

Draft Regulations laid before Senedd Cymru under section 123(2)(b) of the Public Health (Wales) Act 2017, for approval by resolution of Senedd Cymru.

DRAFT WELSH STATUTORY
INSTRUMENTS

2024 No. (W.)

PUBLIC HEALTH, WALES

**The Special Procedures Approved
Premises and Vehicles (Wales)
Regulations 2024**

EXPLANATORY NOTE

(This note is not part of the Regulations)

Part 4 of the Public Health (Wales) Act 2017 (“the Act”) provides that certain individuals who perform special procedures (as listed in section 57 of the Act) in Wales must be licensed by a local authority.

Section 69 of the Act requires the performance of a special procedure, carried on in the course of a business, to be performed at a premises or in a vehicle approved by a local authority (unless that premises or vehicle is not required to be approved).

Part 2 of these Regulations sets out the circumstances in which the requirement that a special procedure must be performed at premises or in a vehicle approved by a local authority is disapplied.

Part 3 of these Regulations makes provision about applications for approval certificates generally required for the performance, in the course of a business, of a special procedure at premises or in a vehicle, including the criteria that must be met in order for an application for an approval certificate to be granted. Part 3 also makes provision about the form and content of an application form.

Part 4 of these Regulations makes provision about the grant or refusal of an application for an approval certificate.

Part 5 of these Regulations makes provision about the form and content of an approval certificate issued by a local authority when approving an application for a premises or vehicle.

Part 6 of these Regulations sets out the mandatory approval conditions which apply to an approval certificate.

Part 7 of these Regulations makes provision about an application made by a certificate holder to the local authority to vary an approval certificate.

Part 8 of these Regulations makes provision about an application made by a certificate holder to the local authority to renew an approval certificate.

Part 9 of these Regulations makes provision about the circumstances and manner in which a certificate holder may apply to the local authority for a copy of an approval certificate.

Part 10 of these Regulations makes provision about fees in relation to approval certificates.

Section 72 of the Act makes provision about the voluntary termination of an approval certificate and the notice that may be given by the certificate holder to the local authority. Part 11 of these Regulations makes further provision about the notice requirements when given by a certificate holder to a local authority to voluntarily terminate an approval certificate.

Part 12 of these Regulations makes provision about the procedure a local authority must follow to give notice to an applicant or certificate holder where the local authority proposes to refuse an application made under these Regulations, and the right of that applicant or certificate holder to make representations to the local authority about the local authority's proposals. Part 12 also makes provision about the requirement for a local authority to notify the applicant or certificate holder of its decision.

Part 13 makes provision about an appeal against the refusal of an application, including the right to appeal to the magistrates' court or the Crown Court.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.

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2024 No. (W.)

PUBLIC HEALTH, WALES

**The Special Procedures Approved
Premises and Vehicles (Wales)
Regulations 2024**

Made

Coming into force

29 November 2024

The Welsh Ministers, in exercise of the powers conferred by sections 69(8) and (9), 70(3), (7), (8) and (9), 71(4), 72(5) and 76(4) and (5) of the Public Health (Wales) Act 2017(1), make the following Regulations.

In accordance with section 123(2)(b) of the Public Health (Wales) Act 2017, a draft of these Regulations was laid before, and approved by, resolution of Senedd Cymru(2).

PART 1

General

Title and coming into force

1.—(1) The title of these Regulations is the Special Procedures Approved Premises and Vehicles (Wales) Regulations 2024.

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- (1) 2017 anaw 2 (“the Act”). See section 124(1) of the Act for the definition of “regulations”.
- (2) The reference in section 123 of the Act to the National Assembly for Wales now has effect as a reference to Senedd Cymru by virtue of section 150A(2) of the Government of Wales Act 2006 (c. 32). See also section 40 of the Legislation (Wales) Act 2019 (anaw 4) for provision about the procedure that applies to this instrument.

(2) These Regulations come into force on 29 November 2024.

Interpretation

2.—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the Public Health (Wales) Act 2017;

“acupuncture” (“*aciwbigo*”) has the meaning given in section 94(1) of the Act;

“applicable mandatory approval conditions” (“*amodau cymeradwyo mandadol cymwys*”) means the mandatory approval conditions to which an approval certificate is subject to from the date of issue of that certificate;

“application fee” (“*ffi am gais*”) means the fee set by the local authority to accompany an application for an approval certificate;

“application interview” (“*cyfweliad ymgeisio*”) has the meaning given in regulation 8(3);

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

“approval certificate number” (“*rhif y dystysgrif gymeradwyo*”) means the reference number given by the local authority to the approval certificate which is unique to that certificate, and which is specified in it;

“approval certificate period” (“*cyfnod y dystysgrif cymeradwyo*”), in relation to an approval certificate, means the period during which the approval certificate authorises the performance of a special procedure at a premises or in a vehicle as set out in section 70(5) of the Act;

“approval date” (“*dyddiad cymeradwyo*”) has the same meaning as in section 70(5) of the Act;

“certificate holder” (“*deiliad tystysgrif*”) means the person whose application for an approval certificate a local authority has approved under section 70 of the Act and whose name is listed on the approval certificate;

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

“licence holder” (“*deiliad trwydded*”) has the meaning given in section 59(8)(b) of the Act;

“local authority” (“*awdurdod lleol*”) means the local authority as defined by section 124(1) of the Act;

“mandatory approval conditions” (“*amodau cymeradwyo mandadol*”) means the conditions set out in Schedules 3 and 4;

“premises” (“*mangre*”) has the meaning given in section 94(1) of the Act;

“special procedure” (“*triniaeth arbennig*”) has the meaning given in section 57 of the Act;

“temporary approval certificate” (“*tystysgrif gymeradwyo dros dro*”) means an approval certificate that authorises the performance of a special procedure (or special procedures) from an approved premises or vehicle for a period of no longer than seven days;

“vehicle” (“*cerbyd*”) has the meaning given in section 94(1) of the Act.

(2) Except as otherwise provided, a requirement under these Regulations to give a notice (or to notify) is a requirement to give written notice.

(3) A document or notice required by virtue of these Regulations to be “written” includes an electronic communication, as defined in section 15(1) of the Electronic Communications Act 2000(1).

