SCOTTISH EXECUTIVE

Health Department
Directorate of Finance

NHS MEL (2000)18

Dear Colleague

CLINICAL NEGLIGENCE AND OTHER RISKS INDEMNITY SCHEME (CNORIS)

Purpose

1. NHS MEL (1999) 86 advised the NHSiS that new financial risk sharing arrangements for both clinical and non-clinical risks would be introduced from 1st April 2000 and provided an outline of those arrangements.

2. This MEL is to advise that the necessary statutory provision for the new Scheme came into effect on 1st April 2000, and to provide more detailed information on the Scheme's coverage and operation.

Detail

3. Attached is a copy of the Regulations (SSI 2000 No.54 The National Health Service (Clinical Negligence and Other Risks Indemnity Scheme) (Scotland) 2000) that establishes the new Scheme. The Regulations provide the framework within which the Scheme is to be administered. The attached Annex A and supporting appendices provide a summary explanation of the individual regulations and, where necessary, provide more detailed advice and guidance on:

- Which NHSiS bodies are covered by the Scheme (for whom membership is mandatory) (paragraph 2 of Annex A)
- The types of liability and financial loss covered by the Scheme (paragraphs 3 - 5)
- The Scheme's administrative and management arrangements (paragraphs 6 – 11)

20 April 2000

Addresses

For action
Chief Executives, NHS Trusts

General Managers, Health Boards
Common Services Agency
Scottish Ambulance Service
State Hospitals Board for Scotland
Directors of Finance,
Health Boards and NHS Trusts

For information
Chief Executive, Clinical
Standards Board for Scotland

The Director,
Mental Welfare Commission

General Manager, Health Education
Board for Scotland

Executive Director, SCPMDE

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- The contribution setting (paragraphs 13 – 24) and collection arrangements (paragraphs 25 – 27)

- The procedural requirements for handling claims for liabilities and losses that are covered by the Scheme (paragraphs 28 – 32)

- The criteria and arrangements for obtaining reimbursements from the financial risk pool (paragraphs 33 – 44)

- The criteria and arrangements for setting risk management standards and assessing operational compliance and/or performance (paragraph 45 – 52)

4. Annex B is a comprehensive Question and Answer section that both supports and provides additional information to Annex A.

5. Additionally the Scheme Managers, Willis Scotland Ltd., are sending all members a separate documentation pack that includes a contribution statement, Scheme summary, claims handling protocol and application forms for claiming reimbursement from the pool.

6. A key principle in developing the clinical risk management standards for this Scheme is that it should compliment and not duplicate the work of the Clinical Standards Board for Scotland (CSBS) or other clinical governance initiatives. To that end a Standards Committee has been established to assist the Scheme Managers in developing, reviewing and updating the standards for the clinical components of the risk pool. The Committee includes representatives of the CSBS and medical and nursing representatives nominated by the Chief Medical Officer and Chief Nursing Officer respectively.

7. Following the initial meetings of the Standards Committee, a draft of the Level 1 standards has been prepared and attached as Appendix 2 for possible comment. Any comments received will be considered by the Standards Committee and taken into account before the final version of the standards are formally issued at the end of May 2000.

Action Required

8. Chief Executives and General Managers should ensure that:

- copies of this MEL are distributed to key staff with responsibility for dealing with negligence claims, financial losses and risk management issues;

- any comments on the Level 1 standards at Appendix 2 are submitted to the SE Health Department (Colette Gilchrist, Room 250 St Andrew's House) for no later that 19th May 2000.

- arrangements are made to implement or undertake, and where appropriate comply with, the procedural requirements detailed in both Annex A and Annex B.

Yours sincerely

JOHN ALDRIDGE
Director of Finance

ANNEX A

CNORIS: SUMMARY OF ENABLING REGULATIONS AND SUPPORTING GUIDANCE

Regulation 1 ~ Citation, commencement and interpretation
Regulation 2 ~ Establishment of the Scheme

1. No explanation required.

1. Regulation 3 ~ Members of the Scheme

2. The regulation lists the type of NHSiS body that will participate in the Scheme and effectively renders their membership mandatory. In more detail the bodies covered are:

- NHS Trusts
- Health Boards
- Scottish Ambulance Service Board
- Common Services Agency
- State Hospital Board for Scotland
- Health Education Board for Scotland
- The Scottish Council for Postgraduate Medical & Dental Education
- Clinical Standards Board for Scotland
- Health Technology Board for Scotland

2. Regulation 4 ~ Liabilities to which the Scheme applies

3. This regulation provides a summary list of the types of liability and loss that are covered by the Scheme. In short these are:

- settled clinical negligence claims for all NHS clinical activities of medical and dental practitioners, nurses, midwives, PAMs, ambulance personnel, laboratory staff and relevant technicians for claim settlements on incidents that occurred post-, or were not reported pre-, 1st April 2000 (i.e. new clinical pool cases). For claims lodged before 1st April 2000 but settled thereafter (i.e. residual pool cases) the existing MDDUS scheme criteria will apply.

- settled non-clinical claims (except those covered by previous or remaining commercial insurance cover) on incidents occurring from 1st April 2000, and incidents that had occurred but were not reported until after 1st April 2000, for NHS activities that cover:

- Employers' liability (see exception note below)
- Public liability (including Directors' and Officers' liability)
- Products liability
- Professional indemnity
- Fidelity, including Trustees of Endowment Funds
- Money
- Income generation but only in respect of NHS to NHS activities

2.1.1 Notes

(i) Liabilities under the NHS (Scotland) (Injury Benefits) Amendment (No.2) Regulation 1999 are **not** covered by the Scheme.

(ii) The 'Run Off' liabilities for 'Claims Made' policies that covered the above liabilities, i.e. public and product liability and professional indemnity, are included in the Scheme except where the risk falls within those listed below.

4. By exclusion the following are **not** covered:

- Risks arising from work or services to third parties whether income generation or not
- Business Interruption (income generation)
- PFI/PPP
- Motor vehicles and motor third party risks
- Engineering
- Medical Malpractice (Private Healthcare)
- Personal Accident
- Property damage including endowment property/leased equipment

5. It should be appreciated that the above listings are not necessarily exhaustive. Specific queries about what is in and what is out of the Scheme should, in the first instance, be referred to the Scheme Managers, Willis Scotland Ltd. (either Alan Barn (Scheme Manager) 0141 306 1855 or Brian Kennedy (Deputy Scheme Manager) 0141 306 1885).

3. Regulation 5 ~ Administration and management of the Scheme

6. The regulation confirms that Scottish Ministers are responsible for the Scheme's administration but they may appoint managers to deal with the operational requirements.

3.1 Scheme Managers

7. As previously advised, the design, implementation and certain management elements of the scheme have, following a competitive tender process, been outsourced under a contract with Willis Scotland Ltd. for an initial three-year period. In summary the services they provide are:

- actuarial: calculating members' contributions

- financial: issuing contribution demands, monitoring and reporting on budgetary issues

- risk management: setting standards and assessing compliance of same

- claims management: recording and routing of claim activity, control for reimbursements from the pool

8. Further details on the operational aspects of the above are provided in the appropriate paragraphs below.

9. To assist with the general administration of the Scheme, two cross-service groups will be established namely the Standards Committee and the Joint Administration Group.

3.2 Standards Committee

10. A key aim for the clinical component of the new Scheme is that it must complement and facilitate, and not duplicate, the development of other initiatives to improve clinical standards and performance. It is also important that the risk management standards developed are generic to the NHSiS and reflect the relative levels of financial risk that could arise from the clinical negligence of the Scheme's members. To that end the Standards Committee has been drawn from the NHSiS to work with the Scheme Managers in developing, reviewing and updating the standards for the clinical components of the risk pool. A sub-group has been formed to consider the non-clinical risk component on a similar basis.

3.3 Joint Administration Group

11. The Joint Administration Group membership will be drawn from senior staff in Trusts and Health Boards and, together with representatives from the Standards Committee, Health Department, Willis and CLO, it will meet regularly to review the Scheme's structure and effectiveness and, more generally, to reflect members' interests. This Group has still to be formally established and further details on its membership and modus operandi will be issued later.

4. Regulation 6 ~ Provision of Information

12. This regulation enables Ministers or, as authorised, the Scheme's managers to obtain information from members or their agents (e.g. CLO, loss adjusters etc.) for the purposes of managing or administering the Scheme. A primary need for information is for determining contribution levels and processing applications for reimbursement from the pool. However, the Scheme Managers will also use the information to produce reports for funding and risk management applications for regular issue to members.

5. Regulation 7 ~ Contributions to the Scheme

13. Under this regulation members are required to pay into the pool an annual contribution that is calculated and collected having regard to the sub-provisions of the regulation. In practical terms the position is as follows.

