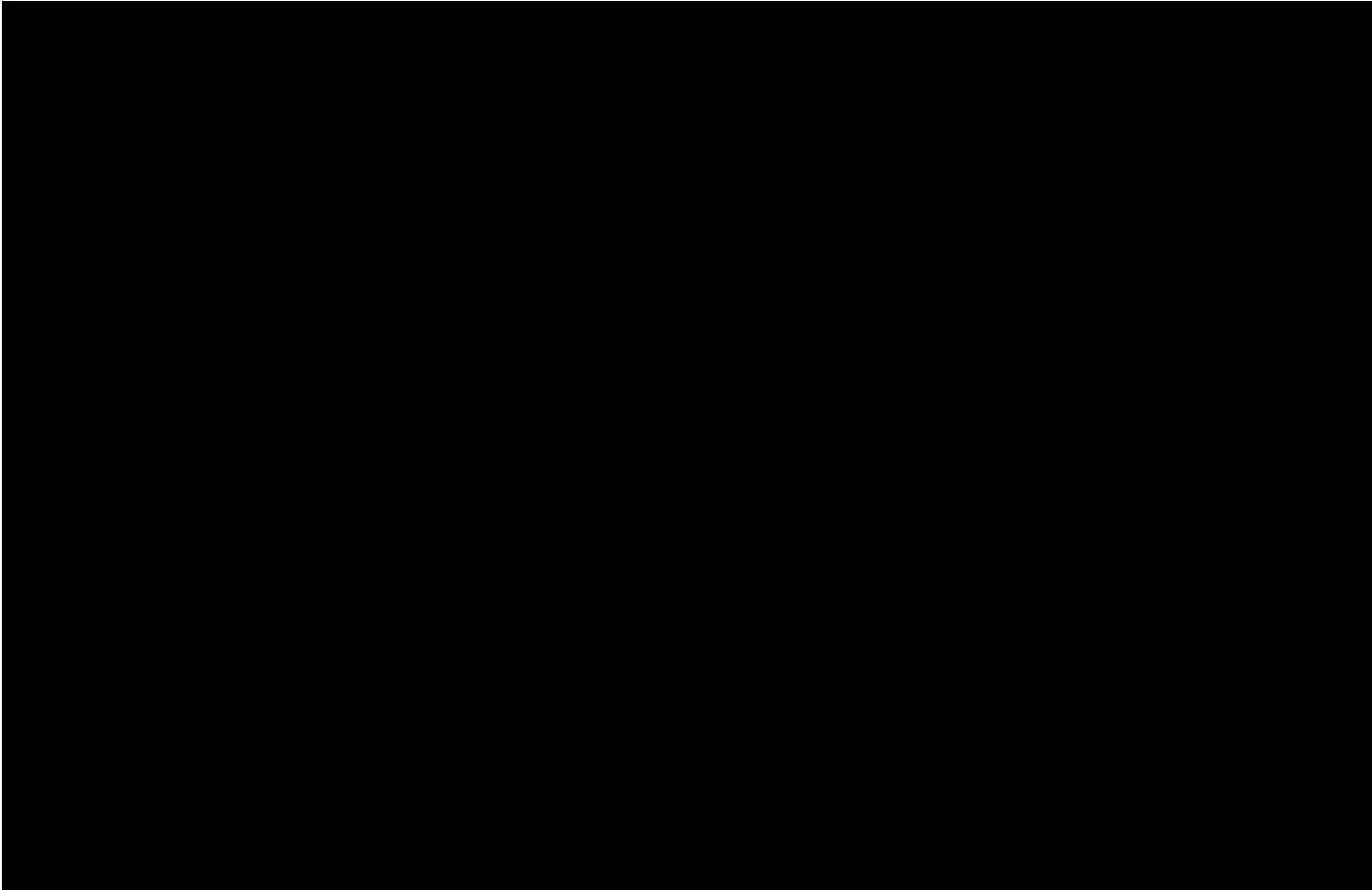
5.0 Forms/Attachments

- Form QS-005-1 – Sanitation Log
- Form QS-005-2 – Annual Floor Washing Log
- Form QS-005-3 – Evaluation Questionnaire

6.0 Definitions

- 6.1 IPA: Isopropyl Alcohol (70%)
- 6.2 Third Party Logistics Provider (3PL): A third party company used for incoming receipt of goods, warehousing, distribution of goods and other fulfillment services on behalf of Methapharm.

7.0 Procedure



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Standard Operating Procedure

Title:

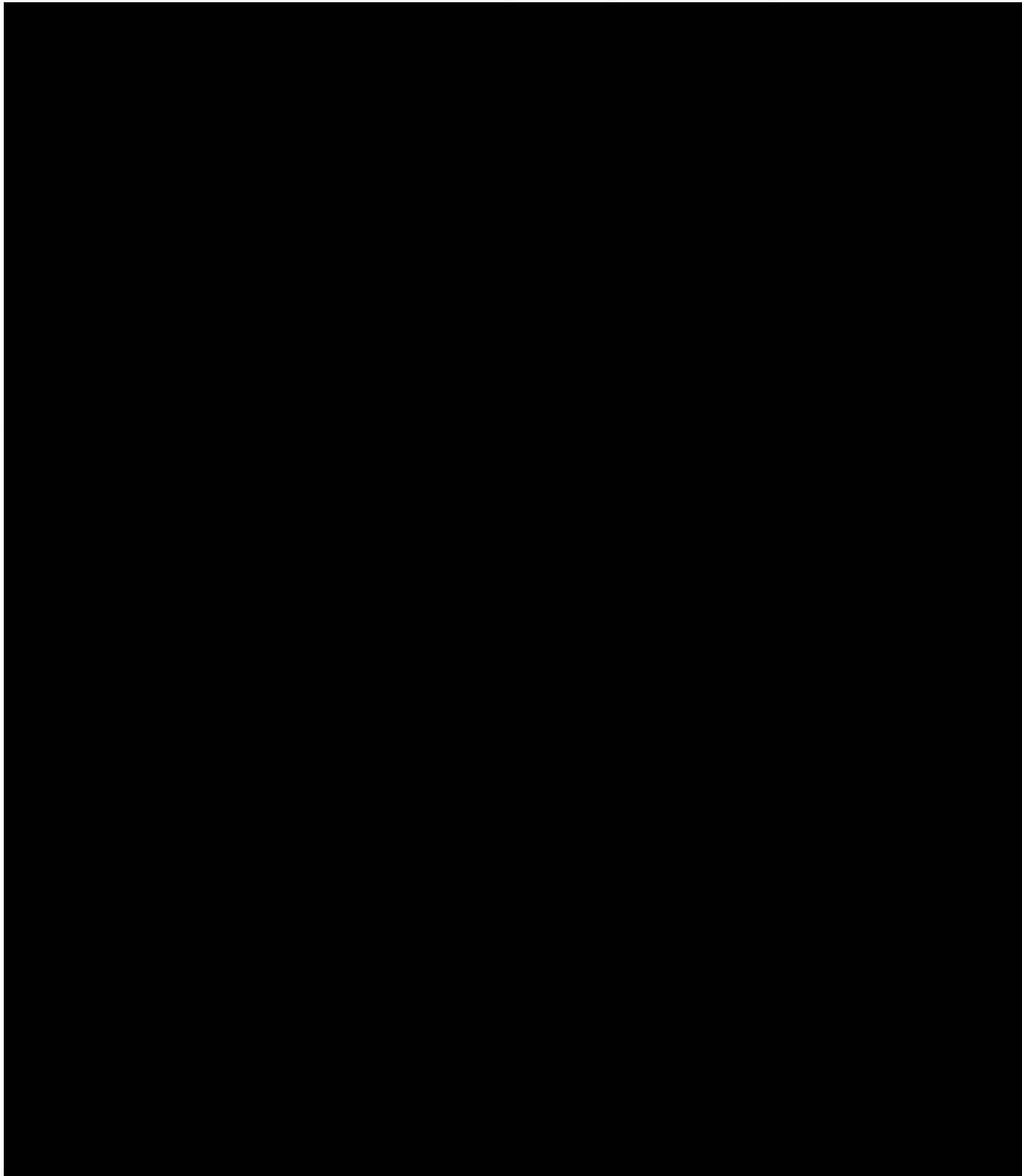
Sanitation

Effective Date: OCT 14 2021


Section: Operations

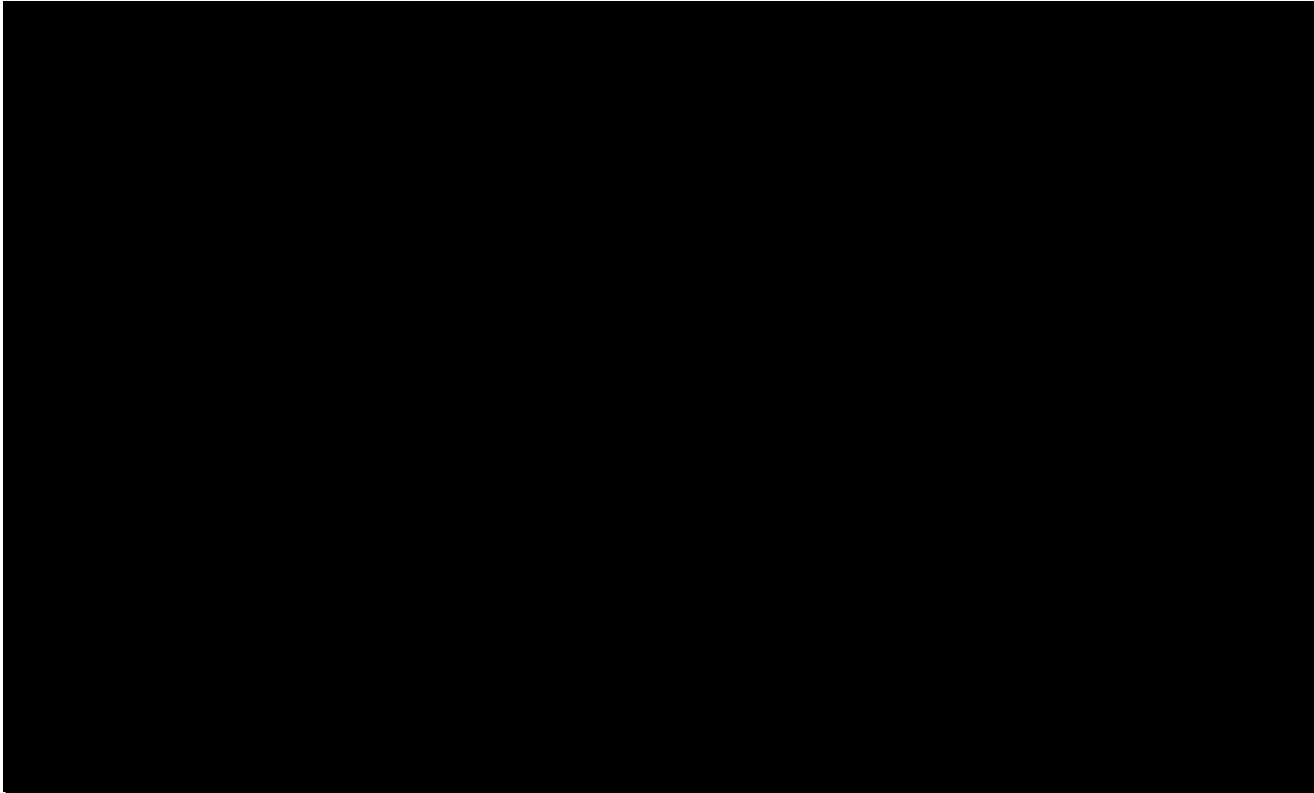
SOP Number: QS-005.005

Page 3 of 5

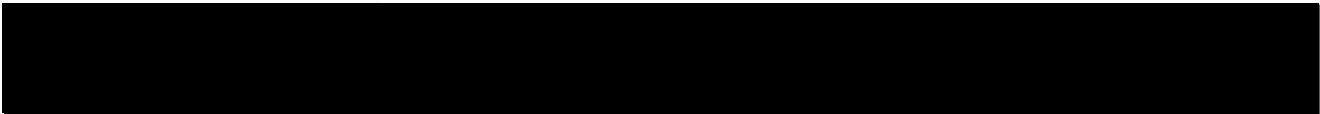


Confidential Trade Secrets

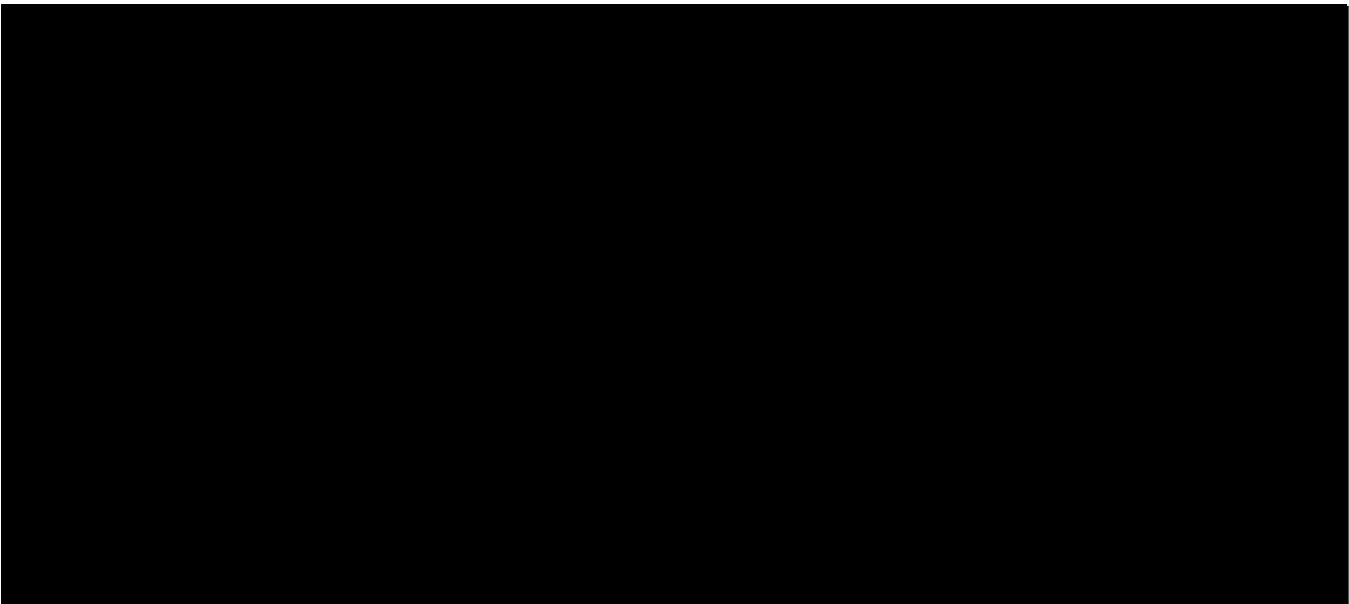
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	Sanitation	SOP Number: QS-005.005
	Effective Date: OCT 14 2021	Page 4 of 5




8.0 Records

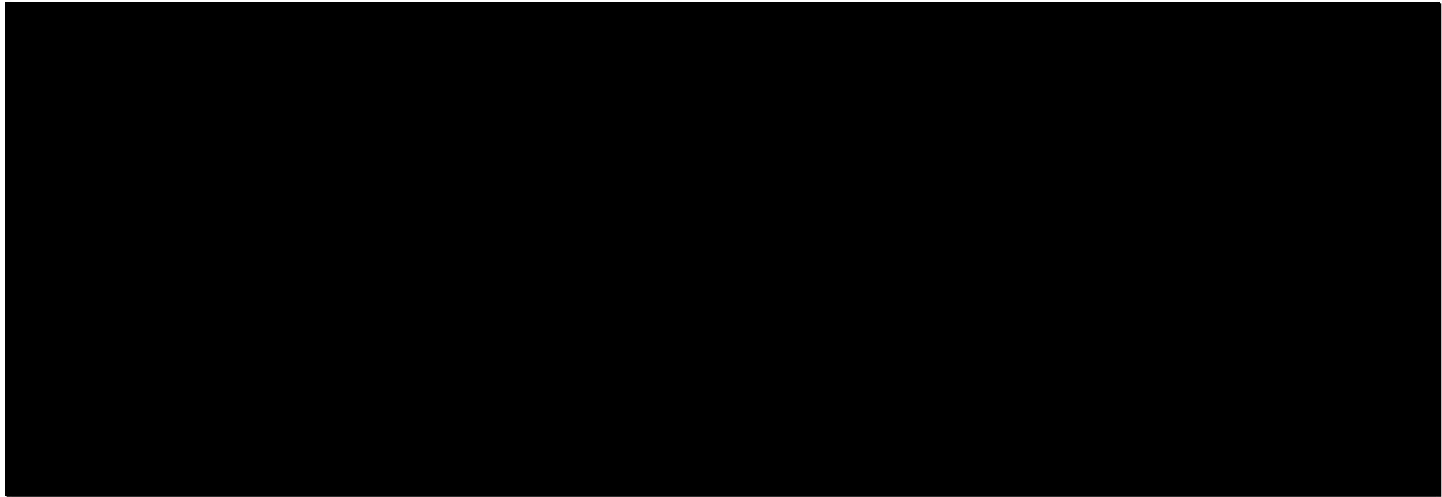


9.0 Revision History


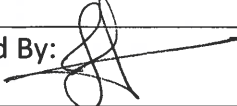




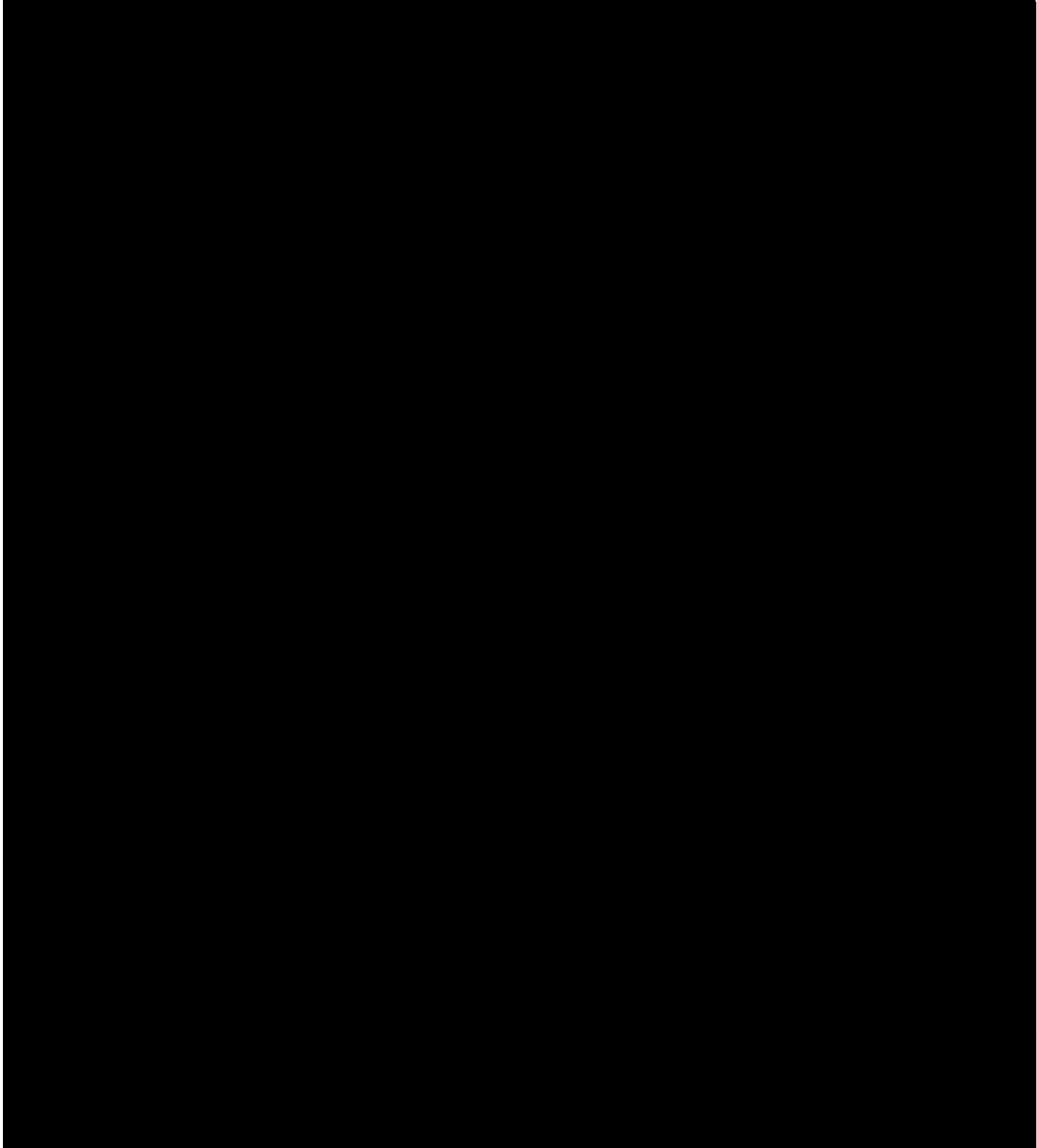
Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Operations
	Sanitation	SOP Number: QS-005.005
	Effective Date: OCT 14 2021	Page 5 of 5