PART 2

Exempted premises and vehicles

Exempted premises or vehicles

3. The requirement in section 69(2) of the Act that a person carrying on a business in the course of which a special procedure is performed must perform that procedure at a premises or in a vehicle that has been approved by the local authority under section 70 of the Act does not apply in respect of the following—

- (a) acupuncture performed on a client from a premises or vehicle used to any extent by that client as a dwelling;
- (b) any special procedure performed in a regulated independent healthcare establishment.

4. In this regulation—

“dwelling” (“*annedd*”) includes (but is not limited to)—

- (a) an “adult care home” which has the meaning given in section 28(1) of the Act;
- (b) a “hospice” which means premises wholly or mainly used for the provision of palliative care to persons, who are suffering from a progressive disease in its final stages, by or on behalf of an establishment the primary

(1) 2000 c. 7; section 15(1) was amended by the Communications Act 2003 (c. 21).

function of which is the provision of such care.

“regulated independent healthcare establishment” (*“sefydliad gofal iechyd annibynnol a reoleiddir”*) means—

- (a) an independent clinic as defined by section 2(4) of the Care Standards Act 2000⁽¹⁾ and as prescribed by regulation 4 of the Independent Health Care (Wales) Regulations 2011⁽²⁾;
- (b) an independent hospital as defined by section 2(2) and (3) of the Care Standards Act 2000 and as prescribed by regulation 3 of the Independent Health Care (Wales) Regulations 2011;
- (c) a private dental practice as defined by regulation 3(1) of the Private Dentistry (Wales) Regulations 2017⁽³⁾.

PART 3

Application for an approval certificate

Form of application

5.—(1) Each application for an approval certificate must relate to either a single—

- (a) premises, or
- (b) vehicle.

(2) An application for an approval certificate must be in the form specified in Schedule 1.

(3) An application may be made either in paper form or by means of electronic submission.

(4) In the case of a temporary approval certificate, an application must be made at least 28 working days prior to the intended approval date of the temporary approval certificate.

Information to be provided by the applicant

6.—(1) After submitting an application for an approval certificate but before it is determined, the applicant must provide the local authority with any further information that the local authority considers necessary to enable it to determine the application.

(2) The local authority must refuse an application if the applicant fails to provide the local authority with the information requested under paragraph (1).

(1) 2000 c. 14.

(2) S.I. 2011/734 (W. 112), amended by S.I. 2017/202 (W. 57); there are other amending instruments, but none is relevant.

(3) S.I. 2017/202 (W. 57). See regulation 4 of those Regulations for undertakings which are not private dental practices.

Fees to accompany an application

7.—(1) An application is to be accompanied by whatever application fee is set by the local authority.

(2) The application fee (if any) is to be set by the local authority having regard to the costs incurred by the local authority or expected to be incurred by the local authority in connection with dealing with applications under these Regulations.

(3) An application for an approval certificate is not to be treated as having been duly made until the application fee has been received in cleared funds by the local authority.

Criteria for an approval certificate to be granted

8.—(1) The criteria that must be met by an applicant for an approval certificate in order for the application to be granted are set out in paragraphs (2) to (5).

(2) The applicant must—

- (a) be 18 years of age or over,
- (b) provide evidence that the applicant holds a regulated Level 2 Award, and
- (c) submit a plan of the premises or vehicle to which the application relates that complies with paragraph (5).

(3) The applicant must undertake and pass an application interview with the local authority, which consists of questions asked by the local authority and answered by the applicant, to demonstrate the applicant's knowledge of the following matters—

- (a) duties imposed, under or by virtue of Part 4 of the Act, on a certificate holder,
- (b) the mandatory approval conditions, and
- (c) the implications of non-compliance with the mandatory approval conditions.

(4) The premises or vehicle to which the application relates must—

- (a) be inspected by the local authority,
- (b) be kept in good repair to ensure the safe and hygienic performance of the specified special procedure, and
- (c) reflect the specifications provided in the plan accompanying the application.

(5) The plan accompanying the application must include (where applicable)—

- (a) the points of entry and exit to the premises or vehicle,
- (b) the measurements and a description of the shape of the areas (such as rooms) (if any) within the premises or vehicle,

- (c) the points of entry and exit to the areas (such as rooms) (if any) within the premises or vehicle,
- (d) the location of the following (if any)—
 - (i) equipment sinks,
 - (ii) sharps bins,
 - (iii) staff rooms,
 - (iv) storage areas, facilities or rooms for products and/or equipment,
 - (v) toilets,
 - (vi) waiting areas or rooms,
 - (vii) wash hand basins,
 - (viii) waste bins,
 - (ix) windows, and
 - (x) workstations.

(6) In this regulation—

“regulated Level 2 Award” (“*Dyfarniad Lefel 2 a reoleiddir*”) means a Level 2 Award, regulated by Qualifications Wales⁽¹⁾, in Infection Prevention and Control for Special Procedures Practitioners;

“sharps bin” (“*bin offer miniog*”) means a rigid, specialised container that complies with the EWC Code 20 01 99⁽²⁾ designed to safely dispose of sharps associated with the performance of special procedures;

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

- (a) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (b) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (c) 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.

(1) Qualifications Wales was established under section 2 of the Qualifications Wales Act 2015 (anaw 5).

(2) 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/>.

PART 4

Grant or refusal of an approval certificate

Grant or refusal of application for an approval certificate

9.—(1) This regulation applies where an application for an approval certificate approving a premises or vehicle is made to a local authority in accordance with Part 3.

(2) If the local authority is satisfied that all of the approval criteria set out in regulation 8 are met, the local authority must grant the application for an approval certificate and issue an approval certificate to the applicant, approving a premises or vehicle in respect of performance of special procedure.

(3) If the local authority is not satisfied that all of the approval criteria set out in regulation 8 are met, the local authority must give the applicant notice that the application for an approval certificate is refused so far as it relates to the approval of that premises or vehicle.

(4) The notice must—

- (a) set out the reasons why the local authority refuses the application, and
- (b) state that the applicant may appeal under Parts 12 and 13 against the decision.

PART 5

Form and content of approval certificate

Form and content of approval certificate

10.—(1) An approval certificate must be in the form set out in Schedule 2.

(2) The text included in square brackets in the form in Schedule 2 is intended as guidance.

(3) A copy of the applicable mandatory approval conditions must be annexed to the approval certificate.

(4) For the purposes of Schedule 2 “acupuncture”, “body piercing”, “electrolysis” and “tattooing” each has the same meaning as given in section 94(1) of the Act.

