Project:

# Complaint Management at nvm - Overview

Dokument:

**Brief Overview**

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|---|---|---|---|
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# Introduction

The following document outlines the basic complaint processing methods at nvm. A fixed process ensures uniform processing and the identification of the cause of complaints.
Special interest is given to the identification of reportable incidents, which must be reported immediately to the company's security officer.
The analysis and recording of complaints is intended to prevent or rule out repetitions of similar or similar complaints. Furthermore, the findings of the cause analysis shall serve the continuous improvement of our products.
By a regulated and fastest possible handling of the complaint the customer satisfaction is to be reconstituted and our performance is to be proven.
Insight into Standard Operation Procedures, policies, agreements and the general approach is given.

## Used Abbreviations

| | | |
|---|---|---|
| FO | *Formblatt* | Form |
| PB | *Prozessbeschreibung* | Process Description (equals Standard Operation Procedure) |
| nvm | | nal von minden GmbH |
| QM | | Quality Management |
| CAPA | | Corrective Action Preventive Action |

## Applicable Documents

| | |
|---|---|
| PB04 – Risikomanagement | Riskmanagement |
| PB05 - CAPA | |
| PB07 - Medical devices - Monitoring and reporting system (Vigilance System) | |
| PB17 – Lenkung von Dokumenten & Daten | Control of Documents and Records |
| PB06 - Kundenreklamation | Complaintmanagement |
| SOP22 – Bearbeitung v K.rekl. | Processing of customer complaints |
| SOP14 – Umgang mit qual. K.rekl. | Dealing with quality-related customer complaints |
| FO064 Complaint Form | |
| FO155 Complaint list | |
| FO198 Deviation report | |
| R-DRP-2017-01 Disaster Recovery Plan | |
| R-BCP-2017-01 Business Continuity Plan | |

## Generally Aplicable

### Process flow

Complaints are processed by complaint management (part of the quality management department) in Regensburg. The complaint manager controls incoming complaints. A distinction is made between customer complaints (external) and internal complaints.Throughout each step it is essential that there is consultation and communication with everyone involved and defined at nvm.

