



Procedure

Verification of Complaints and Appeals

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Rev No.

Description of revision – text changes marked in yellow

4

- Update in the title of the Standard Operating Procedure (SOP)
- Update according to new SOP template
- Description of the actual procedure for handling of complaints (processing in Synergi Life, not documented in a CAPA list anymore)
- Addition of “Submission, investigation and decision on complaints and appeals will not result in any discriminatory actions against the complainant and appellant in 5.2.
- Updated new roles and responsibilities in Procedure Flowchart 6
- Updated MDD documents with their respective MDR counterparts

Training

Class and/or online training required?

Yes No



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1 OBJECTIVE

This SOP describes the process to ensure a uniform and structured approach for handling of complaint and appeal by DNV MEDCERT and to make certain that they (complaint and appeal) are evaluated, validated and investigated to reach a decision.

2 SCOPE

This SOP applies to all departments and employees and to the customers certified by DNV MEDCERT. This procedure is applicable for all appeals and complaints which are addressed to DNV MEDCERT relating to certification activities for which DNV MEDCERT is responsible and the certified customers. Any conflict of interest indicated by any individual or company will be handled as a complaint and according to this procedure.

3 RELEVANT REGULATORY INFORMATION

Document ID	Document Title
DIN EN ISO/IEC 17021-1:2015	<p>Conformity assessment – Requirements for bodies providing audit and certification of management systems</p> <p>9.7 Appeals</p> <p>9.8. Complaints</p>
MDR 2017/745	<p>Annex VII 2.2 The quality management system of the notified body shall address complaints and appeals.</p>
ISO/IEC 17011:2017	<p>Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies</p> <p>7.12 Complaints</p> <p>7.13 Appeals</p>

4 RESPONSIBILITIES

In any case, it will be ensured that the person engaged in appeal-processing process/ complaint – processing is not previously directly involved in the subject of the complaint or appeal. The Responsible Person or Unit has the responsibility to monitor overall process of the complaint and appeal handling and resolve the complaint and appeal satisfactorily according to this process.

In case of an appeal related to issuing, suspending, withdrawing or restricting scope of a certificate, Head of Certification Body (HoCB) is responsible (HoCB in column “**RESPONSIBILITIES**”).

If the complainant is an existing customer, Head of Operations (HoOPS) is responsible for complaints related to operational handling of certification processes including audit process and assessment of technical documentation and the persons involved (HoOPS in column “**RESPONSIBILITIES**”).

For complaints submitted by a third party (market actors, accreditation bodies, scheme owners or other regulatory body) regarding a customer certified by DNV MEDCERT, HoCB is responsible. In the case of complaints concerning conflict of interest, HoCB is responsible.

The responsibilities for the individual procedure steps are defined in the column „**RESPONSIBILITIES**“ in procedure flowcharts 6.

Assignee

An assignee is named by the responsible party to handle a case, make appropriate analysis and take action to resolve a complaint or an appeal. In a case of complaint, Assignee shall not be involved in the subject matter of the complaint. In case of appeal, Assignee shall not be involved in the decision caused by the appeal.

Mediation Committee

Mediation Committee consists of chairman and selected members depending on the nature of complaint or appeal (Form 820201). In case, joint interest of appellant and a member of the Mediation Committee exists, that member is replaced by another person for the duration of processing the appeal. Employees of DNV MEDCERT are neither allowed to be members of the Mediation Committee nor are individuals who have any economic interest in DNV MEDCERT.

All activities in the Mediation Committee is carried out voluntarily. DNV MEDCERT pays only for the extra expenses connected with the work of Mediation Committee. Members of the Mediation Committee are committed to handle all information and documents - which they become aware of as a member - strictly confidential.

It is the responsibility of the Mediation Committee to hear and interview involved parties and to take all available information into consideration for a decision. For all decisions are made, regulatory and normative requirements and designation/accreditation rules - which are applicable for DNV MEDCERT - must be considered.

5 PROCEDURE

5.1 Overview Interface Processes



5.2 Definitions

Complaint: complaints are defined as expressions of dissatisfaction from customers, suppliers, other business partners or third parties about DNV MEDCERT, its services or its customers.

