STATUTORY RULES OF NORTHERN IRELAND

2021 No. 293

PUBLIC HEALTH

The Health Protection (Coronavirus, International Travel) (2021 Consolidation) (Amendment No. 8) Regulations (Northern Ireland) 2021

Made - - - - 30th October 2021

Coming into operation in accordance with regulations 1(2) and (3)

The Department of Health(**a**) makes the following Regulations in exercise of the powers conferred by sections 25B and 25F of the Public Health Act (Northern Ireland) 1967(**b**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Health Protection (Coronavirus, International Travel) (2021 Consolidation) (Amendment No. 8) Regulations (Northern Ireland) 2021.

(2) Except as specified in paragraph (3), these Regulations come into operation at 4.00 a.m. on 31 October 2021.

(3) Regulations 4 and 5 come into operation at 4.00 a.m. on 1 November 2021.

(4) An amendment made by these Regulations does not apply in relation to a person arriving in Northern Ireland before the coming into operation of the provision containing the amendment.

(5) In these Regulations "the principal Regulations" means the Health Protection (Coronavirus, International Travel) Regulations (Northern Ireland) 2021(**c**).

Amendment of principal Regulations

2. The principal Regulations are amended in accordance with regulations 3 to 8.

Amendment of regulation 2 (Interpretation)

3.—(1) Regulation 2 (Interpretation) is amended as follows.

(2) In paragraph (1), at the appropriate place insert—

> ""day 2 LFD test" means a test for coronavirus which complies with, and is undertaken in the circumstances described in Schedule;".

(3) After paragraph (3), insert—

> "(4) For the purposes of these Regulations an LFD is a device—

(**a**) 2016 c. 5 (N.I.), s. 1(5).
(**b**) 1967 c. 36 (N.I.).
(**c**) S.R. 2021 No. 99 as amended by S.R. 2021 Nos. 108, 121, 132, 154, 189, 213, 214, 218, 225, 230, 241, 262, 278, 282 and 284.

(a) that can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002(**a**),

(b) has been validated no more than 18 months before being used by or on a person,

(c) has been confirmed as having the required sensitivity and specificity using at least 150 positive clinical samples and 250 negative clinical samples against a laboratory based RT-PCR test that is itself within the performance specification of the target product profile published by the Medicines and Healthcare Products Regulatory Agency for laboratory based SARS-CoV-2 PCR tests, by—

(i) the Secretary of State, or

(ii) a laboratory which is accredited to ISO standard 15189 or ISO/IEC standard 17025 by the United Kingdom Accreditation Service ("UKAS") or an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation ("ILAC") Mutual Recognition Arrangement or the European Co-operation for Accreditation ("EA") Multilateral Agreement, other than a laboratory which processes tests provided by the test provider for the purposes of these Regulations or is owned by the person carrying out an LFD test or the device manufacturer, or

(d) a laboratory which is accredited by UKAS to ISO standard 15189 or ISO/TEC standard 17025, other than a laboratory which processes LFD tests for the purposes of these Regulations or is owned by the person carrying out that test or the device manufacturer.".

Amendment of regulation 3 (Interpretation: red list and non-red list countries and arrivals)

4. In regulation 3, for paragraph (3) substitute—

"(3) For the purposes of these Regulations, a person (P) is not treated as arriving in, departing from or transiting through a country or territory, or part of a country or territory, if P arrives in and leaves that country, territory or part thereof by air or sea and—

(a) at all times whilst there remains on the vessel upon which P arrived and no other passenger is permitted to be taken on board, or

(b) at all times whilst there remains on the aircraft upon which P arrived, or

(c) remains at all times whilst waiting for a flight departing from the airport at which P disembarked from an aircraft, within that airport, and departs on a flight from that airport without first passing through immigration control.".

Amendment of Schedule 1 (Red list countries)

5. In Schedule 1, for the existing text substitute "No countries are currently listed for the purposes of this Schedule".

Amendment of Schedule 2B (Criteria to be an eligible arrival)

6.—(1) Schedule 2B (criteria to be an eligible arrival) is amended as follows.

(2) In paragraph 2, omit sub-paragraph (c).

(3) In paragraph 3, after "if P" insert "is ordinarily resident in Northern Ireland and".