PART 6

Mandatory approval conditions

Mandatory approval conditions

11.—(1) This regulation makes provision about the mandatory approval conditions that are to apply to

approval certificates, for the purposes of section 70(3)(c) of the Act.

(2) An approval certificate is subject to the conditions set out in Schedule 3.

(3) A temporary approval certificate is subject to the conditions set out in Schedule 4.

PART 7

Variation of approval certificate

Application to vary

12.—(1) A local authority may, on an application by the certificate holder, vary an approval certificate.

(2) Each application to vary an approval certificate must relate to either a single—

- (a) premises, or
- (b) vehicle.

(3) An application to vary an approval certificate must—

- (a) be made to the local authority that granted the approval certificate,
- (b) be made either in paper form or by means of electronic submission,
- (c) include particulars of the changes proposed to be made to the approval certificate,
- (d) include the approval certificate number of the premises or vehicle to which the application relates, and
- (e) include a declaration signed by the certificate holder that states to the best of their knowledge the information provided by the certificate holder in the application is true and the certificate holder understands that it is an offence under section 82(7) of the Act to give information which is false or misleading (whether knowingly or recklessly).

(4) If an application to vary an approval certificate relates to structural or design changes to the premises or vehicle detailed on the approval certificate, it must also include—

- (a) particulars of the changes proposed to be made at the premises or in the vehicle, and
- (b) an updated plan required by regulation 8(2)(c) which clearly shows those proposed changes.

(5) An application to vary an approval certificate by adding a description of a special procedure, the performance of which is to be authorised by the approval certificate—

- (a) must specify the special procedure concerned, and
- (b) is to be treated for the purposes of this Part as being an application for the issue of an approval certificate authorising the performance of that procedure (and the date of the variation is to be treated, for the application of this regulation in respect of that procedure, as being the date of the issue of an approval certificate authorising the performance of the procedure).

(6) Paragraph (5)(b) does not apply for the purposes of the determination of the approval certificate.

Information to be provided by the certificate holder

13. After submitting an application to vary an approval certificate but before it is determined, the certificate holder must—

- (a) satisfy the local authority at an inspection of the premises or vehicle that the proposed variations at the proposed premises or in the approved vehicle reflect the variations described in the application to vary (if required), and
- (b) provide such further information as required by the local authority to make a determination.

Fees to accompany an application to vary

14.—(1) An application to vary an approval certificate is to be accompanied by whatever application fee is set by the local authority.

(2) The application fee (if any) is to be set by the local authority having regard to the costs incurred by the local authority or expected to be incurred by the local authority in connection with dealing with applications to vary under these Regulations.

(3) An application to vary an approval certificate is not to be treated as having been duly made until the application fee has been received in cleared funds by the local authority.

Grant or refusal of an application to vary an approval certificate

15.—(1) This regulation applies where an application to vary an approval certificate is made to a local authority in accordance with Part 7.

(2) If the local authority is satisfied that an application to vary in accordance with Part 7 has been made, the local authority must grant the application to vary an approval certificate and issue the varied approval certificate to the certificate holder.

(3) If the local authority is not satisfied that an application to vary in accordance with Part 7 has been made, the local authority must give the certificate holder notice that the application for an approval certificate is refused so far as it relates to the variation of that approval certificate.

(4) The notice must—

- (a) set out the reasons why the local authority refuses the application, and
- (b) state that the certificate holder may appeal under Parts 12 and 13 against the decision.

Effect of a variation of an approval certificate

16.—(1) The effect of a variation may be such as to (among other things)—

- (a) add or remove a description of special procedure the performance of which is authorised by the approval certificate;
- (b) authorise the change of name of the certificate holder or registered name of the business associated with the approval certificate;
- (c) authorise the performance of a special procedure at a premises or in a vehicle that has undergone any structural or design change(s).

(2) An approval certificate must not be varied under this Part so as to—

- (a) transfer the approval certificate from the certificate holder to another individual (including where there has been a change in ownership or management in relation to the approved premises or vehicle);
- (b) shorten or extend the approval certificate period;
- (c) terminate the approval certificate.

PART 8

Renewal of approval certificate

Application to renew

17.—(1) A local authority may, on an application by the certificate holder, renew an approval certificate.

(2) Each application to renew an approval certificate must relate to either a single—

- (a) premises, or
- (b) vehicle.

(3) An application to renew an approval certificate must—

- (a) be made to the local authority that granted the approval certificate,
- (b) be made at least 28 working days prior to the expiry of the approval date listed on the approval certificate,
- (c) be made either in paper form or by means of electronic submission,
- (d) include the approval certificate number of the premises or vehicle to which the application relates, and
- (e) be made in the form specified in Schedule 1.

(4) Paragraph 3(e) is subject to the provisions in regulation 20.

Information to be provided by the certificate holder

18. After submitting an application to renew an approval certificate but before it is determined, the certificate holder must provide the local authority with any further information that the local authority considers necessary to enable it to determine the application.

Fees to accompany an application to renew

19.—(1) An application to renew an approval certificate is to be accompanied by whatever application fee is set by the local authority.

(2) The application fee (if any) is to be set by the local authority, having regard to the costs incurred by the local authority or expected to be incurred by the local authority in connection with dealing with applications to renew under these Regulations.

(3) An application to renew an approval certificate is not to be treated as having been duly made until the application fee has been received in cleared funds by the local authority.

Criteria for the renewal of an approval certificate

20.—(1) The criteria that must be met by a certificate holder for an approval certificate to be renewed is set out in paragraph (2).

(2) The criteria in regulation 8 applies as if an application to renew an approval certificate were an application for an approval certificate, except the criteria in regulation 8(2)(b) and (3) which do not apply.

Grant or refusal of an application to renew an approval certificate

21.—(1) This regulation applies where an application to renew an approval certificate is made to a local authority in accordance with Part 8.

(2) If the local authority is satisfied that all of the renewal criteria set out in regulation 20 are met, it must grant the application to renew an approval certificate and issue an approval certificate to the certificate holder, approving a premises or vehicle in respect of the performance of special procedure.

(3) If the local authority is not satisfied that all of the renewal criteria set out in regulation 20 are met, the local authority must give the certificate holder notice that the application to renew an approval certificate is refused.

(4) The notice must—

- (a) set out the reasons why the local authority refuses the application, and
- (b) state that the certificate holder may appeal under Parts 12 and 13 against the decision.