5.1 Contribution Calculation: General

14. The financial risk pool established under the regulations will be managed as a single pool but has three components, i.e. the:

- 'New Scheme – Clinical', i.e. clinical negligence claims on incidents occurring and reported on or after 1st April 2000 and incidents incurred but not reported (IBNRs) as at 1st April 2000.

- 'New Scheme – Non-clinical', i.e. 'other risks' claims (see paragraph 3 above) on incidents occurring and reported on or after 1st April 2000 and IBNRs as at 1st April 2000 (except for claims that are covered by previous commercial insurance cover)

- 'Residuals Pool', i.e. known clinical negligence claims before 1st April 2000

15. Responsibility for calculating the contribution for each element rests with the Scheme's Managers. The overall pool is to be funded on a 'pay as you go' basis, i.e. the contributions collected in any one year should be sufficient to meet the expected level of reimbursements from the pool, under the terms of the Scheme, in that year.

16. The calculation for the first and second year will include a contingency to smooth out possible fluctuations for individual members and to provide a necessary degree of in-year financial risk protection. However, any surplus year-end balance will be carried forward to the next and, from the third year onwards, will be used to offset the subsequent year's contribution.

17. In the event of a potential shortfall between the contribution total and reimbursements from the pool, the regulations provide that a supplementary in-year contribution notice may be issued to members. However, as indicated above, steps will be taken to minimise the likelihood of this occurrence.

5.2 Contribution Calculation: New Scheme

18. The calculation for New Scheme contributions will take account of the following:

- overall, the amount liable for reimbursement from the pool in the year for which the contributions are to be collected;
- for each member, the nature and scope of their field of activity, e.g. Acute Trust/Primary Care Trust and level of activity in key risk areas that historically can lead to a liability from negligence or a financial loss;
- for each member, the effectiveness of steps they take or are taking to reduce the recognised risk factors and thereby the incidence and cost of claims starting from 1st April 2001;
- for each member (increasingly over time), their claims history starting from 1st April 2003;
- for each member, their choice of 'deductible' level below which they will be liable to meet the full value of any claim (subject to an annual aggregate cap).

19. Details of the risk management standards and the performance assessment process (3rd bullet point above) are provided at 45 *et seq* below. However, in brief, there will be three levels of risk management standard and for each one achieved (and maintained) the member's contribution will be discounted on the following basis:

- Level 1 10%
- Level 2 15%
- Level 3 20%

20. The other variable in the contribution setting process is the 'deductible' (5th bullet point above). Members have the choice of accepting the minimum deductible level or a higher one from the following range:

- £25,000
- £50,000
- £75,000

21. Once selected the deductible will remain in force for the membership year in question. The member may change the deductible for a later year but for pool reimbursement purposes the deductible applied will be that in force on the date on which the claim in question was lodged.

5.3 Contribution Calculation: Residuals Pool

22. For the financial year beginning 1st April 2000 the Residuals Pool will be operated on the same basis as the outgoing MDDUS scheme with the exception that the current 'Reserve' (the pool) will no longer be maintained on a 'contribution free' basis. In effect this means that the estimated demand on the central pool, using the MDDUS scheme criteria, for 2000/01 will need to be collected by way of member contributions under the following formula:

Estimated financial demand on Residuals Pool
Less 1999/00 closing balance from MDDUS Reserve
Net fund requirement ~ collected from Health Boards on a weighted capitation basis

23. Health Boards and Trusts were consulted on the use of a weighted-capitation based calculation for 2000/01 and the decision above reflects the majority view. It does, however, mean that contributions can be levied at Health Board level only and, within any Board area, this may be disproportionate to the amount of liability faced for clinical negligence claims.

24. For future years the intention is to operate the Residuals Pool on a financial risk-spreading basis (as opposed to risk-sharing basis for the New Scheme cases). Under this arrangement individual members, i.e. both Trusts and Health Boards, would contribute a sum that is proportional to their financial exposure for remaining pre-1st April 2000 claims. However, the intention is to scope this arrangement and consult Trust and Health Board members before making a final decision on its introduction.

5.4 Contribution Collection

25. The regulations require that members be given written notice of their contribution requirement for the first year's membership (2000/01) by no later than 30th April 2000. Thereafter, notices in respect of the subsequent financial year should be issued no later than 31st December in the in the preceding year.

26. The Scheme managers will issue the contribution notices that will detail the individual pool amounts and total payable. Copies will be passed to the Scottish Executive Health Department (SEHD) who will collect the contributions in respect of Health Boards, Special Health Boards and the CSA through 'payment on behalf' arrangements. Trusts are required to pay the amount due, within 28 days of the notice date, direct to the SEHD through normal OPG arrangements quoting cost centre 2442 account code 70751.

27. As indicated at paragraph 25, the 2000/01 contribution for the Residuals Pool will be charged at Health Board level only. It will be for individual Health Boards to agree with their Trusts how much, if any, of their contribution deduction is passed on the Trusts.

6. Regulation 8 ~ Submission of claims by members

28. This regulation enables Scottish Ministers to direct how claims for compensation, which may result in a reimbursement from the pool, are notified to the Scheme Managers and handled. The following is a summary of the claims handling procedure from 1st April 2000 and should be read in conjunction with the information pack issued separately by the Scheme managers.

29. Members should continue to submit **compensation claims for clinical negligence** directly to CLO who will notify the Scheme Managers monthly of all such cases (with details) received. The monthly report will, amongst other information, include details of settlements (interim and final) and adverse expense payments as authorised by the member.

30. Members must submit all **non-clinical compensation claims** that are likely to exceed £1,000 to the Scheme Managers to determine whether the claim is likely to settle above or below the member's chosen deductible level.

31. **Claims that are expected to settle above member's chosen deductible level** will be retained and processed by the Scheme Manager's appointed loss adjuster. However, where the case is expected to result in, or subsequently requires Court action then it will be referred to CLO for handling as a matter of course.

32. **Claims that are expected to settle below the member's chosen deductible level** will be referred to the member's preferred claims handling agent, i.e. CLO, the Scheme's loss adjuster or any other agent that the member wishes. In this regard it should be noted that:

- the preferred claims handling agent will continue to handle the claim even where it appears that settlement above the members' chosen deductible level is possible;

- members may elect to change their preferred claims handling agent on giving the scheme manager prior notice of one month;

- members, or their appointed claim handlers, must submit to the scheme managers a monthly report on, amongst other things, settlements (interim and final) and adverse expense payments as authorised by the member.

7. Regulation 9 ~ Payments under the Scheme

33. This regulation provides the framework for determining what may be reimbursed from the pool and under what conditions. In this regard the rules and reimbursement process are summarised below. A standard form on which to apply for a reimbursement from the pool will be issued separately to members by the Scheme Managers as part of the support documentation to this MEL.

34. Where necessary, prior written approval must be sought from the SEHD for any proposed settlement that will breach the member's delegated limit for compensation claim

payments and financial losses. At present there is a blanket limit of £100,000 + costs for compensation cases and £5,000 for financial losses but both are under review. Further advice on this aspect will issue later.

35. Applications for reimbursement from the pool in respect of settled claims must be submitted to the Scheme Managers within two months of the settlement date.

36. The Scheme Managers will, within 2 weeks of receipt, authorise and submit the application to the SEHD for reimbursement.

37. Expenditure that will rank for reimbursement purposes under the **New Scheme**, and the calculation base, is:

(1) Amount of Award (if applicable)
PLUS (2) Adverse Expenses (if applicable)
PLUS (3) Claims Adjustment Costs
PLUS (4) Member's Legal Costs

(5) TOTAL EXPENDITURE

LESS (6) Member's Deductible (see paragraph 21)

(7) AMOUNT TO BE REIMBURSED (if a positive amount)

38. As a general rule the deductible is applied to each claim. However, in the event of **serial loss from a single incident** one deductible will apply. It should be noted that under the New Scheme the pool covers successfully **repudiated cases** as well as cases that result in an award.

39. Additionally, under the New Scheme there are **aggregate caps** applying separately to the Clinical and Non-clinical elements of the pool to protect individual members from a run of higher value settlements in any one financial year. The New Scheme incorporates a Non-ranking deductible of £10,000 i.e. losses below £10,000 do not rank towards the aggregate cap. Above £10,000, and below whichever deductible is selected, the sums paid by each member will aggregate and, upon reaching a pre-determined cap, the chosen deductible will automatically drop to £10,000 for each and every occurrence until the end of the financial year. The level of aggregate caps is set as follows:

- Members selecting a £25,000 deductible will have a £250,000 Aggregate Cap.
- Members selecting a £50,000 deductible will have a £500,000 Aggregate Cap.
- Members selecting a £75,000 deductible will have a £750,000 Aggregate Cap.

