	Document No.: MDSAP AS P0005.002	Page: 1 of 9
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Responsible Office/Division Title: Assessment Program Procedure		Project Manager: Marc-Henri Winter, USFDA

Table of Contents

- 1. Purpose/Policy
- 2. Scope
- 3. Definitions/Acronyms
- 4. Authorities/Responsibilities
- 5. Procedures
- 6. Forms
- 7. Reference Documents
- 8. Document History
- Approval Sign-Off Sheet
- Appendix 1
- Appendix 2

1. Purpose/Policy

The purpose of this procedure is to describe the tasks and responsibilities relative to the definition, approval, implementation, review and update of assessment program specific to a particular auditing organization, in the framework of the Medical Device Single Audit Program.

The assessment program is the set of key information necessary for the planning, follow-up and monitoring of assessment activities applied to an Auditing Organization.

2. Scope

The scope of this procedure covers review activities by the Assessment Program Manager and the decisions made by the Technical Review and Recognition Committee (TRRC) related to the definition, approval, implementation, review and update of the Assessment Program specific to an Auditing Organization.

3. Definitions/Acronyms

Assessment Program: Documented sequence of all assessment activities

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 2 of 9
---------------------------------	-------------------------------------	-------------

planned for a 4-year assessment cycle and specific to a particular Auditing Organization for the purpose of its initial recognition and the maintenance or renewal of this recognition.

Special Assessment: Assessment activity performed in addition to the regular annual assessment (surveillance, re-recognition). It is generally implemented to perform the follow-up of critical nonconformities, assess significant changes of the AO's organization, address a request for extension of scope of recognition, or "for cause". It can have the format of an assessment-audit performed on-site or remotely, or of a documentary assessment, as determined by the APM, taking into account the objectives of the special assessment.

4. Authorities/Responsibilities

Technical Review and Recognition Committee (TRRC):

- Approves the Assessment Program
- Makes recognition decisions, based on the completion of the outcome of the implementation of the Assessment Program

Assessment Program Manager (APM):

- Interfaces with the auditing organization (AO)
- Drafts the initial Assessment Program and future amendments
- Ensures the effective planning of the assessment activities listed in the Assessment Program and of follow-up activities where necessary
- Verifies the implementation of assessment activities by the assessment team according to the Assessment Program
- Reviews assessment outcomes and proposes recognition decisions to the TRRC

Assessment Team:

- Performs the assessment activities, according to the Assessment Program under direction from the Assessment Program Manager
- Makes recommendations regarding; a recognition decision, follow-up activities relative to the findings of the assessment, and for the update of the Assessment Program

5. Procedures

The flowchart MDSAP AS F0005.1 presents the sequence of tasks involved in the drafting, issuance and revision of the APMF.

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 3 of 9
---------------------------------	-------------------------------------	-------------

1. Initial release of the Auditing Organization Assessment Program

The APM initiates the drafting of the Assessment Program based on the information included in the MDSAP AS F0010 AO Application upon completion of the Application Review per procedure MDSAP AS P0010 Application Review and Stage 1 Assessment.

The form MDSAP AS F0005.2 AO Assessment Program Management File (APMF) (Microsoft Excel file) – includes several sections. At a minimum, the APM completes the following tabs:

- AO
- Critical Locations
- Activities
- Technical Areas

The initial draft of the APMF specifies the considered scope of recognition and lists all baseline activities relative to an initial recognition 4-year cycle, with limited specifics. The diagram in appendix 1 presents the different assessment activities considered as baseline for a regular Assessment Program (i.e., excluding special assessment activities).

The Stage 1 Assessment may be performed either on-site or remotely. The Stage 1 Assessment must be a separate assessment from Stage 2. The APM recommends the assessment modality taking into account the existing knowledge of the AO and uses the form MDSAP AS F0005.3 – AOAP Approval to document the rationale. The rationale may take into account whether:

- The AO was accredited in the framework of a regulatory scheme and
- The history of assessment of the AO under an accreditation program does not raise significant concern.

To perform the assessment remotely, the assessors need either:

- a web-based conferencing infrastructure, allowing direct information and document sharing, or
- other teleconferencing system with prior transmission of the necessary documents.

The APM sends its recommendation for the APMF to the TRRC for approval and addresses any concern expressed by the TRRC.

The stage 1 assessment activities are then implemented according to the procedure MDSAP AS P0013 Stage 1 Assessment.

Upon completion of the Stage 1 Assessment process, the APM reviews and revises the draft APMF, taking into account the findings and recommendations of the assessment team.

At a minimum, the APM completes the following tabs:

- Assessment Program (assessment activities relative to the full first

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 4 of 9
------------------------------	-------------------------------------	-------------

- assessment cycle)
- Assessment Program Change Log

The APM:

- Documents the request for approval in Form MDSAP AS F0005.3 Assessment Program Approval,
- Attaches the AO application for recognition and the Stage 1 report,
- Presents the draft APMF to the TRRC for approval.

