

1. Purpose

This procedure defines TUV USA, Inc.'s responsibilities for receiving, evaluating, and making decisions on complaints, appeals and disputes concerning the certification system activities or decisions, and the maintenance of relative records.

2. Scope

This procedure covers:

- Complaints made by TUV USA clients against TUV USA;
- Complaints made by interested third parties against TUV USA certified clients;
- Appeals on audit results;
- Dispute on the decisions taken by TUV USA on Complaints and Appeals.

3. References

- AS9101D Requirements for Aviation, Space and Defense Quality Management System Certification Programs;
- ISO 17021 "Conformity assessment — Requirements for bodies providing audit and certification of management systems";
- IMDRF/MDSAP WG/N3 Final – Requirements for Medical Device Auditing Organization for Regulatory Authority Recognition;
- TÜV NORD CERT Requirements for Complaints, Appeals and Disputes (e.g. CERT-120-VA-012)

4. Definitions

4.1. Complaint

Complaints are information or feedback received from TUV USA clients against TUV USA or received from interested third parties related to TUV USA certified clients that may represent a problem on its services/ products provided and must be investigated. The validity of the complaints will be determined prior to taking any necessary action/s.

4.2. Appeal

When client/s disagrees with the audit result and/or the issued non-conformities against its management system during the conclusion of the on-site audit, client can appeal against the audit results or the issued nonconformities.

4.3. Dispute

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When a client disagrees with the result of an Appeal results or disagrees with the Lead Auditor during the on-site audit it must be brought to the knowledge of the TUV USA Managing Director for evaluation. The dispute needs to be submitted either by the client and/or the Lead Auditor in writing stating clearly what the dispute is related to.

Note: All complaints appeals and disputes are requested to be submitted in writing, however, if those are received orally (via phone or in person) the person receiving it must collect the details of the complaint and write an e-mail to TUV USA Quality Manager.

5. Responsibilities

- All TUV USA personnel whether employee or subcontracted are responsible for informing the TUV USA Quality Manager about a received complaint, appeal and dispute;
- TUV USA Quality Manager is responsible to enter the received complaints, appeal and disputes in the ICAR system and assign the responsible person to perform the investigation. The Quality Manager is also responsible to communicate the complaints, appeals and disputes to TÜV NORD CERT (TNC) when it is related to their accreditation by entering this information into TNC Complaints tool.
- The Division Directors receive, acknowledge, take appropriate actions and communicate the resolutions;
- TUV USA Managing Director receive, acknowledge, take appropriate actions and communicate the resolutions for those complaints, appeals and disputes which couldn't be resolved by the Directors of Divisions due any reason;
- All TUV USA personnel are responsible to keep anonymous the identity of the complainant, unless if s/he want it to be known, a written consent will be required from the complainant. This process is subject to TUV USA requirements for confidentiality;
- All TUV USA personnel is responsible for provide the certified organization with contact information of Accreditation Bodies and/ or Regulatory Authorities, when requested.

Note: Personnel that are directly involved in activities related to the issued will not be assigned to investigate the appeal, complaint of dispute.

6. Procedure

6.1. Complaints

Complaints can be received from many sources such as the TUV USA website, e-mail, letter, phone call etc. and by any person acting on behalf of TUV USA.

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The TUV USA Quality Manager, will enter the complaint in the ICAR system assigning the complaint to the Director of the respective Division.

Regardless of the type or source of the issue(s), the Director of the Division has 30 calendar days to:

- Confirm the receipt of the complaint to the complainant;
- Determine whether the complaint is valid or not;
- Respond to the complainant informing the actions to be taken;
- Fill in the ICAR system with the requested information.

If the complaint is determined valid, it will be treated as a nonconformity according to the procedure GOP015 Nonconformity Management and CAPA.

If it is determined not valid, the reason has to be captured in the ICAR system and communicated in writing to the complainant (via e-mail). This communication has to be attached to the ICAR as evidence of response.

6.1.1 Complaints from third parties on TUV USA certified clients

On receipt of a complaint, the Division Director or designee will confirm whether the complaint relates to certification activities; i.e., if there was an issue with previous audit activities through a review of audit reports.

Complaints will also be reviewed to determine if there is an issue with the effectiveness of the client's management system. Information from complaints is used to determine if onsite investigation/assessments are required or not. If it is determined that an onsite investigation/assessment is required, the client is informed and a Special Assessment is conducted to determine if appropriate corrective action measures have been put in place.

If detected during Special Assessments, the Lead Auditor issues nonconformities for issues directly related to the complaint that has not been adequately addressed. Additional nonconformities may also be documented if they are discovered during the Special Assessment.

