

 Responsible Office/Division	Document No.: MDSAP AS P0016.003	Page: 1 of 15
	Version Date: 2016-08-15	Effective Date: 2013-12-16
Title: MDSAP Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) 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

1. Purpose/Policy

The purpose of this procedure is to describe the process to plan and perform on-site assessments of auditing organization.

2. Scope

This procedure applies to assessments performed on-site, including assessments performed at the head office of the auditing organization for their initial recognition (Stage 2 On-Site Assessment), for the annual surveillance or for their re-recognition, or at critical locations. Special On-Site Assessments are out of the scope of the present procedure and performed in accordance with procedure MDSAP AS P0020. The Assessment Program Manager (APM), the assessors and the Assessment Team Leader (ATL) are responsible for the implementation of this procedure.

3. Definitions/Acronyms

Audit report flagging: a status assigned to an audit report of a manufacturer issued by an AO and based on the grade of the nonconformities identified during the corresponding audit (using the document GHTF/SG3/N19:2012 – Quality Management System – Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange). Audit report flagging, per procedure MDSAP AU P0023, identifies audit reports that necessitate the review by the Regulatory Authorities (RA) for evaluation for the purpose of determining if there is a need for enforcement action in relation to the manufacturer.

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 2 of 15
---	-------------------------------------	--------------

AO: Auditing Organization

RA: Regulatory Authority

APM: Assessment Program Manager

ATL: Assessment Team Leader

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager (APM):

- Initiates the on-site assessment procedure to ensure the implementation of the AO assessment Program
- Selects the assessors to form the assessment team
- Send the assignment information to the assessors
- Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the assessment
- Reviews the assessment plan for consistency with the assignment
- Reviews the assessment report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the Auditing Organization's Assessment Program as necessary.

Assessment Team Leader (ATL)

- Issues the assessment plan
- Assigns responsibilities among the assessors and ensures the progress towards the assessment objectives
- Leads the assessment opening and closing meetings with the AO
- Finalizes and approves the assessment report
- Issues nonconformity reports and manages their closure

Assessment team (including the ATL)

- Assesses a sample of audit reports issued by the AO (off-site, prior to the on-site visit – not applicable to the initial assessment)
- Assesses the AO quality management system and practices according to the MDSAP AO Assessment Model.

5. Procedures

The document MDSAP AS F0016.1 On-Site Assessment Flowchart illustrates this procedure.

The on-site assessment process is organized in 3 phases: *planning*,

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 3 of 15
---	-------------------------------------	--------------

assessment and follow-up

Planning

The APM selects the assessors taking into account the needed competence. An assessment team is composed of at least 2 assessors from different Regulatory Authorities.

For Stage 2 On-Site Assessment at the head office, it is recommended to select the same assessment team as for the Stage 1 Assessment. For Surveillance On-Site Assessment, it is recommended to select assessors among the assessment team that performed the Stage 2 On-Site Assessment, or the last Re-recognition On-Site Assessment if applicable.

For Re-recognition On-Site Assessment, the assessors should not be any of the assessment team leaders from the previous assessment cycle's assessment activities.

For On-Site Assessment at a critical location, the assessment team leader should have participated in an assessment activity at the head office.

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 preselects another assessor and repeats the previous task.

The APM sends an assignment letter (or email) to the confirmed assessors including details on scope, objectives and specifics of the on-site assessment.

The APM liaises with the AO regulatory correspondent or management representative to determine the on-site assessment dates.

Once the dates are fixed, the APM sends to the AO, with copy to the assessors, the On-Site Assessment Announcement Letter using the template MDSAP AS F0016.2.

The Assessment Team Leader prepares the assessment plan, using form MDSAP AS F0016.3. The plan intends to ensure that all understand the scope of the assessment and that the AO employees are available to cover each assessment topic. The APM sends the assessment plan at least 15 calendar days before the on-site assessment, giving the opportunity to both the APM and the AO Regulatory Correspondent to provide comments, as necessary.

Note: The assessment plan is not a binding document. It will be eventually reviewed during the On-Site Assessment and the schedule may again be adjusted, as necessary, during the on-site assessment, in particular during the

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 4 of 15
---	-------------------------------------	--------------

opening meeting.

Assessment Tasks

AO Audit Report sample Assessment

Prior to surveillance or re-recognition assessments at the AO head office or a critical location, the ATL organizes the review of audit reports provided by the auditing organization per procedure MDSAP AU P0023 on collection of AO audit reports.

