

## SCHEDULE 3 Regulation 11(2)

### Mandatory approval conditions: **approval certificate**

#### **General**

- 1.— (1) The certificate holder must not permit any licence holders to perform a special procedure where the approved premises or vehicle, or any part thereof, presents, or is likely to present, a significant risk of harm to human health.
- (2) The certificate holder must ensure that the approved premises or vehicle is used in such a way that minimises the risk of harm to human health.
- (3) The certificate holder must not compromise the safety, health or well-being of clients, licence holders, staff or members of the public using their premises or vehicle.
- (4) The certificate holder must keep and maintain an up-to-date record of all licence holders operating from the approved premises or vehicle, including each special procedure the licence holder is licensed to perform.
- (5) The certificate holder must only permit licence holders to operate from the approved premises or vehicle where the premises or vehicle are identified in their special procedure licence.
- (6) The maximum number of workstations approved for use at the approved premises or vehicle and stated on the approval certificate must not be exceeded.
- (7) The certificate holder must ensure that all licence holders operating from the approved premises or vehicle act in a way that does not contradict the special procedure licence issued in relation to the special procedures identified in the special procedure licence (including the mandatory licensing conditions).

#### **Matters relating to the approval certificate**

- 2.— (1) A copy of the applicable mandatory approval conditions must be readily available for inspection upon request by an authorised officer or a client.
- (2) The approval certificate must not be altered in any way and must remain legible.
- (3) In the event of the approval certificate becoming mislaid, stolen or damaged, the certificate holder must apply, within a reasonable period, to obtain a replacement from the issuing local authority.
- (4) On the expiry of the approval certificate, the expired certificate must be returned to the issuing local authority in accordance with the instructions provided by that authority.
- (5) The certificate holder must have in place insurance cover at all times during the approval certificate period. Evidence of valid insurance cover must be readily available for inspection by any authorised officer.

#### **Matters relating to displaying of notices and restricted access**

- 3.— (1) The approval certificate must be displayed at or near the customer entrance of the approved premises or vehicle, or part thereof which is the subject of the approval certificate, and in a position that enables it to be easily read by clients and members of the public.
- (2) The certificate holder must display a notice stating that special procedures will not be performed on any person who is or appears to be intoxicated, whether by virtue of drink, drugs or other means. This notice must be in a location that enables it to be easily read by clients and members of the public.

- (3) The certificate holder must not allow animals into the approved premises or vehicle other than registered assistance dogs accompanying a client.
- (4) A notice containing hand washing instructions must be clearly displayed at every wash hand basin within the approved premises or vehicle.
- (5) The certificate holder must ensure that the licence holder adheres to their obligation to only permit a client to be accompanied by an individual if their presence during the special procedure does not present an increased risk of infection.
- (6) Access to the special procedures work area must be restricted to the licence holder, the certificate holder, persons authorised by the certificate holder or licence holder (which includes the client and an individual accompanying the client) and registered assistance dogs (if applicable). Any other individuals will only be permitted to access a part of the approved premises or vehicle where it does not present an increased risk of infection.
- (7) Areas within the approved premises or vehicle where public access is prohibited must be clearly identified and members of the public must be restricted from accessing—
  - (a) workstations (unless they are authorised by the certificate holder or licence holder (to include a client and an individual accompanying a client)),
  - (b) areas and rooms where refuse arising from the special procedure is collected and stored, and
  - (c) any areas where equipment and products relating to special procedures are stored.