In the event that the Technical Review and Recognition Committee (TRRC) does not approve the APMF, the TRRC records the decision, with rationale, and specifies the necessary changes. The APM corrects the APMF as requested by the TRRC or, as applicable submits a revised draft Assessment Program to the TRRC.

2. Implementation of the Assessment Program applied to an Auditing Organization

Once approved, the APM plans the agreed assessment activities accordingly and coordinates with the AO and the assessors for the performance of an assessment activity according to the Assessment Program. Additional details relative to the planning, performance and completion of individual assessment activities are included in the corresponding procedure. (MDSAP AS P0012,13 &16)

The APM is responsible for initiating and planning the specific assessment activities, in coordination with the auditing organization and the assessment team, respecting the timeline of assessment activities as specified in the APMF.

The APM may not be part of the assessment team for an AO within his/her portfolio. The APM may nevertheless be an assessor for activities relative to an AO outside his/her portfolio.

3. Update of the Assessment Program for an Auditing Organization Following Stage 2 Assessment

Following the performance of the Stage 2 on-site assessment according to procedure MDSAP AS P0016 On-Site Assessment, the APM adds details to the APMF, and in particular specific information relative to witnessed audits and the assessment of the critical locations, if applicable, taking into account the recommendation of the assessment team.

If these details do not contradict information from the approved APMF, the updated APMF is provided to the TRRC for information.

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 5 of 9
------------------------------	-------------------------------------	-------------

If these details require modifying information in the approved APMF, the APM submits an updated APMF to the Technical Review and Recognition Committee (TRRC) for re-approval. The APM documents the request for approval in Form MDSAP AS F0005.3 Assessment Program Approval, explains the reason for the update and attaches the stage 2 assessment report, and, if available, the corresponding recognition decision.

4. Maintenance, review and update of the Assessment Program applied to an Auditing Organization

Prior to surveillance or re-recognition assessment, the APM sends a request for review of the recognition scope to the AO. Appendix 2 includes a template letter that may be used for this purpose.

Upon receipt of the response from the AO, the APM reviews it to identify any change potentially impacting the Assessment Program.

The APM also reviews other sources of information relative to the AO, including:

- Prior assessment activity reports including, where applicable the review of samples of AO audit reports (see procedure MDSAP AS P0016 On-Site Assessment)
- Recommendations from assessment team
- Nonconformity status and trends
- Status of conditions associated with prior recognition decisions, if applicable
- Notice of change received from the AO
- Complaints relative to the AO activity performance
- Change of applicable recognition requirements
- Other available data, as appropriate

Likewise, after each assessment activity, the APM reviews the recommendation of the assessment team regarding the adequacy of the APMF.

The AO may also submit a notice of change using form MDSAP AS F0005.5.

The change may relate to either:

- Change of their organization without direct impact on the scope of recognition (e.g. deployment of a new IT solution for the management of auditing activities), or
- Request for extending the scope of recognition (e.g. New technical area, new critical location).

The APM evaluates the impact of this change

As an outcome of these reviews the APM may:

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 6 of 9
------------------------------	-------------------------------------	-------------

- Specify focus for the assessment team to take into account while performing the assessment activity
- Propose modifications to already planned assessment activities
- Propose to add special assessment activities, in the format of either:
 - o Special On-Site Assessment, or
 - o Special Remote Assessment, or

For Special Assessment, the APM also determines its modality of implementation, in particular whether announced or unannounced.

The APM submits any change to the APMF for approval to the TRRC when the modification involves additional assessment activities or substantial modification to already planned assessment activities. The APM documents the request for approval in the MDSAP AS F0005.3 Assessment Program Approval Form, explains the reason for the update and attaches the supporting documentation.

The APM is responsible for initiating and planning the specific assessment activities, in coordination with the auditing organization and the assessment team, respecting the timeline of assessment activities as specified in the APMF. The APM follows the procedure corresponding to the considered assessment activity:

- MDSAP AS P0016 On-Site Assessment (Stage 2, Surveillance, Re-recognition at the head office or critical locations)
- MDSAP AS P0012: Witnessed Audit Procedure
- MDSAP AS P0014 Special Remote Assessment
- MDSAP AS P0020 Special On-Site Assessment

6. Forms

MDSAP AS F0005.1 –Assessment Program Flowchart

MDSAP AS F0005.2 – Assessment Program Management File Form

MDSAP AS F0005.3 – Assessment Program Approval Form

MDSAP AS F0005.5 – Notice of Change

7. Reference Documents

MDSAP AS P0010 – *AO Application for Recognition Procedure*

MDSAP AS P0013 – *Stage 1 Assessment*

MDSAP AS P0016 – *On-Site Assessment (Stage 2, Surveillance, Re-recognition at the head office or critical locations)*

