

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

DRAFT WELSH STATUTORY
INSTRUMENTS

202X No. (W.)

PUBLIC HEALTH, WALES

**The Special Procedures Approved
Premises and Vehicles (Wales)
Regulations 202X**

EXPLANATORY NOTE

(This note is not part of the Regulations)

Part 4 of the Public Health (Wales) Act 2017 (“the Act”) establishes a mandatory licensing scheme for individuals wishing to perform special procedures (as listed in section 57 of the Act) in Wales.

Section 69 of the Act requires that the performance of a special procedure, in the course of a business, must be performed at a premises or in a vehicle that has been approved by a local authority (unless that premises or vehicle is exempt).

Part 1 of these Regulations sets out the circumstances in which the requirement that a special procedure must be performed at premises or in a vehicle which is approved by a local authority is disapplied.

Part 2 of these Regulations makes provision for applications for approval certificates including the criteria that must be met in order for an application for an approval certificate to be granted and the form and content of an application form (as set out in Schedule 1 to these Regulations).

Part 3 of these Regulations makes provision for the form and content of an approval certificate (as set out in Schedule 2 to these Regulations).

Part 4 of these Regulations sets out the applicable mandatory approval conditions which an approval certificate is subject to (as set out in Schedules 3 and 4 to these Regulations).

Part 5 of these Regulations makes provision for the variation of an approval certificate.

Part 6 of these Regulations makes provision for the renewal of an approval certificate.

Part 7 of these Regulations makes provision for applying for a copy of an approval certificate.

Part 8 of these Regulations makes provision for fees in relation to approval certificates.

Part 9 of these Regulations make further provision about the notice of voluntary termination of an approval certificate. This applies when a certificate holder may give notice to a local authority under section 72 of the Act that they wish to voluntarily terminate an approval certificate.

Part 10 of these Regulations makes provision around when a local authority is required to give notice to an applicant or certificate holder that they intend to refuse an application, and the right for that applicant or certificate holder to make representations to the local authority.

Part 11 makes provision around appeals in respect of applications, 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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**The Special Procedures Approved
Premises and Vehicles (Wales)
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Made ***

Coming into force ***

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

Title and coming into force

1.—(1) The title of these Regulations is the Special Procedures Approved Premises and Vehicles (Wales) Regulations 202X.

(2) These Regulations come into force on 202X.

Interpretation

2. In these Regulations—

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

(1) 2017 anaw 2. *See* section 124(1) of that Act for the definition of “regulations”.

(2) The reference in section 123 of the Public Health (Wales) Act 2017 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).

“applicable mandatory licensing conditions” (“*amodau trwyddedu mandadol cymwys*”) has the meaning given in section 63(7) of the Act;

“applicant” (“*ceisydd*”) means a person who makes an application for an approval certificate;

“application” (“*cais*”) means, unless otherwise specified, an application—

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

as the case may be;

“application fee” (“*ffi am gais*”) means the fee prescribed by the local authority to accompany an application;

“application for a special procedure licence” (“*cais am drwydded triniaeth arbennig*”) means an application—

- (a) for a special procedure licence,
- (b) to vary a special procedure licence,
- (c) to renew a special procedure licence,
- (d) for a copy of a special procedure licence;

“approval certificate” (“*tystysgrif gymeradwyo*”), unless the contrary intention appears, has the same meaning as in section 70 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 criteria” (“*meini prawf cymeradwyo*”) means the criteria that must be met in order for an approval certificate to be granted;

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

“approval period” (“*cyfnod cymeradwyo*”) 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;

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

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

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

“compliance inspection” (*“arolygiad cydymffurfedd”*) has the meaning given in regulation 4(4) and is to be read accordingly;

“insurance cover” (*“sicrwydd yswiriant”*) means a valid policy of insurance which was issued by an authorised insurer to insure the applicant in respect of any public liability which may occur at the premises or vehicle in the course of a special procedure being performed;

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

“licence number” (*“rhif y drwydded”*) means the number given by the local authority to the special procedure licence which is unique to that licence and which is specified in it;

