MDSAP Transmittal Number: 2025-02

Transmittal Date: 2025/05/22

Title: Reopening of AO application for recognition process and introduction of eligibility and prioritization criteria

Purpose: The purpose of this transmittal is to inform RAs, AOs, Official Observers and Affiliates Members of the following:

1. The reopening of AO applications for recognition; and,
2. The introduction of criteria for screening and prioritizing applications for recognition.

Background: On February 7th, 2022, the MDSAP Regulatory Authority Council (RAC) posted an update on the website indicating that a temporary halt on the acceptance of new Auditing Organizations (AOs) was put in place as of the 2nd of the same month. This measure was put in place because of the "efforts of MDSAP Regulatory Authorities to support operations aimed at addressing the COVID-19 public health emergency".

The MDSAP RAC wish to resume accepting applications for recognition from new AOs to support ongoing growth in the MDSAP. Since assessment resources remain limited and the initial assessment of a new AO requires a disproportionate effort compared to maintaining an existing recognition, measures are required to screen applicants for recognition to a) exclude applicants with a low likelihood of success and long-term participation, and b) rank applicants when the number of applicants exceeds the Regulatory Authorities' ability to assess new AOs.

This approach seeks to maximize the benefits to program stakeholders that accepting new AOs can bring while minimizing the impact on assessment resources and program performance.

1. Reopening of AO application process

The MDSAP RAC is pleased to announce that the application process for AO recognition will reopen in mid-2025 – upon re-opening candidates will have a period of ninety (90) days to submit their application. A further transmittal will be released to announce the opening and closing date for applications. Candidates that have previously submitted an application are asked to resubmit their application using the most recent version of the application documentation, including the form MDSAP AS F0010.1.002 available at https://mdsap.global/auditing-organizations/becoming-recognized.

To better coordinate assessment resources and avoid overcommitting RAs, a limited number of applications will be selected for assessment and potential recognition. The number of applications selected will depend on the available assessment resources. Applicants will be informed whether their application is selected once the application window closes and all submitted applications have been screened. Applicants whose application does not proceed may reapply during subsequent application windows.

Further application windows will periodically open once additional assessment resources become available. Future application windows will be publicly announced.

2. Introduction of eligibility and prioritization criteria

Because the recognition of new candidate AOs requires significant RA assessment resources, it is desirable to screen applications to exclude candidates with a low probability of success and long-term participation in the program. Furthermore, where the number of applicants exceeds the Regulatory Authorities' capacity, it is desirable to rank applicants considering technical factors as well as the applicants' ability to address identified areas of priority for the program.

Applicants will be screened for eligibility based on existing eligibility criteria in ISO/IEC 17021-1:2015 and IMDRF/MDSAP WG/N3 2nd Edition, demonstrated financial stability, and access to sufficient auditing and certification resources.

Applicants that meet the existing screening criteria will be scored and ranked using criteria targeting the following areas of interest:
- Demonstrated ability to operate as an AO;
- Demonstrated ability to conduct regulatory audits;
- Recognized technical competence in the field of medical devices;
- Experience with MDSAP audit model and procedures and knowledge of general MDSAP principles;
- Size of client base;
- Technical areas served;
- Geographical areas served; and,
- Ease of assessment.

A ranked list of eligible candidates will be used by the MDSAP RAC to inform their decision about which applications to select for assessment.

AOs interested in applying for MDSAP recognition can review the information and application package provided at https://mdsap.global/auditing-organizations/becoming-recognized or can contact the MDSAP RAC Secretariat (MDSAP.RAC.Secretariat@tga.gov.au) for a copy. Please also contact the RAC Secretariat with any questions about the application process.

Approver: Tracey DUFFY, RAC Chair

Effective Date: To be advised

Distribution: RAs, AOs, Observers, Affiliates, Website

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