Confidential Trade Secrets

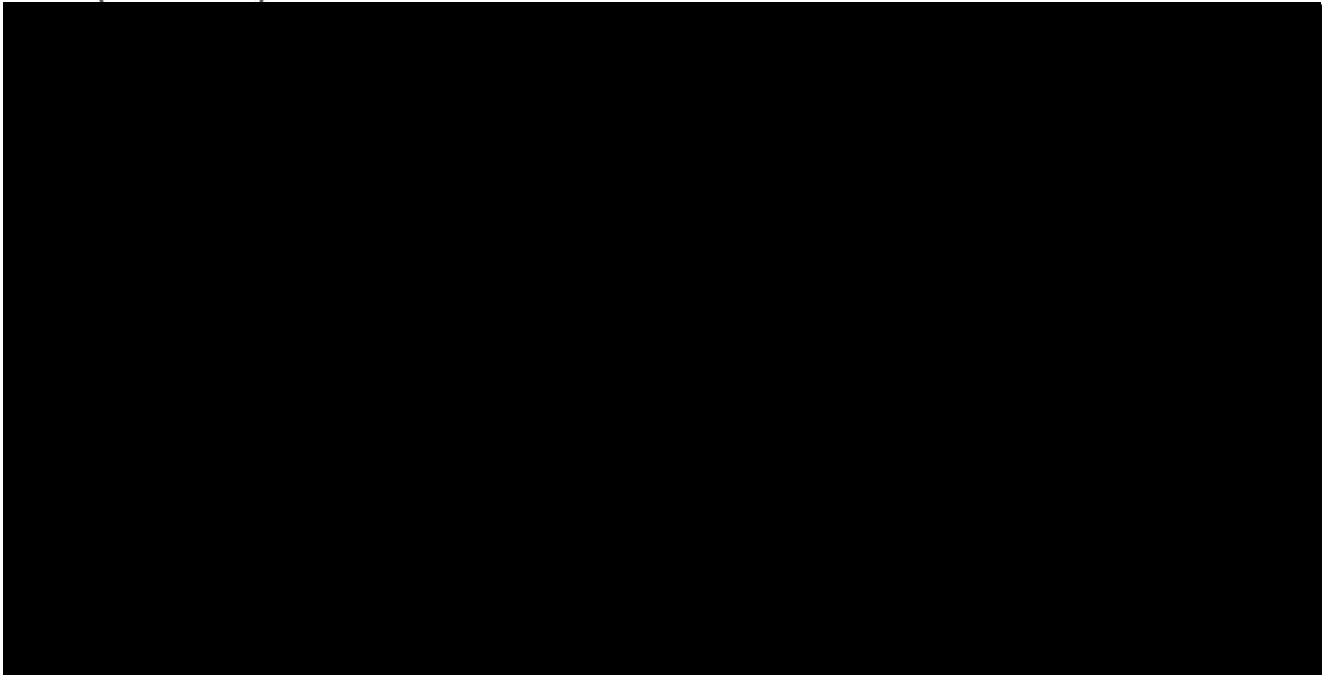
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	Effective Date: OCT 14 2021	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Sept. 27/2021	Date: Sept 27, 2021	Date: Sept 28. 2021




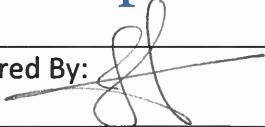


Confidential Trade Secrets

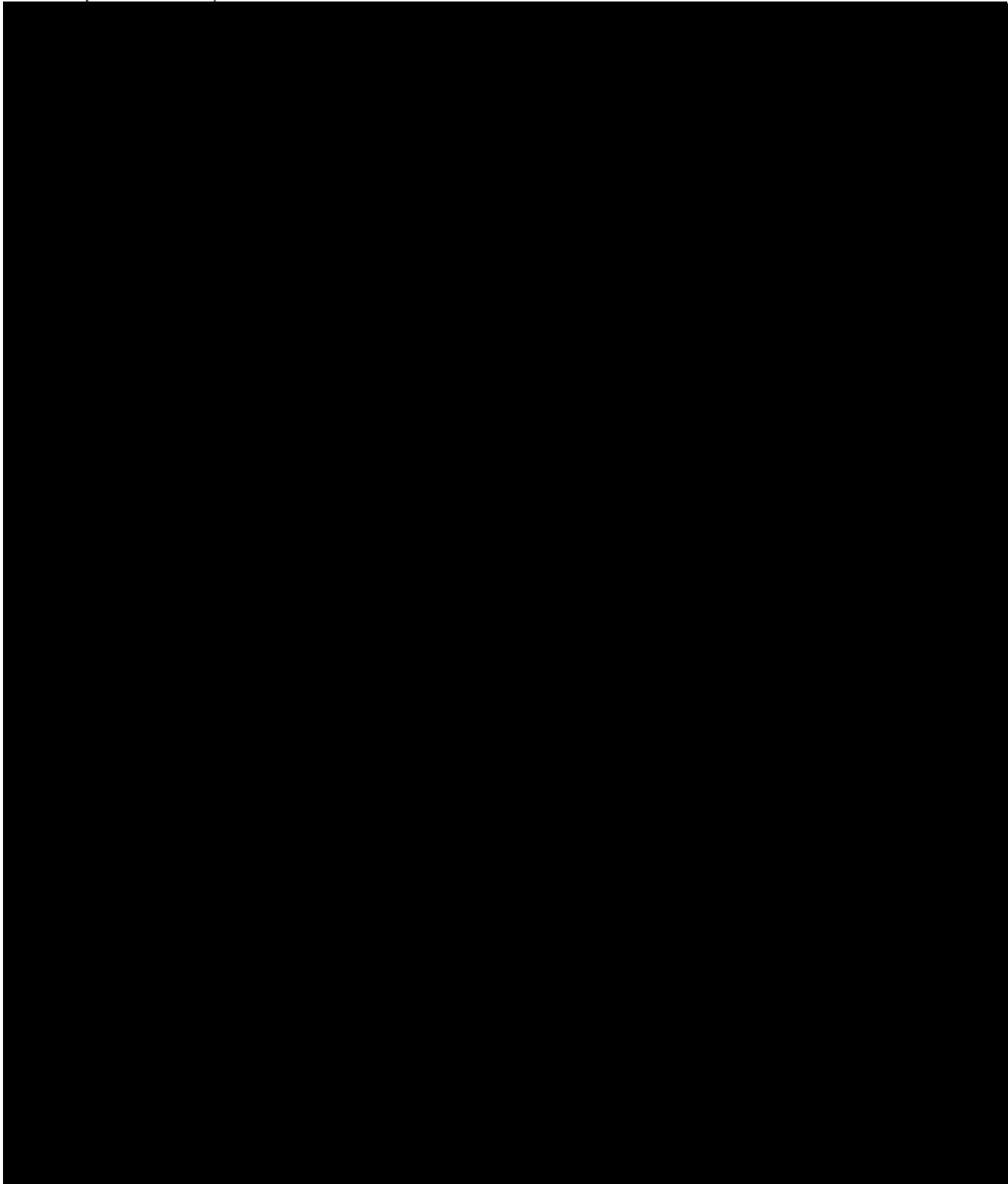
Exempt from disclosure pursuant to Section 119.0715, F.S.

	Title: Annual Floor Washing Log	Form QS-005-2.005
	Effective Date: OCT 14 2021	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Sept. 27/2021	Date: Sept 27, 2021	Date: Sept 28. 2021




Confidential Trade Secrets

	Title: Evaluation Questionnaire	Form QS-005-3.005
	Effective Date: OCT 14 2021	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Sept 27/2021	Date: Sept 27, 2021	Date: Sept 28. 2021.

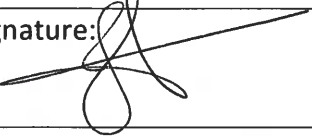




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Exempt from disclosure pursuant to Section 119.0715, F.S.

 methapharm Standard Operating Procedure	Title:	Section: Operations
	Pest Control	SOP Number: QS-006.003
	Effective Date: OCT 14 2021	Page 1 of 3

Issued by: Quality Assurance	Copy No.: Electronic Copy
Note: Not a controlled copy unless the above space is completed in red ink or text.	

Prepared by: Operations Administrative Coordinator	Signature: 	Date: Sept .27/2021
Reviewed by: Department Management	Signature: 	Date: Sept 27, 2021
Approved by: QA Management	Signature: 	Date: Sept 28. 2021

1.0 Purpose

To provide a procedure for Pest Control of the Methapharm Inc. (Methapharm) Warehouse.

2.0 Scope

- 2.1 This procedure covers to Pest Control activities in the Warehouse where active pharmaceutical ingredients (API), drug products and/or medical devices are stored.
- 2.2 For any API, drug products and medical devices which are imported, distributed and/or wholesaled by Methapharm, but which are received and stored at a third-party logistics provider (3PL), the 3PL will follow their own internal procedures for pest control activities.


3.0 Responsibility

- 3.1 It is the responsibility of the Methapharm Operations Department to ensure that an active and effective Pest Control program is in place at Methapharm.
- 3.2 Methapharm Operations Department is responsible for confirming any corrective actions taken in response to an infestation or incident are completed.

4.0 References and Related SOPs

- HPFBI Good Manufacturing Practices (GMP) Guidelines – C.02.004
- FDA 21 CFR 211.56
- QS-015 – Deviations and Non-conformances
- QS-020 – Record Control and Retention
- QS-040 – Contractors and Consultants

Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Operations
	Pest Control	SOP Number: QS-006.003
	Effective Date: OCT 14 2021	Page 2 of 3

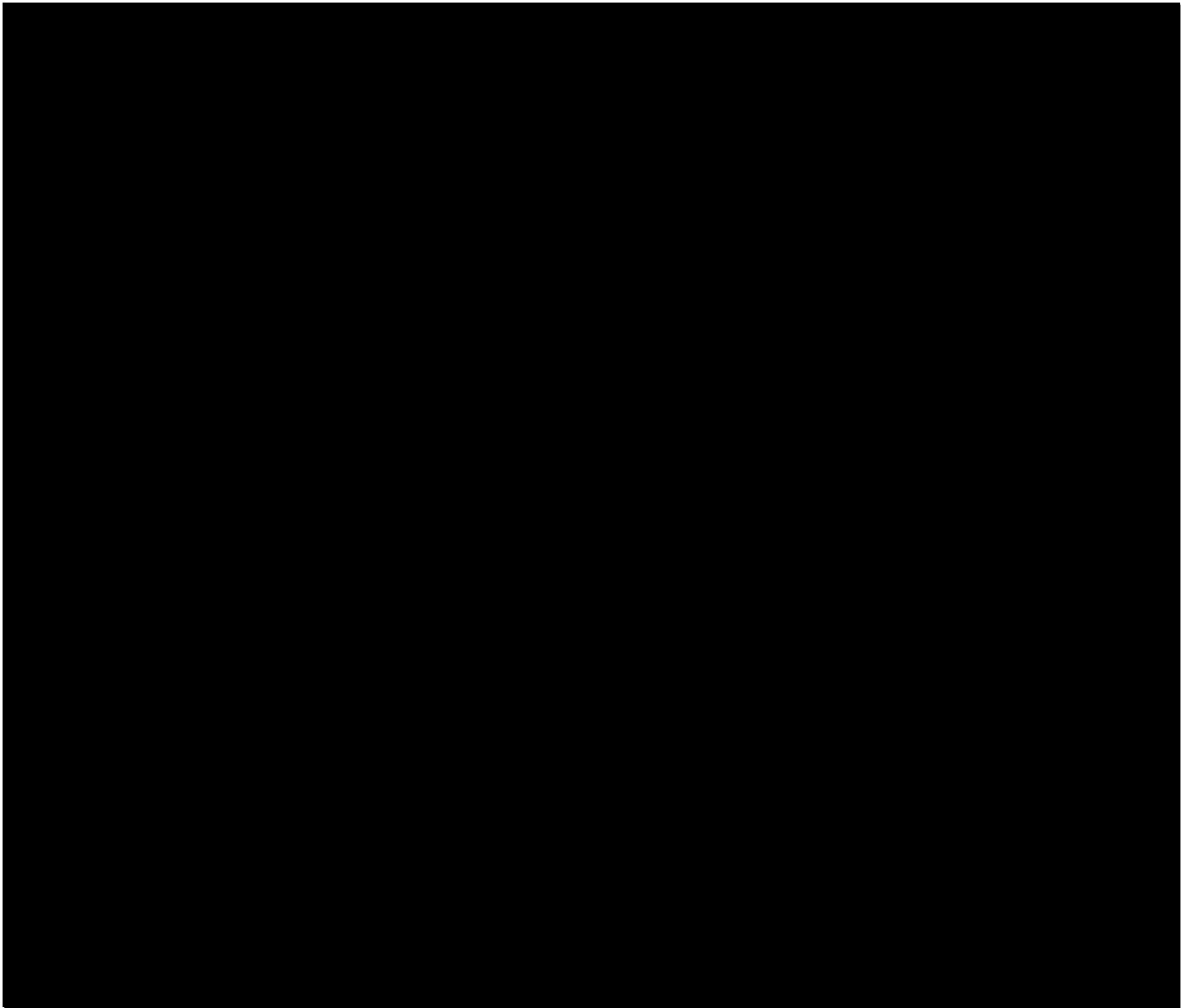
5.0 Forms/Attachments

Form QS-006-1 – Evaluation Questionnaire


6.0 Definitions

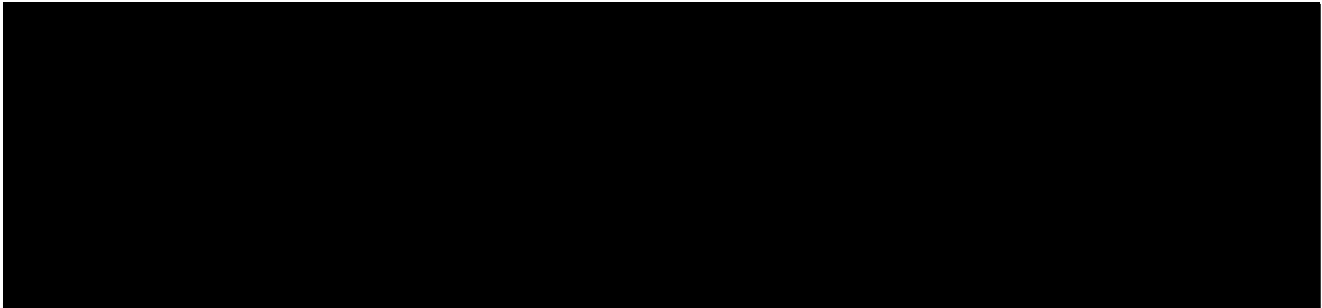
- 6.1 Third Party Logistics Provider (3PL): A third party company used for incoming receipt of goods, warehousing, distribution of goods and other fulfillment services on behalf of Methapharm.

7.0 Procedure

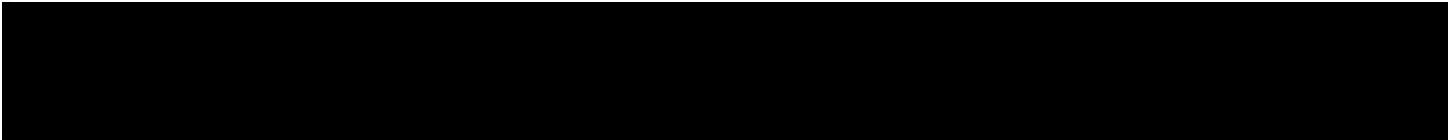


Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Operations
	Pest Control	SOP Number: QS-006.003
	Effective Date: OCT 14 2021	Page 3 of 3







8.0 Records

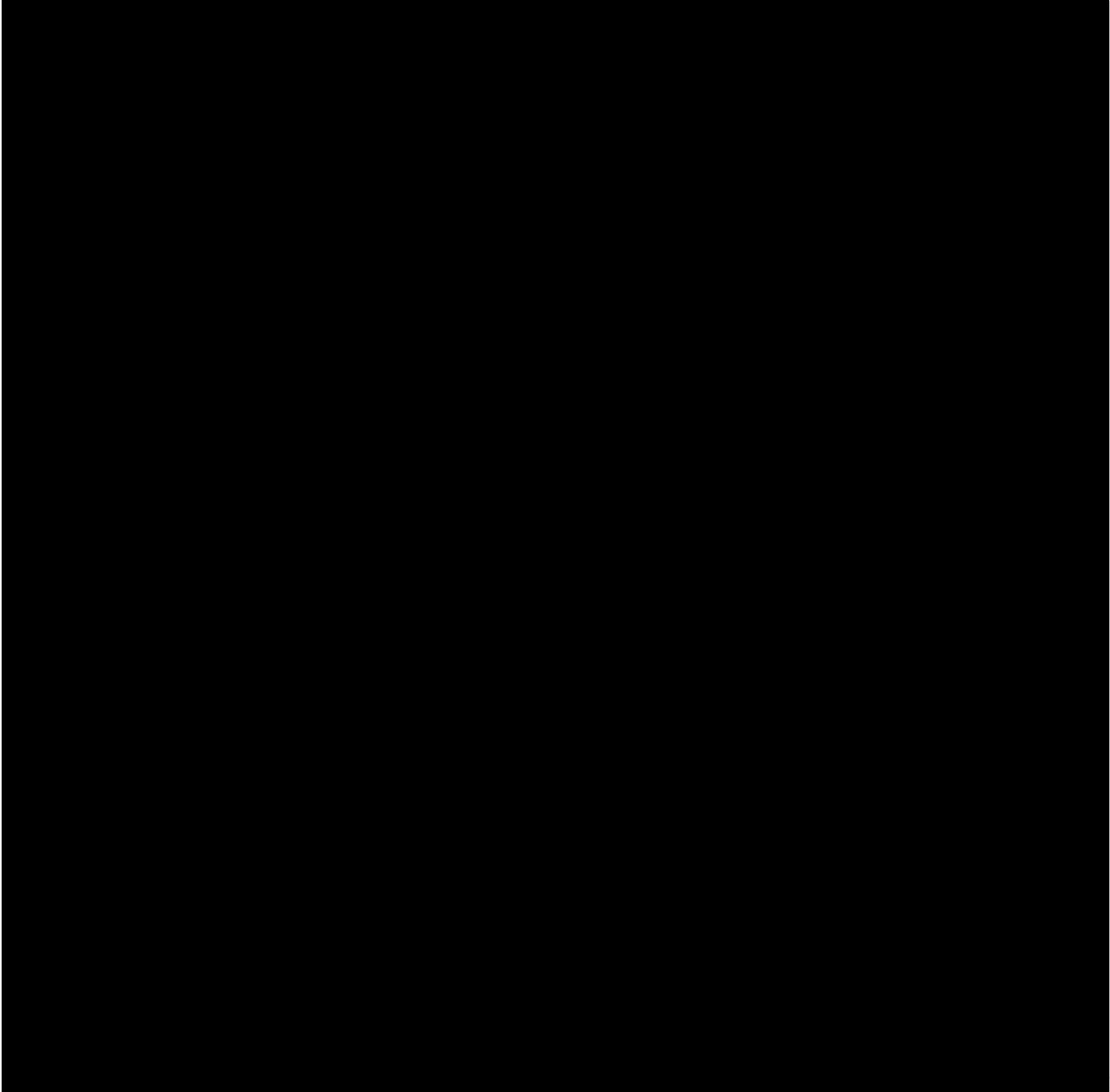


9.0 Revision History




Confidential Trade Secrets

	Title: Evaluation Questionnaire	Form QS-006-1.003
	Effective Date: OCT 14 2021	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Sept. 27/2021	Date: Sept 27, 2021	Date: Sept 28. 2021

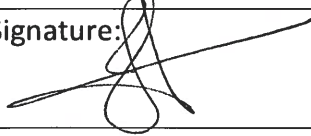

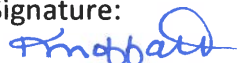


Confidential Trade Secrets

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

 Standard Operating Procedure	Title:	Section: Operations
	Hygiene	SOP Number: QS-007.003
	Effective Date: OCT 14 2021	Page 1 of 3

Issued by: Quality Assurance	Copy No.: Electronic Copy
Note: Not a controlled copy unless the above space is completed in red ink or text.	

Prepared by: Operations Administrative Coordinator	Signature: 	Date: Sept. 27/2021
Reviewed by: Department Management	Signature: 	Date: Sept 27, 2021
Approved by: QA Management	Signature: 	Date: Sept 28. 2021

1.0 Purpose

To provide a procedure for personal hygiene requirements for the Methapharm Inc. (Methapharm) warehouse.

2.0 Scope

- 2.1 This procedure applies to all employees at Methapharm who have access to any area of the Warehouse where active pharmaceutical ingredients (API), drug products and/or medical devices are stored and handled.
- 2.2 For any API, drug products and medical devices which are imported, distributed and/or wholesaled by Methapharm, but which are received and stored at a third-party logistics provider (3PL), the 3PL will follow their own internal procedures for hygiene activities.

3.0 Responsibility

It is the responsibility of all Methapharm employees involved in warehouse activities to read, understand, and follow this procedure.


4.0 References and Related SOPs

HPFBI Good Manufacturing Practices (GMP) Guidelines – C.02.008
 FDA 21 CFR 211.28

5.0 Forms/Attachments

Form QS-007-1 – Evaluation Questionnaire

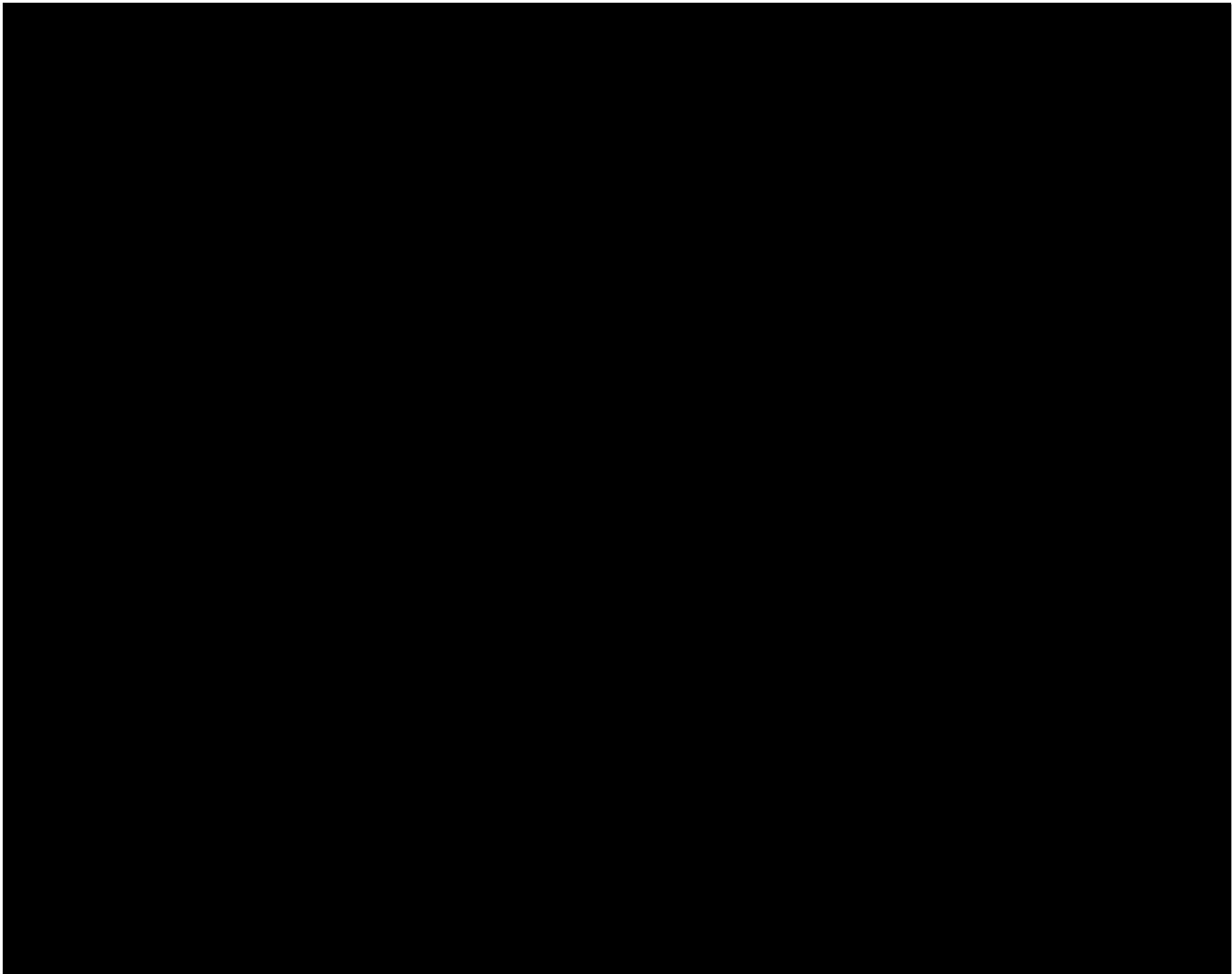
Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Operations
	Hygiene	SOP Number: QS-007.003
	Effective Date: OCT 14 2021	Page 2 of 3

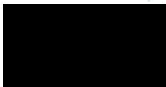
6.0 Definitions

- 6.1 Third Party Logistics Provider (3PL): A third party company used for incoming receipt of goods, warehousing, distribution of goods and other fulfillment services on behalf of Methapharm.