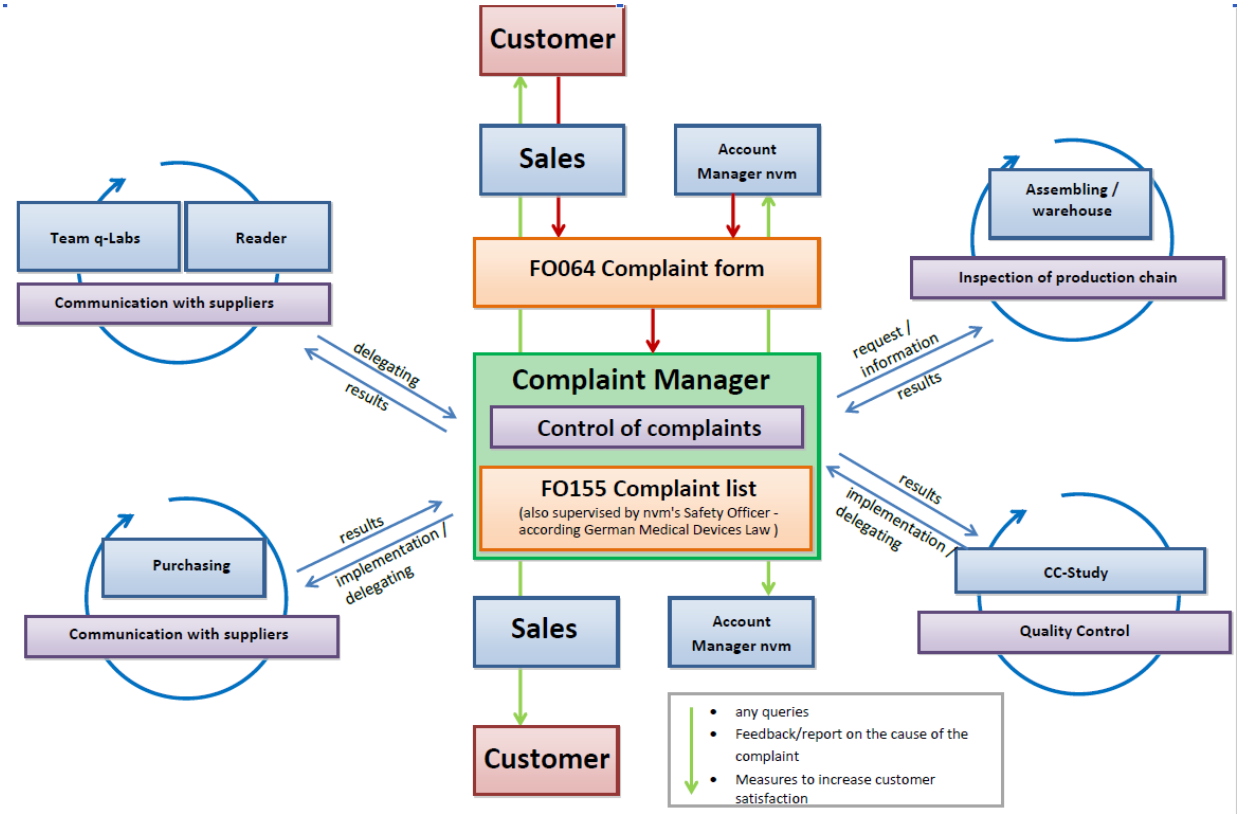


Figure1: Complaint processing chart

## Complaint Management at nvm

nvm is committed to delivering high quality products and services that respond to the customer's needs. nvm values the benefits of effective complaint handling. We believe our customers should be able to provide feedback (both positive and negative) about our products and services and the way we provide them.

Effective complaint management is about accountability, access and business improvement and is an important part of our client service.

Key points are:

- Client-focused service: Careful and prompt attention to complaints can help us understand the needs of our customers and stakeholders, prevent further problems, increase client satisfaction and improve performance. Good complaints management systems encourage client-focused service delivery.
- Business improvement. Complaints are a valuable source of feedback that help us find opportunities for staff and business improvement by using complaints data to identify areas where processes and systems can be improved. Business area managers will regularly review and analyse complaints to identify potential hot spots and areas for improvement.

## Non-conformity and CAPA process

Non-conformity
Non-conformities can be divided into categories:

- Complaints (Customer/Service)
- Non-compliant products (NCP14)) (Production)
- Other deviations

Examples of this could be:

- Malfunction
- Specification deviations
- Process deviations
- etc

Every employee is obliged to report non-conformities from complaints or NCPs(non conforming products) via the complaint department. Non-conformities in processes or other deviations are to be communicated to the QM-department by means of the form "FO198 Deviation report".

## Analysis

In the initial investigation, the obvious or highly probable cause is determined. If necessary, the facts of the case should be further scrutinised.

In the monthly case meeting "Complaints", a team consisting of employees of the complaint department as well as the QM department (if necessary, experts from other specialist groups can be called in) analyses repeated or particularly serious cases. The further procedure is mutually determined and the processing assigned.

## Classification of safety relevance

In the case of products already placed on the market, the safety relevance of this non-compliance is assessed in accordance with the vigilance criteria and, if necessary, a notification procedure is initiated (see PB07 "Medical Devices - Monitoring and Reporting System (Vigilance System)"). The safety relevance is assessed by the Safety Officer for Medical Devices.

## Error assessment

The error analysis assesses whether this nonconformity is subject to a "deviation or CAPA process" or is eliminated by a simple correction. The criterion for the "CAPA process" is whether the nonconformity follows a trend (e.g. cluster formation of the same nonconformities, such as accumulation of false-positive results with the same parameters) or whether intolerable limit transgressions (e.g. deviations in cut-off) occurred. In processes, this criterion can be based on the persistence of an error in certain processes (clustering) or on individual defects classified as serious and requiring correction.

## Correction

Corrections that are not depicted using the "deviation" or "CAPA process" are documented in complaints management.