“local authority” (*“awdurdod lleol”*) means the local authority granting an application for, and issuing, an approval certificate;

“mandatory approval conditions” (*“amodau cymeradwyo mandadol”*) has the meaning given in section 70 of the Act and as set out in Schedule 3 or 4 to these Regulations;

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

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

“renewal criteria” (*“meini prawf adnewyddu”*) means the criteria that must be met in order for the renewal of an approval certificate to be granted;

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

“special procedures work area” (*“man gwaith triniaethau arbennig”*) means an area or room where special procedures are performed and includes any—

- (a) wash hand basins,
- (b) waste bins,
- (c) workstations,
- (d) other facilities to support the performance of the special procedure;

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

“temporary approval certificate” (*“tystysgrif gymeradwyo dros dro ”*) means an approval that

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

authorises the performance of a special procedure 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;

“workstation” (“*gweithfan*”) means the area, space or zone within 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,
- (c) a trolley that is used for the placement and storage of the instruments and products used by the licence holder to perform the special procedure,
- (d) a sharps bin.

Part 1

Exempted Premises and Vehicles

Exempted premises or vehicles for the purposes of section 69(8) of the Act

3. The requirements in section 69(2) of the Act do not apply in respect of acupuncture performed for the purposes of providing palliative care.

Part 2

Applications for an approval certificate

Applicable approval criteria for an approval certificate to be granted

4.—(1) The approval criteria that must be met are set out in paragraphs (2) to (4).

(2) The applicant—

- (i) must be 18 years of age or over,
- (ii) must submit an application in accordance with regulation 6.

(3) The application referred to in paragraph (2) must be accompanied by—

- (i) the application fee (if any),
- (ii) a plan of the premises or vehicle to which the application relates that complies with paragraph (5),

- (iii) evidence of valid insurance cover held by the applicant in respect of the premises or vehicle,
- (iv) evidence of the successful completion of a regulated Level 2 Award held by the applicant.

(4) The premises or vehicle to which the application relates to must be subject to, and satisfactorily pass, a compliance inspection with the determining local authority.

(5) The plan referred to in paragraph (3)(ii) must include (where applicable)—

- (a) the points of entry and exit to the premises or vehicle,
- (b) the measurements and shape of any room within the premises or vehicle,
- (c) the points of entry and exit to any room within the premises or vehicle,
- (d) the location of 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.

Applicable approval criteria for a temporary approval certificate to be granted

5. Where an applicant wishes to make an application for a temporary approval certificate, the applicant must—

- (a) comply with the approval criteria set out in regulation 4, and
- (b) make an application at least 28 working days prior to the intended approval date of the temporary approval certificate.

Application for an approval certificate

6.—(1) Each application for the issue of an approval certificate must relate to either a single premises or vehicle.

(2) An application for an approval certificate must be in the form, and contain the information, specified in Schedule 1 to these Regulations.

(3) The text included in square brackets in the form at Schedule 1 to these Regulations are intended as guidance for completing the form.

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

(5) The application fee referred to in regulation 4(3)(i) is to be set by the local authority having regard to the costs incurred or expected to be incurred by the authority in connection with dealing with applications.

(6) An application is not to be treated as having been made until the application fee has been received in cleared funds by the local authority.

(7) At any time after receiving but before determining an application, a local authority may require the applicant to provide it with any further information that it considers necessary to enable it to determine the application.

(8) The further information referred to in paragraph (7) may include any information that the local authority considers necessary for the purpose of verifying the identity of the applicant.

(9) If an applicant fails to provide information which has been requested under paragraph (7) or (8), the local authority may decline to proceed with the application.

Approval of application for an approval certificate for the purposes of section 70(3)(b) of the Act

7. If the local authority is satisfied that the approval criteria set out in regulation 4 (or regulation 5 as the case may be) are met, it 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.

Refusal of application for an approval certificate for the purposes of section 70(7)(b) of the Act

8. If the local authority is not satisfied that the approval criteria set out in regulation 4 (or regulation 5 as the case may be) 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.