40. In the event of a **structured settlement** the member will remain liable for the selected deductible that is applicable to the claim but thereafter the pool will meet all costs.

41. Expenditure that will rank for reimbursement purposes under the **Residuals Pool** and the calculation base, is:

(1) Amount of Award
PLUS (2) Adverse Expenses

(3) TOTAL EXPENDITURE

LESS (4) Member's Deductible (per MDDUS scheme ~ see below)
(5) NET EXPENDITURE

LESS (6) 25% of Net Expenditure
(7) AMOUNT TO BE REIMBURSED

42. As stated at paragraph 22, for the financial year beginning 1st April 2000 the Residuals Pool will be operated on the same basis as the outgoing MDDUS scheme. Therefore, the terms and conditions detailed in MEL(1999)63 remain in force with the exception of the individual 'thresholds' (i.e. deductibles), which for 2000/01 will be last year's levels plus a 5% uplift. A Table listing the revised thresholds is attached at Appendix 1.

43. It should be noted that, unlike the New Scheme, the member's own legal costs do not rank for reimbursement calculation purposes.

44. Applications for reimbursement from the Residuals Pool should be submitted to the Scheme Manager in the first instance and not to the Management Executive as in the past.

RISK MANAGEMENT STANDARDS AND ASSESSMENTS (NEW SCHEME)

45. Regulation 7 provides that, in setting the contribution, due regard may be given to the steps taken, or being taken, by a member to reduce the incidence of the liabilities or loss covered by the Scheme. In practice those steps will be measured against a set of risk management standards developed by the scheme managers in consultation with the Standards Committee (see paragraph 10) for the clinical negligence elements of the Scheme, and a sub-group of the Committee for the non-clinical elements.

Standards

46. For both elements there will be three levels of standard that can be achieved progressively over a three-year period, commencing in Year 2, in order to obtain a contribution discount of 10%, 15% and 20% respectively.

47. The intention is to develop a set of standards that is unique to Scotland that, together with the necessary assessment process, will not overlap or duplicate other standard setting or assessment processes. To that end the **strategy for developing the clinical negligence risk management standards** is as follows.

- Level 1 (the 1st Year) standards will focus on the managerial and procedural requirements necessary for sound risk management to be applied across both the clinical and non-clinical sectors by all members as appropriate.

- Levels 2 and 3 will focus on areas of clinical risk by reference to existing professional standards and guidelines including the specific and generic standards developed by the CSBS. Further work is required to finalise the framework for Levels 2 and 3 to ensure that they complement the efforts of other agencies in Scotland. Additional guidance will be developed and issued towards the end of 2000/01.

48. Attached, as Appendix 2, is a provisional draft of the Level 1 standards developed in consultation with both the Standards Committee and the CSBS. The final version will be issued by the end of May or early June and, where appropriate, will take account of any comments received from members between now and then. Whilst these will be regarded the formal Level 1 standards for 2000/01 they will be subject to updating and amendment in light of experience.

49. The **non-clinical risk management standards** are being developed currently and will include a requirement to establish a core risk management system that is supplemented by organisational risk control standards for a range of key areas. [Attached, as Appendix 2, is an initial draft that will be formalised and issued by the end of May or early June].

Assessments

50. The Scheme Managers (Willis Scotland Ltd) will undertake the assessments for standards compliance and will separately provide detail on the process with their own documentation pack. However, in summary, Willis shall pay an initial visit to all members during the first financial year to offer advice and guidance on the standards and the underlying requirements. Thereafter it will be for individual members to decide when they wish their assessment visit to be undertaken, and to invite Willis to do so accordingly. In subsequent years, the timing of the re-assessment of Level 1 visit and Levels 2 and 3 assessment visits will be for the member to determine. The latest that such visits can be undertaken (to ensure any discount to the following year's contribution) is February prior to the new membership year.

51. For most members it should be possible for the assessment visit for Level 1 (clinical and non-clinical) to be accommodated within two working days. Some larger or more complex Trusts will require longer. Level 2 and 3 assessment visits will take slightly longer. After each assessment visit, members will receive a report detailing the outcome. Where the member does not meet the required criteria, the Scheme Managers will indicate the areas of non-compliance to enable members to address them.

52. It should be noted that Willis Scotland Ltd., or their appointees, are acting as independent assessors for scheme purposes and are doing so under contract to the SEHD. On this basis Willis will undertake no fee-based consultancy work that will in any way compromise that independence. Members wishing consultancy services to develop or further enhance their risk management effectiveness, which they may well wish to do, remain free to secure these services from other providers.

Scottish Executive Health Department
Directorate of Finance
April 2000

CLINICAL NEGLIGENCE AND OTHER RISKS INDEMNITY SCHEME (CNORIS)

1. This Annex provides further details (to Annex A) on the Clinical Negligence component of CNORIS. It contains general advice on what the Indemnity Scheme covers and, through a

Question and Answer section, gives examples of the applicability of NHS (Clinical) Indemnity to common situations.

SECTION 1: GENERAL GUIDANCE

Interpretation

2. In this Annex the term:

2.1 "an NHS body" and "NHS bodies" include:

Health Boards, special Health Boards and NHS Trusts but excludes all GP practices, general dental practices, pharmacists and opticians' practices;

2.2 "health care professionals" includes:

doctors, dentists, nurses, midwives, health visitors, hospital pharmacy practitioners, registered ophthalmic or registered dispensing opticians working in a hospital setting, members of professions allied to medicine (PAMS), dentistry, ambulance personnel, laboratory staff and relevant technicians.

Definitions

3. Clinical negligence is:

"A breach of duty of care by members of the health care professions employed by NHS bodies in connection with their diagnosis of any illness or the care or treatment of any person, by act or omission, whilst the member was acting in their professional capacity in the course of their employment."

4. In this definition "breach of duty of care" has its legal meaning. NHS bodies will need to take legal advice in individual cases, but the general position will be that the following must all apply before liability for negligence exists.

4.1 there must have been a duty of care owned to the person treated by the relevant professional(s);

4.2 the standard of care appropriate to such duty must not have been attained and therefore the duty breached, whether by action or inaction, advice given or failure to advise;

4.3 such a breach must be demonstrated on a balance of probabilities to have caused the injury or damage and therefore the resulting loss complained of;

4.4 any loss sustained as a result of the injury or damage must be of a kind that the courts recognise and for which they allow compensation; and

4.5 the injury and resulting loss must have been reasonably foreseeable as a possible consequence of the breach.

Principles for NHS Indemnity

5. NHS bodies are legally liable for the negligent acts and omissions of their employees or agents (the principle of vicarious liability), and should have arrangements for meeting this liability. NHS Indemnity applies where:

5.1 the negligent health care professional was working under a contract of employment (as opposed to a contract for services) and the negligence occurred in the course of that employment; or

5.2 the negligent health care professional, although not working under a contract of employment, with an NHS body, was contracted by that body to provide services to a person to whom an NHS body owed a duty of care.

6. Where the principles outlined in paragraph 5 apply, NHS bodies should accept full financial liability where negligent harm has occurred. They should not seek to recover their costs either in part or in full from the health care professional concerned or from any indemnities they may have. A health care professional will however be liable for any additional expenses of an NHS body if he/she has elected to be separately defended. If he/she unreasonably fails to co-operate fully in the defence of the claim or action against the NHS body, the NHS body may, at its discretion, seek to recover part or all of any liability which it may incur.

Coverage

7. NHS Indemnity **applies** to staff in the course of their NHS employment. It also covers people in certain other categories whenever the NHS body owes a duty of care to the person harmed, including, for example, locums, medical academic staff with honorary contracts, students, those conducting clinical trials on NHS patients, charitable volunteers and people undergoing further professional education, training and examinations.

8. NHS Indemnity **does not apply** to general medical and dental practitioners working as independent contractors under contract for services. General practitioners are responsible for making their own indemnity arrangements, as are other self-employed health care professionals such as chiropodists and independent midwives. Neither does NHS Indemnity apply to employees of general practices or to employees of private hospitals (even when treating NHS patients) local education authorities or voluntary agencies. However, GPs, or dentists who are directly employed by Health Boards or NHS Trusts are covered.

SECTION 2: QUESTIONS AND ANSWERS

General Issues

1. **Who is covered by NHS Indemnity?**

NHS bodies are liable at law for the negligent acts and omissions of their staff in the course of their NHS employment. Under NHS Indemnity, NHS bodies take direct responsibility for

costs and damages arising from clinical negligence where they (as employers) are vicariously liable for the acts and omissions of their health care professional staff.

2. **Is private work in NHS hospitals covered by NHS Indemnity?**

NHS bodies will not be responsible for a health care professional's private practice, even in a NHS hospital. However, where junior medical staff, nurses or PAMS are involved in the care of private patients in NHS hospitals, they would normally be doing so as part of their contract with the NHS Trust. It remains advisable that any junior doctor who might be involved in any work outside the scope of his or her employment should have medical defence (or insurance) cover.

