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	Version Date: 2025-05-22	Effective Date: To be advised
Title: Auditing Organization (AO) Application For Recognition Procedure		Project Manager: Frédéric HAMELIN, Health Canada

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1. Purpose/Policy

The purpose of this document is to describe the procedure for opening the application process for candidate Auditing Organizations (AOs) to apply for MDSAP recognition. It includes screening and ranking applications received, selecting applications to retain, and reviewing retained candidate AOs' applications and related information for suitability and completeness prior to beginning recognition assessments,

2. Scope

This procedure addresses the process from the opening of the application window to the review of retained applications and decisions for recognition, including applicable work products.

3. Definitions/Acronyms

AO: Auditing Organization

RAC: Regulatory Authority Council

APM: Assessment Program Manager

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LPM: Lead Project Manager

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Regulatory Authority Council (RAC) Secretariat:

- Monitors the MDSAP.RAC.Secretariat email inbox for requests for application packages, submissions of completed application packages, or any other requests for information regarding the application process;
- Screens and reviews received application packages for completeness;
- In conjunction with the LPM, prepares and dispatches official communications – including application rejection letters as applicable – to the candidate AOs.
- In the event that the Secretariat position is vacant, the authorities and responsibilities of the Secretariat can be performed by a designated APM or LPM.

Lead Project Manager (LPM):

- 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 RAC when the application review process is put on hold, pending clarification from the candidate AO;
- Consults with the RAC, and seeks concurrence from the RAC when the APM proposes to reject the application package;
- Assists in the preparation of official communication with the candidate AO to be issued by the RAC Secretariat;
- Signs all communication to the candidate AO;

Assessment Program Manager (APM):

- Reviews available assessment resources and recommends the number of applications to retain to the RAC
- Collectively assign an APM to review and manage retained applications
- Reviews the application package;
- Communicates with the candidate AO as necessary;
- Reports to the LPM on the outcome of the application package review.

Technical Review and Recognition Committee (TRRC)

- Scores and ranks applications

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- Reviews the application package if its rejection is recommended by the APM and provides its recommendation to the LPM.

Regulatory Authority Council (RAC):

- Is informed of application packages received, and of the outcome of the LPM review;
- Makes final decision on rejecting or approving 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.

5. Procedure

5.1 Determining the number of applications to retain

- 5.1.1 On a periodic basis, RAs provide APMs with an estimate of available resources over the next 18 months
- 5.1.2 The APM group evaluates the resources needed to perform the oversight of existing AOs over the following 18 months in light of each individual AO's assessment program.
- 5.1.3 The APM group uses the information on available resources and needed resources to estimate the number of additional oversight activities that can be undertaken and consequently the number of applications that can be processed. This recommendation is communicated to the RAC.
- 5.1.4 The RAC accepts or adjusts the APM recommendation and sets the number of new applications that can be accepted in the following cohort.
- 5.1.5 The details of the application cohort is communicated to stakeholders (for example, on the MDSAP website):
 - 5.1.5.1 The dates of the application window during which applications can be submitted.
 - 5.1.5.2 The number of applications that will be retained and accepted into the recognition process.

Note: The next application window is only opened once the applications accepted from the previous cohort have completed the recognition process.

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5.2 Provision of Application Package Forms and Documents to candidate AOs

5.2.1 Upon request during an open application window, the RAC Secretariat provides (or arranges for the provision of) an MDSAP candidate AO 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

MDSAP AS G0010.1.001 Auditor Training

These documents are also available at: <https://mdsap.global/auditing-organizations/becoming-recognized>

- 5.2.2 The RAC Secretariat informs the candidate AO 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 AO prior to submission.
 - The candidate AO must submit an electronic version of the completed application package to the MDSAP mailbox: MDSAP.RAC.Secretariat@tga.gov.au, specifying “MDSAP Application Package” in the “Subject:” line.

5.2.3 The RAC Secretariat informs the LPM of any requests for MDSAP candidate AO Application Packages.

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5.3 Receipt and Processing the Application Package

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

- 5.3.1 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.
- 5.3.2 Application packages received outside of an open application window are returned to the applicant with an invitation to apply during the next application window.
- 5.3.3 Once an application package is received, the RAC Secretariat informs the LPM.
- 5.3.4 The RAC Secretariat reviews the application package for completeness and confirms that the mandatory acceptance criteria are met and completes the appropriate sections of the MDSAP AS F0010.3 AO Application Review Checklist.
- 5.3.5 If there are any discrepancies or incomplete required fields, the RAC Secretariat may request the missing information directly from the candidate AO or return the application package to the candidate AO as incomplete.
- 5.3.6 If more than one application is received, found complete and to meet the mandatory criteria, the applications are scored and ranked by the TRRC. The ranked list of applications is communicated to the RAC.
- 5.3.7 The RAC selects the applications to retain and communicates this selection to the LPM and the APM group.
- 5.3.8 The LPM prepares decision letters for the candidate AOs indicating whether their application was retained or not. The RAC Secretariat transmits these decision letters to the applicant AOs.
- 5.3.9 The APM group confers and assigns the retained candidate AO(s) files to an APM(s).
- 5.3.10 The APM reviews the application package and candidate AO website to verify the accuracy and coherence of the information provided, and confirms that the information does not raise significant concerns in

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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 candidate AO appears sufficiently prepared for the next stage of assessment (Stage 1).

- 5.3.11 If the Application is not acceptable, the APM informs the LPM. The LPM consults the TRRC regarding the potential rejection of the application package. If rejection of the application package is recommended, the LPM informs the RAC for concurrence and the RAC Secretariat issues the application rejection letter, signed by the LPM.
- 5.3.12 If any element of the application package is not clear, the APM may request clarification from the candidate AO as necessary; or, with LPM concurrence, clarification can be sought during the Stage 1 assessment.
- 5.3.12.1 If it is determined that the candidate AO 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 APM (with the concurrence of the LPM) will formally communicate the concerns with the candidate AO 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 RAC 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 LPM may seek input from the 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 5.3.10 above.

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

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

5.3.14 The APM will notify the candidate AO, RAC Secretariat, and LPM of the satisfactory review of the application package and will assure all necessary documents are available for initiation of a Stage 1 assessment.

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

5. 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

6. 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

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7. 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 (2 nd Edition) Adjusted formatting	Kimberly Lewandowski- Walker/Hiromi Kumada
004	2022-11-22	Updated email address for Health Canada in section 5.3 Updated to IMDRF/MDSAP WG/N4 (2 nd Edition) in section 7	Hiromi Kumada
005	2025-03-05	Revised process to introduce: <ul style="list-style-type: none"> • Application windows • Screening using mandatory acceptance criteria • Ranking of applications • Other updates to workflow 	Frédéric HAMELIN

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Approval

Approved: SIGNATURE ON FILE
 CHAIR, MDSAP RAC

Date: 2025/05/22