SCHEDULE 3 Regulation 7

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

PART 1

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES

1.—(1) The licence holder shall provide separate premises or separate parts of premises referred to in this Part as "the designated premises", for the activities specified in the following sub-paragraphs, namely—

(a) the production and the testing involved in the production of cell cultures for use in the production of vaccine;

(b) the production and the testing involved in the production of vaccine prepared from viruses; and

(c) the production and the testing involved in the production of vaccine prepared from micro-organisms or detoxified microbial toxins,

and shall ensure that only persons necessary to each of the above mentioned activities shall have access to the designated premises provided for that activity.

2. The licence holder shall ensure that any procedure which, in the course of any of the activities specified in the preceding paragraph involves or might involve—

(a) the presence of transmissible agents; or

(b) the use of cell cultures, animal tissues or micro-organisms,

other than those from which the vaccine is produced, shall not be carried out in the designated premises referred to in paragraph 1.

3. The licence holder shall ensure that no person who has been in contact with transmissible agents or experimental animals (other than those connected with the vaccine being produced in the designated premises referred to in paragraph 1) shall enter the designated premises on the same day that such contact has occurred.

4. Before an animal is used in the production of a vaccine, the licence holder shall take all reasonable steps to ensure that it is free from disease, and to that end shall keep the animal in quarantine and under observation for such period as the licensing authority may specify.

5. The licence holder shall ensure—

(a) that animals used in the production of vaccine are isolated and shall provide separate premises (not being the designated premises referred to in paragraph 1) for this purpose; and

(b) that only persons engaged in the production and testing of vaccines or in the maintenance of animals or premises shall have access to the separate premises in which the animals are isolated.

6. The licence holder shall provide a separate room in the premises referred to in paragraph 5 which is capable of being washed and disinfected and which is to be used for the purpose of—

(a) the inoculation of animals; and

(b) the collection of material to be used in the preparation of vaccine.

7. Without prejudice to any other requirements to keep records, where vaccines contain or might contain micro-organisms or microbial toxins, the licence holder shall keep a durable record, readily available for inspection by a person authorised by the licensing authority, of the origin, properties and characteristics of the cell cultures used in the production of those vaccines and shall ensure that that record is not destroyed for a period of five years from the date when the relevant production occurred.

8. Nothing in this Schedule shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.

PART 2

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SMALLPOX VACCINES

1. The licence holder shall ensure that animals used in the production of smallpox vaccine—

(a) shall only be inoculated on a part of the skin that has been depilated and cleansed and which cannot be soiled by urine or faeces, and

(b) are kept under observation for 28 days after the collection of the vaccinal material.

2. Should any animal during the 28 day period referred to in paragraph 1 be found to be suffering from any infection other than vaccinia or show serious or persistent signs of ill health, vaccinal material obtained from that animal shall not be used in the production of smallpox vaccine.

3. Where it is necessary for an animal which has been inoculated for use in the production of smallpox vaccine to be killed, the licence holder shall ensure that—

(a) the vaccinal material is collected immediately after the animal has been killed;

(b) if the licensing authority so directs, a post-mortem examination of the carcass of the animal is made by a person with experience of the diseases of the particular animal which has been killed;

(c) a durable record of the examination is made and retained for a period of five years from the date when the animal was killed, and kept readily available for inspection by a person authorised by the licensing authority; and

(d) where the examination indicates that the animal was suffering from diseases other than vaccinia, no vaccinal material obtained from that animal is used in the production of smallpox vaccine.

PART 3

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO BCG VACCINES

1. The licence holder shall provide separate premises or separate parts of premises for the production of BCG vaccine, and shall ensure that only persons necessary to the production and testing of that vaccine shall have access to those separate premises or separate parts of premises.

2. The licence holder shall ensure that any procedure which involves or might involve—

(a) the presence of transmissible agents other than BCG, or

(b) the use of microbial cultures other than BCG,

shall not be carried out in the separate premises or separate parts of premises referred to in paragraph 1 of this Schedule.

3. The licence holder shall ensure that all media, glassware and other apparatus issued in the production of BCG vaccine shall be kept and prepared for use in the separate premises or separate parts of premises referred to in paragraph 1 of this Part of this Schedule.

4. The licence holder shall not permit animals to be in the separate premises or separate parts of premises referred to in paragraph 1 of this Part of this Schedule and where it is necessary to use animals for testing BCG vaccine, the tests shall not be carried out in those separate premises or separate parts of premises.

