The Committee will meet at 10.30am in Committee Room 2.

1. **Delegated powers scrutiny:** The Committee will consider the delegated powers provisions in the following bill—

   Management of Offenders (Scotland) Bill as amended at Stage 2.

2. **Delegated powers scrutiny:** The Committee will consider the delegated powers provisions in the following bill—

   Human Tissue (Scotland) Bill at Stage 1.

3. **Executive responses:** The Committee will consider responses from the Executive to points raised on the following—

   - the TSE (Scotland) Amendment (No.2) Regulations 2005, *(SSI 2005/469)*
   
   - the Pollution Prevention and Control (Designation of Public Participation Directive) (Scotland) Order 2005, *(SSI 2005/461)*.

4. **Draft instruments subject to approval:** The Committee will consider the following—

   - the Regional Transport Partnerships (Establishment, Constitution and Membership) (Scotland) Order 2005 *(SSI 2005/draft)*
   
   - the Civil Partnership Act 2004 (Consequential Amendments) (Scotland) Order 2005 *(SSI 2005/draft)*.

5. **Instruments subject to approval:** The Committee will consider the following—
the Food Protection (Emergency Prohibitions) (Amnesic Shellfish Poisoning) (West Coast) (No.12) (Scotland) Order 2005, (SSI 2005/497)

the Food Protection (Emergency Prohibitions) (Amnesic Shellfish Poisoning) (East Coast) (Scotland) Order 2005, (SSI 2005/498)


6. **Instruments subject to annulment:** The Committee will consider the following—

   the Tryptophan in Food (Scotland) Regulations 2005, (SSI 2005/479)

   the Reporting of Prices of Milk Products (Scotland) Regulations 2005, (SSI 2005/484)

   the Removal, Storage and Disposal of Vehicles (Prescribed Sums and Charges etc.) Amendment (Scotland) Regulations 2005, (SSI 2005/486)

   the Civil Contingencies Act 2004 (Contingency Planning) (Scotland) Regulations 2005, (SSI 2005/494)

   the Police Pensions (Part-time Service) Amendment (Scotland) Regulations 2005, (SSI 2005/495)

   the Salmonella in Broiler Flocks (Sampling Powers) (Scotland) Regulations 2005, (SSI 2005/496)

   the Additional Support for Learning Dispute Resolution (Scotland) Regulations 2005, (SSI 2005/501)

   the Animals and Animal Products (Import and Export) (Scotland) Amendment (No.2) Regulations 2005, (SSI 2005/502)

   the Food Hygiene (Scotland) Regulations 2005, (SSI 2005/505)

   the Pollution Prevention and Control (Public Participation etc.) (Scotland) Regulations 2005, (SSI 2005/510)

   the National Health Service (Superannuation Scheme, Injury Benefits and Compensation for Premature Retirement) (Scotland) Amendment Regulations 2005, (SSI 2005/512).

7. **Instruments not subject to Parliamentary procedure:** The Committee will consider the following—

8. **Instruments not laid before the Parliament:** The Committee will consider the following—


the Smoking, Health and Social Care (Scotland) Act 2005 (Commencement No.1) Order 2005, **(SSI 2005/492)**

the Civil Contingencies Act 2004 (Commencement) (Scotland) Order 2005, **(SSI 2005/493)**

Act of Sederunt (Summary Applications, Statutory Applications and Appeals etc. Rules) Amendment (Mental Health (Care and Treatment) (Scotland) Act 2003) 2005, **(SSI 2005/504)**.

Ruth Cooper  
Clerk to the Committee  
Tel: 0131 348 5212
The following papers are relevant to this meeting:

**Agenda Items 1 – 8**

Legal brief (Private) – to follow  
SL/S2/05/28/1

**Agenda Item 1**

Delegated powers memorandum  
SL/S2/05/28/2
Bill as amended at Stage 2 (circulated to Members only)

**Agenda Item 2**

Delegated powers memorandum  
SL/S2/05/28/3
Bill and accompanying documents (circulated to Members only)

**Agenda Item 3**

Executive responses  
SL/S2/05/28/4

**Agenda Items 4 – 8**

Copies of instruments (circulated to Members only)
SUBORDINATE LEGISLATION COMMITTEE

