This Statutory Instrument, in part, corrects errors in S.I. 2021/582 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2021 No. 914

PUBLIC HEALTH, ENGLAND

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021

Made - - - -	*at 11.10 a.m. on 30th July 2021*
Laid before Parliament	*at 2.30 p.m. on 30th July 2021*

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 45B, 45C, 45F(2), 45P(2) and 60A of the Public Health (Control of Disease) Act 1984(**1**).

In accordance with section 45Q(3) of that Act, the Secretary of State is of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of the Act which imposes or enables the imposition of a special restriction or requirement or any other restriction or requirement which has or would have a significant effect on a person's rights.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 7) Regulations 2021.

(2) Except for regulations 9 to 11 and regulation 12(b), these Regulations come into force at 4.00 a.m. on 2nd August 2021.

(3) Regulations 9 to 11 and regulation 12(b) come into force on 23rd August 2021.

(4) These Regulations extend to England and Wales, and apply in relation to England only.

(**1**) 1984 c. 22. Part 2A was inserted by section 129 of the Health and Social Care Act 2008 (c. 14).

Amendment to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021

2. The Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(**2**) are amended in accordance with regulations 3 to 10.

Amendment of regulation 2A

3.—(1) Regulation 2A (exemptions for vaccinated travellers and others) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (b), after "United Kingdom" insert "or a relevant country";

(b) after sub-paragraph (b) insert—

"(ba) if the course of doses was received in the United States of America, is ordinarily resident in the United States of America;";

(c) in sub-paragraph (c), for the words "through the NHS COVID pass" to the end substitute—

"through—

(i) the NHS COVID pass, or equivalent from NHS Scotland, NHS Wales or the Department of Health in Northern Ireland;

(ii) the EU Digital COVID Certificate; or

(iii) the Centers for Disease Control and Prevention vaccination card;";

(d) after sub-paragraph (c), insert—

"(ca) is able to provide proof if required by an immigration officer or the operator of the relevant service on which P travels to England of meeting the requirement in sub-paragraph (ba); and".

(3) In sub-paragraph (b) of paragraph (4), after "participation" insert "if required by an immigration officer or the operator of the relevant service on which P travels to England".

(4) After paragraph (4) insert—

"(4A) P—

(a) has participated or is participating in a clinical trial regulated in the United States of America by the Food and Drugs Administration of a vaccine for vaccination against coronavirus;

(b) is able if required by an immigration officer or the operator of the relevant service on which P travels to England to provide proof of such participation through the Centers for Disease Control and Prevention vaccination card;

(c) has declared on the Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria for reduced isolation and testing requirements; and

(d) is ordinarily resident in the United States of America and is able to provide proof of that residence if required by an immigration officer or the operator of the relevant service on which P travels to England.".

(5) In sub-paragraph (b) of paragraph (5), at the end insert "or a relevant country".

(6) In paragraph (10)—

(a) for the definition of "authorised vaccine" substitute—

""authorised vaccine" means a medicinal product for vaccination against coronavirus authorised—

(**2**) S.I. 2021/582 amended by S.I. 2021/589, 670, 731, 766, 795 and 865.

(a) in relation to doses received in the United Kingdom—

(i) for supply in the United Kingdom in accordance with a marketing authorisation, or

(ii) by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012;

(b) in relation to doses received in a relevant country, for supply in that country following evaluation by the relevant regulator for the country;";

(b) for the definition of "marketing authorisation" substitute—

""marketing authorisation"—

(a) in relation to a vaccine authorised for supply in the United Kingdom or in a member State, has the meaning given in regulation 8(1) (general interpretation) of the Human Medicines Regulations 2012;

(b) in relation to a vaccine authorised for supply in a relevant country other than a member State, means a marketing authorisation granted by the relevant regulator for the country;";

(c) after the definition of "NHS Wales" insert—

""relevant country" means a country listed in the first column of the table in paragraph (11);

"relevant regulator", in relation to a relevant country, means the regulator identified in the corresponding row of the second column of the table in paragraph (11), and a reference to a regulator in that table is a reference to the regulatory authority of that name designated as a Stringent Regulatory Authority by the World Health Organization pursuant to the operation of the COVAX Facility(**3**);";

(d) after paragraph (10) insert—

"(11) The table referred to in the definitions of "relevant country" and "relevant regulator" follows—

Relevant country	*Relevant regulator*
a member State	European Medicines Agency
Andorra	European Medicines Agency
Iceland	European Medicines Agency
Lichtenstein	European Medicines Agency
Monaco	European Medicines Agency
Norway	European Medicines Agency
San Marino	European Medicines Agency
Switzerland	Swissmedic
the United States of America	United States Food and Drug Administration
Vatican City State	European Medicines Agency"

(**3**) A list of the regulatory authorities designated as Stringent Regulatory Authorities has been published by the World Health Organization and is available online athttps://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

Amendment of regulation 7

4.—(1) Regulation 7 (requirement to undertake workforce tests) is amended as follows.

