

Compliance and enforcement policy

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting	Authority
Agenda item	14
Paper number	HFEA (16/09/2015) 771
Meeting date	16 September 2015
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Output:

For information or decision?	For decision
Recommendation	It is recommended that the Authority agrees the revisions proposed in this paper and its annexes.
Resource implications	In budget
Implementation date	Draft policy to be published on website and publicised in a Clinic Focus article. September to December 2015: focussed consultation and piloting of policy. Implementation of final revisions: December 2015. Final revisions referred to Authority early 2016.
Communication(s)	Policy to be published in final form April 2016.
Organisational risk	<input type="checkbox"/> Low <input type="checkbox"/> Medium <input checked="" type="checkbox"/> High
Annexes	Annex 1: A review of matters to be considered on renewal or grant of a licence as referenced in indicative applications guidance Annex 2: Advantages and disadvantages of licences of different lengths Annex 3: Factors which a Licensing Committee may consider to be aggravating features when considering whether to impose regulatory sanctions Annex 4: Compliance and Enforcement Policy showing proposed track changes

1. Background

- 1.1. The HFEA's Compliance and Enforcement (C&E) policy ([http://www.hfea.gov.uk/docs/Compliance_and_Enforcement_Policy_\(2011\).pdf](http://www.hfea.gov.uk/docs/Compliance_and_Enforcement_Policy_(2011).pdf)) sets out our approach on the escalation and management of concerns about regulatory compliance. This policy is part of a suite of documents that also includes the Indicative Sanctions Guidance (http://www.hfea.gov.uk/docs/Indicative_Sanctions_Guidance.PDF) and the Indicative Applications Guidance (http://www.hfea.gov.uk/docs/2009-08-21_Indicative_applications_guidance.pdf).
- 1.2. This paper sets out draft proposals and recommendations for the update of this suite of documents based on learning from recent experiences and feedback from Authority members and committee Chairs on the factors that should be taken into account when considering regulatory sanctions. This paper is one of a series that sets out the proposed future direction of the regulatory regime based on previous findings and experience and in consideration of the goals of the HFEA's strategy.
- 1.3. This revised policy will be subject to a focused consultation and will be piloted in the next three months. Final recommendations and proposals will be referred to the Authority early in 2016 prior to implementation in April 2016.

2. The C&E policy: review and recommendations

- 2.1. The C&E policy is a living document that guides the compliance team when there are difficult decisions to be made. The biggest challenges arise when decisions are made about whether regulatory non compliance poses such a significant risk that suspension or revocation of a licence may be warranted. Experience suggests that the principles and application of the current policy are broadly effective in guiding the compliance team's activities in a considerate and proportionate way.
- 2.2. Routine inspection findings are based on a snapshot of evidence and observations but are effective in highlighting where improvements are required. In the majority of cases non compliances observed on inspection do not pose an immediate and/or direct risk to patients, their gametes or embryos and effective recommendations for improvement can be framed and implemented. In this respect the levels of scrutiny applied in the course of routine regulatory activity appears appropriately calibrated.
- 2.3. Learning from a recent case suggests that where serious regulatory sanctions may be warranted then consideration should be given to the conduct of a more forensic review of a clinic's practices: to determine whether the critical non-compliance(s) prompting action represent one off anomalies, a practice, or are indicative of other serious failings.

