

Understanding how the Compliance and Enforcement policy will be applied

Introduction

The 'Compliance and Enforcement' 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 is a revised version of the HFEA's existing policy, and it sets out a clear framework for how inspectors will apply a risk-based evaluation of any issues identified during inspections or any other compliance related activities for example incidents, complaints and/or whistleblowing.

Identification of concerns

The HFEA has not changed its approach to ensuring compliance with regulatory requirements. Areas of concern noted during inspections usually occur due to failure to follow regulatory requirements and/or code of practice or professional body guidance. In addition, adverse incidents, complaints, or whistleblowing reports may require further investigation including on-site visits to the centre by inspectors.

During any inspection or investigation, we will discuss our concerns with the Person Responsible (PR) and relevant centre staff in order to establish the facts, review any available evidence and also seek external expert opinion if needed. These are our standard compliance activities that are routine and have not changed. Once we have established that there is a non-compliance or concern, we have routinely considered these on the basis of risk (seriousness, likelihood, impact) and take into account the engagement of the PR and broader context of the centre and its compliance history. The processes that we follow are set out in the new Compliance and Enforcement policy which will come into effect on 1 June 2021.

How the policy works in practice

This is a risk-based evaluation process that is applied to the 'worst-case scenario' once this has been clearly established. The policy is not intended to be used prior to any inspection or investigation as the facts will not yet have been established. However, if a PR or centre staff do not co-operate with inspectors (for example not responding to requests for evidence or information), then we may need to draw conclusions based on any limited information we have.

Although we initiate the evaluation on the most significant area of concern, we will also take into account the number and seriousness of other concerns identified. This happens when we consider relevant mitigating or aggravating factors as set out in the policy. We will also take into account how well, or otherwise, the PR has engaged with or addressed issues identified and the factors we will consider are set out in the policy.

Calculating the risk score

Likelihood is where we consider how many instances have occurred already and/or whether it will happen again if not properly addressed or corrected.

- How many times has it happened?
- Will it happen again?
- How often could it happen?

Impact is where we consider the effect of the issue and/or if not properly addressed or corrected. This could be for example large numbers affected less severely, or a severe effect on one individual.

- How wide is the impact?
- Does it impact patients, partner, donors or children born as a result of treatment?
- Does it impact the quality and safety of gametes and embryos?

The risk score

The risk score is calculated after establishing the likelihood and impact of the concern or issue. This is then evaluated in the broader context, taking into account mitigating and aggravating factors as well as the responses of the PR. Once these are considered, the risk score may be adjusted down or up. For example, if the PR has taken action to correct the issue immediately (revised processes, staff training, audits, suspension of activities) then this is likely to reduce the likelihood and impact and therefore the overall risk score. Conversely, if no corrective actions have been taken and activities have continued unchanged this would potentially increase the likelihood and impact, therefore the risk score will be increased.

Whilst the policy describes the risk score for the worst-case scenario or non-compliance the inspectors will be taking into account all findings. For example, a very high number of what are classified as 'other' areas of non-compliance in an inspection report may indicate a more serious issue and therefore a higher likelihood of significant failings with a wide impact. This will be reflected in the risk score.

The policy is designed to allow for the risk score to be reviewed following any further evidence or information provided to or received by the inspectors.

Actions taken by inspectors

There are some indicative examples in the policy of the actions that inspectors may take. These actions escalate in seriousness from Level 1 through to Level 3. We have always taken action proportionate to the risk, however our new policy now documents the range of actions we may take. These actions escalate from Level 1 to 3 in line with the increase in risk. By setting these out in the policy we want to make it clearer to centres how these actions reflect the level of concerns we have in relation to the evaluation of risk.