## Observation

Non-conformities remain under observation via the complaint statistics. A detailed trend analysis takes place in the monthly QM / complaint meeting.

In addition, an evaluation of the available data on non-conformity such as the BfArM reporting list is carried out once a year. Any anomalies from these evaluations can then again lead to a "CAPA process".

Every staff member is obliged to report non-conformities from complaints or NCPs to the complaint department. Non-conformities in a process or other deviations must be communicated to the QM16) department using the form "FO198 Deviation report".

## Root cause analysis

The following steps are required for the root cause analysis

- to apply suitable methods of investigation (no guesswork)
- to carry out a risk assessment with the proviso:
- which risk does the detected non-conformity represent?
- was the risk assessed in the risk analysis, correctly classified and evaluated?
- Evaluation of the impact on delivered and not yet delivered products

Without a clear determination of the cause, no or only a conditional conclusion of the non-conformity is possible.

## Correction

After the cause analysis for e.g. individual events which do not represent a remedial action in the sense of a "CAPA" (e.g. subsequent delivery of missing parts, the absence of which cannot be traced back to any process error, missing knowledge or other remediable erroneous circumstance after the cause analysis), corrections are performed without opening a "CAPA".

## Monitoring and Review

As with communication and consultation, monitoring and review is an ongoing part of complaint management that is integral to every step of the process.

Monitoring and reviews ensure that the nvm Complaint Management is captured, used and maintained.

The nvm Complaint Management is a part of the annual Management Report and is also an important subject to the annual TÜV audit.

# APPENDIX

Complaint Management - nvm
Selected Examples

## FO064 – Customer Complaint Form

new art laboratories

### FO064 Customer Complaint Form
### Rapid Tests

Rev 01/21.11.2011

nal von minden

Customer Name: _____ Date: _____

Customer ID No.: _____ Editor: _____

Product Name: _____ Cat.-No.: _____

Product LOT: _____

nature of the complaint: False Positive ☐ False Negative ☐ Invalid ☐

Migration Problem ■ Weak lines ☐ T- or C-Line _____

| | |
|---|---|
| Other quality problem description: | |
| Which parameters are affected? (For Multi Tests) | |
| How often did the defect occure? (example: 1of 10? 3 of 3? 2 of 200?) | |
| Did the failure occure with one specimen from one patient or with different specimen (how much)? | |
| Which kind of laboratory sample? Blood, Serum, Plasm | |
| Which other methods did the customer used to compare? (GC/MS, Elisa, Rapid Test…?) | |
| Can customer provide cut-Offs, readings or values of other methods? | |
| Did the customer follow the instructions for use? | |
| Did the customer stored the product appropriate? | |
| Is cross reaction possible? (Patient using other medicines?) | |
| Is high-dose-hook-effect possible? (Too high analyte concentration?) | |
| Any other helpful information/notes? | |

