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| **Legal Scope:**  Global  **Business Scope:**  Cross Business  **Process Scope:**  3.1 Quality Management (QM) : Complaint Management |

**1. Process Overview**

**2. Process Objectives**

* Defining the handling of cases raised by any internal or external party or discovered through active mark surveillance.
* Defining case handling to address the inquirers issue, as well as internal and external follow up actions against compliance to rules and regulations.
* Ensuring the systematic categorizing and investigation of any form of mark misuses to strengthen the protection of our marks of conformity and the TÜV Rheinland brand overall.
* Ensuring the systematic detecting, categorizing, and resolving of complaints to learn about and close quality gaps and increase customer satisfaction by improving our services.
* Ensuring compliance/conformity to requirements, such as accreditation standards.
* Ensuring traceability of any complaint on local, regional, and global level by the same systematic approach, using the same tools/instruments.
* Ensuring effective resolution of appeals to protect TÜV Rheinland its brand name, clients, and other users of conformity assessment against incorrect decisions.
* Building greater trust in conformity assessment activities through a professional approach to managing complaints and appeals.

**3. Principles, Terms and Abbreviations**

| **Terms/Abbreviations** | **Description** |
| --- | --- |
| Active Mark Surveillance | Actively spot-checking objects advertised/labelled in reference to TÜV Rheinland, including online research for mark misuse, trade fair surveillance, and mystery shopping incl. retest to control the use of TÜV Rheinland marks |
| Appeal | Request to reconsider a certification, inspection, validation or verification decision |
| BF | Business Field |
| BS | Business Stream |
| CAPA | Corrective Action & Preventive Action |
| Case Owner | Either specifically dedicated personnel assigned by BO AQM/RO QHSE or, if not assigned: Quality Expert or Local Officer QM |
| Complaint | Expression of dissatisfaction other than appeal, by any person or organization to a conformity assessment body, accreditation body, or a validation and verification body relating to the activities of that body, where a response is expected |
| Conformity Assessment Body | Body that performs conformity assessment services - Responsible for complaint/appeal decisions regarding their conformity assessment services |
| FLE | First Level Employee – dedicated personnel assigned by BO AQM/RO QHSE. |
| Inquirer | Person or party contacting TR (Customer, Authorities, Legal, Private Consumer, TR Staff etc.) |
| KA | Key Account |
| KAM | Key Account Manager |
| Mark Misuse | Unauthorized use of TÜV Rheinland marks of conformity / trademarks, or other referencing to TÜV Rheinland e.g. falsification of documents, certified object changed in a non-authorized way |
| Medical Vigilance | The information that medical device manufacturers are required to provide to a notified body regarding incidents related to medical devices falling within the scope of the manufacturer’s quality management systems, which have been certified by TÜV Rheinland. This information is mandatory and essential for the notified body to fulfill its regulatory responsibilities effectively. |
| PPI | Process Performance Indicator |
| Business Field Contact Person | Technical expert from the involved Business Field/Department |
| TR | TÜV Rheinland |
| TR Service Delivery | Any activity related to “Performance Process” as defined in corporate [process map](https://corp.portal.tuv.group/FIRSTspiritWeb/intranet/media/m020/qhse/bilder_22/a_qm_1/Prozesslandkarte_Abb._2_Update_13.09.2021.jpg) |

*Other abbreviations of functions (e.g. GFM/GFC) are documented within the RACI matrix.*

**Principles**

All Mark Surveillance Cases, Appeals, Medical Vigilance Cases and Service Delivery Complaints must be registered in the Complaint Database in Salesforce.

The complaint database shall not be used for personnel evaluation, stored data is not analyzed on a personal basis. Evaluations are carried out to identify improvement and corrective measures.

If complaints result in individual personnel measures, these measures are not recorded in the complaint management system in Salesforce; they are regulated outside the scope of this SOP.

If individual personnel measures are taken, these are only permissible after related works council has been informed in advance. The rights and duties of works council remain unaffected.

The applicable group works council agreement [module U4 Salesforce “Complaint Management”](https://team.emea.tuv.group/sites/005237/Lists/Betriebliche%20Regelungen%20Lib/Attachments/4486/2022-01-24%20KBV%20IT%20Modul%20U4%20Complaint%20Management%20Endfassung.pdf) must be observed as an applicable document.

The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the service delivery activities related to the complaint or appeal.

Investigation and decision on appeals/complaints shall not result in any discriminatory actions.

