Licence Committee – minutes

All Centres
Variation of all licences without application
European Union (EU) Exit requirements

Date:	Thursday, 4 March 2021
Venue:	Teleconference
Attendees:	Jonathan Herring (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Ermal Kirby
Executive:	Dee Knoyle – Committee Secretary Paula Robinson - Head of Planning & Governance Catherine Burwood - Licensing Manager Emily Tiemann - Regulatory Policy Manager Karen Conyers – Inspector (Observer) Sarah Stedman - Inspector (Observer for Induction)
Legal Adviser:	Darryn Hale – DAC Beachcroft LLP
Observers:	Alison Marsden - Authority Member (Induction)

1. Declaration of interest

- Members of the committee declared that they had no conflicts of interest in relation to this item.

2. The committee had before it:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

3. The following papers were considered by the committee:

- Relicensing Exercise for European Union (EU) Exit Requirements including:
  - Annex A – Amendments to Standard Licence Conditions (SLCs)
  - Annex B – List of licences to be varied

4. Background

European Union (EU) Exit

4.1. As a result of the United Kingdom (UK) leaving the European Union, changes have been made to various pieces of legislation, including the Human Fertilisation and Embryology Act 1990 (as amended). As a consequence of these changes, the HFEA is required to vary some Standard Licence Conditions (SLCs) for all licences.

4.2. The licences of all HFEA licensed centres contain a list of SLCs. Research licences contain a set of research SLCs, while all other licences contain a set of treatment and storage SLCs. These SLCs are rarely changed.

4.3. At its meeting in November 2020, the Authority agreed to delegate to the HFEA Chair the power to make any decisions necessary to give effect to the 2020 EU Exit Regulations and other relevant legislation and the application thereof. The proposed revisions of the SLCs were duly approved by the Chair of the HFEA on 16 February 2021.

4.4. The proposed revisions to SLCs would ensure that centres' licences remain in line with requirements when the EU Exit transition period ends on 30 June 2021.

4.5. The Executive reported that the proposed changes to the SLCs have been shared with the fertility sector and to date no issues have been raised.

5. Consideration of variations without application

5.1. The committee noted that the Authority may vary a licence without application from a centre in circumstances in which it has the power to revoke the licence under S18(2) of the HF&E Act 1990 (as amended). The type of variations that can be made without application under section 18A(5)(a) and (b), include varying or removing a condition or adding a condition to a centre's licence.

5.2. Under S18(2) (i) the Authority may revoke a licence otherwise than on application if 'it is satisfied that there has been any other material change of circumstances since the licence was granted'.

5.3. The UK's departure from the EU constitutes such a material change of circumstances involving changes across several areas of UK law, including the HF&E Act 1990 (as amended) and related pieces of legislation.

5.4. The committee noted that, if it accepts that, in this case, there are grounds to revoke all active licences, it may then rely on the power under section 18A to vary the licences to amend the SLCs.

Administrative process for varying all licences

5.5. The Head of Planning and Governance advised the committee of the steps that would be taken to vary all centres' licences in one exercise. This would include issuing an 'offer' licence, accompanied by a notice of proposal to vary the licence, which is required to comply with section 19(2) of the HF&E Act 1990 (as amended).

5.6. The committee noted that all centres are required to acknowledge the offer licence in order to receive a final HFEA licence.

5.7. The committee was informed that processes are in place to ensure that the necessary administrative steps are taken to efficiently record the variation and accuracy of each centre's licence.

5.8. The committee noted that the minutes of the Licence Committee meeting will be issued, and then published, along with the offer licences. This would be in accordance with the usual process for issuing new licences, which PRs were accustomed to. This would occur in the second half of April, to allow sufficient time for all the new offer licences to be drafted and checked. Meanwhile an article would be placed in the Clinic Focus newsletter to advise the sector of the decision.

