CERTIFICATION OF DEATH (SCOTLAND) BILL

POLICY MEMORANDUM

INTRODUCTION

1. This document relates to the Certification of Death (Scotland) Bill introduced in the Scottish Parliament on 7 October 2010. It has been prepared by the Scottish Government to satisfy Rule 9.3.3(c) of the Parliament’s Standing Orders. The contents are entirely the responsibility of the Scottish Government and have not been endorsed by the Parliament. Explanatory Notes and other accompanying documents are published separately as SP Bill 58–EN.

BACKGROUND

2. In 2005 it was agreed that Scotland’s burial and cremation legislation required updating as much of it was over 100 years old and did not reflect 21st century life. This coincided with a need to examine the processes governing death certification following the inquiry into the case of Dr Harold Shipman. Following the publication of the Shipman Inquiry’s Third Report in June 2003, an independent review group was established in January 2005 by the then Scottish Executive to bring forward recommendations on the law relating to burial, cremation and death certification.

3. The Review Group produced a report in October 2007 which was published in April 2008. The Scottish Government consulted on the report’s recommendations early in 2010. The Scottish Government has given priority to introducing legislation on the aspects of the report relating to death certification, with the remaining aspects related to burial and cremation to be introduced at a later date.

4. The UK Government has also updated its legislation in relation to death certification. Primary legislation has been passed by the Westminster Parliament (the Coroners and Justice Act 2009) and further work, including pilots, is underway. Secondary legislation outlining the detail of the new system to be established in England and Wales is expected to be brought forward next year.

Current Arrangements

5. The following flow chart (Figure 1) and paragraphs set out the current arrangements for death certification in Scotland.
Figure 1 - Current Process

Death occurs

Certifying doctor completes Medical Certificate of Cause of Death (MCCD) form and gives it to informant to take to the registrar to register the death

Informant attends registration office and completes registration

Burial

All relevant documents passed to burial authority (cemetery) before burial can take place

Cremation

A Form B and Form C must be completed by two separate independent doctors to authorise cremation

An application for cremation (Form A) must be signed by the next of kin/executor and the funeral director

All relevant documentation must be handed to the medical referee who will, if content, authorise cremation and complete Form F

Funeral takes place

Description of Current Arrangements

6. When a person dies, a doctor will usually certify cause of death and produce a Medical Certificate of Cause of Death (MCCD) form (otherwise known as a Form 11).

7. This MCCD has three purposes:

- The first is the legal requirement to record the fact and cause of death and information on the deceased to enable disposal of the body to take place;
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- The second is to enable the registration of the death by a Registrar of Births, Deaths and Marriages (hereafter "a registrar"); and
- The third is to provide information on the cause of death which may be used for the purposes of national statistics on mortality.

The Procurator Fiscal

8. In cases where the doctor cannot certify or if the death falls into certain categories of deaths that must be enquired into then the death will be reported to the Procurator Fiscal (PF) for investigation, including a post mortem (or in some cases a type of post mortem referred to as a ‘view and grant’) if required. The PF has a duty to investigate all sudden, suspicious, accidental, unexpected and unexplained deaths and any death occurring in circumstances that give rise to serious public concern. Once the investigation is complete, the body is released with Form E1 which allows for the body to be cremated if that is the chosen method of disposal.

Registration of Death

9. The MCCD can only be completed by a registered medical practitioner. The MCCD must be presented within 7 days of the death to a suitably qualified informant, such as a relative of the deceased. That person has a statutory obligation, within 8 days of the death, to inform a registrar to enable the death to be registered. The registrar will then issue an Extract of an Entry in a Register of Deaths (commonly called a ‘death certificate’). This Extract is legal proof of the death. These arrangements are governed by the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (the 1965 Act). It is a legal requirement to register a death and there are statutory penalties which can be imposed for failure to do so.

10. For deaths in Scotland, it is currently a requirement under the 1965 Act that any registered medical practitioner who was in attendance on the deceased during his/her last illness has a duty to complete the MCCD. Following the move to practice based patient lists with the Primary Medical Services (Scotland) Act 2004 and GP practices withdrawing from the responsibility for out-of-hours arrangements, in most areas it would be expected that a medical practitioner from the patient’s practice would be asked to sign the certificate, although any registered practitioner could, subject to adequate information such as the case notes, make a decision based on best clinical judgement (he/she does not have to view the body). In the event that the GP or registered medical practitioner felt that they had insufficient information at their disposal to complete the declaration on the MCCD, there would be a referral to the PF.

11. The content of the MCCD has to comply with the World Health Organisation’s (WHO) recommendations to ensure comparability for epidemiological purposes. The information recorded on the certificate includes the name of the deceased, the date and place of death, when he/she was last seen alive by the certifying doctor, the cause of death and any contributory factors. The MCCD is prescribed in secondary legislation under section 24 of the 1965 Act (in the Registration of Births, Still-births, Deaths and Marriages (Prescription of Forms) (Scotland) Regulations 1997).

12. The death is registered by the registrar who issues a form (Form 14) confirming the registration of the death. A full Extract of the Entry into the Register of Deaths may also be
provided for a fee. An Abbreviated Extract is provided free of charge. In normal practice it is only after a Form 14 has been issued that a burial may proceed. A cremation may not proceed without the registration of the death, i.e. without a Form 14.

Cremation

13. Additional procedures are required to enable cremation to proceed. An application for cremation (Form A) signed by the executor or next of kin must be completed plus two additional forms (Forms B and C) must be completed by separate doctors who are paid fees totalling around £147. This cost is usually met by a relative. The completion of forms B and C should in theory constitute two separate checks which are totally independent of each other. However, it is recognised that this is not always the case in practice.

14. In addition, when a body is cremated, a third doctor, the medical referee at the crematorium, performs the final check on the papers. The medical referee, who must be of at least 5 years medical standing, can refuse to authorise the cremation if he/she is not satisfied that there has been adequate inquiry by the persons signing certificates or is not satisfied that the fact and cause of death have been definitely ascertained. The cremation authority pays the medical referee a fee which is recouped through the cremation fee which is charged by the authority to the nearest relative.

15. There are currently 26 crematoria in Scotland, with around 114 medical referees or deputies. Medical referees tend to be self employed and are approached through their medical practice to become medical referees. The cremation authority will approach a referee from its pool of referees on an ‘as and when’ basis and payment will be made accordingly.