- 2.4.** When a decision not to recommend grant of a licence is being considered this may be at a time when the relations between the HFEA and the licensed clinic are strained. In such circumstances, there can be a reluctance to conduct further investigations for fear of accusations of harassment. Clinic staff may feel or allege they are being treated differently and or disproportionately. To provide clarity and ensure transparency, it is recommended that the current policy is updated to explain that informal action may include further, potentially forensic scrutiny of a clinic's practices where there have been observations of non-compliance that have posed or may pose a future risk to the safety of patients or to their gametes or embryos, or where a serious breach of the Act is observed or suspected. In enshrining this in the policy this should ensure clinics are only subject to such scrutiny if concerns are suitably serious while empowering the compliance team in what may otherwise be challenging circumstances.
- 2.5.** The current C&E policy does not set out the circumstances in which a report of the findings of any investigation will be drafted and referred to a licensing committee. It is recommended that a report should be drafted whenever improvements are required and that the report should be referred to a licensing committee and be published on the HFEA's website. It is recommended that where an investigation concludes that concerns have no foundation and that there are no recommendations for improvement then no further action beyond documenting this finding in the management review records will be taken.
- 2.6.** Amendments to the current policy are also proposed to rationalise the practical sequence of events. The compliance team's current practice is to hold a management review meeting when a concern is identified to decide whether a concern is sufficiently serious to warrant further investigation and to decide and document the agreed course of action. It is recommended that the policy is updated to reflect this current practice.
- 2.7.** Proposed changes (including additional minor changes to those outlined above) are tracked in the copy of the C&E policy at annex 4.

3. The indicative applications guidance: review and recommendations

- 3.1.** The indicative applications guidance sets out the matters to be considered on renewal or grant of a licence and provides a framework for deciding the length of licence to grant.
- 3.2.** A review of the current guidance is included at annexes 1 and 2. As a result of the review it is recommended that consideration be given to fairly substantive changes to the guidance.
- 3.3.** It is recommended that the guidance is amended to reference matters outlined below.

- Consideration of the clinic history should routinely include (but not be restricted to) consideration of the committee minutes from the time of the clinic's last renewal or four years (if the licence was renewed less than four years prior to the application under consideration); 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;
- When considering 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 PRs commitment (or otherwise) to implement corrective actions within agreed timescales; and most importantly, 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.
- When considering the duration of a licence the committee should also consider the quality of service provided by the clinic. To assure consistency and proportionality consideration of quality should be based on observation of the clinics long term trends in success rates, and; feedback provided by patients.

3.4. In relation to the length of licence to be granted it is recommended that four year licences remain the norm for treatment clinics; three year licences are considered where there are concerns that warrant further focused inspection after one year; two year licences are not routinely issued; one year licences are issued where there are wide ranging concerns that mean a full inspection within one year is indicated; consideration is given to the issue of Special Directions in exceptional circumstances where a clinic's licence is likely to expire before it can be demonstrated that substantive improvements have been effective.

4. Indicative sanctions guidance: review and recommendations

- 4.1.** Experience suggests that the principles and application of the current policy are broadly effective, ensuring the proportionality and consistency in relation to regulatory sanctions.
- 4.2.** A review of the current guidance is included at annex 3. As a result of the review it is recommended that consideration be given to changes to the guidance with respect to factors listed as aggravating. The recommendations for change aim to align the guidance with the sections of the Act that outline when the Authority may revoke vary or suspend a licence.
- 4.3.** In summary it is recommended the guidance is revised to list the following as aggravating factors:
- 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 provided and or the quality of service (option two at point 1 of annex 3).

- 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.
- Failure by the PR to ensure suitability of staff; that proper equipment is used or that premises are suitable particularly where this has or may impact on the safety of patients their gametes or embryos and or the quality of service.

Annex 1: A review of matters to be considered on renewal or grant of a licence as referenced in indicative applications guidance

The current indicative applications guidance sets out the matters that a Licensing Committee (LC) (either a Licence Committee of the Authority or the Executive Licensing Panel) will normally take into account when deciding the duration of a licence. The following annex records whether information on these matters is currently made available to these committees and makes suggestions for revising the guidance. The recommendations for revision are informed by feedback from Committee Chair's, Authority members (in the course of a workshop), and on the basis of current decision making practices of the Executive.

