

Compliance and Enforcement Policy

SOP Number: QP-03

Version: 1.0

Authored By: Trish Davies

Approved By: The Authority September 2009

Effective Date: 1st October 2009

Review Date: 1st October 2010

CHANGE HISTORY

Version	Change Details	Author	Approver
0.1	Amended paras 16 and 31	D Gomez	T Davies
0.2	Major rewrite (4.12.08)	D Gomez	Carmel Dodson Brown
0.3	Amended paras 2009-03-25	D Gomez	T Davies
1.0	In accordance with recommendations of Compliance Committee made on 2 nd September 2009 and approved by the Authority on 9 th September 2009; the following paragraphs of this Compliance policy were amended to reflect the amendments to the Act and new licensing arrangements effective from 1 st October 2009: paragraphs 3.3(d) and (e); 3.5; 3.8; 3.11; 5.1; 5.8; 5.9; and 7.2 .	D Gomez	Authority

Distribution

TRIM
Quality File

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

COMPLIANCE AND ENFORCEMENT POLICY

1. POLICY STATEMENT/INTENTION

- 1.1 This document and appendices set out the Authority's policy on the approach to be adopted, and the measures taken, by the Authority's Compliance Department in order to promote and maintain compliance by licensed centres with :-
- a) the provisions of the Human Fertilisation and Embryology Act 1990 as amended ("the Act");
 - b) licence conditions;
 - c) directions issued by the Authority; and
 - d) the Code of Practice issued by the Authority under Section 25 of the Act.
- 1.2 This policy replaces all previous policies relating to these matters.

2. INTRODUCTION

- 2.1 Under the Act, the Authority has a duty to inspect centres licensed by it, at periodic intervals. During the course of an inspection, it may be noted that a centre has failed to comply with the provisions of the Act; the conditions attached to its licence; relevant directions issued by the Authority; or the Code of Practice issued by the Authority. The purpose of the inspection process, and the principles underpinning the Authority's approach to the inspection of licensed centres, is set out in section 4 below.
- 2.2 Under Section 15A of the Act, the Authority has a duty to investigate all serious adverse events and serious adverse reactions of which it becomes aware, and to take appropriate control measures. The Authority also has a duty to assist other EEA competent authorities and, where requested by such authorities, to undertake inspections into serious adverse events or serious adverse reactions. In addition, the Authority may become aware of matters that do not fall within the definition of a serious adverse event or serious adverse reaction under the Act, but which the Authority considers to be an adverse incident requiring further action by it. The Authority's approach to the handling of serious adverse events and serious adverse reactions, and to adverse incidents, is set out in section 5 below.
- 2.3 Occasionally, the Authority receives complaints from patients or members of the public about treatment or services received at a licensed centre. The Authority's approach to handling such complaints is set out in section 6 below.
- 2.4 As from October 2009, the Authority will have a specific statutory duty to promote compliance with the requirements of the Act, and the Code of Practice issued by it under Section 25 of the Act. In fulfilling this and all its statutory duties, the Authority will be required to have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).
- 2.5 In producing this policy, the Authority has paid due regard to the provisions of the Regulators Compliance Code (the Statutory Code of Practice for Regulators issued by the Department for Business Enterprise and Regulatory Reform on 17th December 2007) and in particular, the principles and guidance in that Code which relate to risk assessment; inspection and other visits; compliance and enforcement actions; and accountability.

3. GENERAL PRINCIPLES

3.1 Where the Authority becomes aware that a licensed centre has failed to comply with the provisions of the Act; the conditions attached to its licence; relevant directions issued by the Authority; or the Code of Practice issued by the Authority, it will normally first seek to encourage that centre to undertake any necessary remedial action and improvements. Where a centre persistently fails to comply, the Authority will seek to achieve compliance via an escalating scale of informal measures to formal enforcement action. The diagram at Appendix 1 demonstrates this approach.

3.2 Informal action may include:-

- a) informing the Person Responsible in writing of the minimum levels of remedial action identified that that the Person Responsible must undertake and the timescales for doing so if formal enforcement is to be avoided;
- b) meeting with the Person Responsible to discuss requirements and improvement options (including formulating an improvement plan);
- c) sending a warning letter to the Person Responsible, informing him that formal enforcement will be undertaken if the identified remedial actions are not completed within a given time scale;
- d) use of unannounced inspection visits to monitor compliance.