28th Meeting, 2005 (Session 2)

Tuesday 25th October, 2005

Delegated powers memorandum

Management of Offenders Bill

Effect of amendments to sections 7(1), (2) and (5)

Power conferred on: the Scottish Ministers
Power exercisable by: order made by statutory instrument
Parliamentary procedure: draft affirmative procedure of the Scottish Parliament with prior consultation of specified interested parties

1. Sections 7(1) and (2) of the introduction print of the Bill provided Scottish Ministers with the power by order to transfer functions under or by virtue of section 27(1) of the Social Work (Scotland) Act 1968 (“the 1968 Act”) from local authorities to a community justice authority (“CJA”). The Parliamentary procedure, set out in subsection (5) of that print, is draft affirmative.

2. Amendment at stage 2 to section 7(1) extended the range of functions that can be transferred so as to include functions under or by virtue of sections 27(1A) (persons subject to voluntary supervision), 27ZA (persons arrested or with deferred sentence, and particularly those with dependency problems) and 27B (persons in hostels during a period of supervision) of the 1968 Act, and also to include certain functions of the Prisons (Scotland) Act 1989 (c.45) (namely, those exercisable by Scottish Ministers which relate to the preparation of offenders for release).

3. The order making power in subsection (5) was also amended at stage 2. It now provides that the order cannot be laid unless Scottish Ministers have consulted the CJA (and, in the case of the 1968 Act functions, the local authorities with the CJA area too) as respects a draft order, and secured their agreement to the draft being laid. This amendment was made to respond directly to concerns that the local authorities raised.

New section 10A (Scheme of accreditation and procedure etc. of the Risk Management Authority)

Effect on section 11 of the Criminal Justice (Scotland) Act 2003 (accreditation, education and training)

4. Although not strictly a new power, the Committee may wish to be aware of the effect of the amendments made by new section 10A of the Bill on the existing powers contained in section 11 of the Criminal Justice (Scotland) Act 2003.
5. A fundamental part of the new Risk Management Authority/Order for Lifelong Restriction system established by Part 1 of the 2003 Act is that the risk assessments that the High Court will rely on when deciding whether to make an OLR should be prepared by a person accredited by the RMA and in a manner accredited by the RMA. The Justice Department have been drafting the Accreditation Scheme under section 11 of that Act that sets out the accreditation process. As part of this we need to allow for appeals against decisions by the RMA e.g. that a person should not be accredited, or that their accreditation should be withdrawn. The scheme that has been devised effectively splits the RMA Board into an Accreditation Committee and an Appeals Committee, so that all decisions are dealt with in-house rather than requiring an external body such as the Court of Session to rule on questions of professional competence. This is, of course, without prejudice to a person’s right to seek a judicial review at the Court of Session of any decision concerning the accreditation process.

6. The problem we have encountered is that the 2003 Act only provides for decisions to be made by “the Authority”, and it is not clear whether powers can be conferred on or delegated to committees or to staff.

7. Section 10A(2) amends section 11 of the 2003 Act to provide that an order under section 11 may authorise decisions to be taken by a committee, and appeals against such decisions to be determined by (another) committee. It also provides that the procedure for decisions and appeals may be prescribed in the order, and that the order may make provision as to the membership of the committees and as to any quorum.

8. Section 10A(3) makes it clear that the Risk Management Authority has general power to establish committees and sub-committees, to regulate their procedure and to delegate its functions to committees, sub-committees, members and staff. This general power is circumscribed by any specific provision made in the order under section 11 of the 2003 Act in relation to decisions and appeals on accreditation.

9. By virtue of section 88 of the 2003 Act, orders under section 11 are to be made by statutory instrument and are subject to the draft affirmative procedure.

New section 11(1B) (New section 1AA (release of certain sexual offenders) of the Prisoners and Criminal Proceedings (Scotland) Act 1993)

Effect on section 20 (the Parole Board for Scotland) of the Prisoners and Criminal Proceedings (Scotland) Act 1993

10. Section 11(1B) does not create any new order making powers. However, the Committee will wish to note the effect of the amendment made by section 11(1B) on the powers in section 20 of the Prisoners and Criminal Proceedings (Scotland) Act 1993 (the 1993 Act).