7.0 Procedure



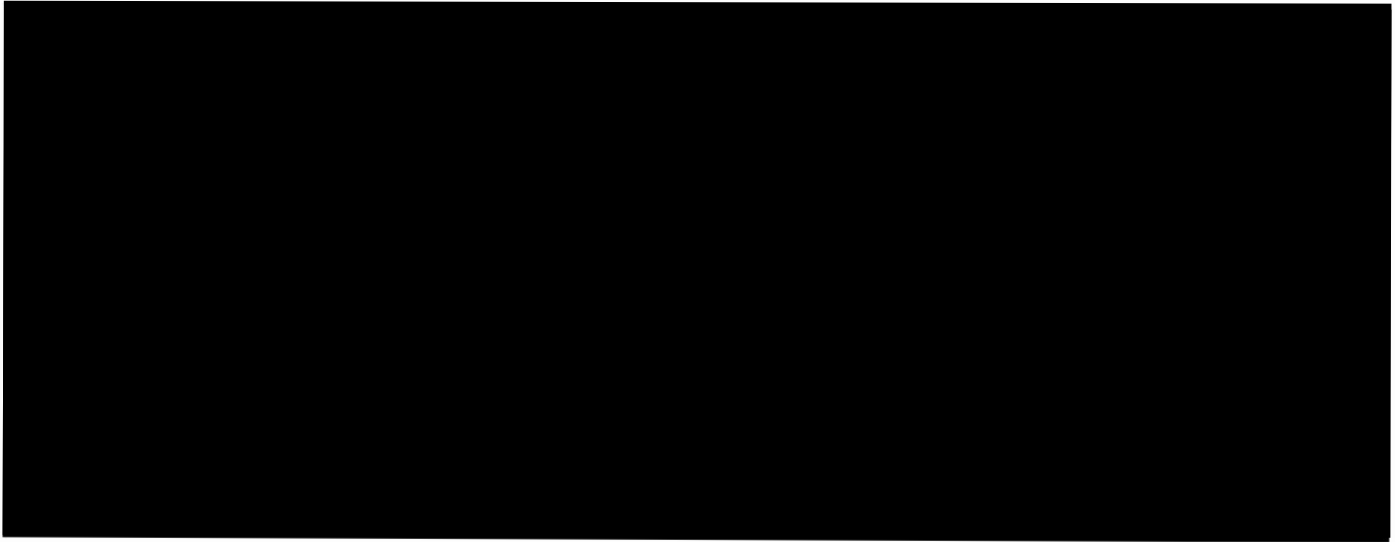
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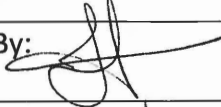
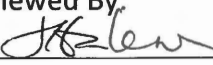
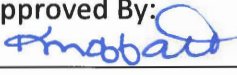
Confidential Trade Secrets

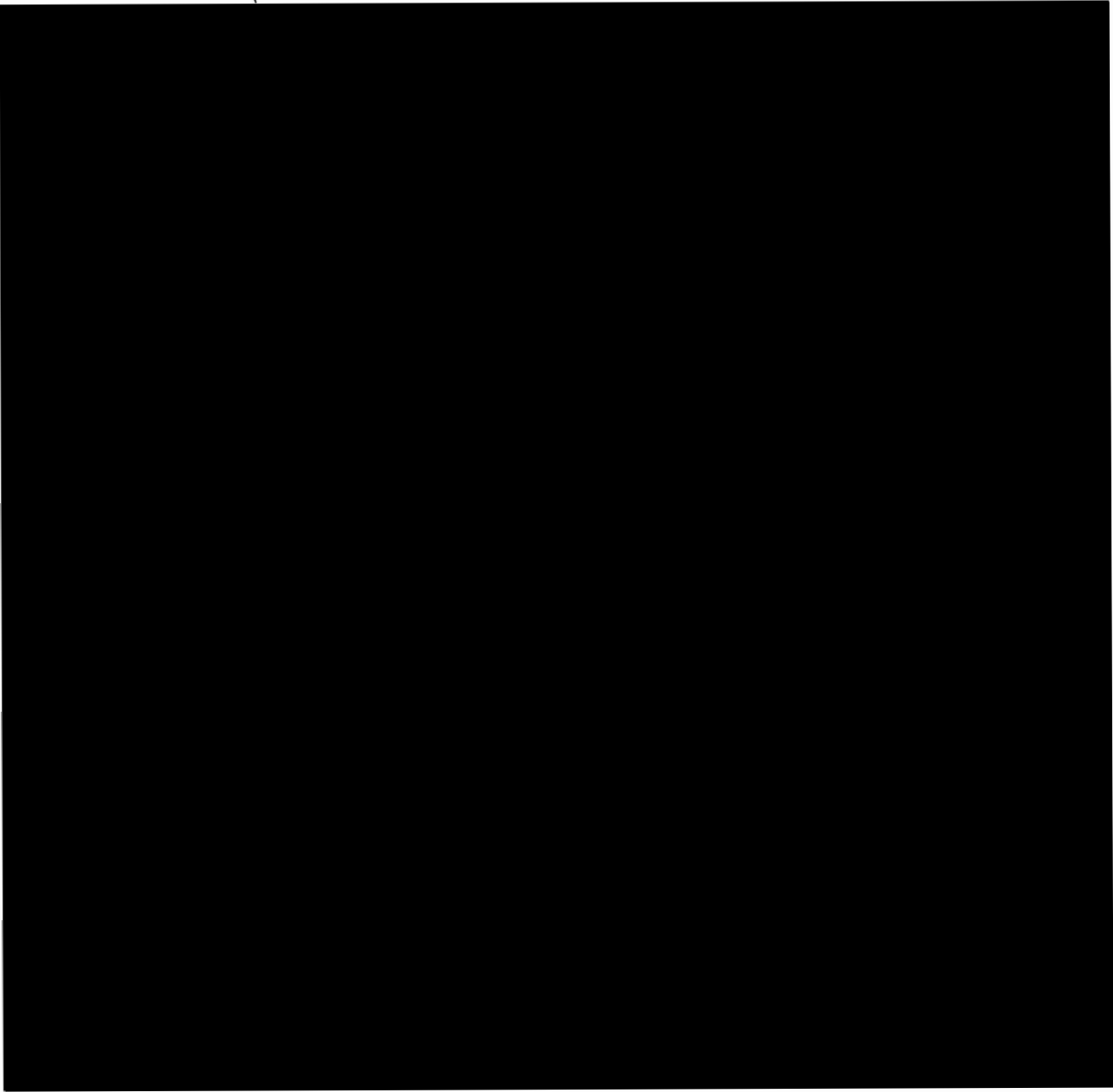
 Standard Operating Procedure	Title:	Section: Operations
	Hygiene	SOP Number: QS-007.003
	Effective Date: OCT 14 2021	Page 3 of 3

9.0 Revision History



Confidential Trade Secrets

	Title: Evaluation Questionnaire	Form QS-007-1.003
	Effective Date: OCT 14 2021	Page 1 of 1
Prepared By: 	Reviewed By: 	Approved By: 
Date: Sept. 27/2021	Date: Sept 27, 2021	Date: Sept 28.2021



Confidential Trade Secrets

 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 1 of 13

Issued by: Quality Assurance
Note: Controlled Copies are identified in SOP footer.

Prepared by: Operations Supervisor	Name: Jaime Theoret	Signature/Date: Refer to QT-9 QMS
Reviewed by: Director, Operations	Name: John Zanin	Signature/Date: Refer to QT-9 QMS
Approved by: Director, QA	Name: Nina Kazarians	Signature/Date: Refer to QT-9 QMS

1.0 Purpose

To provide a procedure for the receipt of incoming Goods by Methapharm Inc. (Methapharm).

2.0 Scope

2.1 This procedure applies to the receipt of incoming goods including, but not limited to active pharmaceutical ingredients (API), drug products, medical devices, and packaging components by Methapharm (hereinafter referred to collectively as 'Goods').

Note: Packaging components include any labels, cartons, boxes (both coded or non-coded), for use in the packaging of a finished drug product, medical device, or natural health product. Packaging components do not include regular shipping boxes.

Note: This SOP does not apply to packaging components received at and released by Methapharm's Contracting Manufacturing Organization(s) (CMO).

3.0 Responsibility

3.1 It is the responsibility of Methapharm Operations Personnel involved with ordering and/or receiving Goods to follow this procedure.

3.2 Methapharm QA is responsible for reviewing documentation and determining disposition of Goods.

4.0 References and Related SOPs

QS-014 – QA Review and Disposition of Raw Materials and Finished Goods

QS-015 – Deviations and Non-conformances

QS-020 – Record Control and Retention

Confidential Trade Secrets

 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 2 of 13

QS-021 – Retain Samples

Section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.384(b) through (h))

5.0 Forms/Attachments

Form QS-013-1 - Stock Receipt – 3PL/CMO

Form QS-013-2 - Methacholine Chloride API Receipt Summary

Form QS-013-3 – Medical Device or Other Bulk Receipt Summary

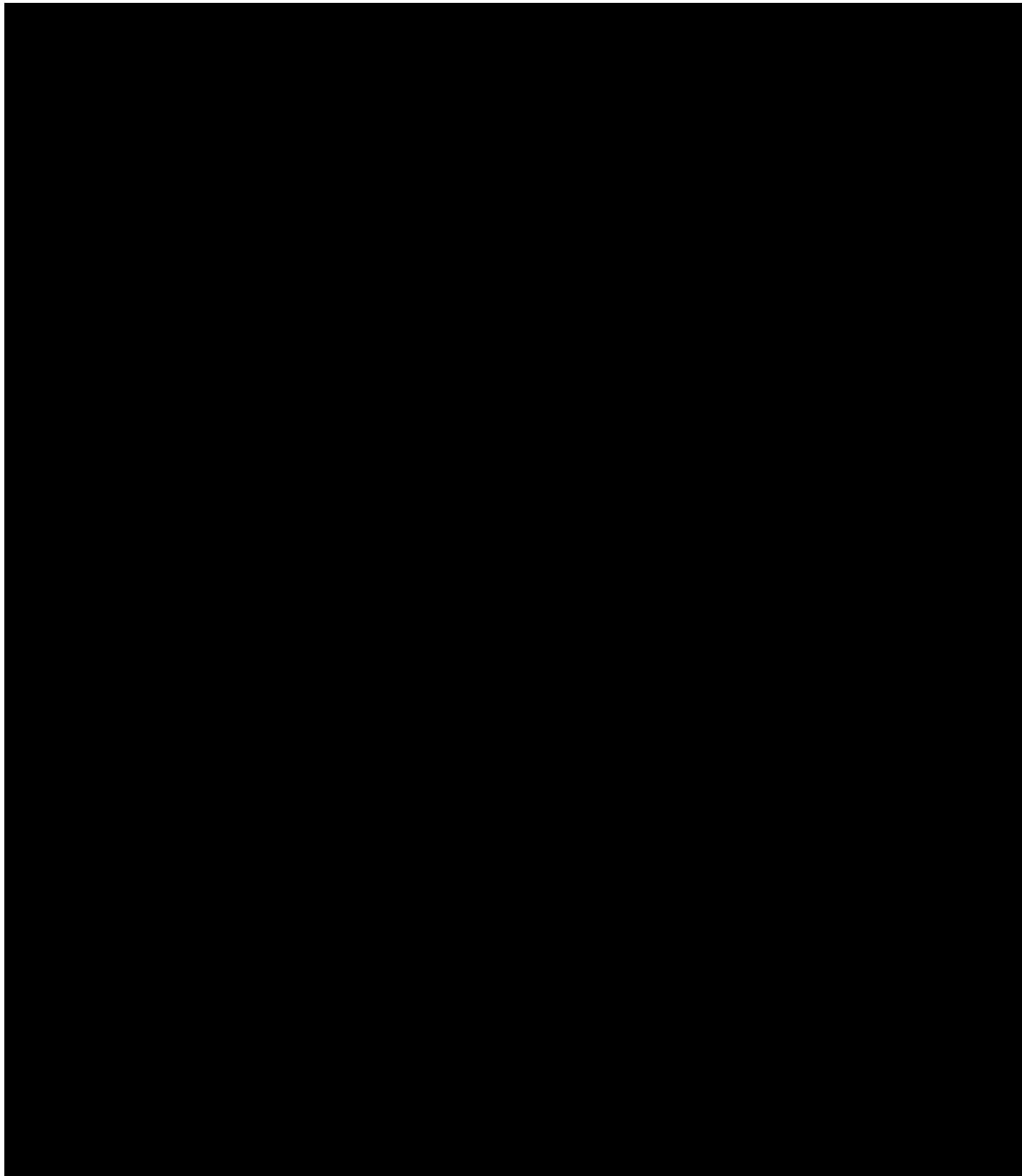
Form QS-013-4 – Stock Receipt - Methapharm

Form QS-013-5 – Evaluation Questionnaire

6.0 Definitions

- 6.1 Contract Manufacturer: Also called Contract Manufacturing Organization (CMO). An organization that performs the operations of receipt of materials, production, packaging/repackaging, labeling/relabeling, quality control, release, and/or storage of a drug product for Methapharm.
- 6.2 Drug Identification Number (DIN): A computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.
- 6.3 Expiry Date: In the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month (a) the date up to and including which a drug or device maintains its labelled potency, purity and physical characteristics, and (b) the date, after which the manufacturer recommends that the drug or device not be used. In the case of an API, whichever of the following dates is applicable, expressed at a minimum as a year and month (a) the re-test date, or (b) the date after which the manufacturer recommends that the API not be used.
- 6.4 Lot or Batch: A quantity of any drug in dosage form, a raw material, device, or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number that appears on the label of the finished product.

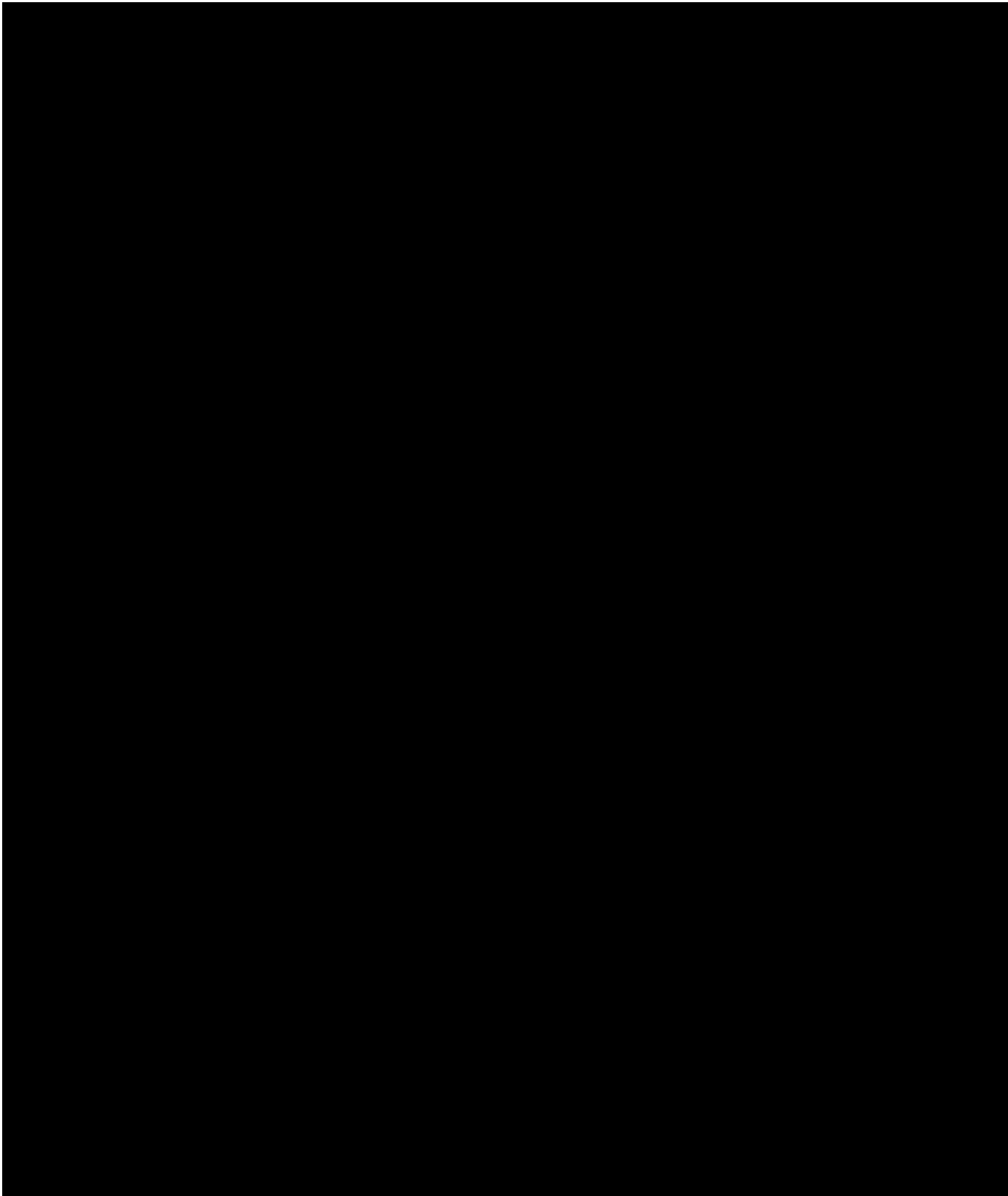
 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 4 of 13



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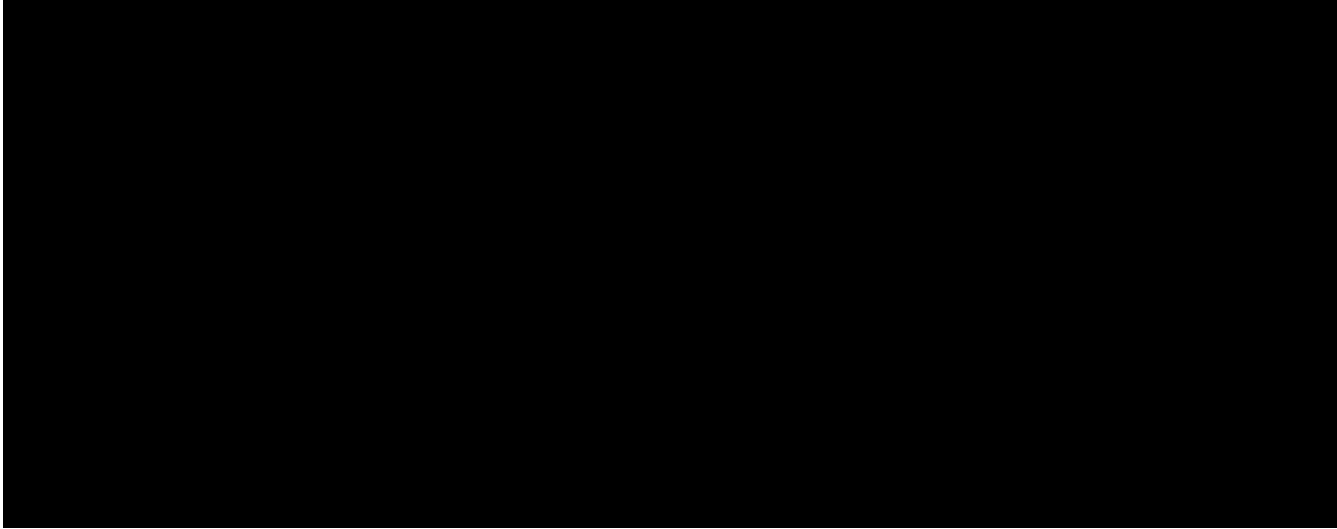
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		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 5 of 13