Appeal: appeals are defined as expressions of disagreement with the decision made by DNV MEDCERT in context of certification procedure (for e.g. suspension, withdrawal or refusal of a certificate).

5.3 Complaints and Appeals Handling

5.3.1 General – Receipt and Registration

Submission, investigation and decision on complaints and appeals will not result in any discriminatory actions against complainant and appellant. Confidentiality with regards to complainant and the reason for the complaint is maintained. It is pointed out to the complainant and appellant that complaints and appeals are only subjected to the procedure if they are presented in written form. In order to proceed on any agreed verbal complaint and appeal, the sender shall be asked to send it in writing. The receiver of the complaint or appeal shall immediately notify the responsible person.

All complaints and appeals will be registered, handled and processed within the CAPA tool Synergi Life and defined actions and required records and evidence will be uploaded there.

5.3.2 Appeal Process

An appeal is forwarded to HoCB. An assignee is appointed. This is an independent member of the Certification Body (CB) who is not directly involved in subject of the appeal. If necessary, a Mediation Committee may be consulted.

Receipt of the appeal will be confirmed to the appellant. Assignee shall conduct an initial assessment of the content of the appeal severity, escalation level, required time for resolution and requested remedy and other necessary aspect to support effectiveness of process and responsiveness. Result of such initial assessment should be communicated to the appelleant as per requested.

Investigation process of the appeal consist of review, determine the root cause, propose necessary action or remediation to solve the problem, propose effective corrective and preventive actions and define criteria for the effectiveness of the action. Responsible unit ensures that the actions are adequately implemented within the due date and are effective to solve the problem.

Results of previous similar appeals are considered when deciding which measures to take. Assignee communicates with the appellant during the process of handling to update the appellant regarding decisions and actions. Result of the processing of the appeal will be communicated in written form to the appellant and, if applicable, to the parties involved. CB give a formal notice to the appellant informing the end of appeal-handling process. Documentation of record is uploaded in DMS and Synergi Life.

5.3.3 Complaint Procedure

Complaints are forwarded to the responsible person. An assignee, a person not involved in the subject of the complaint, is named. Receipt of the complaint will be confirmed to the complainant. Assignee shall conduct an initial assessment of the content of the complaint severity, escalation level, required time for resolution, subject area of the complaint, requested remedy and other necessary aspect to support effectiveness of process and responsiveness. Result of such an initial assessment should be communicated to the customer as per requested. Assignee shall communicate or escalate the complaint to the relevant line manager/ unit depending on the result of initial assessment.

In case of complaint from third party stakeholders about a certified client concerned with regards to their certification, an investigation of the complaint will take the effectiveness of the certified management system into account. DNV MEDCERT will also immediately refer any valid complaints about a certified client to the concerned certified customer. In the case of a complaint concerning conflict of interest, Committee of Safeguarding Impartiality may be involved.

Investigation process of complaint consist of review, determine the root cause, propose necessary action or remediation to solve the problem, propose effective corrective and preventive actions and define criteria for the effectiveness of the action. Responsible unit ensures that the actions are adequately implemented within the due date and with the aim of reaching a satisfying solution or agreement between the complainant and DNV MEDCERT. If necessary, Mediation Committee may be consulted. Results of previous similar complaints are considered when deciding which measures to take.

Assignee communicates with the complainant during the process of handling to update complainant regarding decisions and actions. Progress and the result of processing of complaint will be communicated in written form to the complainant. In case of a complaint from third party, it will be determined together with the certified client and the complainant (third party) if the subject of the complaint and its resolution shall be made public.

All complaints are recorded and processed (including any appropriate correction and preventive action are taken) via CAPA tool Synergi Life. Documentation of record is uploaded in DMS and Synergi Life.

5.3.4 Whistleblower Complaints about MDSAP Customers

Complaints/information about MDSAP audited/certified customers indicating public health threat or serious doubt in safety and effectiveness of medical devices must be forwarded to the recognizing Regulatory Authorities.