3.3 Formal action may include:

- a) referring the case for consideration by the Licence Committee with a recommendation that the licence should be varied (including by imposing additional conditions);
- b) referring the case for consideration by the Licence Committee with a recommendation that the licence should be revoked (or suspended);
- c) referring the case for consideration by the Licence Committee with a recommendation for a short term licence and/or additional scheduled inspections to monitor compliance;
- d) exercising powers under paragraph 7 of Schedule 3B to the Act (taking possession of material from licensed centres during an inspection)
- e) applying for a warrant in accordance with paragraph 5 of Schedule 3B to the Act;
- f) where a criminal offence may have been committed, referring the matter to the police for criminal investigation; or
- g) Where professional codes of conduct may have been breached, referring the professional concerned to the relevant professional body.

3.4 The Authority's compliance department may take formal action if:-

- a) there are concerns about the ability of the Person Responsible to discharge his duties under Section 17 of the Act;
- b) the centre has not completed or does not appear likely to complete any necessary remedial action within the stipulated time frame;
- c) the centre has a previous history of non-compliance or failure to undertake remedial actions promptly or within required timeframes;
- d) there is a risk to patients or service users, or to gametes and embryos; or
- e) there is evidence that a criminal offence may have been, or is being, committed.

3.5 In deciding whether to take formal or informal action, the Authority's compliance department will use professional judgement, may take legal advice; and will act proportionately. The compliance department will not make a recommendation for the revocation (or suspension) of the Licence unless one or more of the requirements of Section 18(2) of the Act are met.

3.6 The key mechanism in deciding what action (if any) to take, will be the Management Review. Where the compliance department becomes aware that a centre may not be complying with the Act; licence conditions; directions; or the Code of Practice, a management review meeting will be held in relation to that centre. Subsequent review meetings may be held to monitor the situation.

3.7 The conduct of the Management Review meeting will be in accordance with the department's internal protocol and the review meetings will be minuted to provide an audit trail of the consideration of the case and to demonstrate compliance with the principles set out in this policy.

3.8 The management review will be conducted by a senior member of staff in the Authority's Compliance Department (at least "Head" level) and the person conducting the review may require the attendance of such other persons as s/he considers appropriate. Where the review is conducted by the Director of Compliance, s/he will not sit on the Executive Licensing Panel considering any recommendation made by him/her. Those conducting the review will at all times, seek to act in a way which is:

- Fair and non-discriminatory
- Targeted
- Efficient and effective
- Transparent
- Focused on patients
- Proportionate
- Risk focussed
- Timely
- Co-ordinated
- Consistent

3.9 In taking action or making recommendations to the Licence Committee, the Authority's compliance department will take account of the **attitude** of the PR and the centre's compliance history, the **risk** to patients and the **impact** on people using the service.

3.10 Any recommendations made in respect of proposed conditions should be "SMART" (Specific, Measurable, Achievable, Realistic and Time-bound)

- 3.11 The person conducting the Management Review shall formulate any recommendations to be made at its conclusion. Where the recommendation is that the matter should be referred to the police or that a warrant should be obtained, the recommendation must be brought to the attention of the Director of Compliance and the Chief Executive.
- 3.12 Where the Authority has reasonable grounds for suspecting that an offence under the 1990 Act is being or has been committed on any premises, it may apply to a Justice of the Peace for a warrant to enter, search and seize materials from those premises.
- 3.13 Where the Chief Executive has been informed that the recommendation of the Management Review is that a warrant should be applied for, he shall inform the Chair of the Authority of the recommendation and the reasons for it.
- 3.14 The Chair may consult the Deputy Chair and the Chair of the Audit and Governance Committee about the recommendation.
- 3.15 In the event of a disagreement amongst those consulted, the Chair may veto the recommendation. The decision to apply for the warrant shall otherwise be made by the Chief Executive.

4. THE INSPECTION PROCESS

4.1 The purpose of a routine inspection is to:-

- a) assess the extent to which centres comply with the Act; licence conditions; directions and the provisions of the Code of Practice;
- b) provide an independent and professional perspective on the running of the centre;
- c) promote good practice so that centres can improve the quality of service they provide to patients and donors;
- d) provide centres with a positive learning experience;
- e) provide centres with the opportunity to feed back on their experience of the inspection process, in order to assist the Authority to continually improve its procedures;
- f) give patients reliable information about a centre's compliance with statutory and other obligations, and about the quality and safety of licensed activities undertaken at that centre.

