

<b>Annex B</b>
----------------

### FEEDBACK ON NEW HFEA INSPECTION REPORT FORMAT

Below is a copy of the inspection report feedback form which was sent to all Persons Responsible, Nominal Licensees, HFEA Inspector, BFS, ACE, BAS, CHILD, FNG, and RCOG. The participants were given six weeks to feedback any comments, of which 30 replied.

Given below is the percentage breakdown of how each question was answered, followed by the comments which are quoted verbatim.

**Name:**

**Position:**

**Organisation:**

Please indicate your views below:

1	<p>Is the new format clear, informative and easy to follow?</p> <p>Comment: Yes – 93%</p> <p>No – 7%</p>	<input type="checkbox"/> Yes  <input type="checkbox"/> No
2	<p>Are there additional information/ sections you would like to see in the new format?</p> <p>Comment: Yes – 38%</p> <p>No – 62%</p>	<input type="checkbox"/> Yes  <input type="checkbox"/> No
3	<p>Do you feel that the new format will give a fair reflection of the activities carried out at your centre?</p> <p>Comment: Yes – 90%</p> <p>No – 10%</p>	<input type="checkbox"/> Yes  <input type="checkbox"/> No
4	<p>Any other comments you wish to make</p> <p>Please see below</p>	

## Comments

### From Centres

“Unclear what is inspector’s protocol. How is licensed treatment reviewed against PI, CP etc. Satellite links – who should be named and usually use main centre protocols. Should be a section for units appeals in last 3 years licensing history, unsure as to why licensing history is necessary”.

“Although this is fine, it does not apply to us at all, as we only have a storage licence. Please could we know how this would be made clear and in what format to be relevant for us”.

“Not all recommendations need to be complied with. All should be considered but it maybe appropriate that no changes are needed. Only written complaints are counted in clinical practice in the NHS. CVs presumably to remain confidential. If so the column should identify ‘CV seen’ only”.

“However the all important issue is the audit trail, particularly in the laboratories. The audit criteria against which the Centre will be assessed should be agreed and made public. The crucial issue is to have in place a system that would have, for example, detected the problems developing in the Hampshire clinic. I would suggest the proposed forms are piloted in a number of Centres with feedback from all parties”.

“I have read the proposed format etc.. it looks fine to me”.

“On the whole except section 4 which I found confusing. This format makes it appear as though the centre had a poor or non existent pat info/lab protocols rather than needing an amendment. The headings to the table are not clear either”.

“Hopefully as before the centre will be able to reply to a report and make comments, which if valid could lead to a final amendment of the report”.

“Perhaps some explanatory notes may help patients understanding”.

“A great development on the last version”.

“Space for a personal statement or response. Section 1 – Specify patient demographic. Section 2 – don’t think length of service is a useful yardstick. There are many features which will affect staff turnover. Sometimes it may be possible to be stuck with someone for many years”.

“Nominal Licensee on front page, Andrologist in section 2, replace senior embryologist with senior scientist”.

“Our centre carries out transport IVF with the Bridge centre. We therefore do not have a licence for IVF treatment. However each inspection the HFEA

checks our IVF records, information, results, consents and protocols. In fact all areas of our IVF practice including the operating theatre. In our feedback from the licence committee IVF is included despite our licence only being for DI. A large percentage of our time is spent IVF. I consider it to be extremely unjust that transport IVF is not considered to be an activity of the centre. The HFEA feedback their findings but never credit us with carrying out the activity. This seems very one sided and very unfair”.

“Research projects should obtain approval of the Trusts Research & Development Committee”.

“An illustration of the commendations should be included where relevant, in addition to the conditions and recommendations”.

“I would suggest that the information reflect whether the clinic is located within an NHS hospital, in a private hospital or in a freestanding building. Furthermore, the information should reflect whether the clinic consultant is NHS accredited or not, and give qualifications of the medical staff, along with other details. The word ‘consultant’ is widely abused and the information provided should reflect the true status of the personnel of the centre”.

“Why not include the centre stats as submitted to the HFEA? Would it be useful information to know the percentage of 2/3 embryo transfers? If the centre has had an adverse incident, there should be a statement from the HFEA describing why it is happy that the incident is resolved”.

“The information does not reflect the culture within Units. It is very bland and does not reflect the way the Unit responds to patients. Many centres have to treat the patients within their Health authority area and therefore the patient demographic information must reflect the profile of the geographical area and general population. Within section one the question relating to private/NHS – is this a breakdown in percent or numbers per purchasing authority or is it a yes/no option?

Within section two do all staff now have to submit a CV at each Inspection – is this relevant as the members of staff within some Units change frequently. How is the CPD programme available within Unit be measured? Will each member of the teams have to produce evidence of CPD at Inspections? Within section three is the percentage of 2/3 embryo transfers reflect whether they were elective or actual? What about the number of one embryo transfers?

All members of staff expressed concern at the thought of information being made public before they were aware of what was being said. We are presuming that the HFEA will only publish after the Person Responsible has accepted the report issued by the HFEA”.

From Inspectors

“P6: should there not be some check on embryo freezing PI, CR, etc? But you need to have results as well, should there not be some assessment of results?”

“In section 2 the staff list does not follow the same format of that requires in the application form i.e. the position OF Andrologist is missing. Is this deliberate or an oversight”.

“See 3 pages = no 2, 4 & 11. P2 – Counsellors telephone number on display, HFEA leaflets on display. P4 – staff to cover for consultants, embryologist & nurses. P11 - egg sharing ovum donors”.

“In section 5.1 note keeping & 5.2 environments i.e. rooms, waiting areas and labs. Maybe good idea having the recommendations at the end – clear instructions with regard to the overall improvements that are needed”.