SOP MS Complaints and Appeals

Possible influences of the change

Does the change affect any QM documentation?		☐ Yes[1]	☒ No[2]
1) Affected Documents	---		
2) Justification	Initial version		
Does the change affect any project?		☐ Yes[3]	☒ No[4]
3) Documents affected	---		
4) Justification	Initial version		
Does the change affect any requirements?		☐ Yes[5]	☒ No[6]
5) Documents affected	---		
6) Justification	Initial version		

Training

Is training necessary?		☒ Yes	☐ No[7]
7) Justification	---		

Validity

This document is valid from:	22.06.2021

Created by:	Sükran Pisirici, CRM	07.05.2021	
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Reviewed by:	Alena Oppermann, MD	11.05.2021	
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SOP MS Complaints and Appeals

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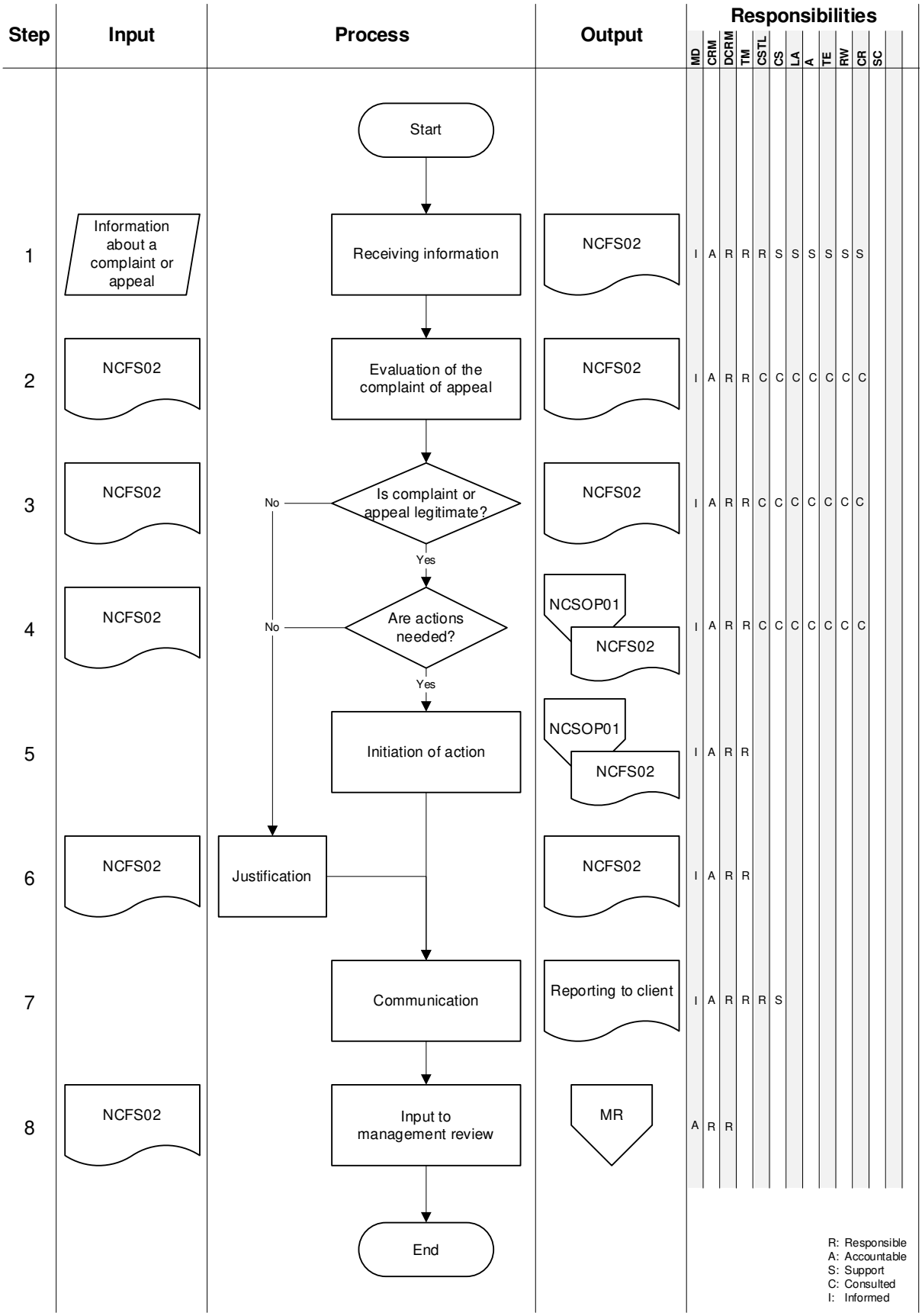
1 Purpose

The aim of this SOP is to identify nonconformities and to guide their handling.

