Compliance and enforcement policy

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	**8**		
Paper number	HFEA (09/03/2016) 788		
Meeting date	09 March 2016		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For decision		
Recommendation	It is recommended that the Authority agrees the revised Compliance and enforcement policy and 'Guidance on licensing'		
Resource implications	In budget		
Implementation date	1 April 2016		
Communication(s)	Publication through usual channels		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Compliance and enforcement policy Annex 2: Guidance on licensing		

1. Background

1.1. It is good practice that regulators set out in public their general approach in ensuring compliance with regulatory requirements. The regulated need to know what is expected of them to achieve compliance and the steps that the regulator might take if compliance is not evident. The HFEA has had such a Compliance and enforcement policy since 2009. The policy sets out, first, the routine actions by which the HFEA judges compliance, notably inspection and the licensing process; and, second, importantly, the steps we would take to escalate and manage concerns about regulatory compliance.

1.2. At its September 2015 meeting the Authority considered a proposed revised policy together with changes to two 'indicative' guidance documents provided to licensing committees[1]; the first regarding the length of licences granted[2] and the second regarding the potential sanctions that might be applied[3], where concerns relating to poor performance are evident.

1.3. The Authority agreed that the proposed documents should be subject to focused consultation – and piloting – which has now been undertaken. This paper presents the revised policy (at annex 1) and proposes a new single guidance document on licensing drawing together the two documents referred to above (at annex 2).

2. The compliance and enforcement policy

2.1. The compliance and enforcement policy aims to provide licensed centres and society with clear signals about the responses and standards they can expect from the Authority when it is dealing with non-compliance. The policy also guides the compliance team when there are difficult decisions to be made about whether non-compliance with regulatory requirements poses a significant risk such that suspension or revocation of a licence may be warranted.

2.2. The consultation exercise sought views through Clinic Focus and we also engaged members of the Licensed Centres Panel and principal professional stakeholders. There was a modest response, but all respondents were supportive and saw considerable sense in the proposals – on the basis that it provided greater clarity and certainty about the conduct of any review or investigation when performance concerns are evident.

2.3. The main proposed changes to the policy relate to the factors that govern the escalation of concerns and the arrangements for investigating them, and then the reporting of them to a licensing

[1] The HFEA Licence Committee, and the Executive Licensing Panel
[2] HFEA guidance on periods for which new or renewed licences should be granted
[3] HFEA indicative sanctions guidance for Licence Committees

committee. The aim throughout has been to provide greater clarity and transparency – to the licensed centre and to the HFEA team. The revised document is slightly different in style to that consulted on to make the policy clearer for centres and HFEA staff.

2.4. It is important to note the policy places no new or additional requirements on licensed centres. No material changes to the way we go about inspection and checking compliance at a routine level are expected. Greater clarity as to how we go about dealing with concerns is provided, but again these are not new or additional requirements.

2.5. Routine inspection findings, based on evidence and observations, are effective in highlighting where improvements are required. Usually there is no immediate and/or direct risk to patients, their gametes or embryos; and effective recommendations for improvement can be framed and implemented. These matters are set out in section 2 of the policy. For many centres most of the time this is the only element of the policy that they will need to be familiar with.

2.6. Where there is a possibility further to inspections, or from other information or activity, that more serious regulatory sanctions may need to be applied (due to the severity and nature of the non-compliance) further review of a clinic's practices is needed. The first step in doing so will be a management review. This is set out in section 3 of the policy. Such a review might be needed to determine whether a particular non-compliance (s), represent a one-off occurrence, a practice, or are indicative of other serious failings. Relations between the HFEA and the licensed centre can become strained at such times and there may be barriers to conducting further investigations for fear of accusations of harassment; and centre staff may feel or allege they are being treated differently and/or disproportionately.

2.7. The policy has been revised to clarify the action that may be appropriate in such circumstances. Such action might include further, potentially forensic, scrutiny of a centre's practices where there are, or may be, risks to the safety of patients or to their gametes or embryos, or where a serious breach of the Act is observed or suspected. The aim is to ensure that centres are only subject to such scrutiny if concerns are suitably serious, while empowering the compliance team in what may otherwise be challenging circumstances.