Part 3

Form and content of approval certificate

Form and content of approval certificate

9.—(1) Subject to the following paragraphs of this regulation, an approval certificate is to be in the form set out in Schedule 2 to these Regulations.

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

(3) A copy of the applicable mandatory approval conditions set out in either Schedule 3 or 4 to these Regulations must be annexed to the approval certificate.

Part 4

Mandatory approval conditions

Applicable mandatory approval conditions for an approval certificate

10. An approval certificate granted under section 70 of the Act is subject to the mandatory approval conditions set out in Schedule 3 to these Regulations.

Applicable mandatory approval conditions for a temporary approval certificate

11. An approval granted under section 70 of the Act, in relation to which a temporary approval certificate is issued, is subject to the mandatory approval conditions set out in Schedule 4 to these Regulations.

Part 5

Variation of approval certificate

Variation of an approval certificate

12.—(1) A local authority may, on an application to this effect by a certificate holder, vary an approval certificate issued by it.

(2) Each application to vary an approval certificate must relate to either a single premises or vehicle.

(3) 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).

(4) An approval certificate must not be varied under this regulation so as to—

- (a) transfer the approval certificate from the certificate holder to another individual,
- (b) shorten or extend the approval period,
- (c) terminate the approval certificate.

Application to vary an approval certificate

13.—(1) Subject to paragraphs (4), (5) and (6), an application to vary an approval certificate is to be—

- (a) made in whatever way the local authority concerned may require,
- (b) made either in paper form or by means of electronic submission,
- (c) accompanied by the application fee (if any).

(2) The application fee referred to in paragraph (1)(c) is to be set by the local authority having regard to the costs incurred or expected to be incurred by the authority in connection with dealing with applications to vary.

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

(4) If an application to vary an approval certificate relates to any structural or design change(s) of the premises or vehicle, it must include—

- (a) particulars of the changes proposed to be made at the premises or in the vehicle, and
- (b) updated copy of the plan that is required in regulation 4(3)(ii) which clearly shows those proposed changes.

(5) At any time after reviewing but before determining an application for the purpose set out in regulation 12(3)(c), a local authority may undertake a compliance inspection of the premises or vehicle to which the application relates to.

(6) At any time after reviewing but before determining an application under paragraph (1) a local authority may require the certificate holder to provide it with any further information that it considers necessary to enable it to determine the application.

(7) An application to vary an approval certificate by adding a description of special procedure, the

performance of which is to be authorised by the approval certificate—

- (a) must specify the procedure concerned, and
- (b) is to be treated for the purposes of this regulation 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).

(8) Paragraph (7)(b) does not apply for the purposes of the determination of the approval certificate.

Part 6

Renewal of approval certificate

Applicable renewal criteria for the renewal of an approval certificate

14.—(1) The renewal criteria that must be met are set out in paragraphs (2) to (4).

(2) The certificate holder must submit an application in accordance with regulation 15 to the issuing local authority.

(3) The application referred to paragraph (2) must be accompanied by—

- (a) the application fee (if any),
- (b) evidence of valid insurance cover.

(4) The premises or vehicle to which the application relates must be subject to, and satisfactorily pass, a compliance inspection with the determining local authority.

Application to renew an approval certificate

15.—(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 premises or vehicle.

(3) An application to renew an approval certificate is to be made to the local authority that granted the approval certificate.

(4) An application to renew an approval certificate is to—

- (a) be made in whatever way the local authority concerned may require,
- (b) include whatever information the local authority concerned may require,

(c) be made either in paper form or by means of electronic submission.

(5) The application fee referred to in regulation 14(3)(a) is to be set by the local authority, having regard to the costs incurred or expected to be incurred by the authority in connection with dealing with applications to renew.

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

- (a) comply with the renewal criteria set out in regulation 14,
- (b) be made at least 28 working days prior to the expiry of the approval date listed on the approval certificate,
- (c) include particulars of any 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 to.

(7) An application is not to be treated as having been made until the application fee has been received by the local authority.

(8) At any time after receiving but before determining an application, a local authority may require the certificate holder to provide it with any further information that it considers necessary to enable it to determine the application.