5.9. The committee noted that any routine variations to centres' current licences (eg, change of Licence Holder) that are processed between now and 1 July 2021 will also be taken into account so that all varied licences reflect all approved variations. Such routine variations would result in minor changes to the numbering of individual licence references listed in the paper before the committee.

Changes to Standard Licence Conditions (SLCs)

5.10. The committee was presented with the changes to SLCs, which included one set for centres operating in Great Britain (GB) and one set for centres operating in Northern Ireland (NI). The Policy Manager outlined the reasons for each revision.

5.11. The committee noted that the following SLCs have been changed because of EU Exit:

T20, T30, T31, T51, T53, T100, T101, R48, R59, R60 and R67.

5.12. The committee noted that the revised SLCs have been carefully drafted by the HFEA with input on technical details from other professional bodies such as the MHRA. The SLCs have also been reviewed by a Legal Adviser.

5.13. The committee noted that in addition to the changes to the above SLCs, the Executive also proposed a change to SLC T21, which would otherwise be the only SLC still to include an out-of-date reference to the old CPA(UK) Ltd testing accreditation system. The CPA no longer exists. Similar changes have also been incorporated into the SLCs listed above that refer to testing. Previously, in 2018, the Authority had agreed to update this reference while making other changes to SLC T53 only. The current relicensing exercise would enable all such references to be updated in the same way.

Practical considerations for clinics

5.14. The committee discussed affordability and the practicalities associated with EU Exit requirements but noted that there is a transitional period in respect of compliance using CE and UK(NI), or UKCA marked medical devices.

5.15. The committee also asked whether a traceability system would be in place in Great Britain to replace the use of the Single European Code applied to gametes and embryos. The committee heard that tracing would still be a requirement under General Direction 13 (each set of gametes and embryos must still carry unique and accurate identification), and that centres could continue with the current system if they wish to.

Recommendations

5.16. The Executive recommended the variation without application of all active HFEA licences, as listed in Annex B (which can also be found at the bottom of these minutes), to reflect the changes in the SLCs listed in Annex A (which can also be found at the bottom of these minutes) on the basis of the grounds set out at 5.1, 5.2 and 5.3 above, in accordance with section 18A of the HF&E Act 1990 (as amended). The committee noted that, if agreed, a notice of proposal to vary the licence would then be sent to each centre. The committee also noted that, if the variation without application is approved for all centres, the varied licences would come into force on 1 July 2021.

5.17. The committee noted that a variation to change the SLCs listed in Annex A would ensure that SLCs are consistent with current legislation, enacted as part of the EU Exit process. The changes would also ensure that the SLCs correctly reference the UKAS accreditation system for testing.

6. Decision

Legal Advice to the Licence Committee

6.1. The Legal Adviser to the committee agreed that the legal basis for the variation without application to all active HFEA licences, was correct.

Variation of licences without application

6.2. The committee was satisfied that there are grounds to revoke all active HFEA licences, due to the UK's departure from the EU, and the accompanying legislative changes, constituting a material change of circumstances.

6.3. The committee endorsed the Executive's recommendation for the variation of all active HFEA licences, as listed in Annex B, without application, to reflect the changes in the SLCs listed in Annex A, to amend T20, T30, T31, T51, T53, T100, T101, R48, R59, R60 and R67, on the basis of the grounds set out at 5.1, 5.2 and 5.3 above, in accordance with section 18A of the HF&E Act 1990 (as amended).

6.4. The committee endorsed the Executive's recommendation, also to update SLC T21, to address the obsolete reference to the CPA (UK) Ltd accreditation system.

Notice of Proposal

6.5. The committee also confirmed that it would send a notice of proposal to vary the licences to each centre, with the offer of a licence.

Licence

6.6. The committee agreed that, if no representations or any other information is received within 28 days, the final licence should be issued.

6.7. The committee noted that all varied offer licences, acknowledged and accepted by the centres, would be finalised on 1 July 2021.