Expiry of approval certificate

22.—(1) For the purposes of this Part the expiry of an approval certificate will take effect at the earliest of—

- (a) the end of the approval certificate period;
- (b) the date upon which the approval certificate is revoked;
- (c) the date upon which the approval certificate is voluntarily terminated.

(2) But the expiry of an approval certificate will not take effect where—

- (a) an application for renewal is pending;
- (b) the time within which representations may be made under Part 12 is yet to expire;
- (c) an appeal brought under Part 13 remains to be determined.

PART 9

Copy of approval certificate

Application for a copy of an approval certificate

23.—(1) If an approval certificate is mislaid, stolen, or damaged, the certificate holder may apply to the local authority by which it was issued for a copy.

(2) An application for a copy of an approval certificate must—

- (a) be made to the local authority that granted the approval certificate,
- (b) be made either in paper form or by means of electronic submission,

- (c) include an explanation why a copy of an approval certificate is sought, and
- (d) where possible, provide confirmation of the approval certificate number.

Fees to accompany an application for a copy of an approval certificate

24.—(1) An application for a copy of an approval certificate is to be accompanied by whatever application fee is set by the local authority.

(2) The application fee (if any) is to be set by the local authority, having regard to the costs incurred by the local authority or expected to be incurred by the local authority in connection with dealing with applications for copies of approval certificates under these Regulations.

(3) An application for a copy of an approval certificate is not to be treated as having been duly made until the application fee has been received in cleared funds by the local authority.

Grant or refusal of application for a copy of an approval certificate

25.—(1) The local authority must grant the application if it is satisfied that—

- (a) the approval certificate has been mislaid, stolen or damaged, and
- (b) where the approval certificate has been mislaid or stolen, the loss or theft has been reported to the police.

(2) As soon as reasonably practicable after granting an application, a local authority must issue a copy of the approval certificate to the certificate holder.

(3) If a local authority is not satisfied under paragraph (1) it must issue a notice to the certificate holder which—

- (a) includes the reasons why the local authority refuses the application, and
- (b) states the certificate holder may appeal under Parts 12 and 13 against the decision.

Copy of an approval certificate

26. A copy of an approval certificate issued by a local authority under regulation 25 must be—

- (a) certified by the local authority as a true copy, and
- (b) treated for the purposes of these Regulations and any requirements imposed by or under these Regulations as being the original approval certificate.

PART 10

Fees

Application fee

27.—(1) This regulation makes provision about the way in which a local authority determines the amount of the application fee for the purposes of section 70(8)(a) of the Act.

(2) The costs to which a local authority must, in determining the application fee, have regard (in accordance with regulation 7) include, in particular, costs incurred by the local authority or expected to be incurred by the local authority in connection with applications and the following activities (but not limited to)—

- (a) the receipt, recording and scrutiny of the application,
- (b) undertaking an application interview and inspection of the premises or vehicle,
- (c) follow up actions associated with the application interview and inspection of the premises or vehicle,
- (d) approving or refusing the application, and
- (e) specifying the officer grade and time associated with each of these functions.

(3) A local authority must review the level of the fee—

- (a) at the end of the period of 1 year beginning with the day on which these Regulations come into force, and
- (b) at subsequent intervals of no more than 1 year.

(4) The application fee may not be paid in instalments.

(5) A local authority may refund the whole or part of the application fee already paid.

(6) If after the application fee is paid it becomes apparent that a lesser fee should have been paid, the excess must be refunded.

Compliance fee

28.—(1) This regulation makes provision about the way in which a local authority determines the amount of the compliance fee (if any) for the purposes of section 76(2) of the Act.

(2) The costs to which a local authority must, in determining the compliance fee have regard (in accordance with section 76(4) of the Act) include, in particular, costs incurred by the local authority or expected to be incurred by the local authority in

connection with the following activities (but not limited to)—

- (a) maintaining records on the local authority database,
- (b) maintaining the register established under section 75 of the Act,
- (c) an authorised officer exercising the powers of entry etc. under section 84 of the Act and undertaking unannounced visits, which may in some cases result in the exercise of the powers of inspection etc. under section 88 of the Act,
- (d) taking action against the certificate holder and exercising the power to revoke an approval certificate under section 73 of the Act, and
- (e) specifying the officer grade and time associated with each of these functions.

(3) A local authority must review the level of the fee—

- (a) at the end of the period of 1 year beginning with the day on which these Regulations come into force, and
- (b) at subsequent intervals of no more than 1 year.

(4) The compliance fee may not be paid in instalments.

(5) A local authority may refund the whole or part of the compliance fee already paid.

(6) If after the compliance fee is paid it becomes apparent that a lesser fee should have been paid, the excess must be refunded.

(7) Any compliance fee that is due to a local authority and remains unpaid may be recoverable by that local authority by way of a civil debt.

(8) In this regulation—

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

“compliance fee” (*“ffi gydymffurfio”*) means a fee that may be charged by the local authority under section 76(2) of the Act.

PART 11

Notice of voluntary termination of approval certificate

Notice of voluntary termination of approval certificate

29. Where a certificate holder wishes an approval certificate to cease to have effect and gives notice

under section 72(1) of the Act to the local authority that has granted and issued the approval certificate, the notice must include—

- (a) the intended date the approval certificate will cease to have effect,
- (b) the approval certificate number,
- (c) details of the certificate holder to include their full name, date of birth, address and contact details,
- (d) in the case of an approved premises, the address of the premises,
- (e) in the case of an approved vehicle that has a registration number, the registration number of the vehicle,
- (f) in the case of an approved vehicle that does not have a registration number, whatever identifying details of the vehicle that the local authority has considered appropriate in accordance with section 71(3)(b) of the Act, and
- (g) the name of any persons that the certificate holder thinks likely to be affected by the notice.

PART 12

Notices and right to make representations

Application and interpretation

30.—(1) This Part applies if a local authority proposes to give notice to P that it intends to refuse an application.

(2) In Parts 12 and 13—

“an application” (“*cais*”) means an application—

- (a) for an approval certificate,
- (b) to vary an approval certificate,
- (c) to renew an approval certificate, and
- (d) for a copy of an approval certificate;

“P” (“*P*”) means the applicant or certificate holder.

