Your Logo

Your Company Name

Add to Cart

MANUFACTURING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-10 Manufacturing Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the manufacturing process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the overall Manufacturing process and includes or makes reference to the procedures necessary for the process.

NOTE: The Manufacturing process includes all QC inspections and tests within it. Quality is not a separate process.

2.0 THEORY

Manufacturing operations or tasks must be conducted under controlled conditions to ensure product quality. By this we mean:

- [redacted]

3.0 PROBLEM RESOLUTION

All employees are instructed to immediately notify a Responsible Authority (RA) whenever a process or product related problem occurs that cannot be corrected according to established process controls and could [redacted]

It is understood that the appropriate responsible authority will [redacted]

- [redacted]

4.0 REQUIREMENTS

The Company implements production and service provision under controlled conditions, which includes:

- [redacted]

- [redacted]
- [redacted]
- [redacted]

5.0 PRODUCTION DOCUMENTATION

Documented information includes [redacted]

Documented information that defines characteristics of products and services includes [redacted]

When required to demonstrate product qualification, the Company [redacted]

The Company ensures all documented information required to accompany the products and services are present at delivery.

5.1 All revision controlled production documents are [redacted]

5.2 In addition to this process procedure, additional production documentation may be required for a given order or production operation. Where required, these are [redacted]

5.3 Such documentation includes [redacted]

5.4 Records that are created for temporary retention of miscellaneous information are not [redacted]

6.0 PRODUCT IDENTIFICATION

The Company maintains the identification of the configuration of products and services to identify [redacted]

The Company controls acceptance authority media, such as [redacted]

6.1 Product is identified in shop areas by any of the following methods:

- [redacted]
- [redacted]
- [redacted]

[redacted]

6.2 Lot traceability or individual serialization of parts is to be maintained on the paperwork (travelers, routers, etc.) as required. Supervisory staff will [redacted]
Traceability requirements include:

- [redacted]

6.3 Bad (nonconforming) product that has failed an inspection or test and cannot be reworked to comply with requirements is [redacted]
See the ***QMS-14 Control of Nonconformities Procedure***.

6.4 Any parts or product not marked with a tag are [redacted]

6.5 IDENTIFICATION OF TRANSFER CONTAINERS
6.5.1 Whenever a portion of chemical is transferred from its original container to a smaller temporary container, [redacted]
6.5.2 Whenever a portion of chemical is transferred from its original container to a smaller permanent container, [redacted]

7.0 PRODUCT HANDLING

7.1 Work instructions and/or training operations instruct Operators on the proper and safe handling of product throughout its life cycle, and includes [redacted]

7.2 In all cases, Operators are [redacted]

7.3 The Company provides suitable safety and personal protection equipment for handling hazardous or toxic materials. Operators are [redacted]

8.0 PRESERVATION

8.1 Operators will [redacted]

8.2 Operators will [redacted]

8.3 Operators will [redacted]

8.4 Operators will [redacted]

8.5 FOD: Foreign Object Damage, Prevention, Detection and Removal: Work instructions and training methods ensure that handling and preservation practices reduce the introduction of foreign objects (FOD) into products.

8.6 [redacted]

8.7 [redacted]

9.0 EXTERNAL PROVIDER PROPERTY CONTROL

The Company identifies, verifies, protects and safeguards External Provider property provided for use or incorporation into products and services. When property is lost, damaged or otherwise found to be unsuitable for use, the Company documents findings and reports to the Customer.

9.1 External Provider Property (Property) means [redacted]

Hardware property includes:

- [redacted]

9.2 All External Provider furnished hardware property shall [redacted]

9.3 Property shall be identified [redacted]

9.4 Sensitive material, as defined by the External Provider, shall [redacted]

9.5 Property shall only be used as instructed or required by External Provider contract and [redacted]

9.6 External Provider equipment shall [redacted]

9.7 The Responsible Authority investigates [redacted]

9.8 Requirements for the control of External Provider property shall [redacted]

10.0 VALIDATION OF PROCESSES

10.1 Unless otherwise specified by engineering requirements, the form named ***Validation-Verification*** is used to record results of validation and verification activities (may be referred to as "special processes").

