

SCHEDULE 3 Regulation 7(3)

Mandatory licensing conditions: **general conditions**

General

- 1.— (1) The licence holder may only perform a special procedure that they are licensed to perform in the approved premises or vehicle specified on their licence (unless exceptions apply).
- (2) The licence holder may not perform the special procedure in, or in any part of, an approved premises or an approved vehicle, if there is, or is likely to be, a risk of harm to human health.
- (3) The licence holder may only perform the special procedure in such a way that minimises the risk of harm to human health.
- (4) The licence holder must carry out activities in connection with performing the special procedure in a way that does not contradict the approval certificate (including the mandatory approval conditions) issued in relation to the premises or vehicle identified in the special procedure licence.

Matters relating to the licence

- 2.— (1) The licence holder must ensure that Part 1 or Part 2 of their special procedure licence is displayed in a position that enables it to be easily read by clients and members of the public.
- (2) A copy of the applicable mandatory licensing conditions must be readily available upon request by an authorised officer or client.
- (3) The special procedure licence must not be altered in any way and must remain legible.
- (4) In the event of the special procedure licence becoming mislaid, stolen or damaged, the licence holder must apply, within a reasonable period, to obtain a replacement from the issuing local authority.
- (5) If the licence holder is convicted of a relevant offence during the licence period, the licence holder must immediately notify the issuing local authority of the conviction. This notification must be in writing and must include the date of the conviction, details of the relevant offence, sentence or penalty imposed (including the duration of any sentence) and any other information that the issuing local authority may reasonably require.
- (6) On the expiry of the special procedure licence, the expired licence must be returned to the issuing local authority in accordance with the instructions provided by that authority.

The client and client consultation

- 3.— (1) The licence holder must not undertake a special procedure on a client if they suspect the client is not fit and well.
- (2) The licence holder must not perform a special procedure on an individual who is or appears to be intoxicated, whether by virtue of drink, drugs or by any other means.
- (3) The licence holder must undertake a consultation with the client and, where the licence holder considers it appropriate, with the parent or legal guardian of the client, before performing the special procedure. This consultation must be by way of a written client consultation form which must include the following—

- (a) full name of client,
 - (b) a statement confirming that the licence holder has verified the client's age,
 - (c) contact details of the client,
 - (d) a full explanation of the process, risks and contraindications of the special procedure,
 - (e) an explanation of the social impacts of a special procedure performed on the client's face or neck (if applicable),
 - (f) a relevant medical history of the client, including significant or relevant health conditions such as heart disease, epilepsy, diabetes, conditions that compromise immunity, allergies, pregnancy and details of prescribed medication including anticoagulants,
 - (g) a record of whether a client has applied a topical anaesthetic to themselves prior to the special procedure (and if so, confirmation that the licence holder is satisfied the topical anaesthetic is approved and authorised by the Medicines and Healthcare Products Regulatory Agency⁽¹⁾), and
 - (h) an explanation of the aftercare advice for the special procedure being performed.
- (4) The completed client consultation form must be signed by the licence holder and countersigned by the client, or where the licence holder considers it appropriate, the parent or legal guardian of the client.
- (5) Where any contraindications are identified during the client consultation, the licence holder must not perform the special procedure unless the licence holder is satisfied that the special procedure can still be performed safely. If the licence holder has any concerns regarding the health of the client, the licence holder must not perform the special procedure until they are in receipt of medical advice or approval from the client's GP or medical consultant. A copy of this information must be included in the licence holder's written records in relation to the client.
- (6) Before and after the special procedure is performed the licence holder must give the client or, where the licence holder considers it appropriate, the parent or legal guardian of the client, the opportunity to ask any questions relating to the special procedure and the aftercare advice.
- (7) The licence holder must ensure that aftercare advice is provided to the client or, where the licence holder considers it appropriate, to the parent or legal guardian of the client. This advice must be provided using plain language and in an easy to understand format. It must be given verbally and in written form to the client, or where the licence holder considers it appropriate, to the parent or legal guardian of the client, and must include the contact details of the licence holder who performed the special procedure. A copy of the advice must be included in the licence holder's written records in relation to the client.

Record keeping

- 4.—(1) The licence holder must retain written records in relation to the client for 3 years beginning with the day on which the special procedure is performed. These records must include a copy of the completed and signed client consultation form.
- (2) The licence holder must keep and maintain a register of incidents associated with the performance of special procedures by the licence holder. This register must include—
- (a) the date of the incident,
 - (b) details of the incident,

(1) The Medicines and Healthcare Products Regulatory Agency is an Executive Agency of the Department of Health and Social Care.