POLICY OBJECTIVES AND AIMS OF THE BILL

Aims

16. The Scottish Government has the following overarching policy aims for this Bill:

- To introduce a single system of independent, effective scrutiny applicable to deaths that do not require a PF investigation;
- To improve the quality and accuracy of the medical certificate of cause of death (MCCD) form; and
- To provide improved public health information and strengthened clinical governance in relation to deaths.

17. While the events surrounding the Harold Shipman case were the original driver for change in systems of death certification throughout the UK, no death certification system is able to guarantee that the kind of criminal activities carried out by Shipman could be prevented. Instead, the proposed new system covers only those cases which are not examined by the Procurator Fiscal Service and therefore not within the scope of the criminal justice authorities. As such, it focuses on the aims outlined above, although in doing so it will establish arrangements which should also act as a deterrent to criminal activity or malpractice.
18. The Bill seeks to make improvements to the death certification system which are financially sustainable, proportionate and do not impose undue delays on bereaved families arranging a funeral. In addition, the Bill seeks to provide an opportunity to bereaved families whose relatives have died overseas to have a post mortem conducted in Scotland.

Scottish Government Consultation

19. The Scottish Government consulted on the two alternative models of death certification proposed by the Review Group: the Medical Investigator (MI) model and the Medical Examiner (ME) model. In both models it was proposed that a statistician would run regular statistical tests on all death data to identify unusual results and patterns of behaviour over time both nationally and at local NHS Board level. The difference between the two models, as proposed by the Review Group, lay in the level of scrutiny of MCCD forms:

- Under the MI model, Medical Investigators (MIs) would comprehensively scrutinise a 1% random sample of deaths, plus any deaths where concerns had been raised e.g. by a relative or doctor (estimated to account for up to a further 1% of all deaths) and countersign the 2% of MCCDs linked to those deaths; and
- Under the ME model, this comprehensive scrutiny would also take place but, in addition, Medical Examiners (MEs) would undertake a basic level of scrutiny of all other deaths (with much of this work carried out as administrative checks by their assistants) and therefore countersign all MCCDs in Scotland.

Basic Scrutiny

20. Basic scrutiny amounted to the administrative checking of the MCCD form completed by the certifying doctor. It did not extend to looking at medical records or discussions with health professionals or family members.

Comprehensive Scrutiny

21. Comprehensive scrutiny included the basic scrutiny (as above), review of the health care records and taking other evidence including discussing the circumstances surrounding the death with any attending doctor or those responsible for the deceased’s care and, in some cases, talking with relatives.

22. The Review Group did not express a preference for any one model. The Scottish Government expressed an initial preference for the MI model in its consultation.

23. The consultation attracted 102 responses. Of these, 56 respondents commented on the models and a small majority (52%) of these were in favour of the Scottish Government’s preferred option, the MI model, while just over a third favoured the ME model. Seven respondents wanted neither model, either because they were content with the existing system or because they wanted an alternative, such as the model being developed in England and Wales. An analysis of the consultation is available on the Scottish Government’s website at: http://www.scotland.gov.uk/Publications/2010/07/12161026/0.
24. Following the consultation, further work has been undertaken to address and take into account points made by consultees. A range of stakeholder meetings has been conducted to examine key issues and to explain to stakeholders the Government’s proposals and the rationale which underpins them. These engagements have clearly demonstrated a need to improve the clinical standards applied to death certification through enhanced education and training.

**Strengthened Model: The Medical Reviewer Model**

25. Following further consideration in light of the consultation responses and discussion with key stakeholders, the Scottish Government has developed a strengthened version of the MI model proposed by the Review Group and this is the model that has been set out in the Bill. The following paragraphs explain this model, which is described here and in the Bill as the Medical Reviewer (MR) model.

26. Under this model, a Senior Medical Reviewer (SMR) and potentially up to six regionally based Medical Reviewers (MRs), all medically qualified, will be employed by Healthcare Improvement Scotland (HIS). Each MR and the SMR will be supported by an administrative assistant. In addition, there will be a statistician (a non statutory role) located with, and employed by, NHS National Services Scotland (NHS NSS) (within Information Services Division) who will produce both national and local statistics for further consideration by the MRs. The statistician will also be supported by an assistant.

27. The Bill sets out the obligation for HIS to appoint the MRs and SMR to carry out the functions set out in the Bill. As part of HIS, the MRs and SMR will be accountable to the HIS Board, but will have a high degree of operational independence in the exercise of their functions. Employment of the SMR and MRs by HIS fits with its purpose as a national organisation and is seen as advantageous in terms of ensuring an appropriate degree of independence from territorial NHS Boards.

28. The exact number of MRs required will be decided following test site work on the operation of the new system. The Financial Memorandum outlines in more detail the cost of employment of up to six MRs, an SMR, one statistician and statistical and medical support staff and the workload this would entail. The proposals for six regionally based MRs and an SMR take into account the additional duties to be performed under the strengthened model which are set out below.

29. The scrutiny (review) to be conducted by MRs will involve the following:

- Comprehensive checks of all (relevant) paperwork associated with the death including the MCCD, appropriate medical records and the results of any medical investigations;
- A discussion with the certifying doctor and other relevant clinical and healthcare staff, as required;
- A discussion with the family of the deceased or an informal carer, as required; and
- Consideration of any other relevant evidence, such as (arranging to) view the body, if necessary (rarely).
30. The MR will be required to consider whether to approve the MCCD for every death subject to scrutiny (unless referred to the PF); approval is likely to take the form of a countersignature and the MCCD forms will be updated to allow for this. All other MCCDs not subject to scrutiny will feature the signature of the certifying doctor only.

31. A doctor signing an MCCD has a professional responsibility to undertake this role to the best of his/her ability and to record information and cause of death according to their professional opinion; in order to respect that professional opinion, the Bill does not seek to force certifying doctors to, for example, record a different cause of death to that stated on the original MCCD. Accordingly, where there is disagreement between the MR and the certifying doctor regarding the information provided on the MCCD, the Bill sets out a procedure which gives the certifying doctor an opportunity to issue a replacement certificate following discussion with the MR.

