

SCHEDULES

[^{F1}SCHEDULE 3A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments	
F1	Sch. 3A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522) , regs 1, 30
<i>Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2</i>	
10	Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.
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<i>Relevant provisions of the third Directive</i>	
Organisation and management (requirements as to Annex I, Part A organisational structure, management systems, and third party agreements)	
Personnel (number, competence, responsibilities and Annex I, Part B training)	
Equipment and materials (appropriate for use, validation, Annex I, Part C maintenance, and specifications)	
Facilities and premises (suitability, environment, storage, and Annex I, Part D maintenance)	
Documentation and records (standard operating procedures, Annex I, Part E document control, record reliability)	
Quality review (quality management system, investigations, Annex I, Part F] corrective action, and reviews)	
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Changes to legislation:

There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2.