7. Chair's signature

7.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Jonathan Herring

Date

23 March 2021

Annex A

Amendments to certain Standard Licence Conditions (SLCs)

Relicensing project – proposed changes to SLCs

EU Exit-related changes:

Ref	Original version	New GB version	New NI version
T20	In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1 and Directive 2003/94/EC. It must be demonstrated and documented that the chosen environment achieves the quality and safety required. NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.	In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1. It must be demonstrated and documented that the chosen environment achieves the quality and safety required. NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.	**Same as GB version**
T30	Wherever possible only CE marked medical devices must be used.	Wherever possible only CE marked, CE and UK(NI) marked, or UKCA marked medical devices must be used. NOTE: CE marked medical devices will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June	Wherever possible only CE marked or CE and UK(NI) marked medical devices must be used. NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices used in Northern Ireland should be CE marked if certified by a

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		2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.	notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulation 2002 (as amended).
T31	The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.	The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of the Medical Devices Regulations 2002 (as amended).	**Same as GB version.**
T51	The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:	The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:	The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:

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	a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b.** blood samples must be obtained within a timeframe specified by the Authority.	**a.** the test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b:** blood samples must be obtained within a timeframe specified by the Authority. NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.	**a:** the test must be carried out by a laboratory accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b:** blood samples must be obtained within a timeframe specified by the Authority. NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices (including testing kits) used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).
T53	The centre must ensure that the laboratory tests required by licence	The centre must ensure that the laboratory tests required by licence	The centre must ensure that the laboratory tests required by licence

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	condition T52 meet the following requirements, namely: **a.** The test must be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. CE marked testing kits must be used where appropriate. **b.** Blood samples must be obtained within a timeframe specified by the Authority, and **c.** Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing.	condition T52 meet the following requirements, namely: **a:** The test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. **b:** Blood samples must be obtained within a timeframe specified by the Authority, and **c:** Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing. NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to	condition T52 meet the following requirements, namely: **a:** The test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked testing kits where appropriate. **b:** blood samples must be obtained within a timeframe specified by the Authority, and **c:** Donor sperm must be quarantined for a minimum of 180 days, after which repeat serological testing is required. If the blood sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing. NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices (including testing kits) used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).

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		1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.	
T100	The documented procedures referred to in licence condition T99 include the following information: **a.** the unique and accurate identification of each patient/donor **b.** the unique and accurate identification of each set of gametes and embryos, including the Single European Code applied to each set of gametes and embryos when required by General Direction 0006 **c.** date of procurement **d.** place of procurement **e.** type of treatment **f.** description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and **g.** description of all processing steps applied to the procurement, use and storage of gametes and embryos.	The documented procedures referred to in licence condition T99 include the following information: **a.** the unique and accurate identification of each patient/donor **b.** the unique and accurate identification of each set of gametes and embryos **c.** date of procurement **d.** place of procurement **e.** type of treatment **f.** description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and **g.** description of all processing steps applied to the procurement, use and storage of gametes and embryos.	The documented procedures referred to in licence condition T99 include the following information: **a.** the unique and accurate identification of each patient/donor **b.** the unique and accurate identification of each set of gametes and embryos, including the Single European Code applied to each set of gametes and embryos when required by General Direction 0013 (NI) **c.** date of procurement **d.** place of procurement **e.** type of treatment **f.** description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and **g.** description of all processing steps applied to the procurement, use and storage of gametes and embryos.
T101	The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing,	The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing,	The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing,

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	use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying. Containers holding gametes and embryos or the paperwork attaching to any containers must be labelled with a SEC in those circumstances specified in General Direction 0006.	use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.	use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying. Containers holding gametes and embryos or the paperwork attaching to any containers must be labelled with a Single European Code in those circumstances specified in General Direction 0013 (NI).
R48	Unless otherwise specified in licence condition R47, where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.	Unless otherwise specified in licence condition R47, where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.	**Same as GB version.**
R59	Wherever possible only CE marked medical devices must be used.	Wherever possible only CE marked, CE and UK(NI) marked, or UKCA marked medical devices must be used. NOTE: CE marked medical devices will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical	Wherever possible only CE marked or CE and UK(NI) marked medical devices must be used. NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in