32. However, whilst it is expected that agreement between the certifying doctor and the MR will be reached in the majority of cases, the Bill recognises that this may not always be the case. Provision is therefore made to allow for a second opinion to be sought from the SMR and, if necessary, a further opportunity given to the certifying doctor to issue a replacement certificate. In most cases, it is likely that the changes required to the MCCD will be linked to issues of quality and standards rather than concerns about the cause or manner of death. However, where a disagreement does occur concerning the cause of death and this cannot be resolved, the SMR can refer the case to the PF for investigation into the cause of death.

33. Any scrutiny/discussions undertaken by the MR will be documented in order to provide a record of the discussions undertaken.

34. Where the review of an MCCD gives rise to any suspicions of criminality, the MR or the SMR must report the matter to the PF.

Deaths Subject to Review

Randomly Selected Cases

35. The scrutiny system to be carried out by the MRs will review around 500 randomly selected cases annually. This is a similar level to the 1% recommended by the Review Group. Further information on this is provided at paragraphs 55-61 below. The Registrar General (RG) for Scotland, through his office, the General Register Office for Scotland (GROS), records and retains the records of all deaths that occur in Scotland. Computer systems at GROS will be utilised to call up a random sample of cases for scrutiny at the point when an individual comes to register the death at a local registrar’s office. The GROS computer system will alert the local registrar that the case has been selected for review under the Act and that registration of the death should not be completed until the review is complete.

Interested Person Reviews

36. In addition, as also proposed by the Review Group, there is power for “interested persons” to make an application where they wish a review to be conducted by an MR. This is
expected to add a further 500 deaths annually to the cases scrutinised. The numbers referred by interested persons will of course be flexible.

37. Interested persons able to refer cases to the MRs are as follows:

- anyone classed as an “informant” under the 1965 Act i.e.:
  - any relative;
  - any person present at the death;
  - executor or legal representative of the deceased;
  - occupier at time of death of any premises where death took place; and
  - any other person who has knowledge of the particulars to be registered in the absence of those people named above;

- and the following:
  - a health professional or other carer involved with the deceased’s care prior to death;
  - the funeral director;
  - persons in charge of the place of disposal of the deceased; and
  - any other persons specified by Scottish Ministers by order.

38. In both the randomly selected cases and interested person applications, the MR will, in the carrying out the review, have the power to examine health records of the deceased person, seek the views of the doctor who completed the MCCD, and consider other evidence or documents which he/she thinks will assist them (in pre-registration cases, this could potentially include viewing the body, although the circumstances in which this will be necessary are very limited).

39. The following flow charts (Figures 2 and 3) set out how the new system of reviews (scrutiny) will operate:
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Figure 2 - Random Review

Death occurs

Certifying doctor completes MCCD and gives it to informant to take to the registrar to register the death

Informant attends registration office to register and is informed that the death has been chosen for random scrutiny and registration cannot be completed until scrutiny has been concluded

MR alerted that a case has been selected for scrutiny and arrangements made to pass the MCCD to MR

MR undertakes review

Changes required to MCCD but MR and certifying doctor cannot agree - MCCD referred to SMR for second opinion

Changes required to MCCD – MR and certifying doctor agree changes; an amended MCCD is returned to MR to approve

MR approves MCCD

Funeral takes place

SMR agrees with certifying doctor and approves MCCD

SMR agrees with MR. Certifying doctor agrees to amend MCCD approved by SMR

Funeral takes place

SMR agrees to approve MCCD or signifies that review is complete

SMR agrees with MR. Certifying doctor does not agree to amend

Funeral takes place

Case is referred by SMR to PF. PF reviews cause of death
Figure 3 - Interested Person Review

Informant contacts MR and requests a review of MCCD

MR considers circumstances on receipt of application

MR initiates review process

MR asks RG to flag up to anyone registering the death

Registrar either does not issue disposal form, or tells MR that disposal has already taken place

MR undertakes review, contacts certifying doctor

MR decides whether MCCD is in order; ‘second opinion’ process may apply, if required

Case is referred by SMR to PF, if required; PF reviews case

PF carries out investigation, (including post mortem by pathologist, if body

Cause of death confirmed

MR/SMR decides MCCD is in order, approves form or otherwise completes review; MR notifies all interested parties

Pathologist signs new MCCD form (previous form goes to GROS); interested parties notified

Confirmation of registration issued by registrar, if pre-registration case

Funeral takes place

Additional Retrospective and Prospective Scrutiny

40. MRs may also decide that, following consideration of national and local statistics, there is a need for further checks to be carried out in a particular area (e.g. a particular geographic area), hospital, practice or in respect of a particular individual. The MR could then ask the statistician to carry out additional sampling retrospectively for whatever period is deemed appropriate. The statistician would gather information to allow the MR to conduct the additional checks. These additional retrospective checks could be carried out on records of deaths already available from GROS and by accessing MCCDs and medical records previously linked to those deaths. Retrospective checks could be authorised for a specified period of time, such as the previous 6 months, but could go back further as MRs will not be subject to the three-year time limit applicable in interested person applications.
41. The only limitation on retrospective reviews is that the formal review procedure (which results in MRs approving MCCDs etc.) only applies to MCCDs completed from commencement of the Act; however, this will not prevent MRs from requesting sight of MCCDs completed prior to the coming into force of the Act on an administrative basis and following up any general issues of concern through clinical governance routes.

42. Equally, MRs will have a power to conduct additional pre-registration scrutiny in such cases as they consider appropriate. This power is likely to be used rarely - if there was a serious issue with a practice etc. requiring that level of additional scrutiny then the NHS Board should already have been approached with a view to taking action to deal with the issue. Again, the power available to the MR to instruct this further work underlines the robustness of the proposed new system and allows additional scrutiny (over and above the random sample and interested person scrutiny proposed) to be carried out where the MR decides that it is appropriate to do so. Hospitals or practices whose records are subject to these additional checks will be informed of the process as will the relevant NHS Board(s).

43. In these cases, the review process will follow the same steps as set out in Figure 3 above, from the point at which the MR undertakes the review.

Referral by District Registrars

44. In addition to the above, district registrars will have the power to refer MCCDs for review where they consider it appropriate to do so.

45. In these cases, the review process will follow the same steps as set out in figure 3 above, from the point at which the MR undertakes the review.