Approval of application to renew an approval certificate

16. If the local authority is satisfied that all of the renewal criteria set out in regulation 14 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.

Refusal of application to renew an approval certificate

17. If the local authority is not satisfied that all of the renewal criteria set out in regulation 14 are met, the local authority must give the certificate holder notice that the application to renew an approval certificate is refused.

Expiry of approval certificate

18.—(1) An approval certificate is to be treated for the purposes of this Part as expiring with whichever is the earliest of—

- (a) the end of the approval period,

- (b) the date with the expiry of which revocation of the approval certificate has effect,
 - (c) the date with the expiry of which the approval certificate ceases to have effect under section 72(3) of the Act (voluntary termination of approval).
- (2) An application to renew an approval certificate is not to be treated as expired under paragraph (1) while—
- (a) the application for renewal is pending,
 - (b) an appeal may be brought under Part 11 of these Regulations in respect of the application,
 - (c) an appeal brought in respect of the application under Part 11 of these Regulations, within the period for bringing an appeal under that Part, remains to be determined.

Part 7

Copy of approval certificate

Application for a copy of an approval certificate

19.—(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 under paragraph (1) is to be—

- (a) made in whatever way the local authority concerned may require,
- (b) made either in paper form or by means of electronic submission, and
- (c) accompanied by the application fee (if any).

(3) The application fee referred to in paragraph (2)(c) is to be set by the local authority having regard to the costs incurred or expected to be incurred by the authority in connection with dealing with applications for copies of approval certificates.

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

(5) The local authority must grant the application if it is satisfied—

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

(6) As soon as reasonably practicable after granting an application under paragraph (1), a local authority is

to issue a copy of the approval certificate to the certificate holder.

Copy of an approval certificate

20. A copy of an approval certificate issued by a local authority under regulation 19 is—

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

Part 8

Fees

Application fee

21.—(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(7)(a) of the Act.

(2) All local authorities must work collaboratively, and take into account such collaboration, when considering the application fee that is to be set.

(3) Following such collaboration, each local authority is to determine—

- (a) the application fee, and
- (b) the circumstances, cases or descriptions of cases (if any) where no application fee or a reduced fee is required.

(4) All local authorities may collectively review the level of the fee—

- (a) at the end of the period of one year beginning with the date on which these Regulations come into force, and
- (b) at the end of each subsequent period of three years thereafter.

(5) When determining the application fee, local authorities must have regard to the costs incurred or expected to be incurred by them in connection with dealing with the application and the following activities (but not limited to)—

- (a) the receipt, recording and scrutiny of the application,
- (b) undertaking a compliance inspection (where appropriate),
- (c) follow up actions associated with the compliance inspection,
- (d) approving or refusing the application, and

(e) specifying the officer grade associated with each of these functions.

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

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

(8) 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

22.—(1) The certificate holder must pay the compliance fee in the amount and in the manner determined by the local authority under these Regulations.

(2) All local authorities must work collaboratively, and take into account such collaboration, when considering the compliance fee that is to be set.

(3) Following such collaboration, each local authority is to determine—

(a) the compliance fee, and

(b) the circumstances, cases or descriptions of cases (if any) where a reduced compliance fee is required.

(4) All local authorities may collectively review the level of the fee—

(a) at the end of the period of one year beginning with the date on which these Regulations come into force, and

(b) at the end of each subsequent period of three years thereafter.

(5) When determining the compliance fee, local authorities must have regard to the costs incurred or expected to be incurred by them in connection with dealing with section 76(2) of the Act and the following activities (but not limited to)—

(a) maintaining accurate records on the local authority database and the register established under section 75 of the Act,

(b) undertaking unannounced visits,

(c) taking informal or formal action as a result of a visit or a client request,

(d) specifying the officer grade associated with each of these functions.

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

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

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

(9) Unless the compliance fee has been paid, a certificate holder is not permitted to progress an application or an application for a special procedure licence.

(10) 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.

