


Name of Document: G-005-03- Interim audit description Approved by: Eoin McGrath Responsible: Iris Bargalló Entry: Interim Audit Process Description	Creation date: 08/05/2013 Effective date 09/05/2013 Review date: 06/03/2017 Modification: Interim Audit fees included in total fees.	
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## Interim Audit Description

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### 1 Introduction

- 1.1 The change of the duration of the accreditation cycle from 3 to 4 years was the result of a proposal by the JACIE Board on 30 March 2008 and adopted on 10 October 2008. The 4-year accreditation cycle was introduced with effect from 1 January.
- 1.2 There are no changes to the procedure for requesting and preparing for accreditation/reaccreditation and the inspection process will remain as it is.

### 2 Focus


- 2.1 The interim audit focuses primarily on the **quality management system**. JACIE reserves the right to examine any issues identified in the previous inspection report.

### 3 Process

- 3.1 At the end of the 2<sup>nd</sup> year of accreditation, the centre will receive a request for documentation by the JACIE Office 3 months before the second year of accreditation ends.
- 3.2 The interim audit will be based on these documents and assessed by the same inspectors that participated in the previous full Inspection. Where an inspector is no longer available, a substitute will be appointed.
- 3.3 The audit does not introduce any new requirements or questions not already addressed by the Standards.

### 4 Scope

- 4.1 The audit will be based on a condensed version of the JACIE Inspection Checklist. It is available for download from the Document Centre on the JACIE web site at [www.jacie.org](http://www.jacie.org).
- 4.2 The audit will focus on the functioning of the quality system. The auditor will assess:
  - 4.2.1 Evidence of continuous educational and training activity
  - 4.2.2 Quarterly reports on quality management activities and/or minutes of meetings where these activities were reported

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4.2.3 Internal annual reports on the performance of the quality management system

4.2.4 Evidence of regular review and approval of SOPs and other documentation

4.2.5 Evidence of internal audits

4.2.6 Evidence of regular meetings e.g. minutes, agenda

4.2.7 Reports of Serious Adverse Events (SAEs), their review and evidence of corrective actions

4.2.8 Evidence of review of donor records

4.2.9 Evidence of outcome analysis

4.2.10 Current status of licence/authorisation by the regulatory authorities.

4.2.11 Evidence of validation of procedures or equipment

4.2.12 Evidence of environmental monitoring

4.3 The auditor will receive a copy of the most recent Inspection Report and Annual Report for the centre. JACIE reserves the right to examine any issues identified in the previous inspection report.

## 5 Format

5.1 Desk-based review of documentation. There is no dedicated on-site visit the facilities unless this is determined to be necessary from the document review. JACIE also reserves the right to perform an onsite visit at any time.

## 6 Consequences

6.1 The audit is a *check-up* on the operation of the quality management system. The audit will lead to an assessment of the actual state of quality management in the programme and may identify deficiencies or highlight areas that require attention.

6.1.1 If deficiencies are reported, the centre should submit corrective actions within a time period not exceeding 6 months from receipt of the Interim Audit Checklist completed by the auditor(s).

6.1.2 Failure to correct deficiencies within this time period may result in suspension of accreditation.

6.2 Centres are still required to submit annual reports at the end of Year 1, Year 2 and Year 3 of the accreditation period.