Links to Clinical Governance

46. The relationship between the MRs and NHS Boards is a key part of this new scrutiny system. MRs will be responsible for conducting scrutiny and also considering the statistical outputs provided to them by the statistician. MRs may at any time wish to highlight to NHS Boards issues linked to an individual scrutiny case or to the statistics provided by the statistician. It would be the responsibility of NHS Boards, and in particular, Medical Directors, as part of their duty of clinical governance, to take cognisance of the information provided by the MR and to take whatever action they consider to be appropriate. The Bill places a duty on NHS Boards to co-operate with the MRs and SMR. In carrying out their duties, NHS Boards may wish to conduct further investigation of an individual, practice or hospital, for example, and could also compare the information provided by the MR to other information held by Boards such as prescribing patterns, complaints and annual appraisal reports. Although in some cases MRs may be flagging up the need for NHS Boards to investigate further the behaviour or practices of a particular individual, practice or hospital, in other cases the MRs may draw Boards’ attention to general issues that simply require additional training or guidance.

47. It is the correlation of the accurate information and strong links under the new scrutiny system with well established clinical governance systems in NHS Boards that helps to ensure that it will be robust.
Other Activities

48. The MRs will also require to have close and effective working relationships with certifying doctors, registrars and the local PF. Additional elements are included in the MR model to help support those relationships. In particular, both certifying doctors and registrars will be able to call the local regional MR by phone to request assistance on any aspect of the scrutiny system, or where they have concerns regarding the completion of an MCCD. This additional support will ensure that a source of advice is available to certifying doctors and registrars which is not currently available.

49. The MRs (including the SMR) will have a training and education role in relation to death certification, in respect of doctors and other healthcare professionals. This might involve, for example, giving presentations about their role and the certification of death generally to medical students, providing input for guidance on the certification of death and the provision of training for doctors’ continuing professional development.

50. In relation to the PF, the Bill does not in any way seek to change the existing powers and duties of the Lord Advocate or PFs. Where criminality is suspected in any case, the MR or the SMR must report their suspicions to the PF and thereafter follow the directions of the PF.

Summary of Medical Reviewer Role

51. The following bullet points summarise the role of the MRs:

- to undertake comprehensive scrutiny of a sample of around 500 deaths annually and to consider any interested person cases reported to them (estimated to amount to an additional 500 deaths annually);
- to consider reports from the statistician and make available and discuss those reports with the relevant NHS Board Medical Directors for further investigation or action;
- to perform additional checks where he or she believes further scrutiny is required e.g. at regional, hospital, practice or individual level, in the light of information gathered by the statistician (up to 100% of deaths if required);
- to directly support certifying doctors in making effective decisions in relation to death certification through, for example, phone support;
- to directly support and guide registrars where information provided on MCCDs is inaccurate, incomplete or requires further inquiry;
- to potentially offer ‘on-the-job’ and ‘off-the-job’ education and training of doctors and other healthcare professionals, for example through speaking about their role and through continuing professional development; and
- to liaise closely with PFs.

The Senior Medical Reviewer

52. The role of the SMR will be to provide leadership for the new system and, particularly, he or she will have responsibility for leading a change in culture in the NHS in terms of the attitude and priority given to the certification of death. This can be done in a number of ways. Strong links should be developed with NHS Boards, consultant networks and doctors, including...
general practitioners. A form of education and training can be offered, for example, through talking at events and to groups of doctors, and there should be close liaison with the appropriate Royal Colleges and with NHS National Education for Scotland (NES) on training. The SMR will be responsible for managing the MR service and the team of staff and will be accountable for this through the HIS Board. He or she will be a primary source of expert advice on the certification of death.

53. In addition, where there is a disagreement between an MR and a certifying doctor over an MCCD under review, the SMR has a statutory role in the process which provides an opportunity for a ‘second opinion’; in such a case, the SMR may conduct a review of the MCCD and the associated health records etc. (as described above).

**Reporting Requirements**

54. The SMR will be required to provide a report to Scottish Ministers for each financial year on the activities of the SMR and MRs and produce other information reasonably requested by Scottish Ministers. These reports will also be published.

55. The following bullet points summarise the role of the SMR:

- strategic leadership and the promotion of improved and consistent high quality standards nationally in relation to death certification;
- provision of professional leadership and peer support to MRs, including support for aspects such as continuing professional development and medical revalidation;
- input to development of medical education and training in relation to death certification, linking in with NHS Education for Scotland (NES) and the Royal Colleges;
- delivery of a proportion of education and training at national level by giving seminars, conference talks, local sessions etc;
- management of MRs and their staff and reporting to the HIS Board;
- provision of ‘second opinion’ where there is disagreement between an MR and a certifying doctor, and, where necessary, carrying out a full review of the case; and
- liaison with the Chief Medical Officer and Scottish Government officials, the Scottish Association of Medical Directors and COPFS and other appropriate persons (such as counterparts in other parts of the UK).

**Further Information Regarding the Sampling Process**

56. Following consideration of available research evidence, costs and practicalities, the Burial and Cremation Review Group considered that a 1% random sample should be proposed. The Review Group considered the following published research on mortality monitoring at the time and fixed sampling systems used for NHS fraud detection:

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- “Using hospital mortality rates to judge hospital performance: a bad idea that just won’t go away” by Lilford and Pronovost (2010); in: British Medical Journal, 20 April, 340: c2016;
- “Can mortality monitoring in general practice be made to work?” by Guthrie (2005), in: British Journal of General Practice, September 1, 55(518): 660-662;

57. The work conducted by Professor Lilford and Dr Peter Pronovost, though based on the use of hospital mortality rates, concludes that: “Deeper understanding will depend not on statistical or organisational studies carried out in isolation but on synthesis of both subjects…”. They also argue for “…use of (hospital mortality rates) … not as the basis for judgement leading to sanction or reward, but as a signal to identify where further investigation is necessary”.

58. The studies carried out by Bruce Guthrie and others concluded that “at best mortality monitoring can act as a backstop to detect a particularly prolific serial killer when other means of detection have failed. Policy should focus on changes likely to improve detection of individual murders such as reform of death certification …”.

59. The Review Group’s approach reflected their consideration of costs and benefits. They considered that comprehensive scrutiny of a 1% random sample would be sufficient as a deterrent, recognising that no system can guarantee to detect crime. Anything greater than this was considered to create significant resource problems. The scope for additional referral of cases by interested persons was considered to form an important additional element of the scrutiny system and meant that, overall, an estimated 2% of cases annually would be comprehensively reviewed. This, coupled with the wider statistical analysis was considered to provide safeguards and allow trends to be detected over time.

