

Standard Operating Procedure

Reporting Deviations from External Organisations

SOP: QS/Proc/7 version 1

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Introduction and aim of procedure

onCore UK uses standard operating procedures (SOP's) 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 training and as a set of instructions for trained staff to follow.

The aim of this procedure is to describe the methods used by external organisations to:

- record all planned and unplanned deviations from set procedures
- ensure all planned deviations are authorised before they are implemented
- perform and record an assessment of the impact of each unplanned deviation
- document the implementation of corrective and preventative actions

Applications and Restrictions

This procedure covers the reporting of planned and unplanned deviations against onCore UKs procedures and processes. The reporting process applies to deviations reported by personnel external to onCore UK.

This procedure is relevant only to staff trained to record, investigate and/or sign off deviations.

Related documents

Form QS-Fm/PIIn-Dev/1	Record of planned deviations from an external source
Form QS-Fm-UnPI-Dev/1	Record of unplanned deviations from an external source
QS/Training/Temp/1	Recording Deviations from Standard Operating Procedures

Definitions

Deviation An event occurring outside of established and documented practices which may result in non-compliance with a system or with the requirements of the client

Planned deviation A deviation which is planned in advance and is required to resolve a short term problem that may have an impact on practices.
Planned deviations must be authorised in advance before they are implemented and will have a fixed duration

Unplanned deviation A deviation to established practices which occurs during the execution of a procedure or is discovered after the procedure has been carried out

Root cause The underlying cause of the deviation

Corrective action Actions taken to correct an unplanned deviation

Preventative action Actions taken to prevent the reoccurrence of a deviation

Local supervisor The line manager responsible for the procedure to which the deviation relates. This may be a member of onCore UK staff or, for work carried out on behalf of onCore UK, a lab manager, pathologist, Network Coordinator or other supervisor determined locally

1. Unplanned Deviation

Note 1: If a deviation is considered to require correction immediately it can be reported by telephone to any member of the onCore UK Management team, prior to completion of the form.

Note 2: All deviations shall be recorded and faxed to the Head of Quality and Standards or in her absence to any member of the onCore UK Management team within 24 hours of discovery.

- 1.1 Details of unplanned deviations reported by external sources (e.g. a hospital) shall be recorded on the onCore UK Record of Unplanned Deviations from an External Source form, by the person discovering the deviation, as follows:
- 1.2 Describe the process or part of the process in which the deviation took place e.g. processing of blood.
- 1.3 Record the procedure number and title which the deviation relates to.
- 1.4 Enter as much detail as possible regarding the deviation, in particular any relevant identifying codes or data entries.

Note: Under no circumstances shall any information or data be recorded that could identify an individual donor.

- 1.5 Print the name of the person reporting the deviation, the date the report was made and the name of the organisation where the deviation occurred.
- 1.6 If work was halted due to the deviation enter the date the work was halted, the date the work was resumed, the name and signature of the person authorising the resumption of work and the date.
- 1.7 A full investigation of every unplanned deviation shall take place at the earliest opportunity. Full details of the investigation shall be entered into the investigation section, including names of the investigators and brief details of any telephone calls or correspondence relating to the investigation. Resolutions or proposed actions should **not** be recorded in this section of the form

Note: Copies of any relevant correspondence should be attached to the completed form and sent to the Head of Quality and Standards (HQS) at onCore UK.

- 1.8 Upon completion of the investigation, an assessment of the impact of the deviation, the perceived severity level of the impact and the root cause of the deviation shall be recorded by the person discovering the deviation.

- 1.9 Corrective actions shall be proposed in the Proposed Corrective Actions section. These are actions that can be taken to put right the deviation.
- 1.10 Preventative actions shall be proposed in the Proposed Preventative Actions section. These are long term actions, put in place to prevent the deviation occurring again.
- 1.11 When all details of the investigation and proposed corrective and preventative actions have been detailed the form shall be signed and dated by the person(s) proposing the actions.
- 1.12 The local supervisor shall be responsible for reviewing and authorising the appropriate actions before passing the completed form to the HQS at onCore UK.
- 1.13 The details of the deviation shall be entered onto Q-Pulse by the HQS and the deviation progressed to resolution as described in SOP QS/Proc/9.
- 1.14 The Q-Pulse Record number shall be entered onto the Deviation form and the form signed and dated by the HQS.
- 1.15 Upon completion and closure of the deviation the HQS will feedback to the person raising the deviation details of any actions take by onCore UK regarding preventative and corrective actions.

2. Planned Deviation

Note: all planned deviations must be approved by the HQS at onCore UK prior to implementation.

- 2.1 Details of planned deviations proposed by external sources (e.g. a hospital) shall be recorded on the onCore UK Record of Planned Deviation from an External Source as follows:
 - 2.2 Print the name of the person requesting the deviation and enter the date.
 - 2.3 Enter the name of the organisation and the process in which the planned deviation is taking place.
 - 2.4 Record the procedure number and title which the deviation relates to.
 - 2.5 Give as much detail as possible and a detailed reason for the deviation, including justification for making the deviation.
 - 2.6 Assess the impact of the deviation on the process, enter as much information as possible about the assessment, the perceived

severity of the impact and the period that the deviation will be implemented.

- 2.7 When all the details have been entered onto the form pass it to the local supervisor for review and authorisation.
- 2.8 When the form has been reviewed, signed and authorised it should be sent to the HQS at onCore UK, or in her absence to any member of the onCore UK Management team, accompanied by any supporting evidence.
- 2.9 The details of the proposed deviation will be reviewed and authorised if appropriate and the deviation owner notified of the decision and the signed form will be faxed back to the requester immediately.
- 2.10 The details of the deviation shall be entered onto Q-Pulse by the HQS and the deviation progressed to resolution as described in SOP QS/Proc/9.
- 2.11 The Q-Pulse Record number shall be entered onto the Deviation form and signed and dated by the HQS.
- 2.12 If the planned duration of the deviation requires extending the deviation owner shall notify the HQS via email giving a justification for the extension.
- 2.13 The HQS shall review the request, notify the owner of the decision and update the Q-Pulse record if necessary.
- 2.14 If the deviation returns to normal before the agreed date the deviation owner shall notify the HQS via email. The HQS shall update the Q-Pulse record accordingly.

History

Version	Date issued	Changes to previous version
1		New number as this version is controlled by Q-Pulse. New forms designed. Procedure gives more detail of information required for Corrective and Preventative Actions. Includes reference to input of data into Q-Pulse This version supersedes SOP QS001 v1 which has been withdrawn

END

Uncontrolled when printed