



Objection, Complaint and Dispute Evaluation Procedure

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1. PURPOSE

The purpose of this procedure is to explain the evaluation process of objections, complaints and disputes that may be related to the certification services carried out by KAREV within the scope of (EU) 2017/745 regulation and EN ISO 13485.

2. SCOPE

This procedure covers the rules and principles relating with the evaluation of appeals, complaints, and disputes relating with conformity assessment activities and outcomes and decisions of relevant organs within the context of conformity assessment services that are carried out by KAREV.

3. RESPONSIBILITIES

- Technical Manager
- Related Unit Managers
- Objection, Complaint, Dispute Committee
- Quality management representative
- Customer Relations and Audit Planning Specialist

4. DEFINITION

Complaint: It is the expression of dissatisfaction conveyed from any person/institutions/organizations to the certification body, accreditation body and competent authority.

Objection: It is the written application made by the person/institutions/organizations receiving service from KAREV against the decisions taken by the relevant units of KAREV on matters concerning them, in case they are not accepted.

Dispute: It is the application made by the persons/institutions/organizations served by KAREV, when they put forward opposing views on a right and interest and cannot reach a consensus regarding the differences in interpretation.

Objection, Complaint and Dispute Evaluation Committee: Persons selected from within the organization who are not subject to the complaint and can take responsibility for the decision.

Team Leader: Responsible for the unit where Complaint, Objection and Dispute activities are opened.

5. IMPLEMENTATION

5.1. Acceptance of Applications relating with Objection, Complaint and Dispute

Applications relating with objection, complaint, and dispute are received by the division providing conformity assessment services to the institution in written form. Applications not bearing names, signatures, and addresses or that are determined to have false names and signatures are not processed.



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Applications accepted by the related unit are planned and executed through the KAREV Document Management System under the coordination of the related units. It is recorded on the Customer Objection and Complaint Follow-up Form in printed form.

The team leader can determine or follow up the responsible persons who will carry out the activity tracking through the system.

In the case of objection, complaint and dispute, a preliminary assessment is made by the team leader. Application is subjected to the preliminary assessment by the relevant unit according to Article 5.2 or 5.3. Subjects cannot be resolved after preliminary assessment are forwarded to the Objection, Complaints and Disputes Committee.

Objection/complaints are recorded by Objection, Complaint and Dispute Committee on the Customer Objection and Complaint Follow-up Form and they are followed up.

Period of objections that can be made to the outcomes of conformity assessment activities which are realized by KAREV is 30 (thirty) days starting from the date of notification of decision.

5.2. Evaluation of Objection, Complaint and Dispute Applications

5.2.1 Evaluation of Objections

Application is made subject to preliminary evaluation by the team leader providing the conformity assessment service as to whether it is related with the subject of service provision or not, whether it is made in accordance with the periods that are foreseen in relevant procedures or not and whether there are any tangible and/or calculation mistakes in the processes or not, by requesting detailed information and documents from the applicant and from other relevant parties if required.

As a result of preliminary evaluation;

- Application that is required to be taken into evaluation is notified to the applicant within maximum 3 days following the application date by stating that “application has been processed”.
- Application that should not taken into evaluation are notified to the applicant within maximum 3 days following the application date by stating “the reasoning why application should not be processed” in written form.

Personnel who have been assigned in the conformity assessment activities relating with the application subject do not take part in the evaluation process.

As a result of the preliminary assessment made by the Team Leader;

As a result of the preliminary evaluation made by the team leader, if deemed necessary, the system approves the opening and the activity is planned. The system assigns its own number to the opened activity, and its list can be tracked or reported on the system.

Outcome of applications which are resolved by the official of the team leader as a result of this evaluation is notified to the applicant.



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If required, corrective and preventive action is started by the team leader, and it is processed in accordance with Corrective and Preventive Actions Procedure and information is provided about the stages and outcome of activity being realized to the applicant.

If the applicant is found to be right as a result of the evaluation of applications being made, no charges are collected for the inspection/audit etc. that are realized and/or for the experiment costs or else said charges are collected from the applicant.

In below stated situations where application regarding the subject of objection is not resolved as a result of preliminary assessment by the team leader, application relating with the objection is taken into the agenda of Objection, Complaint, and Dispute Committee.

- If it is the subject of objection relating with the resolution of decision organ,
- In situations where the application can not be resolved by the relevant division,
- In situations where applicant does not accept the outcome that is notified to them and where they insist on their claim,
- In situations where it is not possible to resolve the application within the frame of duties, authorizations and responsibilities of relevant division.

