Compliance and Enforcement Policy

Introduction

1. This policy sets out the Human Fertilisation and Embryology Authority's ('the Authority') Regulatory Aims which underpin all the Authority's compliance and enforcement activities. This policy will normally be used by inspectors and serves a clear and transparent statement of the circumstances in which clinics can expect regulatory action to be taken. This policy supersedes all previous Compliance and Enforcement policies.

2. In the exercise of this policy, the inspectors will act effectively, efficiently and economically and so far as is relevant, have regard to the Regulator's Code and principles of best regulatory practice, including that regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed.

3. This policy provides an overarching tool to guide decision making in relation to compliance and enforcement activities. The policy may require some subjective input and evaluation from inspectors and does not automatically generate decisions. The procedures set out in this document aim to ensure fairness and consistency in the Authority's compliance and enforcement activities and will normally be followed by inspectors when regulatory action is necessary to achieve one or more of the Authority's Regulatory Aims.

4. The policy sets out a range of regulatory actions that may be taken by an inspector, some of which may be taken without recourse to a licensing committee[1] i.e., during post-inspection monitoring or other informal engagement with clinics. The reports produced by inspectors following an inspection or clinic visit are usually considered by a licensing committee which has delegated authority to make a range of licensing decisions. The delegated powers are set out in the Authority's Standing Orders. This policy sets out the range of regulatory action that may be recommended by an inspector in a report submitted to the Authority's licensing committee.

Regulatory Aims

5. The Regulatory Aims underpinning the Authority's compliance and enforcement activities include:

5.1. Promoting compliance with the requirements imposed by or under the Human Fertilisation and Embryology Act 1990 ('the 1990 Act') and the Code of Practice.

[1] References in this policy to licensing committee(s) includes the Executive Licensing Panel, any licence committee or any committee that hears representations or appeals against licensing decisions.

5.2. Protecting those using or affected by the services offered at licensed clinics and ensuring the quality and safety of gametes and embryos.

5.3. Maintaining public confidence in the safe, effective, and ethical conduct of licensed activities.

When the procedure set out in this policy will be engaged

6. The Authority's inspection activities are a statutory requirement and the procedure set out in this policy will normally be followed by inspectors if issues of concern or non-compliance are identified in the course of scheduled and unscheduled clinic inspections, clinic visits outside of inspections, investigations into incidents (serious adverse events and serious adverse reactions), complaints, whistle-blowing disclosures or referrals from other regulators, professional bodies or government agencies or any other circumstances which may give rise to risks or concerns about a clinic's compliance. In other words, in any circumstances in which regulatory action in one form or another is or may be required, the procedure set out in this policy will normally be followed.

7. This policy will be used in conjunction with the Authority's standard operating procedures for compliance activities. Non-compliances and concerns will be investigated, and inspectors will seek evidence or assurance from the Person Responsible (PR) and clinic staff to establish the nature and seriousness of the issue. Immediate actions or mitigating steps taken in response to any finding(s) will be noted. Throughout this process, there will be open and transparent communication with the PR regarding any concerns or issues identified. The steps set out in this policy will be implemented once the facts have been established and available evidence has been evaluated. The risk score may be re-evaluated if new evidence emerges which materially changes the conclusions reached by inspectors.

8. In any of the circumstances referred to in paragraph 6 above, inspectors will consider whether regulatory action is necessary by asking the following four questions.

8.1. Is regulatory action necessary to protect those using or affected by the services offered at licensed clinics or to protect clinic staff?

8.2. Is regulatory action necessary to ensure the quality and safety of gametes or embryos?

8.3. Is regulatory action necessary to maintain public confidence in the regulatory scheme?

8.4. Is there evidence of non-compliance with statutory requirements, licence conditions, General or Special Directions or the Code of Practice, or do the facts available suggest there may have been or is likely to be non-compliance?

9. If one or more of the questions at paragraph 8 above is answered in the affirmative, regulatory action will be necessary and inspectors will then proceed with the further steps set out below.