(2) In paragraph (2), for "paragraph (7)" substitute "paragraphs (7) and (10)".

(3) In paragraph (9), for "Where" substitute "Subject to paragraph (10), where".

(4) After paragraph (9) insert—

"(10) Paragraphs (2) and (9) do not apply where—

(a) P is a person described in any of the following paragraphs of Schedule 4—

(i) paragraph 6 (seamen and masters),

(ii) paragraph 7 (pilots),

(iii) paragraph 8 (inspectors and surveyors of ships),

(iv) paragraph 9 (aircraft crew and pilots),

(v) paragraph 10 (international rail crew, passenger and freight operator),

(vi) paragraph 15 (Channel Tunnel system workers);

(b) P meets the condition in paragraph 11 of Schedule 4 (travel on conveyance without passengers etc.); and

(c) P—

(i) does not disembark from or leave the conveyance on which P travelled to England at any time when the conveyance is moored at a port in England or is otherwise stationary in England, or

(ii) travelled to England on the same conveyance on which they left England and did not disembark from or leave that conveyance at any time when it was moored at a port in a country outside the common travel area or was otherwise stationary in such a country.".

Amendment of regulation 16

5. In regulation 16 (requirement to ensure passengers have completed a passenger locator form), for paragraph (1) substitute—

"(1) An operator must ensure that—

(a) a passenger—

(i) who presents at immigration control at the Channel Tunnel shuttle terminal area in France, with the intention of boarding a shuttle service destined for the United Kingdom, has completed a Passenger Locator Form,

(ii) who arrives at a port in England on a relevant service other than a shuttle service has completed a Passenger Locator Form; and

(b) a passenger possesses evidence that they are a person described in a paragraph of Schedule 4 (exemptions), where they have indicated on the Passenger Locator Form that they are such a person.

(1A) Paragraph (1)(b) does not apply in relation to a person described in paragraph 13(2)(c)(i) of Schedule 4 (road haulage worker), who is the driver of a goods vehicle that has been or will be conveyed to England on the relevant service.".

Amendment of regulation 17A

6. In regulation 17A(2)(a) (requirement to ensure passengers possess evidence of vaccination)(**4**) for "(4)(b), or" substitute "(3)(ca), (4)(b), (4A)(b) and (d) or".

Amendment of regulation 19

7. In regulation 19 (offences and penalties) for paragraph (9) substitute—

"(9) In relation to the offence in paragraph (7)(b), it is a defence—

(a) for an operator alleged to have failed to ensure that a passenger has completed a Passenger Locator Form, to show that they recorded a unique passenger reference number for the relevant passenger; or

(b) for an operator alleged to have failed to ensure that a passenger possesses evidence of eligibility for an exemption claimed in a Passenger Locator Form, to show that the passenger presented a document purporting to be appropriate evidence which the operator, or a person acting on behalf of the operator, could not reasonably have been expected to know was not appropriate evidence,

before that passenger presented at immigration control at the Channel Tunnel shuttle terminal area or boarded the relevant service, as the case may be.".

Amendment of Schedule 4

8. In paragraph 11 of Schedule 4—

(a) in sub-paragraph (1), in the opening words, for "regulation 3(10)(c)" substitute "regulations 3(10)(c) and 7(10)(b)";

(b) in sub-paragraph (2)(b), for "10(1)(b)" substitute "10(b)".

Amendment of Schedule 8

9.—(1) Schedule 8 (mandatory testing after arrival in England) is amended as follows.

(2) In sub-paragraph (2)(c)(ii) of paragraph 6 (day 2 tests: general test requirements), for the words "greater than" to the end substitute "greater than or equal to 99% (or a 95% two-sided confidence interval entirely above 97%),".

(3) In sub-paragraph (1)(g)(ii) of paragraph 7 (day 2 tests: private provider requirements)—

(a) at the end of paragraph (bb), omit "and";

(b) at the end of paragraph (cc), insert—

"; and

(dd) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test)".

(4) In paragraph 8 (day 8 tests: general test requirements)—

(a) for sub-paragraph (2) substitute—

"(2) A test complies with this sub-paragraph where—

(a) it is a semi-quantitative test for the detection of coronavirus which—

(i) targets a minimum of two distinguishable SARS-CoV-2 genes other than the S gene and performance reference controls,

(**4**) Regulation 17A was inserted by S.I. 2021/865.

