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Title: MDSAP Witnessed Audit Procedure		Project Manager: Marc-Henri Winter, USFDA

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1. Purpose/Policy

The purpose of this procedure is to describe the process to plan and perform witnessed audits during which MDSAP assessors observe AO auditors auditing a manufacturer, to evaluate the ability of the AO to reliably follow the auditing and reporting requirements of the Program.

2. Scope

This procedure applies to witness audits performed at a medical device manufacturer. A witnessed audit is an assessment activity part of every annual assessment (Initial, Surveillance, Re-recognition). The Technical Review and Recommendation Committee (TRRC) may recommend adding special witnessed audits as a result of prior assessment activities or complaints.

The Assessment Program Manager (APM), the assessors, and the Assessment Team Leader (ATL) are responsible for the implementation of this procedure.

3. Definitions/Acronyms

APM: Assessment Program Manager

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ATL: Assessment Team Leader

AO: Auditing Organisation

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager (APM):

- Initiates the witnessed audit procedure to ensure the implementation of the AO Assessment Program
- Liaises with the AO to obtain the planning of upcoming audits of medical device manufacturers, and selects the audit to witness
- Selects the assessors to form the assessment team
- Sends the assignment information to the assessors
- Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the witnessed audit
- Reviews the witnessed audit report and, if necessary, forwards the report to the Technical Review and Recognition Committee (TRRC) for review and a recognition-decision,
- Updates the Assessment Program Management File as necessary

Assessment Team Leader (ATL)

- Leads the pre-audit and post-audit meetings with the AO audit team
- Assigns responsibilities among the assessors and ensures that the witnessed audit objectives are met
- Leads the closing meeting with the AO audit team leader and AO management representative
- Finalizes and approves the witnessed audit report

Assessment team (including the ATL)

- Observes the AO auditing practices
- Informs the AO auditors of identified deficiencies
- Review the AO audit report for consistency with the audit findings
- Issue nonconformity reports if applicable
- Drafts the witnessed audit report

5. Procedures

The document MDSAP AS F0012.1 Witnessed Audit Flowchart illustrates this procedure.

The witnessed audit process is organized in 3 phases: *planning, assessment and follow-up*.

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Planning

The APM must have access to the AO audit planning. Pending the implementation of the MDSAP portal, the APM liaises with the AO regulatory correspondent to obtain this planning for the following semester. This planning must specify the following information:

- Manufacturer name and address
- Scope of certification
- Corresponding technical areas
- Selected auditors
- Audited facility (name and address)
- Type of audit
- Considered audit dates
- Audit duration, and
- Coordinating AO location (head office or critical location)

After receiving the AO audit planning, the APM selects the audit to witness, taking into account the applicable specifics mentioned in the MDSAP AS F0005.2 Assessment Program Management File. The selection criteria include in the priority order below:

- Type of audit (preference for initial or re-audits/recertification)
- Audited facility (preference for facilities implementing or controlling all the processes according to the MDSAP Audit Model)
- Coordinating AO location (to evaluate the consistency of auditing practices across the AO)
- Auditors (to avoid witnessing the same auditor repeatedly)
- Technical areas (to evaluate the competency of the AO in various domains)

A manufacturer must not be subjected to several witnessed audits during 2 consecutive assessment cycles.

The APM informs the AO of the selected audit to witness and requests the AO to complete the MDSAP AS F0012.2 Manufacturer Profile Form.

The APM selects the assessors taking into account the needed competence. The number of assessors assigned to a particular witnessed audit must be equal or greater than the number of AO auditors performing the audit. The assessment team should include at least one assessor who participated in prior assessment activities of the Auditing Organization.

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 selects another assessor and repeats the previous task.

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The APM sends an assignment letter (or email) to the confirmed assessors including details of the scope, objectives and specifics of the witnessed audit.

