

Dealing with non-conformance

SEPA understands that MACS participants may not always conform with the requirements documented in a published performance standard.

This MACS technical guide outlines what actions are expected of both the operator and SEPA when such an incident occurs; and details how SEPA will manage the non-conformance process.

What happens when an operator non-conformance occurs?

Three categories of potential operator non-conformance with current MACS performance standards have been identified. Each category requires a different set of responses and processes, which are described below. Further detail of the key processes and responsibilities in categories B and C can be found in [Annex A](#).

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 has been cancelled prior to submission and/or reorganised) then the operator 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.

NOTE: With respect to the overall control of non-conforming work, adherence with the requirements of both MACS and ISO/IEC 17025 will be routinely audited by UKAS at an operator's annual assessment visit.

Category B: Reporting of analytical results under concession

In exceptional circumstance, SEPA will accept the submission of analytical results that are associated with a non-conformance (i.e. results generated when sample handling or analysis has not been undertaken according to documented procedures; or results associated with a quality control failure).

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

NOTE: All results falling under this category must be clearly identified by the operator as being 'non-conforming' upon submission to SEPA. They will remain at pending status in SEPA's LIMS until an associated concession request has been received and assessed by SEPA.

Category C: Sample and data management non-conformances

Where it is identified that an operator has not conformed with the sample and data management requirements of MACS (i.e. failure to adhere to AMP establishment and/or survey/scheduling rules; or submission of incorrect data which subsequently requires amendment or cancellation) then details of the non-conformance event must be recorded in the QMS of both the operator and SEPA.

The operator 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 whether data amendment, cancellation and/or additional sampling is required on a case-by-case basis.

NOTE: Identification that a category C non-conformance has occurred may be made by either SEPA or the operator. In either case, notification of the issue **must** be provided to the other party immediately.

What if SEPA doesn't do everything it says it will?

If an operator is dissatisfied with the level of service SEPA provides in relation to any aspect of MACS, then a complaint against SEPA should be raised in accordance with the operator's quality management policies; and SEPA notified immediately.

How is a concession requested?

- Where SEPA has deemed that a concession to report analytical results is required, the operator must complete and submit Section A of the 'Operator concession request form' (MACS-TG-03F). An example can be found in [Annex B](#).
- Completed concession request forms must be sent to the specified SEPA email address as soon as is reasonably practicable, and ideally within seven calendar days of the submission of any non-conforming data.
- SEPA will assess completed requests and notify the operator by return email of its final decision (i.e. concession granted or request rejected) within five working days of the date of receipt.
- Submission of a concession request form prior to data being received by SEPA systems, or failure to supply SEPA with all requested information, will result in that request being returned to the operator for revision prior to any assessment being undertaken.
- In the event of a request being returned to the operator, SEPA will no longer consider that request active. All associated service level agreements will be reset upon re-submission of a request.
- Where no concession request is received by SEPA, the 56 calendar day 100% reporting target applies (see MACS-WAT-02, clause 6.5.5).
- Once this target is exceeded, any results remaining at pending status in SEPA's LIMS will be cancelled; and additional sampling required by the operator.

Glossary

AMP – annual monitoring plan

concession – an approval, granted to release a non-conforming product or service for use or delivery, e.g. a written agreement from SEPA explicitly permitting an operator to submit data associated with a quality control failure.

LIMS – laboratory information management system.

MACS – Measurement Assurance and Certification Scotland

non-conformance – a departure from an agreed arrangement between an approval authority and an individual or group performing work, i.e. failure of an operator or laboratory to adhere to the stated requirements of MACS and/or ISO/IEC 17025. All incidences of non-conformance, and detail of any corrective action(s) taken, **must** be recorded under an operator's quality management system.

QMS – quality management system

SEPA – Scottish Environment Protection Agency

UKAS – United Kingdom Accreditation Service

About this MACS technical guide

This guide is one of a series produced by SEPA to support self-monitoring operators certified under MACS. Each guidance document is intended to either: provide operators 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 provides the definitive guidance.

All MACS documentation is subject to review and amendment. For the latest versions of all MACS technical guides, please refer to the [SEPA website](#).

