EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (CORONAVIRUS, TESTING REQUIREMENTS AND STANDARDS) (ENGLAND) (AMENDMENT) REGULATIONS 2021

2021 No. 682

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument seeks to extend the current deadline for private covid test providers to be granted accreditation through the UKAS (National Accreditation Body for the United Kingdom) accreditation process. Currently, some providers have until 30 June 2021 to achieve accreditation; this SI would extend this deadline to 31 August 2021, with a view to reduce resource constraints and ensure that a greater number of high-quality test providers are able to successfully pass through the process.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial 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 As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 This instrument amends the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 ("the Testing Requirements Regulations"). The legislative context for those Regulations is set out at paragraphs 6.1 to 6.5 of the Explanatory Memorandum to those Regulations published on www.legislation.gov.uk.

6.2 This instrument also amends the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 ("the International Travel Regulations"). The legislative context for those Regulations is set out at paragraphs

6.1 to 6.5 of the Explanatory Memorandum to those Regulations published on www.legislation.gov.uk.

6.3 This instrument is made subject to the negative resolution procedure because the Secretary of State and the Parliamentary Under Secretary of State are satisfied that it does not contain any provision imposing or enabling the imposition of restrictions or requirements having a significant effect on a person's rights. The instrument serves to extend the existing timeframe for accreditation.

7. Policy background

What is being done and why?

7.1 This instrument will extend the deadline for private test providers currently working towards a deadline of 30 June to be granted accreditation through the UKAS accreditation process. This amendment will give those providers until 31 August to achieve accreditation; ensuring that a greater number of high-quality applicants are able to successfully pass through the process, and that UKAS resource constraints are reduced. The deadline for test providers who were working towards a later deadline has also been extended.

7.2 It will also set out in legislation the process for attaining full accreditation with UKAS in accordance with the extended deadline:

(a) The test provider must achieve a positive recommendation from UKAS, setting out the results of UKAS's appraisal of the provider's competence to receive accreditation by 30 June 2021, or by a date 4 months after the date on which the provider completed stage two, whichever is the later. The positive recommendation will include any actions which UKAS requires the provider to undertake before UKAS will proceed with the application for accreditation. A test provider who does not achieve a positive recommendation by the appropriate date must not provide tests until such time as they achieve a positive recommendation from UKAS.

(b) The test provider must achieve accreditation by UKAS to the relevant ISO standards by 31 August 2021, or by a date 6 months after the date on which the provider completed stage two, whichever is the later. (c). A test provider who is not accredited by UKAS by the relevant date must cease to provide tests until such time as they have been accredited by UKAS to the relevant ISO standard.

7.3 The instrument amends Schedule 8 of the International Travel Regulations to modify the requirements of Regulation 6 of the Testing Requirements Regulations so that providers providing tests in accordance with that Schedule are only required to make one declaration of compliance to the Department.

7.4 The instrument amends Schedule 10 of the International Travel Regulations to apply the same accreditation process as required by Regulation 6 of the Testing Requirements Regulations to tests providers proving tests in accordance with that Schedule.

Explanations

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

7.5 The current legislation provides for a deadline of 30 June for some private covid test providers be granted accreditation, as per the UKAS accreditation process.

Why is it being changed?

7.6 The current deadline is being extended to ensure that a greater number of high-quality applicants are able to successfully pass through the process. This extension will help to reduce UKAS resource constraints, by better managing the input of application materials into UKAS and lessen the administrative pressure point that would have otherwise presented a potential risk to the process.

What will it now do?

7.7 Private test providers who would have otherwise had to achieve accreditation by the existing 30 June deadline will now have until 31 August. This deadline extension will provide them more time to collate the evidence and take the corrective actions needed to support their application, as well as provide UKAS with more time to process this material.

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 A formal consultation process was not required for this instrument; as the proposed amendment is a minor update to the existing accreditation process.

11. Guidance

11.1 All providers who are currently participating in the accreditation process and are working towards the current deadline of 30 June will be emailed to inform them of the new deadline.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

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

12.3 An Impact Assessment has not been prepared for this instrument because the amendments merely (1) extend the deadline within the existing accreditation process (2) removes the need for some test providers under the International Travel Regulations to make two declarations to the Department and (3) brings tests provided in accordance with the Schedule 10 to the International Travel Regulations into the same accreditation process , and as such will not negatively impact any individuals, organisations, or businesses.

13. Regulating small business

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

13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is to inform them of the extension to the current deadline to achieve accreditation. This deadline extension will give providers more time to complete their application for accreditation, and remove the need to follow different

accreditation processes for tests provided under the Testing Requirements Regulations and the International Testing Regulations – as such will not have a negative impact on the requirements on small businesses.

13.3 The basis for the final decision on what action to take to assist small businesses was taken with respect to the net positive impact this amendment will have, as well as the relatively minor nature of the proposed change.

14. Monitoring & review

14.1 A statutory review clause is in the Testing Requirements Regulations. The Secretary of State must review the need for requirements imposed by those Regulations, which this instrument amends.

15. Contact

15.1 Keshav Phakey at the Department of Health and Social Care. Email: Keshav.Phakey@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Matthew Russell, Deputy Director for Private Sector Testing, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

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