Application relating with the subject of objection is taken into the agenda of Objection, Complaint and Dispute Committee by the relevant division. Agenda and meeting activities relating with the applications about the objection that are submitted to the committee agenda are carried out by Objection, Complaint, and Dispute Committee.

Decisions taken by the Objection, Complaints and Disputes Committee are followed by the team leader receiving the application.

If there are any objection that are considered to be justified, corrective action is started by the Quality Management Representative in accordance with Corrective and Preventive Action Procedure.

Committee decision relating with the application is sent together with the Objection and Complaint Process Evaluation Questionnaire to the applicant by the relevant division in written form. After the answered questionnaires are kept and evaluated by the relevant divisions, the analysis outcomes that are obtained are transmitted to the Management Representative.

5.2.2. Evaluation of Complaints

5.2.2.1 Evaluation of Complaints relating with the services obtained by Person/Institutions/Organizations getting Conformity Assessment Service from KAREV

Application relating with the complaints originating from the works and transactions regarding the processes belonging to the conformity assessment services which they have obtained from KAREV is made subject to preliminary evaluation by the team leader with respect to particulars as to whether they are related with the subject of service provided or not and whether there are any disputes relating with the directive about the processes and quality system documentation or not by requesting detailed information and documents from the applicant and from other relevant parties if required.



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As a result of Preliminary evaluation;

- Regarding the application that must be taken into evaluation, written notification is made to the applicant within maximum 3 days following the date of application by stating that “application has been processed”.
- Regarding applications that must not be taken into evaluation, written notification is made to the applicant within maximum 3 days following the date of application by stating “reasoning for not processing the application.”

Personnel who are assigned in the conformity assessment activity being the subject of application can not take part in the assessment process.

If the complaint subject can be resolved by the relevant division, notification is made to the applicant in written form. In case the complaint reoccurs or the same complaint occurs systematically, the relevant division is evaluated and corrective action is initiated according to the Corrective and Preventive Action Procedure.

In the following cases where the subject of the complaint cannot be resolved by the team leader;

- Situations where the application can not be resolved by the relevant division,
- Situations where the applicant does not accept the result that is notified to them and where they insist on their claim,
- Situations where it is not possible to resolve the application within the frame of tasks, authorizations, and responsibilities of relevant division.

Application relating with the subject of complaint is taken into the agenda of Objection, Complaint and Dispute Committee by the relevant division. Agenda and meeting activities relating with the applications about the complaint that are submitted to the committee agenda are carried out by Objection, Complaint, and Dispute Committee.

Decisions taken by the Objection, Complaints and Disputes Committee are followed by the team leader receiving the application. If there are any complaint that are considered to be justified, corrective action is started by the Quality Management Representative in accordance with Corrective and Preventive Action Procedure.

Committee decision relating with the application is sent together with the Objection and Complaint Process Evaluation Questionnaire to the applicant by the relevant division in written form. After the answered questionnaires are kept and evaluated by the relevant divisions, the analysis outcomes that are obtained are transmitted to the Management Representative.

The maximum time required for the resolution of incoming complaints and objections is 45 days. The result of the complaint and objection shall be promptly notified in writing. If this period is extended, the Team Leader may request an extension by presenting the reason for the extension to the Technical Manager. The reason is evaluated and the customer is informed within 3 days.

5.2.2.2 Evaluation of Complaints of Third-Party Person/Institutions/Organizations

Application relating with complaints of third party person/institutions/organizations that are using/benefiting from or being influenced from conformity assessment services or quality management representative which are the complaint subject, is made subject to preliminary



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evaluation as to whether the complaint is related with the service subject or not and with respect to information, documents, and products regarding the complaint context, by requesting detailed information and documents from other relevant parties if required.

As a result of Preliminary evaluation;

- Regarding the application that must be taken into evaluation, written notification is made to the applicant within maximum 3 days following the date of application by stating that “application has been processed”.
- Regarding applications that must not be taken into evaluation, written notification is made to the applicant within maximum 3 days following the date of application by stating “reasoning for not processing the application.

As a result of preliminary evaluation that is made by relevant division, customer complaints originating from persons/institutions/organizations having conformity assessment services being the complaint subject, are notified to the relevant persons/institutions/organizations providing conformity assessment services, in written form and information is requested regarding the arrangements/activities they have realized/will realize as relating with the complaint.

