Table of Contents

1. Purpose/Policy

The purpose of this document is to describe the procedure for reviewing a candidate Auditing Organization's (AO) application and related information to ensure that the information about the AO and its management system is sufficient for the conduct of the assessment stage.

2. Scope

This procedure applies to the MDSAP Team's work products, processes, services, and quality management system.

3. Definitions/Acronyms

Regulatory Authority Council (RAC) Secretariat:

- Monitors the MDSAP email inbox for requests for application packages, submissions of completed application packages, or any other requests for information regarding the application process;
- Reviews received application packages for completeness;

- Prepares official communications – including application rejection letters as applicable – to the candidate Auditing Organizations.
- In the event that the Secretariat position is vacant, the authorities and responsibilities of the Secretariat can be performed by a designated Assessment Program Manager or Lead Project Manager.

Lead Project Manager:
- Designates the Assessment Program Manager to manage the assessment process for the Auditing Organization;
- Decides when issues requiring clarification identified during the review of the application package can be addressed during Stage 1 or Stage 2 assessments;
- Liaises with the Regulatory Authority Council when the application review process is put on hold, pending clarification from the Auditing Organization;
- Consults with the Regulatory Authority Council, and seeks concurrence of the Regulatory Authority Council when the Assessment Program Manager proposes to reject the application package;
- Assists in the preparation official communication with the Auditing Organization to be issued by RAC Secretariat;
- Signs all communication to the Auditing Organization;
- Disseminates AO approval / rejection information to the participating Regulatory Authorities.

Assessment Program Manager:
- Reviews the application package;
- Communicates with the candidate Auditing Organization as necessary;
- Reports to the Lead Project Manager on the outcome of the application package review.

Technical Review and Recognition Committee (TRRC)
- Reviews the application package if its rejection is recommended by the Assessment Program Manager and provides its recommendation to the Lead Project Manager.

Regulatory Authority Council (RAC):
- Is informed of application packages received, and of the outcome of their review;
- Makes final decision on rejecting an application;
- Is notified if it is necessary to put the application on hold and consulted during the application package review process when undefined or unclear MDSAP Program expectations are identified;
- Is consulted prior to resuming the application package review process after an application package was put on hold due to potential threats to impartiality.

4. Authorities/Responsibilities

MDSAP: Medical Device Single Audit Program

AO: Auditing Organization

RAC: Regulatory Authority Council

5. Procedures

5.1 Provision of Application Package Forms and Documents to candidate Auditing Organizations.

5.1.1 Upon request, the RAC Secretariat provides (or arranges for the provision of) an MDSAP candidate Auditing Organization Application Package consisting of:

MDSAP AS F0010.1 AO Application for Recognition Form

MDSAP AS F0010.4 Supplemental AO Application Matrix – IMDRF/MDSAP WG/N4

MDSAP AS F0010.5 AO Recognition Application Additional Information Sheet

MDSAP AS F0010.6 AO Application Matrix

MDSAP AS F0010.7 AO Critical Location Information Form

MDSAP AS F0010.8 Auditor and Technical Expert Competency Summary

These documents are available at:

5.1.2 https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-assessment-procedures-and-forms The RAC Secretariat informs the Auditing Organization that:

- The AO Application for Recognition Form (MDSAP AS F0010.1) must be electronically or physically signed by a duly authorized representative of the candidate Auditing Organization prior to submission.
- The candidate Auditing Organization must submit an electronic version of the completed application package to the MDSAP

mailbox: MDSAP@fda.hhs.gov, specifying “MDSAP Application Package” in the “Subject:” line.

5.1.3 The RAC Secretariat informs the Lead Project Manager and the MDSAP Team of any requests for MDSAP candidate Auditing Organization Application Packages.

5.2 Receipt and Processing the Application Package

5.2.1 The flowchart MDSAP AS F0010.2 Handling of Application for MDSAP Recognition Flowchart – illustrates this section of the procedure.

5.2.2 All application packages for recognition should be submitted to the RAC Secretariat. If an application package is received by anyone else, the application package must be forwarded to the RAC Secretariat for processing.

5.2.3 Once an application package is received, the RAC Secretariat informs the Lead Project Manager and the MDSAP Team.

5.2.4 The Lead Project Manager designates an Assessment Program Manager for the Auditing Organization and communicates this designation to the RAC Secretariat.

5.2.5 The RAC Secretariat reviews the application package for completeness and completes the appropriate sections of the MDSAP AS F0010.3 AO Application Review Checklist.

5.2.6 If there are any discrepancies or incomplete required fields, the RAC Secretariat may request the missing information directly from the candidate Auditing Organization or return the application package to the candidate Auditing Organization as incomplete.

5.2.7 If the application appears to be complete, the RAC Secretariat forwards the application and MDSAP AS F0010.3 AO Application Review Checklist to the Assessment Program Manager.

5.2.8 The Assessment Program Manager reviews the application package and candidate Auditing Organization website to verify the accuracy and coherence of the information provided, and confirms that the information does not raise significant concerns in term of resources, experience, knowledge, or impartiality.