11. Section 11(1B) inserts a new section 1AA into the 1993 Act to provide that sex offenders whose conviction makes them subject to the notification requirements of Part 2 of the Sexual Offences Act 2003 (the 2003 Act) and who have been sentenced to more than six months but less than 4 years will be released on licence at the halfway point of sentence and be subject to supervision in the community for the remainder of the sentence.
12. New section 1AA also applies the powers in section 17 of the 1993 Act for Scottish Ministers to revoke the licence of an offender in this category and return him to custody either at their own hand or on the recommendation of the Parole Board. Prisoners returned to custody will be entitled to make representations to the Board about the decision to revoke their licence and to be considered for an oral hearing before the Board considers their suitability for re-release. The Parole Board can direct Scottish Ministers to re-release the prisoner following appropriate considerations.

13. Section 20(4)&(5) of the 1993 Act provides that Scottish Ministers may by rules make provision with respect to the proceedings of the Parole Board and give directions as to the matters to be taken into account when discharging its functions under Part 1 of the 1993 Act (detention, transfer and release of offenders). These powers would allow Scottish Ministers to make new rules or give new directions as required in respect of the category of offender to whom new section 1AA applies. There are no plans at present to change the existing rules. To date, no directions have been made under the section 20(5) powers. None are intended in relation to this category of prisoner.
SUBORDINATE LEGISLATION COMMITTEE

28th Meeting, 2005 (Session 2)

Tuesday 25th October, 2005

Delegated powers memorandum

Human Tissue (Scotland) Bill

Purpose

1. This memorandum, which is required by Rule 9.4A of the Parliament’s Standing Orders, has been prepared by the Scottish Executive to assist consideration by the Subordinate Legislation Committee, in accordance with Rule 9.6.2 of the Standing Orders, of the provisions of the Human Tissue (Scotland) Bill conferring power to make subordinate legislation. It describes the purpose of each such provision and explains why the matter is to be left to subordinate legislation. The following paragraphs outline the main provisions of the Bill. This memorandum should be read in conjunction with the Explanatory Notes, Policy Memorandum and Financial Memorandum for the Bill.

Outline of the Bill

2. This Bill deals with the removal and use of body parts in a number of circumstances. In particular, it makes provision in relation to transplantation from dead and living donors; removal of parts from a deceased person’s body and use of those body parts for the purposes of research, education or training, or audit; the carrying out of a post-mortem examination, the removal of parts from a deceased person’s body during such an examination and retention and use thereafter for the purposes of the post-mortem examination or for the purposes of research, education or training, or audit; use of certain body parts removed during an examination of a body for the purposes of the functions, or under the authority of the procurator fiscal and no longer needed for fiscal purposes; regulation of anatomical examinations and public display of an anatomical specimen or a body or part of a body which has been used for anatomical examination. While the activities regulated mainly relate to dead bodies, the Bill also regulates transplants from living donors.

Parts of the Bill

3. The Bill is divided into seven Parts which deal with the following proposed measures:

Part 1: Transplantation etc.

Part 1 of the Bill gives the Scottish Ministers duties and powers in relation to transplantation of parts of a human body. It regulates the removal and use of parts of the body of a deceased person for the purposes of transplantation, research, education or training or audit and, in particular, provides for a system of authorisation in relation to such activities. It also makes provision in relation to the preservation of body parts for transplantation and transplants.
involving live donors and prohibits commercial dealing in human body parts for transplantation.

**Part 2: Post-Mortem Examinations**

Part 2 regulates the carrying out of a post-mortem examination which is not instructed by the Procurator Fiscal and the removal and use of parts of a human body during such a post-mortem examination. Such activities are subject to a system of authorisation. Part 2 also makes provision in relation to organs or tissue sample removed from a body during an examination having the characteristics of a post-mortem examination, which was carried out before the requirements under Part 2 come into force. It enables such organs and tissue sample which were held immediately before that day for use for certain purposes to be retained and used on and after that day for those purposes without authorisation.