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		Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.	Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).
R60	The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and when applicable the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.	The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of the Medical Devices Regulations 2002 (as amended).	**Same as GB version.**
R67	The centre must ensure that the laboratory tests required by licence condition R66 meet the following requirements, namely: **a.** the test must be carried out by a qualified laboratory which has suitable accreditation (for example by CPA (UK)	The centre must ensure that the laboratory tests required by licence condition R66 meet the following requirements, namely: **a:** the test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national	The centre must ensure that the laboratory tests required by licence condition R66 meet the following requirements, namely: **a:** test must be carried out by a laboratory which is accredited to conduct that test by UKAS, the national

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	Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b.** blood samples must be obtained within a timeframe specified by the Authority.	accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked, CE and UK(NI) marked, or UKCA marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b:** blood samples must be obtained within a timeframe specified by the Authority. NOTE: CE marked medical devices (including testing kits) will continue to be accepted on the UK market until 30 June 2023. Medical devices placed on the GB market after 30 June 2023 must be UKCA marked rather than CE marked, as set out in the Medical Devices Regulations 2002 (as amended). This requirement does not prevent centres from continuing (after 30 June 2023) to use CE marked medical devices which were on the market prior to 1 July 2023. The UK Government has guaranteed unfettered access for NI businesses to the rest of the UK internal market. This means that any conformity mark held by a NI business which validates a medical device for sale on the NI market is valid for the whole of the UK. Accordingly, NI businesses can continue to place CE marked and CE and UK(NI) marked devices on the GB market after 30 June 2023.	accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard, using CE marked or CE and UK(NI) marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and **b:** blood samples must be obtained within a timeframe specified by the Authority. NOTE: The UKCA mark is not available for devices placed on the NI market. Medical devices (including testing kits) used in Northern Ireland should be CE marked if certified by a notified body in the European Union. Medical devices certified for the market in Northern Ireland by a UK notified body should be both CE and UK(NI) marked as set out in the Medical Devices Regulations 2002 (as amended).

And:

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T21	If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics (cytogenetics and molecular genetics), haematology, bacteriology, virology and clinical biochemistry.	If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must be accredited to conduct the relevant test(s) by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics (cytogenetics and molecular genetics), haematology, bacteriology, virology and clinical biochemistry.	**Same as GB version.**
The above change is being proposed in addition, since otherwise T21 would be the only SLC still to include an out-of-date reference to the old CPA(UK) Ltd accreditation system. The CPA no longer exists. (Similar changes are already incorporated into the SLCs listed above that refer to testing, but these also have EU Exit-related changes in them.).			

Annex B

Licences to be varied

Key - Licence types

T&S: Treatment and Storage

T&S (embryo): Treatment (including embryo testing) and Storage

T&S (embryo/ PNT): Treatment (including embryo testing with PNT) and Storage

Treatment Insem. ptnr / dnr sperm and storage: Treatment (Insemination using partner / donor sperm) and Storage

Treatment (Insem. prtnr sperm): Treatment (Insemination using partner sperm)

Storage Only: Storage Only

Research: Research

Centre number	Centre name	Licence reference	Licence type
0004	Ninewells Hospital	L0004/17/b	T&S
0005	Fertility Exeter	L0005/18/b	T&S
0006	The Lister Fertility Clinic	L0006/16/c	T&S (embryo)
0007	Hewitt Fertility Centre	L0007/17/d	T&S (embryo)
0008	CARE Fertility Tamworth	L0008/16/g	T&S
0011	London Sperm Bank	L0011/21/c	Storage
0013	Centre for Reproductive Medicine, Coventry	L0013/15/c	T&S
0013	Centre for Reproductive Medicine, Coventry	R0155/7/a	Research
0015	Sussex Downs Fertility Centre	L0015/18/c	T&S
0016	CARE Northampton	L/0016/16/b	T&S (embryo)
0017	Newcastle Fertility Centre at Life	R/0152/7/a	Research
0017	Newcastle Fertility Centre at Life	L/0017/16/a	T&S (embryo/ PNT)
0019	Aberdeen Fertility Centre	L/0019/16/a	T&S

