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|   | <b>Version Date:</b><br>2019-11-22         | <b>Effective Date:</b><br>2013-12-16                |
| <b>Responsible Office/Division</b><br><b>Title:</b> Special Remote Assessment Procedure |  | <b>Project Manager:</b><br>Marc-Henri Winter, USFDA |

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### 1. Purpose/Policy

The purpose of this procedure is to describe the process for performing Special Remote Assessments of an auditing organisation in the framework of the MDSAP.

Special Remote 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.

### 2. Scope

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

### 3. Definitions/Acronyms

**APM:** Assessment Program Manager

**ATL:** Assessment Team Leader

**AO:** Auditing Organisation

### 4. Authorities/Responsibilities

#### Assessment Program Manager

- Plans and schedules the Special Remote Assessment activities
- Selects the assessors involved in these activities
- Reviews the outcome of the Special Remote Assessment activities and

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determines their impact on the recognition decision and the AO assessment Program.

- Forwards the results of the Special Remote Assessment to the Technical Review and Recognition Committee (TRRC)

### **Assessor**

The assessor:

- Reviews and analyses the management system documentation of the auditing organization and other requested documents
- Documents the results of the assessment in a documentary assessment report

## **5. Procedures**

The flowchart MDSAP AS F0014.1 illustrates this procedure.

### **Planning phase**

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

- when the AO assessment program specifies the need to perform a Special Remote Assessment in order to verify the effective closure of AO nonconformities (See procedures MDSAP AS P0005);
- when an application for scope extension is received from the AO;
- when a notification of significant changes requiring 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;
- in rare instances, to confirm the activities at a Critical Location in situations where an on-site assessment is unwarranted or impractical.

The APM informs the AO of the required activity and requests the relevant information and documents in an audit announcement letter. The announcement letter describes the purpose of the special documentary assessment, details the information to be submitted, and includes an appropriate deadline for submitting the information (typically 15 calendar days.)

Once the AO submits the required information, the APM reviews the submission for completeness. If the submission is incomplete, the APM informs the AO in writing and requests the missing information.

Once a complete submission is received, the APM identifies the assessor competencies required for the special documentary assessment. The APM then

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selects an assessor for the activity that meets the identified competency requirements. In case of Special Remote Assessment triggered by the outcome of prior assessment activities, the preferred assessor will be one of the assessment team who raised the concerns being re-evaluated. In all other situation, any assessor familiar with the Auditing Organization's management system is preferable. When performing a follow-up Special Remote Assessment as a result of AO nonconformities, the ATL of the audit during which the nonconformities were issued is the preferred assessor.

The selected assessor confirms his/her agreement and indicates his/her 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 preselects another assessor and repeat the previous task.

Once the assessor is assigned, the APM provides the assessor with the information supplied by the AO as well as supporting documents as appropriate. Information transmitted to the assessor includes the objectives of the documentary assessment, the information submitted by the AO for the assessment, and the relevant background information including as applicable:

- the past nonconformities and the AO's responses and evidence of implementation and verification of corrective action
- the AO's application for recognition scope extension
- the notice of change and supporting documents
- the original complaint(s) about the AO and the AO's response(s)
- the inspection report of medical device manufacturer
- etc.

The APM and assessor agree on a due date for the documentary assessment report.

### **Documentary phase**

The assigned assessor performs the Special Remote Assessment by evaluating the evidence provided by the AO against the recognition criteria and documenting the results of the evaluation.

If the evidence provided by the AO is insufficient to draw a reliable conclusion of conformity, the assessor may request that additional information or evidence be submitted. The Assessors informs the APM of the request. Requests for additional information should be issued with short deadlines for response.

The assessors reviews the additional information received from the Auditing Organization.

### **Optional interactive phase**

The assessor may find helpful to setup a teleconference with the Auditing

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Organization in order to confirm the conclusions drawn from the review of the supplied documentation. If so, the assessor informs the APM and liaises with the Auditing Organization in order to schedule a teleconference.

### **Follow-up**

Once the assessor has completed the assessment, the Special Remote Assessment report and any necessary nonconformities are completed and forwarded to the APM.

The Assessment Program Manager reviews the Special Remote Assessment report and any associate nonconformity reports.

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

The nonconformities are recorded using Form MDSAP AS F0015.2 AO Nonconformity Report.

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

- determines whether the objectives of the Special Remote Assessment are satisfied
- proposes whether additional assessment activities are necessary, including special assessment-audit
- the AO Assessment Program Management File (APMF) should be updated
- makes recommendation on:
  - o on-going recognition or re-recognition
  - o expanding the scope of recognition
  - o modifying or reducing the scope of recognition
  - o suspension or revocation of the recognition

The APM forwards the Special Remote Assessment file to the TRRC for review and decision in accordance with procedure MDSAP AS P0017 Technical Review and Recognition Decision Making Procedure.”

Following the completion of the Special Documentary Assessment, the APM updates the AO assessment Program Management File (APMF) in accordance with the MDSAP AS P0005 Auditing Organization Assessment Program Procedure.

## **6. Forms**

MDSAP AS F0014.1 Special Remote Assessment Flowchart  
MDSAP AS F0014.2 Special Remote Assessment Report

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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 (2<sup>nd</sup> Edition) – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition  
IMDRF/MDSAP WG/N6 – Regulatory Assessor Competence and Training Requirements  
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**

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| VERSION<br>No. | VERSION<br>DATE | DESCRIPTION OF CHANGE  | AUTHOR<br>NAME/PROJECT<br>MANAGER                           |
|----------------|-----------------|--|---|
| 001            | 2013-12-12      | Initial Release  | Marc-Henri Winter   |
| 002            | 2016-08-15      | Minor grammatical changes<br>throughout the document   | Liliane Brown   |
| 003            | 2019-11-22      | <p>Added provision on page 2 to allow for remote assessments of Critical Locations if on-site assessment is unwarranted or impractical</p> <p>Removed reference to MDSAP AS P0015 Nonconformity Procedure in section 5</p> <p>Added MDSAP AS F0015.2 AO Nonconformity Report in section 6<br/>Adjusted formatting</p> <p>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</p> | Marc-Henri Winter/Kimberly Lewandowski-Walker/Hiromi Kumada |

Version      003  
Approval

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