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1. Purpose/Policy

MDSAP Management performs periodic reviews to determine its continuing suitability, adequacy and effectiveness of the quality management system (QMS) in achieving the stated quality objectives. This procedure establishes the method and level by which management reviews are performed within MDSAP. This document defines:

- who is involved, and
- what their responsibilities are: schedule for management review meetings, and periodic review of the quality system itself, etc.

2. Scope

This procedure applies to the MDSAP internal quality management system. MDSAP management reviews will include routine (at least once a year) and if necessary *ad hoc* reviews of summary reports, trend analyses, and abstracts of quality management system activities such as audit/assessment results, corrective action of nonconformities including continual improvement and control of documented information, etc. Individual issues of high importance or high risk may be presented at management review meetings, or may necessitate a special ad hoc meeting to keep MDSAP management informed regarding critical issues and to obtain support for problem resolution.

3. Definitions/Acronyms

Action Item: An action to be taken as a result of a discussion at a meeting and recorded in the minutes of that meeting.

Action Plan: A plan that describes what needs to be done, the responsible entity, and when it needs to be completed.

Corrective Action (CA): Action to eliminate the cause of a nonconformity and to prevent recurrence. There can be more than one cause of a nonconformity. (ISO 9000:2015)

Effectiveness: Extent to which planned activities are realized and planned results are achieved. (ISO 9000:2015)

Management Review: A periodic management meeting to review the status and effectiveness of the organization's quality management system. (ASQ-Quality Glossary)

- Review: Determination of the suitability, adequacy or effectiveness or an object to achieve established objectives (ISO 9001:2015)

Monitoring: Determining the status of a system, a process, a product, a service or an activity (ISO 9001:2015)

Nonconformity: Non-fulfillment of a requirement. (ISO 9000:2015)

- MDSAP specifically in this program what are considered "direct" and "indirect" nonconformities to give some priority for corrective actions.

Quality Management System – (QMS): Part of a management system with regard to quality (ISO 9000:2015)

- Management system: set of interrelated or interacting elements of an organization to establish policies and objectives and process to achieve those objectives (ISO 9000:2015)

Requirement: Need or expectation that is stated generally implied or obligatory (ISO 9000:2015)

4. Authorities/Responsibilities

A) MDSAP Regulatory Authority Council (RAC) Chair person

a. Ensures that the delegation of assignments and responsibility are followed by all MDSAP members, as appropriate
b. Ensures that any corrective actions determined as a result of management review activity are carried out and validated for effectiveness (can be delegated to any member of the RAC)

c. Ensures that an effective quality management system program is operational, and that the management review procedure/policy is followed

B) MDSAP Regulatory Authority Council (RAC)
- Conducts management review
- Assures necessary resources are provided to meet MDSAP needs
- Assigns action items and plans and approves system changes
- Designates personnel to assist in the management review activities

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C) Lead Project Manager
- Chairs the management review meeting
- Drafts Management Review Agenda and Report
- Provides requested information as needed
- May assist in the review activities
- Ensures action items and plans are issued, monitored and completed
- Communicates the results of the management review to team

D) MDSAP QMS Management Representative
- Provides information for review
- Assists in completion of action items
- As directed, ensures implementation of any changes identified in their respective area

E) RAC Secretariat
- Coordinates and collects the information for the management review
- Assembles summary report and documents action items and plans
- Monitors implementation of system changes approved as a result of action items and plans
- Maintains management review reports

NOTE: In the event that the position of RAC Secretariat is vacant, these duties may be alternatively performed by the MDSAP QMS Representative or an MDSAP QMS Site Representative.

5. Procedures

Management review

1. At a minimum, a review of the quality management system is performed annually, although, when possible the review can be conducted on a biannual basis (e.g., March and September). The management review is scheduled by the RAC Chair person or acting person and at least one person per MDSAP team shall attend. This review can be initiated as a conference call or in

person.

This review examines the quality management system and determines if it meets the conditions set by the RAC, MDSAP team and any external standards, e.g. ISO/IEC, as required. The review will serve as a guide in making future determinations towards the effectiveness and direction of the quality management system. The quality management system may need to be modified due to changes that have or are expected to take place in the organization, staffing, budget, activities or workload.

2. The RAC Secretariat assembles the needed information and records for the review and forwards them to the MDSAP QMS Management Representative, Lead Project Manager, and RAC.

3. The review consists of, but is not limited to, the following:
   - Follow-up actions from previous management reviews
   - Suitability of policies and procedures
   - Reports from RAC, Lead Project Manager and MDSAP QMS Management Representative
   - Outcome of recent internal audits
   - Effectiveness of previous actions taken
   - Corrective actions and their resolution
   - Assessments by external bodies
   - Changes in the volume and type of the work
   - Customer feedback
   - Complaints
   - MDSAP Resource Assessment
   - Recommendations for improvement including other factors, such as quality control activities, resources and training, and
   - Changes in Regulatory requirements that have been incorporated into MDSAP guidance and procedures.

4. Quorum: A quorum will exist when at least three (3) of the participating regulatory authorities are represented at the annual and *ad hoc* management review meetings.

   4.1. Ad Hoc meetings will be called when information must be presented to and discussed which cannot wait until the yearly review. Generally, this will be because of a quality issue of high risk or high visibility. Because *ad hoc* meetings may relate to time-critical information, all quorum requirements as explained above must be met. However, the discussions do not have to be conducted in real time. Members may respond and vote by email or phone, or other means of technology.

5. The RAC Secretariat with the help of the Lead Project Manager consolidates the findings and forwards the draft report to the MDSAP QMS Management Representative, Lead Project Manager, and RAC.

6. The management review attendees review and concur/non-concur with the draft report.

7. The Lead Project Manager approves the final report and the RAC Secretariat distributes.

8. If needed, a corrective action using Concern Resolution Report Log is initiated for identified action items and plans by the MDSAP QMS Management Representative for the assigned personnel to complete. Investigation is undertaken and findings submitted to the MDSAP QMS Management Representative, Lead Project Manager, and RAC.

9. Action items and plans are closed when they are completed and are determined to be effective where applicable.

6. Forms

MDSAP QMS F0005.1 Management Review Report Form
MDSAP QMS F0005.2 Management Review Agenda Form (Optional)
Concern Resolution Report Log

7. Reference Documents

MDSAP QMS P0009 - Nonconformity and Corrective Action Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown
002	2016-10-11	Document was revised to reflect the ISO 9001:2015 revisions	Liliane Brown
003	2019-01-11	"Nonconformance" was replaced by "nonconformity". The title for F0013.1 was corrected. (Concern Resolution Report Form) Added provision for MDSAP QMS Representatives or Site Representatives to assume duties of RAC Secretariat pertaining to management review in the event the Secretariat position is vacant Adjusted formatting	Hiromi Kumada/Kimberly Lewandowski-Walker
004	2024-01-18	Periodic review Adjusted formatting Replaced Concern Resolution Report Form with Concern Resolution Report Log	Hiromi Kumada

Version Approval 004

Approved: Signature on file Date:2024-01-18

CHAIR, MDSAP RAC