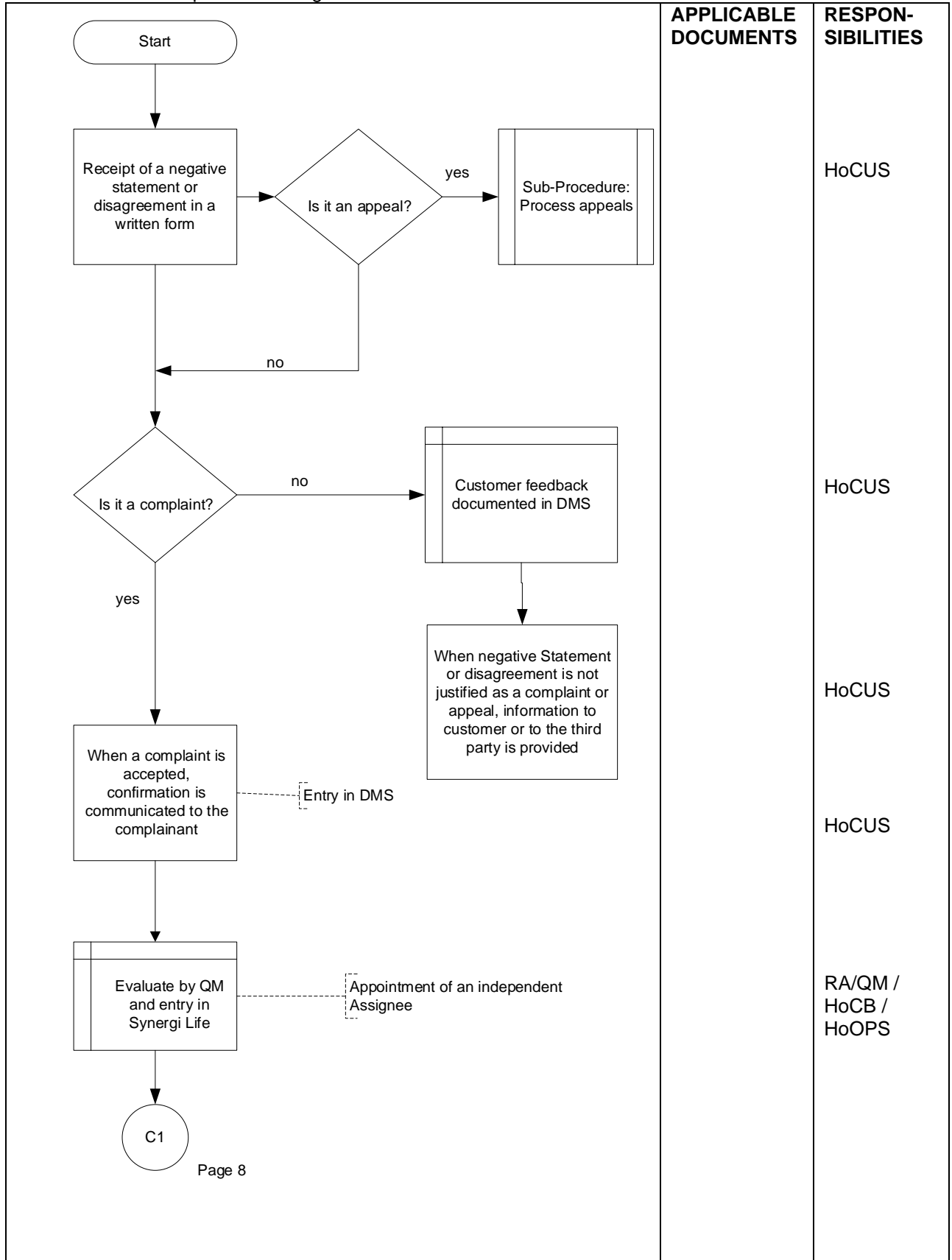


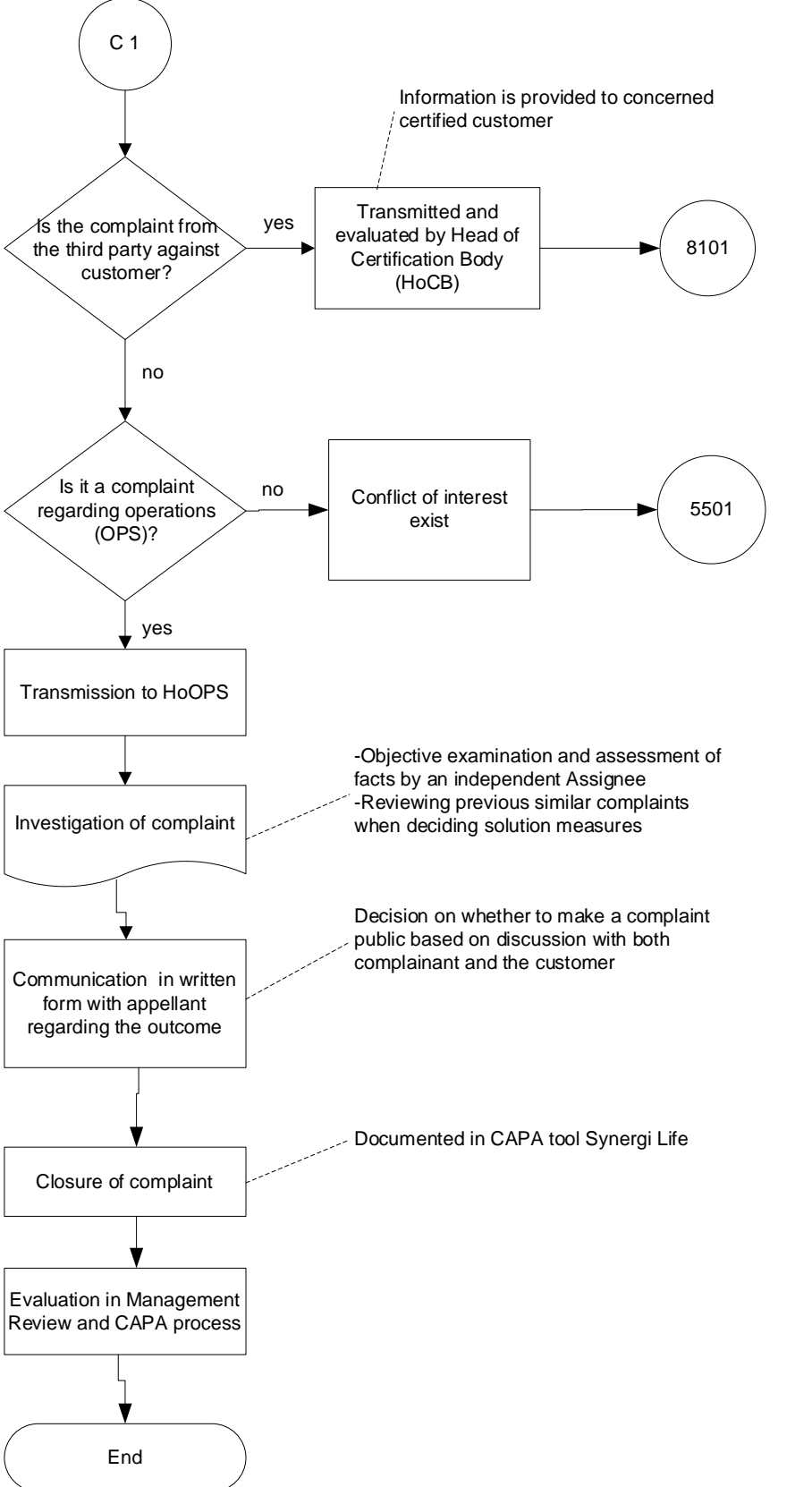
5.4 Analysis of Complaint and Appeal Data

Analysis of data/trends related to complaint and appeal is part of Management Review (SOP 6501). To enable improvement or as corrective/preventive action to the certification services, possibility to make subject of complaint(s) and/or its resolution public shall be considered.