Matters to be considered on renewal or grant of a licence	Reporting of these matters	Comment and suggestion on the continuing reference to this requirement in the guidance
1. Adherence to the regulatory principles published by the Authority	<ul style="list-style-type: none"> • Reports are currently structured to report inspection findings with reference to regulatory principles. However, the report does not specifically comment on compliance with principles. 	<ul style="list-style-type: none"> • As reference to regulatory principles is inherent in compliance with statutory requirements then it is not considered likely to be an advantage for LC or ELP to be guided to consider these matters specifically when considering the duration of a licence. • It is recommended that the guidance to consider regulatory principles is removed from the applications guidance
2. History of compliance with statutory requirements; Directions issued by the Authority; Licence Conditions; and the Code of Practice issued by the Authority	<ul style="list-style-type: none"> • A clinic's "history of compliance" in terms of the implementation of recommendations made in previous reports is commented on explicitly in inspection reports. Reports also document co-operation with any guidance, alerts, advice and/or recommendations made in the time between inspections. • Information about a clinic's history is also 	<ul style="list-style-type: none"> • Making an assessment of the "history" of non-compliance is a very significant factor in informing the Executive's recommendation relating to the duration of any licence to be granted. • To maintain consistency, it is recommended that guidance clarifies that consideration of the clinic history should routinely include

	<p>contained in minutes made available to the LC.</p>	<p>(but not be restricted to) consideration of the committee minutes from the time of the clinic’s last renewal or four years (if the licence was renewed less than four years prior to the application under consideration); 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. It is recommended that the committee papers should therefore include four years of licensing history in the form of committee minutes to show a picture of compliance over the entire time period since the last grant of the licence.</p> <ul style="list-style-type: none"> • As noted below where there is a previous occurrence of failure to implement recommendations for improvement and/or take appropriate action with respect to alerts, advice or guidance then there may be justifiable reason to return to a clinic earlier than the two year norm so that evidence of the implementation of effective corrective action can be reviewed in the course of a focused site visit. This is not meant to be punitive but is intended to encourage and ensure regulatory compliance.
<p>3. Compliance with recommendations made by Licence Committee/Executive Licensing Panel/Compliance Department</p>	<ul style="list-style-type: none"> • See above – this is captured in consideration of a clinic’s history 	<ul style="list-style-type: none"> • It is recommended that this is removed from the applications guidance

<p>4. Status of the quality management systems in place at the premises to be licensed</p> <p>Status of the premises and facilities at the premises to be licensed</p> <p>Timely provision of accurate Register data to the Authority</p>	<ul style="list-style-type: none"> • All non-compliance with statutory requirements – including these aspects of practice - is commented on in reports. 	<ul style="list-style-type: none"> • In the absence of assurance that the PR has or will ensure compliance with statutory requirements then the statutory test for issue of a licence (as outlined in decision trees) cannot be met and a licence cannot be recommended or granted. • These three aspects of compliance (the requirement to have a QMS, suitable premises and to submit data to the HFEA) have no unique role in ensuring the safety of gametes, embryos or patients however and it is recommended that this is removed from the applications guidance. • It is recommended that the guidance is revised to note that when considering 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 PRs commitment (or otherwise) to implement corrective actions within agreed timescales; and most importantly, the risks to safety of patients, their embryos or gametes and or the quality of service of non-compliances as they remain at the time that the decision is being made. • This recommendation aims to ensure proportionality - so even if a report documents a large number of non-compliances, where there has been a prompt and effective response it is recognised that the risks associated with non-
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		<p>compliance have been mitigated. Where the PRs response indicates failure to commit to make improvements or even failure to appreciate the seriousness of non-compliance then there may be reduced confidence that compliance can be assured going forward and therefore there may be justifiable reason to return to a clinic earlier than the two year norm so that evidence of the implementation of effective corrective action can be reviewed in the course of a focused site visit. As above this is not meant to be punitive but is intended to encourage and ensure regulatory compliance.</p>
<p>5. Number of incidents reported by the clinic in comparison to the average number of incidents reported per clinic</p>	<ul style="list-style-type: none"> The Executive does not compare the number of incidents reported by clinics. Serious incidents (grade A and some grade B incidents) are the subject of reports to LC 	<ul style="list-style-type: none"> Any reference to specific incidents in routine inspection reports could have the effect of deterring open and transparent incident reporting and this in turn could impact on opportunities for learning from incidents. It is recommended that the guidance is revised to remove reference to these matters. It is noted that in considering an incident investigation report a LC would take into account the risks of any non-compliance or failure identified in the investigation and the clinic's history and this should provide assurance that due consideration is given to incidents in matters of licensing.
<p>6. Number of complaints made to the Authority against the Clinic in comparison to the average number of complaints per clinic</p>	<ul style="list-style-type: none"> The Executive does not compare the number of complaints made against clinics and this is not referenced in inspection reports. The number of complaints reported is small and 	<ul style="list-style-type: none"> It is recommended that the guidance is revised to remove reference to these matters.