The ATL selects one or both of the following two approaches:

Approach 1 - Audit *File* Review:

The ATL selects a few audit reports (3 to 5) and requests the AO to provide the relevant records relative to the planning and the performance of the audit (audit file), as well as the review of the audit report and the audit and certification decision.

The selection may either be random or be guided by considerations such as:

- Audit type
- Technical area
- Geographic area
- Auditor
- Device class
- Report flagging status (i.e. whether or not the report included nonconformities whose grade triggered the audit report flagging per procedure MDSAP AU P0023)

For an on-site assessment at a critical location, the sample should relate to activities of this critical location.

The review aims at assessing the documents in term of relevance, consistency and compliance with the AO's procedures and the applicable recognition criteria, at each phase of the process. The ATL documents the outcome of the review in the corresponding appendix of the MDSAP AS F0016.5 On-Site Assessment Report.

Approach 2 - Audit *Report* Review:

The ATL selects a representative sample of reports. The selection may be random or guided by considerations as mentioned for audit *file* review. It should include a large proportion of reports whose flagging status did not trigger their review upon receipt. The review aims at assessing the audit reports compliance to the applicable audit reports requirements. The ATL documents the outcome of the review in the corresponding appendix of the MDSAP AS F0016.5 On-Site Assessment Report.

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 5 of 15
---	-------------------------------------	--------------

In both cases, the assessment team may identify nonconformities but should consider them final only after the on-site assessment and further review of the concern with the AO.

On-Site Assessment

The assessment is organized in 3 phases:

- Opening meeting
- Investigation phase
- Closing meeting

The appendix 1 and 2 of this procedure detail the content and other specifics of both the opening meeting and the closing meeting.

The investigation phase follows the assessment approach developed in the IMDRF/MDSAP WG/N5 - Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations

When a nonconformity is identified, the assessor explains it to the AO and records it using the form MDSAP AS F0015.2 AO Nonconformity Form. The nonconformities are presented by the ATL during the closing meeting to the top management and the regulatory correspondent. The nonconformity forms are then addressed according to the AO Nonconformities Procedure MDSAP AS P0015.

The Assessment Team Leader generates the assessment report using the form MDSAP AS F0016.5. All Assessment team members review and approve it. The ATL sends it to the APM and the AO contact officer within 30 calendar days following the closing meeting unless the findings of the assessment dictate a shorter turnaround.

Follow-up

Once the ATL has received and reviewed the action plans addressing the nonconformities according to the AO Nonconformities Procedure MDSAP AS P0015, the ATL provides the APM with its assessment report, AO Nonconformity report and recommendations.

The APM reviews the assessment report and associated information and prepares the file for review by the TRRC in accordance with procedure MDSAP AS P0017 Technical Review and Recognition Decision Making Procedure.

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

6. Forms

MDSAP AS F0005.2 – Assessment Program Management File
MDSAP AS F0016.1 – On-Site Assessment Process Flowchart

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 6 of 15
---	-------------------------------------	--------------

MDSAP AS F0016.2 – On-Site Assessment Announcement Letter Template
MDSAP AS F0016.3 – Assessment Plan Form
MDSAP AS F0016.5 – On-Site Assessment Report Form

7. Reference Documents

IMDRF/MDSAP WG/N5 - *Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations*

IMDRF/MDSAP WG/N6 - *Regulatory Authority Assessor Competence and Training Requirements.*

IMDRF/MDSAP WG/N11 - *Grading Nonconformities Issued to Auditing Organizations by Recognizing Regulatory Authorities and Principles on the Decision-Making Process and Criteria for the Recognition of Auditing Organizations.*

MDSAP AS P0013 – *Stage 1 Assessment Procedure*

MDSAP AS P0005 – *AO Assessment Program Procedure*

MDSAP AU P0023 – *Flagging/Collection and Review of AO Audit Reports Procedure*

MDSAP AS P0015 – *AO Nonconformity Procedure*

MDSAP AS P0017 – *Technical Review and Recognition Decision Procedure*

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Mar-Henri Winter
002	2015-10-29	Page 6, Reference documents: IMDRF/ MDSAP WG/N11 was posted as draft. This document was finalized February 2014. Therefore the word “draft” was removed. (minor change no need for version to be approved by RAC)	Liliane Brown
003	2016-08-15	Just some minor grammatical changes throughout the document on the IMDRF documents	Liliane Brown

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 7 of 15
---	-------------------------------------	--------------

Version 3
Approval

Approved: Signature on file
Team leader for CHAIR, MDSAP RAC

Date: 2016-08-15

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 8 of 15
---	-------------------------------------	--------------

Appendix 1

Opening Meeting of an On-Site Assessment

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

The purpose of the opening meeting is to:

- State the on-site assessment objectives,
- Confirm the audit plan,
- Briefly present how the audit activities will be conducted
- Confirm communication channels,
- To provide an opportunity for the auditee to ask questions.