6 PROCEDURE FLOWCHARTS

6.1. Flowchart A - Complaint Handling

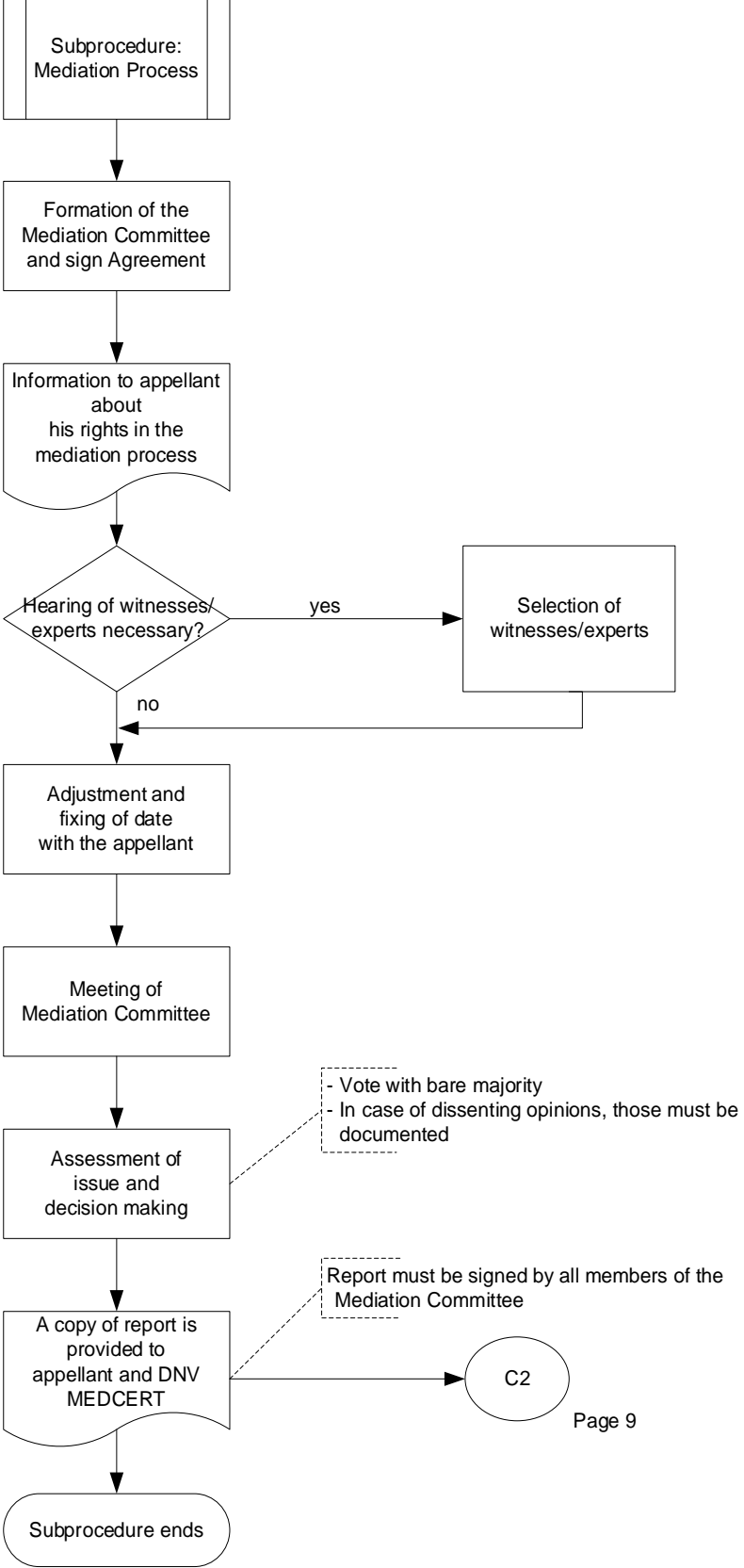


	APPLICABLE DOCUMENTS	RESPON-SIBILITIES
 <pre> graph TD C1((C 1)) --> D1{Is the complaint from the third party against customer?} D1 -- yes --> B1[Transmitted and evaluated by Head of Certification Body (HoCB)] D1 -- no --> D2{Is it a complaint regarding operations (OPS)?} B1 --> E1((8101)) D2 -- no --> B2[Conflict of interest exist] D2 -- yes --> B3[Transmission to HoOPS] B2 --> E2((5501)) B3 --> B4[Investigation of complaint] B4 --> B5[Communication in written form with appellant regarding the outcome] B5 --> B6[Closure of complaint] B6 --> B7[Evaluation in Management Review and CAPA process] B7 --> E3((End)) </pre> <p>Information is provided to concerned certified customer</p> <p>-Objective examination and assessment of facts by an independent Assignee -Reviewing previous similar complaints when deciding solution measures</p> <p>Decision on whether to make a complaint public based on discussion with both complainant and the customer</p> <p>Documented in CAPA tool Synergi Life</p>	<p>820201</p> <p>8501</p> <p>8501</p>	<p>HoCB</p> <p>RM/QM / Committee for Safeguardin g Impartiality</p> <p>HoOPS</p> <p>Assignee</p> <p>Assignee Mediation Committee / HoCB / HoOPS</p> <p>HoCB / HoOPS</p> <p>RA/QM / HoCB / HoOPS</p>

6.2 Flowchart B - Process Appeals

	APPLICABLE DOCUMENTS	RESPONSIBILITIES
<p>Subprocedure: Process appeals</p> <p>Confirmation receipt of the appeal to the customer or third party within 5 working days</p> <p>Transmission to QM and entry in Synergi Life</p> <p>Transmission to the HoCB</p> <p>Initial assessment conducted by the Assignee and communication to the appellant</p> <p>Evaluation of the appeal</p> <p>Implementation of CAPA or mitigation measures or solutions</p> <p>Result is communicated to the appellant in a written form</p> <p>A formal notice is provided by CB to the appellant</p> <p>Subprocedure ends</p> <p>- Appointment of an independent Assignee or formation of Mediation Committee if needed - See 6.3 Flowchart 3</p> <p>Evaluation includes