The APM liaises with the Assessors and the AO regulatory correspondent to determine the actual witnessed audit dates and to obtain the following information:

- Contact information of the AO auditors
- Evidence of their competence to perform the selected audit or rationale for their selection
- Rationale for the audit duration
- Copy of the information provided by the AO to the auditors regarding the audit to perform
- Completed MDSAP AS F0012.2 Manufacturer Profile Form.
- Manufacturer's quality manual
- Last audit report of the manufacturer (if any)
- Audit plan prepared by the AO audit team

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

Prior to the audit, the assessors should review the information provided by the AO, as well as the information available on the medical device manufacturer in the RA's information systems. The assessors should be mindful that the information from the RA's databases may not be accessible by the AO auditors.

Assessment

The witnessed-audit is organized in 4 steps:

- Pre-audit meeting
- Audit observation
- Audit report review
- Closing meeting including the provision of nonconformity reports as applicable

Except for the observation phase, all steps take place between the assessment team and the AO auditors, in the absence of any manufacturer's representative. The audit report review phase is a desktop remote activity by the ATL.

Pre-audit meeting

The pre-audit meeting aims at introducing the assessors and auditors, clarifying the witnessed audit objectives and rules, the role of the assessment team during the audit, and initiate discussions on the preparation of the audit team for the audit. See details in Appendix 1 of this procedure.

Audit observation

The assessors document the finding during the audit observation and record any

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nonconformities on the MDSAP AS F0015.2: AO Nonconformity Report Form. Note: nonconformities may result from the auditor not satisfying some specified requirements as well as from the auditor not identifying manufacturer's nonconformities. To enable the assessors to detect the latter concern, they must be able to review the documents presented to the auditors.

The assessors must not influence the conduct of the audit by the AO auditors.

The assessment team and the audit team arrange time along the audit for the AO Auditors to report on

- The progress of the audit towards its objectives and with reference to the audit plan, and
- The audit findings identified

Review of the audit report

The AO auditors must provide their audit report to the manufacturer and the ATL within the timeline specified by the AO's procedure, not exceeding 15 calendar days. The ATL and the assessment team reviews the audit report to assess its consistency with the audit findings and its compliance with the requirements applicable to audit reports as well as its suitability in presenting a faithful and complete account of the audit.

Closing meeting

If nonconformities against the Auditing Organization are identified during the observation phase or the review of the audit report, they are recorded on the MDSAP AS F0015.2 AO Nonconformity Report Form.

The meeting is usually performed remotely and takes place within 15 calendar days following the receipt of the audit report from the AO auditors. The ATL liaises with the AO auditors, assessors and the APM to schedule.

The nonconformities and conclusions are presented by the ATL during the closing meeting to the auditors, assessors and AO Representatives during the closing. See details in Appendix 2 of this procedure.

The Assessment Team Leader generates the witnessed audit report using the form MDSAP AS F0012.3 specific to Witnessed Audits. All assessment team members contribute to, review and approve the report.

Follow-up

Once the ATL has received, reviewed and approved the action plans for the nonconformities recorded using the MDSAP AS F0015.2 AO Nonconformity Report Form, the ATL provides the APM with the assessment report, AO Nonconformity reports and recommendations.

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The APM reviews the witnessed audit report and associated information and provides any necessary feedback to the assessment team.

Refer to procedure MDSAP AS P0017 Technical Review and Recognition Decision Making for a description of the circumstances when the APM prepares a file for review by the Technical Review and Recognition Committee (TRRC) (e.g. at the conclusion of the initial recognition process, at the end of each year's surveillance and witnessed activities, at the conclusion of a re-recognition assessment activity and in circumstances where identified nonconformity requires escalation.