**Part 3: Tissue Sample or Organs No Longer Required for Procurator Fiscal Purposes**

Part 3 of the Bill provides a means by which tissue sample and organs removed from the body of a deceased person during an examination of the body for the purposes of the functions, or under the authority of the procurator fiscal, and which are no longer required for the fiscal’s purposes, to be retained and used for similar purposes to those for which body parts removed during a hospital post-mortem examination may be used. It also regulates the use for such purposes of tissue sample and organs removed from the body of a deceased person during an examination of the body for the purposes of the functions, or under the authority of the fiscal which is carried out before certain provisions of the Bill come into force.

**Part 4: Supplementary Provision**

Part 4 contains provisions supplementary to Parts 1 to 3.

**Part 5: Amendment of the Anatomy Act 1984**

Part 5 of the Bill amends the Anatomy Act 1984 which regulates the use of bodies of deceased persons and parts of such bodies for anatomical examination. It extends the meaning of anatomical examination and the regulatory requirements to bodies and body parts which are imported for use for anatomical examination in Scotland. It also prohibits the public display of anatomical specimens, bodies or body parts except in specified circumstances and generally amends the regulatory process under the 1984 Act by, for example, introducing a right of appeal against licensing decisions made under the 1984 Act by Scottish Ministers and providing that Scottish Ministers may prepare a code of practice relating to activities referred to in the Act.

**Part 6: Miscellaneous**

Part 6 contains a number of miscellaneous provisions related to earlier parts of the Bill. It gives the Scottish Ministers power to make arrangements with a public authority in the UK for assistance with the Ministers’ functions under certain provisions of the Bill. It gives the Scottish Ministers powers by regulations to amend the Act which the Bill will become for the purposes of implementing any Community obligation of the UK relating to material which consists of, includes or is derived from human cells and dealing with matters arising out of or related to such an obligation.
Part 7: General

Part 7 contains a number of general provisions related to earlier parts of the Bill. It gives the Scottish Ministers powers by order to make further provision which is incidental to or consequent on the Bill and to allow transitional or savings provisions as required in implementing the Bill’s provisions.

Delegated Powers

4. The Bill confers powers on the Scottish Ministers to make orders and regulations in relation to a range of matters dealt with in the Bill. Some of the powers contained in the Bill are new, while others replace or update existing powers in the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Anatomy Act 1984.

5. Section 56(2) of the Bill confers power on the Scottish Ministers to make the necessary commencement order. As this is a commencement provision there is no parliamentary procedure.

6. This Memorandum describes provisions of the Human Tissue (Scotland) Bill which confer power to make subordinate legislation. It sets out:

- the persons upon whom, or the body upon which, power to make subordinate legislation is conferred and the form in which the power is to be exercised;
- why it is considered appropriate to delegate the power to subordinate legislation and the purpose of each such provision;
- the Parliamentary procedure to which the exercise of the power to make subordinate legislation is to be subject, if any.

7. In deciding whether to adopt negative or affirmative resolution procedure, careful consideration has been given to the degree of parliamentary scrutiny that is felt to be required for the regulations, balancing the need for the appropriate level of scrutiny with the need to avoid using up parliamentary time unnecessarily. Affirmative procedure is used where the order or regulation making powers allow for the modification of any enactment or where there is significant public interest. Negative resolution procedure is used otherwise.

Part 1: Transplantation etc.

Relevant provision: Section 12(1)(b)

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

8. Section 12(1)(b) of the Bill gives Scottish Ministers powers to make regulations to provide for the persons who may be authorised to remove a part of the body of a deceased person for the purposes of transplantation, research, education or training or audit. Section 12(2) provides that such regulations may in particular provide for a registered medical practitioner to authorise the carrying out of the removal by a person who is not a registered
medical practitioner. The intention is that the person authorised to carry out the removal of body parts will be someone who has been trained to do so but who may not be a registered medical practitioner. The regulations will make detailed provision as to which person will satisfy these requirements and how the authorisation process will work in practice. It is considered appropriate to confine this sort of detail to subordinate legislation rather than primary legislation because it may be necessary over time to change the requirements as to who may be an authorised person under this provision. This provision is subject to negative procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Relevant provision: Section 15(3)**

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9. **Section 15(3)** of the Bill gives the Scottish Ministers powers by regulations to provide that no offence is committed under section 15(1)(b) (in relation to the removal of an organ or part of an organ from the body of a living adult intending that it be used for transplantation) or under section 15(2)(b) (in relation to use for transplantation an organ or part of an organ which has come from the body of a living adult) where the requirements of section 15(3) are met.