To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see ISO/IEC 17025:2017 cl. 3.2) for a client, or been employed by a client, shall not be used to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

**4. Scope of Application**

**Appeals** regarding a certification, inspection, validation or verification decision,

**Mark Surveillance**: Possible mark misuse, complaints against a conformity assessment body towards a result of assessment,

**Service Delivery Complaints** against TR service delivery in the conformity assessment, accreditation, and validation or verification process,

**Medical Vigilance Cases**: Reporting by medical device manufacturers of incidents such as device malfunctions, product defects, or any unexpected or serious events that may impact patient health and safety. These notifications are submitted to TÜV Rheinland entities as notified bodies to enable them to monitor the safety and performance of medical products, conduct investigations and take actions as needed to safeguard patient well-being.

These feedbacks may be raised by end users, internal or external customers, TR staff, authorities or others, as well as arising through Active Mark Surveillance, the active discovery of possible mark misuse.

**Out of Scope:**

* Complaints regarding invoicing (Z-Complaints)
* Compliance related complaints
* Internal complaints that do not refer to the customer service delivery process.

**5. Process Flow**

| **Process Flow Chart** | **Description of Process Steps** | **Responsible\*** |
| --- | --- | --- |
|  | 5.1 Case incoming  5.2 Forward case to related FLE.  5.3a Register case in complaint database in Salesforce.  5.3b Automatic registration for cases incoming through a group mail address linked to Salesforce or via Contact Center  5.4 Case is listed in team specific list (FLE Queue): add all available information / attachments to the case and assign Case Owner and BO AQM.  Complaints against employees or complaints containing sensitive data as “confidential”.  5.5 Define criticality, reason for complaint and other categories as needed. Assign a BF Contact Person (if not done yet). | Inquirer  Notifier  FLE  FLE  Case Owner (or FLE) |
|  | **Appeal**  5.6 Investigate whether the appeal is valid and will be accepted towards appellant.  5.7a If the appeal is not valid, ensure that the result is answered (where possible) to appellant in the name of the CAB and recorded in Salesforce.  5.8a If the appellant accepts the decision, close the case with closing reason “Not Valid”.  If the appellant does not accept the decision on appeal, other institutions such as an Advisory Board may be consulted by the appellant.  5.7b If the reason of the appeal is valid, perform immediate actions to solve the issue.  5.8b After immediate action is finished, ensure that an answer (where possible) has been given and recorded.  Close case with closing reason “Valid”.  5.9 For all cases of level 2 and 3 open the follow up action “CAPA” in Salesforce, perform a root cause analysis, from which corrective and preventive measures shall be derived and effectiveness check performed.  5.10 Ensure that a final answer is given (where necessary) and recorded.  Close follow up action. | Case Owner incl. relevant decision maker of CAB (or Accreditation Body\*\*)  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  BF Contact Person + Case Owner  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  BF Contact Person + Case Owner  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM |
|  | **Mark Surveillance**  5.6 Evaluate whether the case is related to TÜV Rheinland.  5.7a If the case is not related to TR, ensure that an answer is given (where possible) to the inquirer and the answer is recorded in Salesforce.  Close case with closing reason “No Misuse”.  5.7b If the case is related to TR, investigate whether a misuse can be confirmed. Involve BF Contact Person and other experts as needed to confirm.  5.8a If no misuse was found, ensure that an answer is given (where possible) to the inquirer and the answer is recorded.  Close case with closing reason “No Misuse”.  5.8b If misuse was found, ensure that an answer is given (where possible) to the inquirer and the answer is recorded.  Close case with closing reason “Misuse”.    5.9 To follow up on misuse, open the follow up action “External Action” in Salesforce and perform as applicable.  5.10 Ensure that a final answer is given (where necessary) and recorded.  Close follow up action. | Case Owner (+ BF Contact Person)    Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  Case Owner + BF Contact Person    Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  Case Owner + Employee Responsible  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM |
|  | **Service Delivery Complaint Process**  5.6 Evaluate whether the complaint is valid. Involve BF Contact Person and other experts as needed.  5.7a If the complaint is not valid, ensure that an answer is given (where possible) and recorded in Salesforce.  Close case with closing reason “Not Valid”.  5.7b If the complaint is valid, perform an immediate action to solve the issue of the complainant.  5.8 After immediate action is finished, ensure that an answer (where possible) has been given and recorded.  Close case with closing reason “Valid”.  5.9 For all cases of level 2 and 3 open follow up action “CAPA” in Salesforce, perform a root cause analysis, from which corrective and preventive measures shall be derived and effectiveness check performed. Record all in Salesforce.  5.10 Ensure that a final answer is given (where necessary) and recorded.  Close follow up action. | Case Owner + BF Contact Person    Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  Case Owner + BF Contact Person  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM  Case Owner + BF Contact Person  Case Owner  Level 1+2: Case Owner  Level 3: BO AQM |
|  | **Medical Vigilance**  5.6 Evaluate whether the manufacturer submitted an incident report.  5.7a If a report has been submitted by the manufacturer, close case, regardless of whether any measures are planned or not.  5.7b If the manufacturer did not send an incident report, send a request to the manufacturer to provide a due date.  5.8b Once the due date is submitted, close case.  5.8c If the due date is not submitted in time, send a reminder to the manufacturer. If applicable, define and carry out possible consequences of non-response.  5.9b If the due date is available, open an “Action” in Salesforce to remind the case owner of the submission of due date.  5.10b Once the report has been submitted, close “Action” task.  5.10c If the report is not available on the due date, send a reminder to the manufacturer. If applicable, define and carry out possible consequences of non-response. | Case Owner (+ BF Contact Person)    Case Owner  Case Owner  Case Owner  Case Owner (+ BF)  Case Owner    Case Owner  Case Owner (+ BF) |
|  | 5.8a If measures are resulting from the incident, open an “Action” in Salesforce for further evaluation of the measures by BF.  5.9a Close the “Action” after the evaluation is complete.  5.10a If the evaluation by a defined expert of the BF determines that a reminder is necessary to pay attention to specific issues during the next audit, open a “Medical Task” in Salesforce.  5.11a The ”Medical Task” can be closed once the defined task is finalized. | Case Owner  BF staff assigned to the “Action”  BF staff assigned to the “Action”  BF staff assigned to the “Medical Task” |