60. The Scottish Government agrees with the Review Group that no system can guarantee to detect criminality or malpractice and believes the most effective way to address current concerns related to the processes and outcomes concerning death certification is to improve quality standards and clinical governance in this area of NHS activity, while also providing a deterrent against malpractice. The system proposed by the Bill therefore emphasises the importance of establishing a system which improves education and training in this area and which will result in adherence to higher standards by clinicians in delivering on this function. In line with this, the Scottish Government’s view is that random sampling of around 500 cases per year should form part of an audit cycle of activity with the results from the sample considered, analysed and acted on as set out above. The level of the random sample may be expected to vary and the Bill is therefore deliberately silent on the size of the sample to allow for future variances in the sample level if required. It is considered that sampling should be based on a number of cases rather than a percentage, although the sample size which has been determined as appropriate (around 500 cases) is in line with the Review Group’s approach (in 2009 there were 53,856 deaths in Scotland, GROS, 2010).

61. However, the value of the Bill’s review (scrutiny) system, and its role in providing a deterrent against malpractice, should be considered as an entire package comprising the random
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sample activity and audit cycle, interested person / district registrar reviews and the opportunity for additional retrospective and prospective checks to be undertaken by MRs. This latter element will allow efforts to be more focussed on individuals or areas where likely problems have been identified and can be carried out at a level of up to 100% of cases for the area, practice or hospital in question.

62. It is also important to recognise the potential for important links between the work of the statistician looking at death certification and existing work on hospital standardised mortality ratios undertaken by NHS NSS. This work currently considers probabilities of death for all patients compared to actual deaths, but does not examine the recorded cause of death. However, data files will be available which would allow more detailed analysis to be done on causes of death in e.g. particular localities, and comparisons made to original diagnosis. It is expected that the NHS NSS statisticians will collaborate on the links between the two data sets.

The Impact of Scrutiny on Timetabling of Funerals

63. The additional checks required for those deaths selected for scrutiny pre-registration will introduce an extra step to be completed before a body can be released for a funeral.

64. When the Review Group considered these issues a few years ago, the average time lag between a death and the funeral was around 3-4 days.

65. From some informal research of recent online family newspaper announcements (which contain both date of death and date of funeral) it is our impression that the average wait for a funeral was close to 7 days in most cases.

66. It is anticipated that this aspect of the system will be examined and tested as part of the operational test of the new system, with a view to ensuring that scrutiny will, as a norm, be completed immediately following death (i.e. within a day or two of the death) and therefore have no perceptible impact for bereaved families on the scheduling of funerals.

67. There may however be exceptional circumstances where selection for scrutiny impacts on the scheduling of funerals because the scrutiny of an individual’s records takes longer than normal (for example, where records may need to be retrieved from rural and remote locations or where public holidays constrain the swift retrieval of records).

68. In addition, it is recognised that there may be circumstances in which the delays inherent in a scrutiny system, even when they are fairly short, might create difficulties for particular bereaved families. This is perhaps especially true in randomly selected cases where the family of the deceased will only learn that the MCCD relating to the deceased is to be reviewed at the point at which they seek to register the death.

69. Accordingly, in cases randomly selected for review, families will be able to request that registration takes place in parallel with the review process to allow the funeral to proceed as soon as possible after the registration requirements have been met. Where timing difficulties are raised with the registrar as an issue, at the point where the case has been flagged for scrutiny, the
The registrar will be in a position to discuss this with the family member and will refer the question to the MR for a decision on whether registration may proceed in parallel with scrutiny. Guidance will be provided to the public and to registrars on this aspect of the review process.

70. The following bullet points summarise how this aspect of the system will work:

- New system will include guidance for families, registrars and others on scrutiny;
- MCCD is completed by certifying doctor;
- Informant presents MCCD to registrar and case flagged for review;
- Registrar provides information to informant about review and informant can indicate if he/she wishes registration to take place in parallel with the review, and the reasons justifying this;
- Registrar refers the matter to the MR to seek approval for registration to take place straight away (MCCD may be faxed to MR);
- MR considers whether there is a good cause to justify this and whether there is likely to be a need to retain the body to allow a referral to the PF e.g. where he/she has a valid concern about the cause of death on the MCCD. In some cases this may require a telephone call to the certifying doctor before a decision can be taken;
- The registrar is notified of the decision and notifies the informant;
- If the MR considers that use can be made of this expedited procedure, the registrar may allow the death to be registered and the funeral may take place according to the family’s requirements; and
- Scrutiny proceeds in parallel with family kept informed of outcome as usual.

71. In most cases the above process would take place within office hours and would not require any out-of-hours working. However, there are currently circumstances in which registrars open their offices in an emergency e.g. at a weekend and there may therefore be circumstances in which out of hours working by a MR would be required. These issues will be considered further during the consideration of guidance and contracts for the MRs.

72. This alternative and expedited process will be fully consulted on and additional details set out in guidance. However, circumstances in which it may be appropriate to make use of the expedited procedure include the following:

- Where a funeral is taking place outwith Scotland;
- Where a child has died;
- For reasons of faith where it is a strict requirement of that faith that a funeral takes place very quickly e.g. within 24 hours; and
- Where the body is being donated to medical research and has to be preserved quickly.

73. This expedited procedure is only available in cases which are randomly selected for review.
This document relates to the Certification of Death (Scotland) Bill (SP Bill 58) as introduced in the Scottish Parliament on 7 October 2010

Resourcing

74. The Financial Memorandum sets out in detail the anticipated costs of the new system.

75. A modest fee may be charged in respect of the functions of medical reviewers (but not their functions relating to post-mortems in cases where the death occurs outwith Scotland) including those relating to the national statistician.

Other Changes

Medical Referees

76. The role of medical referees (and deputies) at crematoriums will be abolished. The responsibilities they currently have for checking that bodies are safe for cremation e.g. by checking whether a pacemaker or other implant require to be removed, will be carried out in future by certifying doctors.

77. This would be done by including a requirement to conduct checks of medical records and record such information on the revised MCCD. Any subsequent required physical removal of, for example, a pacemaker or implant would be carried out either by funeral directors (if an easy to remove pacemaker) or (in the case of implants, which can be more difficult to remove) a medical practitioner. In the case of a death occurring abroad (and potentially other cases from outwith Scotland, depending on legislative developments in the rest of the UK), MRs would carry out the necessary paperwork checks to ensure bodies are safe for cremation.