10. The requirements are that the Scottish Ministers must be satisfied that no reward has been or will be given in contravention of the provisions of section 17 (prohibition of commercial dealings in parts of a human body for transplantation) and that such other requirements or conditions as may be specified in the regulations are complied with. Where regulations provide for such an exception from the offence provisions in section 15(1)(b) or 15(2)(b), it is sufficient if the person reasonably believes that the exception applies (section 15(5)). Section 15(4) provides that regulations under section 15(3) must include provision as to appeals against decisions made in relation to matters which fall to be decided under the regulations.

11. Again, it is considered to be more appropriate for detailed provisions to be confined to subordinate legislation as requirements or conditions may change over time. The current requirements and conditions are set out in the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989 No. 2480), and it is likely that these will in general be carried forward in the regulations made under section 15(3). The conditions in particular deal with a number of detailed and sensitive issues which could well require modification to take account of changing circumstances and practice. It is also important that the requirements and conditions should maintain consistency with the relevant Regulations and statutory Code of Practice made under the equivalent provisions (sections 26(2)(h) and 33(3)) of the Human Tissue Act 2004 (c.30). The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Relevant provision: Section 16(1)**

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Parliamentary procedure: Negative resolution procedure

12. Section 16(1)(a) of the Bill gives the Scottish Ministers powers to make regulations requiring such persons (or descriptions of persons) as may be specified in the regulations, to maintain records in connection with the removal of parts from human bodies for transplantation and the use or retention of parts removed from bodies of deceased persons for the purposes of research, education or training or audit; Section 16(1)(b) gives Scottish Ministers powers to make regulations requiring such persons (or descriptions of persons) as may be specified in the regulations to make specified information available to the Scottish Ministers or to a specified authority with respect to such matters.

13. Under section 16(2), the Scottish Ministers must keep a record of the information provided to them in terms of regulations made under subsection (1). Similarly, under section 16(3), any authority specified in the regulations must keep a record of the information provided to it in pursuance of the regulations. Section 16(4) provides that failure to comply with regulations under subsection (1) without reasonable excuse, or knowingly or recklessly supplying false or misleading information, is an offence.

14. Again, it is considered to be more appropriate for detailed provisions to be confined to subordinate legislation as the persons who may maintain such records or provide such information (or any specified authority to which information is to be provided) may change over time. The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Part 3: Tissue sample or organs no longer required for procurator fiscal purposes

Relevant Provision: Section 35(2)(c)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

15. Section 35(2)(c) of the Bill gives the Scottish Ministers the power to specify by order such person (or persons) or group (or groups) of persons who may provide approval to carry out research on an organ removed from the body of a deceased person during an examination of the body carried out for the purposes of the functions or under the authority of the procurator fiscal after the new legislation comes into force and which is no longer required for the purposes of the functions of the fiscal. The intention is that the order will specify that a Research Ethics Committee will be able to provide such approval, in order to provide a safeguard against research being carried out on such organs for undesirable purposes.

16. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the persons or groups who may undertake the regulatory role currently undertaken by the Research Ethics Committee may change over time. The order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 36(2)(c)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure
17. **Section 36(2)(c)** of the Bill gives the Scottish Ministers powers to specify by order the person or holder of a post who is defined as the “manager of an establishment” in an establishment other than a health service hospital or a university for the purposes of sections 33(2) and 35(2)(a). In terms of those sections, the “manager of an establishment” is the person who has received written notification from the procurator fiscal that an organ or tissue removed from the body of a deceased person is no longer required for fiscal purposes and can therefore be used for specified purposes.

18. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the establishments in which such activities may be undertaken may change over time. The order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Relevant Provision: Section 43(2)**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Order made by Statutory Instrument
- **Parliamentary procedure:** Negative resolution procedure

19. **Section 43(2)** of the Bill gives the Scottish Ministers powers to make an order to specify such person (or persons) or group (or groups) of persons who may carry out either “existing approved research”, that is research approved before the new legislation comes into force, or “new approved research” which is research approved on or after the day on which section 35 of the Bill (removal and use of an organ no longer required for procurator fiscal purposes) comes into force. The intention is that the order will specify that such research is to be approved by a Research Ethics Committee in order to provide a safeguard against research being carried out on such organs for undesirable purposes.

20. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the persons or groups who may undertake the regulatory role currently undertaken by the Research Ethics Committee may change over time. The Order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Part 4: Parts 1 to 3 Supplementary Provision**

**Relevant Provision: Section 47**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Regulations made by Statutory Instrument
- **Parliamentary procedure:** Negative resolution procedure

21. **Section 47(a)** of the Bill gives the Scottish Ministers powers to prescribe by regulations the form in which authorisation for certain activities under Parts 2 and 3 of the Bill can be given by nominees, nearest relatives or persons with parental rights and responsibilities in relation to a child. Section 47(b) gives Scottish Ministers powers to prescribe by regulations descriptions of persons who are eligible to act as witnesses to authorisation in certain cases.
22. Subordinate legislation is considered more appropriate for this sort of detail than primary legislation. This is especially the case here as the forms in which authorisation may be provided may require to be updated from time to time. The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.
Part 5: Amendment of the Anatomy Act 1984

Relevant Provision: Section 48(6) new section 4B(3) of the 1984 Act

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

23. Section 48(6) of the Bill (new section 4B(3) of the 1984 Act) gives the Scottish Ministers the power to amend by order the statutory period of 3 years beginning with the date of the deceased’s death which governs the use of imported bodies for anatomical examination. This gives Scottish Ministers the same power as they already have governing the use of bodies for anatomical examination from the UK and seeks to create the same conditions for imported bodies as apply to bodies from the UK. The same statutory period of three years and the power to amend this period by order in relation to use of non-imported bodies is provided for in section 4(10) of the 1984 Act. The power is required to allow for the need to account for varying and at present unforeseen circumstances, around the availability and preservation of available bodies. If there was a shortage of available bodies, then Ministers may want to consider extending the period to, for example, 4 years.

24. It is considered appropriate to confine this to subordinate legislation to be consistent with the present arrangement for bodies from the UK. The order under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 48(9) new section 6A(4) of the 1984 Act

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

25. Section 48(9) of the Bill (new section 6A(4) of the 1984 Act) gives Scottish Ministers the power to specify the content of the records that must be kept by a person who has been granted a public display licence under new section 6A(3) of the 1984 Act. The need for a public display licence is a new provision which seeks to forbid the public display of anatomical specimens, bodies or body parts except in specified circumstances, including under a licence granted by Scottish Ministers. In the same way that other licence holders at present under the Act are required to keep appropriate records, it makes sense that public display licence holders should also keep appropriate records.

26. Subordinate legislation is considered more appropriate for the detail of the record keeping, which may require to be updated from time to time, and this is consistent with the present arrangements of record keeping by other licence holders (under section 3(5)(a) of the 1984 Act). The regulations under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.
27. **Section 48(12)(a)** of the Bill amends existing regulation making powers under section 8 of the 1984 Act. Currently, under section 8(1)(a) of the 1984 Act, the regulation making power of the Scottish Ministers applies in relation to bodies the anatomical examination of which is lawful by virtue of section 4, with a view to securing their efficient and orderly examination and the decent disposal of bodies and body parts after their examination has been concluded. Section 48(12)(a) extends the scope of this regulation making power to include a reference new section 4A, which covers the lawful examination of imported bodies. This is necessary to ensure consistency of approach in relation to imported and non-imported bodies.

28. The existing regulation-making powers under section 8 of the 1984 Act are subject to negative resolution procedure.

29. **Section 48(12)(b)** of the Bill also amends existing regulation making powers under section 8 of the 1984 Act. Currently, under section 8(1)(b) of the 1984 Act, the regulation making powers that exist with a view to securing that body parts are decently cared for apply in relation to body parts the possession of which is lawful by virtue of section 6 of the 1984 Act. Section 6 is a general provision relating to the lawful possession of body parts. Section 48(12)(b) changes the scope of this regulation making power so that it applies in relation to body parts the possession of which is authorised under section 5(5) of the 1984 Act. Section 5(5) makes provision for the process of authorisation of possession of body parts by licence where Scottish Ministers consider it desirable to grant such a licence in the interests of education or research. The effect therefore will be that the regulation making power that exists with a view to securing that body parts are decently cared for will be narrowed to cover those situations where a licence has already been granted in the interests of education or research.