#### **Design, structure and physical environment**

- 4.—(1) A special procedure must only be performed at a workstation within the approved premises or vehicle.
  - (2) The certificate holder must ensure that the design, size, structure and repair of the premises or vehicle enables effective cleaning and disinfection.
  - (3) All internal surfaces, fixtures, fittings and facilities within the special procedures work area must be of such material and design, and be kept in good order and repair to enable effective cleaning and disinfection where contamination from blood or bodily fluids is likely.
  - (4) Where a waiting area is provided, it must be physically segregated from the special procedures work area.
  - (5) The approved premises or vehicle must have ready access to toilet facilities for use by licence holders, staff and clients.
  - (6) Where toilet facilities are provided at the approved premises or vehicle, they must be ventilated and contain a wash hand basin with an adequate supply of running water (hot and cold or mixed), liquid soap and paper towels stored in an enclosed dispenser.
  - (7) The workstation must have sufficient space to enable the safe and hygienic performance of the special procedure.
  - (8) The special procedures work area must accommodate all workstations and facilities for the clean storage of equipment, instruments and products used for or in conjunction with special procedures to prevent the risk of contamination.
  - (9) Suitable facilities must be provided for the hygienic storage of equipment, instruments and products used for or in conjunction with special procedures to avoid the risk of contamination.
  - (10) Suitable arrangements must be provided for the secure storage, management and retrieval of clients' records relating to the special procedures that are offered and performed.

- (11) The certificate holder must ensure that there is a suitably stocked, readily accessible first aid kit at the approved premises or vehicle which meets the first aid needs of the special procedures being performed there.
- (12) Lighting must be suitable and sufficient to ensure the safe operation of the premises or vehicle and to facilitate effective cleaning and disinfection. Where necessary, local lighting must be provided at each workstation to ensure the safe and hygienic performance of the special procedure.
- (13) Adequate ventilation must be provided to the special procedures work area within the approved premises or vehicle.
- (14) A suitable number of readily accessible wash hand basins must be provided in each special procedures work area. The wash hand basins must be in good working order and repair.
- (15) All wash hand basins in a special procedures work area must include an adequate supply of running water (hot and cold or mixed), liquid soap and paper towels stored in an enclosed dispenser in close proximity to the wash hand basin.
- (16) The certificate holder must ensure that all wash hand basins for the licence holders' use are fully stocked with liquid soap and paper towels.
- (17) Wash hand basins must only be used for the purposes of washing hands and forearms.

#### **Decontamination, cleaning, disinfection and sterilisation**

- 5.—
- (1) All parts of the approved premises or vehicle must be kept clean and tidy.
  - (2) A suitable and sufficient cleaning schedule for the premises, fixtures, fittings, furniture, equipment and instruments must be in operation.
  - (3) Equipment, facilities and arrangements must be provided for the decontamination, cleaning, disinfecting and, where required, sterilisation of work tools, instruments and other items. This provision must be segregated from all workstations, and it must reflect the procedures performed at the approved premises or vehicle.
  - (4) All equipment used for the purpose of cleaning, disinfecting or sterilising must be used, maintained and serviced in accordance with the manufacturer's instructions and be accompanied by documented records to demonstrate that the appropriate quality tests have been carried out to validate the use of that equipment.

#### **Waste including sharps**

- 6.—
- (1) Suitable provision must be made for the collection, storage and disposal of waste and other refuse.
  - (2) An adequate number of easy to clean, non-hand-operated waste bins must be provided in the special procedures work area. The waste bins must be appropriately constructed and kept in a sound and clean condition.
  - (3) The certificate holder must provide a suitable number of sharps bins and ensure they are safely located in close proximity to all workstations.
  - (4) The certificate holder must ensure that suitable provision has been made for the disposal and segregated storage of domestic waste and clinical, non-hazardous waste.
  - (5) All clinical, non-hazardous waste (yellow waste bags and sharps bins) must have their point of origin (name and address of business) marked on them prior to disposal.
  - (6) The certificate holder must ensure that the clinical, non-hazardous waste (yellow waste bags and sharps bins) is collected regularly by a licensed waste carrier. A record of consigned controlled waste must be retained at the premises or vehicle and available for inspection by an authorised officer.