**\*Responsible for the process step**

**\*\*Depending on accreditation requirements, appeals will have to be filed with Accreditation Body, who act as final level of an appeal and the conformity assessment body shall abide by their decision, accreditation requirements and accreditation body´s decision must be followed.**

**Communication:**

* A notification of receipt of an inquiry (complaint/appeal) shall be given to the inquirer where possible.
* A (preliminary) answer shall be given to inquirer as soon as sufficient information is available where possible.
* A written notice in the name of the Conformity Assessment Body containing the outcome of the complaint/appeal shall be given to the inquirer where possible.
* The description of this process is available on the TÜV Rheinland website for all interested parties: [Procedure for Complaints and Appeals | WO | TÜV Rheinland (tuv.com)](https://www.tuv.com/world/en/complaint-process.html).

**Cross Stream / Region Cases:**

In case of Cross Region cases, the office, which sold the service in question, shall take the lead.

In case of Cross Stream cases, Corporate Complaint Management Team shall act as mediator if requested, coordinating between the Streams involved.

**Criticality:**

Evaluation of Criticality Level 1 (lowest) to 3 (highest) shall be based on key factors (see attachments):

Case Type Mark Surveillance/Medical Vigilance:

* Intention of Inquiry
* Inquirer Type
* Risk

Case Types Service Delivery Complaint/Appeal:

* Occurrence
* Inquirer Type
* Risk.

**Internal Parties to be involved:**

* All Criticality Level 2 Cases: Information to related Regional Field Manager/Coordinator
* All Criticality Level 3 Cases: Information to related Global Field Manager/Coordinator
* The Executive Board shall be informed directly (via assistance) by the case owner about complaints that are addressed to TÜV via group addresses and in which either the Executive Board or the Chairman of the Supervisory Board is addressed. The Executive Board should always be notified if:
* a member of the Executive Board is addressed in the salutation,
* the Chairman of the Supervisory Board is addressed in the case of complaints or is addressed in copy.
* Respective legal department as well as management of legal entity shall be involved in case of possible claim (threat of legal proceedings or actions possibly resulting in damage claims) or if legal steps are to be taken against misusers.
* VTÜ Versicherungsvermittlung GmbH (Insurance Agency Ltd.) shall be involved in case of damage claims against TÜV Rheinland.
* Highest technical authority (e.g. [Technical Competence Center](https://team.emea.tuv.group/sites/004728/Lists/BS%20Products%20TCC%20Directory/AllItems.aspx) of BS Products) within TR shall be involved where available in case a global technical decision is needed, such as: different technical opinions internally or different technical opinion by an authority compared to TR.
* Relevant works council is to be involved if measures are taken against employees (such measures are not recorded in Salesforce).
* Media inquiries shall be sent to Corporate Communications: [contact@press.tuv.com](mailto:contact@press.tuv.com). Media inquiries include:
* Inquiries from journalist, influences, YouTubers etc.
* Inquiries indicating press involvement and media forwarding.
* Topics potentially causing public concern (e.g., large-scale recalls).
* Corporate Communications evaluates inquiries, aligns response strategies if necessary. Corporate Communications triggers crisis management according to MS-0049783 if a potential crisis is identified, establishes a task force, and sends an answer to the inquirer. Any related inquiries to the same subject are referred to Corporate Communications.