Refusal of an application

31. A local authority may refuse an application.

Warning notice of proposal to refuse an application

32. If a local authority proposes to refuse an application under regulation 31, it must give P a notice (“a warning notice”) that sets out what the local authority proposes to do and why.

Right to make representations

33.—(1) A warning notice must state that, within a period specified in the notice, P may either—

- (a) make representations about the proposals, or
- (b) inform the local authority P wishes to make representations.

(2) The period specified in the warning notice must not be less than 14 days beginning with the date of the notice.

(3) The local authority may take the steps specified in the warning notice if—

- (a) within the period specified in the warning notice, P informs the local authority that P does not wish to make representations, or
- (b) the period specified in the warning notice expires and P has neither made representations nor informed the local authority that P wishes to do so.

(4) If, within the period specified in the warning notice, P informs the local authority that P wishes to make representations, the local authority—

- (a) must allow P a further reasonable period to make representations, and
- (b) may take the steps specified in the warning notice, if P fails to make representations within that further period.

(5) If P makes representations (either within the period specified in the warning notice or within the further period allowed under paragraph (4)(a)), the local authority must consider the representations.

(6) The representations made by P under this regulation may be made orally or otherwise, and in the case of oral representations, may be made either by P or by P's representative.

Notice of decision

34.—(1) If, having complied with the requirements in regulation 32, a local authority decides to take the action set out in the warning notice, it must give P a notice of decision setting out the reasons for taking such action.

(2) The notice of decision must also state—

- (a) that P may appeal under Part 13 against the decision, and
- (b) the period within which an appeal may be brought.

(3) If having complied with regulation 32, a local authority decides not to take the action set out in the warning notice, the local authority must give the notice of decision to P.

PART 13

Appeals

Appeal to magistrates' court

35.—(1) P may appeal to a magistrates' court against a decision to refuse an application.

(2) An appeal is to be made within the period of 21 days beginning with the date of the notice of decision to refuse the application.

(3) An appeal is to be by way of complaint for an order, and in accordance with the Magistrates' Courts Act 1980(1).

(4) For the purposes of the time limit for making an appeal, the making of the complaint is to be treated as the making of the appeal.

(5) On an appeal, the magistrates' court may—

(a) confirm the decision of the local authority appealed against, or

(b) quash or vary the decision appealed against,

and may make such order as to costs as it thinks fit.

(6) If the magistrates' court quashes or varies the decision appealed against, it may remit the case to the local authority to dispose of in accordance with directions given by the court.

Appeal to Crown Court

36.—(1) An appeal by either party against the decision of a magistrates' court under regulation 35 may be brought to the Crown Court.

(2) On an appeal to the Crown Court, the Crown Court may—

(a) confirm, vary or reverse the magistrates' court's decision,

(b) remit the case to the magistrates' court or the local authority to dispose of in accordance with directions given by the Crown Court.

Compensation

37.—(1) Where on an appeal under regulation 35 or 36 a court varies or reverses a local authority's decision, the court may order the local authority to compensate the applicant or certificate holder for loss suffered as the result of the decision.

(2) The bringing of an appeal under regulation 35 or 36 in respect of a decision made by a local authority

(1) 1980 c. 43.

does not suspend the effect of the decision or any notice given under Part 12.

Name

Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

Date

SCHEDULE 1 Regulation 5(2)

Form of application for an approval certificate

Insert name and address of relevant local authority and its logo

Application for an approval certificate under section 70 of the Public Health (Wales) Act 2017

PLEASE READ THE FOLLOWING INSTRUCTIONS AND ACCOMPANYING GUIDANCE NOTES FIRST

If you are completing this form by hand, please write legibly in block capitals using ink. Use additional sheets if necessary (marked with the heading “Continuation sheet – application for approval certificate” and include the number of the relevant question and the applicant’s name and address). You may wish to keep a copy of the completed form for your records.

Name of relevant issuing local authority *(see Guidance Note 1):*

.....

Part 1 – Type of approval certificate applied for

Please tick as appropriate

1.1 What type of approval certificate does your application relate to?

Premises Vehicle

1.2 What is the intended duration of your approval certificate?

Temporary (no more than 7 days) 3 years

If you are applying for a temporary approval certificate, please indicate why a certificate is required (for example give details about an exhibition, entertainment or event):

.....
.....
.....

1.3 When do you want the approval certificate to start?

As soon as possible

Specific dates *[For example, state the days you wish an approval certificate to cover; in the case of a temporary approval certificate, you must specify the dates when the approval will be required.]*

..... to

Part 2 - Applicant details (fill in as applicable)

If you are an individual, please fill in Section A. If the application is being made on behalf of a business or organisation (such as a company or partnership), please fill in Section B.

Section A - Individual applicant

2.1 Title: Mr Mrs Miss Ms Dr Other (please specify)

2.2 Surname:

2.3 First name(s):

2.4 Contact telephone number:

2.5 E-mail address (if applicable):

2.6 Date of Birth:

2.7 Applicant's address (residential or business):

.....

..... Postcode:

2.8 Please state the full name of the person who will be listed as the certificate holder on the approval certificate:

.....

2.9 Please confirm that the proposed certificate holder is 18 years of age or over (tick)

2.10 Is the applicant or any person named in this application, involved in any way with any other premises or vehicle in which special procedures are performed?

Yes No

If yes, please provide details:

.....

[For example, the nature and extent of any interest, the address of any premises, or the details of any vehicle, the approval certificate number(s) of any premises or vehicle.]

Section B - Application on behalf of a business or organisation

2.11 Name of applicant business or organisation:

.....

[Use the trading name or registered name of the business or organisation.]

2.12 Company registration number:

.....

2.13 Company type:

.....
[For example, Private limited Company, Partnership, Sole Trader.]

2.14 If you are completing this form on behalf of the business or organisation, please state your full name and role in the business (see Guidance Note 2):

Full name:

Role:

[For example, Owner, Manager, Company Director, Operational Director.]

2.15 Registered office address of business or organisation:

.....

.....

..... Postcode:

2.16 Please provide the full name and contact details of an additional individual within the registered office who can be contacted in respect of this application and for the duration of the intended approval certificate (see Guidance Note 3):

Full name:

Role:

[For example, Regional Manager, Area Manager, Site Manager etc.]

Contact details (telephone number and e-mail address):

.....

2.17 Please state the name of the business/organisation which will be listed as the certificate holder on the approval certificate:

.....

