Procedure: In-Process Inspections

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Simple processes may not require an in-process inspection – delete this procedure if it is not applicable. Note, it is still a requirement that final product is inspected/tested prior to release.

In-process inspections may be important because they can remove non-conforming product earlier in the process allowing more rapid response to non-conformances. Edit this procedure as appropriate.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for performing and recording in-process inspections.

# Scope

The scope of this procedure includes materials, components and sub-assemblies during manufacture and assembly at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Assurance (QA) Inspectors |  |
| Quality Control (QC) Inspectors |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

This procedure describes four types of in-process inspections and how they are documented.

Edit/delete as appropriate.

## Scope and responsibilities

Different types of inspection are available and they depend on the products and processes involved. Types of inspection include:

* job set-up checks
* operator and QC inspections of process outputs
* Statistical Process Control (SPC)
* automated inspections

The sampling program is defined and documented in the production work order (refer to Procedure *QP708: Production Work Order and History Record*).

Regardless of who actually performs in-process inspections, all inspection activities are the responsibility of QA. Automated inspection machines must be set up and validated under the responsibility of QA.

## Set-up inspections

When starting a new production run or when processing equipment is reset, the set-up may need to be verified. QA is responsible for determining whether inspection is required.

When specified, inspections are identified in the production work order.

QC inspectors conduct the set-up inspections. When the inspection is satisfactory, inspectors sign off the work order in the appropriate section. Inspection data may also be recorded, where appropriate.

Sign-off of the work order forms a record of the inspection. It identifies the inspector and inspection status and authorises commencing/continuing production.

Products that fail inspection are identified, segregated and processed in accordance with Procedure *QP805: Control of Non-conforming Product*.

It is not necessary to have independent QC inspectors perform set-up inspections. They may be performed by process operators.

## Process output inspections

Process output inspections are performed according to a sampling plan to achieve the desired probability of identifying non-conformities

Inspection of process output is to verify the result of a particular process. Inspections are performed immediately following the process and in accordance with the sampling plan identified in the work order.

Where practical, production personnel visually inspect the process output. Personnel are trained in what to look for and how to identify non-conforming product. When a formal visual inspection is specified, it is described in the production work order. Results are recorded in the work order.

When specified in the quality plan, appropriately trained inspectors/operators perform more technical inspections that may involve using gauges, templates or other measuring equipment. Inspections are performed according to written instructions and acceptance criteria. Inspections in this category are described and recorded in the production work order.

When the result of the inspection is satisfactory, the inspector/ operator signs off the work order. Where required, inspection data is recorded.

The sign-off on the work order constitutes a record of the inspection, identifies the inspector, identifies the inspection status of the product and authorises continuing production.

Products failing inspection are identified, segregated and processed in accordance with Procedure *QP805: Control of Non-conforming Product*.

## Process performance monitoring

SPC uses a sampling plan suitable for identifying process variations. Results are presented as a data print-out, graph or trend.

Consider writing another procedure to describe SPC practices and processes.

Although SPC is a process control activity, it is also an in-process inspection. SPC may be used as evidence of product conformity.

Process performance monitoring activities are described in Procedure *QP811: Statistical Process Control*. Where appropriate, operators are trained and provided with instruction on SPC.

If you use a commercial computer application for SPC, use the software manual (or Help file) as an instruction manual.

Control charts are retained in the Device History Record (DHR) as evidence of product conformity.

## Automated inspection equipment

Many production processes and machines include automated inspection equipment. Automated inspection equipment must be installed, set up and validated before use. If external contractors are used, they are selected and monitored in accordance with Procedure *QP705: Supplier Evaluation and Monitoring*.

Automated inspection equipment is tested and validated before use. Validation protocols may be prepared jointly by the supplier and QA. However, QA has ultimate responsibility for reviewing and approving protocol, records and reports (refer to Procedure *QP710: Validation of Processes and Software*).

Where custom computer software controls automated inspection equipment, the software is identified (e.g. version no.), validated and controlled.

## Release of product

Products must not pass to the next process stage until all specified in-process inspection activities are completed satisfactorily. Products released for further processing or use are identified with a positive inspection status.

Identification of product status may be in the form of a sticker, tag, mark, colour or signed-off work order accompanying the product (refer to Procedure *QP712: Product Identification and Traceability*).

## Non-conforming product

If non-conforming product is identified, the operator/inspector labels the product with a REJECTED sticker or tag and prepares an NCR (*Form FM805-1: Product Non-Conformity Report*).

Further processing or release of the rejected material is not permitted. All NCRs will be assessed by QA before a final disposition is decided.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP705 | Supplier Evaluation and Monitoring |
| QP708 | Production Work Order and History Record |
| QP710 | Validation of Processes and Software |
| QP712 | Product Identification and Traceability |
| QP805 | Control of Non-conforming Product |
| QP811 | Statistical Process Control |
| FM805-1 | Product Non-Conformity Report |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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