**Case Lead Time till Case Closure (excluding follow up actions):**

Case Type Mark Surveillance/Medical Vigilance:

* 30 calendar days

Case Type Service Delivery Complaints/Appeals:

* 10 calendar days

**Reference Values for Escalation due to Delay:**

|  |  |
| --- | --- |
| * Recording of Case after Incoming: * Clarification with BF Contact Person: * 1. Escalation (if no answer) RFM/C + RO QHSE: * 2. Escalation (if no answer) GFM/C + BO QM: * 3. Escalation (if no answer) B/R-EVP | 1 Workday  4 Workdays  +10 Workdays  +10 Workdays |

**CAPA**

When a nonconformity occurs for a Level 2 or 3 case (or when necessary for a Level 1 case), a Corrective and Preventive Action (CAPA) shall be opened in Salesforce.

The following steps shall be performed to prevent the recurrence of the nonconformity or its occurrence elsewhere:

* Reviewing and analyzing the nonconformity.
* Determining the causes of the nonconformity.
* Determining if similar nonconformities exist or could potentially occur and analyze the range of impact for laboratories (applicable to standard 17025).
* Implementing any necessary actions to address the nonconformity.
* Reviewing the effectiveness of any corrective action taken.
* Updating risks and opportunities identified for the related process, if necessary.
* Making changes to the quality management system, if necessary.
* Corrective actions should be appropriate based on the effects of the nonconformities encountered.

These steps ensure that the nonconformity is thoroughly analyzed, its causes are determined, appropriate actions are taken, and the effectiveness of those actions is reviewed. Additionally, any necessary updates to the quality management system and consideration of associated risks and opportunities are made.

**Actions Against External Mark Misuser:**

**Actions Against a Mark Misuser Shall Include**

(Where possible acc. to contractual agreement and local law):

* Prohibition of mark misuse
* Listing of misusing company (except misuse related to person as object of conformity assessment) on the warning list at <https://www.tuv.com/world/en/warning-list/>.

**Further Action as Applicable**

(acc. To scheme requirements, contractual agreement, and local law):

* Blocking of client for further services
* Informing external parties e.g., committees, market authorities etc.
* Suspension of certificates
* Cancellation of certificates
* Cancellation of General Agreement
* Shorter surveillance cycles, e.g., 4 x factory inspections within next 12 months
* Special inspection
* Sample drawing at point of sale & retest
* Legal actions
* Increased surveillance
* Specific actions as given by accreditation requirements
* Or others

**Reporting (Power BI):**

Overview of cases shall be reported and updated weekly by GO QHSE

[Service Delivery and Mark Surveillance Complaints Report – Power BI](http://de-hv1-pbi-db01/Reports_PBIRS/powerbi/Central%20Functions/Accreditation%20and%20Quality%20Management/Service%20Delivery%20and%20Mark%20Surveillance%20Complaints%20Report):

* Lead Time (see PPI On-time delivery)
* No. of Cases
* Criticality Level

per

* Business Stream
* Business Field
* Region
* Legal Entity
* Type of Case

**Dashboard (Salesforce):**

The backlog of open cases and tasks is monitored by the dashboard in Salesforce:

[Overview Complaints YTD | Salesforce](https://tuv-rheinland.lightning.force.com/lightning/r/Dashboard/01ZTr000004erXxMAI/view)

**6. Process Performance Indicators (Definition & Calculation of KPIs or PPIs)**

**6.1 Definition of indicators**

PPI lead time: Time from notification of a case until closing of a case (excluding follow up actions)

Case Type Mark Surveillance: 30 calendar days = lead time fulfilled

Case Type Medical Vigilance: 30 calendar days = lead time fulfilled

Case Type Service Delivery Complaints: 10 calendar days = lead time fulfilled

Case Type Appeals: 10 calendar days = lead time fulfilled

**6.2 Calculation of indicators**

Lead time fulfillment:

**7. Process Risks & Opportunities**

**7.1 Risks**

* Loss of accreditation if accreditation requirements are not met.
* Loss of customer/business.
* Danger to end consumers caused by non-compliant objects.
* Loss of profit if our marks of conformity are used illegally without certification fees.
* Loss of reputation: misuse can damage our brand.