During the opening meeting, the ATL must address the following topics with the AO Top Management and the managers of the individuals responsible for the functions or processes to be assessed. The ATL notes the start time of opening meeting and circulates the attendance sheet for registration of the attendees.

The level of detail must be adapted to the AO's familiarity with the assessment process.

Presentation of the Assessment Team Members and AO's representatives

- 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 of technical areas

Type of on-site assessment and objectives: Stage 2, Surveillance, Re-recognition

- See specific annex to the type of assessment

Scope of the on-site assessment / assessment plan

- Location and organizational units assessed
- Processes and / or activities to be assessed
- Confirmation, if necessary, of adjustments of the plan, necessary for the proper conduct of the on-site assessment
- On-Site Assessment schedules and other arrangements (date and time of the closing meeting, interim meetings between the assessment team and the AO management, logistics during the assessment ...)

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 9 of 15
---	-------------------------------------	--------------

- Confirm that the ATL and the assessment team members are responsible for the execution of the assessment plan. Any difficulties must be signalled to them.

Conduct and organization of the on-site assessment

- Methods and procedures used to perform the on-site assessment
- Assessment findings: reporting, including the grading of nonconformities
- Premature end of the on-site assessment: a reminder of situations that can lead to termination of the on-site assessment (e.g. lack of access to necessary information, unavailability of key individuals)
- Official communication channels between the assessment team and the AO
- Language used during the on-site assessment;
- Confirm that, during the on-site assessment, the auditee will be kept informed of the progress of the assessment;
- Availability of resources and logistics necessary for the assessment team,
- Guides appointed by the auditee: availability, role (facilitating contacts, guide the assessment team, ensuring security, reporting to management).

Other

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

MDSAP On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure	Document No.: MDSAP AS P0016.003	Page 10 of 15
---	-------------------------------------	---------------

Appendix 2

Closing Meeting of an On-Site Assessment

The closing meeting addresses the specifics mentioned below.

- Objectives of the on-site assessment
- Fulfilment of the on-site assessment plan and objectives
- Obstacles met during the on-site assessment, affecting the fulfilment of the assessment plan and objectives
- Statement of nonconformities, including whether or not they were resolved during the on-site assessment
- Conclusions of the on-site assessment
- Reminder that the conclusions are the result of an assessment based on the sampling of records of the AO's activities. The list of nonconformities identified during the assessment may therefore not be exhaustive.
- Recommendation of the assessment team to the technical review and recognition committee.
- Post-assessment activities in term of:
 - o Timeline to provide the action plans relative to all nonconformities
 - o RA process to provide feedback on the action plans
 - o Remaining assessment activities to complete the assessment (witnessed audit or on-site assessment at critical locations), if applicable
 - o RA process to make a decision on the recognition status of the AO
 - o Opportunity to appeal to the recognition decision

Note: For an initial recognition assessment, the assessment findings and conclusions are established taking into account the results of the both stage 1 and stage 2 assessments.

Appendix 3 Specifics of the on-site assessments

Assessment objectives

Assessment	Objectives
Stage 2 Assessment	<ul style="list-style-type: none"> • Evaluate the conformity of the Auditing Organization's management system documentation to meet all the regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; • Evaluate the evidence of implementation, monitoring, measuring, reporting and reviewing by the Auditing Organization of its activities against policies, procedures and objectives from its management system (consistent with the expectations for recognition); • Review the operational controls of the Auditing Organization's processes, including when implemented by external resources; • Confirm that the Auditing Organization conducted internal audits and management reviews; and, • Confirm the competence of the Auditing Organization and the resources available necessary to fulfill the obligations for the scope of recognition.
Assessment at a Critical Location	<ul style="list-style-type: none"> • Review the relationship between the head office of the Auditing Organization and the Critical Location; • Review, if applicable, the arrangements between the head office of the Auditing Organization and the Critical Location; • Evaluate the management system operated at the critical location to satisfy the requirements of the Auditing Organization; • Evaluate the conformity of the activities undertaken by the Critical Location on behalf of the Auditing Organization to the requirements of the Auditing Organization's management system or to the arrangements between the head office of the Auditing Organization and the Critical Location; • Evaluate the conformity of activities undertaken by the Critical Location on behalf of the Auditing