3. **Would health care professionals be covered if they were working other than in accordance with the duties of their post?**

Health care professionals would be covered by NHS Indemnity for their actions in the course of NHS employment, and this should be interpreted liberally. For work not covered in this way health care professionals may have a civil, or even, in extreme circumstances, criminal liability for their actions.

4. **Are private sector rotations for hospital staff covered?**

The medical staff of independent hospitals are responsible for their own medical defence cover, subject to the requirements of the hospital manager. If NHS staff in the training grades work in independent hospitals as part of their NHS training, they would be covered by a formal contract reflecting the indemnity arrangements.

5. **Are disciplinary proceedings of statutory bodies covered?**

NHS bodies are not financially responsible for the defence of staff involved in disciplinary proceedings conducted by statutory bodies such as the GMC (doctors), UKCC (nurses and midwives), GDC (dentists), CPSM (professions allied to medicine) and RPSGB (pharmacists). It is the responsibility of the practitioner concerned to take out medical defence cover against such an eventuality.

6. **Would health care professionals opting to work under contracts for services rather than as employees of the NHS be covered?**

Health care professionals not employed by an NHS body who are working under a contract of services with an NHS Trust, should ensure that they have their own separate indemnity cover.

7. **Are locum health care professionals covered?**

NHS bodies are financially responsible for the acts and omissions of a locum health care professional, whether "internal" or provided by an external agency, doing the work of a colleague who would be covered.

8. **Are independent midwives covered?**

Independent midwives are self-employed practitioners. In common with all other health care professionals working outside the NHS, they are responsible for making their own indemnity arrangements.

9. **What are the arrangements for staff employed by one Trust working in another?**

It depends on the contractual arrangements. If the work is being done as part of a formal agreement between the Trusts, then the staff involved will be acting within their normal NHS duties and the employing Trust will normally be liable.

10. **Are NHS staff in public health medicine or in community health services doing work for local authorities covered? Are occupational physicians covered?**

Staff working in public health medicine, clinical medical officers or therapists carrying out local authority functions under their NHS contract would be acting in the course of their NHS employment and, therefore, are covered by NHS Indemnity. The same principle applies to occupational physicians employed by NHS bodies.

11. **Are NHS staff working for other agencies, e.g. the Prison Service, covered?**

In general, an NHS body is not financially responsible for the acts of NHS staff when they are working for other agencies, unless the staff are doing so as part of their employment with the NHS body under a contract made between it and another agency. Either the non-NHS body commissioning the work would be responsible, or the health care professional should have separate indemnity cover.

12. **Are NHS staff offering services to voluntary bodies such as the Red Cross or hospices covered?**

The NHS body would be responsible for the actions of its staff only if it were contractually responsible for the clinical staff of the voluntary body. If not, the staff concerned may wish to ensure that they have separate indemnity cover.

13. **Are health care professionals attending victims ("Good Samaritan" acts) covered?**

"Good Samaritan" acts are not part of the health care professional's work for the employing body. Medical defence organisations are willing to provide low-cost cover against the (unusual) event of anyone performing such an act being sued for negligence.

14. **Is Category 2 work covered?**

Category 2 work (e.g. reports for insurance companies) is by definition not undertaken for the employing NHS body and is therefore not covered by NHS Indemnity. Medical defence (or insurance) cover would be appropriate for the individuals concerned.

15. **Are former NHS staff covered?**

NHS Indemnity will cover staff who subsequently left the Service (e.g. on retirement) provided the liability arose in respect of acts or omissions in the course of their NHS employment, regardless of when the claim was notified. NHS bodies may seek their co-operation in statements in the defence of a case.

16. **Are voluntary workers covered?**

Where volunteers work in NHS bodies, they are covered by NHS Indemnity. NHS managers should be aware of all voluntary activity going on in their organisations and should wherever possible confirm volunteers' indemnity position in writing.

General Practitioner Issues

17. **Is a hospital doctor doing a GP locum covered?**

This would not be the responsibility of the NHS body since it would be general practice. The hospital doctor and the general practitioners concerned should ensure that there is appropriate medical defence cover.

18. **Is a GP seeing their own patient in hospital covered?**

A GP providing medical care to patients in hospital under a contractual arrangement, e.g. where the GP was employed as a clinical assistant, will be covered by NHS Indemnity. Where a NHS body provides facilities for patient(s) who continue to be the clinical responsibility of the GP, the GP is responsible and medical defence cover would be appropriate. However, where junior medical staff, nurses or PAMs are involved in the care of a GP's patient in NHS hospitals, they would normally be doing so as part of their contract with the NHS body and thereby are covered by NHS Indemnity.

19. **Are GP trainees working in general practice covered?**

In general practice the responsibility for training and for paying the salary of a GP trainee rests with the trainer. While the trainee is receiving a salary in general practice it is advisable that both the trainee, and indeed other members of the practice, has medical defence (or insurance) cover.

20. **Are GP practices covered?**

GPs are independent practitioners and therefore they and the staff employed by them are not covered by NHS indemnity.

Education & Research Issues

21. **What is the position for clinical academics and research workers?**

NHS bodies are vicariously liable for the work done by university/college medical, nursing and PAMs staff and other research workers in the course of their NHS clinical, teaching or research duties, but not for other work in the university/college. For this purpose, it is recommended that academic staff who have access to patients have written honorary contracts with the relevant NHS body/bodies.

22. **Are students covered?**

NHS Indemnity applies where students are gaining practice experience under the supervision of NHS employees. It also applies to students gaining experience in NHS premises under the supervision of staff employed by universities/colleges who are themselves covered by vicarious liability as above.

23. **Are health care professionals undergoing on-the-job training covered?**

Where an NHS body's staff are providing on-the-job training (e.g. refresher or skills updating courses) for health care professionals, the trainees are covered by NHS Indemnity whether they are normally employed by the NHS or not.

24. **Are clinical trials covered?**

In the case of negligent harm, health care professionals, undertaking clinical trials or studies on volunteers who are NHS patients, whether healthy or patients hoping to obtain therapeutic benefit, in the course of their NHS employment are covered by NHS Indemnity. Similarly, for a trial not involving medicines, the NHS body would take financial responsibility unless the trial were covered by such other indemnity as may have been agreed between the NHS body and those responsible for the trial. In any case, NHS bodies should ensure that they are informed of clinical trials in which their staff are taking part in their NHS employment and that these trials have the required Research Ethics Committee approval. For non-negligent harm, see question 27 below.

25. **Is harm resulting from a default in the drug/equipment covered?**

Where harm is caused due to a defect in a drug or piece of equipment then, under the terms of the Consumer Protection Act 1987, liability lies with the manufacturer, not the health care professional using it. This is known as strict liability. Under normal circumstances, therefore, NHS indemnity would not apply unless there was a question of the health care professional knowing the drug/equipment was faulty and continuing to use it. Strict liability could apply if the drug/equipment had been manufactured by a NHS body itself, for example, a prototype as part of a research programme.

26. **Are Local Research Ethics Committees (LRECs) covered?**

Under the Department's guidelines an LREC is appointed by the Health Board to provide independent advice to NHS bodies within its area on the ethics of research proposals. The Health Board should take full responsibility for members' actions in the course of performance of their duties as LREC members.

27. **Is there any liability for non-negligent harm?**

Legal liability except as described in paragraph 25 does not arise where a person is harmed but no-one has acted negligently. An example of this would be unexpected side-effects of drugs during clinical trials. In exceptional circumstances (and within the delegated limited of £5,000) NHS bodies can consider whether an ex-gratia payment could be offered. NHS bodies should not offer advance indemnities or take out commercial insurance for non-negligent harm, and should not make ex-gratia payments for non-negligent harm where research is sponsored by a non-NHS body.

APPENDIX 1

ARRANGEMENTS FOR REIMBURSEMENT FROM THE RESIDUAL POOL

1. Health Boards and NHS Trusts (employing authorities) are responsible for meeting the costs of all awards which are less than 0.15% of their base revenue allocation (Boards) or expected annual income (Trusts), up to a maximum of £450,000.

2. For awards above the calculated sum, employing authorities will additionally pay one quarter (25%) of the amount by which the award exceeds the calculated sum, thereafter the balance will be met centrally. This is subject to maxima rules, i.e. the employing authority will not be liable to meet the costs:

- for any one award where their contribution exceeds 0.3% of their allocation/income figure;
- where the total payments by employing authorities on all awards in one financial year exceeds 0.5% of their allocation/income figure.

The excess in each case will be met centrally.