(4) After paragraph 4, insert—

"**4A.**—(1) P meets the conditions of this regulation if P—

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

(a) has participated. or is participating in, phase 2 (therapeutic exploratory studies) or phase 3 (clinical efficacy and safety studies) of a clinical trial of a vaccine for vaccination against coronavirus which is regulated by—

(i) the European Medicines Agency, or

(ii) a regulatory authority (other than such an authority in the United Kingdom or the United States of America) which is designated as a Stringent Regulatory Authority by the World Health Organisation(**a**);

(b) if required by an immigration officer or the operator of the relevant service on which P travels to Northern Ireland is able to provide proof of such participation through a participation document, and

(c) has declared on the Passenger Locator Form that P meets the COVID-19 vaccination eligibility criteria.

(2) For the purposes of this regulation "participation document" means a document in English, French or Spanish issued by a relevant person which confirms—

(a) P's full name;

(b) P's date of birth;

(c) the name and manufacturer of the vaccine;

(d) the country or territory in which the clinical trial is taking, or took, place;

(e) the regulatory authority responsible for the regulation of the clinical trial;

(f) the phase of the clinical trial in which P is participating or participated.

(3) For the purposes of paragraph (2) "relevant person" means—

(a) the competent health authority of the country or territory in which the relevant clinical trial is being, or was, carried out, or

(b) the person who is conducting, or conducted, the relevant clinical trial.".

(5) In paragraph 7B—

(a) after subparagraph (1)(a) insert—

"(aa) if P has received a dose of an authorised vaccine in a relevant country, and a dose of a vaccine under the United Kingdom vaccine roll-out overseas, P is deemed to have completed a course of doses of an authorised vaccine;";

(b) in subparagraph 1(b), omit "in the United Kingdom";

(c) after sub-paragraph (1), insert—

"(2) Where P is a person described in paragraph (1)(b), the proof which P provides for the purposes of paragraph 6(1)(a)(ii) must include proof of having received the dose of an authorised vaccine through—

(a) the NHS COVID pass, certification issued by the Department of Health, or equivalent from NHS Scotland or NHS Wales;

(b) the EU Digital COVID certificate;

(c) the Center for Disease Control and Prevention vaccination card; or

(d) a vaccine certificate.".

(6) In paragraph 10—

(a) in the definition of "authorised vaccine", in paragraph (c) for "in a relevant country listed in paragraph 12" substitute "any other country or territory (including a relevant country listed in paragraph 12)";

(b) in the definition of "United Kingdom vaccine roll-out overseas"—

(**a**) The current list national regulators designated as Stringent Regulatory Authorities is available here:https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs.

(i) at the end of paragraph (a), insert "or";

(ii) omit paragraph (b) (and the word "or" following it).

(7) In paragraph 12, insert the following at the appropriate places in alphabetical order—

"Angola";

"Anguilla";

"Argentina";

"Armenia";

"Azerbaijan";

"Belize";

"Bermuda";

"Botswana";

"Cambodia";

"Cayman Islands";

"Costa Rica";

"Djibouti";

"Eswatini";

"Gibraltar";

"Guyana";

"Honduras";

"Lebanon";

"Lesotho";

"Madagascar";

"Mauritius";

"Mongolia";

"Nepal";

"Occupied Palestinian Territories";

"Panama";

"Peru";

"Rwanda";

"Seychelles";

"Sierra Leone";

"Sri Lanka";

"Suriname";

"Tanzania";

"Trinidad and Tobago";

"Tunisia";

"Uganda";

"Uruguay".

Persons who are exempt

7. In Schedule 4 (Persons who are exempt), in Part 1 (Persons who are exempt)—

(a) omit paragraph 8;

(b) in the table, for entries 5, 6, 7, 8, 9 and 10 substitute the following entries—

"5. Seamen and masters	Exempt (no red list arrivals)	Exempt (unless red list arrival)	Exempt	Exempt (residency condition) Partial exemption (work condition)	Exempt (residency condition) Partial exemption (work condition)
6. Pilots (maritime)	Exempt (no red list arrivals)	Exempt (unless red list arrival)	Exempt	Exempt (residency condition) Partial exemption (work condition)	Exempt (residency condition) Partial exemption (work condition)
7. Ship inspectors	Exempt (no red list arrivals)	Exempt (unless red list arrival)	Exempt	Exempt (residency condition) Partial exemption (work condition)	Exempt (residency condition) Partial exemption (work condition)
8. Air crew	Exempt (no red list arrivals)	Exempt (unless red list arrival)	Exempt	Exempt (residency condition) Partial exemption (work condition)	Exempt (residency condition) Partial exemption (work condition)
9. Transit passenger	Exempt	Not exempt	Exempt	Exempt	Exempt
10. Road haulage worker	Exempt	Exempt (unless red list arrival)	Exempt	Exempt (residency condition) Partial exemption (work condition)	Not exempt"

Amendment of Schedule 6

8.—(1) Schedule 6 (Requirement to book and undertake tests (mandatory testing after arrival in Northern Ireland)) is amended as follows.