2.8. The revised policy also now sets out the circumstances in which a report of the findings of any investigation will be drafted and referred to a licensing committee. Where an investigation concludes that concerns have no foundation with no recommendations for improvement the policy states that no further action beyond documenting this finding in the management review record will be taken.

2.9. There are also amendments to the process by which a warrant might be sought. Such a serious decision, though very rare, requires a particular escalation process and for the first time, the revised policy sets out the

principles that should be applied in decided whether to make such an application.

3. Guidance on licensing

3.1. The proposals presented to the Authority in September 2015 also indicated a review of guidance relating to periods for which new or renewed licences should be granted, and guidance on indicative sanctions that may be applied.

3.2. The guidance has been substantially changed and consolidated within a single 'Guidance on licensing' document, at annex 2. This has been done to bring greater coherence and to reflect the fact that a decision on the length of a licence to be issued is a regulatory tool in itself; to see that as separate to guidance on sanctions is artificial. The principal changes are set out below:

The length of licence

3.3. Consideration of the centre's history will routinely include (but not be restricted to) consideration of the committee minutes from the time of the centre's last renewal or four years (whichever is more recent); implementation of recommendations made at the time of the last inspection; and co-operation with any alerts, advice and/or recommendations made in the intervening time.

3.4. In deciding the duration of a licence the committee should consider the scale of non-compliance; the PR's apparent understanding of the impact of the non-compliance; the PR's commitment (or otherwise) to implement corrective actions within agreed timescales; and the risks of non-compliance to safety of patients, their embryos or gametes, and/or the quality of service at the time that the decision is being made.

3.5. The committee should also consider the quality of service provided by the centre. To assure consistency and proportionality consideration of quality should be based on observation of the centre's success rate trends, clinical multiple pregnancy and birth rates and feedback provided by patients.

3.6. The guidance suggests that four year licences remain the norm for treatment centres; three year licences are considered where there are concerns where further focused inspection after one year might be useful; that two year licences are not routinely issued, except in respect of new centres with no licensing history; and one year licences are issued where concerns give rise to the need for a full inspection within one year.

3.7. Consideration is given to the issue of Special Directions, or a short-term licence, in exceptional circumstances, where a centre's licence is likely to expire before it can be demonstrated that substantive improvements have been effective.

3.8. For some time we have grappled with how we might provide a more public assessment of the performance of clinics within a range – for example in the way that Ofsted rate a school 'outstanding', 'good' or 'needing improvement'. As a licensing authority we can grant a licence or not – and there are legal and resource complications in making subjective assessments to promote consumer/patient awareness, comparison and so on.

3.9. However, given the limited range of 'incentives' available to us, we believe there are substantial advantages in better linking centres' relative performance and the length of licence granted – an evidence based judgment made by a licensing committee at the time the licence is granted.

3.10. Members will be aware that a range of options has been considered relating to the forthcoming new website and 'Choose a fertility clinic' tool – regarding the headline measures. Alongside outcome rates and patients' feedback we plan to use the length of licence to provide the 'what do inspectors say about this clinic?' input.

Sanctions

3.11. The changes retain the features of the current guidance particularly regarding the statutory basis for applying sanctions and seeks to closer align guidance with the sections of the Act that set out when the Authority may vary (for example, by adding a condition to a licence), suspend or revoke a licence. The guidance has been revised to emphasise the following as factors that a licensing committee might consider in reaching a decision:

3.12. The guidance also seeks to simplify and clarify the aggravating and mitigating features that a licensing committee may consider in any matters of non-compliance reported to it.

4. Recommendation

4.1. The Authority is to consider:

- the revised Compliance and enforcement policy.
- the new Guidance on licensing.

4.2. If the Authority is content with the documents, we will undertake style and format improvements to ensure that they convey the agreed information as clearly as possible.

Compliance and enforcement policy

1 About this policy

1.1 This Compliance and enforcement Policy (policy) sets out the broad approach that the Authority will take in dealing with non-compliance by licensed clinics and research centres.

