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1. Purpose/Policy

The purpose of this procedure is to describe the process to plan and perform on-site assessments of auditing organization.

2. Scope

This procedure applies to assessments performed on-site, including assessments performed at the head office of the auditing organization for their initial recognition (Stage 2 On-Site Assessment), for the annual surveillance or for their re-recognition, or at critical locations. Special On-Site Assessments are out of the scope of the present procedure and performed in accordance with procedure MDSAP AS P0020. The Assessment Program Manager (APM), the assessors and the Assessment Team Leader (ATL) are responsible for the implementation of this procedure.

3. Definitions/Acronyms

Audit report flagging: a status assigned to an audit report of a manufacturer

issued by an AO and based on the grade of the nonconformities identified during the corresponding audit (using the document GHTF/SG3/N19:2012 – Quality Management System – Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange).

AO: Auditing Organization

RA: Regulatory Authority

APM: Assessment Program Manager

ATL: Assessment Team Leader

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager (APM):

- Initiates the on-site assessment procedure to ensure the implementation of the AO assessment Program
- Selects the assessors to form the assessment team
- Send the assignment information to the assessors
- Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the assessment
- Reviews the assessment plan for consistency with the assignment
- Reviews the assessment report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the Auditing Organization's Assessment Program as necessary.

Assessment Team Leader (ATL)

- Issues the assessment plan
- Assigns responsibilities among the assessors and ensures the progress towards the assessment objectives
- Leads the assessment opening and closing meetings with the AO
- Finalizes and approves the assessment report
- Issues nonconformity reports and manages their closure

Assessment team (including the ATL)

- Assesses a sample of audit reports issued by the AO (off-site, prior to the on-site visit – not applicable to the initial assessment)
- Assesses the AO quality management system and practices according the MDSAP AO Assessment Model.

5. Procedures

The document MDSAP AS F0016.1 On-Site Assessment Flowchart illustrates this procedure.

The on-site assessment process is organized in 3 phases: *planning*, *assessment and follow-up*

Planning

The APM selects the assessors taking into account the needed competence. Whenever possible, an assessment team is composed of at least 2 assessors from different Regulatory Authorities. In special circumstances, the assessment team may be composed by a single assessor (see Single Assessor Assignment Criteria section).

For Stage 2 On-Site Assessment at the head office, it is recommended to select the same assessment team as for the Stage 1 Assessment.
For Surveillance On-Site Assessment, it is recommended to select assessors among the assessment team that performed the Stage 2 On-Site Assessment, or the last Re-recognition On-Site Assessment if applicable.

For Re-recognition On-Site Assessment, the assessors should not be any of the assessment team leaders from the previous assessment cycle's assessment activities.

For On-Site Assessment at a critical location, the assessment team leader should have participated in an assessment activity at the head office.

The selected ATL and assessors confirm their agreement and indicate their availabilities for the assessment activity. If an assessor does not accept the assignment, s/he provides the reason and the APM preselects another assessor and repeats the previous task.

The APM sends an assignment letter (or email) to the confirmed assessors including details on scope, objectives and specifics of the on-site assessment.

The APM liaises with the AO regulatory correspondent or management representative to determine the on-site assessment dates.

Once the dates are fixed, the APM sends to the AO, with copy to the assessors, the On-Site Assessment Announcement email.

The Assessment Team Leader prepares the assessment plan, using form MDSAP AS F0016.3. The plan intends to ensure that all understand the scope of the assessment and that the AO employees are available to cover each

assessment topic. The ATL sends the assessment plan at least 15 calendar days before the on-site assessment, giving the opportunity to the AO and the AO Regulatory Correspondent to provide comments, as necessary, and to the APM without a prior review by the APM being necessary.
Note: The assessment plan is not a binding document. It will be eventually reviewed during the On-Site Assessment and the schedule may again be adjusted, as necessary, during the on-site assessment, in particular during the opening meeting.

Single Assessor Assignment Criteria
In case of limited resources, a single assessor may be assigned to any surveillance assessment performed On-Site; including assessments performed at the head office of the auditing organization for annual surveillance or at critical locations.