Centre number	Centre name	Licence reference	Licence type
0021	Hull IVF Unit	R/0067/11/a	Research
0021	Hull IVF Unit	L/0021/14/a	T&S
0026	BMI The Priory Hospital	L/0026/16/b	T&S
0030	Herts and Essex Fertility Centre	L/0030/18/a	T&S
0031	Assisted Reproduction Unit (ARU), University Hospital of Hartlepool	L/0031/16/a	Storage Only
0033	Manchester Fertility	L/0033/15/b	T&S (embryo)
0035	Oxford Fertility	R/0198/2/b	Research
0035	Oxford Fertility	L/0035/14/b	T&S (embryo)
0037	Glasgow Royal Infirmary	L/0037/15/b	T&S (embryo)
0044	The Centre for Reproductive and Genetic Health	L/0044/17/c	T&S (embryo)
0049	Wales Fertility Institute, Cardiff	L/0049/17/b	T&S
0051	Cambridge IVF	L/0051/16/a	T&S
0055	The James Cook University Hospital	L/0055/18/a	T&S
0057	Wessex Fertility Limited	L/0057/19/a	T&S (embryo)
0061	CARE Sheffield	L/0061/16/a	T&S (embryo)
0067	St Mary's Hospital	R/0026/17/a	Research
0067	St Mary's Hospital	L/0067/19/b	T&S
0068	Leicester Fertility Centre	L/0068/17/c	T&S (embryo)
0070	London Sperm Bank (LSB) London Bridge	L/0070/20/f	Treatment Insem. ptnr / dnr sperm and storage
0075	London Women's Clinic, Darlington	L/0075/17/b	T&S (embryo)
0076	NURTURE Fertility	L/0076/16/a	T&S (embryo)
0077	Regional Fertility Centre, Belfast	L/0077/19/c	T&S
0078	Wolfson Fertility Centre - Hammersmith Hospital	L/0078/16/g	T&S (embryo)

Centre number	Centre name	Licence reference	Licence type
0080	Andrology Unit, Hammersmith Hospital	L/0080/15/c	Storage Only
0086	BMI Chelsfield Park ACU	L/0086/18/c	T&S
0088	London Fertility Centre	L/0088/19/a	T&S
0094	Barts Health Centre for Reproductive Medicine	L/0094/16/a	T&S
0096	Sunderland Fertility Centre	L/0096/22/a	Treatment Insem. ptnr / dnr sperm & Storage
0098	Lanarkshire Acute Hospital NHS Trust	L/0098/17/a	Treatment Insem. ptnr sperm
0100	Bourn Hall Clinic	L/0100/16/a	T&S (embryo)
0101	CARE Nottingham	L/0101/18/a	T&S (embryo)
0102	Guys Hospital	R/0075/13/a	Research
0102	Guys Hospital	L/0102/16/c	T&S (embryo)
0105	London Women's Clinic	L/0105/20/c	T&S (embryo)
0109	King’s Fertility	L/0109/14/g	T&S (embryo)
0119	Birmingham Women's Hospital	L/0119/17/e	T&S (embryo)
0139	CARE Bath	L/0139/14/f	T&S (embryo)
0144	CARE Woking	L/0144/14/e	T&S
0148	Shropshire and Mid-Wales Fertility Centre	L/0148/14/b	T&S
0149	Royal Derby Hospital	L/0149/11/b	Treatment Insem. ptnr / dnr sperm and storage
0151	Gloucestershire Hospitals NHS Trust	L/0151/13/a	Storage Only
0153	Homerton Fertility Centre	L/0153/16/b	T&S
0157	Assisted Reproduction and Gynaecology Centre	L/0157/28/a	T&S (embryo)
0158	Chelsea & Westminster Hospital	L/0158/13/a	T&S
0159	Royal Surrey County Hospital	L/0159/12/b	Storage Only

