Management of Complaints / appeals

This document has been edited by Maurizio Barbiere. He will keep it up to date and will inform the quality officer about changes. The quality officer will then do the necessary to update and distribute the modified document.

REFERENCES :

Upstream	
Downstream	LAB-REC-0310 Complaint and appeal form LAB-PRO-0020 Set up and management of procedures RES-PRO-0010 Correction of Test Report LAB-PRO-0700 Internal Audits LAB-REC-0700 Audit report form LAB-REC-0701 Planning of internal audits

Distribution list

Classifier General Procedures

SCOPE OF APPLICATION

This procedure describes the different steps of the management of customer/client complaints/appeals from their reception to the application of corrective and preventive actions

EQUIPMENT:

DEFINITIONS:

Complaint:	Departure between present situation and an expected situation detected by a customer, client or any external organisation. A complaint justifies an investigation which can bring about the discovery of a non conformity or a defect.
Appeal:	A request for reconsideration an ERLAP decision during an Inter-Laboratory Comparison (ILC)
Non conformity:	The non-fulfilment of specified requirements.
Defect:	The non-fulfilment of intended usage requirements or reasonable expectation.
Corrective action:	Action to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence
Preventive action:	Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence

CONTENTS:

FLOW CHART COMPLEMENTARY INFORMATION:

The procedure, including distribution of responsibilities is shown in the flow chart on the following page.

SHORT DESCRIPTION OF STEPS

Reviewed by : Claudia Tarricone Visa : digitally signed	Approved by : Annette Borowiak Visa : digitally signed

Management of Complaints / appeals

Who			does what ?	
QO	LM	RC	LAB-PRO-0400	Proofs
		e	1 Reception of complaint-appeal	1-Fill LAB-REC-0310
	d		2 Complaint-appeal relevant	2-Fill LAB-REC-0310
i/e	e		No / Yes: 3 Information and cataloguing	3-Fill LAB-REC-0310
	d	c	4 test reports involved?	4-Fill LAB-REC-0310
	e		5 Correction of test report	5-RES-PRO-0010
i	r			5-Fill LAB-REC-0310
e			6 C/CA or PA	6-Fill LAB-REC-0310
c	r	c	C/CA: 7 Disposition/Recording and coding of the anomaly	7-Fill LAB-REC-0310
	r		8 Inquiry of the cause of the anomaly	8-Fill LAB-REC-0310
	r		PA: 9 Choice of a corrective action	9-Fill LAB-REC-0310
	d		10 Implementation	10-Fill LAB-REC-0310
	r		11 Corrective action effective?	Set ACTION Plan inl LAB-REC-0310
	r		12 Choice of a preventive action	12-Fill LAB-REC-0310 12-LAB-REC-0301
i	d		13 Implementation	13-Fill LAB-REC-0310
d			14 Preventive action effective?	14-Fill LAB-REC-0310
e				
e			15 Need internal audit?	15-Fill 15-Fill LAB-REC-0310
			16 Implementation of internal audit	16-LAB-PRO-0700
			17 Modification of quality documents and closing of the anomaly record	

Management of Complaints / appeals

ACRONYMS

Actors:	**Actions and responsibilities**
QO = Quality Officer	d = decides
LM = Manager of the receptor of the complaint/PT coordinator	c = collaborates
RC = Receptor of the complaint	e = executes
	i = gets informed
	r = is responsible

1. *Reception and recording of a Complaint/appeal*: Any person of the staff involved in the PT organization might receive a complaint/appeal pertaining or not to his specific scheme. The receptor of anomaly fills the field "description of the complaint/appeal" of the form LAB-REC-0310.
2. *Complaint/appeal relevant?*: According to the information given by the customer, the LM, together to an independent person as observer, decide whether it relates to a PT scheme, if it is necessary to continue the workflow and reports the reasons of his choice on the form LAB-REC-0310. For the appeal an independent person is involved as impartial evaluator of the issue. The independent person will inform the PT coordinator if the request of the participant is valid and the process of the appeal, through LAB-REC-0310 form, has to proceed.
3. *Information and cataloguing:* The LM communicates to the customer why it has been decided not to treat the complaint/appeal. The LM fills the field Acceptance of the complaint/appeal with "NO" and sends a copy of the form to the quality officer who catalogues it into his personal file and proceeds with the recording of the form: he gives a number (from 0 to 9999) to the complaint and adds it to the access document database (fields: code, version, record number, scope).
4. The LM indicates if a test report (or several) is affected by the request. In the case of a positive answer, the number(s) of the test report is given.
5. The LM corrects the affected test report according to the provisions of procedure RES-PRO-0010.
6. LM and QO deciding if it is more suitable a Correction/Corrective Action (C/CA) or a Preventive action (PA).
7. Disposition and recording of the complaint/appeal: A solution to the complaint/appeal is investigated and implemented by the Laboratory manager. The LM communicates to the client which solution was given to his request. The LM fills the field disposition of the complaint/appeal and sends a copy of the complaint/appeal form to the ERLAP quality officer for recording.
   Recording and coding of the complaint/appeal: The quality officer gives a number (from 0 to 9999) to the complaint/appeal form and store it in quality://forms (fields: code, version, record number, scope).
8. Inquiry of the cause of the complaint/appeal: The LM investigates the source of the anomaly and writes the conclusion on the record LAB-REC-0310. The quality officer may collaborate to the inquiry since his experience in recording/closing all the ERLAP complaint/appeals might allow him to propose existing solutions for the current anomaly.
9. Choice of the corrective action: All possible corrective actions should be listed, then the LM chooses the best-suited corrective action and writes it on LAB-REC-0310. It might happen that no corrective action is needed because it is obvious that the same anomaly cannot be observed anymore.
10. Implementation: The corrective action is implemented under the responsibility of the Laboratory manager.
11. Corrective action effective?: The LM is responsible of the evaluation of the effect of the corrective action. He decides whether the corrective action is appropriate to eliminate the cause of the complaint/appeal. He reports his evaluation and his decision on LAB-REC-0310.
12. Choice of the preventive action: The LM chooses a preventive action. Since a preventive action refers to a potential non-conformity, some tools will be used like analogy with the complaint/appeal or brainstorming in order to look for a preventive action. The preventive action is written on the complaint/appeal form record. It might happen that no preventive action is needed because it is obvious that a similar potential anomaly cannot be observed anymore. The PA is also reported in LAB-REC-0301.
13. Implementation: The preventive action is implemented under the responsibility of the LM according to the action plan established in LAB-REC-0310.

14. Preventive action effective?: The LM is responsible of the evaluation of the effect of the preventive action. He decides whether the preventive action is appropriate to avoid a potential complaint/appeal He reports his evaluation and his decision on the complaint/appeal record and sends the concession form to the quality officer.
15. In the case of repetitive non-conformities that appear on the same scheme, the quality officer foresees an internal audit focussed on this process.
16. The quality officer executes an internal audit according to the procedure for internal audit LAB-PRO-0700.
17. Modification of documentation and closing of the anomaly record: According to the corrective and preventive actions implemented in the previous steps a change of quality documentation may be necessary. The quality officer proceeds with the document revisions according to LAB-PRO-0020. After this the quality officer can close LAB-REC-0310, catalogues it into his record file.