STATUTORY INSTRUMENTS

2010 No. 659

The Health Protection (Notification) Regulations 2010

Duty to notify causative agents found in human samples

4.—(1) The operator of a diagnostic laboratory must notify the Health Protection Agency(**1**) in accordance with this regulation where the diagnostic laboratory identifies a causative agent in a human sample.

(2) The notification must include the following information insofar as it is known to the operator of the diagnostic laboratory—

(a) name and address of the diagnostic laboratory;

(b) details of the causative agent identified;

(c) date of the sample;

(d) nature of the sample;

(e) name of person (P) from whom the sample was taken;

(f) P's date of birth and sex;

(g) P's current home address including postcode;

(h) P's current residence (if not home address);

(i) P's ethnicity;

(j) P's NHS number; and

(k) the name, address and organisation of the person who solicited the test which identified the causative agent.

(3) The notification must be provided in writing within 7 days beginning with the day on which the causative agent is identified.

(4) Without prejudice to paragraph (3), if the operator of the diagnostic laboratory considers that the case is urgent, the notification must be provided orally as soon as reasonably practicable.

(5) In determining whether the case is urgent, the operator of the diagnostic laboratory must have regard to —

(a) the nature of the causative agent;

(b) the nature of the disease which the causative agent causes;

(c) the ease of spread of the causative agent;

(d) the ways in which the spread of the causative agent can be prevented or controlled; and

(e) where known, P's circumstances (including age, sex and occupation).

(6) This regulation does not apply where the operator of the diagnostic laboratory reasonably believes that the Health Protection Agency has already been notified in accordance with this regulation by the operator of another diagnostic laboratory in relation to the same causative agent being found in a sample from the same person.

(**1**) The Health Protection Agency is a body corporate established by section 1 of the Health Protection Agency Act 2004 (c.17).

(7) For the purposes of paragraph (1), a diagnostic laboratory identifies a causative agent where—

(a) the diagnostic laboratory identifies the causative agent; or

(b) the causative agent is identified by another laboratory under an arrangement made with that diagnostic laboratory.

(8) Where paragraph (7)(b) applies, the day on which the causative agent is identified for the purposes of paragraph (3), is the day on which the diagnostic laboratory became aware of the identification by the other laboratory.

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

(10) Any person who commits an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(11) In this regulation—

"causative agent" means—

(a) a causative agent listed in Schedule 2, or

(b) evidence of an infection caused by such an agent;

"diagnostic laboratory" means an institution (or facility within an institution) which is equipped with apparatus and reagents for the performance of diagnostic tests for human infections;

"director of a diagnostic laboratory" means—

(a) the clinical microbiologist, consultant pathologist or other registered medical practitioner or other person in charge of a diagnostic laboratory, or

(b) any other person working in the diagnostic laboratory to whom the function of making a notification under this regulation has been delegated by the person mentioned in paragraph (a); and

"operator of a diagnostic laboratory" means the corporate body that operates the diagnostic laboratory or, if there is no such body, the director of the diagnostic laboratory.