(ii) includes routine in silico assurance against every variant of concern, and

(iii) produces a test solution that provides extracted nucleic acid that is suitable for whole genome sequencing using a specified method;

(b) it is, in relation to a Schedule 11 passenger, a test that can be self-administered;

(c) the manufacturer of any device used for the purposes of the test states that the device—

(i) uses an established molecular detection method,

(ii) has a specificity greater than or equal to 97% (or a 95% two-sided confidence interval entirely above 95%),

(iii) has a sensitivity greater than or equal to 95% (or a 95% two-sided confidence interval entirely above 90%),

(iv) has a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre, and

(v) is suitable for identifying every variant of concern; and

(d) any device used for the purposes of the test—

(i) can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002(**5**), other than solely by virtue of regulation 39(2) of those Regulations, and

(ii) has been validated no more than 18 months before the test is administered or provided to P.";

(b) for sub-paragraph (3) substitute—

"(3) For the purposes of sub-paragraph (2)—

(a) "specified method" means a targeted sequence method specific to SARS-CoV-2 or an equivalent—

(i) amplicon method, or

(ii) sequence bait capture method;

(b) "validated", in relation to a device, has the meaning given by paragraph 2(2) of Schedule 10;

(c) "variant of concern" means a variant of SARS-CoV-2 identified in a designation made by the Secretary of State for the purposes of this paragraph and published in a manner as appears to the Secretary of State to be appropriate.".

(5) For paragraph 9 (day 8 tests: private provider requirements) substitute—

"**Day 8 tests: private provider requirements**

9.—(1) For the purposes of paragraph 8(1)(b)(iii), a private provider complies with this paragraph where—

(a) they comply with the requirements of paragraph 3(1)(a) and (e) to (h) of Schedule 10 as if any reference in those provisions to an appropriate test were a reference to a day 8 test;

(b) if the provider is a laboratory that conducts diagnostic test evaluation for testing in accordance with this Schedule, they have made a declaration to the Department of Health and Social Care that they meet the minimum standards

(**5**) S.I. 2002/618.

for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/InternationalTesting;

(c) they have provided the Department of Health and Social Care with a list of all organisations that they work with (whether by sub-contract or otherwise) to carry out the testing service or to carry out genomic sequencing, indicating the nature of the service that each organisation is providing, and kept that list updated as appropriate;

(d) the person responsible for the taking of samples meets the relevant requirements for accreditation to ISO standard 15189 or ISO/IEC standard 17025 in respect of the taking of samples;

(e) the laboratory used by the test provider for the processing of samples meets the relevant requirements for ISO standard 15189 or ISO/IEC standard 17025 in respect of the evaluation of the established molecular detection method and the genomic sequencing of samples;

(f) they receive the information required by paragraph 10(3) or (4) (as appropriate), and if they administer the test to P, they do so no earlier than the end of the seventh day after the day on which P arrived in England;

(g) each day, they notify the Secretary of State in writing of—

(i) the number of tests they sold on that day, and

(ii) in relation to each test sold on that day—

(aa) the date of the arrival in England of the person in respect of whom the test was sold,

(bb) whether the person in respect of whom the test was sold is an eligible category 2 arrival or not, and

(cc) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test);

(h) they sequence each sample with a cycle threshold less than 30 (equivalent to ~1,000 viral genome copies per millilitre);

(i) in respect of the sequencing of samples, they must secure a reference genome coverage breadth of at least 50% and at least 30 times coverage;

(j) on a request by the Secretary of State or the COVID-19 Genomics UK Consortium, they make samples available for the purpose of dual sequencing;

(k) they preserve and transport samples in a manner that enables genome sequencing;

(l) they have in place a process to remove human reads from any data submitted in a notification to Public Health England pursuant to the Health Protection (Notification) Regulations 2010; and

(m) if they arrange with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, the test provider ensures that X complies with the following so far as relevant to the carrying out of that element—

(i) paragraph 3(1)(e) to (h) of Schedule 10 as applied by paragraph (a) of this sub-paragraph,

(ii) paragraph (c) to (l) of this sub-paragraph,

(iii) paragraph 11(2), (3) and (4).

(2) For the purposes of sub-paragraph (1)(m), "single end-to-end testing service" has the meaning given in paragraph 3(2)(c) of Schedule 10.

(3) For the purposes of sub-paragraph (1)(d) and (e), a person or laboratory (as the case may be) meets the relevant requirements for accreditation to a standard where the person who is the operator of the laboratory complies with the requirements of regulation 6 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 as if—

(a) a reference to an applicable test were a reference to a day 8 test;

(b) a reference to a test provider were a reference to a private provider;

(c) in paragraph (1), the words from "and make a declaration" to "25th November 2020" were omitted.".