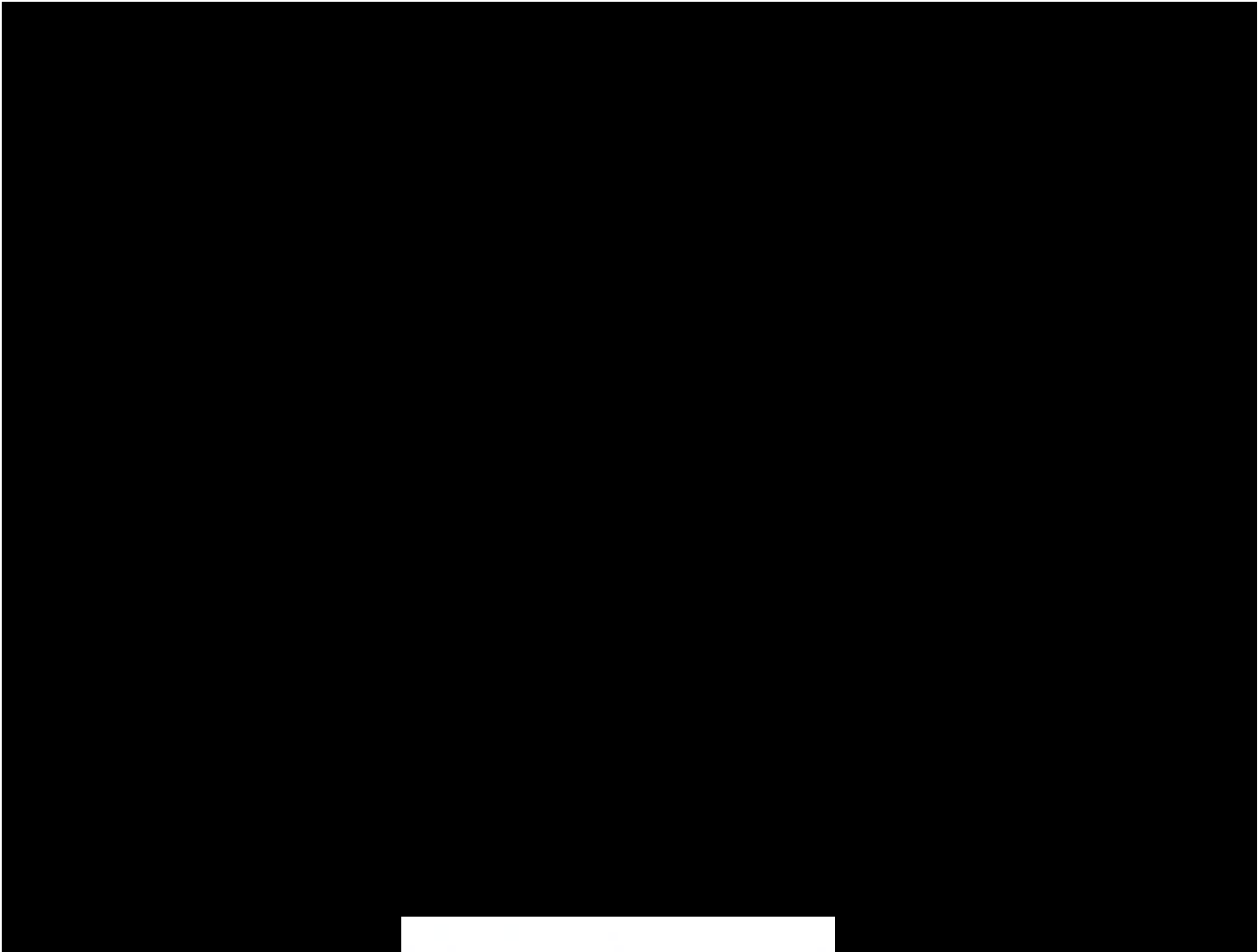
Confidential Trade Secrets

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

 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 6 of 13



Part 2: Receiving Goods at Methapharm

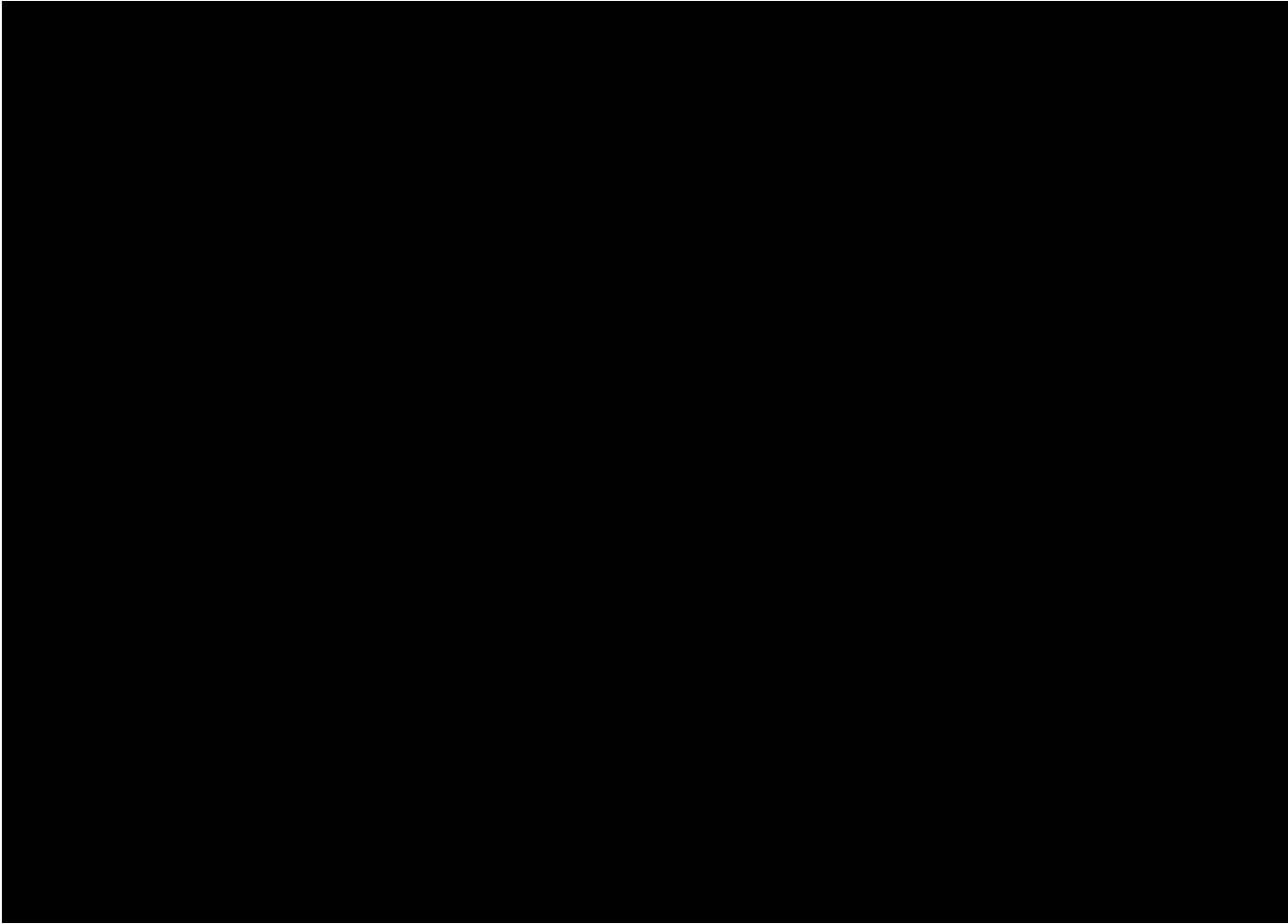


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 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
	Effective Date: OCT 20, 2023	SOP Number: QS-013.007
		Page 7 of 13

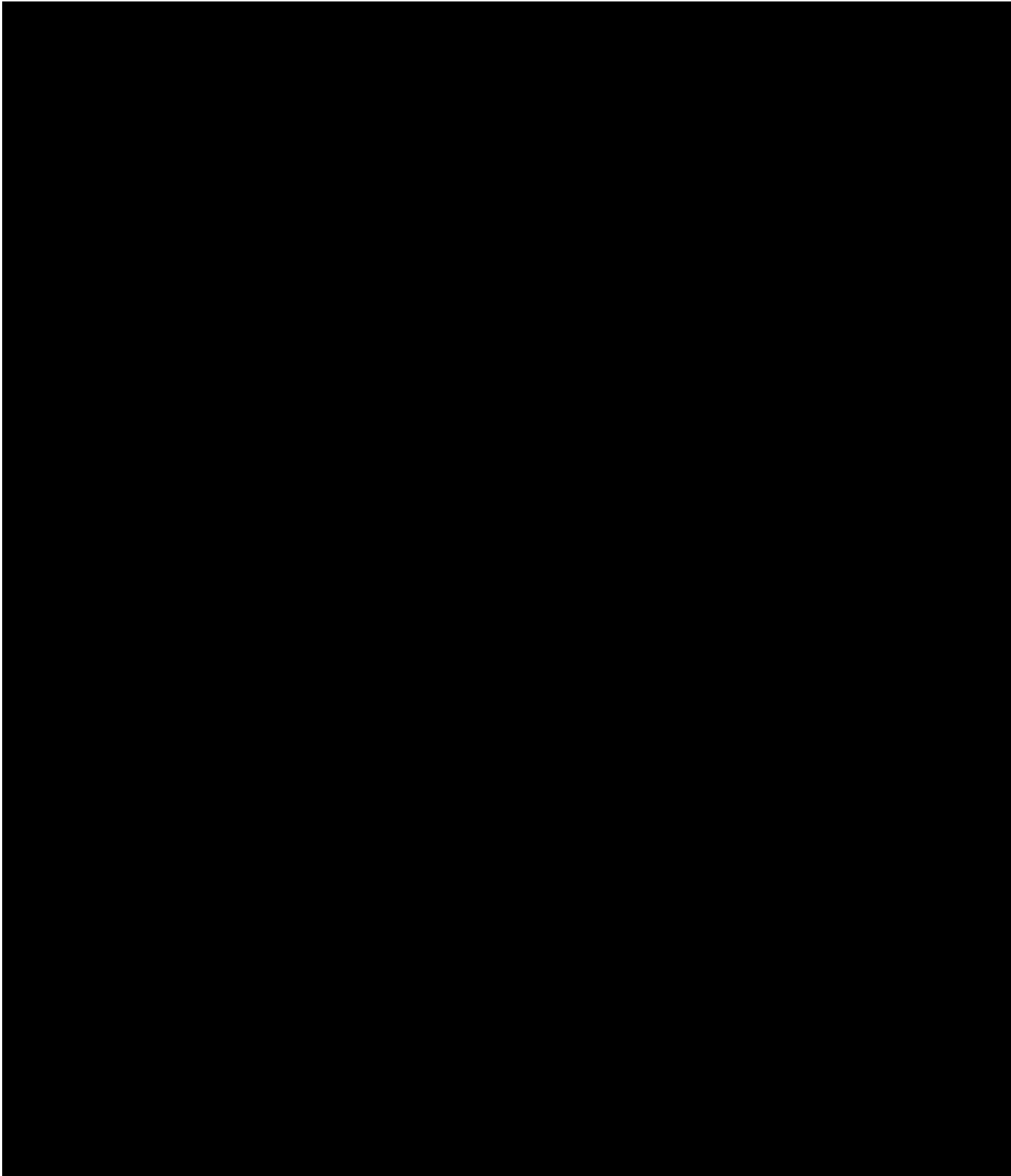


7.3 Inspection (Operations Personnel)



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 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 8 of 13



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Standard Operating Procedure

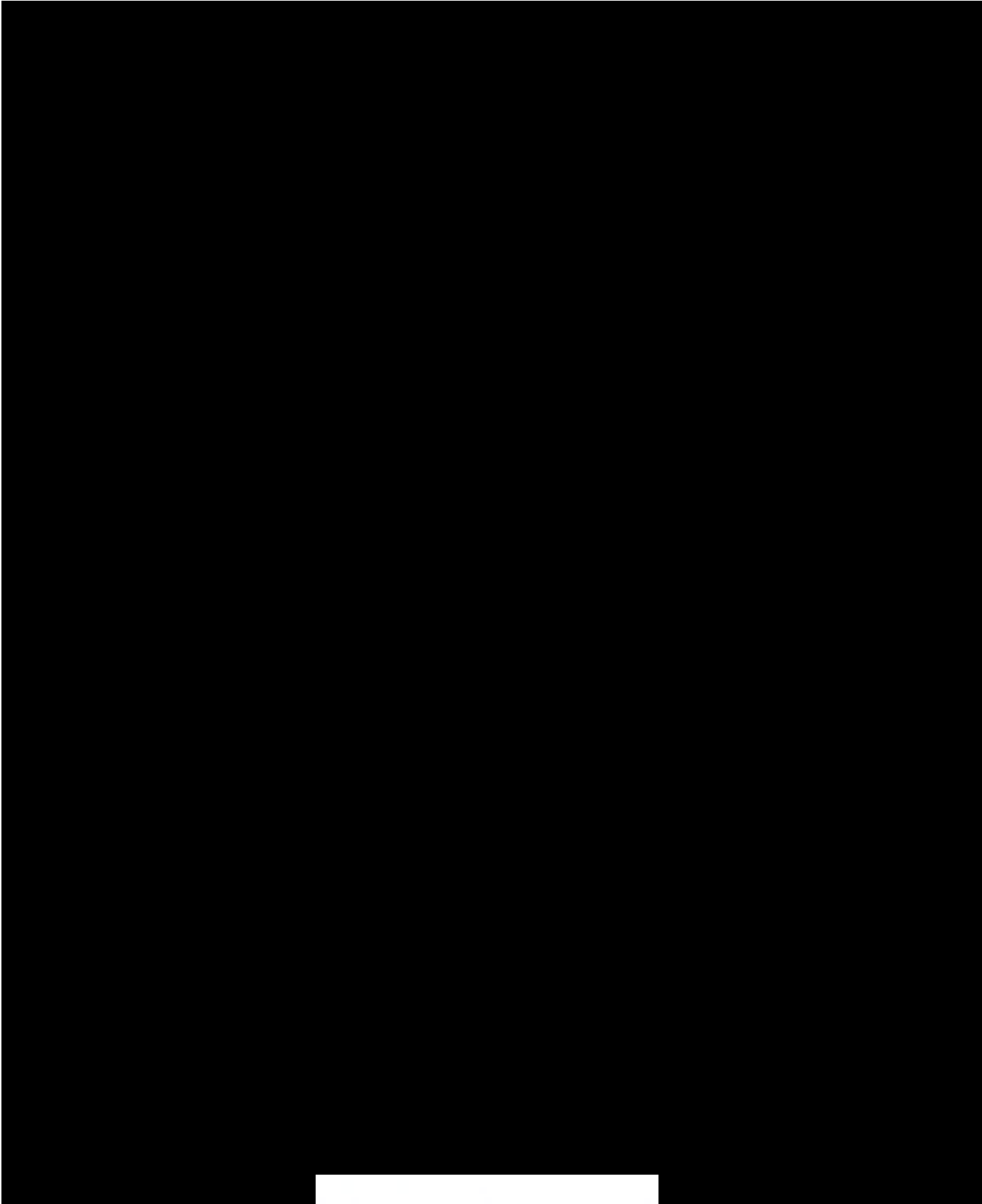
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Receiving Goods

Effective Date: **OCT 20, 2023**

Section: Operations

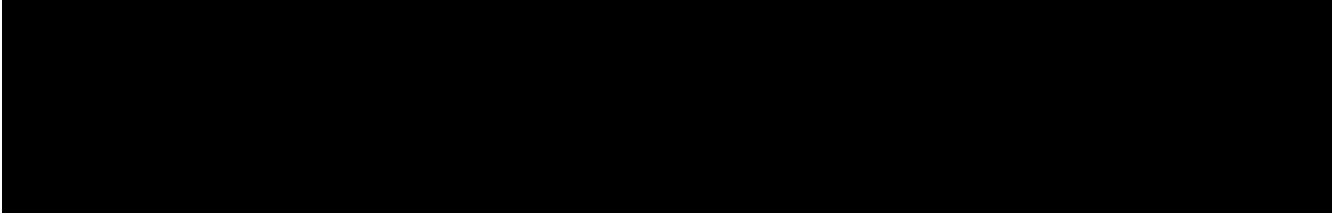
SOP Number: QS-013.007

Page **9** of **13**

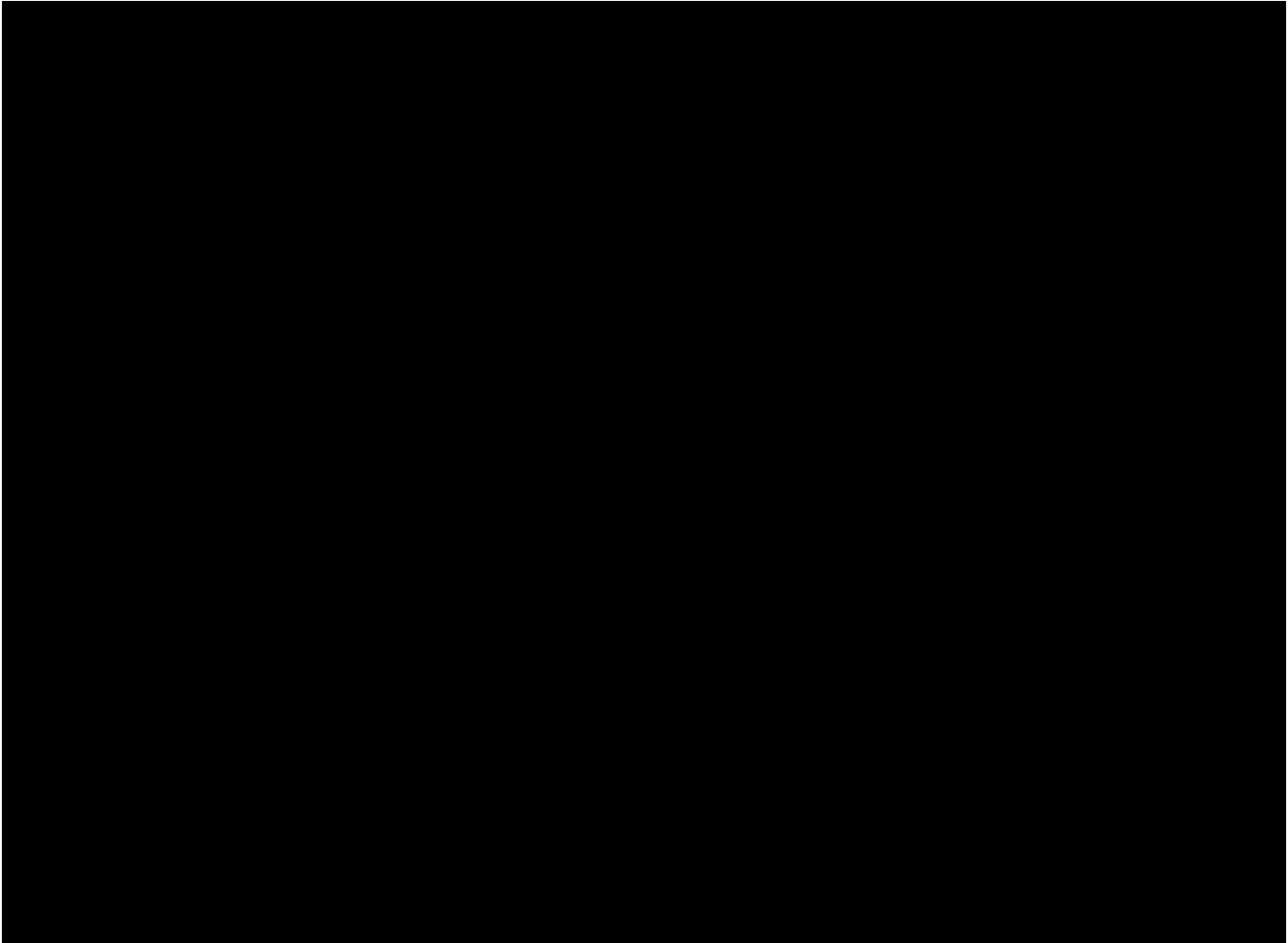


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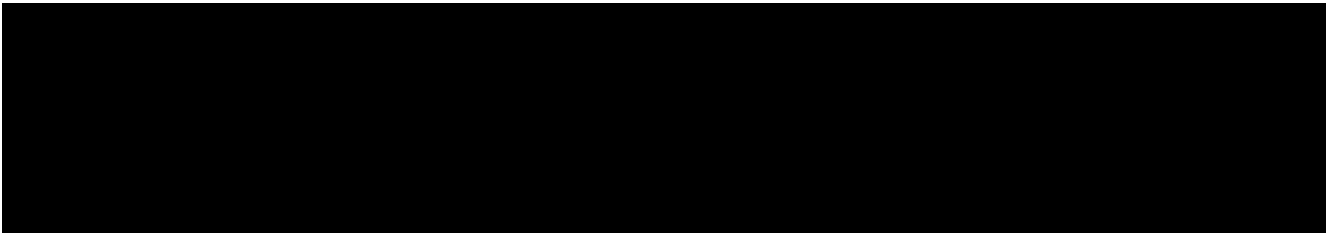
 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 10 of 13