- (c) the name and contact details of the client or other person (which can include the licence holder) who raised the incident, and
 - (d) any remedial actions taken by the licence holder to prevent a recurrence.
- (3) The licence holder must register the incident and take any remedial actions within a reasonable period.
- (4) The licence holder must have in place insurance cover at all times during their licence period. Evidence of valid insurance cover must be readily available for inspection by any authorised officer.

Safety and hygiene practices of the licence holder

- 5.— (1) The licence holder must continue to develop, update and maintain their knowledge of infection prevention and control and their skills for each special procedure that they are licensed to perform. The licence holder must maintain a written record of how they have met this requirement.
- (2) The licence holder must not perform a special procedure on an individual where the performance is, or is likely to be, compromised due to their own intoxication by virtue of drink, drugs or any other means.
- (3) The licence holder must not smoke, vape, consume food or drink in the special procedures work area.
- (4) The licence holder must practise regular and thorough hand hygiene.
- (5) The licence holder's nails must be clean and free from nail extensions, varnish and decoration.
- (6) The licence holder must cover any open wounds, cuts, or boils on an exposed part of their body with an impermeable dressing.
- (7) Any single use, disposable personal protective equipment must be changed in between each client or when there is a break in performing the special procedure.
- (8) If a razor is required in the course of performing the special procedure, the licence holder must ensure that only single use disposable razors are used.
- (9) The licence holder must carry out a visual assessment of the condition of the client's skin where the special procedure is to be performed and decontaminate the skin before performing the special procedure.
- (10) The licence holder must not perform a special procedure on skin that is not intact or where there is evidence of damage, abrasion or infection.
- (11) The licence holder must not supply or apply topical anaesthetics to a client before, during or after a special procedure.
- (12) The licence holder must not perform the special procedure if—
- (a) the licence holder has been made aware that the client has applied a topical anaesthetic to themselves prior to the special procedure, which is not approved and authorised by the Medicines and Healthcare Products Regulatory Agency, or
 - (b) the client has applied a topical anaesthetic to themselves prior to the special procedure and the licence holder has not received sufficient evidence that the topical anaesthetic is approved and authorised by the Medicines and Healthcare Products Regulatory Agency.
- (13) The licence holder must ensure that their workstation is effectively cleaned and disinfected in between each client where there is, or is likely to be, contamination from blood or bodily fluids.
- (14) All special procedures must be undertaken in conditions of privacy appropriate to the special procedure being performed.

- (15) The licence holder must only permit a client to be accompanied by another individual if the presence of that other individual during the special procedure does not present an increased risk of infection.
- (16) The licence holder must not allow animals into the special procedures work area other than registered assistance dogs accompanying a client.

Fixtures and fittings

- 6.— (1) Any fixture or item of furniture used by the client during the performance of the special procedure is to be covered by a disposable paper sheet, towel, or equivalent and changed between each client where contamination from blood or bodily fluids is likely.
- (2) The licence holder must ensure that all fixtures, fittings and items of furniture associated with their workstation are of a non-porous material and in good order and repair to enable effective cleaning and, where contamination from blood or bodily fluids are likely, disinfection.

Equipment and instruments

- 7.— (1) All equipment, instruments and products used by the licence holder must be—
 - (a) used and maintained in accordance with the manufacturer's instructions, and
 - (b) appropriately serviced and validated in accordance with the manufacturer's instructions, and all service and validation records must be kept and maintained for inspection by an authorised officer.
- (2) All instruments and equipment used by the licence holder must be of a non-porous material that can be easily cleaned, disinfected and, where appropriate, sterilised.
- (3) Instruments and equipment must be maintained in good order and repair to enable effective cleaning and must be used and stored in a way that minimises the risk of contamination.
- (4) The licence holder must never reuse or reprocess single use items.
- (5) Only sterile, single use, disposable needles may be used by the licence holder.
- (6) The licence holder must ensure that any equipment which is not disposable, cannot be sterilised and is likely to come into contact with bodily fluids or the site of the special procedure, is protected from such contact. Such equipment must be thoroughly cleaned and disinfected after each use.
- (7) If non-disposable instruments are used in the performance of a special procedure and are likely to come into contact with bodily fluids or the site of the special procedure the licence holder must after using them clean and treat the instruments. The instruments must be cleaned and treated with fit for purpose cleaning, disinfection and sterilisation equipment such as ultrasonic cleaners, instrument baths and autoclaves and autoclave pouches. This does not apply to needles (see paragraph 7(5)).
- (8) Any instrument, equipment, jewellery, or object that is attached to, implanted or inserted in, the client's skin or mucous membrane must be sterilised.
- (9) Any instrument, or equipment used to remove jewellery or an object that is attached to, implanted or inserted in the client's skin or mucous membrane must be sterilised.
- (10) The licence holder must have access to a suitably stocked, readily accessible first aid kit to meet the first aid needs of the special procedure performed.

