


23. The quality management system

This guidance note contains:

 Refer to principles 7, 8, 10 and 11

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

HFEA guidance

- Definition of the quality management system
- Establishing, maintaining and documenting the quality management system
- Quality policy and quality objectives
- Quality manual
- The quality management review ■
- Quality indicators
- Assessing user satisfaction
- Staff suggestions
- Internal audit
- Participating in external reviews, and inter-centre and inter-laboratory comparisons
- Monitoring, evaluation and improvement ■

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3A – Supplementary licence conditions: human application

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive...

Relevant provisions of the third Directive	
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Licence conditions

T32 The centre must put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's Code of Practice.

T33 The following documentation must form part of the quality management system:

- a. a quality manual
- b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence
- c. guidelines



Mandatory requirements (cont)

- T33 (cont)
- d. training and reference manuals, and
 - e. reporting forms.
- T35 Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.
- T36 Centres must audit the activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators. These audits must be performed at least every two years, by trained and competent staff and in an independent way. Findings and corrective actions must be documented and implemented.



HFEA guidance

Definition of the quality management system

23.1 The quality management system is defined as:

'the organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management (ie, the co-ordinated activities to direct and control an organisation with regard to quality), including all activities which contribute to quality, directly or indirectly'.¹

NOTE: This definition indicates that every process and activity taking place in the centre is a part of the quality management system.

23.2 The centre should:

- (a) identify the processes needed for quality management, for providing and managing resources and for assisted conception procedures, and
- (b) ensure these processes, including the interaction between them, are effective and continually improved.

Establishing, maintaining and documenting the quality management system

23.3 Centre management should ensure the quality management system is established and maintained by:

- (a) appointing a quality manager
- (b) establishing a quality policy
- (c) establishing quality objectives and plans
- (d) ensuring resources are available to implement and maintain the system
- (e) making centre staff aware of the importance of the system and the need to keep to its requirements
- (f) defining responsibilities, authorities and reporting relationships in the centre
- (g) conducting management reviews of the system, and
- (h) establishing and reviewing contracts with third parties.

¹ International Organization for Standardization



See also guidance note:

- [24 - Third party agreements](#)

23.4 Centre management should appoint a quality manager who, regardless of their other responsibilities, must be responsible for:

- ensuring that the quality management system is implemented and maintained
- reporting to centre management on how the quality management system works and how effective it is, and
- co-ordinating awareness of centre users' needs and requirements.

23.5 The centre's documents to support its quality management system should include:

- the quality policy, with quality objectives and plans
- a quality manual
- documents needed to ensure the centre's processes are planned and operate effectively, and
- records and procedures required by this Code of Practice.

The centre should ensure that all documents are available for inspection by the HFEA.

Quality policy and quality objectives

23.6 The quality policy is defined as:

'the overall intentions and direction of an organisation related to quality as formally expressed by centre management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning'.²

23.7 Centre management should ensure the quality policy includes a commitment to:

- providing a service that meets its users' needs and requirements
- meeting the provisions of this Code of Practice
- continually improving the effectiveness of the quality management system
- upholding good professional practice, and
- ensuring the health, safety and welfare of all staff and visitors to the centre.

23.8 The quality policy should be:

- signed and issued by the person responsible
- communicated, understood and available throughout the centre, and
- reviewed for continuing suitability.

23.9 Centre management should establish documented quality objectives. These should:

- include objectives needed to meet users' needs and requirements
- be measurable and consistent with the quality policy, and
- be reviewed regularly.

² International Organization for Standardization



23.10 Centre management should establish a plan to achieve and maintain the quality objectives. The plans should be reviewed regularly.

Quality manual

23.11 The centre should establish and maintain a quality manual. The quality manual should include:

- (a) a brief description of the centre, including its legal identity, and the scope of its services
- (b) the quality policy, or reference to it
- (c) an organisation chart defining accountability and reporting relationships in the centre
- (d) text to accompany the organisational chart and a definition of the centre's place in any parent organisation, and
- (e) an outline of the processes and documentation established for the quality management system.

See also guidance note:

- [31 - Record keeping and document control](#)

The quality management review



Interpretation of mandatory requirements

23A

The centre management must regularly review the centre's quality management system and all its services, identifying the need for changes and opportunities for improvement.

23.12 The review of the quality management system should include consideration of changes in:

- (a) the volume and scope of work
- (b) staff
- (c) premises
- (d) the performance of third parties that could affect the quality management system or the centre's services, and
- (e) the results of the following activities:
 - (i) quality indicators for monitoring the centre's performance in patient care
 - (ii) assessment of user satisfaction, and the monitoring and resolution of complaints
 - (iii) staff suggestions
 - (iv) an internal audit of all elements of the quality management system, including assisted conception processes
 - (v) participation in external reviews, and inter-centre and inter-laboratory comparisons
 - (vi) identification, investigation, control, recording and notification of serious adverse events and reactions, and
 - (vii) continual improvement, including the status of corrective and preventive actions.