(2) In paragraph 5(4)(b), after "undertakes a" insert "confirmatory PCR test or a".

(3) In paragraph 6—

(a) number existing text as "(1)";

(b) in (newly numbered) sub-paragraph (1)—

(i) at the end of head (a), omit "or";

(ii) at the end of head (b), insert "or";

(iii) after head (b), insert

"(c) it is an approved LFD test self-administered by P where the device in question is not a nasopharyngeal one.";

(c) after (newly numbered) sub-paragraph (1), insert—

"(2) Where P undertakes a day 2 LFD test provided by an approved private provider and the result of that test if positive—

(a) P must book and undertake a confirmatory PCR test provided by a public provider, and

(b) the approved private provider mentioned in this sub-paragraph must advise P to take the steps referred to in paragraph (a).".

(4) Paragraph 8 is amended as follows—

(a) in sub-paragraph (2)—

(i) in head (a), after "test" insert "in accordance with the manufacturer's instructions for use" and at the end insert "or, in the case of a confirmatory PCR test, in accordance with paragraph 5";

(ii) in paragraph (b), after "test" insert "in accordance with the manufacturer's instructions for use";

(b) for sub-paragraph (3) substitute—

"(3) Subject to paragraph (4), at the time the test is booked P provides the test provider with the following information—

(a) notification that P is to undertake the test under these Regulations;

(b) the information set out in sub-paragraph (6), and

(c) P's home address and where P is—

(i) an eligible non-red list arrival, the address or addresses where they intend to stay during the period of 10 days beginning on the day after the date of their arrival in the United Kingdom;

(ii) a non-eligible non-red list arrival, the address or addresses at which they intend to self-isolate, or are self-isolating, in accordance with regulations 10 to 13 (if different from their home address); or

(iii) a red list arrival, the address of the accommodation where they are complying with managed isolation in accordance with Schedule 7.

(3A) Subject to Paragraph (4),where—

(a) P's day 2 test is a day 2 LFD test, and

(b) the test has not been administered by the test provider or at a site operated for the purpose of administering such tests by or on behalf of the test provider,

P provides the test provider with the information set out in paragraph (3B) within 15 minutes of the test's read time as determined by the manufacturer's instructions for use.

(3B) The information referred subparagraph (3A) is—

(a) a single photograph clearly showing—

(i) the test device in such a way that it is identifiable as having been provided by the test provider;

(ii) the test reference number given in accordance with paragraph 8(5), and

(iii) the test result, and

(b) the address at which P is able to receive a confirmatory test."

(c) in sub-paragraph (5), for "test reference number" at the first place where it appears substitute "separate test reference number in respect of each test to be provided to P".

(5) In paragraph 9—

(a) in sub-paragraph (1), after "test" insert "other than a day 2 LFD test";

(b) for sub-paragraph (4) substitute—

"(4) See also paragraph 7 of Schedule 8 and paragraph 3(1) of Schedule 10 to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 for additional requirements imposed upon approved private providers in respect of notifications to the United Kingdom Health Security Agency arising out of tests."

.

(6) After paragraph 9 insert—

"**Notification of test results (approved private providers):Lateral Flow Device tests**

9A.—(1) This paragraph applies to an approved private provider who administers or provides an LFD test to P in the circumstances described in paragraph 8.

(2) The approved private provider must, within 24 hours of the relevant event—

(a) notify P, or where paragraph 8(4) applies, Y, by email, letter or text message, of the result of P's test, or

(b) make P's test result available to P, or where paragraph 8(4) applies, to Y via a secure web portal in accordance with sub-paragraph (3).

(3) The notification of P's result must include P's name, date of birth, passport number, or travel document reference number (as appropriate), the name and contact details of the test provider and P's test reference number, and must be conveyed using one of the following forms of words, as appropriate—

Form A: negative LFD test result

Your coronavirus (COVID-19) test result is negative. You did not have the virus when the test was done.

You are not required to quarantine.

You should self-isolate again if you get symptoms of coronavirus (COVID-19)—get an NHS coronavirus (COVID-19) test from www.gov.uk/get-coronavirus-test and self-isolate until you get the results.