Deaths Outside Scotland

78. Currently Scottish Ministers have a role under the Cremation (Scotland) Regulations 1935 in giving authority for cremation in Scotland where a death has occurred abroad and there is sufficient certification equivalent to the certificates required under those Regulations (this does not apply to burials of those who have died abroad, where Scottish Ministers have no involvement).

79. The administrative element is undertaken on behalf of Scottish Ministers by civil servants and Senior Medical Officers who check the paperwork and the cause of death. The paperwork is then passed to the relevant medical referee to sign off with Form F (authority to cremate) and the cremation can proceed.

80. These overseas deaths have already been certified by a doctor abroad and the deaths have been registered before the remains come back to Scotland. In such cases, the authorities in the country in which the person died will have completed their investigations (if any) into the circumstances of the death, and will have released the remains for disposal.

81. Where the current checks by the Scottish Government fail to establish a satisfactory cause of death, current administrative practice is to refuse to authorise a cremation. This can be distressing for families who then either have to arrange a private post mortem in an attempt to establish cause of death or have to opt instead for burial. This is discussed further below.
82. The Scottish Government handles an average of 130 requests a year for cremation authorisations resulting from repatriation of Scots who have died abroad. There are no statistics on the total number of annual repatriations (i.e. burials and cremations) but assuming the 40/60 split between burial and cremation in Scotland applies also to deaths of Scots abroad one can estimate a total of around 250 deaths per year requiring repatriation for a funeral service. It is estimated that in around 10% of these cases the cause of death will not have been established.

Disposal Requirements Applying to Deaths Occurring Outside Scotland

83. Under the new system, there will be a duty on persons having charge of a place of interment or cremation to ensure that the disposal is authorised by the correct certification (which for deaths outside Scotland is likely to be certification equivalent to the MCCD and the certificate of registration of death). In addition, where a person has died outside Scotland and it is intended that he or she be cremated in Scotland, the case will be referred to an MR, who will examine the paperwork to determine whether it is safe for the body to be cremated, such as checking for information about whether the deceased had a pacemaker or other implant that might be hazardous during the cremation process.

Proposals Regarding Post Mortems of Deaths Abroad

84. With the exception of certain powers in relation to service personnel who die abroad, the Lord Advocate does not have jurisdiction to investigate deaths occurring outside Scotland, nor any power to instruct post mortems of such deaths. This is in contrast to the position in England and Wales where Coroners hold such powers. There was a high level of agreement amongst those who responded to the Scottish Government consultation (just over 40%) that when the death of a person who is normally resident in Scotland occurs abroad, a government body in Scotland should be able to assist in the arranging of a post mortem to seek to establish the cause of death if this is unknown.

85. There was a high level of agreement (just over 40%) among those who responded to the consultation question included in the recent SG consultation paper: “When death of a person who is normally resident in Scotland occurs abroad should a Government body be able to arrange a post mortem to establish the cause of death if this is unknown?”

86. Agreement has been reached with the Crown Office & Procurator Fiscal Service that a power should be given to allow MRs to assist in the arranging of a post mortem (including providing financial assistance) to help support relatives whose family member is returned to Scotland for disposal and no cause of death is available. This power will be used in limited circumstances (to be set out in guidance) where it is deemed appropriate on compassionate grounds to address a need that a bereaved family may have to establish the cause of death. This might be, for example, to establish whether a hereditary medical condition may have existed. Extensive experience of dealing with bereaved families in this situation has demonstrated that a post mortem can help them through their bereavement, but that the inability of Government to help arrange such a post mortem leaves them with no option but to carry out the procedure privately, the cost of which is prohibitive for some. This compares poorly with the position in England and Wales where post mortems of deaths abroad can be instructed by the coronial authorities.
87. This limited power would not be made available where a cause of death is already available (so, for example, it will not be available as a means of settling disputes over the cause of death) and will not amount to an investigation into the wider circumstances surrounding the death (such wider investigation functions are exclusively held by the Lord Advocate in Scotland, but those functions do not, in any event, extend outwith Scotland).

88. It is estimated that, annually, a maximum of 25 deaths abroad do not have a clear cause of death and could therefore potentially fall into this category, warranting a post mortem on compassionate grounds. At a cost of £500 per post mortem (based on current figures) this would cost a modest amount (£12,500 per annum) which would be borne by Healthcare Improvement Scotland (out of funding provided by the Scottish Government). There would be no separate or additional charge to the families affected.

Stillbirths

89. There are already procedures in place to try and identify the cause of death in most stillbirth cases as all stillbirths are already investigated by maternity units with post mortems offered and currently undertaken in around half of cases. There are also policy changes already underway, due to come into effect in 2011, which require cause of death to be specified according to new stated categories which will reduce the high proportion of categorised ‘unexplained’ causes of deaths for stillbirths. In addition an increased use of post mortems is encouraged (two thirds of stillbirths used to have a post mortem in 1998). In the light of this, additional scrutiny of stillbirth certificates by MRs is regarded as unnecessary.

90. Nevertheless, there are other activities proposed which are aimed at improving the quality and accuracy of stillbirth certificates. The following paragraphs set out Scottish Ministers’ (largely non-legislative) proposals in this area.

91. It is proposed to add improved guidance at the beginning of the Stillbirth Certificate (Form 6) about the importance of providing complete and accurate information. This is to try and avoid any situation where registrars may have to ask potentially distressing questions of parents when they register a stillbirth because the information on the certificate is incomplete or inaccurate; or to avoid unnecessary referral to the PF.

92. An additional way to improve the quality and accuracy of stillbirth certificates would be through education and training of midwives and doctors. It is therefore planned to incorporate this as part of on-the-job training for other healthcare professionals and within the e-Learning modules and guidance for doctors as is being developed for the new death certification system.

93. It is also intended to ensure that stillbirths are considered in any guidance on clinical governance, particularly in cases where a midwife or a doctor persistently makes mistakes.

94. Since the posts of medical referees will be abolished under the new system, it will also be necessary for persons in charge of crematoria/cemeteries to check that the stillbirth certificate and confirmation of registration have been produced prior to disposal (similar to the proposals with regards to other deaths).
95. Furthermore, it has been agreed with COPFS that, in future, where no doctor or midwife is present at a stillbirth, such cases should be referred directly to the PF. It is therefore proposed to repeal the existing provision in the 1965 Act which enables a stillbirth declaration to be made by a non-clinician (i.e. Form 7, Declaration as to Still-Birth, would be withdrawn as it would no longer serve a function). In such cases, the PF will, if satisfied, issue an authorisation which will allow burial or cremation to proceed.