7.4 QA Verification (Methapharm QA)

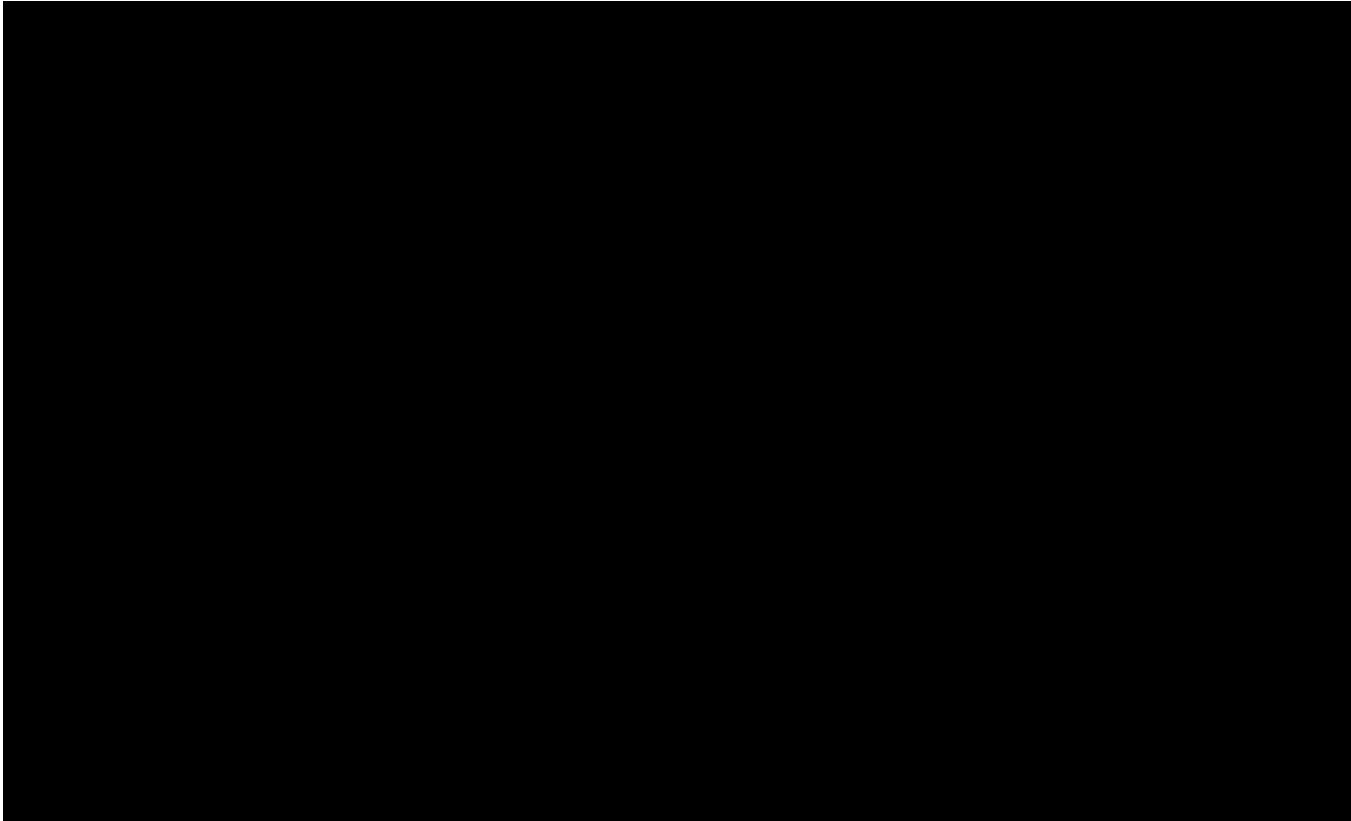


7.5 Movement of Goods (Operations Department)

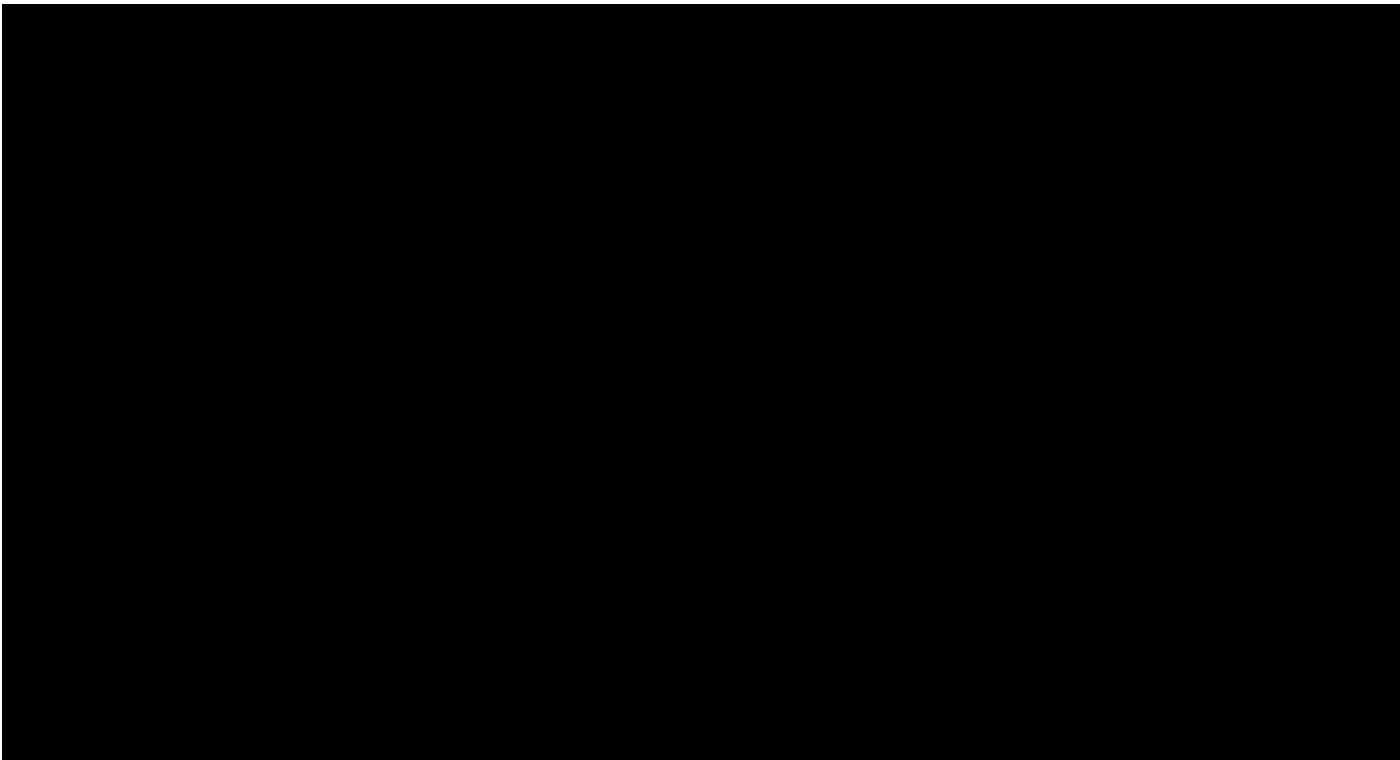


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 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
		SOP Number: QS-013.007
	Effective Date: OCT 20, 2023	Page 11 of 13



8.0 Records



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Standard Operating Procedure

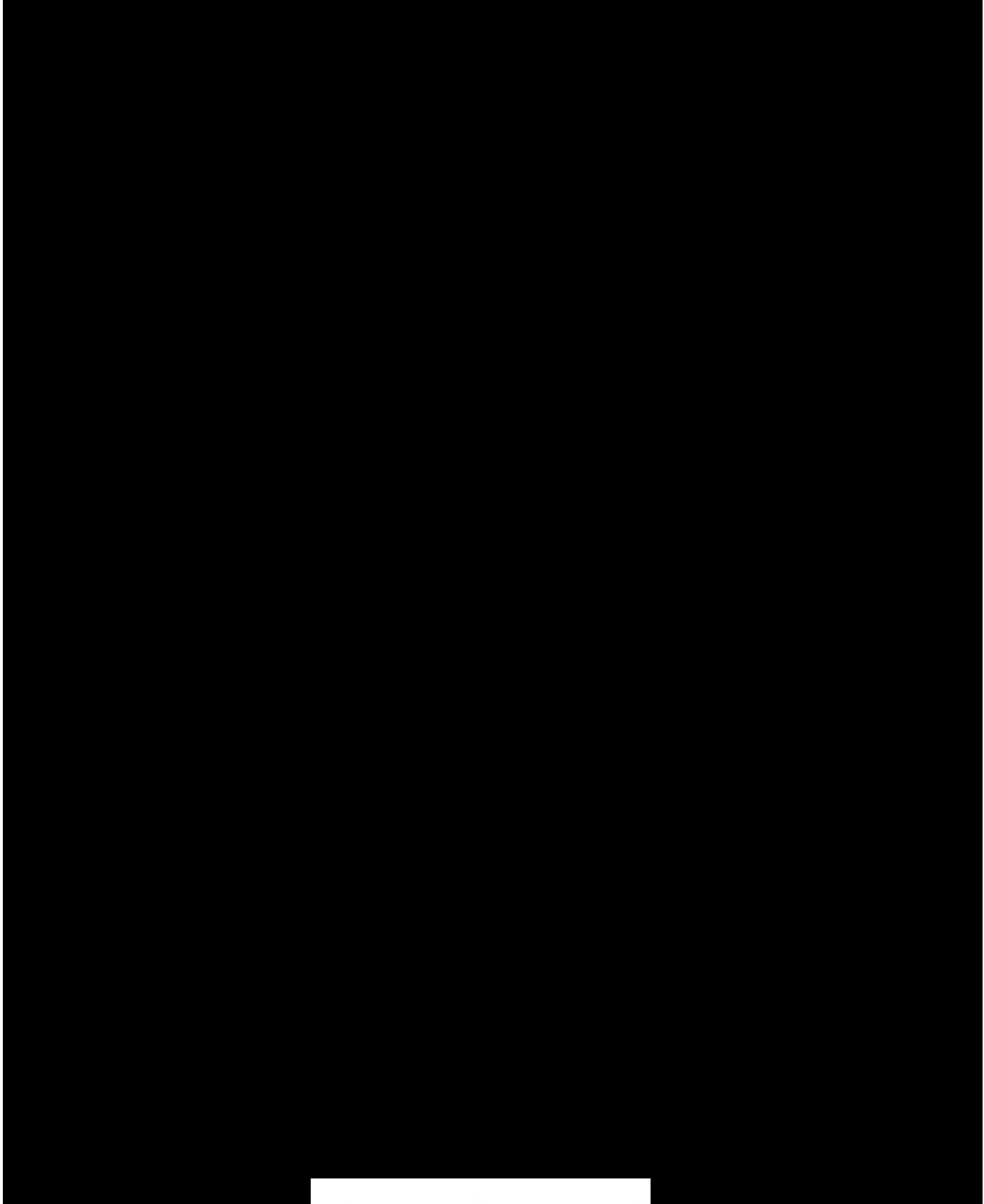
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Effective Date: **OCT 20, 2023**

Section: Operations

SOP Number: QS-013.007

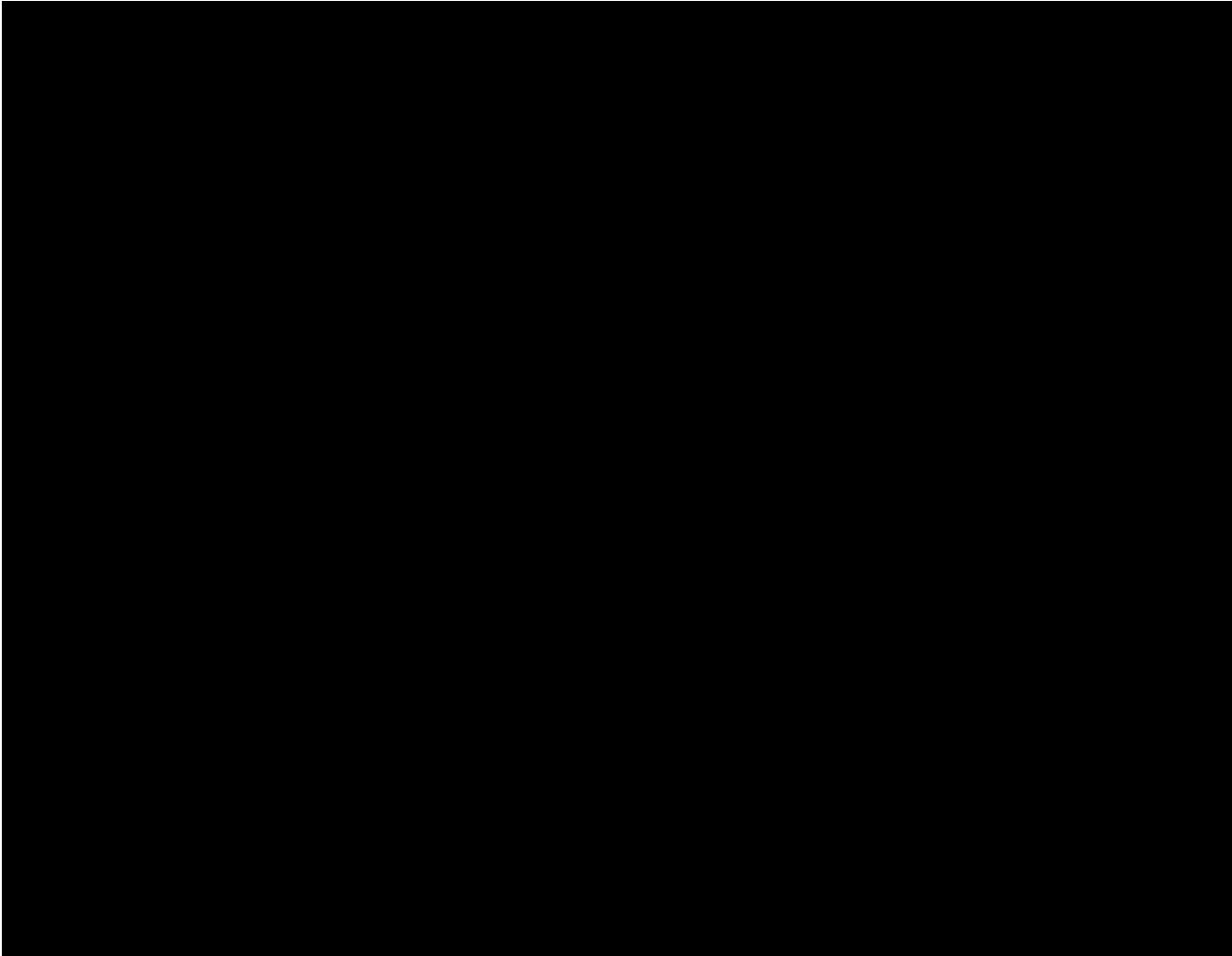
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Confidential Trade Secrets

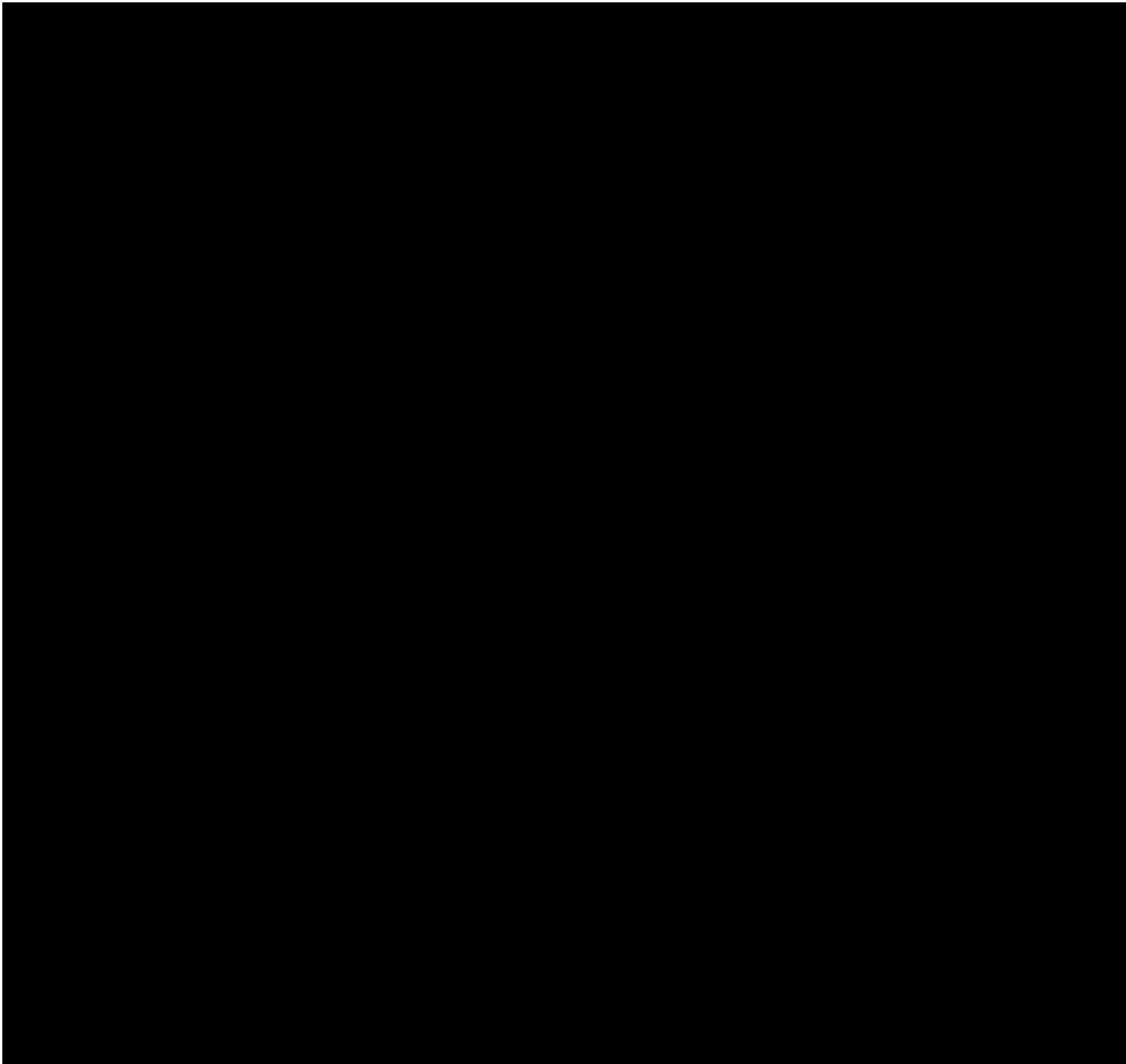
Exempt from disclosure pursuant to Section 119.0715, F.S.

 Standard Operating Procedure	Title: Receiving Goods	Section: Operations
	Effective Date: OCT 20, 2023	SOP Number: QS-013.007
		Page 13 of 13



Confidential Trade Secrets

	Title: Stock Receipt – 3PL/CMO	Form QS-013-1.007
	Effective Date: OCT 20, 2023	Page 1 of 1



Confidential Trade Secrets

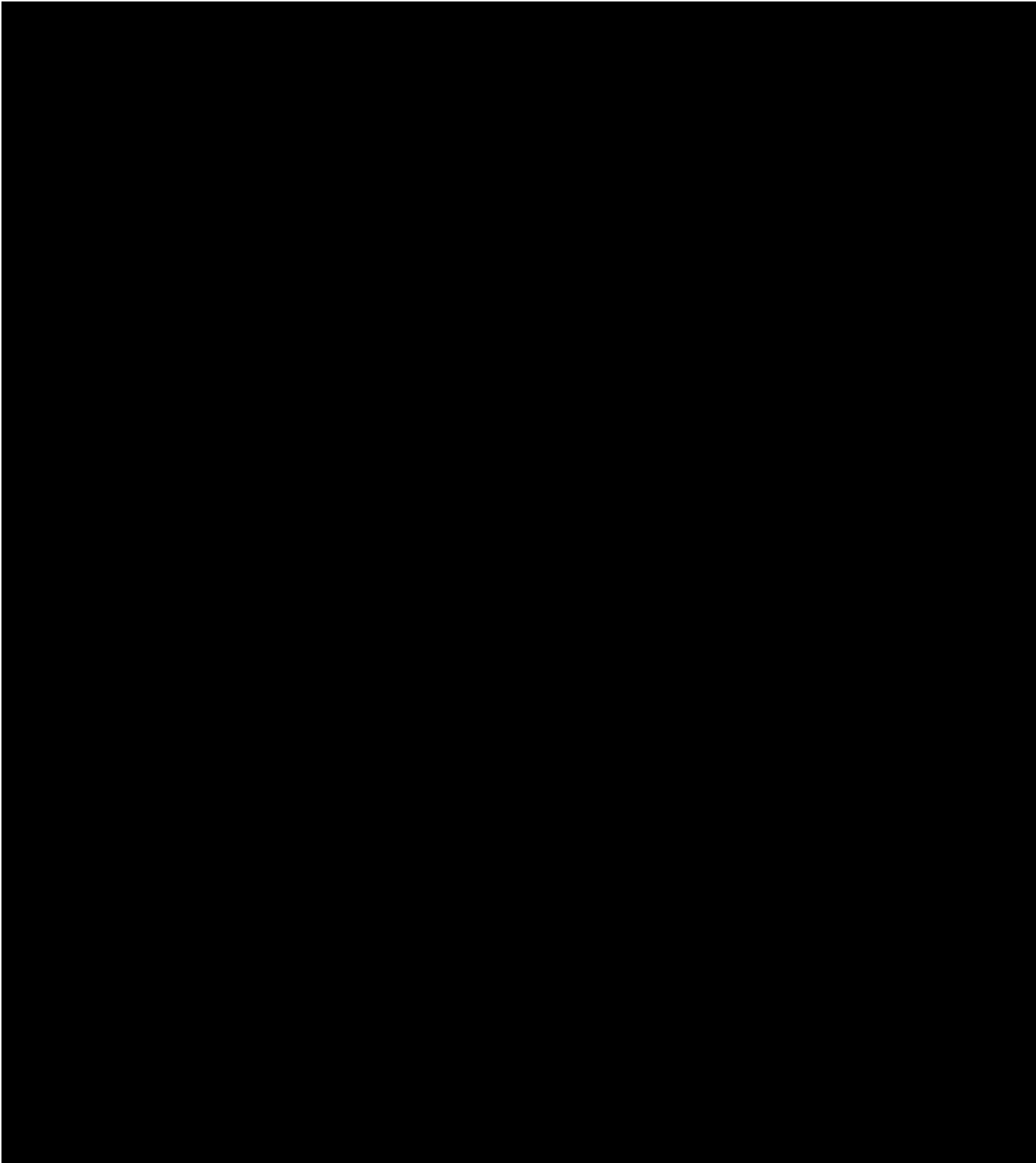


Title: **Methacholine Chloride
API Receipt Summary**

Form QS-013-2.007

Effective Date: **OCT 20, 2023**

Page **1** of **1**



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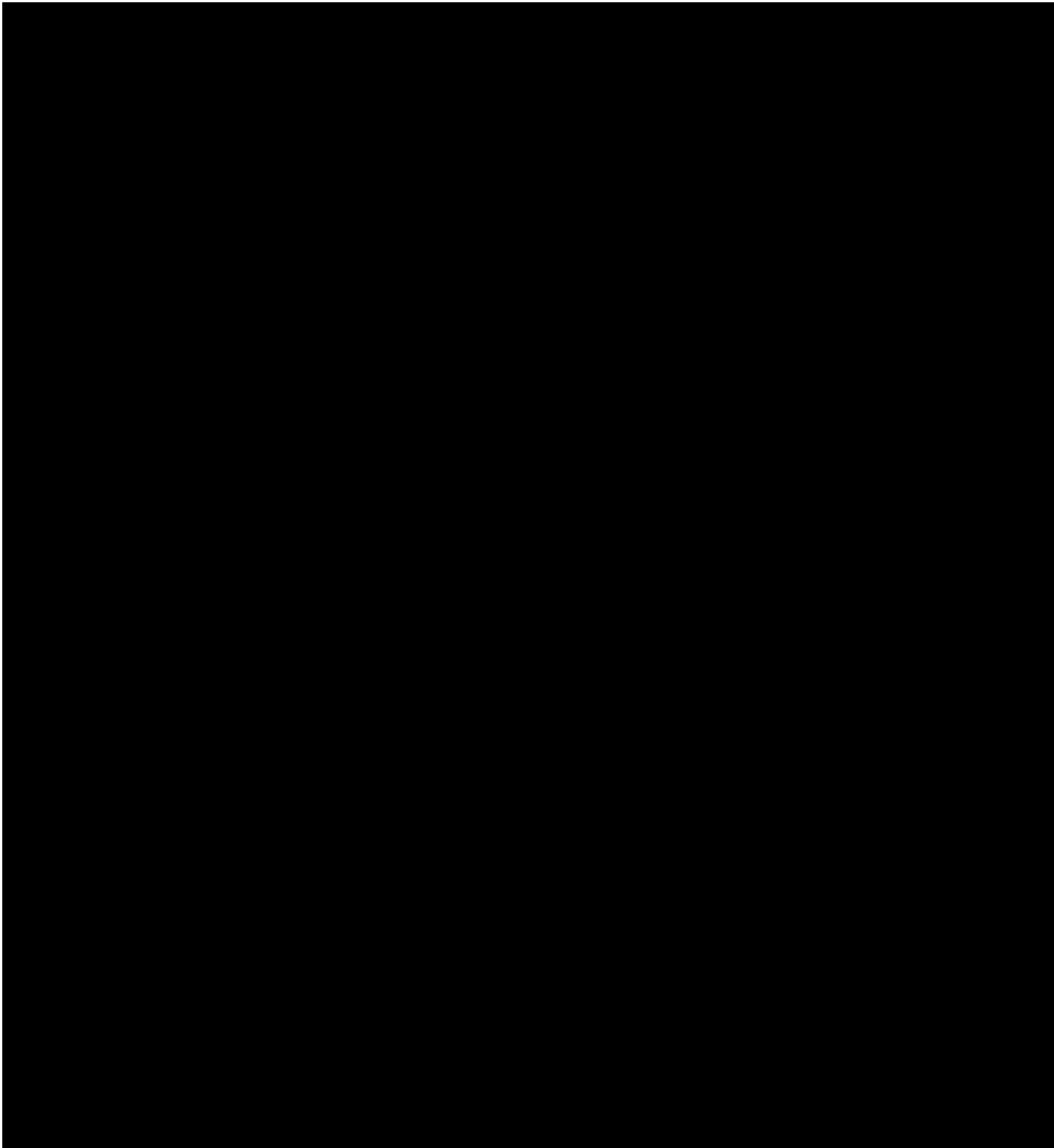


