Quality System Work Instruction
10-10-0901: QCS – Nonconformance Process
rev-14a00 - Approved by: QMR

1.0 Purpose and Scope

The purpose of this work instruction is to define the initiation, review and disposition suspect nonconformances in product, equipment assets and associated work instructions.

This work instruction is applicable to the Material Review Board, and departments involved in the business operations which can identify possible nonconforming products (e.g. Shipping and Receiving Inspection, Final Lot Inspection, Storage inspection, Customer Support, ..)

1.1 Definitions

C&P Actions – Corrective and Preventive Action Cases

MRB – Material Review Board

QCS – Quality Compliance System: Online system to manage & report quality compliance

Assets: Equipment assets supporting manufacturing, inspection, storage and transport of products

Product: Raw Material, in-process products, end-products

Accept: Accept as-is, analysis has determined no nonconformance.

Rework: A nonconformance disposition whereby a nonconforming product or asset is made to conform to a prior specified requirement by completion, reprocessing, or other corrective means. If the nonconformance is a written document, then the document is revised.

Reclassify: Reclassify product or asset for another application.
(not applicable to written documents)

Scrap: Product or asset cannot be reworked, and must be isolated & scrapped. In the case of a written document, the document is obsoleted.

1.2 Discussion

Nonconforming products can include out of specification raw materials, in-process products and end-products. If a nonconforming product is suspected, the company's Material Review Board (MRB), analyzes the details and dispositions product as: Accept, Rework, Reclassify or Scrap. For products determined to be nonconforming, product is isolated and rework or scrap actions initiated.

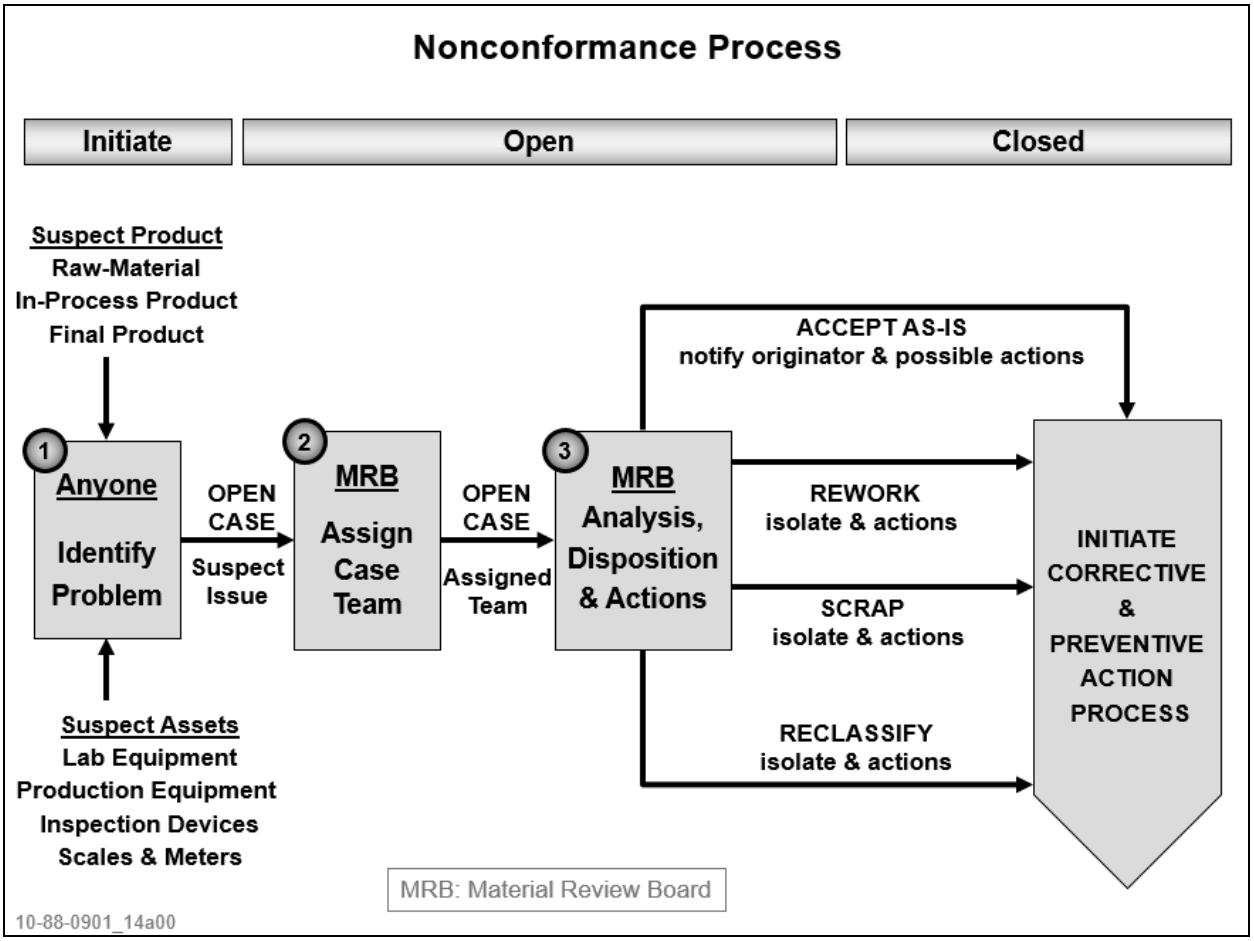
Nonconforming equipment can include out of specification laboratory equipment, portable inspection devices, shop-scales, or meters which may have an expired calibration date, provide inconsistent results, or possibly been damaged. If a nonconformance is suspected, the company's Material Review Board (MRB), analyzes the details and dispositions equipment as: Accept, Rework, Reclassify or Scrap. For equipment determined to be nonconforming, isolate the equipment and initiate rework or scrap.