MDSAP AS P0012 – *Witnessed Audit*

MDSAP AS P0014 – *Special Remote Assessment*

MDSAP AS P0020 – *Special On-Site Assessment*

MDSAP AS P0017 – *Technical Review and Recognition Decision*

MDSAP AS P0034 - *Guidance for Regulatory Authority Assessors on the Method*

Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 7 of 9
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of Assessment for MDSAP Auditing Organizations

8. Document History

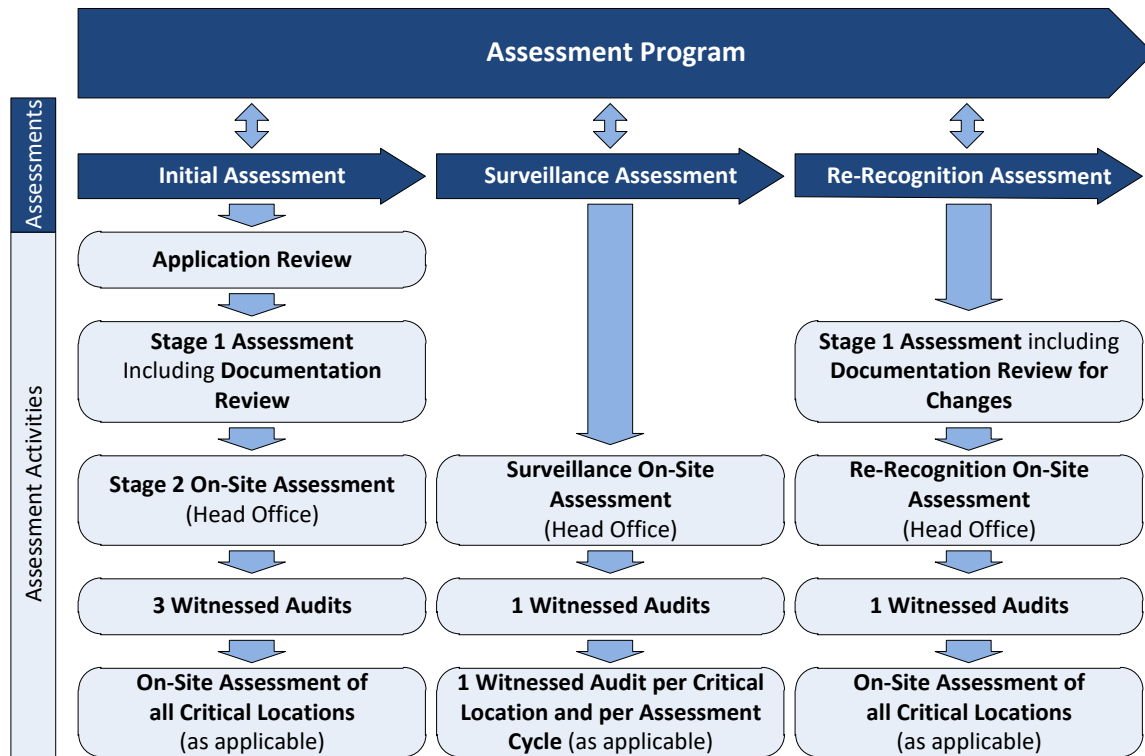
VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Robert G. Ruff
002	2019-11-22	Removed reference to IMDRF MDSAP WG N5 - Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations and replaced with MDSAP AS P0034 - Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations Adjusted formatting	Marc-Henri Winter, US FDA

Version 002
Approval

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

Appendix 1

Diagram Representing the Baseline Activities of the Assessment Program as applied to each Auditing Organization



Assessment Program Procedure	Document No.: MDSAP AS P0005.002	Page 9 of 9
------------------------------	-------------------------------------	-------------

Appendix 2

Template Letter prior to Annual Assessment Activities and Instructions

Note: The information below may be requested by email or mail

RE: Request for update of information relative to the scope of recognition under the Medical Device Single Audit Program (MDSAP) prior to the next annual assessment

Dear [Name of the Regulatory Correspondent],

In order to plan the next annual assessment of [AO name], we are providing you with a copy of the information on file relative to the current scope of recognition under MDSAP.

Please return as applicable before [Date]:

- A confirmation that the provided information remains current, or
- The completed form for Notice of Change, specifying all the applicable changes.

In either case, please provide the statistics relative to the audit and certification activities of medical device manufacturers (both in the and outside the framework of the Medical Device Single Audit Program: number of auditors, number of staff, number of certified manufacturers, number of audits performed, and number of auditor-days)

year	#Auditors	#Staff	#Certified Manufacturers	#Audits performed	#Auditor-days	#MDSAP audits	#MDSAP auditor-days

[Prior to Re-recognition Assessment, include the following:]

Please also return the form MDSAP AS F0010.5 – AO Application Matrix – with its table listing the requirements from ISO/IEC 17021 and IMDRF MDSAP N3 filled in to identify the AO documents addressing these requirements and provide the identified documents.

[APM Name]
Assessment Program Manager

[Agency]
[Agency Address]
Tel.
email