96. Finally, it is planned to record additional relevant information on Form 6, in line with proposed changes to the MCCD form, including additional questions about public health.

Dealing with Pandemics and/or Severe Epidemics

97. Clearly, in a situation of a severe epidemic or pandemic (such as pandemic flu), which would be expected to continue over a period of some months, it would be difficult for a scrutiny system to run effectively. This is because the volume of deaths taking place may be significantly higher than usual, placing additional pressure on systems; certifying doctors would have very little time to provide additional information to an MR; it may be more difficult for hospitals to find and transmit non-electronic patient records; because funerals may need to take place straight away to prevent the development of backlogs; and because of the distress this could cause. In addition, certifying doctors, registrars and PFs may fall ill and MRs themselves, as doctors, might also find themselves being redeployed to provide frontline assistance as required.

98. The Bill therefore provides a power for Scottish Ministers to suspend, by order, the scrutiny system in an epidemic situation (or, where necessary, to prevent the spread of disease).

Unexplained Deaths

99. This is an area where there appears to be a considerable amount of confusion about current requirements and inconsistency in how the current system operates around the country. It is intended that (non-legislative) steps are taken to improve the future handling of this issue.

100. In future, it is proposed that where a death occurs and the cause of death is unknown or undetermined it will be referred to the PF for investigation. Where a death has occurred in hospital, a post mortem can already be undertaken to try and establish what caused the death before a PF referral takes place. Where a case is referred to the PF, he/she will take a view on the need for further investigation and a post mortem (such as a view and grant). Thereafter, there may be a number of different outcomes and the PF will take the decision on the appropriate type of disposal in these cases.

Testing and Implementing the New System

101. Full implementation would be no earlier than 2013-14. However, to deliver an immediate improvement in the information available to NHS Boards and the Scottish Government, the new NHS NSS national statistician could begin work immediately following the passage of the primary legislation, i.e. from 2011-12.
102. Provided that primary legislation is completed in the 2010-11 legislative session, secondary legislation could be consulted on and go through the Scottish Parliament in 2011-12. Stakeholders agree that a further transitional period of at least one year would then be required to run small test sites to test how the process would operate in practice. Two test sites in two different areas of the country, for example, one rural and one urban area are anticipated. Test sites would be expected to take place during 2012-13 and run for at least six months to allow for evaluation before full implementation in 2013-14. Alternatively, work on secondary legislation could take place in parallel with the test sites. A full implementation plan will be drawn up in due course. The overarching aim of testing the system will be to ensure that the system is as efficient as possible and to allow individual elements of the system to be tested and adapted as a result of the information gained from the test sites.

103. The Financial Memorandum sets out more detail on the anticipated mechanics and costs of the test sites.

104. The test sites will be run largely on an administrative basis.

105. In addition to secondary legislation, there would need to be a comprehensive assessment of the guidance, training and information required for key groups. This would include the following:

- Members of the public, who will require general information about the new system and how it might affect them; specific advice will be required if their relative is randomly selected for scrutiny; guidance will be required on contact with the MRs and information on how to refer a case (as an interested person) to the MRs;
- Registrars, who will require guidance and training on the new system, including the interface with members of the public who will be affected by scrutiny;
- Certifying doctors and pathologists, who will require additional guidance and training on the new system and how to engage with the MRs; and
- Funeral directors, who will require information about the new system and the impact on funeral arrangements.

106. Key stakeholders will be involved in further development of all of the above, including NHS Education for Scotland (NES) and the Royal Colleges on training issues. In addition, close working with Crown Office is anticipated.

ALTERNATIVE APPROACHES

107. England and Wales are set to introduce a Medical Examiner (ME) system and primary legislation for this is included in the Coroners and Justice Act 2009. Under this system, every death that does not require a Coroner's post mortem or inquest will be scrutinised and countersigned by the ME. The UK Government envisages recruiting 240 FTE MEs (up to 1,000 part-time posts) plus the same number of assistants and a National Medical Examiner. The ME will give advice to attending doctors, Coroners and their staff, talk to relatives, view the body if necessary, and check medical records before giving authorisation and releasing the body for registration and disposal.
108. Many of the details are yet to be confirmed as pilots are still underway and to be evaluated but the proposed changes are intended to provide a simpler process for bereaved families and provide increased scrutiny and transparency. Certifying doctors will have access to MEs to discuss cause of death to improve the quality of registration. Funeral directors will benefit from simplified forms and better data to help meet health and hygiene requirements. Registrars will benefit from improved certification processes with fewer requirements on them to understand and seek to interpret medical information on MCCD forms.

109. The legislation includes a power to raise public fees, although the details on who and how to collect have still to be specified in regulations. Because of the significant investment required to recruit a relatively high number of doctors, any public fee is likely to be close to the level of the current cremation fee in England (slightly higher than the existing £147 fee in Scotland). The UK Government has undertaken to ensure that the new system costs no more than the existing system (£45 million a year).

110. Northern Ireland is also considering the review of their system of death certification though no public consultation has yet taken place.

111. In terms of practical issues arising from different systems, it is not considered that these will necessarily present any insurmountable problems. Close working with relevant parties to work up generic guidance (or a protocol) has been agreed with counterparts in England and Wales, with the aim of ensuring that there is clarity around the arrangements for transferring remains from and to Scotland.

112. The Scottish Government believes that the model set out in the draft Bill is the right model for Scotland. This follows consideration of the original Review Group recommendations, a formal consultation exercise, consideration of the England and Wales model and many discussions with stakeholders.

113. The Scottish Government believes any scrutiny system should build on the existing structure and established processes of the NHS, as well as on the professionalism and high standards of health professionals in Scotland.

114. According to Scottish Ministers’ view, the approach taken in England and Wales of requiring the actions of a certifying doctor to be double checked in every single case is not an efficient, required or desirable use of resources. Under the current system up to three doctors can be involved in providing certification for cremation, including additional scrutiny from the crematorium referee. Practice has shown that such checking tends to be perfunctory. It is neither necessary nor proportionate as a means of ensuring that an effective level of monitoring and governance is in place. Rather than requiring costly and unnecessary checks of the actions of every single doctor in certifying every single death in Scotland, focus should be on building on existing systems of clinical governance, seeking to drive up standards and quality throughout the process and introducing a level of deterrence. Fundamentally, therefore, this can be achieved through a scrutiny system that checks a (flexible) sample of cases supplemented by the ability of certain interested parties to refer cases and the power of the MRs to conduct additional checks where they feel this is of value. This system should seek and lead to improvements over time.
and can then also adapt to those improvements. In this way it can be adapted and made responsive to needs as they change over time.