Title: **Medical Device or Other Bulk Receipt Summary**

Form QS-013-3.007

Effective Date: **OCT 20, 2023**

Page **1** of **1**



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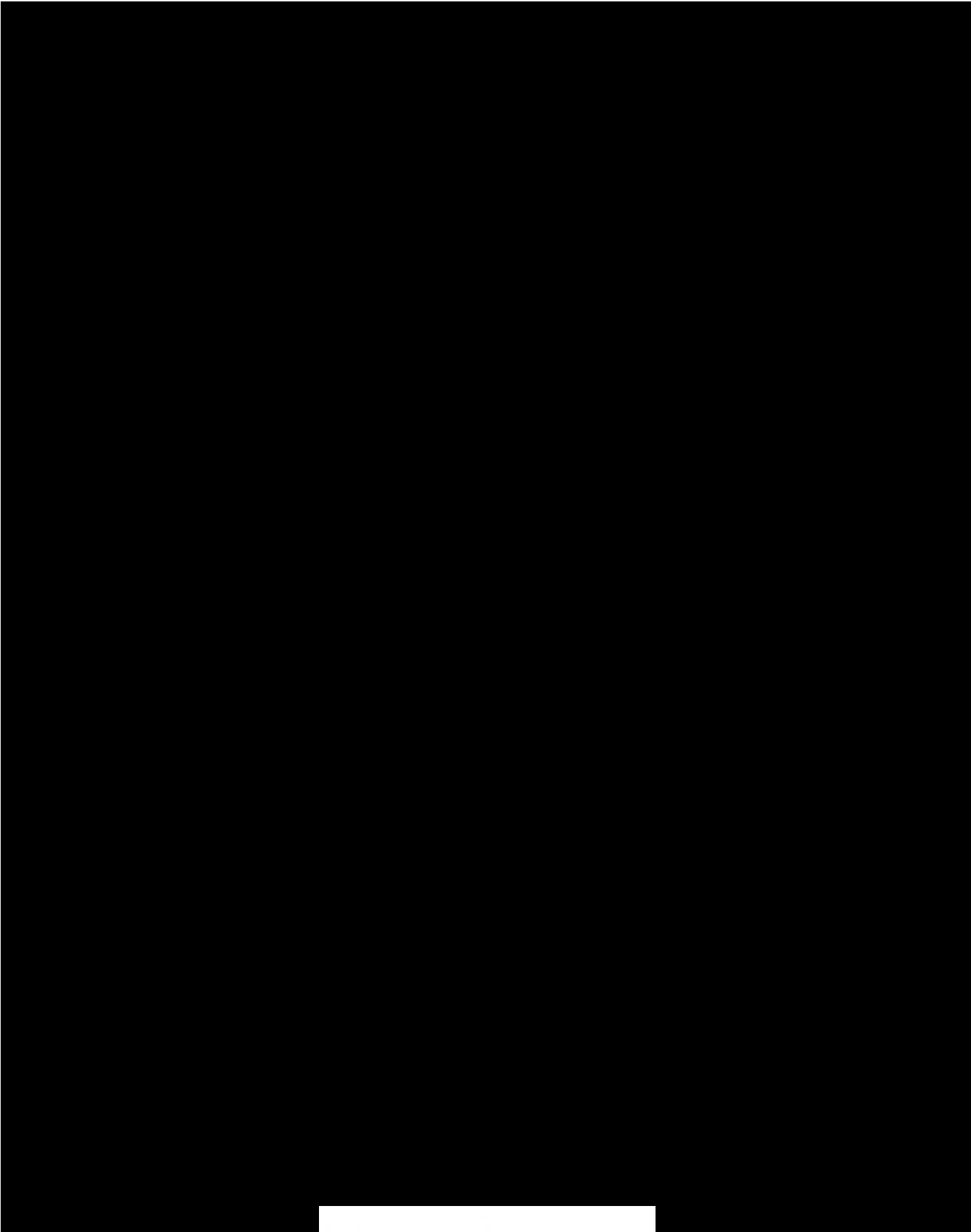


Title: **Stock Receipt -
Methapharm**

Form QS-013-4.007

Effective Date: **OCT 20, 2023**

Page **1** of **2**



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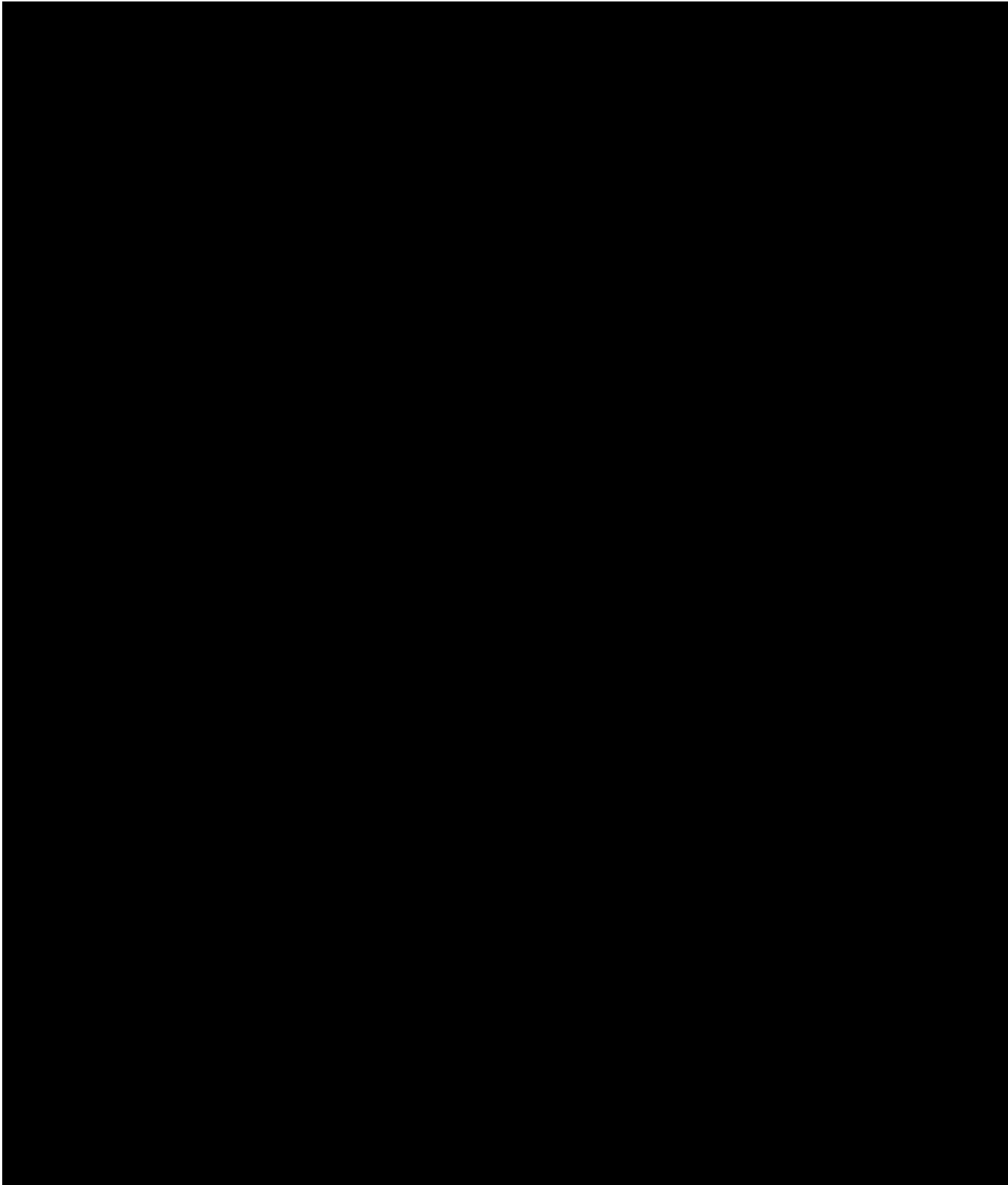


Title: **Stock Receipt -
Methapharm**

Form QS-013-4.007

Effective Date: **OCT 20, 2023**

Page **2** of **2**



Confidential Trade Secrets

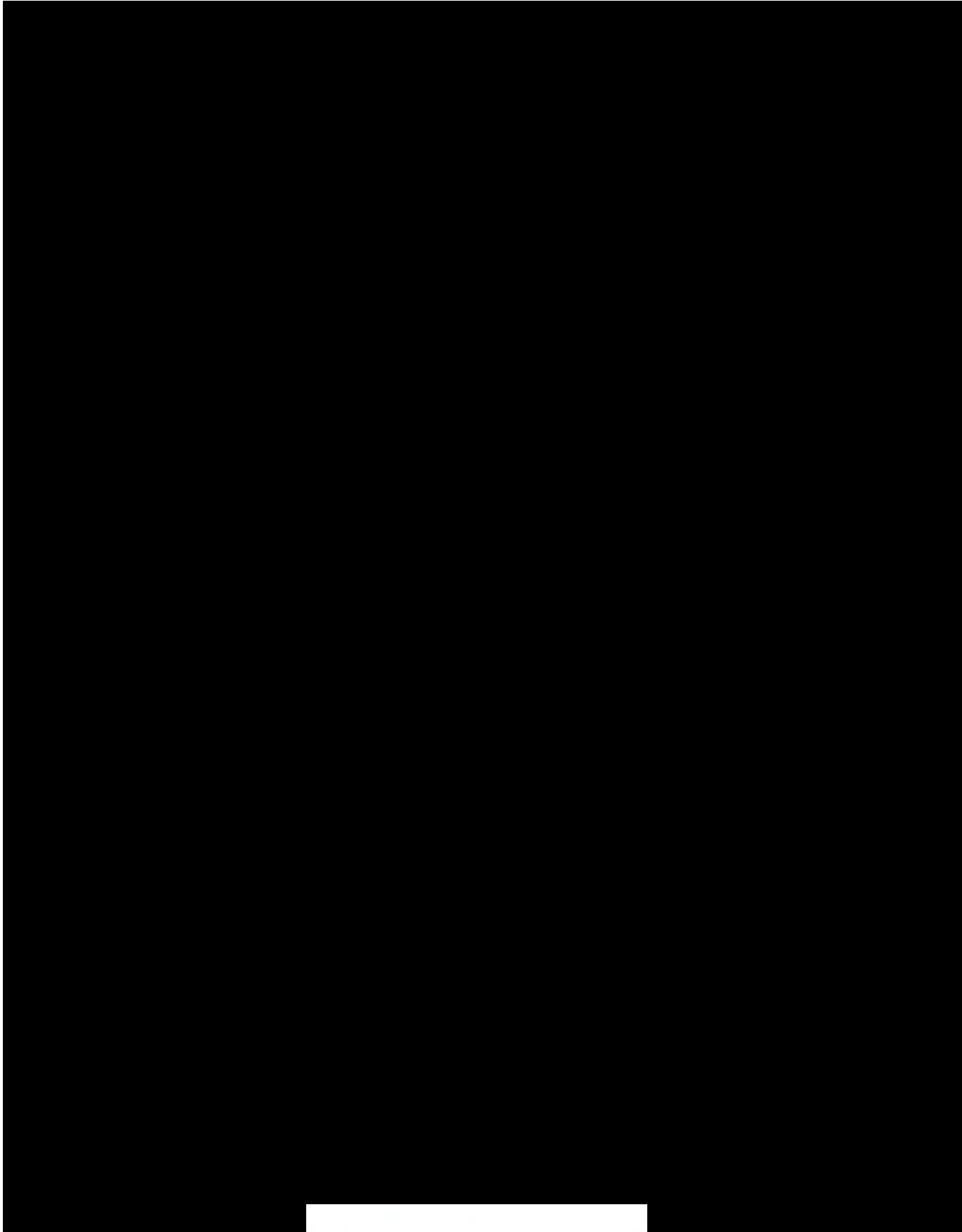


Title: **Evaluation
Questionnaire**

Form QS-013-5.007


Effective Date: **OCT 20, 2023**

Page **1** of **1**



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

 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
	Effective Date: AUG 27 2021	SOP Number: QS-015.005
		Page 1 of 14

Issued by: Quality Assurance	Copy No.: Electronic Copy
Note: Not a controlled copy unless the above space is completed in red ink or text.	

Prepared by: QA Associate <i>Mark Dumas</i>	Signature: <i>[Signature]</i>	Date: <i>11-Aug-2021</i>
Reviewed by: Department Management	Signature: <i>[Signature]</i>	Date: <i>aug 11. 2021</i>
Approved by: QA Management	Signature: <i>[Signature]</i>	Date: <i>aug 11. 2021</i>

1.0 Purpose

To describe the procedure for reporting of quality incidents, non-conformances and deviations, collectively referred to as 'Deviations', at Methapharm Inc. (Methapharm).


2.0 Scope

- 2.1 This procedure applies to the documentation and assessment of quality incidents, non-conformances and deviations, collectively referred to as 'Deviations' for Methapharm processes and products through Good Manufacturing Practices (GMP) and/or Good Pharmacovigilance Practices (GVP) activities.
- 2.2 This procedure does not apply to administrative or pre-marketed activities.

3.0 Responsibility

- 3.1 It is the responsibility of all employees involved in GMP and/or GVP activities to:
 - o Report and/or document deviations and non-compliance/non-conformance of GMP/GVP activity to approved procedures and product quality.
 - o Notify their Department Manager and Quality Assurance (QA) immediately (within one (1) business day) upon discovery of a deviation.
 - o Initiate a Deviation Report Form immediately (within one (1) business day) upon discovery of a deviation.
 - o Provide support with the investigation, as required.
 - o Complete assigned action items to address the deviation, correct and/or prevent a recurrence.
 - o Submit supporting documentation for assigned action items to QA for closure.

Confidential Trade Secrets

 Standard Operating Procedure	Title:	Section: Quality Systems
	Deviations and Non-conformances	SOP Number: QS-015.005
	Effective Date: AUG 27 2021	Page 2 of 14

3.2 It is the responsibility of Department Managers to:

- Provide Subject Matter Expert (SME) input and assist with the investigation in a timely manner.
- Ensure that actions items assigned to your department are completed by assigned due date.

3.3 It is the responsibility of Quality Assurance to:

- Assign a Deviation Report Number and assist the investigation to ensure timely completion of the of the deviation.
- Appoint an investigator from the affected department, if required, to investigate the deviation.
- Track the status of the investigation to ensure deviation is completed by required due date.
- Track the status of assigned action items to ensure they are closed by assigned due date.

3.4 It is the responsibility of QA Management to:

- Manage the deviation system at Methapharm.
- Determine product disposition, if applicable.
- Review and approve Deviation Reports.
- Perform trend analysis.

4.0 References and Related SOPs


QS-001 – Standard Operating Procedures
QS-002 – Training Program
QS-017 – Complaint Handling
QS-020 – Record Control and Retention
QS-029 – Corrective Action and Preventive Action (CAPA) Program
QS-043 – Quality Risk Management

5.0 Forms/Attachments

Form QS-015-1 – Deviation Report Form
Form QS-015-2 – Planned Deviation Report Form
Form QS-015-3 – Evaluation Questionnaire

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Controlled Copy. Printed on: Oct 06, 2023. Valid until 11:59PM.

 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
		SOP Number: QS-015.005
	Effective Date: AUG 27 2021	Page 3 of 14

6.0 Definitions

6.1 Corrective Action / Preventive Actions (CAPA):

- **Corrective Action:** Action taken to eliminate the root cause(s) of a detected issue, problem or non-conformance. Corrective action is typically taken to immediately resolve the deviation or issue.
- **Preventive Action:** Action taken to prevent reoccurrence. Preventive actions are typically designed to prevent the issue, problem, non-conformance from reoccurring.
- **Required Action:** An action that is an outcome of a process change (i.e., Change Control Form, Planned Deviation). These actions may not necessarily be the results of identified problems or non-conformances but have nevertheless been identified as a required deliverable. Refer to SOP QS-029 Corrective Action and Preventive Action (CAPA) Program for further details.

6.2 Deviation: Also called an unplanned deviation. Any unexpected event, error, out-of-specification (OOS) or atypical result, unexpected trend or non-conformance, which is not consistent with established Methapharm GMP and/or GVP documents or regulatory requirements. A non-conformance is also considered a deviation as per this SOP. Non-conformances can be a malfunction or error associated with written procedures or specifications including those pertaining to premises, equipment, sanitation and testing that may have an impact on the Safety, Integrity, Strength, Purity and/or Quality (SISPQ) of a drug product, Active Pharmaceutical Products (API), medical device or Good Manufacturing Practices (GMP) facility. While carrying out day-to-day activities, there is a probability of unplanned deviations (unforeseen deviations) occurring. Such unexpected events may be related to procedures, processes, systems, equipment, etc.


6.3 Planned Deviation: Any deliberate or intentional non-conformance or deviation Planned prior to the execution of an activity, which is to be undertaken following documented, justifiable and approved rationale.

6.4 Quality Incidents: Any incident that may have occurred which can have potential impact on the Safety, Integrity, Strength, Purity and/or Quality (SISPQ) of a Product.

6.5 Root Cause: An identified reason for the presence of an issue, defect or problem. The root cause addresses the “Why” of the issue, defect, or problem that has occurred.

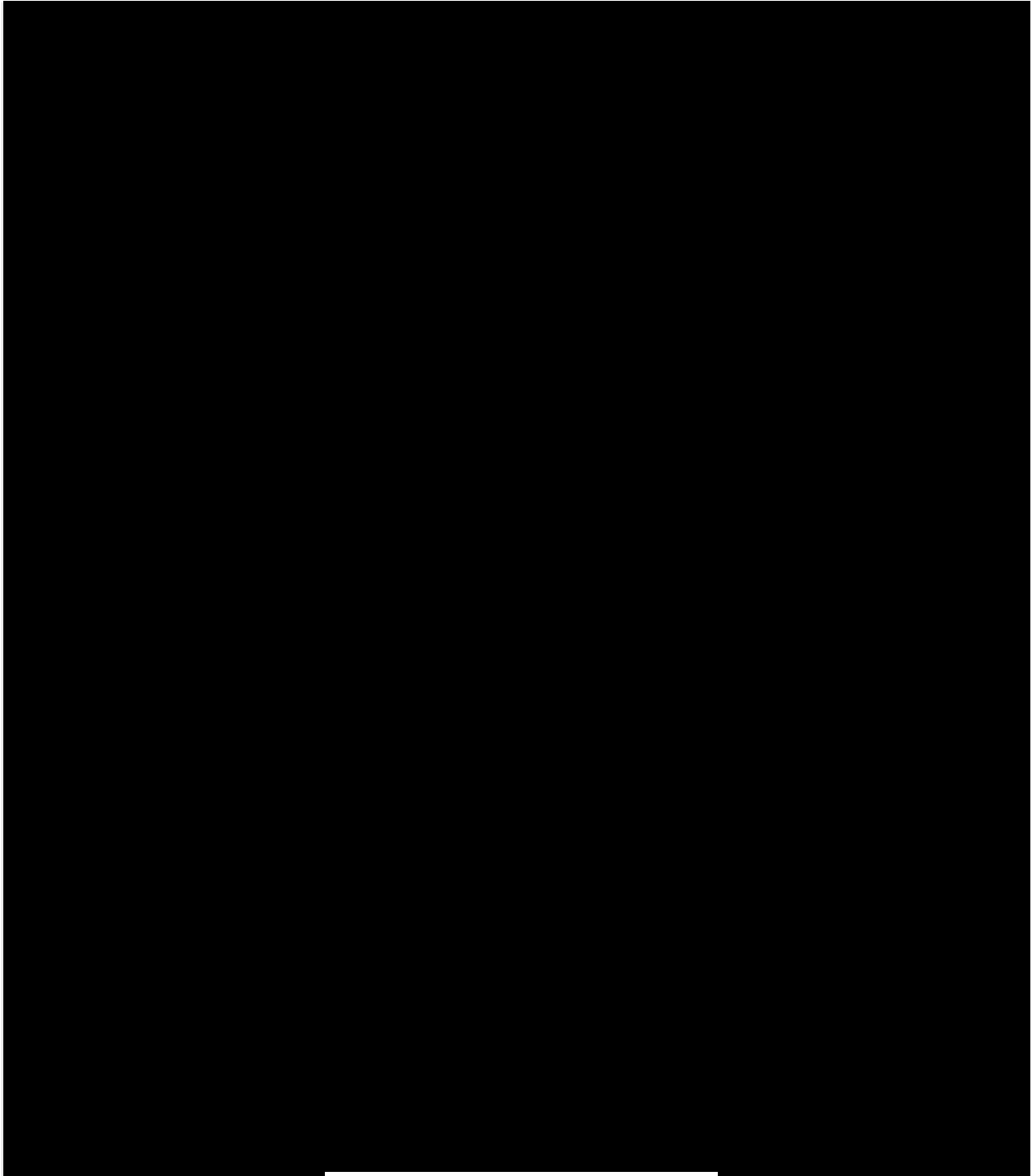
Confidential Trade Secrets

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 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
	Effective Date: AUG 27 2021	SOP Number: QS-015.005
		Page 4 of 14

7.0 Procedure

7.1 Deviation Reporting – Deviations



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Standard Operating Procedure