The purpose of the initial review of the application package is not to take the place of the Stage 1, Stage 2 assessments and Witnessed Audits (and associated document reviews) but to determine if the Auditing Organization appears sufficiently prepared for the next stage of assessment (Stage 1).

5.2.9 If the Application is not acceptable, the Assessment Program Manager informs the Lead Project Manager. The Lead Project Manager consults the Technical Review and Recognition Committee regarding the potential rejection of the application package. If rejection of the application package is recommended, the Lead Project Manager informs the Regulatory Authority Council for concurrence and the RAC Secretariat issues the application rejection letter, signed by the Lead Project Manager.

5.2.10 If any element of the application package is not clear, the Assessment Program Manager may request clarification from the Auditing Organization as necessary; or, with Lead Project Manager concurrence, clarification can be sought during the Stage 1 assessment.

5.2.10.1 If it is determined that the candidate Auditing Organization does not appear to have sufficient resources, experience and knowledge to perform MDSAP audits; or has apparent threats to impartiality, or any other nonconformity with MDSAP requirements (e.g. ISO/IEC 17021-1:2015, IMDRF/MDSAP WG/N3(2nd Edition), IMDRF/MDSAP WG/N4), the Assessment Program Manager (with the concurrence of the Lead Project Manager) will formally communicate the concerns with the candidate Auditing Organization and explain the applicable MDSAP Program expectations as necessary. The application package review and subsequent assessment activities will be placed on hold until the concerns are resolved.

The Regulatory Authority Council will be notified of any application package that is placed on hold and the reason why the application was placed on hold.

Note: When apparent nonconformities are identified, the Lead Project Manager may seek input from the Regulatory Authority Council (RAC) when determining what are the MDSAP Program expectations related to the specific concerns identified. The RAC will be contacted prior to responding to any apparent threats to impartiality.

Upon receipt of the requested information, the process resumes at step 5.2.8 above.

5.2.10.2 Alternatively, for minor concerns, the Assessment Program Manager and the Lead Project Manager may decide that the requested clarifications can be reviewed as part of Stage 1 or Stage 2 assessments. In such case, both the Assessment Program Manager and the Lead Project Manager sign the MDSAP AS F0010.3 AO Application Review Checklist.

5.2.11 Upon satisfactory review of the application package, the Assessment Program Manager assures completion of the MDSAP AS F0010.3 AO Application Review Checklist and creates an Assessment Program Management File for the candidate Auditing Organization per MDSAP AS P0005 Assessment Program Procedure.

5.2.12 The Assessment Program Manager will notify the candidate Auditing Organization, RAC Secretariat, and Lead Project Manager of the satisfactory review of the application package and will assure all necessary documents are available for initiation of a Stage 1 assessment.

5.2.13 The Assessment Program Manager will initiate the AO folder, posts the application data and review outcome and proceeds according to the MDSAP AS P0005 Assessment Program Procedure.

5.3 Method for Sharing Information within Regulatory Authorities

The information related to application package request or submission should be disseminated to the MDSAP team through emails.

The email addresses for each Regulatory Authority is as follows:

- Australia: MDSAP@tga.gov.au.
- Brazil: MDSAP@anvisa.gov.br
- Canada: qs.mdb@hc-sc.gc.ca
- Japan: MDSAP@pmda.go.jp
- USA: MDSAP@fda.hhs.gov

6. Forms

MDSAP AS F0010.1 AO Application for Recognition Form
MDSAP AS F0010.3 AO Application Review Checklist

MDSAP AS F0010.4 Supplemental AO Application Matrix - IMDRF N4
MDSAP AS F0010.5 AO Recognition application Additional Information Sheet
MDSAP AS F0010.6 AO Application Matrix
MDSAP AS F0010.7 AO Critical Location Information Form
MDSAP AS F0010.8 Auditor and Technical Expert Competency Summary

7. Reference Documents

MDSAP AS F0010.2 Handling of Application for MDSAP Recognition Flowchart
MDSAP AS P0005 Assessment Program Procedure
ISO/IEC 17021-1:2015: Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management System
IMDRF/MDSAP WG/N3 (2nd Edition): Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
IMDRF/MDSAP WG/N4 (2nd Edition): Competence and Training Requirements for Auditing Organizations

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-07-09	Initial Release	Robert G. Ruff
002	2015-09-22	On page 6; Japan's mail address was added due to its participation to MDSAP Pilot including minor update throughout the document.	Liliane Brown
003	2019-11-22	Updated project manager Added language to allow for the provision of an alternate in the event that the Secretariat position is vacant Updated to ISO17021-1:2015 and IMDRF/MDSAP WG/N3 (2nd Edition) Adjusted formatting	Kimberly Lewandowski-Walker/Hiromi Kumada
004	2022-11-21	Updated email address for Health Canada in section 5.3 Updated link for MDSAP Assessment documents in section 5.1.1 Updated to IMDRF/MDSAP WG/N4 (2nd Edition) in section 7	Hiromi Kumada

Version Approval 004

Approved: ON FILE Date: 2022-11-21

CHAIR, MDSAP RAC