Table of Contents

1. Purpose/Policy

The purpose of this procedure is to describe the process for performing Special On-Site assessments of an auditing organisation in the framework of the MDSAP.

Special On-Site Assessments are used to verify the effective closure of nonconformities, to investigate complaints, and to collect and evaluate information in response to significant changes or other information received by the MDSAP Regulatory Authorities. Special On-Site Assessments can be either announced or unannounced.

2. Scope

This procedure applies to the MDSAP Assessment Program Manager (APM) assigned to the auditing organization (AO) and to the assessors selected to perform the assessment.

3. Definitions/Acronyms

APM: Assessment Program Manager

ATL: Assessment Team Leader

AO: Auditing Organisation

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager

- Plans and schedules the Special On-Site Assessment activities
- Selects the assessors involved in these activities
- Reviews the outcome of the Special On-Site Assessment activities and determines their impact on the recognition decision and the AO assessment Program
- Forwards the results of the Special On-Site Assessment to the Technical Review and Recognition Committee (TRRC)

Assessors

The Audit Team Leader (ATL):

- Assists the APM in identifying the information that the AO needs to submit prior to the interactive phase
- Reviews and analyses the information submitted by the AO in preparation for the interactive phase
- Prepares and issues the assessment plan
- Leads the assessment team during the On-Site phase of the assessment
- Conducts on-site assessment activities
- Documents the results of the assessment in an assessment report

The Assessors (other than the ATL):

- Conduct on-site and remote assessment activities as assigned by the ATL

5. Procedures

The flowchart MDSAP AS F0020.1 illustrates this procedure.

Initiation Phase

The APM initiates a Special On-Site Assessment to address various situations such as (not an exhaustive list):

- when the AO assessment Program specifies the need to perform a special assessment in order to verify the effective closure of AO nonconformities (See procedure MDSAP AS P0005);
- when an application for scope extension is received from the AO and the extension cannot be granted through a special documentary assessment;
- when a notification of significant changes requiring on-site investigation is received from the AO;
- when deemed necessary to investigate complaints about the AO;
- to assess the implementation of new or modified recognition criteria; or,
- when the inspection of a medical device manufacturer raises concerns

about the performance of the AO.

The APM first identifies the assessor competencies required for the Special On-Site Assessment. The APM then selects the ATL and assessors for the activity that meets the identified competency requirements. If the assessment aims at following up AO nonconformities from prior assessment activities, the ATL of the audit during which the nonconformities were issued is the preferred ATL for the special assessment.

The selected ATL and assessors confirm their agreement and indicate their availabilities for the assessment activity. In case an assessor does not accept the assignment, a reason is provided. An alternate assessor may be proposed. The APM selects another assessor and repeat the previous task.

Once the assessment team is selected and the assessors have agreed to participate, assignment letters are sent to the assessment team detailing the scope and objectives of the activity.

In the case of an unannounced Special On-Site Assessment, the activity proceeds directly to the On-Site phase once the assessment team is assigned.

For announced Special On-Site Assessments, the APM and the assessment team collaborate to identify any information that the AO needs to submit in preparation for the activity. If the APM and assessment team do not identify any information requiring a prior documentary review prior to the assessment, the activity proceeds to the On-Site phase once the announcement letter is issued.

The APM then informs the AO of the Special On-Site Assessment activity and requests the relevant information, if any, in an assessment announcement letter. The announcement letter describes the purpose of the Special On-Site Assessment, details the information to be submitted, and includes an appropriate deadline for submitting the information (typically 15 calendar days.)

Documentary Phase

The AO submits the required information directly to the ATL who reviews the submission for completeness. If the submission is incomplete, the ATL informs the APM and AO in writing and requests the missing information.

Once a completed submission is received, the ATL (and assessors, if requested by the ATL) reviews the information. Upon completion of this review, the ATL informs the APM that the on-site phase can now be scheduled.

Should the ATL feel that further information needs to be submitted by the AO, or if there are any other outstanding issues that need to be resolved prior to the on-

site phase, the ATL informs the APM of the situation. The APM and ATL work collaboratively to resolve the issue with the AO.