Eligibility of the AO
The APM may assign only one assessor to perform On-Site assessment activities at the head office of the auditing organization for the annual surveillance, or at critical locations if:

- The AO has already been recognized under MDSAP Scheme with no outstanding conditions placed as part of the recognition, AND
- The AO has less than 300 active sites identifiable in MDSAP Regulatory Exchange Platform – secure (REPs), AND
- The previous ATL agrees that the assessment could be conducted by a single assessor, taking into account the AOs performance during past audits, AND
- The changes notified by the AO ahead of the assessment activities are not such that a new recognition decision would be necessary, AND
- The APM must confirm that the AO is eligible, based in the compliance history over the past 3 years;

When applicable, REPs reports indicating performance with respect to report submission and other relevant metrics should be considered.

Assessor Competence and Experience
The APM may assign only one assessor to perform On-Site assessment activities if the proposed assignee has the competence to perform the assessment.

The assigned assessor shall demonstrate participation in at least 2 assessments as ATL for the considered type of assessment (on-site assessment vs. witnessed audit) in the previous 24 months.

For On-Site Assessment at a critical location, the assessor should have participated in an assessment activity at the head office of the same AO.

Preference must be given to an assessor who has been part of an assessment team at the AO in the past 24 months.

Miscellaneous
Use of the single assessor should be presented by the responsible APM to the other APMs based on the above applicability criteria for approval.

Additional time should be added to the assessment when a single assessor is used.

The use of a single assessor should not be permitted for two consecutive years.

Preference must be given to perform the next assessment with a completely different assessment team.

Assessment
AO Audit Report Sample Assessment
Prior to surveillance or re-recognition assessments at the AO head office or a critical location, the ATL organizes the review of audit reports provided by the auditing organization.

The ATL selects one or both of the following two approaches:

Approach 1 - Audit *File* Review:
The ATL selects a sample of audit reports (3 to 5) and requests the AO to provide the relevant records relative to the planning and the performance of the audit (audit file), as well as the review of the audit report and the audit and certification decision.

The selection may either be random or be guided by considerations such as:
- Audit type
- Technical area
- Geographic area
- Auditor
- Device class
- Report flagging status

For an on-site assessment at a critical location, the sample should relate to activities of this critical location.

The review aims at assessing the documents in term of relevance, consistency

and compliance with the AO's procedures and the applicable recognition criteria, at each phase of the process. The ATL documents the outcome of the review in the corresponding appendix of the MDSAP AS F0016.5 On-Site Assessment Report.

Approach 2 - Audit *Report* Review:
The ATL selects a representative sample of reports. The selection may be random or guided by considerations as mentioned for audit *file* review. It should include a large proportion of reports whose flagging status did not trigger their review upon receipt. The review aims at assessing the audit reports compliance to the applicable audit reports requirements. The ATL documents the outcome of the review in the corresponding appendix of the MDSAP AS F0016.5 On-Site Assessment Report.

In both cases, the assessment team may identify nonconformities but should consider them final only after the on-site assessment and further review of the concern with the AO. MDSAP AU P0019 Medical Device Regulatory Audit Reports Policy may additionally be used a guidance on audit report content requirements.

On-Site Assessment
The assessment is organized in 3 phases:
- Opening meeting
- Investigation phase
- Closing meeting

The appendix 1 and 2 of this procedure detail the content and other specifics of both the opening meeting and the closing meeting.

The investigation phase follows the assessment approach developed in the MDSAP AS P0034 - Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations.

When a nonconformity is identified, the assessor explains it to the AO and records it using the form MDSAP AS F0015.2 AO Nonconformity Form. The nonconformities are presented by the ATL during the closing meeting to the top management and the regulatory correspondent. The AO is responsible for providing a remediation plan for each of the nonconformities within 15 working days from the date the nonconformity was issued, giving priority to grade 3 and 4 nonconformities, per the IMDRF/MDSAP WG/N11 document.

Findings identified in Stage 1 assessments that are still open in the Stage 2 assessment should be raised as nonconformities.

The Assessment Team Leader generates the assessment report using the form

MDSAP AS F0016.5. All Assessment team members review and approve it. The ATL sends it to the APM and the AO contact officer within 30 calendar days following the closing meeting unless the findings of the assessment dictate a shorter turnaround.

Follow-up
Once the ATL has received and reviewed the action plans addressing the nonconformities, the ATL provides the APM with its assessment report, AO Nonconformity report and recommendations.

The APM reviews the assessment report and associated information and prepares the file for review by the TRRC in accordance with procedure MDSAP AS P0017 Technical Review and Recognition Decision Making Procedure.