## Definitions

### 7. In this Schedule—

“authorised insurer” (“*yswiriwr awdurdodedig*”), means in relation to a policy of insurance, a person who may carry on in the United Kingdom the business of effecting or carrying out contracts of insurance of the sort provided under the policy of insurance;

“authorised officer” (“*swyddog awdurdodedig*”) has the meaning given in section 83 of the Public Health (Wales) Act 2017;

“insurance cover” (“*sicrwydd yswiriant*”) means a valid public liability policy of insurance issued by an authorised insurer to insure the applicant in relation to the approved premises or vehicle;

“mandatory licensing conditions” (“*amodau trwyddedu mandadol*”) means the conditions to which a special procedure licence is subject to;

“sharps” (“*offer miniog*”) means objects or instruments which are able to cut, graze, puncture or cause injury to the skin and includes all types of needles and single use razors;

“sharps bin” (“*bin offer miniog*”) means a rigid, specialised container that complies with the EWC Code 20 01 99(1) designed to safely dispose of sharps associated with the performance of special procedures;

“special procedure licence” (“*trwydded triniaeth arbennig*”) has the meaning given in section 59 of the Public Health (Wales) Act 2017;

“special procedures work area” (“*man gwaith triniaethau arbennig*”) means a designated area or room used for the purpose of performing a special procedure which—

(a) must include at least—

- (i) 1 workstation,
- (ii) 1 wash hand basin,
- (iii) 1 waste bin,
- (iv) 1 sharps bin (if applicable), and

(b) may also include other facilities and equipment to support the performance of the special procedure;

“workstation” (“*gweithfan*”) means the part of the special procedures work area which contains—

- (c) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (d) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (e) a work surface that is used for the placement and storage of the instruments and products used by the licence holder to perform the special procedure.

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(1) A European Waste Catalogue (“EWC”) Code is a six-digit code used to identify waste (hazardous and non hazardous) as listed in the European Waste Catalogue. An EWC Code (amongst other things) identifies the controls that apply to the movement and management of the waste. EWC Code 20 01 99 relates to hazardous, infectious clinical waste as set out on page 47, paragraph 4.99 of the Welsh Health Technical Memorandum. See <https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/>.

## SCHEDULE 4 Regulation 11(3)

### Mandatory approval conditions: **temporary approval certificate**

#### **General**

- 8.—(1) The certificate holder must not permit any licence holders to perform a special procedure where the approved premises or vehicle, or any part thereof, presents, or is likely to present, a significant risk of harm to human health.
- (2) The certificate holder must ensure that the approved premises or vehicle is used in such a way that minimises the risk of harm to human health.
- (3) The certificate holder must not compromise the safety, health or well-being of clients, licence holders, staff or members of the public using their premises or vehicle.
- (4) The certificate holder must keep and maintain an up-to-date record of all licence holders operating from the approved premises or vehicle, including each special procedure the licence holder is licensed to perform.
- (5) The certificate holder must only permit licence holders to operate from the approved premises or vehicle where the premises or vehicle is specified in their special procedure licence.
- (6) The maximum number of workstations approved for use at the approved premises or vehicle and stated on the approval certificate must not be exceeded.
- (7) The certificate holder must ensure that all licence holders operating from the approved premises or vehicle act in a way that does not contradict the special procedure licence issued in relation to the special procedures identified in the special procedure licence (including the mandatory licensing conditions).

#### **Matters relating to the temporary approval certificate**

- 9.—(1) A copy of the applicable mandatory approval conditions must be readily available for inspection upon request by an authorised officer or a client.
- (2) The approval certificate must not be altered in any way and must remain legible.
- (3) In the event of the approval certificate becoming mislaid, stolen or damaged, the certificate holder must apply, within a reasonable period, to obtain a replacement from the issuing local authority.
- (4) On the expiry of the approval certificate, the expired certificate must be returned to the issuing local authority in accordance with the instructions provided by that authority.
- (5) The certificate holder must have in place insurance cover at all times during the approval certificate period when special procedures are being performed from the approved premises or vehicle. Evidence of valid insurance cover must be readily available for inspection by any authorised officer.