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

6. Forms

MDSAP AS F0005.2 – Assessment Program Management File

MDSAP AS F0012.1 – Witnessed Audit Flowchart

MDSAP AS F0012.2 – Manufacturer Profile Form

MDSAP AS F0012.3 – Witnessed Audit Report Form

MDSAP AS F0015.2 - AO Nonconformity Report Form

7. Reference Documents

MDSAP AS P0034: Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations

MDSAP AS P0005 – AO Assessment Program Procedure

MDSAP AS P0017 –Technical Review and Recognition Decision Making Procedure

8. Document History

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VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Marc-Henri Winter
002	2016-8-16	Section 6. Forms – Remove title referring to a document MDSAP AS F0016.2 Assessment Announcement Letter Template. (template does not exists)	Liliane Brown
003	2020-05-22	Removed the use of the AO Nonconformity Checklist on pages 4 and 6. Replaced with MDSAP AS F0015.2 - AO Nonconformity Report Form Removed MDSAP AS F0016.2 Assessment Announcement letter in section 5 and 6. Removed MDSAP AS P0015 AO Nonconformity Procedure in section 5 and 7. Removed reference to IMDRF MDSAP WG/N5 in section 7. Adjusted formatting throughout the document	Kimberly Lewandowski-Walker/Hiromi Kumada

Version
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Approval

Approved: ON FILE CHAIR, MDSAP RAC Date: 2020-05-22

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Appendix 1

Pre-Audit Meeting of a Witnessed Audit

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

The purpose of the opening meeting is to:

- State the witnessed audit objectives
- Confirm the audit and post-audit activity schedule
- Briefly present the role of the assessors during the witnessed audit
- Confirm communication rules and channels during and after the audit
- Provide an opportunity for the auditee to ask questions

The ATL notes the start time of opening meeting and circulates the attendance sheet for registration of the attendees.

During the opening meeting, the ATL addresses the following topics with a level of detail adapted to the AO auditors' familiarity with the witnessed audit process.

Presentation of the Assessment Team and AO auditors

- 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 technical areas

Witnessed audit objectives

Conduct and organization of the witnessed audit

- Methods and procedures used to perform the witnessed audit
- Need for planned debriefing time between the assessment team and the audit team during the observation phase to give the opportunity to the assessors to question the auditors on the audit, the progress towards the audit objectives, the findings, etc.
- Need for the assessment team to question the audited manufacturer on the contractual agreement with the AO and the communication prior to the audit and from prior audits
- Conditions for the assessors to interject during the audit
- Assessment-audit findings: reporting, including the grading of nonconformities

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- Timeline of the post-audit activities including: 1) post-audit debriefing meeting, 2) provision and review of the audit report, and 3) closing meeting
- Official communication channels between the assessment team and the AO
- Language used

Other

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

Initiating the assessment

During the pre-audit meeting, the assessment team should initiate discussions on:

- The auditors' background (education, professional history, qualifications, familiarity with the audited manufacturer, its products, processes, and related technologies)
- Their employment status (AO employee vs. contractor)
- Situations that could represent a conflict of interest
- Methods used for, extent and outcome of the preparation for the audit

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Appendix 2

Closing Meeting of an Witnessed Audit

The closing meeting aims to obtain the agreement of the AO on the findings of the witnessed audit. Considering the lack of prior opportunity to directly discuss the identified nonconformity with the AO audit team, the ATL should provide the AO representatives and the AO audit team leader with the draft witnessed audit report (Form MDSAP AS F0012.3) and the AO nonconformity reports (Form MDSAP AS F0015.2) prior to the meeting.

The ATL chairs the closing meeting performed through teleconference means. Attendees must include the AO audit team leader and the AO's representatives (such as management representative for quality, regulatory correspondent).

The ATL addresses the following:

- Fulfilment of the witnessed audit objectives
- Obstacles met, including situations that required the ATL to interject
- The identified nonconformities and the expected timeline to answer them
- The conclusion of the witnessed audit
- Expected timeline for the RA to make their recognition decision
- Possibility to appeal to the recognition decision

The AO may comment the finding and conclusions of the witnessed audit and as appropriate, the ATL may take the comments into account and update the report and nonconformity reports accordingly.

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