2 Terms and Definitions

Abbreviation/Term	Definition
A	Auditor
Appeal	any written, electronic, or oral communication against the decision.
Complaint	any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution
Corrective Action	action to eliminate the cause of a nonconformity and to prevent recurrence
Correction	action to eliminate a detected nonconformity
CR	Certifier
CRM	Certification and Recognition Manager
CS	Customer Support
CSTL	Customer Support Team Leader
DCRM	Deputy Certification and Recognition Manager
FS	Form Sheet
LA	Lead Auditor
MD	Managing Director
SC	Steering Committee
SOP	Standard Operation Procedure
TE	Technical Expert
TM	Technical Manager

3 Process Workflow – Complaints and Appeals



3.1 Process Description – complaints and appeals

The following subchapters describe the individual steps of the process workflow.

3.1.1 Receiving information

If an employee becomes aware of a complaint or an appeal, the complaint or appeal is documented in *NCFS02_MS Complaints and Appeals Report.*

If a complaint or appeal is received via e-mail, the e-mail must be enclosed on *NCFS02_MS Complaints and Appeals Report.*

If the complaint or appeal is not clear, it will be reviewed within three business days by contacting the complainant or appellant.

3.1.2 Evaluation of the complaint or appeal

Analysis of the information received is performed in seven working days after receiving or verifying the complaint or appeal to decide if the complaint or appeal is legitimate. The results are documented in *NCFS02_MS Complaints and Appeals Report.*

3.1.3 Is complaint or appeal legitimate?

YES → go to step 4

NO → go to step 8

3.1.4 Are actions needed?

If the complaint or appeal is justified, the reason and need for action are determined.

YES → go to step 5

NO → go to step 6

3.1.5 Initiation of actions

If actions are needed to solve the complaint or appeal, actions are planned and initiated in accordance with *NCSOP01_MS Corrective and Preventive Actions*. If immediate action has already been taken, the action is recorded in *NCFS02_MS Complaints and Appeals Report.*

Appeals and complaints about a certified person are referred to the certified person in question after evaluation of complaint or appeal resulted that the complaint or appeal requires further process.

3.1.6 Justification

If the complaint or appeal is not legitimate, justification is documented in *NCFS02_MS Complaints and Appeals Report.*

3.1.7 Communication

If the complaint or appeal is not taken further, a justification will be provided to the client in written form in three days after the evaluation of the complaint or appeal with *NCFS02_MS Complaints and Appeals Report.*

The client is informed about the complaint or appeal process and any actions planned or taken in written form in three days after the evaluation of the complaint or appeal with *NCFS02_MS Complaints and Appeals Report.* This communication includes the necessity to make the resolutions public and the extent of the publicity.

3.1.8 Management review input

Data on complaints and appeals are included in the management review.

4 Additional Process Requirements

4.1 Personnel Involved to the Evaluation of Complaints and Appeals

Personnel evaluating complaints and appeals must be selected from employees who are not involved in the process related to the complaint and appeal and who do not have any relations defined in *ICSOP01_MS Impartiality.*

A lawyer having signed *HRFS26_ MS Confidentiality and Impartiality Agreement for Supporting Roles* for cases that legal evaluation is needed.

If persons from top management are being evaluated in relation to the relevant appeal/complaint and there are no other personnel with a horizontally equivalent or higher position, an external independent person who has proven his sectoral experience and is not related to the relevant appeal/complaint and has signed the *HRFS26_ MS Confidentiality and Impartiality Agreement for Supporting Roles* shall be involved in the evaluation of the complaint or appeal.

In case that (D)CRM, TM are all involved to the relevant complaint or appeal, a lead auditor fulfilling the impartiality requirements and not involved to the activities related to the complaint or appeal is responsible to the evaluation of the complaint or appeal.

4.2 Record ID

The record ID for NCFS02_MS Complaints and Appeals Report is given as YYYYMMDD(cc)_Vxx in which (cc) is deleted in case that there is only one complaint/appeal report created in for the relevant date.

5 Requirements and References

- EN ISO/IEC 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements (ISO/IEC 17021-1:2015) Clause 9.7, 9.8.
- IAF MD 9: 2017 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) Clause 9.7, 9.8.
- IAF MD 22:2019 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS) Clause 9.7, 9.8.

6 Related Documents

- HRFS26_MS Confidentiality and Impartiality Agreement for External Involvement
- NCFS02_MS Complaints and Appeals Report
- ICSOP01_MS Impartiality
- NCSOP01_MS Corrective and Preventive Actions

7 Change History

Revision	Change description
01	Initial version