A risk-based approach to regulatory action

10. The Authority adopts a risk-based approach to regulation. Risk is the chance that an event or incident could happen and could cause harm. However, risks do not arise in isolation and

therefore, inspectors will consider the wider context within which a clinic operates, and may have regard to a range of factors that may be relevant when determining the risk, and what regulatory action is proportionate.

11. The more severe the impact or likely impact arising from any risk, the greater the imperative to act and the more serious the action taken is likely to be. An imminent risk of serious harm is likely to warrant immediate regulatory action. To ensure consistency of approach in every scenario in which regulatory action is indicated, inspectors will use the risk matrix (see Step 3 below) and the Regulatory Action Table ('RAT') (see Step 5 below). The position on the RAT will indicate the regulatory action required in the circumstances.

12. When following these steps, inspectors will consider all relevant information, evidence, and circumstances they are aware of at the time. Should circumstances change or additional information or evidence become available, it may be necessary for inspectors to go through these steps more than once. The procedure followed by the inspector will be documented on each occasion.

Risk Grading

13. The formula employed in the risk matrix below is likelihood x impact = risk score. Risks will vary depending on the context, but may include for example, the risks arising from the most serious non-compliance in an inspection report, the highest risk factor in any incident or the highest risk factor in any complaint. Risks may also include:

13.1. risk of harm to patients[2], gametes or embryos, or any child(ren) that may be born as a result of proposed treatment.

13.2. risk of harm to staff.

13.3. risk of non-compliances, incidents, or complaints or recurrence of these.

13.4. risk that the public may lose confidence in the regulatory scheme.

Harm may include physical, psychological, or emotional injury or trauma, or financial harm to patients or staff.

14. Risk refers to the highest risk factor(s) or the worst-case scenario(s). The risk score will be determined by reference to the likelihood or probability of the risk event occurring or recurring should action not be taken, and the impact or harm that may result should the risk materialize. In some cases, it is likely that inspectors will be considering a risk event that has already happened. In such circumstances, consideration will be given to the impact that has been experienced and the likelihood of recurrence of the risk event should action not be taken.

An imminent risk of serious harm is likely to warrant immediate action. In circumstances in which inspectors identify an imminent risk, inspectors will usually engage with the Chief Inspector and/or Director of Compliance before proceeding further.

STEP 1: Assessing likelihood

15. Likelihood is the possibility of a risk event occurring or recurring if no action is taken and is a qualitative assessment.

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[2] References in this policy to patient or patients include the person having treatment, their partner if they have one, as well as donors and their partners if they have one.

The possibility or likelihood of a risk event occurring can be:

Remote - will probably not happen or recur;

Unlikely - not expected to happen or recur but it may;

Possible - might happen or recur;

Likely - will happen or recur;

Certain - has happened or will undoubtedly happen or recur more than once or on a frequent basis.

Whether something has happened in the past may be a reasonable indicator of whether it will happen again in the future, particularly if mitigating actions or corrective measures have not been put in place.

16. The assessment of likelihood will be based on information and evidence available at the time the assessment is carried out. This assessment may need to be conducted more than once in the light of any new information that may be made available to the inspector and will be documented.

STEP 2: Assessing Impact

17. Impact refers to the consequences or harm that will be caused if a risk materializes; the actual or likely impact or harm that the risk factor will have on anyone who is or may be affected by it. The impact may be insignificant, minor, moderate, major or catastrophic (see definitions at 18 below) and harm may include physical, psychological or emotional injury or trauma, or financial harm to patients or staff.

18. Inspectors will consider how a risk factor has affected or may affect patients, the quality and safety of gametes or embryos, any child(ren) that may be born as a result of treatment or clinic staff.