	<p>often beyond the remit of the HFEA (being in relation to costs, funding, waiting times etc.).</p>	<ul style="list-style-type: none"> Should a complaint investigation identify serious concerns that warrant recommendations for improvement or even regulatory sanction then this would be escalated to LC in a separate report so, as with incidents, there is assurance that where relevant, due consideration is given to complaints in matters of licensing.
<p>7. Number of multiple embryo transfers in comparison to the annual range set by the Authority</p>	<ul style="list-style-type: none"> The number of multiple embryo transfers is not a proxy for multiple live birth rates or multiple clinical pregnancy rates. Data on the number of multiple embryo transfers are not available to the inspection team and are not therefore included in reports. Clinics receive alerts from the HFEA's risk based assessment tool where there is an upward trend in their clinical multiple pregnancy rate. Clinics are expected to investigate the reasons for the trend and where appropriate to implement improvements. Monitoring of clinics' clinical multiple pregnancy rate is continuous. 	<ul style="list-style-type: none"> It is recommended that the guidance is revised to remove reference to these matters in acknowledgement that compliance with the multiple births target is captured in general consideration of regulatory compliance.
<p>8. Number of live births in comparison to the national average</p>	<ul style="list-style-type: none"> These data are available to the inspection team and are commented on in all reports. Clinics receive alerts from the HFEA's risk based assessment tool where there is a downward trend in their success rates. Clinics are expected to investigate the reasons for the trend and where appropriate to implement improvements. Monitoring of clinics' success 	<ul style="list-style-type: none"> It should be noted that a clinic's response to performance alerts is commented on in reports and so issues of persistent poor performance play a part in the decision on the duration of licence to be recommended. However, this matter goes to the quality of service provided rather than regulatory compliance. Like regulatory compliance the quality of service is a significant factor in determining the recommendation about the duration of a licence.

	rates is continuous.	<p>It is noted however that success rates form only a part of the assessment of quality of service.</p> <ul style="list-style-type: none">• In consideration of this it is recommended that the guidance is revised to note that when considering the duration of a licence the committee should also consider the quality of service provided. To assure consistency and proportionality consideration of quality should be based on observation of the clinics long term trends in success rates, clinical multiple pregnancy rates; and feedback provided by patients.
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Annex 2 – Advantages and disadvantages of licences of different lengths

Length of Licence	Anticipated circumstances of issue	Advantages and disadvantages
4 years	<p>It is suggested that consideration is given to the issue of a 4 year licence where:</p> <ul style="list-style-type: none"> • a clinic has taken appropriate action in relation to any non-compliances identified as posing a risk to patients, their gametes or embryos; • where the Person Responsible has given a commitment to the implementation of 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 birth rates; and patient feedback. 	<p>A four year licence minimises the regulatory burden for clinics with an unannounced observation based interim inspection occurring at year two.</p>
3 years	<p>Licences could be issued for 3 years where a clinic has:</p> <ul style="list-style-type: none"> • a history that indicates a previous failure to implement recommendations for improvement in the time since the last licence renewal; • no history (as with a new clinic – particularly one with no previous history of HFEA requirements) 	<p>A three year licence would allow a clinic 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. Depending on the issues for review this inspection is likely to be announced.</p> <p>The clinic would perceive an increased regulatory burden in the first year but if the interim inspection</p>