#### **Matters relating to displaying of notices and restricted access**

- 10.—(1) The approval certificate must be displayed at or near the customer entrance of the approved premises or vehicle, or part thereof which is the subject of the approval certificate, and in a position that enables it to be easily read by clients and members of the public.
- (2) The certificate holder must display a notice stating that special procedures will not be performed on any person who is or appears to be intoxicated, whether by virtue of drink, drugs or other means. This notice must be in a location that enables it to be easily read by clients and members of the public.

- (3) The certificate holder must not allow animals into the approved premises or vehicle other than registered assistance dogs accompanying a client.
- (4) Access to a special procedures work area must be restricted to the licence holder, the event manager (as certificate holder), persons authorised by the certificate holder or licence holder (which includes the client and an individual accompanying the client) and registered assistance dogs (if applicable).
- (5) A notice containing hand washing instructions must be clearly displayed at every wash hand basin being used solely by licence holders.
- (6) Public access areas must be clearly identified and members of the public must be restricted from accessing—
  - (a) workstations (unless they are authorised by the certificate holder or licence holder (to include a client and an individual accompanying a client)),
  - (b) areas and rooms where refuse arising from the special procedure is collected and stored, and
  - (c) any areas where equipment and products relating to special procedures are stored.

### **Design, structure and physical environment**

- 11.—**(1) The certificate holder must ensure that the design, size, structure and repair of the premises or vehicle enables effective cleaning and disinfection where contamination from blood or bodily fluids is likely.
- (2) A special procedure must only be performed in the workstation designated for that purpose.
  - (3) All internal surfaces, fixtures, fittings and facilities within the special procedures work area must be of such material and design, kept in good order and repair to enable effective cleaning and disinfection where contamination from blood or bodily fluids is likely.
  - (4) The approved premises or vehicle must have ready access to toilet facilities for use by licence holders, staff and clients.
  - (5) Where toilet facilities are provided at the approved premises or vehicle they must be ventilated and contain a wash hand basin with an adequate supply of running water (hot and cold or mixed), liquid soap and paper towels stored in an enclosed dispenser.
  - (6) The workstation must have sufficient space to enable the safe and hygienic performance of the special procedure.
  - (7) The special procedures work area must accommodate all workstations and facilities for the clean storage of equipment, instruments and products used for or in conjunctions with special procedures to prevent the risk of contamination.
  - (8) The certificate holder must ensure that there are suitably stocked, readily accessible first aid kits at the approved premises or vehicle, which meet the first aid needs of the special procedures being performed there and the number of licence holders operating at the event.
  - (9) Lighting must be suitable and sufficient to ensure the safe operation of the premises or vehicle and to facilitate effective cleaning and disinfection. Where necessary, local lighting must be provided at each workstation to ensure the safe and hygienic performance of the special procedure.
  - (10) Adequate ventilation must be provided to the special procedures work area.
  - (11) A suitable number of readily accessible wash hand basins must be provided in the special procedures work area for use by the licence holders. The wash hand basins must be in good working order and repair.

- (12) Wash hand basins used by licence holders must include an adequate supply of running hot and cold or mixed water, liquid soap and paper towels stored in an enclosed dispenser in close proximity to the wash hand basin.
- (13) The certificate holder must ensure that all wash hand basins for the licence holders' use are fully stocked with liquid soap and paper towels for the duration of the exhibition, entertainment or event.
- (14) Wash hand basins must only be used for the purposes of washing hands and forearms.