An insignificant impact includes a near-miss or an event or incident that has no negative or adverse effect and does not cause harm or injury (e.g. completion of an incorrect or unnecessary consent form and no treatment has been provided);

A minor impact causes minor harm or damage requiring minimal support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer but where there are no clinical implications, failure to screen patients and partners within the specified timescales);

A moderate impact causes moderate harm or damage where recovery is expected or rectification can be made without significant intervention, it may also include any harm that has resulted in or may result in a moderate increase in treatment (e.g. surgery being required where it would otherwise not have been required, discrepancies in embryo storage periods stated in consent forms of each gamete provider);

A major impact causes serious harm or damage that can be rectified but only with significant intervention (e.g. missing or incorrectly complete consent to legal parenthood forms requiring a court order of legal parenthood to be made);

A catastrophic impact causes very serious harm or damage to patients, staff, gametes or embryos, or any child(ren) that may be born as a result of proposed treatment and/or centre staff, and may include death or destruction of gametes or embryos (e.g. failure of a cryo-storage dewar, failure to screen a donor at all).

Step 3 Determining the Risk Score

Risk Matrix

A five-point rating will be used when assessing the likelihood and impact of risks.

Likelihood of the risk materialising if no action is taken:
1. **Remote** - will probably not happen or recur; 2. **Unlikely** - not expected to happen or recur but it may; 3. **Possible** - might happen or recur; 4. **Likely** - will happen or recur; 5. **Certain -** has happened – or will undoubtedly happen or recur more than once or on a frequent basis. Whether something has happened in the past may be a reasonable indicator of whether it will happen again in the future if mitigating actions or corrective measures have not been put in place.
Impact that the risk has had or may have:
1. **Insignificant** - includes a near-miss or an event or incident that has no negative or adverse effect and does not cause harm or injury (e.g. completion of an incorrect or unnecessary consent form and no treatment has been provided); 2. **Minor** - causes minor harm or damage requiring minimal support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer but where there are no clinical implications, failure to screen patients and partners within the specified timescales); 3. **Moderate** - causes moderate harm or damage where recovery is expected or rectification can be made without significant intervention, it may also include any harm that has resulted in or may result in a moderate increase in treatment (e.g. surgery being required where it would otherwise not have been required, discrepancies in embryo storage periods stated in consent forms of each gamete provider); 4. **Major** - causes serious harm or damage that can be rectified but only with significant intervention (e.g. missing or incorrectly complete consent to legal parenthood forms requiring a court order of legal parenthood to be made); 5. **Catastrophic** - causes very serious harm or damage to patients, staff, gametes or embryos, or any child(ren) that may be born as a result of proposed treatment and/or centre staff, and may include death or destruction of gametes or embryos (e.g. failure of a cryo-storage dewar, failure to screen a donor at all).

Impact the risk has had or may have						
	Catastrophic	5	10	15	**20**	**25**
	Major	4	8	12	16	**20**
	Moderate	3	6	9	12	15
	Minor	2	4	6	8	10
	Insignificant	1	2	3	4	5
Risk Score = Impact x Likelihood		**Remote**	**Unlikely**	**Possible**	**Likely**	**Certain**
		Likelihood of risk materializing if action is not taken				

STEP 4 Consideration of the broader context

19. Having determined the initial risk score at Step 3 above, the inspector will then reflect on the broader context within which the clinic operates and within which the risk event arises. The broader context refers to any relevant mitigating and aggravating factors (see indicative list at paragraphs 22 and 23 below). Aggravating and mitigating factors may be both directly and indirectly related to the likelihood of the risk materializing and the impact that it may have. Any aggravating and mitigating factors considered will be documented.

20. By section 17 of the 1990 Act, the PR has overall statutory responsibility and must ensure amongst other things, that the clinic is fully compliant and operating to prescribed standards of quality and safety. Consistent with the importance of the role and the duties imposed on a PR by statute, the inspector, when considering the broader context and in determining a clinic's risk score, will consider the role the PR has played in the circumstances. When considering the role of the PR, the factors set out at paragraph 24 below, will be taken into account, as well as whether the PR has demonstrated effective leadership in line with guidance published in the Code of Practice and the PR Role Description[3], and any professional codes of conduct they may be bound by.