Centre number	Centre name	Licence reference	Licence type
0162	NUH Life Fertility Services	L/0162/16/a	Treatment Insem. ptnr / dnr sperm and storage
0167	University College London Hospitals	L/0167/12/c	Treatment Insem. ptnr / dnr sperm and storage
0170	The Gateshead Fertility Unit	L/0170/12/a	T&S
0175	University of Manchester	R/0026/15/a	Research
0179	Centre for Reproduction and Gynaecology Wales and West	L/0179/12/e	T&S
0185	CARE Manchester	L/0185/11/a	T&S (embryo)
0196	Jessop Fertility	L/0196/9/d	T&S (embryo)
0197	Salisbury Fertility Centre	L/0197/11/a	T&S
0198	St Jude's Women's Hospital	L/0198/9/a	T&S
0199	CARE London	L/0199/9/d	T&S (embryo)
0201	Edinburgh Assisted Conception Unit	L/0201/8/b	T&S (embryo)
0206	Reproductive Genetics Institute	L/0206/12/a	T&S (embryo)
0208	CARE Tunbridge Wells	L/0208/9/d	T&S (embryo)
0209	Centre for Human Reproductive Science	R/0173/5/a	Research
0245	Human Genetics & Embryology Laboratories	R/0113/9/a	Research
0246	The Francis Crick Institute	R/0152/2/b	Research
0246	The Francis Crick Institute	R/0162/9/c	Research
0249	Institute of Reproductive and Developmental Biology	R/0174/7/a	Research
0250	GCRM Fertility	L/0250/6/c	T&S
0251	Centre for human development, stem cells and regeneration	R/0142/5/a	Research
0252	Wellcome-MRC Cambridge Stem Cell Institute	R/0178/5/c	Research
0254	The Agora Gynaecology and Fertility Centre	L/0254/6/c	T&S

Centre number	Centre name	Licence reference	Licence type
0258	The Fertility Centre at Whittington Health	L/0258/5/a	Treatment Insem. ptnr / dnr sperm and storage
0259	Beginnings at Epsom & St Helier NHS University Trust	L/0259/6/a	T&S
0276	Reproductive Medicine Clinic, Bristol	L/0276/5/a	Treatment (Insem. prtnr sperm)
0278	Fertility Fusion	L/0278/5/a	Treatment (Insem. prtnr sperm)
0280	CARE Fertility Chester	L/0280/4/e	T&S (embryo)
0282	Cornwall Centre for Reproductive Medicine (CCRM)	L/0282/5/a	Treatment (Insem. prtnr sperm)
0287	Ayrshire Fertility Unit, Crosshouse Hospital	L/0287/4/b	Treatment (Insem. prtnr sperm)
0289	North Middlesex University Hospital (Reproductive Medicines Unit)	L/0289/5/b	Treatment (Insem. prtnr sperm)
0291	Fertility Unit Barking, Havering and Redbridge Hospitals Trust	L/0291/5/b	Treatment (Insem. prtnr sperm)
0293	Andrology Solutions	L/0293/5/a	Treatment Insem. ptnr / dnr sperm and storage
0294	The Orchard Clinic, Craigavon Area Hospital	L/0294/5/a	Treatment (Insem. prtnr sperm)
0295	Bristol Centre for Reproductive Medicine	L/0295/4/b	T&S (embryo)
0299	CREATE Fertility, London Wimbledon	L/0299/5/c	T&S (embryo)
0300	Fisher Bioservices UK	L/0300/4/d	Storage Only
0301	London Women's Clinic, Wales	L/0301/5/a	T&S (embryo)
0307	Complete Fertility Centre Southampton	L/0307/4/a	T&S
0314	Leeds Fertility	L/0314/4/a	T&S (embryo)
0316	Centre for Reproduction & Gynaecology Wales (CRGW)	L/0316/4/a	T&S
0319	Cardiff University School of Biosciences	R/0161/4/a	Research
0320	Hartshorne and Genesis Group	R/0155/4/a	Research