(6) In paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test)—

(a) after sub-paragraph (3), insert—

"(3A) Subject to paragraph (4) and where P is required to comply with regulation 3 (requirement on passengers to provide information), at the time the test is returned for processing P provides to the test provider the unique passenger reference number provided by or on behalf of P as described in regulation 19(18).";

(b) in sub-paragraph (4)—

(i) in the opening words, after "(3)" insert "or (3A)";

(ii) in paragraph (a), after "(3)" insert "and (3A)".

(7) In sub-paragraph (5) of paragraph 11 (notification of test results), after paragraph (b) insert—

"(ba) where P is required to comply with regulation 3, the unique passenger reference number provided by or on behalf of P as described in regulation 19(18);

(bb) P's passport number or travel document number (as appropriate);

(bc) the test reference number given to P in accordance with sub-paragraph (5) of paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test);".

Amendment of Schedule 10

10.—(1) Schedule 10 (optional testing after arrival in England) is amended as follows.

(2) In sub-paragraph (1)(b) of paragraph 2 (appropriate tests)—

(a) for sub-paragraph (i) substitute—

"(i) a sensitivity greater than or equal to 95% (or a 95% two-sided confidence interval entirely above 90%),";

(b) for sub-paragraph (ii) substitute—

"(ii) a specificity greater than or equal to 97% (or a 95% two-sided confidence interval entirely above 95%),".

(3) In paragraph 4 (required circumstances for undertaking testing)—

(a) after sub-paragraph (b), insert—

"(ba) subject to sub-paragraph (c) and where P is required to comply with regulation 3, at the time the test is returned for processing P provides to the test provider the unique passenger reference number provided by or on behalf of P as described in regulation 19(18);";

(b) in sub-paragraph (c)—

(i) in the opening words, after "(b)" insert "or (ba)";

(ii) in paragraph (i), after "(b)" insert "and (ba)".

(4) In sub-paragraph (6) of paragraph 5 (notification of test results), after paragraph (b) insert—

"(ba) where P is required to comply with regulation 3, the unique passenger reference number provided by or on behalf of P as described in regulation 19(18);

(bb) P's passport number or travel document number (as appropriate);

(bc) the test reference number given to P in accordance with sub-paragraph (d) of paragraph 4 (required circumstances for undertaking testing);".

Amendment of the Health Protection (Notification) Regulations 2010

11. In regulation 4ZA (duty to notify PHE of the results of certain mandatory tests) of the Health Protection (Notification) Regulations 2010(**6**)—

(a) in paragraph (1)(c), for "paragraph 7(1)(g) of Schedule 11" substitute "paragraph 7(1)(h) or 9(1)(h) of Schedule 8";

(b) in paragraph (2)(d)(iii), after "number" insert ", including the laboratory's five-letter unique identifier code";

(c) in paragraph (3), for "paragraph 7(1)(g) of Schedule 11" substitute "paragraph 7(1)(h) or 9(1)(h) of Schedule 8".

Transitional and saving provision

12. The amendments made—

(a) by regulations 3 to 8 do not have effect in relation to any traveller who arrived in England before 4.00 a.m. on 2nd August 2021, and

(b) by regulations 9 to 11 do not have effect in relation to any traveller who arrives in England before 23rd August 2021.

Helen Whately
Minister of State
Department of Health and Social Care

At 11.10 a.m. on 30th July 2021

(**6**) S.I. 2010/659. Regulation 4ZA was inserted by S.I. 2021/150 and amended by S.I. 2021/223, 442 and 582.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 ("the International Travel Regulations").

Regulation 3 amends regulation 2A of the International Travel Regulations to exclude certain arrivals from category 2 countries (primarily, those who have received a full course of vaccination in, or who are under 18 and ordinarily resident in, a specified country) from testing and self-isolation requirements.

Regulation 4 amends regulation 7 of the International Travel Regulations to exclude certain individuals operating transport services from the requirement to undertake workforce tests.

Regulation 5 amends regulation 16 of the International Travel Regulations to require operators to ensure that passengers seeking to rely on an exemption in Schedule 4 possess evidence that they are eligible for the exemption.

Regulation 9 amends paragraphs 8 and 9 of Schedule 8 to the International Travel Regulations to bring the technical requirements for day 8 tests into line with the more stringent requirements for day 2 tests.

These Regulations make further minor and consequential amendments to the International Travel Regulations.

Regulation 11 amends regulation 4ZA of the Health Protection (Notification) Regulation 2010 to make minor corrections and other minor amendments.

An impact assessment has not been produced for this instrument. An explanatory memorandum has been published alongside this instrument at www.legislation.gov.uk.