For advice on when you might need to self-isolate and what to do, go to www.nhs.uk/conditions/coronavirus-covid-19 and read "Self-isolation and treating symptoms".

Form B: positive LFD test result

Your coronavirus test result is positive. This means that you probably have the virus.

Even if you have not had symptoms of coronavirus, you must now self-isolate for 10 days from the day after your test date.

You must obtain, take and return a free follow up PCR test from NHS Test and Trace to confirm this. You can obtain your confirmatory PCR test by visiting gov.uk/get-coronavirus-test or by calling 119. This test will be free of charge and will be sent to you as a home test kit. You must take this test in accordance with this notice. If this confirmatory test is negative, you no longer need to self-isolate.

You may be contacted for contact tracing and to check that you, and those who you live or are travelling with, are self-isolating.

You must not travel, including to leave the UK, during self-isolation.

Contact 111 if you need medical help. In an emergency dial 999.

Form C: unclear LFD test result

Your coronavirus test result is unclear. It is not possible to say if you had the virus when the test was done.

You must self-isolate for 10 days from the day after your test date.

You may choose to take another test, and if comes back with a negative result, you no longer need to self-isolate. You may be contacted to check that you are self-isolating.

(4) In this paragraph "relevant event" means—

(a) where the test provider administered the test, the time at which the test provider determined the results of the test;

(b) where the test provider did not administer the test, the time at which the test provider received the information required to be provided by paragraph 8(3)(b).

(5) See also paragraph 7 of Schedule 8 and paragraph 3(1) of Schedule 10 to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Regulations 2021 for additional requirements imposed upon approved private providers in respect of notifications to the United Kingdom Health Security Agency arising out of tests."
.

(7) In paragraph 10(1), for "mandatory tests provided" substitute "any test provided in accordance with this Schedule".

Sealed with the Official Seal of the Department of Health on 30th October 2021

L.S.

Dr Lourda Geoghegan
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Protection (Coronavirus, International Travel) Regulations (Northern Ireland) 2021 ("the principal Regulations").

Regulation 3. These amendments introduce lateral flow device (LFD) test for the detection of Coronavirus (SARS-CoV-2) as an alternative to existing requirements on arrivals deemed to be "eligible travellers" to undertake day 2 polymerase chain reaction (PCR) tests. The amendments provide for the use of LFD tests and the consequences of the results of such tests.

Regulation 4 amends regulation 3(3) to update the circumstances in which those arriving in a country or territory on an aircraft or vessel are not to be treated as having departed from, or transited through, that country or territory without first passing through immigration control.

Regulation 5 removes "Colombia", "Dominican Republic", "Ecuador", "Haiti", "Panama", "Peru" and "Venezuela" from the red list of countries.

Regulation 6-

(a) extends the criteria for an "eligible arrival" to include participants in phase 2 or phase 3 clinical trials for a Coronavirus vaccine which is regulated by the European Medicines Agency or a regulatory authority (other than such an authority in the UK or USA) which is designated as a Stringent Regulatory Authority by the World Health Organisation;

(b) extends the circumstances in which a person is deemed to have completed a course of doses of an authorised vaccine. and

(c) adds the following 35 new countries Argentina; Angola; Azerbaijan; Belize; Botswana; Costa Rica; Djibouti, Eswatini; Guyana; Honduras; Lesotho; Mauritius; Mongolia; Nepal; Panama; Peru; Rwanda; Seychelles; Suriname; Tanzania; Trinidad and Tobago; Tunisia; Uganda; Uruguay; Anguilla; Armenia; Bermuda; Cambodia; Cayman Islands; Gibraltar; Lebanon; Madagascar; Occupied Palestinian Territories; Sierra Leone; Sri Lanka, to paragraph 12 of Schedule 2B (Criteria to be an eligible arrival).

Regulation 7 amends the circumstances relating to mandatory testing after arrival in Northern Ireland.

Regulation 8 amends Schedule 4 to the principal Regulations to remove the "no access to passengers" condition from the exemption from the requirement to provide information (regulation 4) for "Seamen and masters", "Pilots (maritime)", "Ship inspectors", and "Air crew"; and to introduce an exemption from the requirement to provide information (regulation 4) for "Transit passenger" and "Road haulage worker".

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office being the Government Printer for Northern Ireland and the Officer appointed to print Acts of the Northern Ireland Assembly.

£6.90

http://www.legislation.gov.uk/id/nisr/2021/293

ISBN 978-0-33-801750-5