EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (CORONAVIRUS, TESTING REQUIREMENTS AND STANDARDS) (ENGLAND) (AMENDMENT AND TRANSITIONAL PROVISION) REGULATIONS 2023

2023 No. [XXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the UK Health Security Agency ('UKHSA') and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 This instrument implements the policy that from 1 January 2024, organisations providing commercial clinical COVID-19 testing services i.e., diagnostic laboratories, and those carrying out sample collection or point of care testing ("private providers") must be fully accredited against the appropriate ISO Standard by a signatory to the International Laboratory Accreditation Cooperation ("ILAC") Mutual Recognition Arrangement ("MRA") and reflects the publication of the updated ISO Standard 15189:2022. This instrument amends the test device requirements to align with the requirements set out in the Medical Devices Regulations 2002 (S.I. 2002/618) and removes the requirement to submit tests for additional validation. This instrument also removes other additional requirements that were necessary in the early stages of the pandemic, such as the requirement to ensure oversight of the testing process by a clinical scientist, the three-stage UKAS accreditation process, and removes the requirements applying to non-clinical providers.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State at the Department of Health and Social Care, Maria Caulfield, has made the following statement regarding Human Rights:

"In my view the provisions of The Health Protection (Coronavirus, Testing Requirements and Standards) (England) (Amendment and Transitional Provision) Regulations 2023 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument amends the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 (S.I.2020/1549), as amended by the Health Protection (Coronavirus, Testing Requirements and Standards) (England)

(Amendment) Regulations 2021 (S.I.2021682) ("the Testing Requirements and Standards Regulations"). The legislative context for those Regulations is set out at paragraphs 6.1 to 6.5 and 6.1 to 6.3 respectively of the Explanatory Memorandum to those Regulations published on www.legislation.gov.uk.

6.2 In line with the Government's Living with Covid strategy the Testing Requirements and Standards Regulations have been reviewed and updated to reflect the changing epidemiological and immunological picture in England.

7. Policy background

What is being done and why?

7.1 This instrument introduces a requirement for all private providers to be accredited against the appropriate ISO Standards by a signatory to the ILAC MRA to provide testing services in England. This instrument also provides that all private providers must use an approved test device which meets the requirements of the Medical Devices Regulations 2002. This instrument removes the previous three-staged accreditation scheme for private providers, which consisted of 1) applying to UKAS for accreditation and self-declaring against the minimum standards, 2) UKAS appraisal within four weeks to demonstrate minimum standards have been met and identify gaps to resolve to progress, and 3) obtaining full accreditation against the relevant ISO standard through UKAS. This instrument also reflects the publication of the updated ISO Standard 15189:2022. The ISO Standard transition plan allows any existing accredited provider to be re-assessed against the new ISO Standard from 1st April 2023.

Explanations

What did any law do before the changes to be made by this instrument?

7.2 During the COVID-19 pandemic, regulations focused on enabling new providers who self-declared that they met the appropriate quality standards, to be able to rapidly enter the market. The previous three-staged accreditation scheme for private providers consisted of 1) applying to UKAS for accreditation and self-declaring against the minimum standards, 2) UKAS appraisal within four weeks to demonstrate minimum standards have been met and identify gaps to resolve to progress, and 3) obtaining full accreditation against the relevant ISO standard through UKAS. This meant companies could provide testing services to the public without having achieved full accreditation, as long as they were going through the process at the time.

Why is it being changed?

7.3 During the COVID-19 pandemic, regulations focused on enabling new providers who self-declared that they met the appropriate quality standards, to be able to rapidly enter the market. This struck the appropriate balance at the time between protecting public health and growing the market quickly, itself a necessary public health outcome. The balance of priorities has now changed given the overall state of the pandemic and the maturity of the existing market. The urgent need to grow the market quickly no longer applies, and the Department now has the opportunity to review the Testing Requirements and Standards Regulations and remove the special measures which were put into place during the pandemic. The amendments made by this instrument will hold providers to high standards whilst removing the additional requirements that were necessary in the early stages of the pandemic, such as the

requirement to submit tests for additional validation, and the requirement to ensure oversight of the testing process by a clinical scientist. Further, this instrument removes the three-stage accreditation process which had additional administrative steps. This instrument addressed the issue that the current Testing Requirements and Standards Regulations do not reflect the updated ISO Standard 15189:2022. Unless we update the Testing Requirements and Standards Regulations, providers who have already completed accreditation would not be able to provide testing services as and when they transition to the new ISO standards (ISO Standard 15189:2022) prior to the existing Standard being revoked in 2025.This instrument will ensure that those providers will remain compliant with the relevant regulations.

What will it now do?

7.4 The Testing Requirements and Standards Regulations are being amended to require that from 1 January 2024, private providers providing commercial clinical COVID-19 testing services must be accredited against the appropriate ISO Standard by a signatory to the ILAC MRA to provide testing services in England. Private providers continue to be required to use test devices that meet the requirements set out in the Medical Devices Regulations 2002, however they will no longer need to undergo a separate validation process.

7.5 The amendments made by this instrument also reflect the publication of the updated ISO Standard 15189:2022. This instrument does not affect providers who have applied for ISO/IEC 17025:2017 before this instrument comes into force. They may complete the three-stage accreditation process providing they continue to meet the deadlines set out in the three-stage process.

7.6 This instrument also removes the requirements applying to 'front-end' customer facing providers, such as the requirement to self-declare that they meet the appropriate quality standards, and to have overall responsibility for the end-to-end testing service.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 There has been no public consultation in relation to this instrument.

11. Guidance

11.1 All providers who are currently participating in the accreditation process, including those who have already achieved accreditation will be emailed to inform them of the changes to the regulations.

12. Impact

12.1 The impact on business, charities or voluntary bodies is minimal. For businesses, although they now need to complete accreditation *before* providing testing services, they previously still needed to complete that process so the net impact will be minimal.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because low level of impact per business.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through normal compliance activity and will also be in line with the Systematic Review of ISO Standards. The ISO Standards are reviewed around every 5 years to ensure Standards remain up to date and globally relevant.

14.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 at the Department of Health and Social Care, Maria Caulfield, has made the following statement: A statutory review clause is not included in the instrument since the amended requirements are not extensive and are considered to meet the Government's 'de minimis' regulatory impact criteria, meaning no impact assessment is required (in particular, because the impacts are below £5m, and have minimal impact on small business and create no open-ended new powers in legislation).

15. Contact

15.1 Jasmine Walker at the UK Health Security Agency Telephone: email: jasmine.walker@ukhsa.gov.uk can be contacted with any queries regarding the instrument.

15.2 Harry Mayhew, Deputy Director for the Centre for Pandemic Preparedness, at the UK Health Security Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister Caulfield at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.