As per the decision taken by relevant division as a result of preliminary evaluation, by taking the importance of complaint as basis, activities such as examination/audit/experiment can be realized at the institution or on the normal inspection/audit date during the investigation of institution, it is controlled whether records relating with customer complaints are kept in a regular way or not.

As a result of evaluation of all processes that are realized by relevant division, result of processes that are conducted as relating with the complaint about the product/service/experiment is notified to the complaint owner institution/organization/persons in written form.

In below cases where complaint subject can not be resolved by the relevant division;

- Situations where the application can not be resolved by the relevant division,
- Situations where the applicant does not accept the result that is notified to them and where they insist on their claim,
- Situations where it is not possible to resolve the application within the frame of tasks, authorizations, and responsibilities of relevant division.

Application relating with the subject of complaint is taken into the agenda of Objection, Complaint and Dispute Committee by the relevant division. Agenda and meeting activities relating with the applications about the complaint that are submitted to the committee agenda are carried out by Objection, Complaint, and Dispute Committee.

Decisions taken by the Objection, Complaints and Disputes Committee are followed by the team leader receiving the application. If there are any complaint that are considered to be justified, corrective action is started by the Quality Management Representative in accordance with Corrective and Preventive Action Procedure.

The maximum time required for the resolution of incoming complaints and objections is 45 days. The result of the complaint and objection shall be promptly notified in writing. If this period is



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5.3. Processing of the Objection, Complaint and Dispute Committee

It is a committee that is appointed by the Technical Manager and consists of at least 2 people. It is authorized to evaluate and decide on the complaints and objections regarding the certification activities coming from our customers and non-customer institutions and organizations and the decisions of the System Certification Committee taken as a result of these activities. Decisions are taken unanimously. Decisions are made, reviewed and approved by people who are not involved in the matters that are the subject of the complaint. Personnel who took part in the conformity assessment activity, which is the subject of the application, cannot take part in the assessment process.

Applications relating with objection, complaint, and dispute are submitted to Objection, Complaint and Dispute Committee by the relevant divisions together with Objection, Complaint and Dispute Committee Agenda and Decision Form, preliminary evaluation outcomes, processes that are realized as relating with the application, information/documents/reports/decisions and other necessary documents. Committee carries out their works in accordance with their job description. Committee can request detailed information/documents relating with the subject from the representative(s) of relevant division if required. For this purpose, said representatives should attend relevant committee meeting.

Committee members who have been assigned in the conformity assessment activity being the subject of application, can not participate in the decision meeting relating with that application. Committee evaluates the information/documents being submitted and they take decision.

Decision taken by the committee is final and processes that should be realized in accordance with the decision and the notifications that should be made are realized by the relevant divisions.

Regarding the activities within the scope of accreditation, for all the processes that are carried out as relating with objection/complaint/dispute, procedures of accreditation body are considered.

When there are situations that prevent the activities of the objection and complaint committee from being carried out on site (in case of natural disasters such as pandemic, earthquake, etc.), the committee can be held remotely. In the activities of the objection and complaint committee to be carried out remotely, the process is applied as described in Articles 5.2 and 5.3. Interviews between the members of the objection and complaints committee are carried out using video conferencing tools such as Zoom and Microsoft Teams. In remote meetings, the connection is created and sent to the participants.

5.4. Records

The team leader, follow up results of the activities through the system and receives reports.

Records relating with appeals, complaints and disputes are kept as per Record Management Procedure. These records are used for data analysis when required and they are submitted to Management Review Meetings.



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6. RELATED DOCUMENTS

- PR.08 Records Control Procedure
- PR.12 Corrective and Preventive Action Procedure
- FR.07 Customer Objection and Complaint Tracking Form
- FR.08 Objection and Complaint Process Evaluation Questionnaire
- FR.09 Objection, Complaint and Dispute Committee Agenda and Decision Form
- GT.03 Objection, Complaint and Dispute Committee Job Description

7. REVISION HISTORY

Rev. No	Rev. Date	Rev. Description	Reason for revision
00	-	First publication	-
01	12.05.2022	Application changes due to the transition to the Document Management System were explained.	Completion of the transition to the Document Management System application.
02	03.01.2023	The maximum resolution period for the complaint/objection has been added to Article 5.2. The functioning of the committee was detailed in Article 5.3.	Turkak stage 2 audit findings