1.2 The policy has two aims:

- to provide clarity for centres and society about how we will respond to non-compliance in the sector we regulate; and
- to provide HFEA inspectors and other staff with a clear framework for making regulatory decisions.

1.3 This policy has been produced in accordance with the Authority's powers and meets its statutory duties[1] to carry out its functions effectively, efficiently and economically and with due regard to the principles of best regulatory practice. Such practice is guided by the Regulators' Code[2] which sets out that regulators (such as the HFEA) should:

- carry out their activities in a way that supports those they regulate to comply and grow
- provide simple and straightforward ways to engage with those they regulate and hear their views
- should base their regulatory activities on risk
- should share information about compliance and risk
- should ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply
- should ensure that their approach to their regulatory activities is transparent.

1.4 The Authority manages compliance and enforcement through a range of mechanisms. Most non-compliances and performance are addressed through day-to-day contact between the centre and its inspector and through the scheduled statutory inspection and licensing process. This element of the regulatory regime is set out in section 2 below.

1.5 More serious areas of non-compliance or poor performance may be identified through scheduled inspections or from other information or activity. These non-compliances may require other regulatory mechanisms, including investigations, written warnings, referral to professional bodies or the police, or the application of a warrant to search licensed premises. The escalation and management of such serious concerns is set out in section 3 below.

1.6 This policy replaces all previous policies relating to these matters. It should be read alongside the Authority's Guidance on Licensing.

[1] Section 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended)
[2] Better Regulation Delivery Office April 2014
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf

2 Inspections and licensing

2.1 The HFEA's regular interactions with centres is inspection. Centres must be inspected at intervals not exceeding two years. The purpose of an inspection is to:

(a) assess the extent to which centres comply with the requirements of the Human Fertilisation and Embryology Act 1990 (as amended) as set out in licence conditions, Directions, the Code of Practice and all applicable statutory provisions

(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.

2.2 All inspections are:

(a) Evidence-based, consistent, proportionate and open to scrutiny

(b) undertaken in a professional and courteous manner

(c) focused on risk; and

(d) aim to add value for centres and service users.

2.3 During the inspection, the inspection team may identify and require improvements to be made, taking into account any mitigating factors. The inspection team will give the Person Responsible (PR) reasons for making the recommendations.

2.4 After the inspection, the inspection team will prepare a report and show it to the PR in draft. The PR will be given a reasonable opportunity to comment on the findings and recommendations of the draft report.

2.5 The report will be sent to the Executive Licensing Panel or Licence Committee, which will then decide whether a licence should be granted, renewed or allowed to continue. Where there are concerns about the centre's compliance with regulatory requirements, the Executive Licensing Panel or Licence Committee can decide whether a licence should be varied (for example, adding a condition to the licence), revoked or suspended (see section 3).

2.6 After consideration by the Executive Licensing Panel or Licence Committee, inspection reports will normally be published on the Authority's website.

3 The management of centres with serious areas of non-compliance

3.1 Where the inspection team becomes aware of concerns about a centre's compliance or performance, a *management review* meeting will be held to evaluate the risk and determine a proportionate course of action. The review will usually include an inspector and at least one senior member of the team and any such other persons considered appropriate. A record of the management review meeting will be kept.

3.2 Following an evaluation of the quality of the service, in particular the actual or potential risks to the safety of patients, gametes and or embryos arising as a consequence of the concerns under investigation, the management review will consider the most appropriate action, which may include any or all of the following:

(a) implementation of a period of performance monitoring

(b) contacting and/or meeting with the PR and/or other key staff members to discuss concerns

(c) an investigation into the foundation, scope and/or scale of concerns. This may include commissioning a review by an expert

(d) an unannounced or scheduled inspection visit (depending on the nature of the concerns under investigation). Where there are concerns that non-compliance has posed or may pose a risk to the safety of patients, their gametes or embryos, or where a serious breach of the Act is suspected, the inspection may include detailed scrutiny of some or all of a centre's practices. The PR will usually be informed of the details of any concerns or allegations under investigation. Where it is necessary to protect the identity of a whistle-blower or information source the investigation or inspection may be initiated before the full details of any concerns or allegations are provided to the PR

(e) where investigation identifies areas for improvement, completion of a report of the findings of the investigation informing the PR of the required improvements and the timescales for their implementation

(f) where an investigation concludes that concerns have no foundation with no recommendations for improvement no further action beyond documenting this finding in the management review record will be taken

(g) sending a warning letter to the PR, informing them that enforcement will be undertaken if the identified improvements are not completed within a given time scale

(h) referring a report of the findings of an investigation to the Executive Licensing Panel or Licence Committee documenting the recommendations for improvement.