	<ul style="list-style-type: none"> • there are concerns related to quality of service. 	<p>findings were to demonstrate compliance then the clinic could revert to the usual cycle with renewal after a further two years.</p> <p>If the interim inspection failed to find evidence of compliance with recommendations then a committee would have an opportunity to consider regulatory sanctions within one year of the grant of the licence rather than the usual two.</p> <p>The imposition of an interim inspection within one year (rather than a renewal which would be needed if a one year licence were to be granted) would allow the compliance team to conduct a targeted inspection: this would have the effect of minimising the impact on compliance resources while providing a clear signal to the clinic that the Authority requires improvement. The added advantage of a targeted inspection is that the clinic and the compliance team would not focus on activities that were considered fully compliant at the previous inspection.</p> <p>It is noted that should the interim inspection highlight ongoing concerns procedures for imposition of additional licence conditions or for revocation are more complex mid licence but a licence can be varied to impose conditions or a notice of proposal to revoke a licence can be issued at any time. It is rare however for a clinic to fail to implement recommendations for improvement within prescribed timescales.</p> <p>It is recommended that three year licences are</p>
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		adopted as the norm in the circumstances described and for new clinics without any significant experience of HFEA regulatory requirements.
2 years	Licences could be issued for 2 years in the circumstances described above	<p>The options in this case are</p> <ul style="list-style-type: none"> targeted interim at year one followed by renewal at year two, This would send a signal to the clinic that improvement is required but in the absence of an opportunity to revert to the usual two year inspection cycle in the event of satisfactory compliance at year one could impose a disproportionate regulatory burden on the clinic and impact on compliance team resources; renewal at year two only. This could permit persistence of non-compliance, followed by a non-focussed renewal review of all activities including those considered compliant at the time of original renewal. <p>It is not recommended that two year licences are usually issued.</p>
1 year	Licences could be issued for 1 year in the circumstances described above or where concerns are particularly serious.	<p>This would increase the burden of regulation but would have the effect of giving the compliance team a clear opportunity to review improvements made after one year. There would also be opportunity for imposition of additional conditions should non-compliance persist at the time of the one year renewal.</p> <p>This would impact negatively on compliance resources</p>

		<p>with the conduct of a renewal inspection after one year requiring re review of all activities as opposed to those requiring improvement. This would be warranted should concerns be wide ranging.</p> <p>It is recommended that this option is considered 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.</p>
<p>Adjournment and/or issue of Special Directions</p>	<p>Where there is a history that suggests serious concerns about a PR's ability to ensure regulatory compliance then a LC could give consideration to adjourning a decision (perhaps requiring issue of Special Directions) pending the submission of further evidence.</p>	<p>This would have the benefit of allowing grant of a licence only after the PR was able to demonstrate – through the submission of audits or even following a further inspection – not only that recommendations for improvement have been implemented but also that they have been effective in preventing recurrence of non-compliance. Demonstration of the effectiveness of corrective actions requires a clinic to be operational and then to conduct an audit of relevant practices to provide assurance of their compliance with requirements</p> <p>This option may be most effective where there are very serious concerns about the PRs understanding of the need for improvement and/or in the case of serious concerns about performance at a newly licensed clinic where there is inevitably limited information to support a conclusion that a PR is likely to meet requirements.</p>

Annex 3: factors which a Licensing Committee may consider to be aggravating features when considering whether to impose regulatory sanctions