Waste

- 8.— (1) All sharps must be disposed of in a sharps bin. The sharps bin must be kept and used within the special procedures work area.

- (2) The licence holder must ensure that domestic and clinical, non-hazardous waste is appropriately segregated into the correct coloured bags. The licence holder must make arrangements for the disposal of those coloured bags.

Definitions

9. In this Schedule—

“approval certificate” (“*tystysgrif gymeradwyo*”) has the meaning given in section 70(1) of the Public Health (Wales) Act 2017;

“approved premises or vehicle” (“*mangre neu gerbyd a gymeradwywyd*”) means premises or a vehicle approved under section 70(1) of the Public Health (Wales) Act 2017, in respect of a special procedure, by the local authority;

“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;

“client” (“*cleient*”) means a person on whom a special procedure is performed;

“insurance cover” (“*sicrwydd yswiriant*”) means a valid policy of insurance which was issued by an authorised insurer to insure the licence holder in respect of liabilities, in respect of illness, infection, injury and other non-infectious adverse health effects (including allergic reactions), arising from the performance of a special procedure;

“licence period” (“*cyfnod y drwydded*”), in relation to a special procedure licence, has the meaning given in section 59(8)(a) of the Public Health (Wales) Act 2017;

“mandatory approval conditions” (“*amodau cymeradwyo mandadol*”) means the conditions to which an approval certificate is subject to;

“relevant offence” (“*trosedd berthnasol*”) means an offence listed in section 66(8) of the Public Health (Wales) Act 2017;

“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 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—

(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/whm-library/whm-07-01-safe-management-of-healthcare-waste-pdf/>.

- (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.

SCHEDULE 4 Regulation 7(4)

Mandatory licensing conditions: **acupuncture**

10. A licence holder must not perform acupuncture on an intimate body part of a client under the age of 18.
11. A licence holder must thoroughly wash and dry their hands immediately before and after performing acupuncture on each client.
12. A licence holder must wear single use, well fitting gloves where—
 - (a) the client is bleeding or has an open lesion on an exposed part of their body,
 - (b) the licence holder has an open lesion, broken skin or a skin infection on their hand, or
 - (c) the licence holder is handling items that may be contaminated with blood or other body fluids.
13. Where the licence holder is asked to perform acupuncture on a client from a premises or vehicle that is used to any extent by that client as a dwelling, before the licence holder performs the special procedure the licence holder must—
 - (a) undertake and record an assessment of the location where acupuncture is to be performed, having due regard to any risks that can cause harm to human health,
 - (b) where the assessment identifies any risk that could cause harm to human health, take appropriate action to mitigate the harm before performing the special procedure, and
 - (c) include a copy of the assessment in the licence holder's written records in relation to the client.
14. Where the licence holder performs acupuncture on a client from a premises or vehicle that is used to any extent by that client as a dwelling, if a risk of harm to human health is identified during the performance of the special procedure, the licence holder must—
 - (a) remove the risk of harm before continuing to perform the special procedure, or
 - (b) if the risk of harm cannot be removed, cease to perform the special procedure.

Definitions

15. In this Schedule, "intimate body part" means a body part that is listed in section 96(2) of the Public Health (Wales) Act 2017.

SCHEDULE 5 Regulation 7(4)