3.3 Where the management review judges that there are serious risks to the safety of patients, gametes and/or embryos, the following actions may be taken, with or without recourse to the actions described at 3.2 above:

(a) referring a report for consideration by the Executive Licensing Panel or Licence Committee with a recommendation that the licence should be varied (including by the imposition of additional conditions)

(b) referring a report for consideration by the Licence Committee with a recommendation that the licence should be revoked (or suspended)

(c) exercising powers under Section 39 of the Act (taking possession of material from licensed centres during an inspection)

(d) applying for a warrant in accordance with Section 40 of the Act

(e) where a criminal offence may have been committed, consideration given to referring the matter to the police for criminal investigation

(f) where professional codes of conduct may have been breached, referring the professional concerned to the relevant professional body

(g) where concerns may be relevant to another regulator, informing the relevant regulatory body.

3.4 In deciding whether to take any of the actions set out at 3.3 above the Executive should consider that one or more of the following tests are met:

(a) there are concerns about the ability of the PR to discharge his or her duties under Section 17 of the Act

(b) the centre has not completed, or does not appear likely to complete, any necessary recommendations for improvement within the stipulated time frame

(c) the centre has a previous history of non-compliance or failure to implement recommendations for improvement promptly or within required timeframes

(d) there is a risk to patients or service users, or to gametes and embryos

(e) there is evidence that a criminal offence may have been, or is being, committed.

3.5 In deciding what actions to take the Executive will use professional judgement, may take legal advice; and will act proportionately. The inspection team will not make a recommendation for the revocation (or suspension) of the licence unless one or more of the requirements of Section 18(1) or (2) of the Act are met.

3.6 A decision to refer a centre or an individual to an external body should only be made by agreement with the Chief Inspector and/or the Director of Compliance and Information. If it is judged that a matter should be referred to the police or that a warrant should be obtained, the recommendation will be brought to the attention of the Chief Executive.

3.7 Where the Authority has reasonable grounds for suspecting that an offence under the 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.

3.8 Where the Chief Executive has been informed that the recommendation of the management review is that a warrant should be applied for, he or she will inform the Chair of the Authority of the recommendation and the reasons for it. In reaching a decision to seek a warrant, the following principles should be applied:

- the decision should be proportionate to any harm that might be caused
- patient safety should be compromised or at risk of being compromised

- any relevant ongoing licensing or regulatory action has been exhausted or there is a clear reason why acting outside of those actions would be justified
- the decision and the rationale for the decision is carefully and contemporaneously documented.

3.9 The Chair may consult the Deputy Chair and the Chair of the Audit and Governance Committee about the recommendation.

3.10 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.

1 April 2016

Guidance on licensing

1. About this guidance

1.1 This guidance sets out the range of factors that licensing committees of the Authority (the Licence Committee and the Executive Licensing Panel) may take into account when reaching a decision in respect of a licensed clinic or research centres.

1.2 The guidance has two aims:

- to provide clarity for centres and society about the factors which guide any licensing decision by the Authority; and
- to provide members of licensing committees of the Authority with a clear framework for making decisions about the length of a licence and what sanctions, if any, to apply.

1.3 The application of this guidance should ensure that any decision to apply or determine penalties is fair and consistent, although any decision on fairness can only be a matter for a licensing committee.

1.4 This guidance has been produced in accordance with the Authority's powers and meets its statutory duties[1] to carry out its functions effectively, efficiently and economically and with due regard to the principles of best regulatory practice. Such practice is guided by the Regulators' Code which sets out that regulators (such as the HFEA) should:

- carry out their activities in a way that supports those they regulate to comply and grow
- provide simple and straightforward ways to engage with those they regulate and hear their views
- base their regulatory activities on risk
- share information about compliance and risk
- ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply
- ensure that their approach to their regulatory activities is transparent.