.....

2.18 Is the applicant or any person named in this application, involved in any way with any other premises or vehicle in which special procedures are performed?

Yes No

If yes, please provide details:

.....

.....

[For example, the nature and extent of any interest, the address of any premises, or the details of any vehicle, the approval certificate number(s) of any premises or vehicle.]

Part 3 – Premises or Vehicle Details

Where your application relates to a premises, please fill in Section A. If the application relates to a vehicle, please fill in Section B.

Section A – Premises Details

3.1 Trading name used at premises (if applicable):

.....

3.2 Address of the premises:

.....

.....

..... Postcode:

3.3 Telephone number at premises (if applicable):

.....

3.4 Website address details and/or any public facing social media platforms for business (if applicable):

.....

3.5 List of special procedures to be performed from the premises (see Guidance Note 4):

Acupuncture

Body Piercing

Electrolysis

Tattooing

3.6 Are there any other activities (for example activities that are not classed as special procedures) undertaken at the premises? (See Guidance Note 5)

Yes No

If yes, please list those other activities:

.....

3.7 How many licence holders will be working from the premises?

.....

3.8 How many workstations are there in the premises that you are seeking approval for? (See Guidance Note 6)

.....

3.9 What water supply is used for the premises?

Mains water supply Private water supply Both mains/private water supply

3.10 Please state the number and location of any wash hand basins within the premises:

.....

3.11 Please state whether all wash hand basins provide:

o An adequate supply of hot and cold running water Yes No

- **Liquid or foam soap** Yes No
- **Disposable paper towels in an enclosed dispenser** Yes No

3.12 Are all of the fixtures and fittings within the special procedures work area (see *Guidance Note 7*) in good repair and made of nonporous materials that can be easily cleaned and disinfected? Yes No

3.13 Are all of the walls and floors within the premises in good repair? Yes No

3.14 Are all of the walls and floors within the premises made of materials that can be easily cleaned and disinfected? Yes No

3.15 Please provide full details of the equipment and products used in the sterilisation, disinfection and cleaning of any instruments, equipment, fixtures and fittings (including sinks):

.....

.....

.....

3.16 Please state what provision has been made for the storage, collection and disposal of waste (including sharps - see *Guidance Note 8*):

.....

.....

3.17 Please state what provision has been made in relation to:

- **Personal Protective Equipment (PPE)**

.....

.....

- **First Aid**

.....

.....

3.18 Please state what provision has been made for the storage and maintenance of records in relation to:

- **Client information**

.....

.....

- **Suppliers and product use**

.....

.....

- **Cleaning and disinfection regimes**

.....
.....

- **Maintenance and servicing of equipment**

.....
.....

Section B – Vehicle Details

3.19 Trading name used for the vehicle (if applicable):

.....

3.20 Please give details about the vehicle:

Vehicle registration number:

Vehicle identification number (VIN):

A recent colour photograph of the vehicle is to be enclosed with this application (tick to confirm this is included) (*see Guidance Note 9*) Yes

If the vehicle does not have a registration number, give a description of the vehicle and its location (where possible this should include an address with postcode) and provide as much information as possible to identify the vehicle for example the make, model, colour of the vehicle:

.....
.....
.....

3.21 Where in Wales will the vehicle likely be operating from? (*See Guidance Note 10*)

.....

3.22 Website address details and/or any public facing social media platforms for business (if applicable):

.....

3.23 List of special procedures to be performed in the vehicle (*see Guidance Note 4*):

- Acupuncture
- Body Piercing
- Electrolysis
- Tattooing

3.24 Are there any other activities (for example activities that are not classed as special procedures) undertaken at this vehicle? (*See Guidance Note 5*)

Yes No

If yes, please list those other activities:

.....

3.25 How many licence holders will be working in the vehicle?

.....

3.26 How many workstations are there in the vehicle that you are seeking approval for? (See Guidance Note 6)

.....

3.27 What water supply is used in the vehicle?

Mains water supply Private water supply Both mains/private water supply

3.28 Please state the number and location of any wash hand basins in the vehicle:

.....

3.29 Please state whether all wash hand basins provide:

- An adequate supply of hot and cold running water Yes No
- Liquid or foam soap Yes No
- Disposable paper towels in an enclosed dispenser Yes No

3.30 Are all of the fixtures and fittings in the special procedures work area (see Guidance Note 7) in good repair and made of nonporous materials that can be easily cleaned and disinfected? Yes No

3.31 Are all of the walls and floors in the vehicle in good repair? Yes No

3.32 Are all of the walls and floors in the vehicle made of materials that can be easily cleaned and disinfected? Yes No

3.33 Please provide full details of the equipment and products used in the sterilisation, disinfection and cleaning of any instruments, equipment, fixtures and fittings (including sinks):

.....

.....

.....

3.34 Please state what provision has been made for the storage, collection and disposal of waste (including sharps - see Guidance Note 8):

.....

.....

3.35 Please state what provision has been made in relation to:

- Personal Protective Equipment (PPE)

.....

-
- **First Aid**

.....

.....

3.36 Please state what provision has been made for the storage and maintenance of records in relation to:

- **Client information**

.....

.....

- **Suppliers and product use**

.....

.....

- **Cleaning and disinfection regimes**

.....

.....

- **Maintenance and servicing of equipment**

.....

.....

Part 4 – Times of operation

Please complete the table below to indicate the proposed opening and closing times of the premises or vehicle:

	Start	Finish
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

[Please give timings in 24 hour clock (e.g. 16:00) and only give details for the days of the week when you intend the premises or vehicle to be used to perform special procedures.]

Part 5 – Miscellaneous (fill in as applicable)

Please tick as appropriate

5.1 Have you, or any person named in or associated with this application, previously applied for an approval certificate? (Tick all that apply)

No

Yes – application for approval certificate granted

Yes – application to vary granted

Yes – application to renew granted

Yes – application (for an approval certificate, to vary and/or to renew) granted and approval certificate revoked

Yes – application (for an approval certificate, to vary and/or to renew) refused

If yes, please provide details [*For example, the approval certificate number, the reasons why an application was refused, the reasons why approval certificate was revoked.*]:

.....
.....

5.2 Do you have a special procedure licence (see Guidance Note 11)?

Yes No Application pending

If yes, please provide the licence number (see Guidance Note 12):

.....

If an application is pending, please provide the date on which the application was made:

.....