Aggravating features as currently referenced in the indicative sanctions guidance	Comments on these features	Suggested amendment to indicative sanctions guidance
<p>1. Failure to obtain required consents relating to use/storage of gametes and embryos and/or to keep proper records of such consents</p> <p>Failure to comply with consents relating to use/storage of gametes and embryos</p> <p>Failure to comply with witnessing protocols and procedures</p> <p>Failure to comply with multiple birth minimisation strategy without good reason</p> <p>Failure to provide Authority with information required to be included in the Statutory Register under Section 31 of</p>	<p>The HFEA's risk based assessment tool (RBAT) recognises</p> <ul style="list-style-type: none"> • Consent failures • Incorrect identification of gametes/embryos • Multiple Pregnancy • Incorrect or incomplete information on donors <p>as four of the six most significant risks associated with IVF treatment.</p> <p>RBAT also considers the following as significant risks of IVF:</p> <ul style="list-style-type: none"> • Cross infection of gametes, embryos or patients • Damage or Loss of gametes or embryos <p>Where a clinic fails to ensure suitable practices are in place to mitigate these key risks then regulatory sanctions may clearly be warranted.</p> <p>It should be acknowledged however that non-compliances with respect to these areas of</p>	<p>Option 1</p> <p>Failure of the PR to mitigate the risks of the following to be referenced as aggravating features in the indicative sanctions guidance:</p> <ul style="list-style-type: none"> • Consent failures • Incorrect identification of gametes/embryos • Multiple pregnancy rate • Cross infection of gametes, embryos or patients • Incorrect or incomplete information on donors • Damage or loss of gametes or embryos <p>In recognition however that this list is not and cannot be exhaustive and that there may be other factors which could pose risks to the safety of patients and or their gametes or embryos it is proposed that the indicative sanctions guidance could be significantly simplified as suggested below.</p> <p>Option 2</p> <p>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 provided and or the quality of service provided to be referenced as an aggravating feature in the</p>

<p>the Act (critical information about donors for example)</p>	<p>practice are common and regulatory sanctions would not usually be considered necessary unless a clinic failed to act on recommendations for improvement.</p>	<p>indicative sanctions guidance.</p> <p>While this option is broader, it does reflect actual practice and by referencing the requirement for suitable practices this also aligns the guidance to the circumstances described in the Act¹ when a licence may be revoked, varied or suspended.</p>
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¹ **Section 18 (Revocation of licence) of the 1990 Human Fertilisation and Embryology Act (as amended) (the Act)**

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if--

- (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
- (b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17,
- (c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence,
- (d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
- (g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity,
- (i) it is satisfied that there has been any other material change of circumstances since the licence was granted.

Section 17 of the Act

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure--

- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
- (b) that proper equipment is used,
- (d) that suitable practices are used in the course of the activities, . . .
- (e) that the conditions of the licence are complied with,
- (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

19C Power to suspend licence

(1) Where the Authority--

- (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
- (b) is of the opinion that the licence should immediately be suspended,

<p>2. Breach of patient confidentiality</p> <p>Breach of statutory storage periods for storage of gametes/embryos</p> <p>Failure to notify Authority of incidents</p> <p>Failure to properly investigate complaints from users of, or persons affected by, the service offered by the clinic</p>	<p>As described in annex 1, non-compliance with statutory requirements – including these aspects of practice - is commented on in reports and influences any recommendations on the grant or otherwise of a licence.</p> <p>Where failure to ensure compliance with these (or any statutory requirements) has implications for the safety of patients, their gametes or embryos then this might lead to a conclusion that the PR has failed to ensure the use of suitable practices and, therefore, to discharge their duty.</p>	<p>It is recommended that specific reference to these features is removed from the indicative sanctions guidance.</p> <p>It is recommended that 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 provided should be referenced as an aggravating feature in the indicative sanctions guidance.</p>
<p>3. Repeated breaches of licence conditions or failure to comply with Directions issued by the Authority</p> <p>Failure to comply with recommendations or warnings made by Inspector/Compliance Department</p> <p>Failure to comply with recommendations or warnings</p>	<p>As noted in paragraph 2 of annex 1, the history of compliance is commented on in reports and influences any recommendations on the grant or otherwise of a licence.</p>	<p>It is recommended that specific reference to these features is removed from the indicative sanctions guidance.</p> <p>These matters are captured in the recommendations suggested above.</p>