Annex A Key Responsibilities and Processes

Figure A1 – Category B

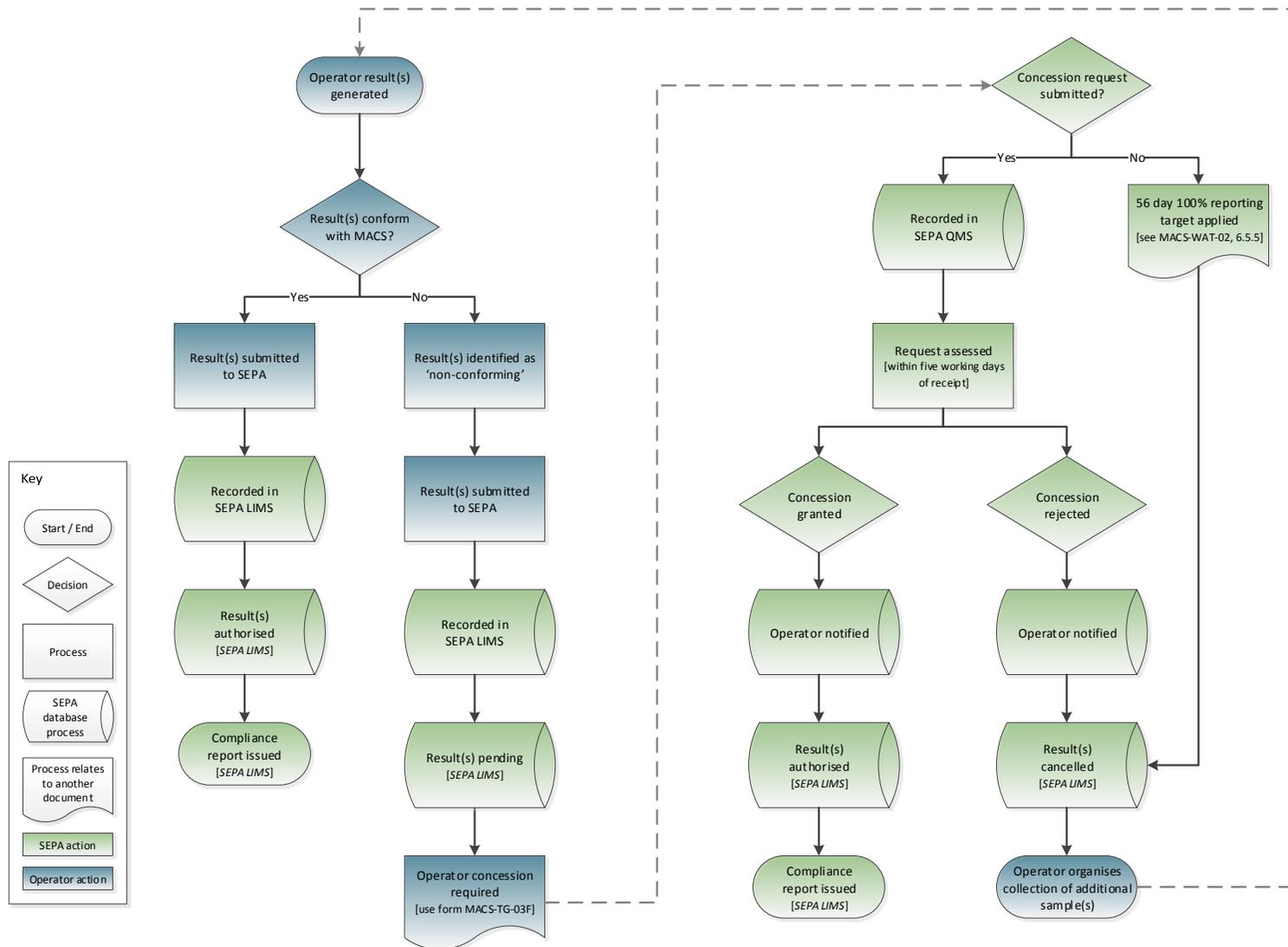
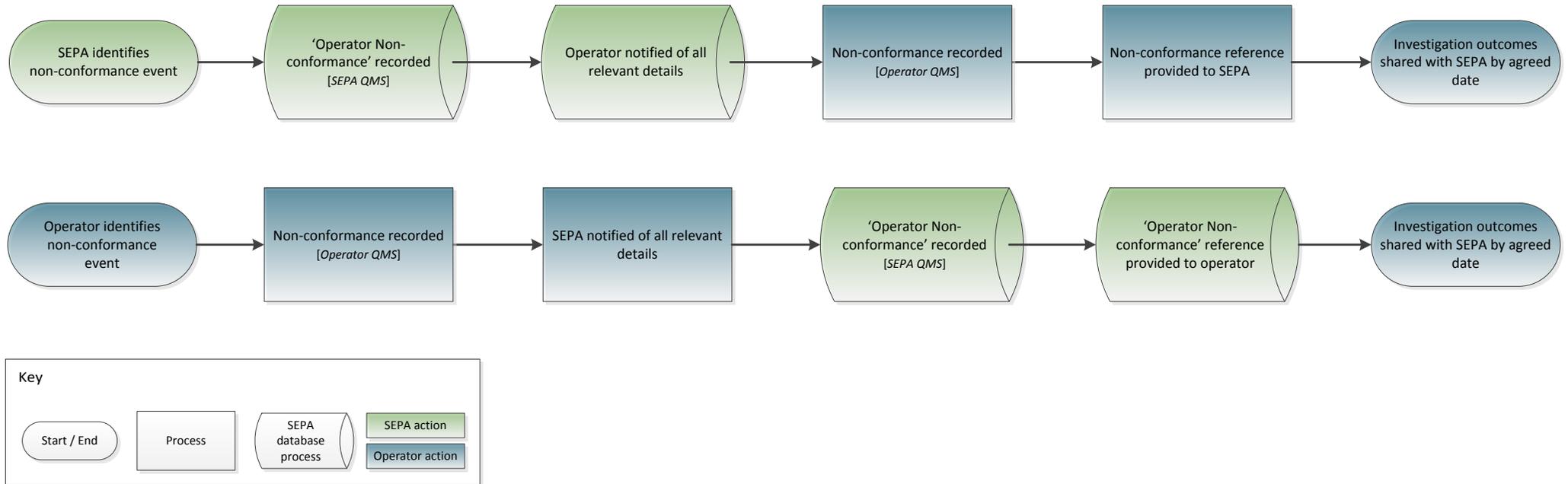


Figure A2 – Category C



Annex B Operator Concession Request Form

Section A: Request (to be completed by the operator and communicated to SEPA)

Operator details				
Name		Non-conformance ref. no.		Date of request

Details of non-conformance (including unique identifiers of determinand(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”.

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

Request information	Date of receipt	Assessment completed	Operator notified	Notification date
		Y / N	Y / N	
Q-Pulse information	Concession logged	Date	By	CA/PA ref. no.
	Y / N			
NEMS information	CA/PA assigned	Sample results	Date	By
	Y / N	Released / Cancelled		

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 to the operator for revision and re-submission. Form MACS-TG-03F is available to download from the [SEPA website](#).