21. This step is an opportunity for the inspector to reassess and if necessary, adjust the risk score by reference to relevant aggravating and mitigating factors and the role the PR has played. The risk score may be adjusted up or down. Any adjustment to the risk score and the factors considered in making the adjustment will be documented. By reference to the RAT at Step 5 below, the risk score will be used to help determine what regulatory action is proportionate and where relevant, what length of licence to recommend.

Mitigating factors

22. These factors are not listed in any hierarchy and this is not an exhaustive list. Not all these factors will be applicable in every case and there may be other factors not listed here that may be relevant and may therefore be taken into consideration.

Patient focus and integrity

22.1. The PR has recognised the impact or potential impact on patients and has done the right thing in response (this may include making full disclosure to patients or donors, offering an apology, offering appropriate support, financial remediation, or further treatment at no or low cost).

Compliance with and understanding of requirements

22.2. The PR understands the requirements or standards that they are expected to meet, has recognised where or in what way the clinic has fallen short, and has taken responsibility for the non-compliances or for enabling a situation or circumstances that resulted in the non-compliances.

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[3] The Person Responsible key behaviours and role description is published online at this link https://www.hfea.gov.uk/media/2993/person-responsible-role-description-and-key-behaviours.pdf

22.3. The PR has taken appropriate remedial action to mitigate the risk of recurrence or has established an action plan and has done so proactively and within reasonable timescales. The PR has demonstrated insight i.e., the PR has reflected on the issue, recognised the shortcomings, and accepted that things should have been done differently to avoid the scenario arising.

Cooperation

22.4. The PR has fully co-operated with inspectors regarding the current issue and has the PR answered questions honestly and provided information freely. The PR has made full disclosure regarding the circumstances of any non-compliances and has encouraged their staff to be cooperative and open with inspectors. The PR provided information within the timescales agreed or specified.

Aggravating factors

23. These factors are not listed in any hierarchy and this is not an exhaustive list. Not all these factors will be applicable in every case and there may be other factors not listed here that may be relevant and may therefore be taken into consideration.

Patient focus and integrity

23.1. Failure to notify patients affected of an incident and or failure to offer appropriate support.

23.2. Failure to investigate or provide an adequate response to patient complaints, including failure to take account of the impact or potential impact of the clinic's actions on patients.

23.3. Any financial or other gain made by the clinic at the patients' expense or as a consequence of what has happened.

Compliance with and understanding of requirements

23.4. The PR does not understand the requirements or standards that they are expected to meet nor recognised where or in what way the clinic has fallen short. The PR has not taken responsibility for the non-compliances or for enabling a situation or circumstances that resulted in the non-compliance.

23.5. The number and seriousness of any non-compliances or issues identified; failure to take the initiative to address non-compliances or the consequences of non-compliances.

23.6. Whether or to what extent the non-compliance occurred deliberately or recklessly, including the extent to which the PR, Licence Holder or other senior staff knew, or ought to have known, of the non-compliance or the risk of the non-compliance occurring.

23.7. The number and seriousness of any incidents i.e. grade A, B or C with grade A being the most serious.

23.8. Failure to report incidents at all, or within the specified timescales.

23.9. Demonstrating a lack of interest or willingness to remedy non-compliances or take appropriate remedial action at all, or within appropriate timescales.

23.10. Failure or repeated and ongoing failure, or inability to identify the appropriate remedial steps that should be taken including failure to implement or embed agreed action plans.

23.11. Demonstrating a lack of insight by for example not recognising the seriousness and impact of non-compliances.

23.12. History of non-compliance or disregard for the system of regulation which may include repeated or ongoing breaches of the statutory framework and repeated or ongoing failure to comply with recommendations for remedial action at all, or within agreed or specified timescales.

Co-operation

23.13. Failure to engage or cooperate with inspectors including failure to let inspectors conduct an inspection of the licensed premises.

23.14. Failure to respond to inspectors' reasonable requests including requests made during an inspection, investigation, or other clinic visit.

23.15. Failure to adhere to the terms of a voluntary undertaking or to comply within the timescales set out in such an undertaking.

23.16. Failure to respond to correspondence or telephone calls from inspectors without good reason.

23.17. Dishonesty or deliberate attempts to mislead or misinform inspectors including providing incorrect or misleading information.