3. In calculating the cost of an award, the employing authority should include both the payment to the Pursuer and the adverse legal expenses of the Action. Once a settlement is reached, Central Legal Office will advise the employing authority and the Management Executive of the amounts which fall to be paid.

4. Thereafter, the employing authority should notify the Management Executive of the amount it wishes to reclaim, under the above formulae, using the form attached.

SEHD Finance Directorate

CENTRAL CONTRIBUTION TO DAMAGES AWARDS: 2000/01

HEALTH AUTHORITY	GENERAL REVENUE ALLOCATION	THRESHOLD LEVEL 1 0.15% of Col (2) WITH £450,000 CEILING	THRESHOLD LEVEL 2 0.3% of Col (2)	THRESHOLD LEVEL 3 0.5% of Col (2)
COL (1)	COL (2)	COL (3)	COL (4)	COL (5)
HEALTH BOARDS	£M	£	£	£
ARGYLL & CLYDE	270.600	405,900	811,800	1,353,000
AYRSHIRE & ARRAN	229.500	344,250	688,500	1,147,500
BORDERS	69.600	104,400	208,800	348,000
DUMFRIES & GALLOWAY	97.400	146,100	292,200	487,000
FIFE	202.400	303,600	607,200	1,012,000
FORTH VALLEY	159.700	239,550	479,100	798,500
GRAMPIAN	294.700	442,050	884,100	1,473,500
GREATER GLASGOW	596.100	450,000	1,788,300	2,980,500
HIGHLAND	132.300	198,450	396,900	661,500
LANARKSHIRE	320.000	450,000	960,000	1,600,000
LOTHIAN	441.200	450,000	1,323,600	2,206,000
ORKNEY	13.100	19,650	39,300	65,500
SHETLAND	15.500	23,250	46,500	77,500

TAYSIDE	254.200	381,300	762,600	1,271,000
WESTERN ISLES	23.200	34,800	69,600	116,000
STATE HOSPITAL	15.400	23,100	46,200	77,000
CSA	90.300	135,450	270,900	451,500
SCOTTISH AMBULANCE SERVICE	91.700	137,550	275,100	458,500

Threshold Level 1 - Level at which individual settlement will receive contribution from the Residuals Pool

Threshold Level 2 - Maximum amount that member will have to contribute for a single settlement

Threshold Level 3 - Maximum amount that member will contribute for all claims settled in any one financial year

CENTRAL CONTRIBUTION TO DAMAGES AWARDS: 2000/01

HEALTH AUTHORITY	ESTIMATES FOR PATIENTS INCOME	MINIMUM AWARD FOR CENTRAL CONTRIBUTION 0.15% OF Col (2) WITH £450,000 CEILING	AWARD ABOVE WHICH ADDITIONAL COSTS MET CENTRALLY 0.3% OF Col (2)	MAXIMUM EXPENDITURE BY EMPLOYING AUTHORITY IN FINANCIAL YEAR (0.5% of Col (2))
COL (1)	COL (2) £M	COL (3) £	COL (4) £	COL (5) £
NHS TRUSTS				
Argyll & Clyde Acute Hospitals	122.300	183,450	366,900	611,500
Ayrshire & Arran Acute Hospitals	140.700	211,050	422,100	703,500
Ayrshire & Arran Primary Care	76.900	115,350	230,700	384,500
Borders General Hospital	34.000	51,000	102,000	170,000
Borders Primary Care	32.800	49,200	98,400	164,000
Dumfries & Galloway Acute & Maternity Hospitals	48.000	72,000	144,000	240,000
Dumfries & Galloway Primary Care	48.000	72,000	144,000	240,000
Fife Acute Hospitals	93.800	140,700	281,400	469,000
Fife Primary Care	84.000	126,000	252,000	420,000
Forth Valley Acute Hospitals	86.000	129,000	258,000	430,000
Forth Valley Primary Care	66.600	99,900	199,800	333,000
Grampian Primary Care	118.800	178,200	356,400	594,000

CENTRAL CONTRIBUTION TO DAMAGES AWARDS: 2000/01

HEALTH AUTHORITY	ESTIMATES FOR PATIENTS INCOME	MINIMUM AWARD FOR CENTRAL CONTRIBUTION 0.15% OF Col (2) WITH £450,000 CEILING	AWARD ABOVE WHICH ADDITIONAL COSTS MET CENTRALLY 0.3% OF Col (2)	MAXIMUM EXPENDITURE BY EMPLOYING AUTHORITY IN FINANCIAL YEAR (0.5% of Col (2))
COL (1)	COL (2)	COL (3)	COL (4)	COL (5)
NHS TRUSTS	£M	£	£	£
Grampian University Hospitals	178.700	268,050	536,100	893,500
Greater Glasgow Primary Care	161.100	241,650	483,300	805,500
Highland Acute	77.500	116,250	232,500	387,500
Highland Primary Care	59.400	89,100	178,200	297,000
Lanarkshire Acute Hospitals	176.500	264,750	529,500	882,500
Lanarkshire Primary Care	106.100	159,150	318,300	530,500
Lomond & Argyll Primary Care	40.400	60,600	121,200	202,000
Lothian Primary Care	139.300	208,950	417,900	696,500
Lothian University Hospitals	266.400	399,600	799,200	1,332,000
North Glasgow University Hospitals	320.700	450,000	962,100	1,603,500
Renfrewshire & Inverclyde Primary Care	72.400	108,600	217,200	362,000
South Glasgow University Hospitals	157.800	236,700	473,400	789,000
Tayside Primary Care	117.900	176,850	353,700	589,500

CENTRAL CONTRIBUTION TO DAMAGES AWARDS: 2000/01

HEALTH AUTHORITY	ESTIMATES FOR PATIENTS INCOME	MINIMUM AWARD FOR CENTRAL CONTRIBUTION 0.15% OF Col (2) WITH £450,000 CEILING	AWARD ABOVE WHICH ADDITIONAL COSTS MET CENTRALLY 0.3% OF Col (2)	MAXIMUM EXPENDITURE BY EMPLOYING AUTHORITY IN FINANCIAL YEAR (0.5% of Col (2))
	COL (1)	COL (2)	COL (3)	COL (4)	COL (5)
NHS TRUSTS	£M	£	£	£
Tayside University Hospitals	189.900	284,850	569,700	949,500
Yorkhill	84.000	126,000	252,000	420,000
West Lothian Healthcare	70.100	105,150	210,300	350,500

CNORIS

CLINICAL RISK MANAGEMENT STANDARDS

1.0	1. Clinical Risk Management Strategy
2.0	**Clinical Risk Manager/Group**
3.0	**Clinical Risk Management System**
4.0	**Clinical Incident Reporting System**
5.0	**Policy for rapid follow-up of significant clinical incidents.**
6.0	**Dealing with Complaints**
7.0	**Information on the risks and benefits of proposed treatment or investigation.**
8.0	**Standards, use, storage and retrieval of medical records.**
9.0	**Clinical Care**
10.0	**Initial and Continuing Professional Competence**

1.0	2. Clinical Risk Management Strategy
Standard:	**The Trust board has a written risk management strategy that makes their commitment to managing clinical risk explicit, and clearly communicated. An Executive Director of the Board is charged with responsibility for clinical risk management, in the context of overall risk management, throughout the Trust.**
Rationale:	***The Board should be prepared to make a public statement of its intent to effectively manage clinical risk throughout the organisation then there is no real prospect that it will occur. While the Board may have a general strategy it will need an individual, at every level in the organisation, to be charged with its execution.***

2.0	**Clinical Risk Manager/Group**
Standard:	**The responsibility for management and co-ordination of clinical risk at a local level within the Trust is clear.**
Rationale	***Throughout the organisation the complex process of clinical risk management will need co-ordination.***

3.0	**Clinical Risk Management System**
Standard:	**A clinical risk management system is in place.**
Rationale	***The full effect of clinical risk management will only be achieved if there is a comprehensive and co-ordinated system throughout the Trust.***

4.0	**Clinical Incident Reporting System**
Standard:	**A Clinical Incident Reporting System is in operation.**
Rationale	***Clinical incident reporting (IR) is a fundamental tool of clinical risk management, the aim of which is to collect information about untoward outcomes of patient care.***

5.0	**Policy for rapid follow-up of significant clinical incidents.**
Standard:	**There is a policy for rapid follow-up of significant clinical incidents, which includes a local definition of 'significant incident'.**
Rationale	***A "Significant Clinical Incident" if not properly managed, may result in loss of public confidence in the Trust, or loss of assets.***

6.0	Dealing with Complaints
Standard:	**An agreed system of dealing with complaints is in place, in line with existing NHS Complaints standards.**
Rationale	***Competent handling of complaints can assist in improving the quality of care and minimising claims.***