1.5 Any centre wishing to offer assisted reproduction services or undertake research on human embryos in the UK can only do so under licence from the HFEA. The Authority has the power to decide what length of time to issue a licence and the factors which guide this decision are set out in section 2 below.

1.6 The Authority also has the power to apply a range of sanctions to a licence, including the power to vary, suspend or revoke the licence. In making such a decision a licensing committee is taking a serious decision with significant consequences for the centre. The factors which guide this decision are set out in section 3 below.

1.7 This guidance replaces all previous guidance relating to these matters[2]. It should be read alongside the Authority's compliance and enforcement policy.

[1] Section 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended)
[2] The HFEA indicative sanctions guidance for licence committees and HFEA guidance on periods for which new or renewed licences should be granted

2. The length of a licence

2.1 A treatment or storage licence cannot be granted for more than five years and a licence for research cannot be granted for more than three years[3]. The Authority has decided that the length of licence granted is a reasonable measure of the quality of service provided by the centre.

2.2 The following are matters that a licensing committee may take into account when deciding the duration of a licence.

- **The centre's history of compliance**: consideration of the clinic history including (but not restricted to)
  - consideration of the committee minutes from the time of the clinic's last licence renewal
  - implementation of recommendations made at the time of the last inspection
  - co-operation with any alerts, advice and/or recommendations made since the last inspection.

  Where there is evidence of failure to implement recommendations for improvement and/or take appropriate action with respect to alerts, advice or guidance, then there may be good reason to undertake a focused site visit to a centre outside of the normal inspection cycle so that evidence of the implementation of effective corrective action can be reviewed. This approach is intended to encourage regulatory compliance.

- **Evidence of non-compliance with statutory requirements**: the licensing committee will consider the scale of non-compliance; the Person Responsible's (PR) apparent understanding of the impact of the non-compliance(s); the PR's commitment (or otherwise) to implement corrective actions within agreed timescales; and, most importantly, the risks to the safety of patients, their embryos or gametes, and/or the quality of service at the time that the licensing decision is made.

  This is to ensure proportionality. Where a report documents a large number of non-compliances, but there has been a prompt and effective response it is recognised that the risks associated with non-compliance are likely to have been mitigated. Where, however, the PR's response indicates a failure to commit to make improvements or a failure to appreciate the seriousness of the non-compliances, it may be appropriate to request a focused site visit within a specified period of time so that evidence of the implementation of effective corrective action can be reviewed. This approach is, again, intended to encourage regulatory compliance.

- **Quality of service provided:** the licensing committee will consider the quality of service provided by the centre. To assure consistency and proportionality consideration of quality is based on observation of the centre's success rate trends, clinical multiple pregnancy and birth rates, and feedback provided by patients.

2.3 In taking into account the factors above, the licensing committee will usually offer an appropriate length of licence based on the following circumstances:

[3] Schedule 2 of the Act

Annex 2

Length of licence	Anticipated circumstances of issue	Consequence
4 years	A four-year licence will usually be offered where: • a centre has taken appropriate and timely action in relation to any non-compliances identified as posing a risk to patients, their gametes or embryos • where the PR has given a commitment to implement all the required recommendations in relation to critical and major non compliances • the clinic's history suggests that the PR has previously implemented recommendations for improvement and/or advice and guidance • there are no serious concerns about the quality of service based on observation of success rates; multiple pregnancy and birth rates; and patient feedback.	A four-year licence minimises the regulatory burden for centres with an unannounced observation based interim inspection occurring at year two.
3 years	A three-year licence will usually be offered where: • there is a history that indicates a previous failure to implement recommendations for improvement in the time since the last licence renewal; • there are concerns related to quality of service; A three-year licence will also usually be offered where the application is for a licence for research.	A three-year licence would allow a centre to be subject to an interim inspection within one year (rather than the usual two) to review evidence of implementation of recommendations and/or to review quality of service. This could be scheduled or unannounced.
2 years	Two-year licences are only usually offered where the centre is new, and there is no licensing history to guide licensing decisions a two-year licence can be offered.	A newly-licensed centre can be offered a licence of any length but it is usual to offer a two year licence enabling an 'interim' (mid-point) inspection during the first year providing a useful indication of early performance and progress.
1 year	A one-year licence will usually be offered where concerns are more serious and there are doubts that improvement will be sustained but there is no immediate and/or direct risks to patients, their gametes or embryos.	A one-year licence has adverse administrative consequences for licensed centres but is necessary where there are serious wide ranging concerns and there is either a poor history of compliance or insufficient information to assure a committee that the required improvements will be made.
Adjournment and/or issue of Special Direction or short-term	Where there is a history that suggests serious concerns about a PR's ability to ensure regulatory compliance, a licensing committee could adjourn a decision (perhaps requiring issue of Special Directions or a short-term	A licence is only granted **after** the PR is able to demonstrate that the recommendations for improvement have been implemented and that they have been **effective** in