Mandatory licensing conditions: **body piercing**

16. The licence holder is prohibited from using a scalpel to perform body piercing.
17. The licence holder must wear gloves when performing the special procedure. The gloves worn by the licence holder must provide the best fit, dexterity and comfort and afford good barrier protection. Where latex gloves can be worn, the latex gloves must be low-protein and powder free. If the client has a known allergy to latex, the licence holder must wear gloves that are a suitable latex free alternative.
18. Gloves must be removed and disposed of immediately after the special procedure is finished. Gloves must be removed, disposed of and replaced where there is a break in the period of time during which the special procedure is performed.
19. The licence holder must wear a single use disposable apron when performing the special procedure where there is a risk of contamination from blood or bodily fluids (or both). The apron must be removed and disposed of immediately after the special procedure is finished. The apron must be removed, disposed of and replaced when there is a break in performing the special procedure.
20. All jewellery, objects or instruments which may come into contact with skin or mucous membrane when piercing is undertaken, or are in close contact with the client's pierced skin or mucous membrane, must be purchased from reputable suppliers and must be single-use and sterilised.
21. Any needle, cannula, biopsy punch, taper, connection pin or rod, needle receiving tube, needle blank, or any other instrument used for the purpose of perforating the client's skin or mucous membrane with the view to enabling jewellery or any object to be attached to, implanted in or removed from the client's body must be purchased from a reputable supplier, be single use and be sterilised.
22. All jewellery or objects used for the body piercing must be of a suitable grade, including surgical stainless steel, 9, 14 or 18 carat gold, niobium, titanium, platinum, or dense low porosity plastic.
23. If the area to be pierced requires marking, a single use water-based marker pen or single use markers must be used. The implement or pen must be disposed of immediately after use.
24. If using a cartridge system for body piercing, the licence holder—
 - (a) must use a sterile cartridge,
 - (b) must use sterilised jewellery or objects supplied in sealed packaging which indicates the part of the body for which it is intended,
 - (c) must maintain records to validate the integrity of the sterile cartridge and sterilised jewellery or object,
 - (d) in relation to ear and nose piercing, must use cartridges that are sealed, within the expiry date and in good condition prior to use,
 - (e) must discard and must not use any cartridges from damaged or blistered packs,
 - (f) must not reload a disposable cartridge and use for multiple piercings, whether or not on the same client,
 - (g) must ensure that a re-usable piercing instrument is cleaned and subsequently disinfected and sterilised before and after each use, and
 - (h) must not use re-usable piercing instruments otherwise than in accordance with the manufacturer's instructions (including those instructions as to the loading and unloading of the cartridge).

SCHEDULE 6 Regulation 7(4)

Mandatory licensing conditions: **electrolysis**

25. A licence holder must not perform electrolysis on an intimate body part of a client under the age of 18.
26. The licence holder must wear gloves when performing the special procedure. The gloves worn by the licence holder must provide the best fit, dexterity and comfort and afford good barrier protection. Where latex gloves can be worn, the latex gloves must be low-protein and powder free. If the client has a known allergy to latex, the licence holder must wear gloves that are a suitable latex free alternative.
27. Gloves must be removed and disposed of immediately after the special procedure is finished. Gloves must be removed, disposed of and replaced where there is a break in the period of time during which the special procedure is performed.

Definitions

28. In this Schedule, “intimate body part” means a body part that is listed in section 96(2) of the Public Health (Wales) Act 2017.

SCHEDULE 7 Regulation 7(4)

Mandatory licensing conditions: **tattooing**

29. The licence holder is prohibited from inserting ink or pigment into the eyeball of any individual.
30. The licence holder must wear gloves when performing the special procedure. The gloves worn by the licence holder must provide the best fit, dexterity and comfort and afford good barrier protection. Where latex gloves can be worn, the latex gloves must be low-protein and powder free. If the client has a known allergy to latex, the licence holder must wear gloves that are a suitable latex free alternative.
31. Gloves must be removed and disposed of immediately after the special procedure is finished. Gloves must be removed, disposed of and replaced where there is a break in the period of time during which the special procedure is performed.
32. The licence holder must wear a single use disposable apron when performing the special procedure. The apron must be removed and disposed of immediately after the special procedure is finished. The apron must be removed, disposed of and replaced when there is a break in performing the special procedure.
33. All products used in the course of performing the special procedure (for example, petroleum jelly, lubricating gel and tattoo stencils) must be single use or dispensed using a clean, single use instrument to a clean, single use receptacle.
34. Products used in the course of performing the special procedure must be labelled with the date of opening and disposed of in accordance with the manufacturer's instructions.
35. Inks and pigments must be sterilised. Any material or substance added to the ink or pigment must also be sterilised.
36. Inks and pigments used in the course of performing the special procedure must be dispensed into clean, single-use receptacles or pre-packed in single use vials and must be used and disposed of in accordance with the manufacturer's instructions.
37. Only sterile water may be used to dilute inks and pigments and to rinse instruments and equipment while tattooing is being performed.
38. The licence holder must ensure that equipment with hollow cavities, equipment wrapped or enclosed in pouches, or porous loads are sterilised using an appropriate vacuum autoclave that is deemed appropriate for that purpose by the manufacturer.
39. The brand, colour code and batch code of each ink or pigment used on a client must be recorded in the licence holder's written records in relation to the client at the time the special procedure is being performed.