4.2 All inspections will be:-

- a) evidence based, consistent, proportionate and open to scrutiny;
- b) undertaken in a professional and courteous manner;
- c) be focused on risk;
- d) aim to add value for centres and service users.

- 4.3 Before undertaking a routine inspection, the Authority's compliance department will notify that centre in advance of the process and procedures to be followed, so that the centre is clear what will be required of it, has an opportunity to prepare and to minimise potential disruption to licensed activities being undertaken.
- 4.4 The core assumption will be that centres wish to demonstrate compliance with the Act; licence conditions; directions and the Code of Practice. The onus is on centres to demonstrate compliance, not on inspectors to find fault.
- 4.5 For each centre, the frequency and focus of inspections will be based on an explicit risk assessment taking account of the likelihood and potential impact of non compliance by that centre.
- 4.6 In assessing risk, the Authority will (where appropriate) seek to make use of online services, self assessment and input from centre's quality management systems.
 - 4.6.1 During the course of an inspection of a licensed centre, the inspection team may identify and require improvements to be made. The inspection team will explain to the Person Responsible for the centre why any improvement needs to be made and the legal basis for requiring it. The team will take account of the challenges a centre might face in meeting a requirement (but must always be mindful of the health, safety and well-being of people who use the service).
 - 4.6.2 A report of every inspection will be prepared. Persons Responsible for licensed centres will be shown the report in draft and will be provided with a reasonable opportunity to comment on the findings and recommendations of the draft report.
- 4.7 The lead inspector will normally provide the Person Responsible with the draft report 28 days after the completion of the inspection. The Person Responsible will be expected to provide any comments on the report within 2 weeks of the report being sent to him.
- 4.8 The final report will be formally signed off by the lead Inspector, on behalf of all the inspection team, as a professional assessment of compliance at the time of the visit; once signed off no changes will be made.
- 4.9 Once signed off, the report will normally be sent to the relevant decision maker for consideration within 30 working days (and sooner wherever possible).
- 4.10 After consideration by the relevant decision maker, routine Inspection Reports will normally be published on the Authority's website. Reports will be produced and published in a style and format which is accessible to all our stakeholders, particularly patients.

5. Serious Adverse Events; Serious Adverse Reactions and Adverse Incidents.

- 5.1 The Authority requires centres to notify it of all adverse incidents by telephone within 12 hours of discovery and to submit an HFEA adverse incident report form to the Authority within 24 hours of discovery. The report must contain the information set out in Direction 0011 (Reporting Adverse Incidents and Near Misses) and a copy of the report form is enclosed at Appendix 2. The Authority defines an adverse incident as "any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre, including serious adverse events and serious

adverse reactions, and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.” Serious Adverse Events, and Serious Adverse Reactions, are defined terms under section 15A of the Act.

- 5.2 The Authority acknowledges the real tension between the need to encourage reporting of serious adverse events, serious adverse reactions and incidents to the Authority in order to promote learning from such occurrences, and the need to ensure both that the Licence Committee has a complete picture of a centre before making its decision, and that where the occurrence reveals doubts about ability or competence, such issues are remedied promptly.
- 5.3 Where the Authority becomes aware of a serious adverse event or serious adverse reaction, or receives a request from an EEA competent Authority, it shall investigate the matter. The Investigation shall be conducted by the Head of Clinical Governance with a multi-disciplinary team made up of employees with relevant expertise.
- 5.4 Adverse Incidents will be triaged by the Incident Inspector when initially notified to the Authority, and will be graded on a scale of A, B or C, according to the criteria set out in Appendix 3. Incidents graded A and B will be discussed and confirmed with the Head of Clinical Governance. The Head of Clinical Governance will routinely review grades at the end of each month.
- 5.5 The Authority will require centres to investigate Grade C incidents themselves, and to produce an annual report to the Authority. The report should identify any relevant remedial actions and learning points.
- 5.6 The Authority will require centres to investigate Grade B incidents themselves, and to produce an incident investigation report to the Authority within 40 working days of the incident occurring. (Appendix 4) The report should identify any relevant remedial actions and learning points. The Authority’s Head of Clinical Governance or the inspector with responsibility for that centre will discuss with the centre the findings and recommendations made in the report, and will monitor how any remedial actions have been implemented. This may be included as part of the next planned inspection.
- 5.7 The Authority will conduct an investigation and incident inspection in relation to all Grade A incidents. The investigation shall be conducted by the Head of Clinical Governance with a multi-disciplinary team made up of employees with relevant expertise. The investigation shall take place as soon as possible after the Authority becomes aware of the incident. The Authority will require centres to investigate Grade A incidents themselves, and to produce a report to the Authority within 40 working days of the incident occurring. A report of the incident investigation will be prepared within 60 days of the inspection, and the Person Responsible for the centre will be provided with a reasonable opportunity to make comments on the draft report.
- 5.8 The Authority’s Licence Committee will be notified of all Grade A incidents and copies of the incident investigation report will be placed before the Licence Committee.
- 5.9 At the conclusion of the investigation (whether undertaken by the centre or the Authority), a management review shall be convened. The review will:-
 - a) confirm the final grading of the matter on a scale of A, B or C;