licence	licence) pending the submission of further evidence.	preventing recurrence of non-compliance.

3. Sanctions

3.1 Where a licensing committee considers it necessary to impose sanctions on a licence, this represents a serious step and will usually only be taken where there is significant non-compliance with the requirements of the Human Fertilisation and Embryology Act 1990 (as amended), licence conditions, Directions, the provisions of the Code of Practice or any other applicable statutory provisions.

3.2 The purpose of sanctions is to:

- promote compliance with the requirements of the Act and the Code of Practice issued by the Authority
- protect those using, or affected by, the services offered at centres licensed by the Authority; and
- maintain public confidence in the conduct of licensed activities within the United Kingdom.

3.3 In considering whether or not to apply a sanction, the licensing committee has to exercise a discretion, and will do so in a way that is fair and reasonable. This will require the licensing committee to take into account the interests of the licence holder or PR against the factors set out in paragraph 3.2, above.

3.4 The sanctions available to a licensing committee are limited by the Human Fertilisation and Embryology Act. The licensing committee can, vary, suspend or revoke a licence.

3.5 A licensing committee may vary a licence (for example, add conditions to a licence where it has the power to revoke a licence)[4]. In deciding whether to vary a licence, the committee may take into account whether:

- the non-compliance is capable of being remedied
- appropriate and realistic conditions can be formulated
- the Person Responsible (PR) has shown insight and is likely to comply with any conditions imposed.

3.6 A licensing committee may suspend a licence[5]where it:

- has reasonable grounds to suspect that there are grounds for revoking the licence; and
- is of the opinion that the licence should immediately be suspended.

3.7 It may, by notice, suspend the licence for up to three months as may be specified in the notice. The licensing committee may, by further notice, renew or further renew the original suspension.

3.8 In deciding to suspend a licence, the licensing committee may take into account the following:

- there is failure by the PR to ensure that suitable practices are used to ensure the safety of patients, their gametes or embryos and/or the quality of service

[4] S.18A (3)
[5] S19C (1) and (2)

- there is failure by the PR to ensure compliance with the conditions of the licence where this may carry a risk to the safety of patients, their gametes or embryos and/or the quality of service
- the PR ceases to be considered a suitable person by virtue of dishonesty and/or failure to cooperate with investigations particularly where this may have compromised the safety of patients, their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure suitability of staff; that proper equipment is used or that premises are suitable, particularly where this has had an impact or may impact on the safety of patients, their gametes or embryos and/or the quality of service
- public confidence in the conduct of licensed activities requires immediate action
- no suitable person is available to act as PR
- conditions cannot be adequately framed and/or would be unworkable in practice
- there is evidence of previous breaches of conditions or Directions issued by the Authority
- there is evidence of a history of significant non-compliance
- there is a reasonable expectation that following a period of suspension performance can return to acceptable standards.

3.9 A licensing committee may revoke a licence[6] where:

- it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading
- it is satisfied that the PR has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17
- it is satisfied that the PR has failed to comply with directions given in connection with any licence
- it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity
- it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence
- it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence
- it ceases to be satisfied that the PR is a suitable person to supervise the licensed activity
- the person responsible dies or is convicted of an offence under this Act, or
- it is satisfied that there has been any other material change of circumstances since the licence was granted.

