Finfish Aquaculture - Dealing with non-conformance

When it comes to quality assurance, things can and do 'go wrong'. SEPA understands that situations will arise where MACS participants are legitimately unable to meet a requirement set out in one of our performance standards. We call this 'non-conformance'.

This MACS technical guide outlines what actions are expected of participants when a non-conformance occurs; and details how SEPA will manage the non-conformance process in the Finfish Aquaculture sector.

What happens when a non-conformance occurs?

Three categories of potential non-conformance with current MACS performance standards have been identified. Each category requires a different set of responses and processes, which are described below:

Category A: Internal sampling and testing non-conformances

In situations where a non-conformance has occurred, but no analytical results are to be submitted to SEPA (e.g. where the affected sample or determinand is to be re-analysed and/or sample collection has been reorganised) then participants need only record the details of that non-conformance in their QMS.

There is no requirement to notify SEPA of the outcome of any investigation, nor is a concession required.

Category B: Reporting of analytical results under concession

SEPA may accept the submission of analytical results that are associated with a non-conformance (i.e. results generated when sampling or testing has not been undertaken according to documented procedures; or results associated with a quality control failure).

In each case, participants must record the details of the non-conformance in their QMS and request a concession from SEPA to report the affected results.

NOTE: All results falling under this category must be clearly identified as being 'non-conforming' upon submission to SEPA.

Category C: Non-conformances identified post-submission

Where data that has been submitted to SEPA is subsequently identified as being either incorrect or non-conforming (e.g. during an internal or external audit), then details of the non-conformance event must be recorded in the QMS of the participant and notified to SEPA.

Participants must investigate the cause of the non-conformance and implement appropriate corrective action(s) to ensure there is no recurrence. These details must be shared with SEPA as soon as the investigation is complete. Based on the evidence provided, SEPA will then determine on a case-by case basis whether data amendment, cancellation and/or additional sampling is required.

NOTE: Identification that a category C non-conformance has occurred may be made by either a MACS participant or SEPA. In either case, notification of the issue should be provided to the other party as soon as is reasonably practicable.

How is a concession requested?

- Where a concession to report analytical results is required, participants should complete and submit Section A of the MACS 'Operator Concession Request Form' (MACS-FFA-TG-01F). An example can be found in **Annex A**.

- Completed concession request forms should be sent to the specified SEPA email address as soon as is reasonably practicable, and ideally within seven calendar days of the non-conformance occurring.

- SEPA will assess completed requests and notify the applicant by return email of its final decision (i.e. concession granted, or request rejected) within 10 working days of the date of receipt.

- Failure to supply SEPA with all requested information will result in a request being returned to the applicant for revision prior to any assessment being undertaken.

- In the event of a request being returned to the applicant, SEPA will no longer consider that request active. All associated service level agreements will be reset upon re-submission of a request.

About this MACS technical guide

This guide is one of a series produced by SEPA to support organisations producing operator monitoring data under MACS. Each guidance document is intended to either: provide participants with assistance on how best to meet a specific requirement of MACS; or give clarity on how SEPA intends to manage a MACS governance process.

Where any discrepancy exists between a MACS performance standard and this technical guide, then the MACS performance standard takes precedence.

All MACS documentation may be subject to review and amendment. For the latest versions of all MACS technical guides, please refer to the **SEPA website**.

Annex A Operator Concession Request Form

Section A: Request (to be completed by the applicant and submitted to SEPA)

Applicant details							
Name		**Company**		**Non-conformance ref. no.**		**Date of request**	

Details of non-conformance (including unique identifiers of sample(s) affected) NOTE: Non-conformance details may be attached in pdf format where this can be directly exported from the quality management system. A list of affected unique identifiers may be attached in Excel format.
Concession request NOTE: Details of the concession request **must** be typed into the text box below.

Please email completed forms to: operator.monitoring@sepa.org.uk; with the subject line "**MACS Operator Concession Request**".

SAMPLE

Section B: Admin. details (FOR SEPA INTERNAL USE ONLY)

Request information	Date of receipt	Assessment completed	Applicant notified	Notification date
		Y / N	Y / N	

QMS information	Concession logged	Date	By	CA/PA ref. no.
	Y / N			

LIMS information	CA/PA assigned	Sample results	Date	By
	Y / N	Released / Cancelled		

SAMPLE

Please note that:

When submitting a concession request the standalone version of this form **must** be used, not this sample copy. Failure to do so will result in the request being immediately returned for revision and re-submission. Form MACS-FFA-TG-01F is available to download from the **SEPA website**.