If appropriate, the APM updates the Assessment Program according to the procedure MDSAP AS P0005 AO Assessment Program.

6. Forms

MDSAP AS F0005.2 – Assessment Program Management File
MDSAP AS F0016.1 – On-Site Assessment Process Flowchart
MDSAP AS F0016.3 – Assessment Plan Form
MDSAP AS F0016.5 – On-Site Assessment Report Form

7. Reference Documents

IMDRF/MDSAP WG/N6 - *Regulatory Authority Assessor Competence and Training Requirements.*
IMDRF/MDSAP WG/N11 - *Grading Nonconformities Issued to Auditing Organizations by Recognizing Regulatory Authorities and Principles on the Decision-Making Process and Criteria for the Recognition of Auditing Organizations.*
MDSAP AS P0013 – *Stage 1 Assessment Procedure*
MDSAP AS P0005 – *AO Assessment Program Procedure*
MDSAP AS P0017 – *Technical Review and Recognition Decision Procedure*
MDSAP AU P0019 - Medical Device Regulatory Audit Reports Policy
MDSAP AS P0034 - *Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations*

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Marc-Henri Winter
002	2015-10-29	Page 6, Reference documents: IMDRF/ MDSAP WG/N11 was posted as draft. This document was finalized February 2014. Therefore the word “draft” was removed. (minor change no need for version to be approved by RAC)	Liliane Brown
003	2016-08-15	Just some minor grammatical changes throughout the document on the IMDRF documents	Liliane Brown
004	2017-06-06	Reference of document titled AU P0023 was removed due that this document was never developed	Liliane Brown

005	2020-05-22	Added “Whenever possible” to paragraph headed with “Planning” on page 2; removed references to MDSAP AS P0015 – AO Nonconformity Procedure; added reference to IMDRF/MDSAP WG/N11 and included the 15 working day timeframe for remediation plans on page 5; corrected minor typographical errors throughout Removed MDSAP AS F0016.2 Assessment Announcement letter in section 5 and 6. Added reference to MDSAP AU P0019 in section 5 and 7 Removed reference to IMDRF/MDSAP WG/N5 - Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations and replaced with MDSAP AS P0034 - Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations Adjusted formatting Updated Key processes and assessment tasks of Appendix 3 to reflect MDSAP AS P0034	Kimberly Lewandowski-Walker/Hiromi Kumada
006	2020-08-04	Added Single Assessor Assignment Criteria in section 5. Corrected fonts.	Thiago Rezende Pereira Cunha/ Hiromi Kumada

Version Approval 006

Approved: ON FILE Date: 2020-08-04

CHAIR, MDSAP RAC

Appendix 1
Opening Meeting of an On-Site Assessment

The Assessment Team Leader (ATL) chairs an opening meeting with the AO Top Management.

The purpose of the opening meeting is to:
- State the on-site assessment objectives,
- Confirm the audit plan,
- Briefly present how the audit activities will be conducted
- Confirm communication channels,
- To provide an opportunity for the auditee to ask questions.

During the opening meeting, the ATL must address the following topics with the AO Top Management and the managers of the individuals responsible for the functions or processes to be assessed. The ATL notes the start time of opening meeting and circulates the attendance sheet for registration of the attendees.

The level of detail must be adapted to the AO's familiarity with the assessment process.

Presentation of the Assessment Team Members and AO's representatives
- Role of the Assessment Team Members (ATL, Assessor)
- Observer: reminder that it should not interfere or intervene in the audit during the assessment

Scope of Recognition
- Assessment criteria,
- AO's Head office
- List of critical locations
- List of technical areas

Type of on-site assessment and objectives: Stage 2, Surveillance, Re-recognition
- See specific annex to the type of assessment

Scope of the on-site assessment / assessment plan
- Location and organizational units assessed
- Processes and / or activities to be assessed
- Confirmation, if necessary, of adjustments of the plan, necessary for the proper conduct of the on-site assessment
- On-Site Assessment schedules and other arrangements (date and time of the closing meeting, interim meetings between the assessment team and

the AO management, logistics during the assessment ...)
- Confirm that the ATL and the assessment team members are responsible for the execution of the assessment plan. Any difficulties must be signalled to them.