If it is known that TUV USA clients are under customer sanctions, special status conditions or have received feedback regarding Management System or product issues (including feedback from OASIS), the Lead Auditor is required to include a review of these situations and include his/her review in the Audit Report.

Note: All the results of the investigation/ evaluation described above will be recorded in the ICAR system.

Information from complaints is also communicated to the Lead Auditor, who is instructed to use the information in planning the next audit.

TUV USA shall verify that the certified client's quality management system, the corrective action and preventive action procedure and its related records regarding from customers

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or other third parties are mentioned in the audit report or in subsequent surveillance or recertification audit reports.

6.1.2 Complaints/ Feedback from OASIS

Complaints or concerns that are obtained through OASIS feedback notices and similar third party complaints will be also entered in the ICAR System and treated in accordance with GOP015 Nonconformity Management and CAPA.

Information from complaints (such as OASIS feedback) is used to determine if investigative onsite assessments are needed to verify that the client's quality management system remains effective.

Note: OASIS feedback notices that are administrative in nature (such as supplier set up or OASIS Administrator assignments) do not require corrective action.

6.1.3 Complaints against clients certified ISO 13485 under the MDSAP Program

For the MDSAP issued certificate if there is any complaint/s (e.g. whistleblowers) received related to a medical device manufacturer that could indicate an issue related to the safety and effectiveness of medical devices or a public health risk, TUV USA Director of MPD or his/her designee will immediately forward information on the complaint received to the recognizing Regulatory Authority(s).

In the event the complainant does not agree with the decision of the Division Director or designee, an appeal can be made to TUV USA Managing Director.

In the event the complainant does not agree with the decision of the TUV USA Managing Director an appeal can be made to the applicable certification scheme accreditation body or regulatory authority.

6.1.4 Complaints in certifications under TÜV NORD CERT's accreditation

Beside the registration into ICAR system, those Complaints related to certifications under TUV NORD Cert (TNC) accreditation are also to be communicated to TNC, by TUV USA Quality Manager, via TNC Complaint tool or any other mean defined by them.

6.2. Audit Appeals

Client organizations are advised of the appeals process for nonconformities during the opening/ closing meeting of the onsite activity. If the client does not agree with audit results and nonconformities, an appeal can be filed by the client.

A formal appeal may be issued against and specific nonconformity in writing via Workflow, e-mail or the customer appeal request form available at TUV USA website.

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The issuer provides details to the technical portion of the NCR that is in appealing. The NCR will contain the audit type and the description of the nonconformity. Evidence of compliance to the standard under question must be provided.

The Division Director or designee will review the audit documentation, and consult with the audit team and client as necessary to determine the validity of the appeal.

Appeals are also recorded in the ICAR system and must be responded by the Managing Director / Director of the Division within 10 business days.

Upon completion of the review, the client and the audit team will be informed of the decision.

6.3. Disputes

The client may dispute a decision to an appeal to the TUV USA Managing Director, who will perform an additional review. If the dispute is against a decision made by the Managing Director it will be presented to the Impartiality Committee. The Impartiality Committee shall review the situation. Upon completion of the review, the client will be informed of the decision.

Submission, investigation and decisions made regarding complaints, disputes and appeals do not result in discriminatory actions against the client.

Disputes are also recorded in the ICAR system and must be responded within 10 business days.

6.4. Progress Report

The client is notified through email regarding the progress of the complaint, appeal or dispute.

7. Outcome and Final Resolution

TUV USA, Inc. is responsible for the resolution of all complaints.

Only those complaints, appeals and disputes that cannot be resolved by TUV USA, Inc. are referred to TNC (when related to their accreditation) or the appropriate Accreditation Body (AB) and/or Regulatory Authority.

The complainant, appellant and those filling the dispute are notified of the outcome and the final resolution of the complaint, dispute or appeal through email notification and/or notification through Workflow.

TUV USA is responsible for communicating with the complainant and the client whether and to what extent the subject of the complaint and its resolution. Information about a particular client or individual shall not be disclosed to a third party without the written

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consent of the client or individual concerned, unless the complaint was received through the OASIS database.

8. Documents and Records

Records of all complaints, disputes and appeals are maintained by TUV USA, Inc. in accordance with the Records Procedure GOP014.

- ICAR System (Workflow)
- Workflow Online Form for Appeals
- GOP016F001 Customer Appeals Request Form
- Customer Contact Form on TUV USA website
- GOP015 Nonconformity Management Procedure

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