5.—(1) The licence holder shall arrange for all persons engaged in the production of BCG vaccine to be examined clinically by a doctor and where appropriate, radiologically and bacteriologically, at least every twelve months and whenever such a person shows signs of ill health.

(2) The licence holder shall ensure (as far as paragraph (c) below is concerned, in so far as is reasonably practicable), that persons falling within the following descriptions shall not engage in the production of BCG vaccine, that is to say—

(a) persons examined as aforesaid who are found to be suffering from active or potentially active tuberculosis lesions,

(b) persons who show a negative reaction when tested with tuberculin, or

(c) persons who are in close contact with a person who is suffering from any active form of tuberculosis.

(3) If on examination in accordance with subparagraph (1), a person engaged in the production of BCG vaccine is found to be suffering from active or potentially active tuberculosis lesions, then, after that person has been removed from the separate premises or separate parts of premises referred to in paragraph (1), the licence holder shall—

(a) make arrangements for those separate premises or separate parts of premises and all equipment used in the production of BCG vaccine to be treated in such a manner as to remove the risk of contamination of the vaccine; and

(b) cease to use any unsealed cultures of BCG and all current preparations of BCG vaccine which may have become contaminated with other Mycobacterium tuberculosis organisms.

6. The licence holder shall ensure that no person who has been in contact with transmissible agents other than BCG vaccine shall enter the separate premises or separate parts of premises referred to in paragraph 1 on the same day that such contact has been made.

PART 4

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO TOXINS

1. The licence holder shall provide separate premises or separate parts of premises for the production and the testing involved in the production of toxins and shall ensure that only persons necessary to the production and testing of toxins (or related toxoids) shall have access to the separate premises or separate parts of those premises.

2. Nothing in paragraph 1 shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.

3. The licence holder shall ensure that any procedure which in the course of the production and testing referred to in the previous paragraph involves or might involve the presence of micro-organisms, plants or animals other than those from which the toxins are to be produced, shall not be carried out in the separate premises or separate parts of premises referred to in paragraph 1.

PART 5

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SERA

1. The licence holder shall ensure that blood used in the production of any serum shall only be collected from living animals in separate premises which—

(a) are used for no other purpose,

(b) have impervious walls and floors, and

(c) are capable of being washed and chemically disinfected.

2. The licence holder shall ensure that an adequate system of manure removal is in operation in the separate premises referred to in paragraph 1.

3. Before an animal is used in the production of any serum, the licence holder shall take all reasonable steps to ensure that it is free from disease and to this end shall keep the animal in quarantine and under observation for such period as the licensing authority may direct.

4. The licence holder shall notify the licensing authority if any animal which has been used in the production of any serum is found to be suffering from an infection other than an infection produced by living organisms against which it is being immunised or shows serious or persistent signs of ill-health not attributable to the process of immunisation and shall withhold any serum obtained from that animal from sale, supply or exportation until he has obtained the consent of the licensing authority in writing to its release.

5. The licence holder shall notify the licensing authority if any post-mortem examination on any animal indicates that any other animals used in the production of any serum are or are likely to be unhealthy, and the licence holder shall not use those animals for the production of any serum until either he has obtained the consent of the licensing authority in writing or has complied with any requirements the licensing authority may consider necessary in the interest of safety.

6. The licence holder shall ensure that laboratories in which any serum is processed are separate from premises in which animals are housed.

7. The licence holder shall provide such number of sterilizers as are necessary for the sterilization of all glassware and other apparatus used in the production of sera.

8. Without prejudice to any other requirements to keep records, the licence holder shall keep the following durable records relating to the production of sera readily available for inspection by a person authorised by the licensing authority, and shall ensure that those records are not destroyed for a period of five years from the date when the relevant production occurred—

(a) as to the cultures used—

(i) the source from which the culture was obtained,

(ii) the nature of the material from which the culture was isolated,

(iii) the date of the isolation, and

(iv) evidence of the identity and specificity of the culture;

(b) as to the procedure used in the immunizing of animals—

(i) the method of preparing the culture or antigen used for immunization,

(ii) the dosage and methods employed in administering the culture or antigen, and

(iii) the time in the course of immunization at which blood is withdrawn for preparation of the serum; and

(c) the results of any tests which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

9. Nothing in this Part shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.