Conduct and organization of the on-site assessment
- Methods and procedures used to perform the on-site assessment
- Assessment findings: reporting, including the grading of nonconformities
- Premature end of the on-site assessment: a reminder of situations that can lead to termination of the on-site assessment (e.g. lack of access to necessary information, unavailability of key individuals)
- Official communication channels between the assessment team and the AO
- Language used during the on-site assessment;
- Confirm that, during the on-site assessment, the auditee will be kept informed of the progress of the assessment;
- Availability of resources and logistics necessary for the assessment team,
- Guides appointed by the auditee: availability, role (facilitating contacts, guide the assessment team, ensuring security, reporting to management).

Other
- Confidentiality: reminder that all the elements discussed and seen during the assessment are confidential,
- Emergency and safety procedures: confirm with the AO,
- Check whether the AO has questions.

Appendix 2
Closing Meeting of an On-Site Assessment

The closing meeting addresses the specifics mentioned below.

- Objectives of the on-site assessment

- Fulfilment of the on-site assessment plan and objectives

- Obstacles met during the on-site assessment, affecting the fulfilment of the assessment plan and objectives

- Statement of nonconformities, including whether or not they were resolved during the on-site assessment

- Conclusions of the on-site assessment

- Reminder that the conclusions are the result of an assessment based on the sampling of records of the AO's activities. The list of nonconformities identified during the assessment may therefore not be exhaustive.

- Recommendation of the assessment team to the technical review and recognition committee.

- Post-assessment activities in term of:

    - Timeline to provide the action plans relative to all nonconformities
    - RA process to provide feedback on the action plans
    - Remaining assessment activities to complete the assessment (witnessed audit or on-site assessment at critical locations), if applicable
    - RA process to make a decision on the recognition status of the AO
    - Opportunity to appeal to the recognition decision

Note: For an initial recognition assessment, the assessment findings and conclusions are established taking into account the results of the both stage 1 and stage 2 assessments.

Appendix 3
Specifics of the on-site assessments

Assessment objectives

Assessment	Objectives
Stage 2 Assessment	• Evaluate the conformity of the Auditing Organization's management system documentation to meet all the regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; • Evaluate the evidence of implementation, monitoring, measuring, reporting and reviewing by the Auditing Organization of its activities against policies, procedures and objectives from its management system (consistent with the expectations for recognition); • Review the operational controls of the Auditing Organization's processes, including when implemented by external resources; • Confirm that the Auditing Organization conducted internal audits and management reviews; and, • Confirm the competence of the Auditing Organization and the resources available necessary to fulfill the obligations for the scope of recognition.
Assessment at a Critical Location	• Review the relationship between the head office of the Auditing Organization and the Critical Location; • Review, if applicable, the arrangements between the head office of the Auditing Organization and the Critical Location; • Evaluate the management system operated at the critical location to satisfy the requirements of the Auditing Organization; • Evaluate the conformity of the activities undertaken by the Critical Location on behalf of the Auditing Organization to the requirements of the Auditing Organization's management system or to the arrangements between the head office of the Auditing Organization and the Critical Location;

	• Evaluate the conformity of activities undertaken by the Critical Location on behalf of the Auditing Organization to the corresponding regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; and, • Evaluate the controls in place at the Critical Location enabling its monitoring by the Auditing Organization.
Surveillance Assessment	• Review of internal audits and management review; • Review of Competence Management activities; • Review of actions taken on nonconformities identified during the previous audit; • Treatment of complaints and appeals; • Evaluation of the effectiveness of the management system with regard to achieving the Auditing Organization's objectives as it relates to the scope of recognition; • Evaluate records of audit and decision on conformity of medical device manufacturer to regulatory requirements; • Evaluate continuing operational control; and, • Review any changes.
Re-recognition Assessment	• Evaluate the effectiveness of the Auditing Organization's management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of recognition; • Confirm the continued conformity of the Auditing Organization's management system to regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; and, • Confirm the commitment of the Auditing Organization to maintain the effectiveness of the management system.

