

 Responsible Office/Division	Document No.: MDSAP AS P0021.002	Pages: 1 of 6
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Title: Appeals 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 for handling appeals by the Auditing Organization (AO) following an unfavorable recognition decision.

2. Scope

This procedure applies involves the Quality Management System Manager (QMS Manager), the Assessment Program Manager (APM), the Regulatory Authority Council (RAC) and the ad-hoc Technical Review and Recommendation Committee (TRRC).

3. Definitions/Acronyms

Appeal: Request by the Auditing Organization for the review by an independent committee of a prior recognition decision.

Appeal Decision: Decision made by the independent committee, either confirming or amending the prior recognition decision contested by the Auditing Organization.

4. Authorities/Responsibilities

Quality Management System Manager (QMS Manager):

- Receives the request for appeal
- Confirms its admissibility
- Coordinates the tasks associated with the appeal
- Gathers information to be presented to the TRRC
- Drafts the Appeal Decision notification letter, and sends it to the AO after signature by the RAC

Appeals Procedure	Document No.: MDSAP AS P0021.002	Page 2 of 6
-------------------	-------------------------------------	-------------

Assessment Program Manager (APM):

- Assists the QMS Manager in gathering the information relative to the case
- Assists the QMS Manager in drafting the Appeal Decision notification letter and sends it to the AO
- Ensures the implementation of the Appeal Decision

Regulatory Authority Council (RAC):

- Designates the Chairperson and the members of the TRRC
- Makes the final Appeal Decision
- Signs the Appeal Decision Letter

Technical Review and Recommendation Committee (TRRC):

- Determines whether to grant to the AO the opportunity to be heard
- As applicable, schedules and leads the AO hearing session
- Makes final recommendations and drafts the Appeal Decision

Assessment Program Manager (APM):

- Attends the TRRC meeting to answer any question from TRRC relative to the assessment Program, the history of assessment and the information included in the corresponding records
- As delegate of the QM, Drafts the Appeal Decision notification letter, and sends it to the AO after signature by the RAC
- Ensures the implementation of the Appeal Decision, and, if applicable, updates the AO Assessment Program (AOAP)

5. Procedures

The flowchart MDSAP AS F0021.1 illustrates the current procedure.

Constitution of the File to address the Request for Appeal

The AO has 15 calendar days following the receipt of the Recognition Decision to submit a request for appeal. An AO may contest any of the following recognition decision:

- Refusal to recognize, including the refusal to assess the compliance of the AO based on the information collected through the application for recognition or the stage 1 assessment
- Preconditioned recognition
- Reduction of scope of recognition
- Suspension of recognition
- Revocation of recognition; or
- Recognition associated with conditions

The AO must fill in the first part of the form MDSAP AS F0021.2 Appeal Request and Processing Form.

Appeals Procedure	Document No.: MDSAP AS P0021.002	Page 3 of 6
-------------------	-------------------------------------	-------------

The request for appeal must include:

- The contested decision
- The rationale for contesting the recognition decision
- The evidence supporting the rationale
- The information on whether the AO requests the opportunity to be heard

Upon receipt of the appeal request, the QMS Manager informs the RAC and the APM.

Within 5 days from the receipt of the request for appeal, the QMS Manager determines the admissibility of the request and informs to the AO, the RAC and the APM. To be admissible, the request for appeal must either suggest that:

- The assessment records do not support the decision
- The assessment reports inaccurately reflects the assessment findings presented at the time of the assessment
- There is information that was available at the time of the assessment but it was not requested by or presented to the assessors, and this information demonstrates that the decision is unfounded
- The decision is inconsistent with precedent recognition decisions
- The assessment processes were not implemented as required

The QMS Manager gathers all relevant information related to the appeal case, from the APM and the assessors as applicable.

If the QMS Manager determines that the information provided by the AO is insufficient to present the file to the TRRC, the QMS Manager requests the AO to provide within 15 calendar days the necessary information.

Review of the Appeal

The RAC designates the chairperson and the members of the TRRC, one per Regulatory Authority. The RAC must ensure the impartiality of the committee. The members of the committee (including the committee's chairperson) may not have participated in:

- Any of the assessment activities supporting the contested recognition decision, and
- The TRRC meeting that reviewed the assessment file and made the contested recognition decision.

The members of the committee must be competent with regards to the assessment and recognition processes and requirements.

If the AO has requested the opportunity to be heard, and the contested decision was not motivated by an immediate risk for the public health, the TRRC chairpersons schedules the hearing session after consultation of all the TRRC members and the AO. If possible, the hearing session should take place within 30 days from the receipt of the request for appeal. The AO and

Appeals Procedure	Document No.: MDSAP AS P0021.002	Page 4 of 6
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the TRRC may ask witnesses (e.g. assessors being part of the on-site assessment-audit) to participate to the hearing session.

If applicable, the TRRC chairperson leads the hearing session according to the agenda in appendix 1. The hearing session is performed through teleconference. The minutes of the hearing session must be recorded and provided to the AO after the session.

The TRRC meets through teleconference in order to make recommendations on the Appeal Decision, i.e.:

- Whether the appeal is denied or accepted
- If accepted, propose an amended recognition decision
- Whether the amended recognition decision changes the recognition status of the AO
- Whether the Assessment Program (AOAP) should be updated

The TRRC records the rationale for the recommended decision.

The RAC reviews the recommended decision and upon approval, endorses it.

Notification and Implementation of the Appeal Decision

The Quality Manager or the Assessment Program Manager prepares the appeal decision notification letter.

The RAC Chairperson reviews, amends as necessary, and signs it

The Quality Manager or the Assessment Program Manager sends the appeal decision notification letter to the AO.

The APM ensures the implementation of the Appeal Decision, according to the phase “Implementation of the decision” presented in the procedure MDSAP AS P0017 Technical Review and Recognition Decision.

6. Forms

MDSAP AS F0021.1 – Appeal Flowchart

MDSAP AS F0021.2 – Appeal Request and Processing 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 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 P0017 – *Technical Review and Recognition Decision Making Procedure*

Appeals Procedure	Document No.: MDSAP AS P0021.002	Page 5 of 6
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8. Document History

VERSION No.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Marc-Henri Winter
002	2015-10-29	Page 4, 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

Version 002
Approval

Approved: Team leader Signature on file Date: 2015/10/29

Appeals Procedure	Document No.: MDSAP AS P0021.002	Page 6 of 6
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Appendix 1

Hearing Session Agenda

- Hearing called to order
- Introduction of all attendees
- Opening statement
- Review of hearing ground rules
- Appellant oral presentation, not to exceed 20 minutes
- Requests for clarification of information from the appellant's oral presentation
- Witnesses presentation, if requested by the TRRC or the appellant
- Requests for clarification of information from the witnesses' oral presentation (by either the TRRC or the appellant)
- TRRC only discussion (without the appellant or witnesses)
- Final request for clarification, if necessary
- Review of the timeline for the remaining steps of the appeal
- Chairperson's concluding remarks
- Hearing adjourned