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1. Purpose/Policy

The purpose of this procedure is to describe the process of the Stage 1 assessment of an auditing organization in the framework of the MDSAP. Stage 1 assessment is the first assessment activity following the initial drafting of the Assessment Program for an Auditing Organization.

Stage 1 assessment includes 2 main activities: documentation review and assessment.

It aims at collecting and reviewing the information necessary to establish the assessment program specific to the auditing organization and to plan the subsequent assessment activities.

2. Scope

This procedure applies to the Assessment Program Manager (APM) assigned to the application from an Auditing Organization (AO) and to the assessors selected to perform the Stage 1 Assessment.

3. Definitions/Acronyms

AO: Auditing Organization

APM: Assessment Program Manager

ATL: Assessment Team Leader

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager

- Plans and schedules the Stage 1 assessment activities
- Selects the assessors involved in these activities
- Reviews the outcome of Stage 1 assessment activities and determines their impact on the assessment plan and subsequent assessment activities

Assessors

Under the responsibility of the Assessment Team Leader (ATL), the assessment team:

- Reviews and analyses the management system documentation of the auditing organization
- Performs the Stage 1 Assessment
- Prepares the Stage 1 Assessment Report
- Reviews the information provided by the AO to satisfy any precondition necessary to progress the assessment process to a Stage 2 On-Site Assessment.

5. Procedures

The flowchart MDSAP AS F0013.1 illustrates this procedure.

Initiation

After the review of the application for recognition by an auditing organization under the MDSAP, the Assessment Program is drafted to include, at a minimum:

- Stage 1 Documentation Review, and
- Stage 1 Assessment

The Assessment Program Manager (APM) identifies the assessors satisfying the criteria for this activity in term of their competence and independence.

The APM selects 2 assessors from 2 Regulatory Authorities. The APM notifies each of them in writing, specifying the type of assessment, the proposed timeline, and the assessor role, i.e. Assessment Team Leader or Assessor. The same assessment team performs both the Stage 1 Documentation Review and the Stage 1 Assessment.

The Assessors confirm their agreement and indicate their availabilities for these Stage 1 assessment activities. In case an assessor does not accept the

assignment, a reason is provided. An alternate assessor may be proposed. The APM preselects another assessor and repeat the previous task.

Once the assessors are assigned for the Stage 1 assessment, the APM provides the assessors with all relevant information provided by the AO along with the application, including:

- The application form
- The scope of recognition form
- The AO Management System Documentation Trace Matrix form.
- The AO management system documentation

The APM liaises with the AO to schedule the Stage 1 Assessment.

The Assessment Team Leader ensures that the following objectives are satisfied.

Stage 1 Assessment Objectives

The Stage 1 Assessment is performed to:

1. Assess the auditing organization's management system documentation;
2. Evaluate the auditing organization's location and site-specific conditions and to undertake discussions with the AO's personnel to determine the preparedness for the Stage 2 On-Site Assessment;
3. Review the auditing organization's status and understanding regarding requirements of ISO 17021-1:2015 and IMDRF/MDSAP WG/N3 (2nd Edition) on *Requirements for Medical Device Auditing Organizations Regulatory Authority Recognition*, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
4. Collect necessary information regarding the scope of the management system, processes and location(s) of the auditing organization, and related statutory and regulatory aspects and compliance (e.g. quality, legal aspects of the AO's operation, associated risks, etc.);
5. Review the need for specific allocation of resources for stage 2 audit and agree with the AO on the details of the Stage 2 On-Site Assessment;
6. Provide a focus for defining the Assessment Program and planning the Stage 2 On-Site Assessment by gaining a sufficient understanding of the auditing organization's management system and site operations in the context of possible significant aspects; and
7. Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the AO is ready for the Stage 2 On-Site Assessment.

Stage 1 Documentation Review

The Stage 1 Documentation Review contributes to these objectives by:

- Collecting information regarding the scope of the auditing organization's management system, its processes, the location(s) involved in its implementation, and other related statutory, liability and regulatory aspects;
- Analysing the scope, extent, level of detail, ability to address the applicable requirements of the auditing organization's management system documentation; and
- Analysing the status and understanding regarding the specified requirements.

Stage 1 Assessment

The stage 1 Assessment contributes to these objectives by:

- Confirming the outcome of the Stage 1 Documentation Review.
- Investigating the organizational structure of the AO, including locations and relationship with external organizations in detail to identify the relevant factors for the planning of following assessment activities.
- Collecting necessary information regarding the scope of the management system, processes and location(s) of the auditing organization, and related statutory and regulatory aspects and compliance. (e.g. quality, legal aspects of the client's operation, associated risks, etc.)
- Evaluating if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 On-Site Assessment.

The Stage 1 Assessment may take one of the following form, as determined as part of the Assessment Program:

- On-site visit at the head office of the auditing organization, ahead of the Stage 2 On-Site Assessment.
- Teleconference / Videoconference provided the setting allows the assessors to access the auditing organization documents being discussed. Prior planning with the AO is required to ensure the remote assessment is effective.

During the course of the Stage 1 Assessment, the ATL should complete MDSAP AS F0013.3 Auditing Organization Key Activities Matrix. This matrix will be used by the Stage 2 Assessment Team to assist in the preparation of Stage 2 Assessment activities including on-site assessments.

Stage 1 Assessment Report

The ATL fills in the MDSAP AS F0013.2 Stage 1 Assessment Report Form. Concerns identified during the stage 1 Assessment are either documented in

the report as observations or issues requiring clarifications (potential nonconformities).

The ATL provides the Stage 1 assessment report to the Assessment Program Manager (APM) and to the AO.