Key processes and assessment tasks from the assessment model, reviewed during each type of assessment activity

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable)	Surveillance	Re-Recognition
Management				
1. Legal entity, legal responsibility liability, financing & eligibility	☒	☒	☐	☒
2. Quality Management System documents	☒	☒	☐	☒
3. Quality policy, quality objectives and quality planning	☒	☒	☒	☒
4. Organizational structure, responsibility, and authority	☒	☒	☐	☒
5. Adequacy of auditing resources	☒	☒	☒	☒
6. Management of impartiality	☒	☒	☒	☒
7. Management review	☒	☒	☒	☒
Use of External Resources				
1. Extent and controls of use of external resources	☒	☒	☒	☒
2. Contractual arrangements with external resources	☒	☒	☒	☒
3. Internal competence to review the outcome of outsourced activities	☒	☒	☐	☒
Measurement, Analysis & Improvement				
1. Procedures relative to measurement, analysis and improvement	☒	☒	☐	☒
2. Sources of quality data	☒	☒	☒	☒
3. Investigation, corrections, corrective actions and preventive actions to address nonconformities and potential nonconformities	☒	☒	☒	☒
4. Reporting of corrective actions impacting the recognition	☒	☒	☒	☒
5. Decision on conformity to regulatory requirements supported by nonconforming audit or audit reports	☒	☒	☒	☒
6. Internal audits	☒	☒	☒	☒
7. Complaint handling and management	☒	☒	☒	☒
8. Communication with external resources having contributed to a nonconformity or complaint	☒	☒	☒	☒
9. Outputs of the Measurement, Analysis and Improvement process as inputs into the management review	☒	☒	☒	☒

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable)	Surveillance	Re-Recognition
Competence Management				
1. Identification of necessary competence to operate as a recognized auditing organization	☒	☒	☐	☒
2. Procedure and criteria for competence evaluation of all personnel involved in audit and certification related activities	☒	☒	☐	☒
3. Identified personnel with demonstrated competence	☒	☒	☒	☒
4. Training to the audit process and certification requirements and access to corresponding current documents	☒	☒	☒	☒
5. Monitoring of personnel's competence and performance	☒	☒	☒	☒
6. Personnel's individual file	☒	☒	☒	☒
7. Effectiveness of the competence evaluation methods and the competence management process	☒	☒	☒	☒
Audit & Decision				
1. Procedures for the control of the Audit & Decision process	☒	☒	☐	☒
2. Audit programme establishment and update; audit time determination; planning of audits	☒	☒	☒	☒
3. Selection and assignment of competent audit team, and communication prior to the audit	☒	☒	☒	☒
4. Audit performance and audit report	☒	☒	☒	☒
5. Review of manufacturer's response to audit findings	☒	☒	☒	☒
6. Technical review of the audit files and decision making on regulatory conformity of the manufacturer	☒	☒	☒	☒
7. Implementation and follow-up of the decision, including unannounced audits	☒	☒	☒	☒
8. Appeals	☒	☐	☒	☒
9. Audit and decision records	☒	☒	☒	☒
10. Effectiveness of the Audit and Decision process	☒	☒	☒	☒

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable)	Surveillance	Re-Recognition
Information Management				
1. Control of documents and records	☒	☒	☐	☒
2. Public information on the audit program	☒	☒	☐	☒
3. Provision to the audited medical device manufacturers of detailed information on the audit and decision related processes	☒	☐	☐	☒
4. Contractual agreements with the audited medical device manufacturer	☒	☒	☒	☒
5. Sharing of information with recognizing Regulatory Authorities on auditing activities, decisions on regulatory compliance and certification status	☒	☒	☒	☒
6. Provision to the public of information on certification status, or certifications granted, suspended or withdrawn	☒	☒	☒	☒
7. Control of confidential information	☒	☒	☐	☒

On-Site Assessment at a Critical Location
Critical locations have a scope of activities defined in the contractual agreement with the head office. The tasks listed above may therefore not be all applicable to a particular critical location. The planning of the assessment at a critical location should take into account the outcome of prior assessments (Stage 1 and Stage 2) to tailor the scope of the assessment.

Guidelines on On-Site Assessment Duration:
The duration of on-site assessment takes into account the need for assessment teams including assessors from 2 different RA. The size of the assessment team – if greater than 2 – should not affect the on-site duration, unless justified.

The suggested duration below are indicative only and may be adjusted as deemed appropriate.

- Stage 2 Assessment : 2.5 days (5 man-days)
- Surveillance Assessment : 2.5 days (5 man-days)
- Re-recognition Assessment: 4 days (8 man-days)
- Assessment at a Critical Location: 1 day (2 man-days), unless the range and extent of activities at the critical location justifies a longer on-site assessment duration.