3.10 In deciding to revoke a licence, the Committee may take into account the following:

- there is failure by the PR to ensure that suitable practices are used to ensure the safety of patients their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure compliance with the conditions of the licence where this may carry a risk to the safety of patients their gametes or embryos and/or the quality of service
- the PR ceases to be considered a suitable person by virtue of dishonesty and or failure to cooperate with investigations particularly where this may have compromised the safety of patients their gametes or embryos and/or the quality of service
- there is failure by the PR to ensure suitability of staff; that proper equipment is used or that premises are suitable particularly where this has had an impact or

[6] S.18 (2)

may impact on the safety of patients their gametes or embryos and/or the quality of service
- public confidence in the conduct of licensed activities requires immediate action
- no suitable person is available to act as PR
- conditions cannot be adequately framed and/or would be unworkable in practice
- there is evidence of previous breaches of conditions or Directions issued by the Authority
- there is evidence of a history of significant non-compliance.

3.11 In making a decision, the licensing committee shall also have regard to the range of sanctions available, and will seek to ensure that any sanction applied is proportionate in all circumstances of the case. When considering whether to impose a sanction and what sanction to impose, a committee may take into account the following aggravating and mitigating features:

Aggravating features	**Mitigating features**
Failure by the PR and centre staff to cooperate with any inspection or investigation undertaken by the executive, or attempts to frustrate any inspection or investigation by introducing delays such as failure to respond to correspondence and being unavailable for meetings and so on.	Full cooperation by the PR and centre staff with any inspection or investigation undertaken by the executive
Non-disclosure of material information that may assist with the inspection or investigation and may conceal relevant facts or evidence.	Full disclosure of material information with no attempt made to conceal facts or evidence
A lack of insight by the PR and centre staff in to the seriousness of the non-compliance and the action being taken by the executive.	Insight demonstrated by the PR and centre staff with regard to the nature and serious of non-compliance and an understanding of the reasons why the action is being taken by the executive
Failure by the PR and centre staff to take any or sufficient and sustained action in remedying non compliance	There is evidence that early and effective remedial action has been taken by the PR and centre staff.
There is limited or no evidence of good cooperation and productive working relationships between the PR and centre staff, such that little or no confidence that remedial action will be sustained can be drawn.	There is evidence of good cooperation and productive working relationships between the PR and centre staff, such that greater confidence that remedial action will be sustained can be drawn.
Failure to provide the Authority with information required to be included in the statutory register under section 31 of the Act, or with any other information required.	The provision of information to the Authority made promptly on request.

1 April 2016

Governance and transparency

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (09/03/2016) 789		
Meeting date	9 March 2016		
Author	Juliet Tizzard, Director of Strategy and Corporate Affairs		
Output:			
For information or decision?	For decision and information		
Recommendation	The Authority is asked to: • note the committees' annual reviews; and • agree the changes to Standing Orders.		
Resource implications	Minimal		
Implementation date	1 April 2016		
Communication(s)	Via the website		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex A: Standing Orders		

1. Introduction

1.1. For the HFEA to be an effective and trusted regulator, we must have high quality decision making processes which are clear to clinics, patients and the wider public. To achieve that, we have a number of committees, with clear instructions from the Authority about how they should make decisions. These are in our Standing Orders and explained on our website.

1.2. This paper is an annual review of our governance structures, consisting of:

- the findings of the annual review of each committee's effectiveness; and
- a review of our Standing Orders.

2. Annual review of committee effectiveness

2.1. All committees have carried out the required annual review of their effectiveness. Generally, the feedback was positive and committees have done well to incorporate new Authority members.

2.2. The committees which make licensing and authorisation decisions have fewer concerns about succession planning and quoracy than in last year's review, although there are still a few technology issues to iron out to ensure remote attendance works smoothly.

2.3. The Scientific and Clinical Advances Advisory Committee is making good use of external speakers. It is spending much of its efforts feeding into patient information about new technologies and would like specific reference to patient information in its terms of reference (see below). It would also like to strengthen links between the committee and professional societies.