23.18. Failure to notify the Authority of any material change in circumstances.

23.19. Failure to perform a root cause analysis to identify underlying causes and implement appropriate solutions.

23.20. Abuse of trust or position.

The Person Responsible

24. Inspectors will consider the extent to which the PR has at the current time and historically:

24.1. fulfilled their duties under section 17 of the 1990 Act.

24.2. has completed the PR Entry Programme ('PREP'), or specified sections of the PREP within specified timescales and demonstrates that they fulfil the requirements of the 'Person Responsible Key Behaviours and Role Description'[4] as published by the Authority.

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[4] The Person Responsible key behaviours and role description is published online at this link https://www.hfea.gov.uk/media/2993/person-responsible-role-description-and-key-behaviours.pdf

24.3. acted with integrity, insight and knowledge and understanding.

24.4. been cooperative, fully engaged and responsive in their dealings with inspectors and any affected patients.

24.5. has open and direct communication with senior staff and where the organisational structure necessitates, the PR has escalated relevant issues to senior management.

24.6. taken responsibility for what has happened.

24.7. has shown insight and taken the initiative to put remedial actions in place without prompting from inspectors.

24.8. has demonstrated that they will embed and sustain the required improvement or changes.

24.9. has been open, transparent, and honest in their dealings with inspectors and affected patients.

24.10. has been proactive in ensuring compliance and implementing corrective actions.

Step 5: Regulatory Action Table (RAT)

25. The RAT is a guide for inspectors. Consistent with the Authority's risk-based approach, the risk score calculated in Step 4 will, by reference to the RAT, guide inspectors in determining what regulatory action is proportionate. In the context of licensing matters, the RAT will guide inspectors in determining what length of licence to recommend. Regulatory action may include Level 1, Level 2 and/or Level 3 actions. These actions are defined in broad terms below in paragraphs 28, 29, and paragraph 30, with the action required, and the timescales within which clinics will be expected to take action escalating in impact from Level 1 to 3 across the table.

Inspectors will have regard to regulatory action taken or recommended in similar cases but may depart from previous cases depending on the particular facts, and the context of the case under consideration.

Risk score 1-4	**Risk score 5-9**	**Risk score 10-12**	**Risk 15-16**	**Risk 20 - 25**
Level 1 action(s) requiring response within reasonable timescales.	Level 1 action(s) requiring more intensive scrutiny or shorter response timescales (e.g., additional audits, seeking legal advice).	Level 1 and/or Level 2 action(s) requiring urgent and/or immediate interventions or actions.	Level 1 and/or 2 action(s) requiring immediate interventions or actions.	Level 3 action

4-year licence	3- or 4-year licence with or without additional conditions	2-year licence with or without additional conditions	1-year licence with or without additional conditions	Recommendation not to grant a licence, or revocation or immediate/ongoing suspension of licence

26. **Level 1** action may include one or more of the following.

26.1. Informing the PR of any non-compliances and identifying the remedial or improvement action that must be taken to achieve compliance and the timescales for doing so if further regulatory action is to be avoided. This communication may be verbal or written and can be in the form of a meeting but should be recorded.

26.2. Performance monitoring including requiring regular verbal or written updates or reports from the PR in relation to the implementation of any remedial or improvement plans with timeframes agreed to by the PR.

26.3. Promoting awareness of requirements and the need for appropriate remedial action including requiring the PR to complete the PREP or specified parts thereof.

26.4. Referring the case for consideration by a licensing committee with a recommendation to impose additional conditions.

27. **Level 2** action may include one or more of the following.

27.1. Calling an accountability meeting with the PR and any relevant clinic staff, relevant inspectors, the Chief Inspector or Director of Compliance (accountability meetings will usually be held at the HFEA offices however this is at the discretion of the Chief Inspector or Director of Compliance).

27.2. Agreeing a voluntary undertaking with the PR in which the PR implements certain prescribed actions or agrees to cease prescribed activities within a specified timescale (voluntary agreements will be formalised in writing by the inspector).