10.2 Validation and verification activities include [redacted]

Provisions for validation and verification includes:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

11.0 PRODUCTION PROCESS VERIFICATION

The Company implements production process verification activities to [redacted]

11.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor or measure production processes are [redacted]

12.0 INSPECTION AND TEST OF PRODUCT OR SERVICE

The Company maintains suitable infrastructure for the provision of products and services, which includes [redacted]

12.1 Receiving inspection is performed according to the ***QMS-09 Receiving Procedure***.

12.2 First Article Inspection

The Company uses a representative item from the first production run of a new part or assembly to verify the production processes, production documentation and tooling are able to produce parts and assemblies that meet requirements. This activity is [redacted]

12.2.1 First article inspections are [redacted]

12.2.2 The Company will [redacted]

12.2.3 Where not provided, the Company will [redacted]

12.2.4 Complete the first article inspection form according to its format and submit to CCB.

12.2.5 Calibrated tools shall be used for first article inspection; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.2.6 [redacted]

12.2.7 Any item failing first article inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.3 In Process Inspections

12.3.1 In-process inspection is performed by [redacted]

12.3.2 In-process inspections are performed [redacted]

The Company ensures documented information for monitoring and measurement activity for product acceptance includes:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

When sampling is used as a means of product acceptance, the sampling plan is [redacted]

12.3.3 Calibrated tools shall be used for in-process inspection; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.3.4 When applicable, complete the production inspection form according to its format.

12.3.5 [redacted]

12.3.6 Any item failing in-process inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.4 Final Inspection

12.4.1 Final inspection is performed by Responsible Authority(s) prior to release of product for packaging and shipping.

12.4.2 100% sampling is required for final inspection unless otherwise specified by Customer contract. When sampling is permitted by Customer contract, [redacted]

12.4.3 Calibrated equipment is used for final inspection and documented information provides traceability to specific monitoring and measurement equipment; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.4.4 Complete the production inspection form according to its format. Prior to final acceptance, confirm [redacted]

12.4.5 Any item failing final inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.4.6 Prior to product delivery to Customer, the Responsible Authority [redacted]

13.0 SHELF LIFE EXTENSION

[redacted]

13.1 Items that are subject to expiration may [redacted] for instance:

13.1.1 [redacted]

13.1.2 [redacted]

13.1.3 [redacted].

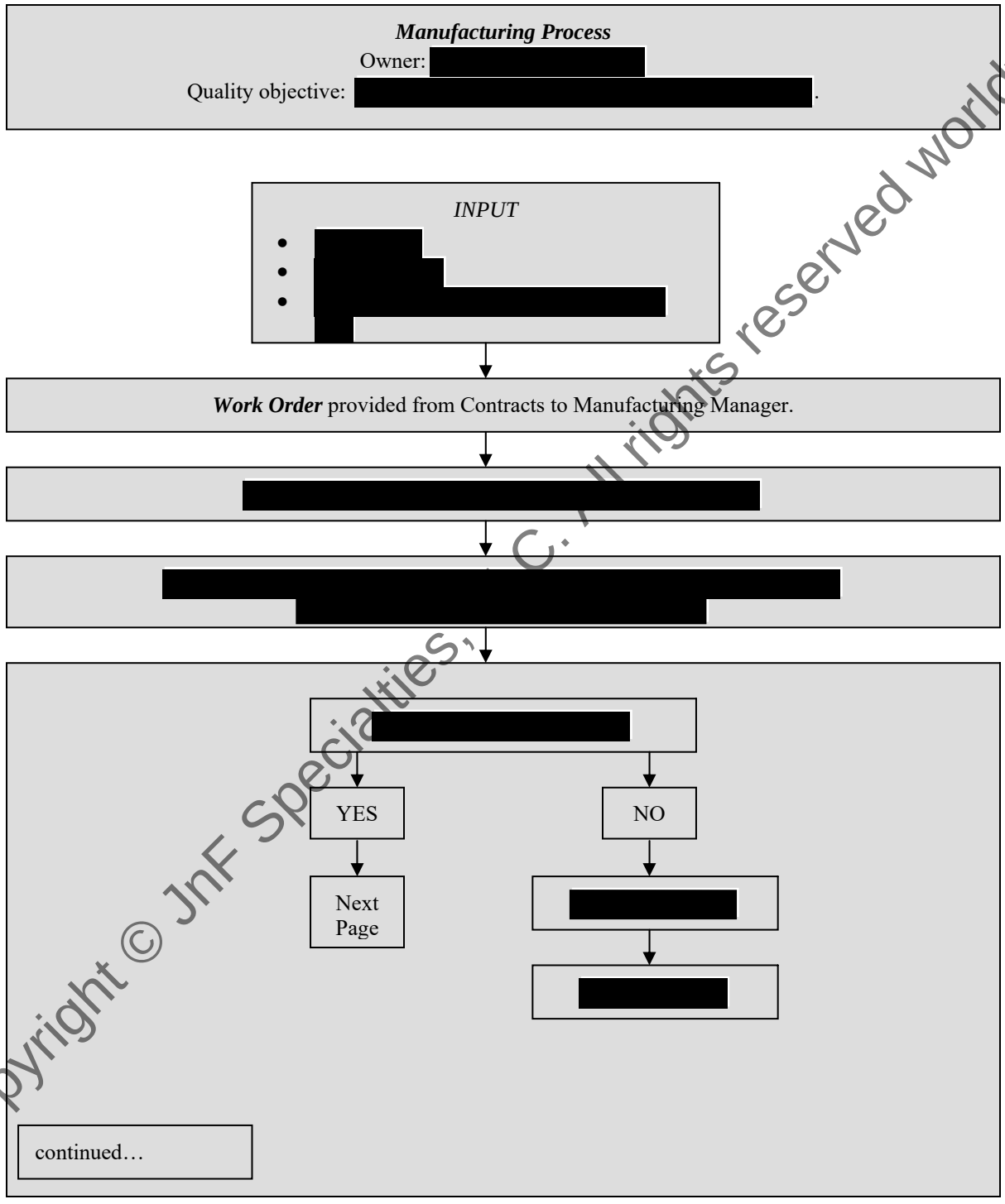
13.1.4 [redacted]