30. **Section 48(12)(c)** of the Bill also amends existing regulation making powers under section 8 of the 1984 Act. Section 48(12)(c) extends the scope of this regulation making power to include a reference new section 6A(3), which grant the Scottish Ministers powers to grant a licence to a person to publicly display a body part if Ministers think it desirable to do so in the interests of teaching or studying, or training in or researching into, the gross
structure of the human body. The purpose of this new section is to put controls in place, which do not exist at present, over the public display of bodies and body parts. Regulations under this provision are to be made with a view to securing that the body parts used for public display under new section 6A are decently cared for and displayed with appropriate respect. This is necessary to ensure consistency of approach in relation to body parts used for public display and body parts used for other purposes, ie anatomical examination in licensed premises, under the 1984 Act.

**Relevant Provision: Section 48(13) new section 8A(2)(a) and (b) of the 1984 Act**

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31. **Section 48(13)** of the Bill (new section 8A(2)(a) and (b) of the 1984 Act) gives Scottish Ministers the power to bring into effect a code of practice to give practical guidance and lay down standards for those who are licensed to carry out anatomical examinations and those who are licensed to publicly display a body or body part. There was an overwhelming response in the consultation to issuing a code of practice, which does not exist at present. A code of practice was seen as facilitating consistency of good practice, providing accessible and readily amended guidance, helping to maintain a consistent practice with the rest of the UK, providing help for license holders and reassurance to the public.

32. The detail of the code of practice will be informed by a consultation exercise with a variety of stakeholders including doctors, licensed teachers, professional bodies, the public and practitioners. In addition the Bill stipulates in section 48(13) (new section 8A(3)(b) of the 1984 Act) that Scottish Ministers will, before confirming the code of practice by order, lay a draft of the code before the Scottish Parliament.

33. The confirmation and bringing into force of the code of practice is considered to be a matter that it appropriate for subordinate legislation, to allow the detail of the code to be updated from time to time. The order under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Part 6: Miscellaneous**

**Relevant Provision: Section 50(1)**

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<td>Power exercisable by:</td>
<td>Regulations made by Statutory Instrument</td>
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<td>Parliamentary procedure:</td>
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34. **Section 50(1)** of the Bill gives the Scottish Ministers powers by regulations to amend the Act which the Bill will become for the purposes of implementing any Community obligation of the UK relating to material which consists of human cells. It is considered appropriate to provide for this power in subordinate legislation because Community obligations may change over time. Transposition of the EU Directive on the Safety of Tissue and Cells into domestic legislation by April 2006 is being taken forward on a UK basis by the 4 Health Departments and much of the detail is still under consideration. The regulations under this provision will be subject to affirmative procedure because the powers allow for amendment of the Act.
Part 7: General

Relevant Provision: Section 52(1)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative or affirmative resolution procedure

35. Section 52(1) of the Bill gives the Scottish Ministers powers by order to make supplementary, incidental, consequential, transitory, transitional or saving provision as they consider necessary for the purposes, or in consequence, of the Act. Such provisions, by their nature, are considered appropriate for subordinate legislation. Section 52(2) provides that such an order may make different provision for different purposes and may modify any enactment, instrument or document. Section 53(3) provides that regulations under section 52 which add to, replace or omit any part of the text of an Act is to be made by way of affirmative resolution procedure. All other regulations under this provision can be made by way of negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 56(2)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: No parliamentary procedure

36. Section 56 of the Bill provides for the short title and commencement arrangements for the Bill.

37. Section 56(2) gives the Scottish Ministers power to appoint a day when provisions of the Bill shall come into force. Section 56(3) provides that different days can be appointed for different purposes.

38. It is standard procedure for such commencement provisions to be dealt with by subordinate legislation. Whilst the order, in common with the usual practice for such orders, is not subject to any parliamentary procedure as such, the Subordinate Legislation Committee will have the opportunity to consider the instrument in terms of its remit.
The TSE (Scotland) Amendment (No.2) Regulations 2005, (SSI 2005/469)

On 6 October 2005 the Subordinate Legislation Committee, having considered the above instrument, sought an explanation of the following matters:-

1. The Committee asked the Executive to explain the obligation on Scottish Ministers in new regulation 10A(3)(c), and in particular to whom the notice mentioned in the provision ought to be given.