5.3 Please confirm which language you wish to use in your dealings with the local authority about your application:

Welsh English

5.4 Please set out any other information you consider to be relevant to your application in respect of the premises or vehicle:

.....
.....
.....
.....

Part 6 - Declaration and Checklist (please complete/tick)

This declaration is to be completed by the proposed certificate holder.

I confirm that, to the best of my knowledge, the information contained in this application is true. I understand that it is an offence under section 82(7) of the Public Health (Wales) Act 2017 to give information which is false or misleading in, or in relation to, this application or I am reckless as to whether it is false or misleading.

I understand that giving false or misleading information (whether knowingly or recklessly) may

result in my approval certificate being revoked.

I also confirm that:

The individual applicant/the business or organisation has the right to occupy the premises or vehicle (delete as applicable),

I am aware of my obligations to obtain valid insurance cover in respect of the premises/vehicle (see *Guidance Note 13*),

I have read and understood the mandatory approval conditions that will be attached to my approval certificate, and

I understand the implications of non-compliance with those mandatory approval conditions. (See *Guidance Note 14*)

Checklist:

- Payment of the application fee has been made/is enclosed (see *Guidance Note 15*)
- Application form fully completed and signed (see *Guidance Note 16*)
- A plan of the premises or vehicle is enclosed (see *Guidance Note 17*)
- Evidence of regulated Level 2 Award is enclosed (see *Guidance Note 18*)
- Recent colour photograph of vehicle is enclosed (if applicable) (see *Guidance Note 9*)
- Copy of identity documents are enclosed (see *Guidance Note 19*)
- I understand if the above requirements are not complied with the application may be rejected

Part 7 – Signature

7.1 Signature of individual applying for approval certificate (in accordance with Part 2 Section A)

Signature:

Print name:

Date:

7.2 Signature on behalf of business/organisation applying for approval certificate (in accordance with Part 2 Section B)

Signature (Person identified in Part 2 Section B 2.14):

Print name:

Date:

Signature (Person identified in Part 2 Section B 2.16):

Print name:

Date:

[Where the application is to be submitted in an electronic form, the signature should be generated

electronically and should be a copy of the person's written signature.]

Guidance Notes

Note 1: Name of relevant issuing local authority

When applying for an approval certificate—

- (a) if the premises is in the area of the local authority, an application is to be made to that local authority;
- (b) if the vehicle is considered to be, or is likely to be, driven, used or kept in the area of the local authority, an application is to be made to that local authority.

Note 2: Identification of person in Part 2 Section B 2.14

If an application is being made on behalf of a business/organisation, the name of the person required to be named in the application form is an individual such as the Owner, Manager, Company Director, Operational Director of the business/organisation.

Note 3: Identification of person in Part 2 Section B 2.16

Applicants must identify an individual who will be the contact for the application as well as the contact for the duration of the intended approval certificate. This individual can be the Regional Manager, Area Manager, Site Manager for the premises/vehicle and be part of the operational/day to day management of the premises/vehicle. This individual may be the same individual as the person identified in **Part 2 Section B 2.14** but they will be required to provide identity documents and must hold a valid regulated Level 2 Award.

Note 4: Meaning of special procedure

The special procedures of acupuncture, body piercing, electrolysis and tattooing all have the same meanings given in section 94(1) of the Public Health (Wales) Act 2017.

Note 5: Performance of other activities in the course of a business

An applicant may include details of other activities which are performed in the course of a business from the premises/vehicle but are not classed as special procedures. For example activities such as beauty treatments, hairdressing, retail etc.

Note 6: Number of workstations

The term “workstation” means the part of the special procedures work area which contains—

- (a) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (b) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (c) 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.

When deciding how many workstations an applicant is seeking approval for, the applicant must consider the size and shape of the premises/vehicle and ensure there is sufficient space between each workstation to enable the safe and hygienic performance of the special procedure(s). Please see the non-statutory guidance for further information.

Note 7: Special procedures work area

The term “special procedures work area” 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.

Note 8: Sharps

The term “sharps” 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.

Note 9: Photograph of vehicle

Applicants are required to submit a recent colour photograph of the vehicle that is subject to approval by the local authority. A photograph is required for all vehicles including those with registration plates.

Note 10: Location of vehicle

Whilst an approval certificate will authorise the performance of special procedures from a vehicle anywhere in Wales, applicants are asked to provide further details around the usual location of the vehicle in Wales and the local authority areas where the vehicle is likely to be used to perform special procedures.

Note 11: Special procedure licence

A special procedure licence has the same meaning given in section 59 of the Public Health (Wales) Act 2017 i.e. a licence issued by a local authority authorising the performance of the special procedure (or special procedures) specified in the licence by the licence holder.

Note 12: Licence number

The “licence number” means the reference number given by the local authority to the approval certificate which is unique to that certificate and which is specified in it.

Note 13: Insurance cover

The term “insurance cover” 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.

Note 14: Non-compliance with mandatory approval conditions

Applicants should be aware that an approval certificate can be revoked if a local authority is satisfied that the certificate holder has failed to comply with an applicable mandatory approval condition, and that the non-compliance presents, or could present, significant risk of harm to human health. See section 73 of the Public Health (Wales) Act 2017 for further details.

Note 15: Payment of the application fee

Applicants are advised to contact the relevant issuing local authority for further information about the amount of the application fee that is due and how payment of the application fee is to be made. This information may be found on the local authority’s website.

Note 16: Submission of application

Applicants are advised to contact the relevant issuing local authority for further information about how an application for an approval certificate is to be submitted. This information may be found on the local authority’s website.

Note 17: Plan of premises or vehicle

The application must be accompanied by a plan which must include (where appropriate)—

- (a) the points of entry and exit to the premises or vehicle,
- (b) the measurements and a description of the shape of the areas (such as rooms) (if any) within the premises or vehicle,
- (c) the points of entry and exit to the areas (such as rooms) (if any) within the premises or vehicle,
- (d) the location of the following (if any)—
 - (i) equipment sinks,
 - (ii) sharps bins,
 - (iii) staff rooms,

- (iv) storage areas, facilities or rooms for products and/or equipment,
- (v) toilets,
- (vi) waiting areas or rooms,
- (vii) wash hand basins,
- (viii) waste bins,
- (ix) windows, and
- (x) workstations.