Part 9

Notice of voluntary termination of approval certificate

Notice of voluntary termination of approval certificate

23. Where a certificate holder wishes an approval certificate to cease to have effect and notice is given to that effect under section 72(1) of the Act to the local authority that has approved or 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) the 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 10

Notices and right to make representations

General

24.—(1) In Parts 10 and 11 of these Regulations, the applicant or certificate holder is referred to as “P”.

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

Refusal of an application

25. A local authority may refuse an application (in respect of all applications).

Warning notice to refuse an application

26. If a local authority proposes to refuse an application under regulation 25, 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

27.—(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

28.—(1) If, having complied with the requirements in regulation 27, a local authority decides to take the action set out in the warning notice, it must set out the reasons for taking it in a notice of decision.

(2) The notice of decision must also state—

- (a) that P may appeal under Part 11 of these Regulations against the decision, and
- (b) the period within which an appeal may be brought.

(3) If having complied with regulation 27, 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 11

Appeals

Appeal to magistrates' court

29.—(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.

(1) 1980 c. 43.

Appeal to Crown Court

30.—(1) An appeal by either party against the decision of a magistrates' court under regulation 28 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

31.—(1) Where on an appeal under regulation 29 or 30 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 29 or 30 in respect of a decision made by a local authority does not suspend the effect of the decision or any notice given under Part 10 of these Regulations.

Name

Date

DRAFT

SCHEDULE 1 Regulation 6(2)

Form of application for an approval certificate

[Insert name and address of relevant local authority and its logo (optional)]

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

PLEASE READ THE FOLLOWING INSTRUCTIONS 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 number of the relevant question). You may wish to keep a copy of the completed form for your records.

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 around an exhibition, entertainment or event):

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

1.3 When do you want the approval certificate to start?

As soon as possible

Specific dates (for example indicate the days you wish an approval certificate to cover)

..... 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 (home or business *[delete as appropriate]*):

.....

..... Postcode:

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

.....

Section B - Application on behalf of a business or organisation

2.9 Name of applicant business or organisation:

.....

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

2.10 Company registration number (if applicable):

.....

2.11 Company type (if applicable):

.....

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

2.12 If you are completing this form on behalf of the business or organisation, please state your full name and role in the business:

Full name:

Role:

[For example Owner, Manager, Director]

2.13 Registered office address of business or organisation:

.....

.....

..... Postcode:

2.14 Please provide the full name and contact details of an additional individual within the registered office who may be contacted in respect of this application:

Full name:

Role:

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

.....

2.15 Please state the full name of the person and name of business/organisation who shall be listed as the certificate holder on the approval certificate:

.....

.....

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

2.17 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 (if applicable):

.....

3.5 List of special procedures to be performed from the premises:

.....
.....
.....
3.6 Are there any other activities (for example activities that are not classed as a special procedure) undertaken at the premises?

Yes No

If yes, please list those other activities:

.....
3.7 How many licence holders will be working from these premises?

.....
3.8 How many workstations will be in operation at these premises?

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

.....
3.10 Please state whether any wash hand basins provide:

- An adequate supply of hot and cold water Yes No
- Non hand operated taps Yes No
- Liquid or foam soap Yes No
- Disposable paper towels in a wall mounted dispenser Yes No

3.11 Are all of the fixtures and fittings within the premises in good repair and made of materials that can be easily cleaned and disinfected? Yes No

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

3.13 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):

.....
.....
.....
3.14 Please state what provision has been made for the storage, collection and disposal of waste (including sharps):

.....
.....
3.15 Please state what provision has been made in relation to:

- **Personal Protective Equipment (PPE)**

.....
.....

- **First Aid**

.....
.....

3.16 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

3.17 Trading name used at vehicle (if applicable):

.....

3.18 Please give details about the vehicle:

Vehicle registration number:

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:

.....
.....

.....
3.19 Website address details (if applicable):
.....

3.20 List of special procedures to be performed in the vehicle:
.....
.....
.....

3.21 Are there any other activities (for example activities that are not classed as a special procedure) undertaken at this vehicle?

Yes No

If yes, please list those other activities:
.....

