

Standard Operating Procedure

Deviations from standard operating procedures

SOP: QS001 version 1

Document status: Open

Document active from: 30 June 2007

Document review due: 29 June 2008

Authorisation: This document is authorised and activated by its publication to the G: drive by the Head of Quality and Standards (HQS).

Distribution list: Master copy is held by the HQS.
Head of Operations
CELL database
Quality Manager, Thermo Fisher Bioservices

Changes to previous version

None, first version.

Introduction and aim of the procedure

onCore UK uses standard operating procedures (SOPs) to ensure that procedures are performed in a standardised way by different individuals who may be working at different sites. Written procedures are used as an aid to staff training and as a set of instructions for trained staff to follow.

The aim of this procedure is:

- to record all planned and unplanned deviations from SOPs,
- to ensure all planned deviations are authorised before they are implemented,
- to assess the impact of each unplanned deviation and, whenever possible, implement corrective actions,
- to investigate the cause of all planned and unplanned deviations and implement preventive actions so that their recurrence can be prevented, and
- to maintain the high quality standards required by the organisation and its clients.

Applications and Restrictions

This procedure covers deviations relating to onCore UK's Standard Operating Procedures. All such deviations shall be recorded and investigated using this procedure.

There are some instances when local procedures are used for work that is relevant to onCore UK, for example in processing tissue samples at Biosample Donation Networks (BDNs) or disposing of infectious waste at the repository. onCore UK has no control over these procedures but holds a copy of some of the active SOPs so that relevant details can be made available to researchers. This procedure describes the action to take should there be deviations to these local procedures.

Only staff trained to record, investigate and/or sign off deviations shall use this procedure.

Associated procedures and supporting documents

Form: QS001.01	Record of planned deviation
Form: QS001.02	Record of unplanned deviation
Form: QS001.03	Log of deviations
Form: QS001.04	Training record - deviations form standard operating procedures
Form: QS001.05	Record of competence - deviations from standard operating procedures
SOP: QS002	Corrective and preventive actions
SOP: QS003	Internal audits
SOP: QS004	Recall procedure
SOP: QS005	Change control

Definitions

A **deviation** is an event occurring within the quality system, usually detected by staff of the area in which the event occurred, which may result in non-compliance with the quality system or with the requirements of the client. Deviations may be planned or unplanned.

A **planned deviation** occurs when an unexpected event prevents an SOP from being followed exactly as written. Such deviations must be authorised before they are implemented and are expected to be short-term solutions to a problem with immediate impact.

An **unplanned deviation** is a deviation that is discovered after the procedure has been carried out.

Corrective action is the action taken to correct an unplanned deviation.

Preventive action is the action taken to prevent the occurrence or recurrence of a deviation.

The **local supervisor** is the person responsible for the work to which the deviation relates. He or she may be a member of onCore UK's staff or, for work performed on behalf of onCore UK, a Lab Manager, Pathologist, Network Co-ordinator or other supervisor as determined locally.

1 Deviations from onCore UK's procedures

1.1 Planned deviations

- 1 Planned deviations must be authorised by the local supervisor and onCore UK's Head of Quality and Standards (HQS) before they are implemented.
- 2 Any member of staff (employed by or working on behalf of onCore UK, including contractors) can request a planned deviation using Form: QS001.01.
- 3 Form QS001.01 must show the reason for the planned deviation and the length of time for which it will be in place. A planned deviation will be authorised only if the authorised procedure, as written in the SOP, cannot be followed. **PLEASE NOTE** form: QS001.01 must not give any information that will allow a patient to be identified since it may be faxed.
- 4 The local supervisor shall record their approval by signing form: QS001.01 and adding any comments. This form can be faxed to the HQS (fax number 020 731 4587) if the planned deviation is needed urgently; verbal approval from the HQS is sufficient to allow the planned deviation to be implemented.