issued by Licence Committee		
<p>Dishonesty</p> <p>Failure to co-operate with investigation or inspection</p> <p>Failure to notify Authority of material change in circumstances</p>	These matters go to the suitability of the PR.	It is recommended that the guidance be revised to reflect that it will be considered an aggravating factor where the person responsible ceases to be considered a suitable person to supervise the licensed activity by virtue of dishonesty and or failure to cooperate with investigations particularly where this may compromise the safety of patients their gametes or embryos and or the quality of service provided.
<p>Abuse of trust/position</p> <p>Disregard for system of regulation</p> <p>Disregard of generally accepted/established guidelines or Code of Practice</p> <p>Failure to respond to correspondence from Authority</p>	Assessment of these matters is considered likely to be subjective	It is recommended that specific reference to these features is removed from the indicative sanctions guidance in acknowledgement.
	<p>The indicative sanctions guidance does not currently reference that failure to ensure the suitability of staff;</p> <p>that proper equipment is used, and; the suitability of premises may be grounds for revocation or suspension of a licence.</p>	It is recommended that the guidance be revised to reflect that it will be considered an aggravating factor where the person responsible fails to ensure suitability of staff; that proper equipment is used and that premises are suitable particularly where this may impact on the safety of patients their gametes or embryos and or the quality of service provided.

Annex 4: Compliance and Enforcement Policy showing proposed track changes

Purpose of this policy

- 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:
- ~~all relevant statutory provisions; the provisions of the Human Fertilisation and Embryology Act 1990 ("the Act");~~
 - licence conditions;
 - directions issued by the Authority; and
 - 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.

When to apply this procedure

- 2.1 The planned inspection process
- 2.2 **The escalation and management of concerns regarding the compliance and or the quality of service provided by** a centre

The enforcement policy

3. THE INSPECTION PROCESS

- 3.1 The purpose of an inspection is to:
- assess the extent to which centres comply with the Act; licence conditions; directions and the provisions of the Code of Practice;
 - provide an independent and professional perspective on the running of the centre;
 - promote good practice so that centres can improve the quality of service they provide to patients and donors;
 - provide centres with a positive learning experience;
 - 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;
 - 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.
- 3.2 All inspections will be:
- evidence based, consistent, proportionate and open to scrutiny;
 - undertaken in a professional and courteous manner;

- c) be focused on risk;
- d) aim to add value for centres and service users.

3.3 ~~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.~~

3.4 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 mitigating factors (those being the factors set out in the Indicative Sanctions Guidance) when considering what recommendations to make. ~~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).~~

3.5 A report ~~of every inspection~~ will be drafted following every inspection. The Persons Responsible ~~for licensed centre~~ 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.

3.6 The ~~final~~ report will be sent to the Executive Licensing Panel or Licence Committee. The Executive Licensing Panel or Licence Committee make the final decision as to whether a licence should be granted, renewed, allowed to continue, varied, revoked or suspended. The Executive Licensing Panel or Licence Committee also make the final decision as to the actions a centre should take in relation to any area(s) of non-compliance identified as part of the inspection visit.