3.22 How many licence holders will be working in this vehicle?
.....

3.23 How many workstations will be in operation in this vehicle?
.....

3.24 Please state the number and location of any wash hand basins in this vehicle:
.....

3.25 Please state whether any wash hand basins provide:

- An adequate supply of hot and cold water Yes No
- Non hand operated taps Yes No
- Liquid or foam soap Yes No
- Disposable paper towels in a wall mounted dispenser Yes No

3.26 Are all of the fixtures and fittings in the vehicle in good repair and made of materials that can be easily cleaned and disinfected? Yes No

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

3.28 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):
.....
.....
.....

3.29 Please state what provision has been made for the storage, collection and disposal of waste

(including sharps):

.....
.....

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

- **Personal Protective Equipment (PPE)**

.....
.....

- **First Aid**

.....
.....

3.31 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 any approval certificate number, the reasons why an application was refused):

.....

5.2 Do you have a special procedure licence? Yes No Application pending

If yes, please provide the licence number:

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.

I confirm that the individual applicant/the business or organisation have/has the right to occupy the premises or vehicle (*delete as applicable*)

Checklist:

- Payment of the application fee has been made/is enclosed
- Application form fully completed and signed
- A plan of the premises or vehicle is enclosed
- Evidence of regulated Level 2 Award is enclosed
- Evidence of valid insurance cover is enclosed
- Copy of documents to verify identity of proposed certificate holder are enclosed
- I understand if the above requirements are not complied with the application may be rejected

Part 7 – Signature

7 Signature of proposed certificate holder

Signature:

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.]

SCHEDULE 2 Regulation 9(1)

Form and content of approval certificate

No: *[Insert approval certificate number]*

APPROVAL CERTIFICATE

*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]*

Part 1 – Details of to whom this approval certificate is issued

This approval certificate is issued to:

.....
[Insert full name of person and/or business/organisation to whom the approval is issued]

Part 2 – Details of approval certificate

This approval certificate came into effect on:

.....
[Insert approval date]

This approval certificate will expire on:

.....
[Insert expiry date]

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

.....
[Insert special procedure(s)]

To be performed from the following approved premises or vehicle [delete as applicable]:

.....
[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]

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

.....

Signed on behalf of the issuing local authority

.....
[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]

THIS APPROVAL CERTIFICATE IS NOT TRANSFERABLE

Schedule 3 Regulation 10

Applicable mandatory approval conditions for an approval certificate

General

1. The certificate holder must operate in accordance with the issued approval certificate and applicable mandatory approval conditions.
2. 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.
3. 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.
4. 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.
5. The certificate holder must keep and maintain an up-to-date record of all licence holders operating from the approved premises or vehicle, including the special procedure(s) they are licensed to perform.
6. 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 licence.
7. The maximum number of workstations approved for use at the approved premises or vehicle and stated on the approval certificate must not be exceeded.
8. The certificate holder is responsible for ensuring that all licence holders operating from the approved premises or vehicle, act in accordance with their applicable mandatory licensing conditions.

Matters relating to the approval certificate

9. The certificate holder must have a copy of the applicable mandatory approval conditions

readily available for inspection by authorised officers of the local authority or any customer upon request.

10. The approval certificate is non-transferable and must not be used by any other person. It must not be altered in any way and must remain legible.
11. Changes to the approval certificate may only be made by the issuing local authority after an application to vary has been provided to and approved by that authority.
12. The approval certificate is invalid if there has been a change in ownership or management in relation to the approved premises or vehicle.
13. In the event of the approval certificate becoming mislaid, stolen or damaged, the certificate holder must notify the issuing local authority immediately and obtain a replacement from the issuing local authority on payment of the application fee.
14. The approval certificate must be returned to the issuing local authority in accordance with the instructions provided by that authority.
15. The certificate holder must ensure that the insurance cover for the premises or vehicle remains valid and takes account of the range of special procedures offered for the duration of the approval period. Insurance certificates must be readily available on the premises or vehicle for inspection by the visiting authorised officers from the local authority.