Centre number	Centre name	Licence reference	Licence type
0321	NewLife Fertility Centre	L/0321/4/a	T&S (embryo)
0322	Brighton Fertility Associates	L/0322/3/a	Treatment Insem. ptnr / dnr sperm and storage
0324	City Fertility	L/0324/3/b	T&S (embryo)
0325	Bourn Hall Clinic Norwich	L/0325/4/a	T&S
0327	Boston Place	L/0327/3/a	T&S (embryo)
0328	Belfast Fertility	L/0328/3/a	T&S
0329	Wales Fertility Institute, Neath	L/0329/3/a	T&S (embryo)
0331	The Gurdon Institute	R/0189/4/c	Research
0332	Oxford Cell and Tissue Biobank	L/0332/3/a	Storage Only
0333	Harley Street Fertility Clinic	L/0333/3/b	T&S (embryo)
0335	In-OVO Fertility Clinic	L/0335/1/a	T&S
0336	Simply Fertility	L/0336/3/c	T&S (embryo)
0338	Reproductive Health Group	L/0338/3/a	T&S (embryo)
0339	CREATE Fertility, London St Paul's	L/0339/3/c	T&S (embryo)
0340	Mechanochemical Cell Biology	R/0155/3/a	Research
0341	The Fertility & Gynaecology Academy	L/0341/2/a	T&S (embryo)
0342	Concept Fertility	L/0342/3/a	T&S
0344	Hewitt Fertility Centre, Knutsford	L/0344/2/b	T&S
0345	Semovo Leeds	L/0345/2/a	Storage Only
0346	Semovo Liverpool	L/0346/2/a	Storage Only
0347	The Physiology Laboratory	R/0193/3/b	Research
0348	CREATE Fertility, Birmingham	L/0348/2/a	T&S (embryo)
0352	Future Health Biobank	L/0352/1/d	Storage Only

Centre number	Centre name	Licence reference	Licence type
0353	X&Y Fertility	L/0353/2/a	Treatment Insem. ptnr / dnr sperm and storage
0354	IVI London (Wimpole Street)	L/0354/2/b	T&S (embryo)
0355	MRC Centre for Reproductive Health	R/0204/2/a	Research
0356	European Sperm Bank UK Ltd	L/0356/2/a	Storage Only
0357	Thames Valley Fertility	L/0357/2/b	T&S (embryo)
0358	CARE Fertility Birmingham	L/0358/2/c	T&S (embryo)
0359	CREATE Fertility, Manchester	L/0359/2/a	T&S (embryo)
0360	Maternal and Fetal Health Research Centre, St Mary's Hospital	R/0026/2/a	Research
0363	Bourn Hall Clinic Wickford	L/0363/2/b	T&S
0364	Semovo Glasgow	L/0364/2/a	Storage Only
0365	IVF London	L/0365/2/a	T&S (embryo)
0367	The Evewell	L/0367/1/b	T&S (embryo)
0368	CREATE Fertility Bristol	L/0368/2/b	T&S (embryo)
0369	Semovo London	L/0369/1/b	Storage Only
0373	Wellcome Centre for Cell Biology	R/0155/1/b	Research
0376	The Jack Copland Centre, Scottish National Blood Transfusion Service (SNBTS)	L/0376/1/a	Storage Only
0379	MRC Laboratory of Molecular Biology	R/0207/1/a	Research
0380	CARE Liverpool	L/0380/1/a	T&S
0382	Aria Fertility	L/0382/1/a	T&S (embryo)