23.13 The centre should normally review its quality management system at least every 12 months but more often when a quality management system is being established.

23.14 The management review should include the results of monitoring, evaluation and improvement activities.



23.15 The results of the review of the quality management system should be recorded and should include the decisions and actions for improving the quality management system. Centre staff should be informed of the results of the quality management review.

See also guidance note:

- [27 – Adverse incidents](#)
- [28 – Complaints](#)

Quality indicators

23.16 The centre should establish quality indicators for systematically monitoring and evaluating the centre's contribution to patient care.

Assessing user satisfaction

23.17 The centre should assess whether or not the service has met users' needs and requirements. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.

Staff suggestions

23.18 Centre management should encourage staff to make suggestions for improving any aspect of the centre's service. Suggestions should be evaluated, implemented as appropriate, and feedback provided to the staff. Records of suggestions and management action should be maintained.

Internal audit

23.19 The centre should establish an internal audit process to determine whether the quality management system:

- conforms to the planned arrangements for assisted conception processes
- conforms to the requirements of this Code of Practice and to the standards established by the centre, and
- is effectively implemented and maintained.

23.20 The centre should establish a documented procedure to:

- define the responsibilities for planning and conducting audits
- define the audit criteria, scope, frequency and methods
- ensure audits are carried out by trained staff
- ensure action is taken promptly to start corrective action
- check the effectiveness of the action taken, in a subsequent audit, and
- keep records of audits, to include:
 - the processes, areas or items audited
 - any areas that do not comply with the quality management system
 - recommendations and timescales for action, and
 - action taken and its effectiveness.



- 23.21** The quality manager should plan the audit programme. It must take into account the importance of the processes and areas to be audited, and the results of previous audits. Auditors should not audit their own areas of responsibility.
- 23.22** The audit should focus in particular on quality indicators established for systematically monitoring and evaluating the centre's assisted conception processes.

Participating in external reviews, and inter-centre and inter-laboratory comparisons

- 23.23** The centre should, where possible, participate in inter-centre comparisons and inter-laboratory comparisons. The centre should evaluate the results of these comparisons and use relevant findings to improve its service.
- 23.24** For inter-laboratory comparisons, the laboratory should establish documented procedures to define the responsibilities and requirements for participation to ensure that:
- (a) a record of participation is maintained, to include reasons for failure to participate
 - (b) supervisory staff and staff doing the examinations evaluate the returned results against agreed performance criteria, and, when nonconformities are identified, participate in implementing and recording corrective action, and
 - (c) the effectiveness of the corrective action is verified. When a formal inter-laboratory comparison programme is not available, the laboratory should develop a way of determining the acceptability of procedures not otherwise evaluated. Whenever possible, this should use external materials, such as exchange of samples with other laboratories.
- 23.25** The centre should assess any external reviews indicating nonconformities or potential nonconformities and take appropriate corrective or preventive action to ensure it continues to comply with the requirements and expectations of this Code of Practice. The centre must keep a record of corrective and preventive action it takes.

Monitoring, evaluation and improvement



Interpretation of mandatory requirements

23B

The centre must plan and implement processes for monitoring, evaluation and improvement.

- 23.26** The centre's processes for monitoring, evaluation and improvement should:
- (a) show that procedures and outcomes are satisfactory when judged against relevant professional standards
 - (b) show that the assisted conception processes are followed in a way that meets users' needs and requirements
 - (c) ensure conformity of the quality management system, and
 - (d) continually improve the effectiveness of the quality management system.
- 23.27** The centre should establish a documented procedure to take corrective action to eliminate the cause of nonconformities. This should include:
- (a) reviewing nonconformities
 - (b) determining the causes of nonconformities
 - (c) evaluating the need for action to ensure nonconformities do not recur
 - (d) promptly determining and implementing action needed
 - (e) recording the results of corrective action taken, and
 - (f) reviewing the corrective action taken.



HFEA guidance (cont)

23.28 The centre should establish a documented procedure to take preventive action to eliminate the causes of potential nonconformities and so prevent them happening. It should include:

- (a) determining potential nonconformities and their causes
- (b) evaluating the need for action to prevent nonconformities happening
- (c) promptly determining and implementing action needed
- (d) recording the results of preventive action taken, and
- (e) reviewing preventive action taken.

NOTE: Preventive action is a way of actively identifying opportunities for improvement rather than reacting to problems or complaints when they happen.



Other legislation, professional guidelines and information

- International Organization for Standardization – www.iso.org