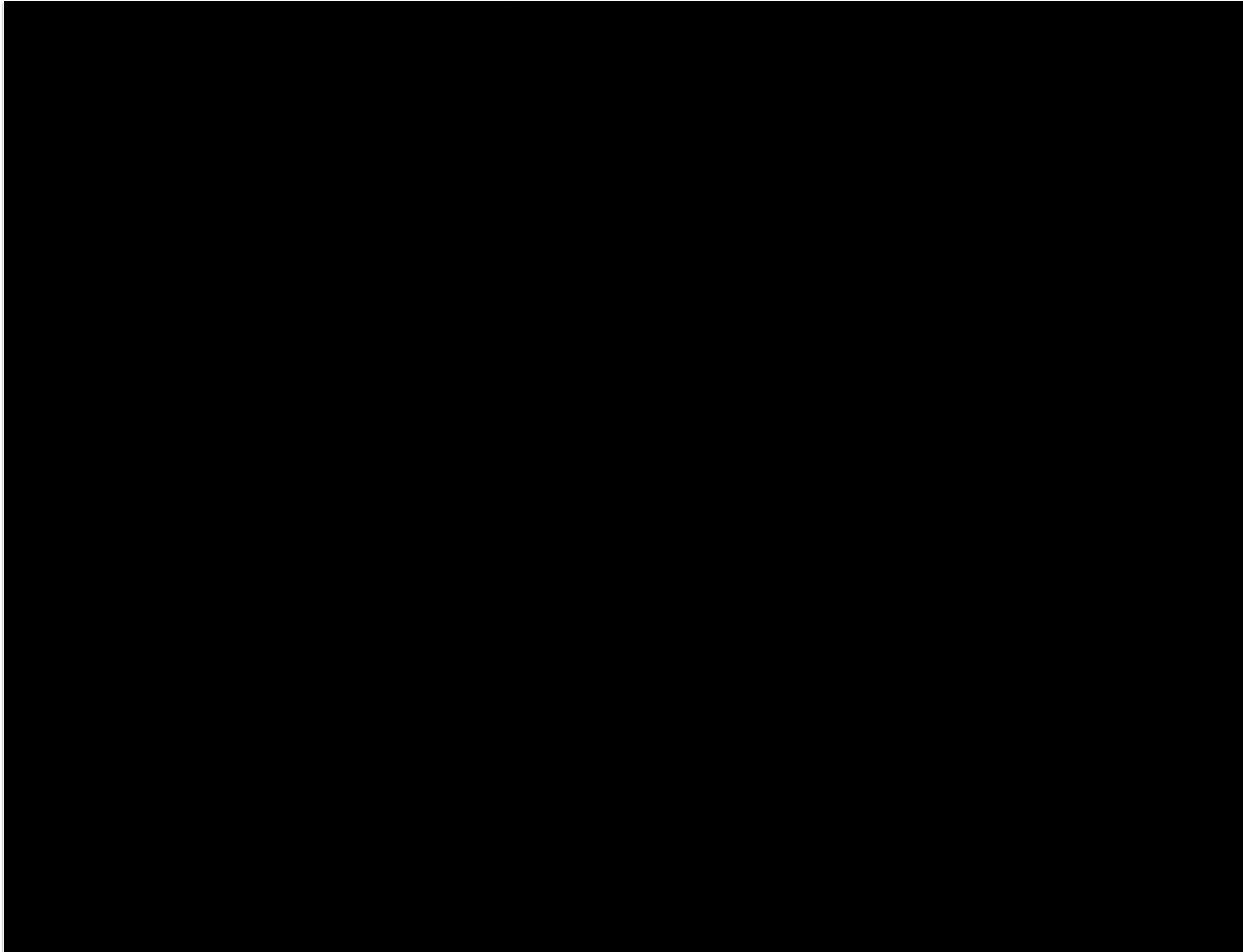
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Deviations and Non-conformances

Effective Date: **AUG 27 2021**

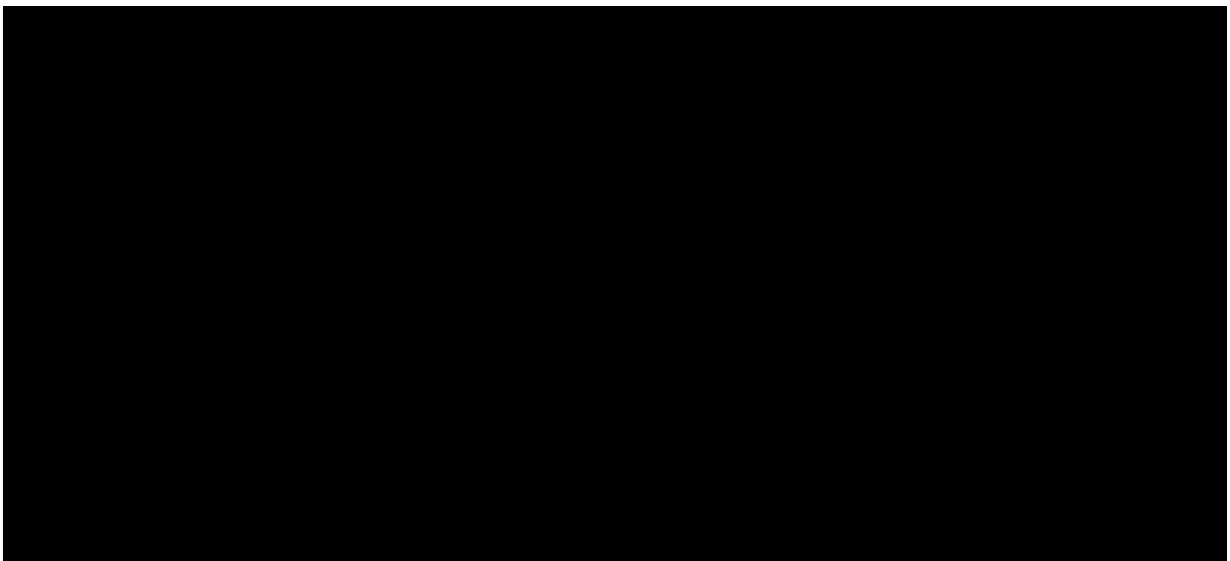
Section: Quality Systems

SOP Number: QS-015.005

Page 5 of 14



7.2 Initial QA Review and Assessment





Standard Operating Procedure

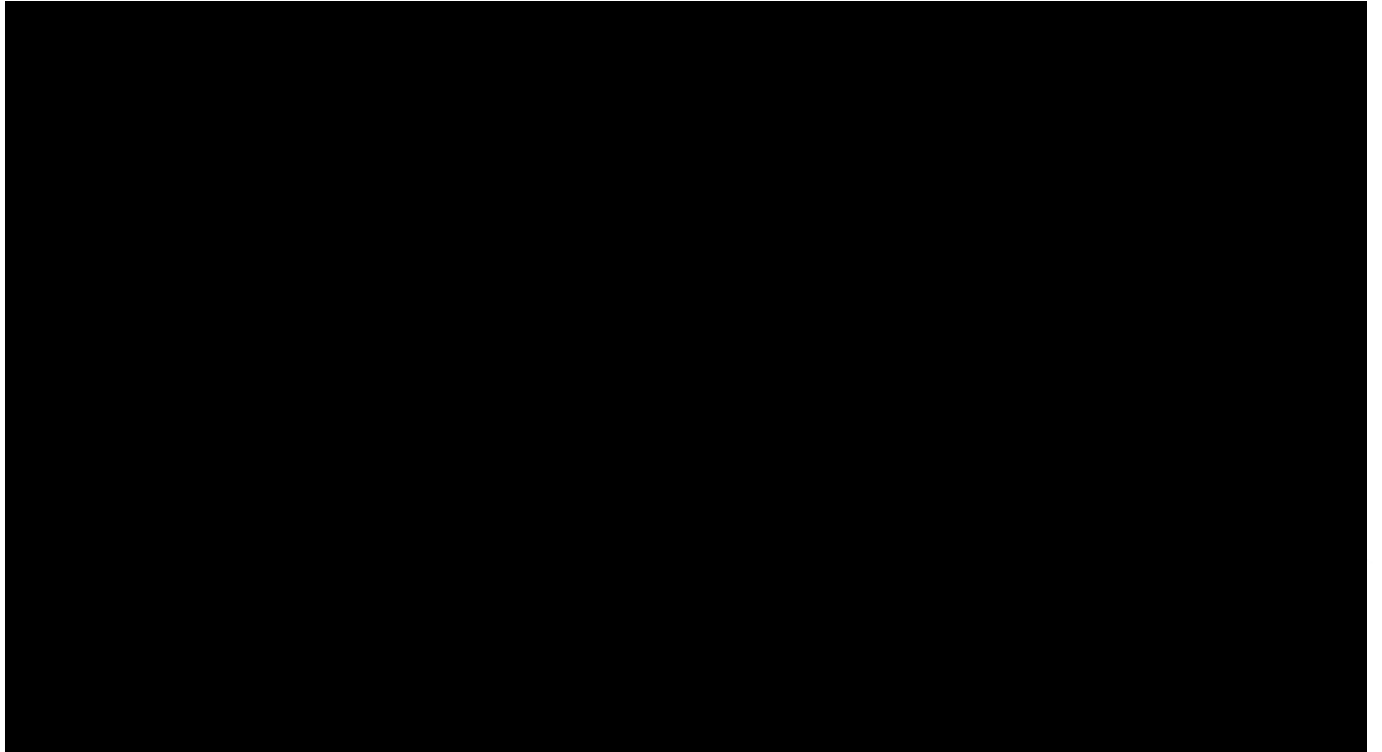
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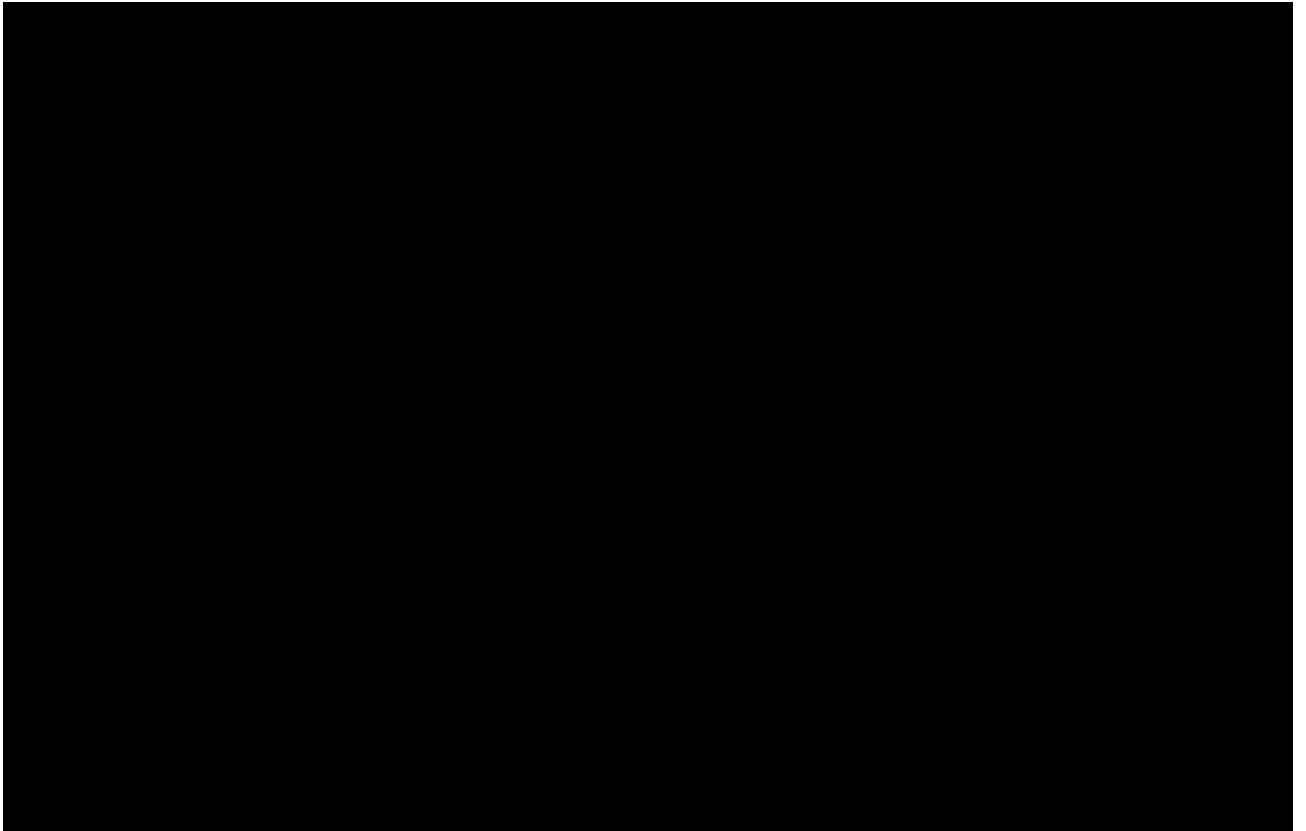
Section: Quality Systems

SOP Number: QS-015.005

Page **6** of **14**



7.3 Investigation





Standard Operating Procedure

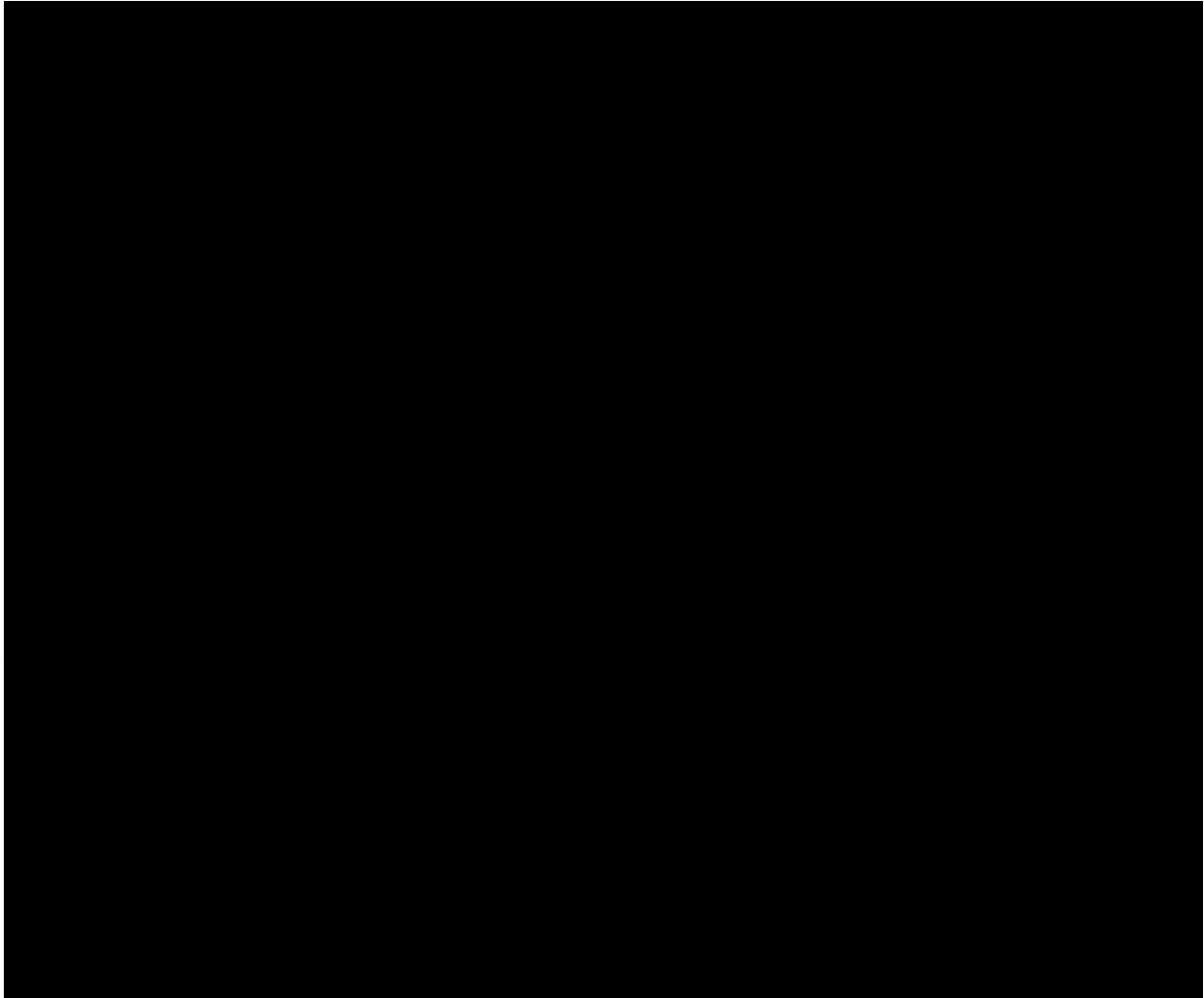
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Effective Date: AUG 27 2021

