2025 MDSAP AUDITING ORGANIZATION (AO) APPLICATIONS – QUESTION RESPONSES

NO.	QUESTION	RESPONSE
1	When do applications open and close?	AO applications for recognition will reopen 1 July 2025 and close 29 September 2025. Please see Transmittal 2025-02 and Transmittal 2025-03 for further information on the application process.
2	Why has prioritization criteria been introduced?	The criteria have been introduced to better match demand for MDSAP Regulatory Authority (RA) assessments with the available RA assessment resources, and to prioritize applicants with a higher likelihood of achieving recognition in a timely manner and participating in the MDSAP over the long term. Further information on eligibility and prioritization criteria is available here.
3	What is meant by "Attestations"?	The application requires certain attestations whereby a senior official of the applicant commits to complying with MDSAP program requirements, declares that the applicant has not been convicted of an offense against medical device regulations, etc. These attestations take the form of a check box agreeing to a predetermined statement and the signature of an official. Notarization of these attestations is not necessary.
4	Is accreditation according to ISO 17021 mandatory?	Accreditation to ISO/IEC 17021-1:2015 is not mandatory. However, ISO/IEC 17021-1:2015 is part of the recognition criteria (with exception to certain requirements).

NO.	QUESTION	RESPONSE
5	Can candidates receive early advice if they are not likely to be eligible for recognition under the program?	Without access to the full application package for any candidate, MDSAP RAs cannot provide advice on the suitability of any organization to become an MDSAP AO. However, to be eligible, candidates must meet all criteria specified in IMDRF MDSAP WG N3 *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*. From comprehensive review of this document, and its complementary document IMDRF MDSAP WG N4 *Competence and Training Requirements for Auditing Organizations*, each candidate can form an opinion as to their suitability for the program.
6	Is there a fast recognition scheme for Notified Bodies (NBs) or Conformity Assessment Bodies (CABs)?	At present, there is no mechanism for the fast recognition of NBs or CABs.
7	Do applicants require a local office in any MDSAP RA jurisdictions (e.g. Australia)?	There is no requirement to establish a local office in any of the MDSAP jurisdictions.
8	Are witnessed audits required for the initial recognition?	The recognition process requires three (3) MDSAP witnessed audits before initial recognition is granted. However, a decision whether to grant a temporary authorization to perform MDSAP audits will be made after a successful Stage 2.
9	Are there any costs associated with submitting the application or recognition and for any subsequent phases of assessment and maintenance of the recognition?	There are no fees payable for submitting an application and undergoing the assessment process to become a recognized MDSAP AO. Commencing 1 January 2025, the MDSAP Regulatory Authority Council (RAC) has implemented an AO Contribution Scheme to ensure the ongoing sustainability, expansion, transparency and maintenance of the MDSAP. The contributions aim to assist with the costs associated with holding the

NO.	QUESTION	RESPONSE
		annual MDSAP Forum, maintenance of the MDSAP website and training/education activities. The contribution from each AO is not equal across all AOs. The contribution is calculated based on how many facilities/clients the AO has. Ie: the more clients the AO has, the greater their contribution. For example, for 2025, the total contributions made by all AOs combined will be $133,330 USD. The amounts contributed by each AO vary depending on the size of their client base. In 2025, some AOs contributed less than $10,000 and other AOs contributed more than $10,000. The contribution scheme operates on a 3-year period so that AOs are aware of the contribution amount each year across the 3 years. The RAC has not yet determined whether new AOs will be required to commence contributions from the time they are recognized; however, further information will be available in June 2025.
10	ISO/IEC 17021-1 is stated as one requirement: Is an accreditation required or is the fulfilment audited in the assessment?	No, accreditation to ISO/IEC 17021-1:2015 is not a pre-requisite to apply for MDSAP recognition. See answer to question 4.
11	Is it possible to insert hyperlinks to the relevant documents in the Application Matrix, rather than references to them?	Hyperlinks are acceptable; however, IM/IT security policies of some participating RAs might disable or remove these. Consequently, please ensure that in such situations the matrix can still be used to perform assessment. Additionally, hyperlinks must lead to a document that each RA can access. Some RAs have access restrictions to outside document repositories.
12	Which audits count for the auditor qualification criteria: We interpretated any ISO 13485,	1. Audits from any medical device regulatory audit scheme can be considered to justify the required number of audits.