review, root cause analysis, proposing actions/solutions, CAPA, and defining criteria for effectiveness of actions</p> <p>C2</p> <p>Review of previous similar appeals are considered when a deciding on a solution</p> <p>The process is documented in DMS and Synergi Life</p>		<p>CUS</p> <p>RA/QM</p> <p>HoCB</p> <p>Independent Assignee / CUS</p> <p>CUS</p> <p>RA/QM / CB</p>

6.3. Flowchart C - Mediation Process

	APPLICABLE DOCUMENTS	RESPONSIBILITIES
 <pre> graph TD Start([Subprocedure: Mediation Process]) --> Step1[Formation of the Mediation Committee and sign Agreement] Step1 --> Step2[Information to appellant about his rights in the mediation process] Step2 --> Decision{Hearing of witnesses/experts necessary?} Decision -- yes --> Step3[Selection of witnesses/experts] Step3 --> Step4[Adjustment and fixing of date with the appellant] Decision -- no --> Step4 Step4 --> Step5[Meeting of Mediation Committee] Step5 --> Step6[Assessment of issue and decision making] Step6 --> Step7[A copy of report is provided to appellant and DNV MEDCERT] Step7 --> Step8([Subprocedure ends]) Note1["- Vote with bare majority - In case of dissenting opinions, those must be documented"] -.-> Step6 Note2["Report must be signed by all members of the Mediation Committee"] -.-> Step7 Step7 --> C2((C2)) C2 --- Page9[Page 9] </pre>	<p>820201</p>	<p>HoCB /HoOPS</p> <p>Mediation Committee</p> <p>Mediation Committee</p> <p>Mediation Committee</p> <p>Mediation Committee</p> <p>Mediation Committee</p> <p>Mediation Committee</p> <p>Mediation Committee</p>



7 RECORDS

DNV MEDCERT Document No.	Document Title
41-3	Terms Abbreviations
5501	Committee for Safeguarding Impartiality
560101	Management Review
8101	Refusal, Suspension and Withdrawal of Certificates
-----	DNV Management System (DMS)
-----	Synergi Life

8 APPLICABLE DOCUMENTS

DNV MEDCERT Document No.	Document Title
5501	Committee for Safeguarding Impartiality
5601	Management Review
8101	Refusal, Suspension and Withdrawal of Certificates
820201	Agreement Member of the Mediation Committee
8501	Corrective and Preventive Actions

9 APPENDICES

Not applicable.