**7.2 Opportunities**

* Protection of end consumers.
* Protection of our brand reputation – also for our compliant clients.
* Improved customer satisfaction.
* Optimization of processes through detection of improvement potential.
* Possible business leads: former misusers becoming later compliant clients.

**8. Process Roles & Responsibilities**

| **Process Roles** | **Responsibilities** |
| --- | --- |
| FLE | * Registering cases of assigned scope to Salesforce Complaint Database, including all case related information. * Assigning to the correct Case Owner. |
| Case Owner | * Acting in the name of the Conformity Assessment Body/Bodies. * Case Owner must not have been involved in the service delivery process of the referred object of a case. * Responsible for supporting the BF in investigating complaints & root cause analysis. * Shall be trained according to the criteria listed under clause “Complaint Management” in “Induction Plan” (MS-0048530). * Ensuring the implementation of complaint management. according to the global complaint management process. * Involving related parties (BF Contact Person) into the process * Ensuring external communication. * Evaluation and closing of cases (Level 1&2). * Reviewing & approval of root cause analysis and CAPA (Level 1&2). * Tracking open complaints and follow-up to ensure on time closure within their scope. |
| BF Contact Person | * Providing the (technical) input for a case rel. to their scope. * (BF) internal investigation & implementation of the team specific CAPAs. * Involving further experts as needed. * Tracking open complaints and follow-up to ensure on time closure within their scope. |
| MD | * Accountable for the complaint handling overall within their scope. |
| BO AQM | * Closing complaints in Salesforce (Level 3). * Review & approve root cause analysis and CAPA (Level 3). * Reporting to Management. * Ensure BS specific training. |
| GO QHSE | * Mediation in Cross-Stream/high profile cases on request. * Providing general process training (material) / eLearning. * Database maintenance & support. * Reporting statistics, maintenance & support. * Defining global process for complaint handling. |
| RO QHSE | * Reporting to Regional Management. * Ensuring region specific training. |
| LO QHSE | * Reporting to Local Management. * Ensuring location specific training. |

**9. Interested Parties**

| **Interested Parties** | **Expectations** |
| --- | --- |
| TÜV Rheinland Group | Protection of the TÜV Rheinland brand |
| Accreditation Body | Fulfilment of accreditation standards |
| Authority | Fulfilment of accreditation standards |
| Notified Body | Fulfilment of accreditation standards |
| External Customer | Fulfilment of contract |
| End Consumer | TÜV Rheinland brand stands for quality and safety |
| BS/BF | Support on cases through QHSE /AQM |
| Service Function QHSE | Fulfilment of accreditation & quality standards |
| Sales/KAM | All information regarding clients |
| Legal | Fulfilment of laws and regulations |
| Public Relations | Information in case of media inquiry |
| Insurance | Information in case of damage claims |
| Workers Council | Protection of employees’ rights |

**10. Records Management**

|  |  |  |  |
| --- | --- | --- | --- |
| **Record Type** | **Retention Period** | **Storage of Record** | **Responsible** |
| Case | 10 years | Salesforce Service Cloud | GO QHSE |

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| --- | --- |
| **11. Specifications** | |
| *N/A* |

|  |  |
| --- | --- |
| **12. Attachments** | |
| *Criticality Rating Matrix - Mark Surveillance & Medical Vigilance.xlsxCriticality Rating Matrix - Service Delivery & Appeal.xlsx* |

|  |  |
| --- | --- |
| **13. Related Documents** | |
| *MS-0031010 - Main Process Quality ManagementMS-0034066 - Problem SolvingMS-0034350 - Problem Solving SheetMS-0044397 - Handling of information about reportable incidents and inquiries under MDR/IVDR and MDD/IVDD/AIMDD in SalesforceMS-0048530 - Induction plan for QHSE and AQM functionsMS-0049783 - Corporate Crisis Management Policy* |

|  |  |
| --- | --- |
| **14. External Reference Documents** | |
| *Process MapProcedure for Complaints and Appeals | WO | TÜV Rheinland (tuv.com)Warning ListService Delivery and Mark Surveillance Complaints Report – Power BITechnical Competence Center of BS ProductsSalesforce “Complaint Management" (KBV IT Module U4) - in German onlyOverview Complaints YTD | SalesforceGlobal CS Survey - Complaint Handling for Local Responsible Person​* |