

## Proposed new Standard Licence Conditions (SLCs)

### EU Exit-related changes:

Ref	Original version	New GB version	New NI version
T20	<p>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.</p> <p><b>NOTE:</b> 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.</p>	<p>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.</p> <p><b>NOTE:</b> 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.</p>	<p><b>Same as GB version</b></p>
T30	<p>Wherever possible only CE marked medical devices must be used.</p>	<p>Wherever possible only CE marked, CE and UK(NI) marked, or UKCA marked medical devices must be used.</p> <p><b>NOTE:</b> 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</p>	<p>Wherever possible only CE marked or CE and UK(NI) marked medical devices must be used.</p> <p><b>NOTE:</b> 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</p>

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		<p>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.</p>	<p>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).</p>
T31	<p>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.</p>	<p>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).</p>	<p><b>Same as GB version.</b></p>

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T51	<p>The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:</p> <p><b>a.</b> 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</p> <p><b>b.</b> blood samples must be obtained within a timeframe specified by the Authority.</p>	<p>The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:</p> <p><b>a.</b> 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</p> <p><b>b:</b> blood samples must be obtained within a timeframe specified by the Authority.</p> <p><b>NOTE:</b> 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</p>	<p>The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:</p> <p><b>a:</b> 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</p> <p><b>b:</b> blood samples must be obtained within a timeframe specified by the Authority.</p> <p><b>NOTE:</b> 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).</p>

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		<p>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.</p>	
T53	<p>The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:</p> <p><b>a.</b> 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.</p> <p><b>b.</b> Blood samples must be obtained within a timeframe specified by the Authority, and</p> <p><b>c.</b> 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</p>	<p>The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:</p> <p><b>a:</b> 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.</p> <p><b>b:</b> Blood samples must be obtained within a timeframe specified by the Authority, and</p> <p><b>c:</b> 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)</p>	<p>The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:</p> <p><b>a:</b> 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.</p> <p><b>b:</b> blood samples must be obtained within a timeframe specified by the Authority, and</p> <p><b>c:</b> 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</p>

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	<p>blood sample should be taken and subjected to repeat serological and NAT testing.</p>	<p>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.</p> <p><b>NOTE:</b> 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.</p>	<p>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.</p> <p><b>NOTE:</b> 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).</p>
T100	The documented procedures referred to in licence condition T99 include the following information:	The documented procedures referred to in licence condition T99 include the following information:	The documented procedures referred to in licence condition T99 include the following information:

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	<p><b>a.</b> the unique and accurate identification of each patient/donor</p> <p><b>b.</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</p> <p><b>c.</b> date of procurement</p> <p><b>d.</b> place of procurement</p> <p><b>e.</b> type of treatment</p> <p><b>f.</b> description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and</p> <p><b>g.</b> description of all processing steps applied to the procurement, use and storage of gametes and embryos.</p>	<p><b>a.</b> the unique and accurate identification of each patient/donor</p> <p><b>b.</b> the unique and accurate identification of each set of gametes and embryos</p> <p><b>c.</b> date of procurement</p> <p><b>d.</b> place of procurement</p> <p><b>e.</b> type of treatment</p> <p><b>f.</b> description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and</p> <p><b>g.</b> description of all processing steps applied to the procurement, use and storage of gametes and embryos.</p>	<p><b>a.</b> the unique and accurate identification of each patient/donor</p> <p><b>b.</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)</p> <p><b>c.</b> date of procurement</p> <p><b>d.</b> place of procurement</p> <p><b>e.</b> type of treatment</p> <p><b>f.</b> description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and</p> <p><b>g.</b> description of all processing steps applied to the procurement, use and storage of gametes and embryos.</p>
T101	<p>The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, 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.</p>	<p>The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, 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</p>	<p>The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, 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.</p>

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	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.	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.	<b>Same as GB version.</b>
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.  <b>NOTE:</b> 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 Devices Regulations 2002 (as amended). This requirement does not prevent	Wherever possible only CE marked or CE and UK(NI) marked medical devices must be used.  <b>NOTE:</b> 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 Northern Ireland by a UK notified body should be both CE and UK(NI) marked as

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		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.	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).	<b>Same as GB version.</b>
R67	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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	<p>condition R66 meet the following requirements, namely:</p> <p><b>a.</b> 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</p> <p><b>b.</b> blood samples must be obtained within a timeframe specified by the Authority.</p>	<p>condition R66 meet the following requirements, namely:</p> <p><b>a:</b> 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</p> <p><b>b:</b> blood samples must be obtained within a timeframe specified by the Authority.</p> <p><b>NOTE:</b> 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</p>	<p>condition R66 meet the following requirements, namely:</p> <p><b>a:</b> 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. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and</p> <p><b>b:</b> blood samples must be obtained within a timeframe specified by the Authority.</p> <p><b>NOTE:</b> 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).</p>

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		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.	

**One further change:**

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T21	<p>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.</p>	<p>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.</p>	<p><b>Same as GB version.</b></p>
<p>The above change is being proposed in addition, since otherwise it would be the only SLC still to include an out-of-date mention of the old CPA(UK) Ltd accreditation system. The CPA no longer exists. UKAS accredit the tests, rather than the laboratories.</p>			