- 5 The original form shall be sent to the HQS, who must sign the form, add any comments and return it to the originator.
- 6 In the case that the HQS is unavailable, any member of the onCore UK Senior Management Team is authorised to act as deputy.
- 7 The member of staff requesting the planned deviation, or the local supervisor, must complete the remainder of Form: QS001.01 when the need for the planned deviation is over. The completed form shall be sent to the HQS; a copy may be held locally if required.
- 8 If a planned deviation is needed beyond the original agreed timeframe a new form: QS001.01 shall be used to authorise an extension to the planned deviation according to steps 3-7 above.
- 9 If a planned deviation is expected to affect more than one BDN, the HQS is responsible for ensuring that all affected BDNs are notified, using form QS001.01, when the planned deviation is to be implemented and when it is revoked.
- 10 A planned deviation may result in the need for additional staff training. The HQS shall determine the need for such training and is responsible for ensuring that the design and delivery of such training is appropriate and proportionate.
- 11 A planned deviation may lead to a permanent change in the standard operating procedure. Such changes shall be identified and implemented using SOP: QS005 Change control.

1.2 Unplanned deviations

- 1 Note that the procedure for handling unplanned deviations is not intended to assign blame; the purpose of the procedure is to identify the impact of the deviation, its root cause and the need for corrective and preventive actions.
- 2 Any member of staff discovering an unplanned deviation must take action. Record details of the deviation on Form: QS001.02 and notify your local supervisor who must appoint a suitable person to investigate the deviation. Record the investigation on Form: QS001.02
- 3 Notify onCore UK's HQS by telephone (020 8731 4595) as soon as the deviation is discovered. The HQS shall decide on the need to halt or continue work, this shall be recorded on form: QS001.02.
- 4 If the deviation occurs at a BDN site, local rules may require the Network Co-ordinator to be notified.
- 5 The investigation may identify the need for an audit to give assurance of the status of other work. If so, record this on Form: QS001.02 and take advice from onCore UK's QA section.
- 6 Use Form: QS001.02 to record all of the possible corrective actions considered. The local supervisor, in conjunction with the HQS, must decide what the most appropriate action is and sign the form to authorise it. It is the responsibility of the local supervisor to ensure that these corrective actions are implemented effectively. Verification of the effectiveness of corrective and preventive actions may include asking the QA section to arrange an independent audit of the area.
- 7 There may be no immediate corrective action since some deviations have no detectable cause, but all deviations must be reviewed, at least once a year, to detect patterns and recurrent problems. Corrective and/or preventive actions may result from such reviews.
- 8 The HQS shall authorise the resumption of work if work has been halted. Verbal authorisation is sufficient but it must be recorded on form: QS001.02.
- 9 Once the deviation is resolved the original completed form: QS001.02 must be sent to the Head of Quality and Standards at onCore UK where a log of deviations (Form: QS001.03) is completed. This form gives brief details of

the deviation and is useful in detecting trends and reviewing deviations. A copy of the original form may be held locally to allow local reviews to take place.

- 10 A deviation may result in the need to recall samples or amend data, or to notify a client of the problems detected. It is the responsibility of the HQS, in conjunction with the onCore UK Senior Management Team, to decide when such action is to be taken and to notify the onCore UK CEO and Head of Operations of this decision.
- 11 Where a deviation investigation or audit finding casts doubt on the correctness or validity of work performed by onCore UK or on onCore UK's behalf, the HQS immediately notifies any interested party whose work may be affected and instigates the recall procedure for any samples that have been deposited in the repository or distributed to researchers. The procedure and responsibilities for recall are documented in SOP: QS004

2 Deviations from local procedures relevant to onCore UK's activities

2.1 Planned deviations

- 1 Please notify onCore UK of any planned deviations to local procedures or standard NHS practices that are relevant to onCore UK's activities. If you wish to receive comments on planned deviations, please contact onCore UK's HQS.
- 2 The HQS shall ensure that records of planned deviations are attached to relevant sample records.

2.2 Unplanned deviations

- 1 Please notify onCore UK's HQS of any unplanned deviations from local procedures or standard NHS practices that are relevant to onCore UK's activities.
- 2 The HQS shall ensure that records of unplanned deviations are attached to relevant sample records.

History

Version	Date issued	Changes to previous version
1	30 Jun 2007	None, new document

END