Nonconforming work instructions supporting products handling, product production and equipment usage can be reworked to represent actual process or obsoleted (scrap) if no longer required.

A confirmed nonconformance may result in one or more corrective actions.

The company Material Review Board is chaired by Quality and has permanent members from key functional areas, such as R&D and Operations. Temporary MRB members can be assigned when additional knowledge of problem and/or resolution is required. Temporary MRB members typically include, receiving for raw materials, operations personnel for in-process material, and customer support for customer suspected non conformance.

2.0 Work Instructions



STEP	RESPONSIBILITY	ACTION
1	Anyone	**Problems Identification** suspect nonconformance identified **Using QCS / 9.0 Nonconformance / New Tab** **a) Update "Problem Identification" Section** - title (descriptive) - description - type (product, equipment, process) - priority - source (e.g. supplier, internal, customer) **b) "Attachments" Section:** add attachments (if any) - additional information & details **c) Save**

STEP	RESPONSIBILITY	ACTION
2	**MRB**	**Assign MRB Case Team** Identify required case team **Using online QCS / 9.0 Nonconformance / Open Tab** **a) Evaluate Open Nonconformance Cases** - Select & Review Individual Cases - update section "Problem Identification" contact initiator if additional information is required fields: title, description, type, code, source field: priority – set appropriately **b) Assign MRB case team** - update section " Assign Material Review Board" field: MRB Member – standard core members field: Other – temporary members with knowledge of problem / resolution
3	**MRB Team**	**Analysis, Actions & Disposition** **Using online QCS / 9.0 Nonconformance / Open Tab** **a) Analysis** - select case, view details - update section "Disposition" with findings field: Problem definition (restate & clarify) field: Investigation Results (team findings) - update section "Attachments" attach supporting documents (lab-spec, analysis, other, ….) - Save **b) Disposition** Determine disposition based on analysis **- Accept:** conforming / no actions **- Rework:** product / asset is to be isolated, reworked & re-inspected or associated documentation is to be revised **- Reclassified:** product / asset reclassified to another application **- Scrap:** product /asset is rejected, isolated, and scrapped or written documents are obsoleted **c) C&P Actions** - update section " Corrective & Preventive Actions" select "Create C&P Actions" (multiple if required) ref: 10-10-1001 QCS- Corrective and Preventive Actions **d) Close** - Update field: Recommended Action /section Disposition with appropriate Disposition (accept, rework, reclassified, scrap) - Save

3.0 References

3.1 Normative References - The following reference contains provisions in which through reference in this text, constitute provisions of this document. References, which are subject to revision, should always be used in the most recent form.

QSP 09.1 Control of Nonconformance
QSP 10.1 Corrective and Preventive Actions

WI 10-10-1001 QCS – Corrective & Preventive of Controlled Documents

3.2 Informative References - The following references are included as bibliographic information, which may contain material useful for execution of this document. References, which are subject to revision, should always be used in the most recent form.

QSP 01.1 Management Review Meetings
QSP 05.1 Control of Quality Records
QSP 06.1 Process Control
QSP 07.1 ID and Traceability
QSP 08.1 Inspection and Testing

WI 10-10-0001 QCS - Access to Online Quality Compliance System

3.3 Documentation/Records - The implementation of this document requires the use of the below listed forms or reasonable facsimiles thereof and may result in records as so indicated in addition to retained completed forms. References, which are subject to revision, should always be used in the most recent form.

QCS – Quality Compliance System