Review of the Stage 1 Assessment Report by the Assessment Program Manager (APM)
The APM reviews the Stage 1 Assessment report.

Taking into account the recommendation of the Assessment Team Leader, the APM determines whether:

- The assessment process may proceed to Stage 2 On-Site Assessment. This applies when the findings of the audit
  - do not require extended timeline for resolution, and
  - are not representative of significant concerns with regards to the ability of the AO to demonstrate compliance to the specified requirements at the time of the Stage 2 On-Site Assessment.
- The assessment process may proceed to Stage 2 On-Site Assessment after resolution of the findings of Stage 1. This applies when the findings of the audit
  - require extended timeline for resolution, or
  - require evidence of effective implementation of the action plan to give confidence in the ability of the AO to satisfy the specified requirements.

If the process is put on hold pending resolution of the findings from Stage 1, the APM consults the TRRC to determine the extent of information necessary to resume the process. The APM informs the AO of the requested information. Upon receipt of the requested information, the APM forwards this information to the Assessment Team Leader for review. If the ATL confirms that this satisfies the condition, the APM may proceed towards the Stage 2 On-Site Assessment and inform the AO.

Following the completion of the Stage 1 Assessment, the APM:

- Finalizes the Assessment Program for the Auditing Organization per procedure MDSAP AS P0005.
- Initiate the Stage 2 On-Site Assessment according to procedure MDSAP AS P0016.

6. Forms

MDSAP AS F0013.1 Stage 1 Assessment Flowchart
MDSAP AS F0013.2 Stage 1 Assessment Report
MDSAP AS F0013.3 Auditing Organization Key Activities Matrix

7. Reference Documents

ISO/IEC 17021-1:2015 *Conformity assessment — Requirements for bodies providing audit and certification of management systems*
IMDRF/MDSAP WG/N3 (2ns Edition) *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*
IMDRF/MDSAP WG/N5 *Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations*
MDSAP AS P0005 *Assessment Program Procedure*
MDSAP AS P0015 *AO Nonconformity Procedure*
MDSAP AS P0016 *On-Site Assessment (Stage 2, Surveillance, Re-recognition, Witnessed Audit, Critical Location)*

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Marc-Henry Winter
002	2014-12-09	Page 4; section Stage 1 Assessment, last paragraph: added the use of a Key Activities Matrix to assist in the preparation of Stage 2 Assessment activities.	Robert G. Ruff
003	2015-09-22	Page 8; added “MHLW/PMDA” to the participating regulatory authorities due to Japan’s participation to MDSAP Pilot. Minor changes to be signed by team lead.	Liliane Brown
004	2016-08-15	Minor grammatical changes throughout the document; updated IMDRF/MDSAP WG/N3 (2nd Edition) title	Liliane Brown

Version 004
Approval

Approved: Signature on file Date: 2016-08-15
Team leader for CHAIR, MDSAP RAC

Appendix 1

Recommendations for communication along the Stage 1 Assessment process

1. Email from the APM to the assessors RE: Assignment Proposal

If the APM uses an email to communicate with the assessors on their pre-selection as assessor, the e-mail should include the following information:

Subject of the e-mail: “Assignment proposal” + Name of the AO.

Body of the email:

- Name of the AO
- Assessment Type: Initial Recognition
- Assessment Activity: Stage 1 Documentation Review + (if applicable) Stage 1 Assessment
- Role: Assessor, Assessment Team Leader
- Considered Assessment Timeline
- Request for acceptance of the assessment assignment, which can be either:
    - Acceptance of assignment
    - Acceptance of assignment with comments (may relate to availability)
    - Refusal

    Note: the acceptance may be automated in the email with answer buttons.

2. Email from the APM to the assessors RE: Assignment Confirmation

If the APM uses an email to communicate with the assessors on their confirmation as an assessor, the e-mail should include the following information:

Subject of the e-mail: “Assignment Confirmation” + Name of the AO.

Body of the email:

- Name of the AO
- Assessment Type: Initial Recognition
- Assessment Activity: Stage 1 Documentation Review + (if applicable) Stage 1 Assessment
- Role: Assessor, Assessment Team Leader
- Considered Assessment Timeline, with reminder to communicate with APM in case an assessment activity must be rescheduled
- Other assessment team member(s) and role

- Reminder that the Stage 1 assessment report is expected to be provided to the APM within XX days after the last day of the assessment

Attachments:
- Application form completed by the AO
- Scope of recognition form as completed by the AO
- AO Management System Documentation Trace Matrix
- AO's management system documentation

3. Communication to the AO in case the process is put on hold as a result of Stage 1

This official notification should be emailed by the Assessment Program Manager with request of acknowledgement of receipt and acknowledgement of reading, with copy by mail.

RE: Status of the Assessment Process for the recognition as an Auditing Organization under the Medical Device Single Audit Program (MDSAP)

Dear [Name of the AO representative]

Considering the outcome of the Stage 1 Assessment of [name of the AO], the Technical Review and Recognition Committee representing the 5 Regulatory Authorities participating in the MDSAP (TGA, ANVISA, Health-Canada, MHLW/PMDA and FDA) agreed to put the process on hold until resolution of the identified issues.

The process will resume after the review by the Assessment Team Leader of the evidence of resolution relative to the following items:
1. [include the list of concerns requiring evidence of resolution]

You must provide this information within 3 months (i.e. before [DATE]). After this date, if we have not received the evidence of resolution of the findings, the assessment process will be terminated.
If you do not intend to provide evidence to resolve these issues by the date indicated above, you may notify me of your decision to terminate the process.