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1. Purpose/Policy

To establish a procedure and to assign responsibilities for identification, documentation and disposition of nonconforming processes, services, and work products.

2. Scope

This procedure applies to any process, service or product within the MDSAP Quality Management System (QMS) which is identified as nonconforming.

Additionally, this procedure applies to any process, service or product identified as nonconforming coming from the MDSAP Regulatory Authorities (RAC) and MDSAP participants.

3. Definitions/Acronyms

Audit: Systematic, independent and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirement are fulfilled. (ISO 1700:2005)

Corrective Action (CA): Action to eliminate the cause of a detected nonconformity or other undesirable situation in order to prevent recurrence. There can be more than one cause of a nonconformity. (ISO 9000:2005)

Fitness-for-Use: A term used to indicate that a product or service fits the customer's defined purpose for that product or service. (ASQ-Quality Glossary)

Nonconformity: Non-fulfillment of a requirement. MDSAP is specifically in this program what are considered "direct" and "indirect" nonconformities to give some priority for corrective actions. (ISO 9001:2005)

On-the-spot-corrective action: An immediate step taken to correct or resolve nonconformity. (J.P Russell, 4th Edition- ASQ Auditing Handbook Principles, Implementation, and Use)

Preventive Action (PA): Action to eliminate the cause of a potential nonconformity or other undesirable potential situation in order to prevent occurrence. There can be more than one cause for a potential nonconformity. (ISO 9000:2005)

4. Authorities/Responsibilities

MDSAP management possesses the authority and the responsibility for controlling nonconformities and the delegating of that responsibility to the appropriate personnel as necessary. Additionally, MDSAP Management has to ensure that MDSAP members are trained in this procedure and that it is followed.

MDSAP personnel can provide recommendations to appropriate management for stopping and restarting production or service delivery when non-conformance is identified that would warrant a work stoppage.

5. Procedures

A) Processes, services and/or products that are considered to be non-conforming may be identified in many ways including:
   - *Incoming products from stakeholders including internal customers:* Product received which are found to be non-conforming are identified, reported, and appropriate action taken;
   - *Services provided by external sources*;
   - *Processes producing negative results*: Any process which does not produce an acceptable result;
   - *Internal Audit*: During the process of conducting internal quality audits, processes may be identified as being non-conforming, and
   - *External Audits if applicable.*.

B) Identified nonconformities with any procedures, process, service, product, or customer requirement are documented on the MDSAP QMS F0006.1 Nonconformance Report (NCR) Form and if a corrective action process has to be activated the MDSAP QMS F0009.1 Corrective Action and Problem Report (CAPR) Form has to be completed for the corrective action process to be initiated. This process involves the evaluation of the impact of the nonconformance on quality and operations.

C) When a nonconformity is detected, action is taken to eliminate the

nonconformity, authorize use, release, or acceptance, and/or action is taken to preclude the original intended use or application. The nonconformity is resolved and verified by MDSAP management or their designee and/or MDSAP Oversight Committee (MOC) in accordance with the corrective action process.

D) MDSAP management in collaboration with MOC is responsible for halting work and ensuring work resumption upon resolution of the nonconformity when appropriate. Authorization of the use, release or acceptance is performed after the corrective action has been taken and approved by MDSAP management or their designee and/or MOC.

E) Dispositions or actions taken on a nonconforming work process/service/product are:
   - *Rework:* action taken on nonconforming product so that it will fulfill the specified requirements;
   - *Use as is:* approving the use of nonconforming process/service/product without rework or redoing. A disclaimer is made that the process/service/product was accepted. The quality requirements that the process/service/product did not meet are specified;
   - *Unable to use:* action taken if unable to resolve the problem. The receiver is notified that the process/service/product is discarded and/or made obsolete.
   - Reworked products are reviewed to verify that they comply with specifications.

F) When necessary, the customer is notified of the nonconformity and specifications may be changed depending on the usage of the product or service.

G) A customer supplied product which is unsuitable will be annotated on the MDSAP QMS Nonconformance Report (NCR) MDSAP QMS F0006.1 and reported to the customer.

H) If properly executed, quality management system will monitor the various aspects of quality on a routine basis. In instances where performance falls outside acceptable limits, the data/report/activity can be questioned and, after investigation, a determination made as to the validity and significance of the nonconformity. The MDSAP quality management process is the principle recourse available for ensuring that only a quality work process/service/product is released. The implementation and maintenance of a robust MDSAP quality management system is critical to mitigating the risk of encountering nonconformities.

6. Forms

MDSAP QMS F0009.1 Corrective Action and Problem Report (CAPR) Form
MDSAP QMS F0010.1 Preventive Action Form
MDSAP QMS F0008.1 Internal Audit/Self Assessment Report Form
MDSAP QMS F0006.1 Nonconformance Report Form (NCR)

7. Reference Documents

MDSAP QMS P0009 Corrective Action Procedure
MDSAP QMS P0010 Preventive Action Procedure
MDSAP QMS P0008 Internal Audit/Self Assessment Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown
002	2013-08-01	Page 1; Section 3 Definition/Acronyms: Revised the definition Audit to reflect the correct definition as proposed by IMDRF MDSAP Work Group, July 11, 2013 "Competency and Training Requirement for Auditing Organization" and "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition.	Liliane Brown

Version
Approval

Approved: Chair, MDSAP RAC - Signature on file Date: 2013/08/01