- b) identify relevant actions to secure any necessary improvements to systems or processes;
- c) identify any learning points and opportunities for the Authority to amend or issue guidance;
- d) decide whether the matter should be referred to a Licence Committee;
- e) decide whether the investigation indicates that the fitness to practise of a healthcare professional may be impaired and whether to refer the matter to the relevant professional body

5.10 Matters which are graded B or C will not normally be referred to the Authority's Licence Committee. Rather, the information about the matter will be considered for general trend analysis and learning points for the fertility sector.

5.11 Information about matters which are graded B or C will be passed to the inspector with responsibility for that centre, and will be used to inform subsequent inspections of that centre, which will focus on any weaknesses identified by the review.

5.12 Where appropriate, the Authority may :-

- a) disseminate alerts, learning points or guidance on issues arising out of serious adverse events, serious adverse reactions or incidents to other licensed centres and stakeholders in the fertility sector and wider health care sector, including other regulatory bodies (whilst protecting patient confidentiality); and
- b) amend existing guidance issued by the Authority or issue new guidance.

5.13 Where the investigation of a serious adverse event, serious adverse reaction or serious incident indicates potential concerns about the fitness to practise of a health care professional, the Authority will refer the matter to a relevant professional body such as the General Medical Council, the Nursing and Midwifery Council or the Health Professions Council. Where such a referral is made, the Authority will notify the licensed centre, and the professional concerned, of the fact of the referral.

5.14. All serious adverse incidents, serious adverse reactions and serious incidents of which the Authority becomes aware, shall be logged on a central database, and the Authority will consider an annual report on these matters. A copy of the report will be placed on the Authority's website. The report will focus on learning points for the fertility sector and will preserve patient confidentiality.

6. Complaints against licensed centres.

6.1 The Authority does not have a specific statutory duty to investigate patient complaints. However, complaints made by patients about the treatment or service that they have received at a licensed centre may impact on the Authority's duty to provide advice and information to patients. Depending on the issues raised, complaints may give rise to our duty to investigate serious adverse events or serious adverse reactions, or may be dealt with as a serious incident.