27.3. Commissioning an independent review or requiring the clinic to commission an independent review into a matter.

27.4. Additional announced or unannounced inspections (to be agreed in consultation with a Senior Inspector and/or the Chief Inspector and/or Director of Compliance).

27.5. Sending a warning letter to the PR informing him/her that enforcement action may be recommended if remedial actions are not taken, or improvements not made within a specified timescale.

27.6. Referring the case for consideration by a licensing committee with a recommendation that an additional announced or unannounced inspection should take place within a specified time.

27.7. Referring the case for consideration by a licensing committee with a recommendation that the licence should be varied, which may include variation by imposing additional conditions under section 18A (2) of the 1990 Act. The imposition of conditions may be appropriate where the risk or non-compliance is capable of being remedied and

where a specific, measurable, achievable, relevant and time-bound condition can be formulated. This recommendation will only be made where there is evidence that the PR is likely to comply with any condition imposed.

27.8. Where professional codes of conduct may have been breached or where the requirements or standards of another regulatory body may have been breached, a recommendation that the individual or clinic is referred to the relevant professional body or regulator. The final decision on any referral will be taken by the Director of Compliance, usually in consultation with the Chief Executive.

27.9. Making a recommendation regarding the PR's failure to fulfil their duties under section 17 of the 1990 Act or that the PR has failed to fulfil their section 17 duties and is therefore not suitable to remain PR, or that a person is not suitable to be appointed as PR.

28. **Level 3** actions may include.

28.1. Referring the case for consideration by a licensing committee with a recommendation that:

28.1.1. an application for the grant, which includes renewal, of a licence should be refused under section 16 of the 1990 Act.

28.1.2. the licence be immediately suspended under section 19C(1) of the 1990 Act or, in any case where a licence has previously been suspended, a recommendation under section 19C(2), that the suspension should continue for a further period of time.

28.1.3. the licence should be revoked under section 18(2) of the 1990 Act.

28.2. In any case in which the RAT indicates Level 3 action, a management review will be held before further steps are taken. Level 3 action will only be recommended following a management review at which a Senior Inspector, the Chief Inspector and/or the Director of Compliance are in attendance and will usually only follow where engagement with the PR to address issues or mitigate risks has been unsuccessful.

28.3. A minute will be kept of any management review meeting where Level 3 action is agreed. In any case in which the management review concludes that regulatory action other than that indicated by the RAT is necessary, reasons for the decision will be recorded in the minutes.

28.4. The use of these powers will always be proportionate and will only be recommended where the relevant statutory tests can be met.

29. Licensing committee procedure where recommendations for action are made.

29.1. In cases in which a recommendation for action has been made and a licensing committee has accepted the recommendation or decides on an alternative to the recommendation, the procedures governing the relevant committee will be engaged and the PR can expect to receive notification of the decision or proposed decision from the relevant committee secretary.

29.2. The committee secretary will serve any statutory notices on the PR and inform them of any right to reconsideration or, where relevant, any right of appeal and the timescale within which these rights must be exercised.

Suspected Criminal Offences

30. Where inspectors have reasonable grounds for suspecting that an offence under the 1990 Act has been committed, the inspector will consult with the Director of Compliance before a decision is reached to recommend to the Chief Executive that the matter be referred to the police for investigation or to apply to a Justice of the Peace for a warrant to enter, search and seize materials from any premises where offences are suspected to have been committed.

31. The final decision to refer a matter to the police for investigation or apply for a warrant rests with the Chief Executive in consultation with the Chair of the Authority. The Chair may consult with the Deputy Chair and Chair of the Audit and Governance Committee about the recommendation. In the event of a disagreement between the Chief Executive, the Chair of the Authority, the Chair or Deputy Chair of the Audit and Governance Committee, the matter will be put to a vote. The Chair of the Authority will hold a casting vote.

The evidence relied on and the decision to refer the matter to the Chief Executive and the Chair will be documented by the inspector. Any decision reached by the Chief Executive and Chair and the members who are consulted will be recorded by the Chief Executive.