
STATUTORY INSTRUMENTS

2021 No. 966

**The Health Protection (Coronavirus, International
Travel and Operator Liability) (England)
(Amendment) (No. 9) Regulations 2021**

Amendments to the Health Protection (Notification) Regulations 2010

- 21.**—(1) The Health Protection (Notification) Regulations 2010^{M1} are amended as follows.
- (2) In regulation 4^{M2} (duty to notify PHE of results of influenza and SARS-Cov-2 tests)—
- (a) in paragraph (2)—
- (i) after sub-paragraph (a) insert—
- “(aa) the date and time the sample was received by the diagnostic laboratory;”;
- (ii) in sub-paragraph (l), after “positive” insert “ or indeterminate ”;
- (b) in paragraph (3A), for “A notification” substitute “ Subject to paragraph (3D), a notification ”;
- (c) in paragraph (3C), for “A notification” substitute “ Subject to paragraph (3D), a notification ”;
- (d) for paragraph (3D) substitute—
- “(3D) A notification which—
- (a) is under paragraph (1)(a) or (b) or (1A)(a), and
- (b) relates to—
- (i) a day 2 or a day 8 test within the meaning of regulation 6 of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021, or
- (i) a test undertaken in accordance with regulation 9(16) of those Regulations, must be provided within 48 hours of the time the diagnostic laboratory received the test sample.”
- (3) In regulation 4ZA^{M3} (duty to notify PHE of results of mandatory tests)—
- (a) in paragraph (2), omit sub-paragraph (d)(viii) and (ix).
- (b) for paragraph (3) substitute—
- “(3) Where the specimen is to be sent to another laboratory for the purposes of sequencing pursuant to paragraph 7(1)(h) or 9(1)(h) of Schedule 8 to the International Travel and Operator Liability Regulations, the operator of the diagnostic laboratory must provide that other laboratory with the specimen number used to fulfil the obligation in paragraph (2)(d)(iii).”.
- (4) After regulation 4ZA insert—

“Duty to notify the UK Health Security Agency of the results of genomic sequencing of mandatory test samples under the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021

4ZB.—(1) The operator of a sequencing laboratory must notify the UK Health Security Agency in accordance with this regulation.

(2) The notification must include the following information so far as it is known to the operator of the sequencing laboratory—

- (a) where the sequencing laboratory is not the source laboratory—
 - (i) the name and address of the source laboratory;
 - (ii) the date and time that the specimen was received by the sequencing laboratory;
- (b) a report of the results of the sequencing;
- (c) the date of that report;
- (d) where the specimen has been sequenced on or after 15th March 2021, a sorted BAM file containing all reads aligning to the SARS-Cov-2 reference genome with unaligned human reads removed;
- (e) any metadata required to reproduce the analysis which produced the results of the sequencing;
- (f) the following information about the specimen—
 - (i) any laboratory comments;
 - (ii) the organism code;
 - (iii) the specimen number;
 - (iv) the specimen type;
 - (v) the specimen date;
 - (vi) the test method applied;
 - (vii) cycle threshold values;
 - (viii) whether the specimen is a variant of concern or a variant under investigation.

(3) Where the sequencing laboratory is not the source laboratory—

- (a) the notification must be provided in writing within 96 hours of receiving the specimen, and
- (b) the sequencing laboratory must—
 - (i) ascertain the specimen number that the source laboratory used to fulfil its obligation in regulation 4ZA(2)(d)(iii) in respect of the specimen, and
 - (ii) use the same specimen number to fulfil the obligation in paragraph (2)(f)(iii).

(4) Where the sequencing laboratory is the source laboratory—

- (a) the notification must be provided in writing within 120 hours of the time SARS-Cov-2 is identified in the specimen, and
- (b) the sequencing laboratory must use the same specimen number to fulfil the obligation in paragraph (2)(f)(iii) as it used to fulfil the obligation in regulation 4ZA(2)(d)(iii).

(5) It is an offence for the operator of a sequencing laboratory to fail without reasonable excuse to comply with this regulation.

(6) Any person who commits an offence under this regulation is liable on summary conviction to a fine.

(7) In this regulation—

“director of a sequencing laboratory” means—

- (a) the clinical microbiologist, consultant pathologist or other registered medical practitioner or other person in charge of the sequencing laboratory, or
- (b) any other person working in the sequencing laboratory to whom the function of making a notification under this regulation has been delegated by the person mentioned in sub-paragraph (a);

“operator of a sequencing laboratory” means the corporate body that operates the sequencing laboratory or, if there is no such body, the director of the sequencing laboratory;

“sequencing laboratory” means a laboratory which sequences a sample pursuant to paragraph 7(1)(h) or 9(1)(h) of Schedule 8 to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021;

“source laboratory” means the diagnostic laboratory which provided the notification required by article 4(1) and 4ZA(1) in respect of the specimen.”.

(5) In regulation 4A ^{M4} (duty on test providers to notify test results)—

- (a) renumber paragraph (7) as paragraph (6);
- (b) in sub-paragraph (a) of paragraph (6) (as renumbered in accordance with this regulation), for “(6)” substitute “ (5) ”;
- (c) renumber paragraph (8) as paragraph (7);
- (d) renumber paragraph (9) as paragraph (8);
- (e) renumber paragraph (10) as paragraph (9).

(6) In paragraph (1)(a) of regulation 7 ^{M5} (electronic communications)—

- (a) after “4(1)” insert “ and (1A) ”;
- (b) after “4ZA” insert “ , 4ZB ”.

Commencement Information

II Reg. 21 in force at 21.9.2021, see [reg. 1\(4\)](#)

Marginal Citations

M1 [S.I. 2010/659](#).

M2 [Regulation 4](#) was amended by [S.I. 2013/235](#), [2020/674](#), [2020/1175](#), [2021/150](#) and [2021/582](#).

M3 [Regulation 4ZA](#) was inserted by [S.I. 2021/150](#) and amended by [S.I. 2021/223](#), [2021/442](#) and [2021/582](#).

M4 [Regulation 4A](#) was inserted by [S.I. 2020/1175](#).

M5 [Regulation 7](#) was amended by [S.I. 2020/1175](#) and [2021/150](#).

Changes to legislation:

There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 9) Regulations 2021, Section 21.