7.0	Information on the risks and benefits of proposed treatment or investigation, or clinical research.
Standard:	**Appropriate information is provided to patients on the risks and benefits of the proposed treatment or investigation, and the alternatives available, before a signature on a Consent Form is sought.**
Rationale	***Complaint / Litigation is less likely to follow if patients understand what they are consenting to.***

8.0	Standards, use, storage and retrieval of medical records.
Standard:	**A comprehensive system for the completion, use, storage and retrieval of medical records is in place. Record-keeping standards are monitored through the clinical audit process.**
Rationale	***Complete and timely records allow a clear picture of events to be obtained which is imperative for managing complaints and litigation.***

9.0	Clinical Care
Standard:	**There are clear procedures for the effectiveness of clinical care.**
Rationale	***The public has a reasonable expectation that clinical staff are competent to perform their duties and learn from errors in the past.***

10.0	Initial and Continuing Professional Competence
Standard:	**There are systems in place to verify the qualifications, competence and appropriate training of all clinical staff.**
Rationale	***A comprehensive induction of clinical staff will enable them to perform the basic tasks of the post safely.***

CNORIS

CLINICAL RISK MANAGEMENT STANDARDS

2.1
2.2 GUIDANCE NOTES

1.0 3. Clinical Risk Management Strategy

2.0 Clinical Risk Manager/Group

3.0 Clinical Risk Management System

4.0 Clinical Incident Reporting System

5.0 Policy for rapid follow-up of significant clinical incidents.

6.0 Dealing with Complaints

7.0 Information on the risks and benefits of proposed treatment or investigation.

8.0 Standards, use, storage and retrieval of medical records.

9.0 Clinical Care

10.0 Initial and Continuing Professional Competence

Guidance Notes

The following section lays out in detail the standards and their associated criteria and the level of assessment to which they are linked.

Examples of the type of data which will help us to assess your achievement of the standard at each level are given.

In giving examples, we have attempted to bridge the fine line between giving advice and being unnecessarily prescriptive. Our suggestions are only advisory, and it is for the Member to decide precisely how it is going to demonstrate achievement of the standards.

The assessment will not depend solely upon documentation and discussion. The Assessors will wish to satisfy themselves not only that the systems are in place, but also that they are actively understood and implemented.

Please note that the Standards are relevant to all Trusts, Health Boards, the Scottish Ambulance Service, the State Hospital and Scottish Blood Transfusion Service.

Standard 1 – Clinical Risk Management Strategy

1.1.1 There is a Trust Board Minute with date accepting the Strategy.

1.1.2 An Executive Director has been appointed to be responsible for clinical risk management.

1.1.3 The Strategy makes clear the responsibility of the Executive Director for clinical risk management.

Verification *Strategy;*
Management organisation job chart;
Job Descriptions; or
Other supporting information.

1.2.1 The Strategy has been communicated to staff via handbooks and other information.

1.2.2 The Strategy is available to the public via publications, Notice Boards etc.

1.2.3 The Strategy is available to service commissioners.

1.2.4 The Trust can produce documentary evidence demonstrating that the Board's strategy is being implemented.

Standard 2 – Clinical Risk Manager / Group

2.1.1 Someone is charged with the responsibility for co-ordination of clinical risk activities.

2.1.2 There is a clear reporting structure for clinical risk management throughout the organisation.

Standard 3 - Clinical RM System

This Standard has been designed to allow the Assessor to judge the overall effectiveness of Risk Management within a Member Trust. This standard will not be assessed at Level 1.

3.2.1 All clinical risk management standards and processes are in place and operational.

3.2.2 A formal risk management forum exists where clinical risk related issues are discussed.

3.2.3 Risk management policy is implemented through the general management arrangements of the Trust.

3.2.4 A Trust-wide clinical risk assessment has been conducted.

3.3.1 There is evidence of implementation of recommendations made from the risk assessment.

Standard 4 – Clinical Incident Reporting System

4.1.1 A scheme must be in operation in [10%] of Directorates and LHCC's.

Verification *Documentation and results*

4.1.2 IR form, or equivalent, gathers significant data about the event.

Verification *The minimum information required on the IR form will be:*
- *Date and time;*
- *Patient identifiers;*
- *Outline of incident, staff involved.*

IR Form and all supporting documentation and actual reports

4.1.3 IR form states clearly that fact only and **not** opinion must be recorded.

4.1.4 The IR form requires immediate reporting of unexpected death/serious injury.

Verification *Policy document and Report form*

4.1.5 IR form or other records first aid for non-patients.

4.1.6 IR form or other allows for notification of equipment failure.

4.1.7 IR form allows "near misses" to be recorded.

4.1.8 Summarised IRs are provided regularly for review and action.

Verification *Exec. Dir. for CRM;*
Trust Board;
Risk Management Group;
LHCC's, etc
Copies of reports

4.1.9 There is a policy to encourage Incident Reporting.

Verification *(Incident Reporting Policy).*

4.1.10 Incident Reporting is part of induction training for all clinical staff.

4.2.1 There is a process in place for detailed investigation of major clinical incidents.

4.2.2 Clinically related events are being reported immediately and before claims are made.

4.2.3 There is evidence of action arising from IR.

4.2.4 Implementation of incident reporting is operating in [25%] of all Directorates.

4.2.5 Person receiving IR's has written instructions on action to be taken.

4.2.6 Incidents are graded for their degree of risk upon receipt of a form and guidance is given for this.

4.2.7 There should be encouragement of openness and constructive criticism of clinical care.

4.3.1 Implementation of incident reporting is operating in all Directorates and LHCC's.

Standard 5 – Policy for rapid follow-up of significant clinical incidents

(The policy/procedure document will be assessed).

5.1.1 The policy covers responsibility for management of the follow-up to the incident.

5.1.2 A nominated person is responsible for disseminating the policy to staff.

5.1.3 The policy is explicit about responsibility for informing patient(s) and with their consent, where appropriate, relative(s).

5.1.4 The policy covers record keeping about the incident.

5.1.5 The policy is explicit about individuals within the Trust who must be informed.

5.1.6 The policy details which other interested parties need to be informed of the event, e.g. GPs, commissioners, LHCC's.

5.1.7 The policy makes it explicit that patients and relatives must be notified before the media.

5.1.8 The policy covers media relations and who will be responsible for them.

5.1.9 For significant, there is a strategy for dealing with multiple enquiries.

Standard 6 – Dealing with Complaints

6.1.1 The method of dealing with complaints is clear and meets NHS guidelines.

Verification *Copy of complaints policy;*
Register;
Board reports
Performance against NHS Guidelines

6.2.1 An audit system is in place to ensure complaints are reviewed and action taken.

6.3.1 There is evidence that all complaints are systematically analysed to ensure that remedial action is taken.

Standard 7 – Information on the risks and benefits of proposed treatment or investigation

N.B. It is unlikely that this Standard will be applicable to the Scottish Ambulance Service or to the State Hospital.

7.1.1 There is patient information available showing the risks/benefits of the most common elective treatments.

Verification *Pre-treatment information leaflets on common surgical procedures (especially minimal access surgery); electro-convulsive therapy; procedures involving general anaesthesia; interventional radiological techniques; cardiac catheterisation, gastro-intestinal (or other) endoscopy; ERCP; complex drug regimes (cytotoxics, TPN, or potent long-acting drugs used for psychoses and/or depression), immunisation*

At Level One, the "spread" of leaflets between different activities within a Trust will not be considered).

7.1.2 All Consent Forms used comply with NHS Guidelines for design and use.

Verification *The Assessor will need to see examples of all consent forms in use – particularly those relating to:*

- *Any intervention carried out under anaesthetic*
- *Sterilisation*
- *Complex therapies not involving anaesthetics*
- *Dental surgery*

Levels 2 and 3 are currently being developed.

Standard 8 – Standards, use, storage and retrieval of medical records

N.B. ***Trusts should be aware of the implications of the Data Protection Act 1998, which came into force on the 1st March 2000. Further guidance is available in the document produced in December 1999 by the Information & Statistics Division of the CSA (The Data Protection Act 1998: An Action Plan for the NHSiS).***

8.1.1 A Caldicott Guardian has been appointed and liases with local records managers.

Verification *Document outlining the role and responsibilities of the Caldicott Guardian.*
Evidence of liaison between the Caldicott Guardian and records managers.

8.1.2 Records are stored so that loss of documents and traces is minimised for in-patients and outpatients.

8.1.3 The medical record contains clear instruction regarding filing of documents.

8.1.4 Operations notes and other key procedures are readily identifiable.

8.1.5 CTG and other machine-produced recordings are securely stored and mounted.

8.1.6 There is an efficient system for identifying and retrieving X-rays.

8.1.7 | *Acute Trusts only* | The storage arrangements allow retrieval on a 24 hour / 7 day arrangement.