Matters relating to displaying of notices and restricted access

16. 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.
17. The certificate holder must display a notice stating that special procedures will not be carried out 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.

18. The certificate holder must display a notice specifying that animals are prohibited from rooms or areas where special procedures are performed, except for assistance animals. This notice must be in a location that enables it to be easily read by clients and members of the public.
19. Hand washing instructions must be clearly displayed at every wash hand basin within the approved premises or vehicle.
20. The certificate holder must ensure that clients are only permitted to access the area in which a special procedure is performed. 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.

Design, structure and physical environment

21. A special procedure must only be performed at a workstation within the approved premises or vehicle.
22. The certificate holder must ensure that the design, size, structure and repair of the premises or vehicle enables effective cleaning and where appropriate disinfection.
23. All internal surfaces, fixtures, fittings and facilities used as part of the special procedure business must be of such material and design, kept in good order and repair to enable effective cleaning and, where appropriate, disinfection.
24. Where a waiting area is provided it must be physically segregated from the area where special procedures are performed.
25. The approved premises or vehicle must have ready access to toilet facilities for use by licence holders, staff and clients.
26. 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 a dispenser.
27. The workstation where the special procedure is performed must have sufficient space to—
 - (a) enable the safe and hygienic performance of the special procedure, and

- (b) accommodate the workstation and facilities for the hygienic storage of equipment, instruments and products used for or in conjunction with special procedures to avoid the risk of contamination.
28. 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.
 29. Suitable arrangements and facilities must be provided for the secure storage, management and retrieval of clients' records relating to the special procedures that are offered and performed.
 30. The certificate holder must provide a suitably stocked, readily accessible first aid kit which has a minimum stock of items to meet the first aid needs of the special procedures practised from the approved premises or vehicle.
 31. 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.
 32. Adequate ventilation must be provided to all rooms within the approved premises or vehicle.
 33. 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.
 34. Any wash hand basins used in a special procedures work area must be fitted with non-hand operated taps and include an adequate supply of running water (hot and cold or mixed), liquid soap and paper towels stored in a dispenser in proximity to the wash hand basin.
 35. The certificate holder must ensure that all wash hand basins for the licence holders' use are fully stocked with liquid soap and paper towels.
 36. Wash hand basins must only be used for the purposes of washing hands and forearms.

Decontamination, cleaning, disinfection and sterilisation

37. All parts of the approved premises or vehicle must be kept clean and tidy.
38. A suitable and sufficient cleaning schedule for the premises, fixtures, fittings, furniture, equipment and instruments must be in operation.
39. 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 the areas/rooms where special procedures are performed and it must reflect the procedures undertaken at the approved premises or vehicle.
40. 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

41. Suitable provision must be made for the collection, storage and disposal of waste and other refuse.
42. An adequate number of easy to clean, non-hand-operated bins must be provided in a special procedures work area and be appropriately constructed, kept in a sound and clean condition.
43. The certificate holder must provide a suitable number of sharps boxes which conform to the current requirements set by the British Standards Institution and ensure they are safely located in close proximity to any workstation(s).
44. 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.
45. All clinical, non-hazardous waste (yellow bags and sharps boxes) must have their point of

origin (name and address of business) marked on them prior to disposal.

46. The certificate holder must ensure that the clinical, non-hazardous waste 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 the authorised officer from the local authority.

Schedule 4 Regulation 11

Applicable mandatory approval conditions for a temporary approval certificate

General

1. The certificate holder must operate in accordance with the issued approval certificate and applicable mandatory approval conditions.
2. 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.
3. 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.
4. 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.
5. The certificate holder must keep and maintain an up-to-date record of all licence holders operating from the approved premises or vehicle, including the special procedure(s) they are licensed to perform.
6. The certificate holder must only permit licence holders to operate from their approved premises or vehicle where the premises or vehicle is specified in their licence.
7. The maximum number of workstations approved for use at the approved premises or vehicle and stated on the approval certificate must not be exceeded.

8. The certificate holder is responsible for ensuring that all licence holders operate in accordance with their applicable mandatory licensing conditions.