On-Site Phase

Except for unannounced assessments, the APM contact the AO to schedule the on-site phase of the Special On-Site Assessment in accordance with the Assessment Program and the availability of the selected assessment team.

Once the dates of the on-site phase of the Special On-Site Assessment are known, the ATL prepares the assessment plan, using the form MDSAP AS F0016.3 Assessment Plan Form, and submits it to the APM. The APM reviews the assessment plan to ensure that it is consistent with the scope and objectives of the special assessment and in accordance with the Assessment Program.

If the Special On-Site Assessment is announced, the ATL forwards the assessment plan to the AO with sufficient time for the AO to ensure the availability of key individuals or to raise any concerns about the feasibility of the plan.

If the Special On-Site Assessment is unannounced, the APM is responsible for forwarding the audit plan with an announcement letter to the AO within 5 working days prior to the assessment.

The assessment team, under the direction of the ATL, performs the Special On-Site Assessment in accordance with the assessment plan.

Once the assessment team has completed the assessment, the ATL prepares the assessment report, using the form MDSAP AS F0016.5, and any necessary nonconformities are recorded using form MDSAP AS F0015.2 - AO Nonconformity Report and forwarded to the APM.

Follow-up phase

The Assessment Program Manager reviews the Assessment report and any associated nonconformity reports.

The APM advises the AO of the results of the Special On-Site Assessment and forwards the report along with any issued non-conformities.

The nonconformities are handled in accordance with IMDRF/MDSAP WG/N:11 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization.

Taking into account the recommendation of the Assessment Team Leader, the

APM:

- determines whether the objectives of the Special On-Site Assessment are satisfied
- proposes whether additional assessment activities are necessary,
- determines if the AO Assessment Program should be updated
- makes recommendation on:
    - on-going recognition or re-recognition
    - expanding the scope of recognition
    - modifying or reducing the scope of recognition
    - suspension or revocation of the recognition

The APM forwards the Special On-Site Assessment file to the TRRC for review and decision in accordance with procedure MDSAP AS P0017 Technical Review and Recognition Decision Making Procedure. The decision of the TRRC must be consistent with the objectives of the Special On-Site Assessment and the current status of recognition of the AO. See examples in the table below:

Reason of the Special On-Site Assessment	Decision on
Follow-up of non-conformities whose remediation is the precondition to the recognition	Lifting the precondition and granting recognition
Follow-up of non-conformities whose remediation is the condition to reinstitute a suspended recognition	Lifting the suspension
Follow-up of non-conformities in other situations	Upholding the recognition
Notice of significant change for extending the scope of recognition	Extending the scope of recognition
Notice of other significant change	Upholding the recognition
Complaints	Upholding the recognition
Change of recognition and monitoring criteria	Upholding the recognition

Following the completion of the Special On-Site Assessment, the APM updates the AO assessment Program in accordance with the MDSAP AS P0005 Assessment Program Procedure.

6. Forms

MDSAP AS F0020.1 - Special Assessment Flowchart
MDSAP AS F0016.3 - Assessment Plan Form
MDSAP AS F0016.5 - Assessment Report Form
MDSAP AS F0015.2 - AO Nonconformity Report

7. Reference Documents

ISO/IEC 17021-1:2015 – *Conformity assessment — Requirements for bodies providing audit and certification of management systems*
IMDRF/MDSAP WG/N3 (2nd ed.) – *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*
IMDRF/MDSAP WG/N6 – *Regulatory Assessor Competence and Training Requirements*
IMDRF/MDSAP WG/N11 - *MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization*
MDSAP AS P0005 –*Assessment Program Procedure*
MDSAP AS P0017 – *Technical Review and Recognition Decision Making Procedure*
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	2019-11-12	Removed reference to MDSAP AS P0015 AO Nonconformity Procedure in various places; updated reference to ISO 17021-1:2015 from ISO 17021:2011 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	Kimberly Lewandowski-Walker/Hiromi Kumada

Version
002
Approval

Approved: ON FILE Date: 2019-11-22
CHAIR, MDSAP RAC