3.7 After consideration by the Executive Licensing Panel or Licence Committee, ~~routine li~~nspection ~~R~~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.~~

4. THE ESCALATION AND MANAGEMENT OF CONCERNS REGARDING THE COMPLIANCE OF A CENTRE

4.1 Where the ~~Authority executive~~ 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~~ 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. as outlined below. MinutesA record of the management review meeting will be kept. ~~it will normally first seek to encourage the 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.~~

4.2 Following an evaluation of the actual or potential risks to the safety of patients, gametes and or embryos arising as a consequence of the concerns under investigation, consideration will be given to the most appropriate action. Informal action, including any or all of the following, may be taken. Informal action may including any or all of the following actions:

- a) implementation of a period of performance monitoring
- b) contacting and/or meeting with the Person Responsible 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 advisor.
- d) an unannounced or scheduled inspection visit (depending on the nature of the concerns under investigation). Where there have been observations of non-compliance that have 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 potentially forensic scrutiny of some or all of a centre's practices. Where it is necessary to protect the identity of a whistleblower 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) ~~contacting the Person Responsible to discuss area(s) of non-compliance and remedial action identified that that the Person Responsible must undertake and the timescales for doing so if formal enforcement is to be avoided;~~
- f) where investigation identifies areas for improvement, completion of a report of the findings of the investigation informing the Person Responsible in writing of the minimum levels of the required improvements identified that that the Person Responsible must undertake and the timescales their implementation if formal enforcement is to be avoided;
- g) ~~meeting with the Person Responsible to discuss requirements and improvement options (including formulating an improvement plan);~~
- h) sending a warning letter to the Person Responsible, informing him that formal enforcement will be undertaken if the identified improvements are not completed within a given time scale;
- i) referring a report of the findings of an investigation to the Executive Licensing Panel or Licence Committee documenting recommendations.

4.3 Where actual risks to the safety of patients, gametes and or embryos are identified then the following actions may be taken without recourse to the actions described above. Formal action may include any or all of the following actions:-

a) referring ~~the casea report~~ for consideration by the Executive Licensing Panel / Licence Committee with a recommendation that the licence should be varied (including by imposing additional conditions);

~~referring the case for consideration by the Executive Licensing Panel/ Licence Committee with a recommendation that an additional inspection be scheduled in order to monitor compliance~~

~~b) referring the casea report for consideration by the Executive Licensing Panel/Licence Committee with a recommendation for that a shortened term licence should be granted;~~

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

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

~~e)d) applying for a warrant in accordance with 40 of the Act;~~

~~f)e) where a criminal offence may have been committed, referring the matter to the police for criminal investigation; or~~

~~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.

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4.4 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 recommendations for improvement within the stipulated time frame;

c) the centre has a previous history of non-compliance or failure to undertake remedial actions implement recommendations for improvement 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.
- 4.5 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(1) or (2) of the Act are met.
- 4.6 ~~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 held in relation to that centre. Subsequent review meetings may be held to monitor the situation.~~
- 4.7 ~~The conduct of the Management Review meeting will be in accordance with the department's 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.~~
- 4.8 The initial management review will include the centre inspector and at least one ~~Head of Department~~senior member of the compliance team and such other persons considered appropriate. 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.
- 4.9 ~~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.~~
- 4.10 ~~Any recommendations made in respect of proposed conditions should be "SMART" (Specific, Measurable, Achievable, Realistic and Time-bound)~~
- 4.11 ~~The Informal action and or recommendations will be formulated by the management review team. Formal action will be agreed with the Chief Inspector and/or the Director of Compliance shall formulate any~~

~~recommendations to be made at the conclusion of the Management Review.~~
Where there is a recommendation ~~is that the matter should be referred to~~
refer a concern to the police or that a warrant should be obtained, the
recommendation will be brought to the attention of the Chief Executive.

- 4.12 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.
- 4.13 Where the Chief Executive has been informed that the recommendation of the Management Review is that a warrant should be applied for, ~~they shall will~~ inform the Chair of the Authority of the recommendation and the reasons for it.
- 4.14 The Chair may consult the Deputy Chair and the Chair of the Audit and Governance Committee about the recommendation.
- 4.15 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.

Under review

Fig. 1: An illustration of the escalating scale of informal measures to formal enforcement action