- 6.2 The Authority will only consider a complaint against a licensed centre where that complaint indicates a potential breach of the Act, licence conditions, directions or the Code of Practice. The Authority will not consider complaints that do not meet this criteria and in particular, will not consider complaints which are essentially contractual disputes between the patient and the centre.
- 6.3 The Authority will not adjudicate on patient complaints or act as a mediator between a patient and the centre. The Authority has no power to require licensed centres to make apologies or to provide refunds.
- 6.4 Before considering a complaint, the Authority will normally require the complainant to have utilised the centre's own complaints procedure, and may adjourn its consideration of the matter until such time as the centre's own investigation and complaints procedures have been concluded.
- 6.5 Complainants will be encouraged to make their complaints on the Authority's standard complaints form.
- 6.6 The Authority will not normally consider complaints if they are made more than six months after the complainant became aware of the matters that gave rise to the complaint, or six months after the conclusion of the centre's own complaints procedure.
- 6.7 The Authority will normally only investigate complaints where it has obtained consent to obtain relevant medical and other records relating to the treatment or service received at the centre, and which is the subject of complaints.
- 6.8 The Authority will not normally consider anonymous complaints, or complaints which it considers to be vexatious, persistent or an abuse of process. A complaint will be considered to be vexatious/persistent or an abuse of process if:-
- (a) it makes demands for action or information that would impact substantially and unreasonably on our work;
 - (b) it is persistently pursued when our complaints procedure has been fully and properly exhausted;
 - (c) the substance of the complaint is continually changed with new issues and concerns being raised whilst the complaint is being addressed or following conclusion of the review/investigation under our complaints procedure;
 - (d) the complainant refuses to identify precisely the issues that they wish to be investigated despite reasonable efforts by staff to help them identify their concerns;
 - (e) it is designed to cause disruption, annoyance or expense or has the effect of harassing the Authority including where the complaint is identical or substantially similar to a previous complaint made by or on behalf of the complainant;
 - (f) it can be fairly characterised as obsessive or manifestly unreasonable; or
 - (g) the subject matter of the complaint is, or has been the subject of legal proceedings.

6.9 When considering complaints the Authority will:-

- a) acknowledge all complaints received within five working days;
- b) keep complainants informed of the progress of their complaint;
- c) endeavour to ensure that complaints are handled fairly and as promptly as possible;
- d) provide persons who are the subject of a complaint with a reasonable opportunity to respond;
- e) inform complainants, the licensed centre and persons who are the subject of a complaint of the outcome of any investigation undertaken by the Authority;
- f) where appropriate, identify actions to secure any necessary improvements;
- g) where appropriate, disseminate learning points to other licensed centres and stakeholders in the fertility sector (whilst protecting patient confidentiality); and
- h) where appropriate, amend existing guidance issued by the Authority or issue new guidance.

6.10 Where a complaint indicates potential concerns about the fitness to practise of a health care professional, the Authority will refer the matter to a relevant professional body such as the General Medical Council, the Nursing and Midwifery Council or the Health Professions Council. Where such a referral is made, the Authority will notify the complainant, the licensed centre, and the professional concerned, of the fact of the referral, and will provide the complainant with the contact details for the relevant professional body.

6.11 Where a complainant is dissatisfied with the initial consideration of a complaint, he may request a review by the Head of Clinical Governance, within 10 working days of notification of the outcome of the initial consideration. A review will only take place if the complainant produces new or additional information which was not, for a valid reason, available at the time of the original consideration and which might have influenced its outcome

6.12. All complaints received by the Authority will be logged on a central complaints database, and the Authority will consider an annual report on the complaints notified to it. A copy of the report will be placed on the Authority's website. The report will focus on learning points for the fertility sector and will preserve patient confidentiality.

7. ROLES AND RESPONSIBILITIES

7.1 Inspectors shall be responsible for:-

- a) applying this policy in practice;
- b) ensuring that centres are informed in good time of the process to be followed during, and the focus of, inspections;

- c) making consistent, objective and evidence based professional judgments about a centre's compliance with the requirements of the Act, licence conditions; directions; and the Code of Practice;
- c) producing timely reports of inspections, and ensuring that the Person Responsible for a centre has a reasonable opportunity to comment on those report in draft;
- d) Keeping a robust audit trail;
- e) bringing concerns about compliance to the attention of the Director of Compliance.

7.2 The Director of Compliance shall be responsible for:-

- a) putting systems in place to ensure the monitoring and consistent application of this policy across the compliance department;
- b) ensuring that the outcomes of management reviews and recommendations made to the Executive Licensing Panel/Licence/Research Licence Committee are regularly audited for consistency;
- c) notifying the Chief Executive of any recommendation to refer a matter to the police or to obtain a warrant;
- d) alerting appropriate health and other services if a centre's licence is revoked or suspended