	<p>Organization to the corresponding regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; and,</p> <ul style="list-style-type: none"> • Evaluate the controls in place at the Critical Location enabling its monitoring by the Auditing Organization.
Surveillance Assessment	<ul style="list-style-type: none"> • Review of internal audits and management review; • Review of Competence Management activities; • Review of actions taken on nonconformities identified during the previous audit; • Treatment of complaints and appeals; • Evaluation of the effectiveness of the management system with regard to achieving the Auditing Organization's objectives as it relates to the scope of recognition; • Evaluate records of audit and decision on conformity of medical device manufacturer to regulatory requirements; • Evaluate continuing operational control; and, • Review any changes.
Re-recognition Assessment	<ul style="list-style-type: none"> • Evaluate the effectiveness of the Auditing Organization's management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of recognition; • Confirm the continued conformity of the Auditing Organization's management system to regulatory requirements including IMDRF/MDSAP WG/N3 and N4 documents; and, • Confirm the commitment of the Auditing Organization to maintain the effectiveness of the management system.

Key processes and assessment tasks from the assessment model, reviewed during each type of assessment activity

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable)	Surveillance	Re-Recognition
Management				
1. Legal entity, legal responsibility liability, financing & eligibility	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Quality Management System documents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Quality policy, quality objectives and quality planning	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4. Organizational structure, responsibility, and authority	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Adequacy of auditing resources	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6. Management of impartiality	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7. Management review	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Use of External Resources				
1. Extent and controls of use of external resources	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2. Contractual arrangements with external resources	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3. Internal competence to review the outcome of outsourced activities	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Measurement, Analysis & Improvement				
1. Procedures relative to measurement, analysis and improvement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Sources of quality data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3. Investigation, corrections, corrective actions and preventive actions to address nonconformities and potential nonconformities	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4. Reporting of corrective actions impacting the recognition	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5. Decision on conformity to regulatory requirements supported by nonconforming audit or audit reports	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6. Management of nonconforming audit reports or certification documents after their sharing and publication	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7. Internal audits	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8. Complaint handling and management	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
9. Communication with external resources having contributed to a nonconformity or complaint	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
10. Outputs of the Measurement, Analysis and Improvement process as inputs into the management review	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable) Surveillance	Re-Recognition
Competence Management			
1. Identification of necessary competence to operate as a recognized auditing organization	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Procedure and criteria for competence evaluation of all personnel involved in audit and certification related activities	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Identified personnel with demonstrated competence	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4. Training to the audit process and certification requirements and access to corresponding current documents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7. Monitoring of personnel's competence and performance	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8. Personnel's individual file	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
9. Effectiveness of the competence evaluation methods and the competence management process	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Audit & Decision			
1. Procedures for the control of the Audit & Decision process	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Audit programme establishment and update; audit time determination; planning of audits	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3. Selection and assignment of competent audit team, and communication prior to the audit	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4. Audit performance and audit report	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5. Review of manufacturer's response to audit findings	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6. Technical review of the audit files and decision making on regulatory conformity of the manufacturer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7. Implementation and follow-up of the decision, including unannounced audits	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8. Appeals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9. Audit and decision records	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	Initial Assessment (Stage 1 + Stage 2)	Critical Location (as applicable) Surveillance	Re-Recognition
Information Management			
1. Control of documents and records	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Public information on the audit program	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Provision to the audited medical device manufacturers of detailed information on the audit and decision related processes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Contractual agreements with the audited medical device manufacturer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5. Sharing of information with recognizing Regulatory Authorities on auditing activities, decisions on regulatory compliance and certification status	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6. Provision to the public of information on certification status, or certifications granted, suspended or withdrawn	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7. Control of confidential information	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

On-Site Assessment at a Critical Location

Critical locations have a scope of activities defined in the contractual agreement with the head office. The tasks listed above may therefore not be all applicable to a particular critical location. The planning of the assessment at a critical location should take into account the outcome of prior assessments (Stage 1 and Stage 2) to tailor the scope of the assessment.

Guidelines on On-Site Assessment Duration:

The duration of on-site assessment takes into account the need for assessment teams including assessors from 2 different RA. The size of the assessment team – if greater than 2 – should not affect the on-site duration, unless justified.

The suggested duration below are indicative only and may be adjusted as deemed appropriate.

- Stage 2 Assessment : 2.5 days (5 man-days)
- Surveillance Assessment : 2.5 days (5 man-days)
- Re-recognition Assessment: 4 days (8 man-days)
- Assessment at a Critical Location: 1 day (2 man-days), unless the range and extent of activities at the critical location justifies a longer on-site assessment duration.