8.1.8 There is clear evidence of audit of record-keeping standards in high-risk specialties within the 12 months prior to the assessment.

Verification *Audit proformas, reports and action plans*

The audit should address clinical note keeping and quality of documentation

High risk in this context means obstetrics, all surgical specialties including podiatry and dental surgery, anaesthetics and A&E including minor injury unit.

8.1.9 There is a mechanism for identifying records that must not be destroyed.

8.1.10 There should be a clear and acknowledged culling policy of records (*reference should be made to MEL (1993) 152: Guidance for the Retention and Destruction of Health Records).*

8.2.1 There is a unified medical record which all specialties use.

Verification *Policy/procedure document on record keeping*
List of specialties

8.2.2 A&E records are contained within the main record for patients who are subsequently admitted.

8.2.3 Nursing, medical and other records (e.g. Care Plans) are filed together when the patient is discharged.

8.2.4 There is a system for measuring efficiency in the recovery of records for in-patients

and outpatients.

8.2.5 The medical record contains a designated place for the recording of hypersensitivity reactions.

8.2.6 A&E records provide for the GP to be sent a copy of the record.

8.2.7 There is clear evidence of clinical audit of record-keeping standards in at least 50% of the specialties within the 12-month period prior to the assessment.

8.2.8 An author of an entry in a record is clearly and easily identifiable, and dated.

8.3.1 There is clear evidence of clinical audit of record-keeping standards in all specialties within the 12 months prior to the assessment.

8.3.2 There is a computer based PAS.

8.3.3 | *Primary Care Trusts* | The storage arrangements allow retrieval on a 24 hour / 7 day arrangement.

Standard 9 – Clinical Care

9.1.1 Trusts should have an explicit strategy for clinical effectiveness which should be part of a broader quality and clinical governance strategy. Organisational arrangements and mechanisms for the systematic monitoring and improvement of the quality of clinical care should be in place.

Verification Strategic documents for clinical effectiveness and quality of care issues should describe both what is to be achieved as well as how it is proposed to achieve it and should answer questions such as:
What are the aims, objectives and priorities?
What is the organisational structure?
What are the reporting arrangements?
Who is responsible/accountable?
How do clinical effectiveness activities relate to arrangements for clinical governance?

9.1.2 Trusts should have an appropriate infrastructure to support clinical audit and clinical effectiveness and be able to provide evidence of: (a) systems to monitor clinical effectiveness activity (including clinical audit); (b) mechanisms to assess and implement relevant clinical guidelines; (c) systems to disseminate relevant information; and (d) an IM&T strategy which supports clinical effectiveness.

Verification What systems are in place for the routine monitoring of clinical activity?
What clinical audits have been undertaken?
What mechanisms are in place to facilitate the adoption and implementation of clinical guidelines?
How do 'important documents' received into the Trust reach the appropriate people?
Is IT being exploited to support clinical effectiveness (e.g. use of Internet/ intranet, electronic data capture, databases)?

9.1.3 Trusts should foster a culture in which clinical effectiveness is integral to all clinical care. Developing clinical effectiveness skills should be central to continuing professional education and development and part of a multidisciplinary systematic approach to continuous quality improvement.

Verification Does the organisation have an annual training programme?
Do all departments and individual staff members have training plans?
How are clinical effectiveness skills being developed?
What is being done to promote multidisciplinary team working?

9.1.4 Clinical effectiveness activities should support priority setting and reflect: (a) the national priority areas identified in Priorities and Planning Guidance; and (b) local priorities identified in the Health Improvement Plan.

Verification Questions which Trusts may wish to consider include: What clinical effectiveness activities have been undertaken in cancer, mental health and coronary heart disease/stroke? To what extent have identified local priorities been addressed? Is there evidence of

contribution to clinical effectiveness activities at regional, national and international levels?

9.1.5 Trusts should ensure that all 'operational sub-units' have identified programmes of clinical effectiveness activity.

Verification Are all health professionals within the Trusts involved in some formalised clinical effectiveness activity?

9.1.6 Trusts should promote clinical effectiveness activities which cross boundaries and support collaboration within and between Primary Care Trusts, Acute Trusts, emerging managed clinical networks and other agencies.

Verification Are there strategies and mechanisms in place to support cross-boundary clinical effectiveness activities?
What is the current level of development/participation in managed clinical networks?

9.1.7 Trusts should be able to demonstrate an increase in public/patient participation in: (a) service planning and standard setting; and (b) monitoring of the quality of care.

Verification How are patients' needs and perspectives ascertained and incorporated into service planning and standard setting?
What use is made of feedback from patients (e.g. complaints, surveys, patient councils) to inform the monitoring of the quality of care?

9.1.8 Trusts should be able to demonstrate that cost effectiveness issues are being addressed alongside clinical effectiveness.

Verification How are health economics questions asked and answered by the Trust?
To what extent is cost effectiveness an integral part of the clinical audit process?
How is the cost effectiveness of new therapies evaluated locally?
What mechanisms are in place for the routine monitoring and reporting of expenditure against drug budgets?
Are the health economics resources which do exist (e.g. in Health Board Public Health Departments) being accessed?

9.1.9 Clinical effectiveness should be a prominent feature of the HIP/TIP process - informing commissioning and underpinning service development.

Verification How are clinical effectiveness priorities and activities reflected in and by the HIP and the TIP?
In what ways have the results of clinical effectiveness been used to influence service developments?

9.1.10 Trusts should be able to demonstrate that clinical effectiveness activities are: (a) informing clinical governance; (b) leading to changes in practice and improvements in standards of care; and (c) providing best value.

Verification How much is being spent on clinical effectiveness activities?
How is the level of resources for clinical effectiveness determined?
Does the current clinical effectiveness programme represent best value?

Levels 2 and 3 are currently under development in line with CSBS Standards.

Standard 10 – Initial and Continuing Professional Competence

10.1.1 All clinical staff must attend a general induction course on joining the Trust.

Verification *Policy documents; course outline and content; records of attendance*

10.1.2 All clinical staff must attend a specific induction appropriate to the specialty in which they are working.

10.1.3 A policy must be in place to ensure that all locum, agency or bank staff undergo appropriate induction training.

10.1.4 There is a locally managed system of CPD, as stated in 'Learning Together' and MEL (2000) 11.

10.1.5 The Trust has a policy requiring relevant clinical staff to be competent to perform basic life support and can demonstrate there is a system in place that fulfils the policy.

Acute Trusts only

Verification *Policy document; registers of attendance*

10.1.6 There is a procedure to verify the registration of clinical staff.

Verification *Human Resources procedures*
Evidence of monitoring compliance with the procedure

10.1.7 Any person operating diagnostic or therapeutic equipment has a sufficient understanding of its use to do so in a safe and efficient manner, and the necessary steps to take in event of equipment failure or accident.

Verification *Training records*
Accreditation or competence testing systems
Equipment manuals, instruction sheets attached to equipment

10.1.8 A Policy should be in place to ensure that appropriate references are taken for all new staff.

10.1.9 All staff should undergo induction / refresher training for incident reporting.

10.2.1 All medical staff in training must attend a specific induction appropriate to the specialty in which they are working.

10.2.2 Training records of CPR training are kept.

10.2.3 Clinical risk management is included in the general induction arrangements for all healthcare staff.

10.2.4 There are policies for assessment in conduct, performance or health of clinical staff.

10.2.5 Competence of medical staff in training.

10.2.6 A policy must be in place for the introduction of new procedures.

10.2.7 The Trust has a policy requiring relevant clinical staff to be competent to perform basic life support and can demonstrate there is a system in

Primary Care

place that fulfils the policy. *Trusts*

10.3.1 90% of eligible staff have attended CPR training in the last 12 months.