case number: _____

P:\QM Public\Formulare\FO064 Customer Complaint Form Rev02

## FO155 - Complaint List

| A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|
| Complaint number | Link Complaint folder | Complaint type | Complaint category | Error type (Error code) | Customer | Country | Date - Complaint entry |
| COM17-00284 | link complaint | Customer Complaint | Assembling/Picking problems | 309 Missing kit components | 311004 | DE | 01.03.2017 |
| COM17-00285 | link complaint | Customer Complaint | Assembling/Picking problems | 312 Wrong amount of tests/packs | 60025 | RO | 01.03.2017 |
| COM17-00286 | link complaint | Customer Complaint | Problems with test performance | 502-RT Incomplete migration/flow | 147276 | CZ | 13.02.2017 |
| COM17-00287 | link complaint | Customer Complaint | Problems with test performance | 502-RT Incomplete migration/flow | 147276 | CZ | 13.02.2017 |
| COM17-00288 | link complaint | Customer Complaint | Problems with test performance | 502-RT Incomplete migration/flow | 158337 | RO | 16.02.2017 |
| COM17-00289 | link complaint | Customer Complaint | Problems with test performance | 502-RT Incomplete migration/flow | 158337 | RO | 16.02.2017 |
| COM17-00290 | link complaint | Customer Complaint | Problems with test performance | 502-RT Incomplete migration/flow | 158337 | RO | 16.02.2017 |
| COM17-00291 | link complaint | Customer Complaint | Transport/Sale errors | 11x Other transport/sale problems | 191168 | DE | 13.02.2017 |
| COM17-00292 | link complaint | Customer Complaint | Assembling/Picking problems | 313 Wrong type of tests/packs | 60025 | RO | 01.03.2017 |
| COM17-00293 | link complaint | Customer Complaint | Problems with test performance | 529 False positive | 640807 | FI | 28.02.2017 |
| COM17-00294 | link complaint | Customer Complaint | Problems with test performance | 528 False negative | 674216 | GB | 24.02.2017 |
| COM17-00295 | link complaint | Customer Complaint | Problems with test performance | 529 False positive | 500078 | IT | 16.02.2017 |
| COM17-00296 | link complaint | Customer Complaint | Problems with test performance | 529 False positive | 500141 | IT | 16.02.2017 |
| COM17-00297 | link complaint | Customer Complaint | Assembling/Picking problems | 313 Wrong type of tests/packs | 663616 | DE | 02.03.2017 |
| COM17-00298 | link complaint | Customer Complaint | Problems with qLabs | 7-0015 INR-Wert zu niedrig im Vergleich zum Lab | 191524 | DE | 01.03.2017 |
| COM17-00299 | link complaint | Customer Complaint | Problems with qLabs | 7-0019 Hardware Probleme | 154787 | DE | 01.03.2017 |
| COM17-00300 | link complaint | Customer Complaint | Problems with qLabs | 7-0015 INR-Wert zu niedrig im Vergleich zum Lab | 186353 | DE | 01.03.2017 |
| COM17-00301 | link complaint | Customer Complaint | Problems with qLabs | 7-0015 INR-Wert zu niedrig im Vergleich zum Lab | 187642 | DE | 03.03.2017 |
| COM17-00302 | link complaint | Customer Complaint | Problems with qLabs | 7-E007.x Fehler bei INR-Wert-Berechnung | 697078 | DE | 02.03.2017 |
| COM17-00303 | link complaint | Customer Complaint | Problems with qLabs | 7-0015 INR-Wert zu niedrig im Vergleich zum Lab | 194962 | DE | 03.03.2017 |
| COM17-00304 | link complaint | Customer Complaint | Transport/Sale errors | 109 Wrong type of tests ordered | 142821 | SK | 03.03.2017 |

## FO198 – Deviation Report

| | Dok.-Nr.: FO198 Revision: 00 | Seite 1 von 2 |
|---|---|---|
| nal von minden | Formblatt Abweichungsmeldung / Deviation Report | FO198 Abweichungs-meldung_Deviation Report |

! "Mouseover Infos" beachten !

| | | | |
|---|---|---|---|
| Abweichungsnummer: | AM- - . (Standort-Bereich-Nummer) | Datum: | |
| Department: | | | |
| Standort | | | |
| ☐ Moers (M) | ☐ Regensburg (R) | ☐ Göttingen (G) | |
| 1. Erstellung der Abweichung | | | |
| Bereich | | | |
| ☐ Complaint (C) | ☐ Process (P) | ☐ Warehouse (W) | |
| ☐ Transport (T) | ☐ Other (O) | | |
| Beteiligte Personen: | | | |
| Beschreibung der Abweichung: | | | |
| (Mögliche) Ursache: | | | |
| Complaint nach FO064 vorhanden: | ☐ ja ☐ entfällt (Bei ja, COM ) | | |
| Sofortmaßnahmen: | | | |
| Abweichung behoben: | ☐ ja ☐ nein ☐ entfällt | | |
| Bewertung mit Begründung: | | | |

| | |
|---|---|
| Ersetzt Version: neu vom: - | Gültig ab: 10.05.2017 |

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