Note 18: Evidence of regulated Level 2 Award

Applicants must hold a Level 2 Award in Infection Prevention and Control for Special Procedures Practitioners (an award that is regulated by Qualifications Wales). Applicants must provide evidence of this award by enclosing either the original certificate or a copy of the certificate. If a copy of the certificate is provided, the original certificate must be made available to the issuing local authority upon request.

In the case of an individual applying for an approval certificate the regulated Level 2 Award must be awarded to that individual.

If the application is being made on behalf of a business/organisation, the individual named/identified in **Part 2 Section B 2.16** of the application form must have been awarded the regulated Level 2 Award.

Note 19: Identity documents

In the case of an individual applying for an approval certificate, they must provide proof of their full name and date of birth.

In the case of an application being made on behalf of a business/organisation, the individual identified in **Part 2 Section B 2.16** of the application form must provide their proof of identity.

The following forms of photographic identification are permitted:

- Valid passport or driving licence,
- If the applicant has neither of the above then the following photographic ID cards are considered suitable: a Biometric residence permit; HM Forces ID card; EEA National ID card; Irish Passport Card; Visa or Work permit.

Applicants may provide a copy of their identification documents to accompany the application form but the original proof of identity must be made available to the issuing local authority upon request.

SCHEDULE 2 Regulation 10(1)

Form and content of approval certificate

Rhif: *[Mewnosoder rhif y dystysgrif gymeradwyo]*

No: *[Insert approval certificate number]*

**TYSTYSGRIF GYMERADWYO
APPROVAL CERTIFICATE**

***Mae'r gymeradwyaeth hon wedi ei dyroddi o dan adran 70 o Ddeddf Iechyd y Cyhoedd (Cymru)
2017 gan***

[Mewnosoder enw'r awdurdod lleol sy'n dyroddi a'r logo]

This approval is issued under section 70 of the Public Health (Wales) Act 2017 by

[Insert the name of the issuing local authority and logo]

Rhan 1 – Manylion deiliad y dystysgrif

Part 1 – Details of the certificate holder

Mae'r dystysgrif gymeradwyo hon wedi ei dyroddi i:

This approval certificate is issued to:

.....
[Mewnosoder enw llawn (h.y. endid cyfreithiol) busnes/sefydliad y fangre/cerbyd. Os yw cais wedi ei wneud gan unigolyn (e.e. nid ar ran busnes/sefydliad), mae enw llawn yr unigolyn hwnnw i'w fewnosod.]

[Insert full name (i.e. legal entity) of the business/organisation of the premises/vehicle. If an application has been made by an individual (e.g. not on behalf of a business/organisation) the full name of that individual is to be inserted.]

Rhan 2 – Manylion y dystysgrif gymeradwyo

Part 2 – Details of approval certificate

Daeth y dystysgrif gymeradwyo hon i rym ar:

This approval certificate came into effect on:

.....
[Mewnosoder y dyddiad cymeradwyo]

[Insert approval date]

Bydd y dystysgrif gymeradwyo hon yn dod i ben ar:

This approval certificate will expire on:

.....
[Mewnosoder y dyddiad dod i ben]

[Insert expiry date]

Mae'r dystysgrif gymeradwyo hon yn awdurdodi'r driniaeth/triniaethau arbennig a ganlyn:

This approval certificate authorises the following special procedure(s):

.....
[Mewnosoder y driniaeth/triniaethau arbennig h.y. Aciwbigo, Tyllu'r Corff, Electrolysis, Tatwio.]

[Insert special procedure(s) i.e. Acupuncture, Body Piercing, Electrolysis, Tattooing.]

I'w rhoi yn y fangre neu'r cerbyd a gymeradwywyd a ganlyn [dileer fel y bo'n gymwys]:
To be performed from the following approved premises or vehicle [delete as applicable]:

.....
[Yn achos cymeradwyo mangre, rhaid mewnosod cyfeiriad y fangre. Yn achos cymeradwyo cerbyd, rhaid mewnosod rhif cofrestru'r cerbyd. Os nad oes gan y cerbyd rif cofrestru, rhaid i'r awdurdod lleol nodi'r cerbyd ym mha ffordd bynnag y mae'n ystyried ei bod yn briodol a mewnosod y manylion hynny yma.]

[In the case of approval of premises, the address of the premises must be inserted. In the case of approval of a vehicle, the registration number of the vehicle must be inserted. If the vehicle does not have a registration number, the local authority must identify the vehicle in whatever way they consider appropriate and insert those details here.]

Uchafswm nifer y gweithfannau mewn cysylltiad â'r fangre neu'r cerbyd a gymeradwywyd uchod yw [dileer fel y bo'n gymwys]:

The maximum number of workstations in respect of the above approved premises or vehicle [delete as applicable]:

.....

Llofnodwyd ar ran yr awdurdod lleol sy'n dyroddi
Signed on behalf of the issuing local authority

.....
[Mewnosoder llofnod y person sydd wedi ei awdurdodi i lofnodi ar ran yr awdurdod. Pan fo'r dystysgrif gymeradwyo wedi ei dyroddi'n electronig, rhaid cynhyrchu'r llofnod yn electronig a rhaid iddo fod yn gopi o lofnod ysgrifenedig y person.]

[Insert signature of person authorised to sign on behalf of the authority. Where the approval certificate is issued electronically, the signature must be generated electronically and be a copy of the person's written signature.]

**MAE'R DYSTYSGRIF GYMERADWYO HON YN DDAROSTYNGEDIG I'R AMODAU
CYMERADWYO MANDADOL SYDD YNGHLWM WRTH Y DYSTYSGRIF HON
THIS APPROVAL CERTIFICATE IS SUBJECT TO THE MANDATORY APPROVAL
CONDITIONS ATTACHED TO THIS CERTIFICATE**

**NID YW'R DYSTYSGRIF HON YN DROSLWYDDADWY
THIS APPROVAL CERTIFICATE IS NOT TRANSFERABLE**

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

“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;

(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/>.

“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—

- (a) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (b) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (c) 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 11(3)

Mandatory approval conditions: temporary 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 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

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 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

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) 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

4.—(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

5.—(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

6.—(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

“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,

(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/>.

- (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—

- (a) a bed, chair or similar, on which a client sits or lies on to undergo a special procedure performed by a licence holder,
- (b) a chair or stool which the licence holder sits on to perform the special procedure (if applicable), and
- (c) 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.