### **Decontamination, cleaning, disinfection and sterilisation**

- 12.**—(1) The certificate holder must ensure that the approved premises or vehicle (or all parts of the premises or vehicle that they are responsible for) are kept clean and tidy at all times.
- (2) A suitable and sufficient cleaning schedule for the approved premises or vehicle must be in operation.
  - (3) Equipment, facilities and arrangements must be provided for the decontamination, cleaning, disinfecting and, where required, sterilisation of work tools, instruments and other items. This provision must be segregated from all workstations, and it must reflect the procedures undertaken at the approved premises or vehicle.
  - (4) Where equipment, facilities and arrangements cannot be provided for the decontamination, cleaning, disinfecting and, where required, sterilisation of work tools, instruments and other items, a single use policy must be operated.
  - (5) All equipment used for the purpose of cleaning, disinfecting or sterilising must be used, maintained and serviced in accordance with the manufacturer's instructions and be accompanied by documented records to demonstrate that the appropriate quality tests have been carried out to validate the use of that equipment.

### **Waste including sharps**

- 13.**—(1) Suitable provision must be made for the collection, storage and disposal of waste and other refuse.
- (2) The certificate holder must provide a suitable number of sharps bins and ensure they are safely located in close proximity to all workstations.
  - (3) An adequate number of easy to clean, non-hand-operated waste bins must be provided in the special procedures work area and be appropriately constructed, kept in a sound and clean condition.
  - (4) The certificate holder must ensure that suitable provision has been made for the disposal and segregated storage of domestic waste and clinical, non-hazardous waste.
  - (5) All clinical, non-hazardous waste (yellow waste bags and sharps bins) must have their point of origin (name and address of business) marked on them prior to disposal.
  - (6) The certificate holder must ensure that the clinical, non-hazardous waste (yellow waste bags and sharps bins) is collected by a licensed waste carrier. A record of consigned controlled waste must be retained at the premises or vehicle and available for inspection by an authorised officer.

### **Definitions**

**14.** In this Schedule—

“authorised insurer” (“*yswiriwr awdurdodedig*”) means, in relation to a policy of insurance, a person who may carry on in the United Kingdom the business of effecting or carrying out contracts of insurance of the sort provided under the policy of insurance;

“authorised officer” (“*swyddog awdurdodedig*”) has the meaning given in section 83 of the Public Health (Wales) Act 2017;

“insurance cover” (“*sicrwydd yswiriant*”) means a valid public liability policy of insurance issued by an authorised insurer to insure the applicant in relation to the approved premises or vehicle;

“mandatory licensing conditions” (“*amodau trwyddedu mandadol*”) means the conditions to which a special procedure licence is subject to;

“sharps” (“*offer miniog*”) means objects or instruments which are able to cut, graze, puncture or cause injury to the skin and includes all types of needles and single use razors;

“sharps bin” (“*bin offer miniog*”) means a rigid, specialised container that complies with the EWC Code 20 01 99(1) designed to safely dispose of sharps associated with the performance of special procedures;

“special procedure licence” (“*trwydded triniaeth arbennig*”) has the meaning given in section 59 of the Public Health (Wales) Act 2017;

“special procedures work area” (“*man gwaith triniaethau arbennig*”) means a designated area or room used for the purpose of performing a special procedure which—

(a) must include at least—

- (i) 1 workstation,
- (ii) 1 wash hand basin,
- (iii) 1 waste bin,
- (iv) 1 sharps bin (if applicable), and

(b) may also include other facilities and equipment to support the performance of the special procedure;

“workstation” (“*gweithfan*”) means the part of the special procedures work area which contains—

- (c) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (d) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (e) a work surface that is used for the placement and storage of the instruments and products used by the licence holder to perform the special procedure.

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(1) A European Waste Catalogue (“EWC”) Code is a six-digit code used to identify waste (hazardous and non hazardous) as listed in the European Waste Catalogue. An EWC Code (amongst other things) identifies the controls that apply to the movement and management of the waste. EWC Code 20 01 99 relates to hazardous, infectious clinical waste as set out on page 47, paragraph 4.99 of the Welsh Health Technical Memorandum. See <https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/>.