13.2 Chemicals that are purchased or prepared by the chem-lab are [redacted]

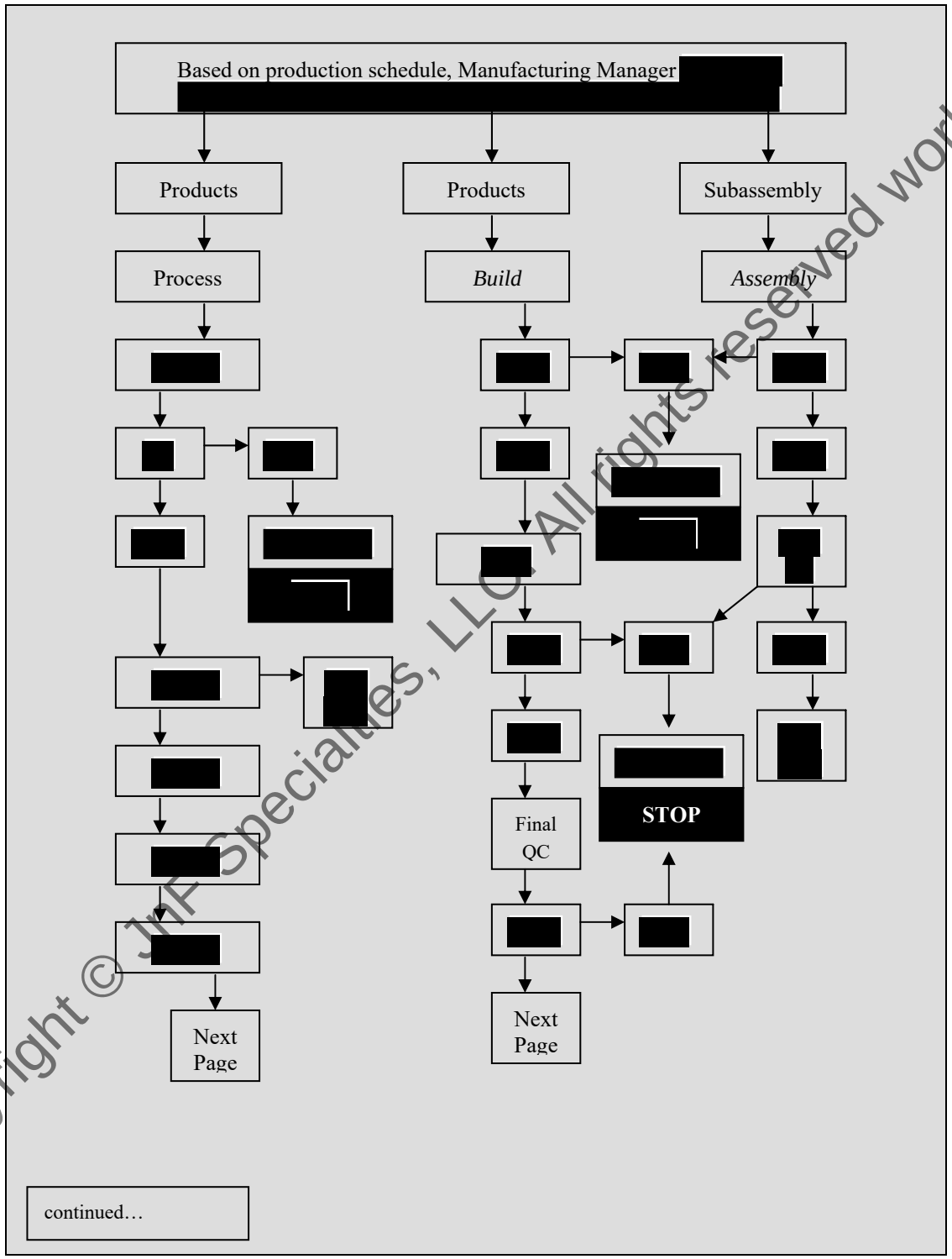
13.3 Raw material components whose shelf life has [redacted]

Left blank intentionally

14.0 PROCESS MAP



from previous page…



from previous page…