2.4. The table below summarises the feedback from each committee.

Committee	Positives	Areas for improvement
Licence Committee	The new members have settled in well. They have demonstrated excellent insight and raised important issues. The scientific expertise within the committee has enabled the committee to function without the attendance of external advisers. The committee has retained oversight of tougher licensing decisions. Successful feedback loop due to attendance of the Head of Governance and Licensing.	Technical problems with some aspects of the video conferencing which need to be addressed, as quoracy can be dependent on attendance via this channel. Member availability is still an issue which could affect quoracy and decision making capability. The committee noted on very rare occasions there are delays in receiving documents which results in tabled papers.
Statutory Approvals	The addition of external advisers has continued to be extremely valuable and	A possible evaluation of the use of Genetic Alliance opinions and exploring a

Committee	has greatly improved the quality of committee's deliberations. Effective chairing to manage differences of opinion whilst maintaining collective ownership of decisions. Successful feedback loop due to attendance of the Head of Governance and Licensing.	patient perspective as an alternative. Keeping the committee up to speed with new technologies and techniques and feedback from the sector via the inspection team. This could be achieved via a periodic workshop. A review of regulation and licensing of x-linked conditions and what conditions are appropriate for PGD testing.
Executive Licensing Panel	The committee functions well, takes consistent decisions despite having a frequently used deputy chair and the paperwork and minutes are well drafted. The volume of work and high frequency of meetings are manageable.	There have been some discussions between Licensing and the Inspectorate to improve the flow of paperwork, but this generally works well.
Audit and Governance Committee	The committee continues to benefit from having external members and the new members have integrated well. The relationships between the chair, committee and internal and external audit are well developed and function well. Recommendations from last year regarding annual reviews have been implemented and inspection observations are in progress. The committee has made suggestions such as the gateway review, which has been extremely helpful to IfQ.	Could challenge the executive even more robustly to get past the natural 'can do' attitude of the HFEA, to really delve in to the issues. Formal reporting to the Authority. This will be introduced from July 2016.
Scientific and Clinical Advances Advisory Committee	The committee has sufficient members with a broad range of views and the meetings are well attended. Successful use of a briefing document for external speakers to provide context on where their contribution fits in to the committee's work. The committee agreed that meetings were chaired well, follow up was effective and papers and minutes were high quality.	The committee felt that there should be greater clarity around the committee's function and what its primary audience should be. The committee could evaluate external speakers more formally. It was agreed that early sight of papers could facilitate expert input by committee members at the drafting stage. Relationships with specialist groups could be strengthened, and collaboration on patient information would be useful.
Remuneration, Appointments and Oversight committees	*Formal reviews not undertaken due to infrequency of meetings*	
Appeals	The committee has heard one appeal this year. The Audit and Governance Committee has had an early discussion of a review of the appeals process in the light of this appeal. This will be considered later in the 2016/17 business year.	

3. Review of Standing Orders

3.1. The Authority agreed, at its September 2015 meeting, to amend the Standing Orders to allow delegation of licensing and authorisation of mitochondrial donation. These changes are reflected (and highlighted) in the Standing Orders (Annex A).

3.2. We have made a number of small consequential amendments to reflect changes of job titles (from Head of Governance and Licensing to Head of Corporate Governance) and names of guidance documents for licensing (see separate paper on the Compliance and enforcement policy).

3.3. One further amendment has been made to the Scientific and Clinical Advances Advisory Committee's purpose. This is to reflect SCAAC's role regarding patient information and safety and efficacy (see page 37 of the Standing Orders).

Functions of the Scientific and Clinical Advances Advisory Committee

6.2 The functions of the Scientific and Clinical Advances Advisory Committee shall be to:

(a) make recommendations to the Authority on ~~policy implications arising out~~ the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas

(b) make recommendations to the Authority on patient information relating to those scientific and clinical developments

(c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and

(d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

4. Recommendation

4.1. The Authority is asked to:

- note the committees' annual reviews; and
- agree the consequential changes to Standing Orders and those regarding SCAAC's remit.