Matters relating to the temporary approval certificate

9. The certificate holder must have a copy of the applicable mandatory approval conditions readily available for inspection by authorised officers of the local authority or any customer upon request.
10. The approval certificate is non-transferable and must not be used by any other person. It must not be altered in any way and must remain legible.
11. In the event of the approval certificate becoming mislaid, stolen or damaged, the certificate holder must notify the issuing local authority immediately and obtain a replacement from the issuing local authority on payment of the application fee.
12. The certificate holder must ensure that the insurance cover for the premises or vehicle remains valid and takes account of the range of special procedures offered for the duration of the approval period. Insurance certificates must be readily available on the premises or vehicle for inspection by the visiting authorised officers from the local authority.

Matters relating to displaying of notices and restricted access

13. 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.
14. The certificate holder must display a notice stating that special procedures will not be carried out 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.
15. The certificate holder must display a notice specifying that animals are prohibited from

rooms or areas where special procedures are performed, except for assistance animals. This notice must be in a location that enables it to be easily read by clients and members of the public.

16. Hand washing instructions must be clearly displayed at every wash hand basin that are being used solely by licence holders.
17. Public access areas must be clearly identified and members of the public must be restricted from accessing—
 - (a) workstations where special procedures are performed (unless they are a client),
 - (b) areas/rooms where refuse arising from the special procedure is collected and stored, and
 - (c) any areas where equipment/products relating to special procedures are stored.

Design, structure and physical environment

18. The certificate holder must ensure that the design, size, structure and repair of the premises or vehicle enables effective cleaning and, where appropriate, disinfection.
19. A special procedure must only be performed in the workstation designated for that purpose. Access to this area must be restricted to authorised persons and the licence holder.
20. All internal surfaces, fixtures, fittings and facilities where the special procedure is performed must be of such material and design, kept in good order and repair to enable effective cleaning and, where appropriate, disinfection.
21. The approved premises or vehicle must have ready access to toilet facilities for use by licence holders, staff and clients.
22. 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 a dispenser.
23. The workstation where the special procedure is performed must have sufficient space to—
 - (a) enable the safe and hygienic performance of the special procedure, and
 - (b) accommodate the workstation and facilities for the hygienic storage of equipment,

instruments and products used for or in conjunction with special procedures to avoid the risk of contamination.

24. The certificate holder must provide suitably stocked, readily accessible first aid kits which have a minimum stock of items to meet the first aid needs of the special procedure practised and the number of licence holders operating at the event.
25. 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.
26. Adequate ventilation must be provided to all rooms within the approved premises or vehicle.
27. A suitable number of readily accessible wash hand basins must be provided to the special procedure workstations for use by the licence holders. The wash hand basins must be in good working order and repair.
28. Wash hand basins used by licence holders must be fitted with non-hand operated taps and include an adequate supply of running hot and cold or mixed water, liquid soap and paper towels stored in a dispenser in close proximity to the wash hand basin.
29. 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.
30. Wash hand basins must only be used for the purposes of washing hands and forearms.

Decontamination, cleaning, disinfection and sterilisation

31. 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.
32. A suitable and sufficient cleaning schedule for the approved premises or vehicle must be in operation.

33. 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 a special procedures work area and it must reflect the procedures undertaken at the approved premises or vehicle.
34. In the case of a temporary event a single use policy must be operated.
35. 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

36. Suitable provision must be made for the collection, storage and disposal of waste and other refuse.
37. The certificate holder must ensure that each special procedure workstation is provided with a sharps box that conforms to the current requirements set by the British Standards Institution and is used solely by the licence holder/s using that workstation.
38. An adequate number of easy to clean, non-hand-operated bins must be provided in the special procedures work area and be appropriately constructed, kept in a sound and clean condition.
39. 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.
40. All clinical, non-hazardous waste (yellow bags and sharps boxes) must have their point of origin (name and address of business) marked on them prior to disposal.
41. The certificate holder must ensure that the clinical, non-hazardous waste 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 the authorised officer from the local authority.

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