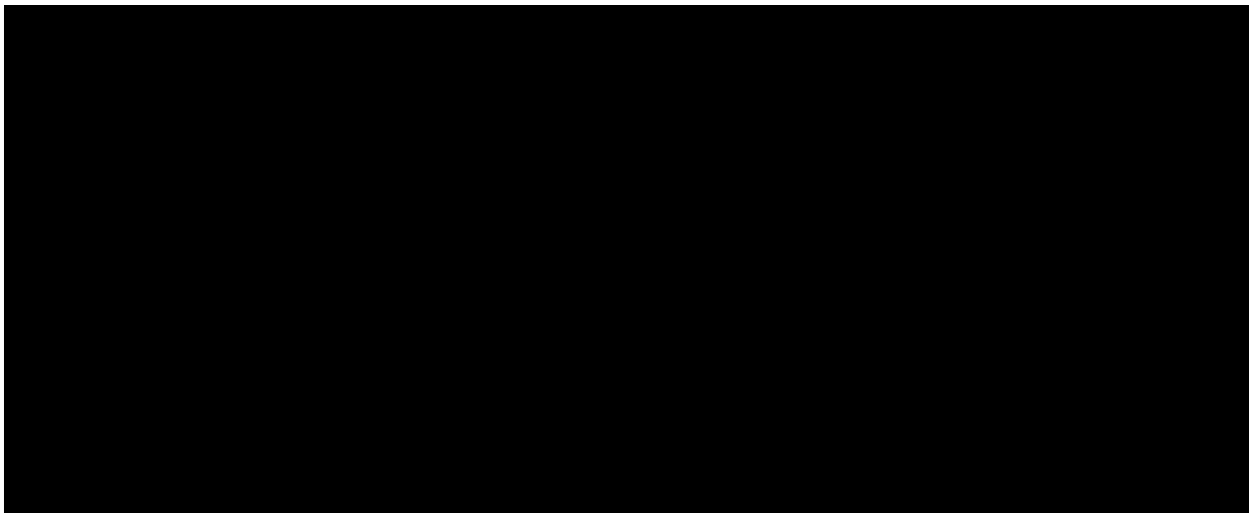
Section: Quality Systems

SOP Number: QS-015.005

Page 7 of 14



7.4 QA Risk Assessment





Standard Operating Procedure

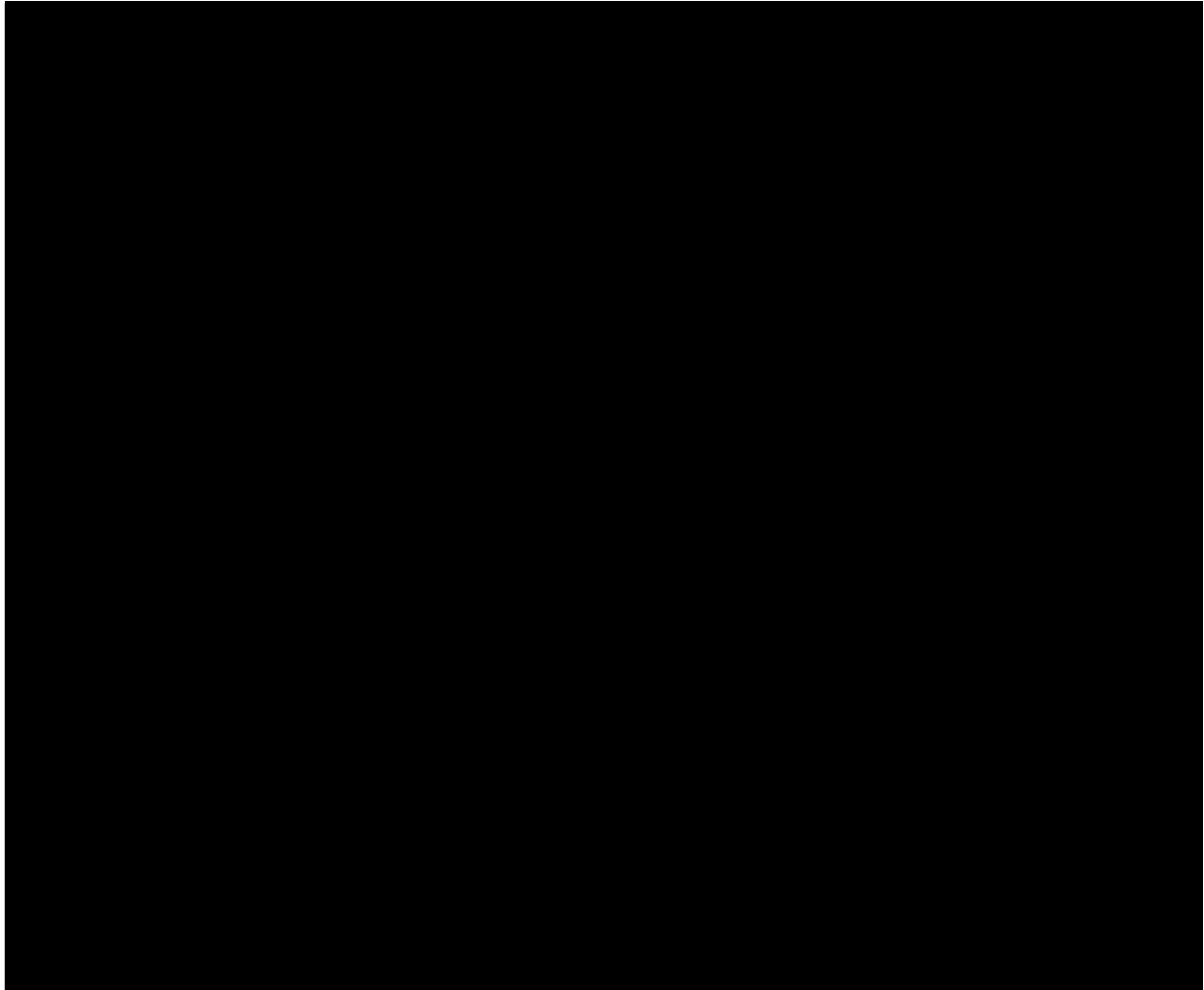
Title:
Deviations and Non-conformances

Effective Date: AUG 27 2021

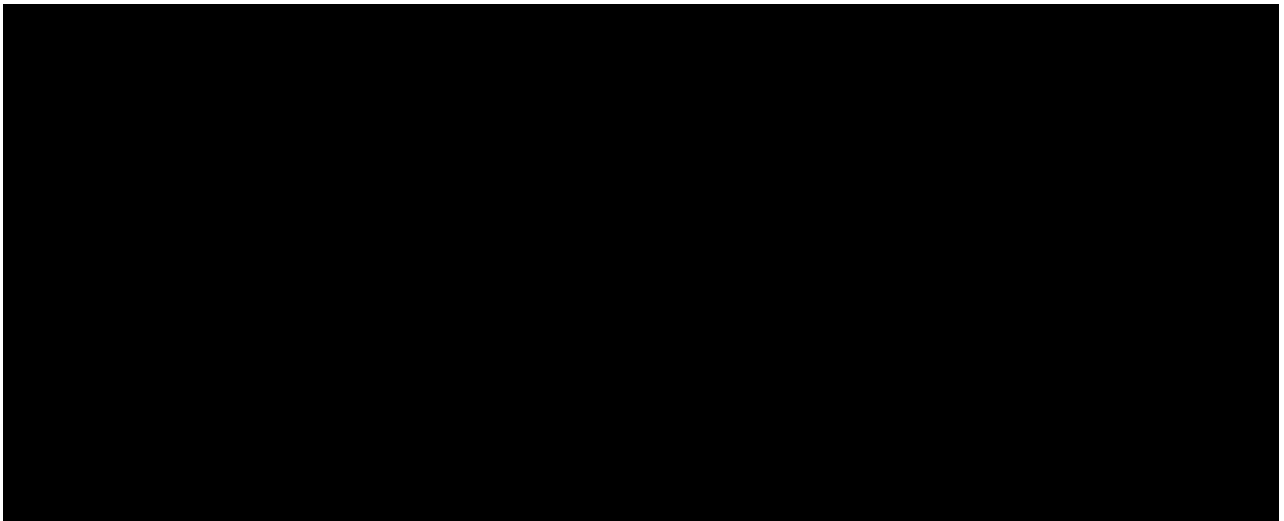
Section: Quality Systems


SOP Number: QS-015.005

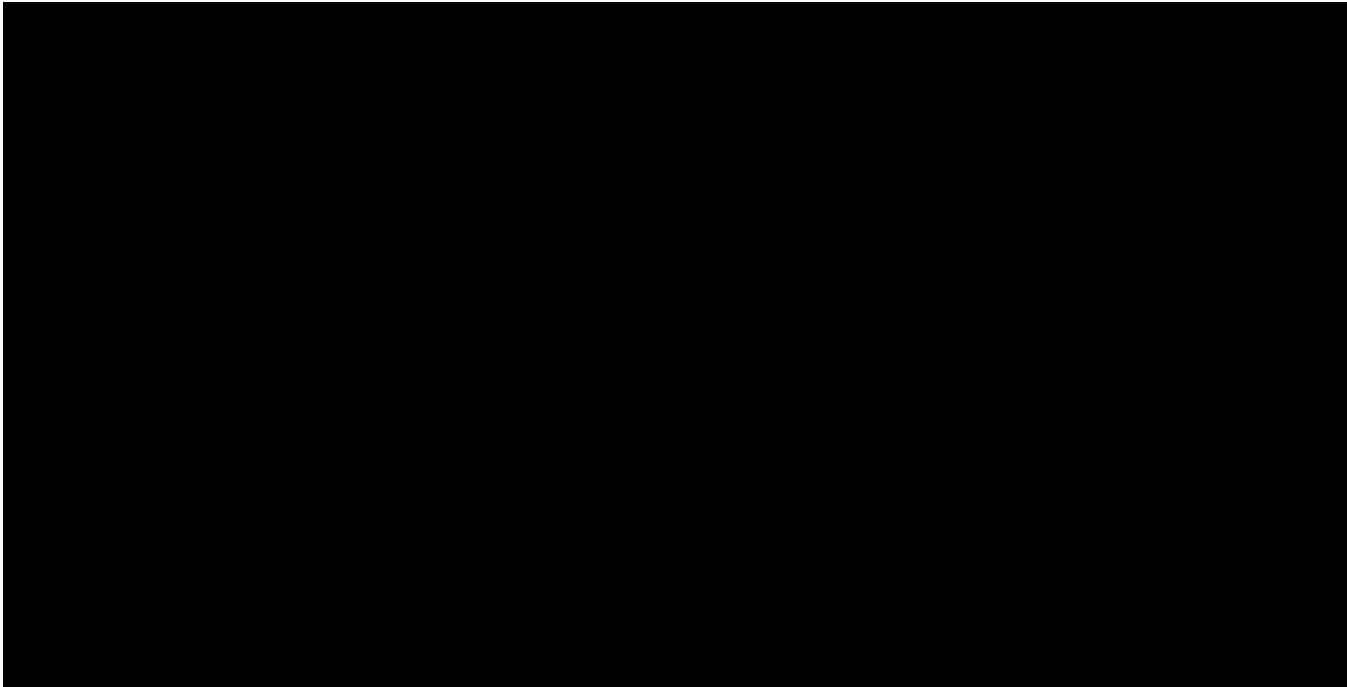
Page 8 of 14



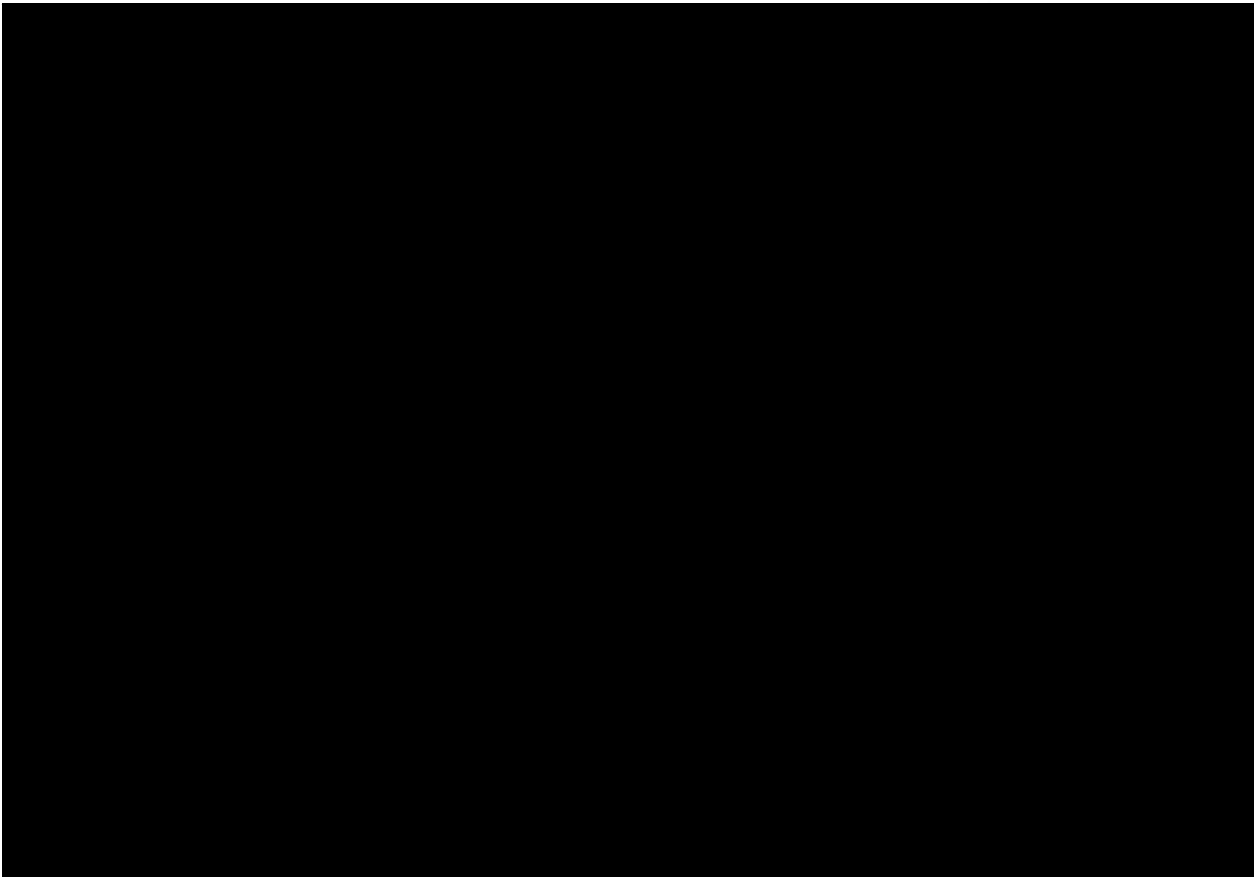
7.5 Corrective and Preventive Actions




 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
		SOP Number: QS-015.005
	Effective Date: AUG 27 2021	Page 9 of 14

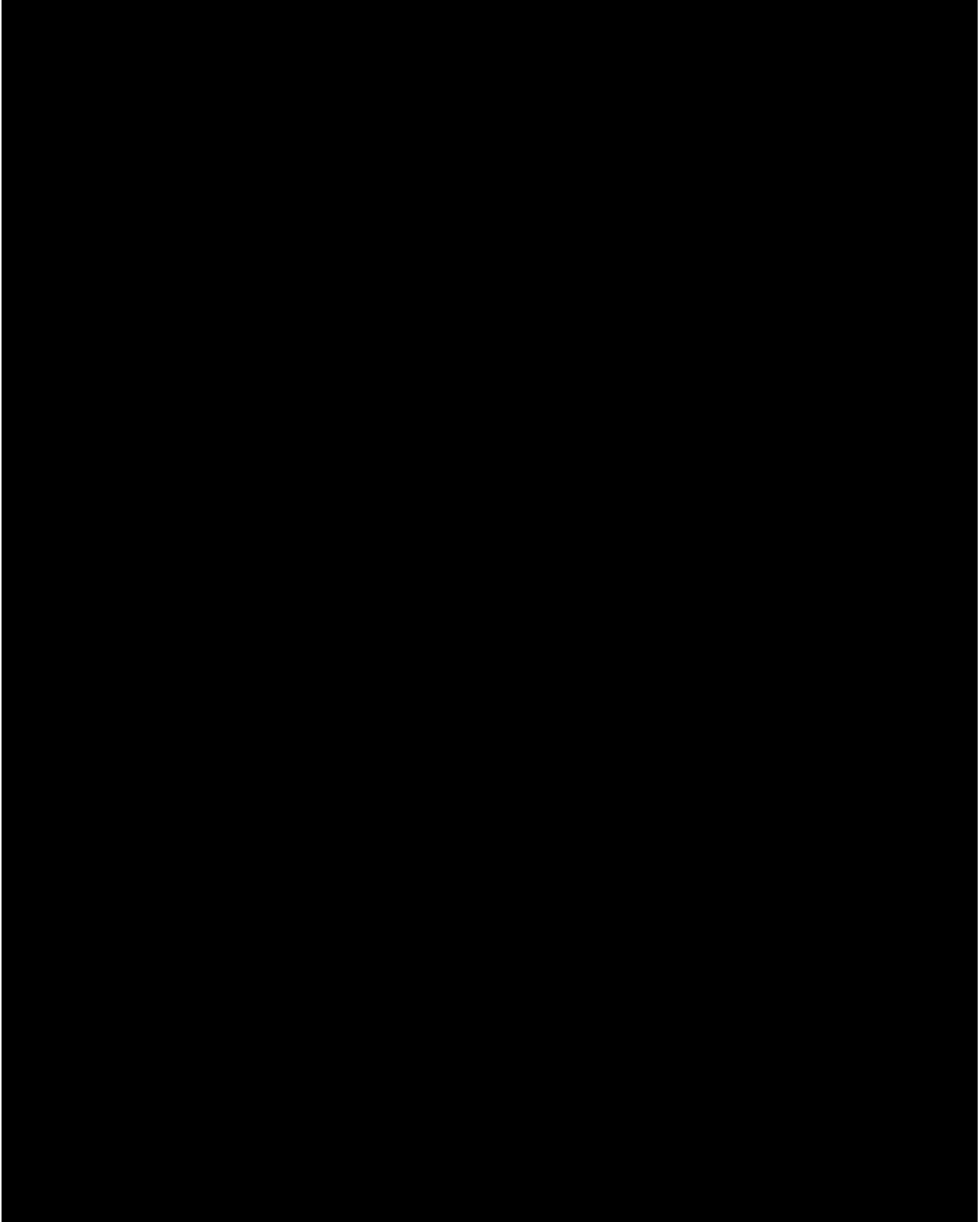



7.6 Summary and Conclusion

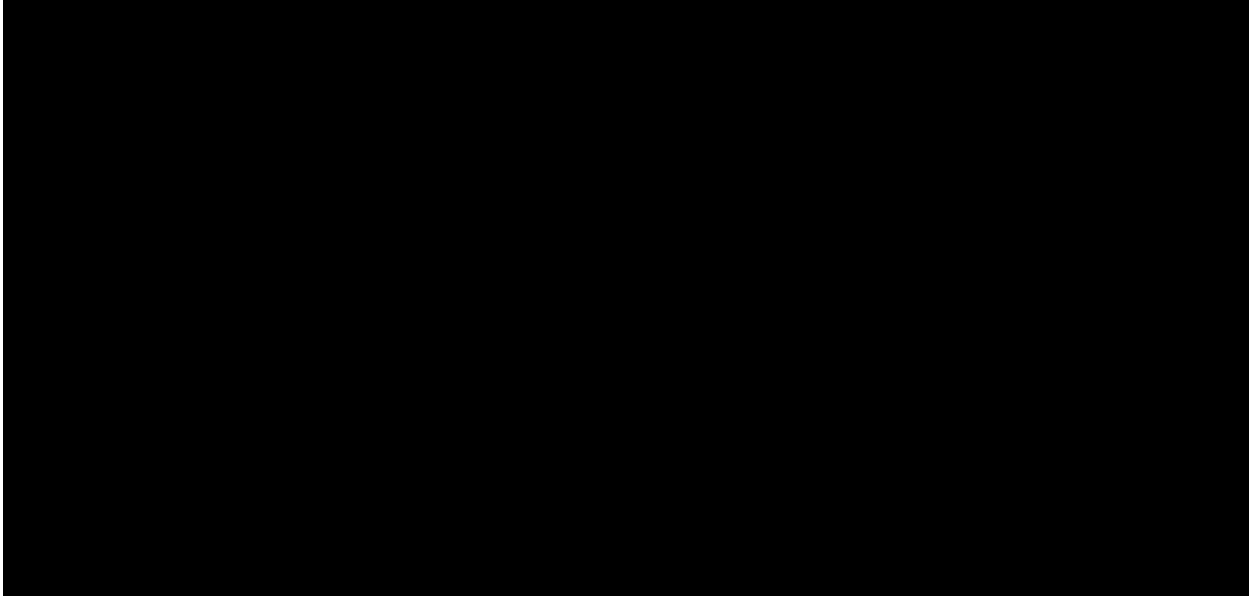


 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
	Effective Date: AUG 27 2021	SOP Number: QS-015.005
		Page 10 of 14

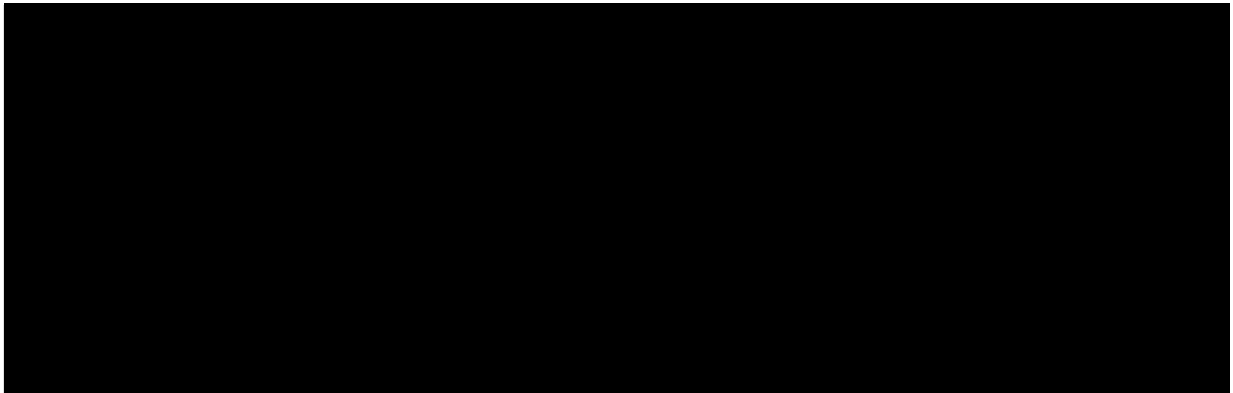
7.7 Deviation Reporting – Planned Deviations



 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
		SOP Number: QS-015.005
	Effective Date: AUG 27 2021	Page 11 of 14




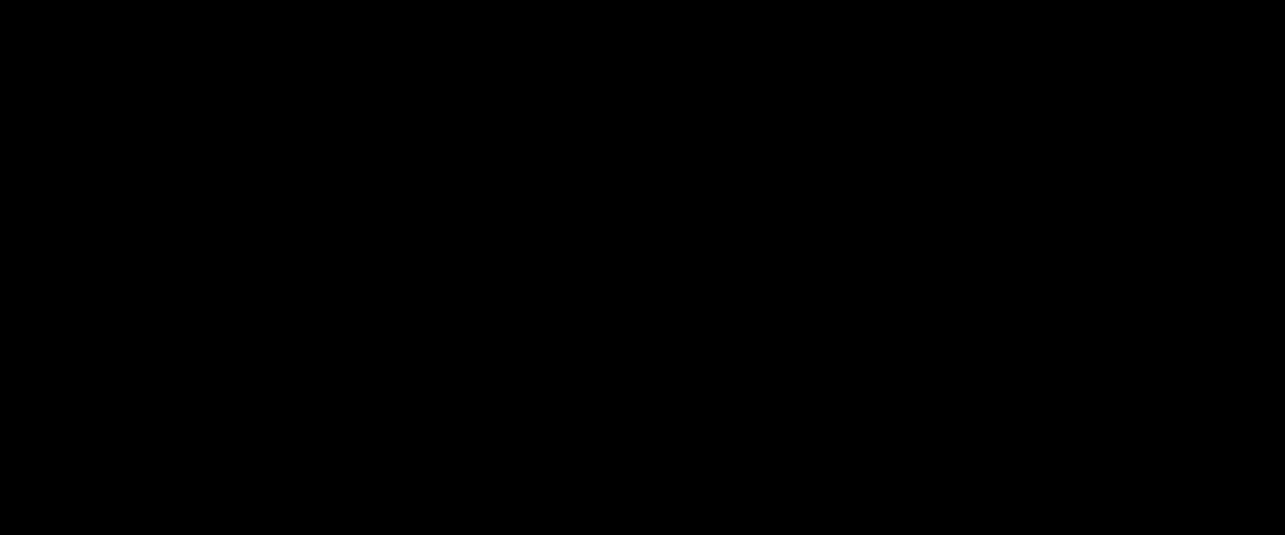
7.8 Assigning Deviation and Planned Deviation Numbers



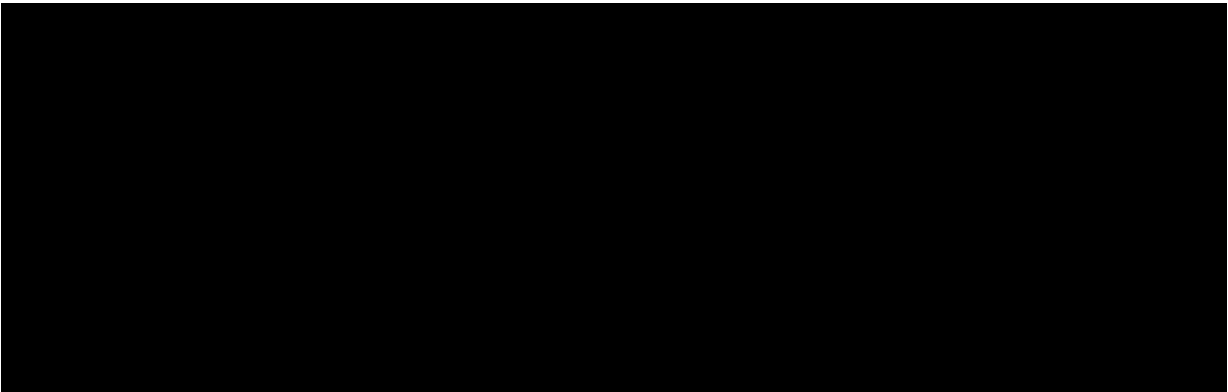
7.9 Updates, Cancellation and Extension Requests



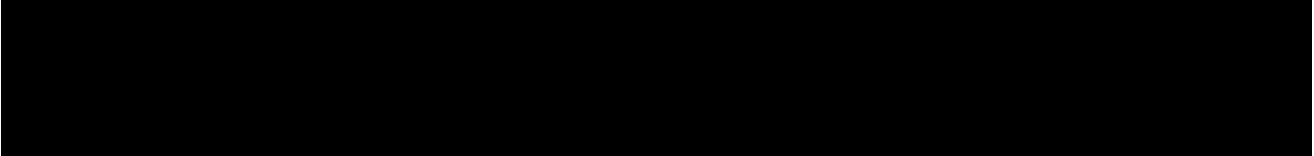
 Standard Operating Procedure	Title: Deviations and Non-conformances	Section: Quality Systems
		SOP Number: QS-015.005
	Effective Date: AUG 27 2021	Page 12 of 14



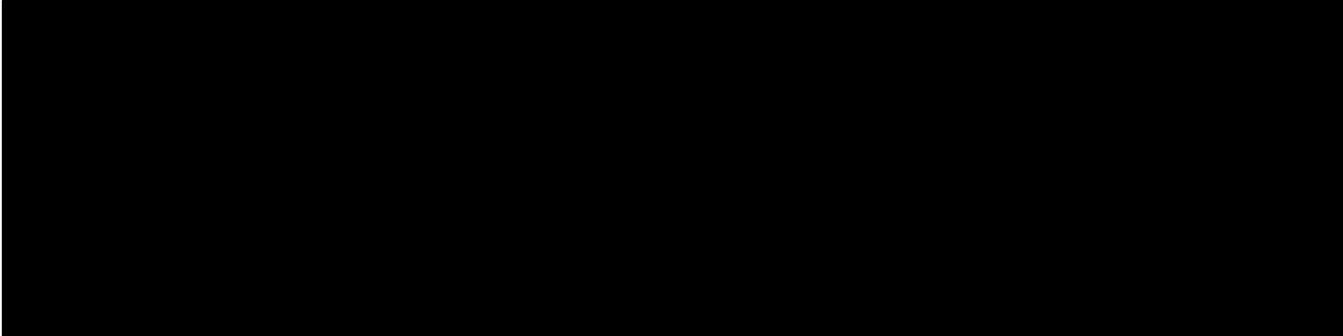
7.10 Tracking and Trending



8.0 Records



9.0 Revision History





Standard Operating Procedure

Title:
Deviations and Non-conformances

Effective Date: **AUG 27 2021**

Section: Quality Systems

SOP Number: QS-015.005

Page **13** of **14**