115. Discussions have been taking place with Medical Directors of NHS Boards to ensure that the most is made of links with systems of clinical governance in NHS Boards. Earlier sections of this Memorandum highlight the practicalities of this. It will mean that the clinical governance committee of an NHS Board will be in a strong position to evaluate and take action on the information provided by the MRs. They will be able to assess it alongside other key information including appraisals and revalidation processes, complaints, prescribing patterns and surgical mortality rates to obtain a clear picture of potential problems and the need to take action to address those problems. This applies both to serious or potentially criminal issues around the actions of a particular doctor and to other issues such as a gap in training.

116. In addition to the role performed by the MRs themselves, Scotland’s system will benefit from its unique capacity to produce a single national set of statistics which can be broken down in any number of ways. Those national statistics will clearly be able to show changes and trends over a period of time.

117. The MR (formerly MI) model has been strengthened in response to specific stakeholder concerns by:

- Acknowledging that there should be room for flexibility in the numbers of cases chosen for random sampling;
- Introducing the concept of additional (up to 100%) scrutiny where considered necessary by the MR;
- Leaving the final numbers of MRs flexible;
- Placing a greater emphasis on training and education;
- Placing greater emphasis on the need for strong leadership of change through the role of the SMR; and
- Allowing more scope in the system for specific support to be given on a daily basis to both doctors and registrars.

118. It is clear that the importance of death certification has to be reinforced and achieving this will require the strong leadership role of the SMR in particular and close relationships with the Royal Colleges but also, importantly, with NHS Boards and practitioners.

CONSULTATION

119. The Scottish Government undertook a consultation on Death Certification, Burial and Cremation which ran from 27 January 2010 to 21 April 2010. This exercise attracted 102 responses, from a range of stakeholders such as local authorities, the funeral industry, health boards and individuals.

120. The consultation was split into four sections:

- When a death occurs;
• Death certification;
• Burial and cremation; and
• Alternative methods of disposal.

121. The consultation document, published responses and the independent analysis of responses can be accessed at the Scottish Government’s publication website through the following links:

• [http://www.scotland.gov.uk/Publications/2010/01/26131024/0](http://www.scotland.gov.uk/Publications/2010/01/26131024/0);
• [http://www.scotland.gov.uk/Publications/2010/06/01155027/0](http://www.scotland.gov.uk/Publications/2010/06/01155027/0); and

122. The Bill only deals with the death certification part of the consultation. Other issues contained in the consultation will be dealt with at a later date.

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT

Equal Opportunities

123. The Bill’s provisions are not discriminatory on the basis of age, gender, race, disability, marital status, religion or sexual orientation. The new system will bring in a common method of certification and review regardless of the method chosen for disposal (i.e. burial or cremation) and will remove the differential treatment of burials (which do not currently attract a fee) compared to cremations (which do attract a fee). People who have traditionally paid for cremation forms to be signed will no longer be charged this levy (currently around £147 payable by the family). Instead a standard fee will be charged for the certification required for all types of disposal, whether burials or cremations. Therefore, anyone who opts for burial will be asked for a small charge which they have not previously been asked to pay. There is currently a split of 40/60 for burial and cremation in Scotland and the majority of bereaved families in Scotland will therefore benefit financially from the new arrangements.

124. An EQIA was undertaken on the policies expected to be included in the Bill to consider the possible impact of these proposals on people according to their age, disability, race, religion and beliefs, general and sexual orientation. Religion and beliefs are important considerations in death certification, in particular the release of bodies for burial and cremation as swiftly as possible.

125. The issue of the delay that may occur if a death (upon registration) is chosen for random review has therefore been an important consideration.

126. As outlined earlier in the Memorandum, in most cases it is estimated funerals will take place within the average timescales expected despite the additional scrutiny step.

127. The arrangements made to ensure that a very quick process can be made available in certain defined circumstances are set out above. This expedited process will be available to all
persons provided sufficient justification can be made and there are no circumstances present which would make this unsuitable. In these limited cases, review would take place in parallel to the funeral arrangements.

**Human Rights**

128. The Scottish Government is satisfied that the provisions of the Bill are compatible with the European Convention on Human Rights. In particular, the view is taken that any delays inherent in the certification process, and the nature of them, are proportionate to the legitimate aims pursued by the Bill.

129. Despite adopting this view, careful consideration has been given to the possibility that a short delay may occur if a death is chosen for the random review at the point of registration (this was an issue which particularly concerned those whose religious beliefs call for the body of the deceased to be disposed of quickly). Accordingly, Scottish Ministers’ proposals, as described above in the Policy Memorandum, include the potential for an expedited review process to be made available in randomly selected cases where this is considered appropriate. This will be set out fully in guidance in due course.

130. Access to the expedited review process is available on a non-discriminatory basis to all persons, provided sufficient justification can be shown.

**Island Communities**

131. Traditionally in the more rural parts of Scotland burial has been the preferred option and this trend is expected to prevail. There may therefore be a disproportionate impact on rural communities in relation to the introduction of fees for burials.

132. There is also more likely to be a delay in retrieving papers required for scrutinising deaths in rural communities, which could affect the timetabling of a greater proportion of funerals. This will be considered further during test sites and as part of the preparation for the implementation of a new system.

**Local Government**

133. Under the new proposals, local authority registrars will play a fuller role at the point of registration. It is anticipated that at the point of registration the registrar will be responsible for informing the family that the death has been chosen for random scrutiny and that registration will not be completed until the scrutiny has been undertaken. This builds on the experience which registrars already have as the public facing end of death certification. Guidance will be produced to support registrars in this enhanced role.

**Sustainable Development**

134. There are no specific issues applicable to death certification.
This document relates to the Certification of Death (Scotland) Bill (SP Bill 58) as introduced in the Scottish Parliament on 7 October 2010

CERTIFICATION OF DEATH (SCOTLAND) BILL

POLICY MEMORANDUM


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