2. The Committee asked the Executive to clarify why the definition of “relevant bovine animal” in new regulation 10A(9)(b) includes an exception by reference to SI 1996/2097, which will be revoked by the time this instrument is in force.

3. The Committee asked the Executive to clarify the meaning of paragraph 12 of new Schedule 1A, and in particular what is meant by the use of the term “the correct test” in that provision.

The Scottish Executive responds as follows:-

The Executive notes the observations of the Committee and is pleased to provide clarification as follows:-

1. The purpose of regulation 10A(3) includes providing the occupier of a slaughterhouse with the opportunity to seek review of a decision of an Official Veterinary Surgeon to suspend or revoke a relevant agreement. The person appointed by the Scottish Ministers will consider the representations of the occupier and submit a written report to them. The Scottish Ministers will consider the representations and the written report and, having decided whether to uphold or overturn the original decision, will intimate their decision direct to the occupier of the slaughterhouse.

2. It had originally been hoped that the instrument would be brought into force before 7 November in order to enforce its animal feeding stuffs provisions. Had that occurred, the prohibition on slaughter of cattle over 30 months of age anywhere other than in slaughterhouses with relevant agreements in place would have covered all cattle, including Beef Assurance Cattle. At present such cattle can be slaughtered for human consumption so the exception was necessary to allow that to continue until 7 November. Unfortunately, when it was decided that the instrument would not come into force until 7 November, the fact that this meant the exception was not necessary was overlooked. The Executive is grateful to the Committee for bringing this matter to its
attention but does not consider that it will affect the validity of the instrument. This point will be dealt with by amendment at the next opportunity.

3. Each slaughterhouse must have a system for ensuring that the result of each laboratory test can be allocated to the carcase from which the sample for analysis was taken. Receipt of the “correct test results” in paragraph 12 of Schedule 1A refers to the receipt of results meeting the requirements of that system.

Scottish Executive Environment and Rural Affairs Department
The Pollution Prevention and Control (Designation of Public Participation Directive) (Scotland) Order 2005, (SSI 2005/461)

1. On 6 October 2005 the Committee asked the Scottish Executive for an explanation of the following matter in respect of the above instrument –

“This Order raises an issue in relation to the use of the enabling power which has been raised previously with the Executive in relation to SSI 2003/204. The Committee notes that the enabling power at paragraph 20(2)(c) of the Pollution Prevention and Control Act 1999 provides specifically for the designation of any other “directive of the Council of the European Communities” but not for designation jointly from the Council and the Parliament.

The Committee is of the view that if the enabling power was capable of extending to co-decision Directives, this intention would have been made explicitly clear in the enabling power. The Committee therefore considers that there are doubts as to whether the Order is intra vires. The Executive is asked for comment.”.

The Scottish Executive responds as follows:

2. As the Committee has noted, this issue has previously been raised with the Executive in the context of S.S.I. 2003/204, which concerned the designation of Directive 2000/76/EC of the European Parliament and the Council on the incineration of waste.

3. As indicated in its letter of 19 June 2003 in response to the Committee’s earlier inquiry concerning S.S.I. 2003/204, the Executive is of the view that the enabling power at paragraph 20(2)(c) of Schedule 1 to the Pollution Prevention and Control Act 1999, insofar as it provides for the designation of “any other Directive of the Council”, does not preclude the designation of a Directive made jointly by the Council and another European Institution, in this case the European Parliament under co-decision procedure. The Executive is therefore satisfied that the present Order is intra vires.

4. The present Order designates Directive 2003/35/EC (“the Public Participation Directive”) to pave the way for the specific regulation-making power under section 2 of the 1999 Act to be used to amend the Pollution Prevention and Control (Scotland) Regulations 2000 (S.S.I. 2000/323), as with the previous amendments to those Regulations. This is in order to transpose Article 4 of the Public Participation Directive insofar as it relates to permitting under the pollution prevention and control regime. The relevant transposing regulations will be laid shortly.