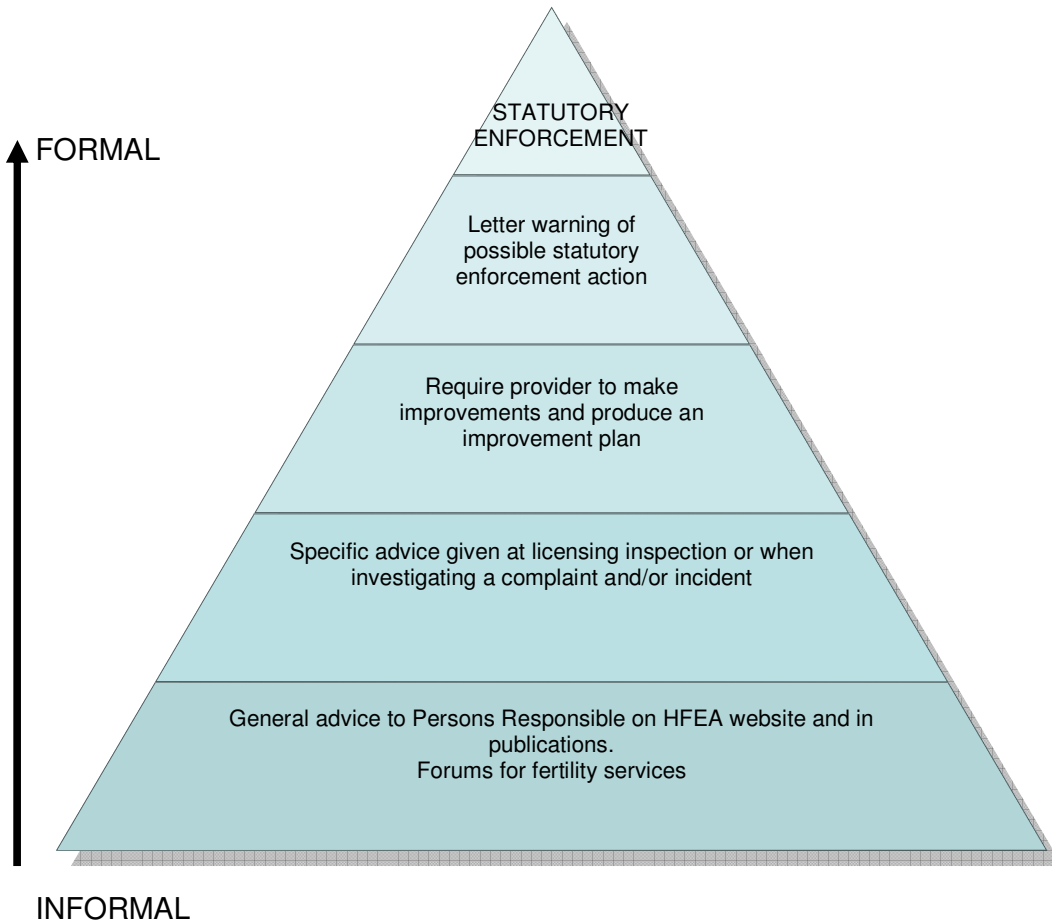
7.3 The Chief Executive shall be responsible for:-

- a) deciding whether or not a matter should be referred to the police;
- b) in consultation with the Chair of the Authority, deciding whether or not an application should be made for a warrant.

8. REVIEW

8.1 This policy will be reviewed annually.

8.2 The date of next review is 1st October 2010.



HFEA Incident Report Form		
Centre Details		
Centre Number		
Centre Name		
Person Responsible		
Report Type (Delete where appropriate)		
		Incident/Near Miss
Location (e.g. lab)		
Details		
Nature of damage/harm/loss		
Procedure involved		
Equipment involved		
Contributory factors identified		
Date incident occurred		
Date incident discovered (if different)		
Date incident reported (if different)		
Patients involved. If yes, please give numbers		
Embryos involved. If yes, please give numbers		
Gametes involved. If yes, please give numbers		
If samples harmed, please advise how many remain for patient		
Staff involved:	Names	Job titles
Witness (names and job title)		
Outcome of incident / near miss		
Patient/Partner informed		
Immediate action taken		

If appropriate, has equipment been quarantined?
Control measures planned
Other parties informed
Hospital management informed?
Additional services offered e.g. counselling and/or a complimentary cycle?
Investigation at local level planned?
Reporter details:
Name
Job title
Email
Phone

Appendix 3

Incident reporting protocols:

Risk matrix used to assess the severity of incidents and near misses, and the likelihood of a recurrence:

STEP1: Taking account of the current controls in place and their adequacy, how likely is it that this particular incident will occur again? Is this at this particular centre or all centres?