NO.	QUESTION	RESPONSE
	combination ISO 13485+ISO 9001, MDR and IVDR could count for the requested audit amount. Is our interpretation correct?	2. However, some MDSAP audits should be included to justify the familiarity of the auditor with the MDSAP audit approach (see MDSAP AU P0002). 3. In cases where audits in accordance with (1) or (2) above are insufficient to meet the criteria set in IMDRF document N4, the AO would be expected to record a rationale justifying the competence of the auditor to audit according the MDSAP Audit Approach. Considering non-regulatory ISO 13485 audits as part of the expected number of audits should in no case represent more than (25%) of the expected number of audits. 4. Before an initial qualification as auditor, a candidate auditor should participate in MDSAP audit as auditor-in-training. 5. Before an initial qualification as MDSAP lead auditor, a candidate lead auditor should be witnessed as lead auditor of an MDSAP audit. 6. Pre-existing qualifications by a separate MDSAP auditing organization can help justify a deviation from (5), but the AO should still record their rationale for trusting the ability of the candidate to lead MDSAP audits without performing a witness audit of the auditor. The auditor should be witnessed leading an MDSAP audit within 12 months following the granting of the qualification to audit under MDSAP. 7. In the case of a candidate lead auditor who is already qualified by the AO as a lead auditor under another medical device regulatory scheme, the AO may deviate from (5), with a recorded rationale for trusting the ability of the candidate to lead MDSAP audits, provided the auditor is witnessed leading an MDSAP audit within 3 years. 8. The qualification of an auditor or lead auditor who – after being initially qualified - would not participate in any MDSAP audit over a sliding 3-

NO.	QUESTION	RESPONSE
		year period should be downgraded back to auditor-in-training and undergo a witnessed MDSAP audit prior to renewing their qualification. 9. Deviations from the expected number of annual audits is permissible providing there are appropriate conditions to enable that auditor to fulfil the expected number of audits on the following year (e.g. an auditor taking parental leave and reducing their travels for a few months but expected to return to a more usual auditing activity afterwards).
13	For the initial qualification / maintenance of competence, is it possible to count also audits carried out in a different CB / Notified Body?	Pre-existing qualifications by a separate MDSAP AO can help justify a deviation from 14(5) [witnessing before being qualified as a lead auditor], but the AO should still record their rationale for trusting the ability of the candidate to lead MDSAP audits without audits without performing a witness audit of the auditor. The auditor should be witnessed leading an MDSAP audit within 12 months following the granting of the qualification to audit under MDSAP.
14	Will the MDSAP RAC/RAs meet with any applicant prior to applications opening or as part of the application process?	The MDSAP RAC is not intending to meet with any candidates prior to applications re-opening or as part of the application process.
15	Are candidates required to attach the manual and the procedures mentioned in MDSAP AS F0010.6 AO Application Matrix and MDSAP AS F0010.4.001 Supplemental AO Application Matrix - IMDRF N4?	Once a candidate AO has been selected for assessment, the Assessment Program Manager (APM) assigned to the AO will contact it to request the submission of required documentation. The complete documentation does not need to be submitted with the initial submission of the application forms.

NO.	QUESTION	RESPONSE
16	In regard to MDSAP AS F0010.8.001 Auditor and Technical Expert Competency Summary, do candidates attach to their application, for each person reported in the Matrix, the documents certifying the assigned qualification?	No, records will be verified during the Stage 1 and/or Stage 2 assessment(s).
17	Can candidates start mandatory training required for some internal staff that need to qualify as auditors?	There is no guarantee that any organization will be prioritized for selection to undergo the assessment process to become recognized. Once a candidate is selected by the MDSAP RAC to move forward with the assessment phase, the process will take a few months before the Stage 2 assessment occurs, at which point the candidate AO would have to demonstrate their auditors' competence.
18	What are the approximate number of person-days required for the MDSAP application?	The number of person-days required depends on a range of factors and your capacity to undertake the application process needs to be considered as part of your response. You will be able to determine how many days after you have reviewed the documentation and requirements.
19	Is it a mandatory requirement for applicants to obtain recognition from the International Medical Device Regulators Forum (IMDRF) prior to submitting an application for the MDSAP?	MDSAP AOs are not required to obtain recognition from IMDRF.
20	Do applicants need to have in-house or affiliated laboratory for an MDSAP application?	No.