Probability of recurrence:

Level	Descriptor	
5	Almost Certain	Likely to occur on many occasions
4	Likely	Probable but not persistent
3	Possible	May occur occasionally
2	Unlikely	Not expected to happen but possible
1	Rare	Difficult to believe it could happen again

STEP 2: Again, taking account of the conditions and current controls in place and their adequacy, how severe would the consequences be if this incident occurred again?

Level	Descriptor	Actual or potential impact on individual	Actual or potential impact on organisation	Numbers affected	Potential for complaint or litigation
5	Severe	Death of patient/staff, loss of ALL samples for many patients	Multi-agency investigation, adverse publicity, prosecution, loss of HFEA licence	One (e.g. death) or many e.g. major dewar failure	Litigation expected/certain Possible prosecution
4	Major	Major harm, professional misconduct, loss of all samples for few patients, recurrent significant breach of COP	Costs, reputation damage, impact on staff morale, disciplinary hearings, loss of HFEA licence or conditions on practice	Smaller numbers 2-5	Litigation expected/certain. Action taken by professional organisations e.g. HSE, MHRA or GMC
3	Moderate	Semi-permanent harm, loss of all samples for one or loss of most samples for some patients, significant breach of COP	RIDDOR or MHRA reportable, compensation costs (complimentary cycle)	1-2	Litigation possible but not certain. High potential for complaint
2	Minor	Short term injury, minor breach COP, avoidable risk, loss of 1 of many samples for a patient.	Minimal risk to organisation	1	Complaint possible, litigation unlikely
1	Insignificant	No injury or adverse outcome	No risk to the organisation	1	Complaint and litigation unlikely

STEP 3: Risk Level Estimator

Likelihood →					
	Almost certain 5	Likely 4	Possible 3	Unlikely 2	Rare 1
Severe 5	25	20	15	10	5
Major 4	20	16	12	8	4
Moderate 3	15	12	9	6	3
Minor 2	10	8	6	4	2
Insignificant 1	5	4	3	2	1

Green 1-5 Grade C	Information only incident. <ul style="list-style-type: none"> Add to database as grade 'C' & save report form to TRIM Acknowledge & close, no paper records required
Yellow 6-12 Grade B	Incident investigation required <ul style="list-style-type: none"> Add to database as grade 'B' & save report form to TRIM Request details to examine adequacy of risk precautions, management controls & revised protocols. Site visit & incident inspection if appropriate Equipment quarantined if appropriate Liaise with external agencies & internal stakeholders Maintain contact with reporter until risks adequately controlled and file closed. If presented to LC, peer reviewed report required Incident & trend analysis. If appropriate, dissemination of information to other centres via HFEA Alert process, quarterly publication (Update) and/or centre's extranet.
Red 15+ Grade A	Incident inspection required <ul style="list-style-type: none"> Add to database as grade 'A' & save report form to TRIM Notify internal stakeholders Maintain contact with reporter – ensure equipment quarantined where appropriate Arrange site visit and incident inspection Incident inspection report Incident & trend analysis. If appropriate, dissemination of information to other centres via HFEA Alert process, quarterly publication (Update) and/or centre's extranet.

Incident Investigation Report

Summary Incident Description & Consequences			
Incident type:			
Specialty/Location:			
Effect on patient:			
Severity level:			
Scope and Level of Investigation			
Involvement and support of Patient and Relatives			
Chronology of events - See table below			
Notable Practice:-			
Care and Service Delivery Problems (Themed and prioritised)			
Contributory Factors			
Root Causes			
Lessons Learned			
Recommendations			
Action Plan - See table below			
Implementation, monitoring and evaluation arrangements			
Arrangements for sharing and learning			
.			
Author		Date	

Chronology of events	
Date & Time	Event

Action Plan - Example			
Incident No:	Action 1 ↓	Action 2 ↓	Action 3 ↓
Root CAUSE Number as per investigation report			
EFFECT on patient/service			
Recommendation(s) to address root cause (or rationale, if no action or recommendation is set) Number as per investigation report			
Action(s) to achieve recommendations Numbered			
Level for action (organisation, directorate, team etc)			
Implementation by whom:-			
Implementation by when:-			
Resource required (time)			
Resource required (money)			
Resource required (other)			
Evidence of completion			
Monitoring and evaluation arrangements			
Sign-off by:-			