10.3.2 There is a section on clinical risk management in the Staff Handbook incorporating key policies and procedures.

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NON CLINICAL RISK MANAGEMENT STANDARDS

1.0	4. Non clinical Risk Management Strategy
2.0	**Risk Assessment**
3.0	**Risk Management System**
4.0	**Monitoring and Review of Performance Management**
5.0	**Incident Reporting System**
6.0	**Policy for rapid follow-up of significant incidents.**
7.0	**Dealing with Complaints**
8.0	**Standards, use, storage and retrieval of records.**
9.0	**Duty of care**
10.0	**Initial and Continuing Professional Competence**

1.0	5. Non clinical Risk Management Strategy
Standard:	**The Trust board has a written risk management strategy that makes their commitment to managing non clinical risk explicit, and clearly communicated. An Executive Director of the Board is charged with responsibility for non clinical risk management, in the context of overall risk management, throughout the Trust.**
Rationale:	***The Board should be prepared to make a public statement of its intent to effectively manage non clinical risk throughout the organisation then there is no real prospect that it will occur. While the Board may have a general strategy it will need an individual, at every level in the organisation, to be charged with its execution.***

2.0	**Risk Assessment**
Standard:	**The Trust Board has a system in place to systematically identify, evaluate and control all risks, to which the Trust is exposed.**
Rationale	***The Board must be aware of its risk profile throughout the entire organisation. While specific risk assessments may have been undertaken, in order to prioritise action, the Trust needs to carry out a Trust-wide exercise to ensure that it is aware of all exposures.***

3.0	**Risk Management System**
Standard:	**A non clinical risk management system is in place.**
Rationale	***The full effect of non clinical risk management will only be achieved if there is a comprehensive and co-ordinated system throughout the Trust.***

4.0	**Monitoring and Review of Performance Management**
Standard:	**Performance indicators are clearly defined, with appropriate monitoring and review systems in place.**
Rationale	***Indicators will assist Trusts in demonstrating performance, and also in highlighting areas that need to be addressed. This will give the board assurance that controls are working satisfactorily and objectives are being met.***

5.0	**Incident Reporting System**
Standard:	**An Incident Reporting System is in operation.**
Rationale	***Incident reporting (IR) is a fundamental tool of risk management, the aim of which is to collect information about adverse events.***

6.0	Policy for rapid follow-up of significant incidents.
Standard:	**There is a policy for rapid follow-up of significant incidents, which includes a local definition of 'significant incident'.**
Rationale	***A "Significant Incident" if not properly managed, may result in loss of public confidence in the Trust, or loss of assets.***

7.0	Dealing with Complaints
Standard:	**An agreed system of dealing with complaints is in place, in line with existing NHS Complaints standards.**
Rationale	***Competent handling of complaints can assist in improving the quality of care and minimising claims.***

8.0	Duty of Care
Standard:	**There is a management system in place to ensure that the Trust complies with all relevant legislation and guidance.**
Rationale	***Organisations should have in place a means of continuously monitoring compliance with health and safety legislation. Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Scottish Executive Health Department.***

9.0	Standards, use, storage and retrieval of records.
Standard:	**A comprehensive system for the completion, use, storage and retrieval of records is in place. Record-keeping standards are monitored through the audit process.**
Rationale	***Complete and timely records allow a clear picture of events to be obtained which is imperative for managing complaints and litigation.***

10.0	Initial and Continuing Professional Competence
Standard:	**There are systems in place to verify the qualifications, competence and appropriate training of all staff.**
Rationale	***A comprehensive induction of staff will enable them to perform the basic tasks of the post safely.***

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NON CLINICAL RISK MANAGEMENT STANDARDS

5.1
5.2 GUIDANCE NOTES

6. Non Clinical Risk Management Strategy

1.0

2.0 Risk Assessment

3.0 Risk Management System

4.0 Monitoring and Review of Performance Management

5.0 Incident Reporting System

6.0 Policy for rapid follow-up of significant incidents.

7.0 Dealing with Complaints

8.0 Duty of care

9.0 Standards, use, storage and retrieval of records.

10.0 Initial and Continuing Professional Competence

Guidance Notes

The following section lays out in detail the standards and their associated criteria and the level of assessment to which they are linked.

Examples of the type of data which will help us to assess your achievement of the standard at each level are given.

In giving examples, we have attempted to bridge the fine line between giving advice and being unnecessarily prescriptive. Our suggestions are only advisory, and it is for the Member to decide precisely how it is going to demonstrate achievement of the standards.

The assessment will not depend solely upon documentation and discussion. The Assessors will wish to satisfy themselves not only that the systems are in place, but also that they are actively understood and implemented.

Please note that where reference is made to 'Trust', this also includes all Health Boards, Island Health Boards, The State Hospital, Scottish Ambulance Service and Common Services Agency.

Standard 1 –Risk Management Strategy

Many Trusts may be moving towards a single risk management strategy, integrating clinical and non-clinical risks. This Standard is not encouraging Trusts to create separate strategies, where a unified strategy already exists. Indeed, it may be best practice to have one single strategy.

1.1.1 There is a Trust Board Minute with date agreeing the Strategy.

1.1.2 An Executive Director has been appointed to be responsible for non-clinical risk management.

1.1.3 **Verification**

Strategy;
Management organisation job chart;
Job Descriptions; or
Other supporting information.

1.2.1 The Strategy has been communicated to staff via handbooks and other information.

1.2.2 The Strategy is available to the public via publications, Notice Boards etc.

1.2.3 The Strategy is available to service commissioners.

1.2.4 The Trust can produce documentary evidence demonstrating that the Board's strategy is being implemented.

Standard 2 – Risk Assessment

2.1.1 There is an organisation-wide risk register that is populated by data representing all known risks.

Verification *Documented risk register*
Diagram documenting risks and responsibilities

2.1.2 Risks are systematically identified and recorded on a continuous basis.

Verification *Risk register*

2.1.3 The range of options for dealing with risk are assessed and are related to an Action Plan. Where appropriate, action points are implemented in order of priority.

Verification *Risk action plan*

2.1.4 All identified risks, and the effectiveness of implemented risk treatments, are monitored and reviewed on a continuous basis.

Verification *Monitoring and review procedure*
Evidence of monitoring and review

2.1.5 The board is informed of and, where necessary, consulted on all significant risks and associated Action Plans on a continuous basis.

Verification *Board reports*
Board minutes
Risk Management Committee minutes

2.1.6 All relevant stakeholders are kept informed and, where appropriate, consulted on the management of significant risks faced by the organisation.

Verification *Correspondence with stakeholders*
Patient surveys

2.1.7 All relevant stakeholders are kept informed and, where appropriate, consulted on the management of significant risks faced by the organisation.

Verification *Correspondence with stakeholders*
Patient surveys

2.1.8 A Risk Assessment is undertaken for all service changes, and changes in service deliveries.

Verification *Trust Implementation Plan*
Individual business cases

2.1.9 The Risk Management Group approves all service changes.

Verification *Minutes of Risk Management Group.*

2.2.1 Hazards are systematically identified, recorded, managed and analysed in accordance with an agreed policy.

Verification *Hazard Reporting Form*
Hazard Reporting Policy / procedure

2.2.2 All identified risks are systematically assessed and prioritised.

Verification *Documented risk assessments*

Risk register

Standard 3 – Risk Management System

This Standard has been designed to allow the Assessor to judge the overall effectiveness of Risk Management within a Member Trust.

3.1.1 A risk management framework is in place and operational.

3.1.2 A formal risk management forum exists where non-clinical risk related issues are discussed.

3.1.3 Risk management policies are implemented through the general management arrangements of the Trust.

3.1.4 There is evidence of implementation of recommendations made from the risk assessment.

Standard 4 – Monitoring and Review of Performance Management

4.1.1 Key indicators capable of showing improvements in management of risk and/or providing early warning of risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Verification **Indicators**
Evidence of usage at all levels

4.1.2 The risk management system is monitored and reviewed by management and the board in order to make improvements to the system.

Verification *Internal audit report(s)*
Health & Safety Committee minutes
Risk Management Committee minutes
Audit Committee minutes

4.1.3 The Internal Audit function, aided as necessary by relevant technical specialists, carries out periodic audits to provide assurances to the board that a suitable risk management system which conforms to this standard is in place and working properly.

Verification *Internal audit report(s)*
Internal audit statement to Chief Executive
Audit Committee minutes
Risk Management Committee minutes
Clinical Governance Committee minutes

4.1.4 All Trusts must comply with the Action Plan contained in 'Towards a Safer Healthier Workplace'.

Verification **Action Plan**

4.1.5 All Trusts must comply with the Action Plan contained in 'Learning Together', MEL (2000) 11.

Verification **Action Plan**

Standard 5 –Incident Reporting System

5.1.1 Incidents, including ill health, are systematically identified, recorded and reported to management in accordance with an agreed policy of positive, non-punitive reporting.

Verification *Incident reporting policy / procedure*
Incident reporting form
Incident reporting guidelines

5.1.2 All reported incidents are responded to and managed in accordance with an agreed policy.

Verification *Incident reporting policy / procedure*
Copies of completed incident report form, which details any immediate action taken.

5.1.3 IR form allows "near misses" to be recorded.

5.1.4 Summarised IRs are provided regularly for review and action.

Verification *Exec. Dir. for Risk Management;*
Trust Board;
Risk Management Group;
LHCC's, etc
Copies of reports

5.1.5 Incident Reporting is part of induction training for all staff.

5.1.6 All reportable incidents are communicated to the relevant external body in accordance with relevant reporting requirements.

Verification *Copies of relevant reports to external bodies*
Incident reporting/management policy/procedure

5.1.7 There is a process in place for detailed investigation of significant incidents.

5.1.8 All reported incidents are graded according to severity and, where appropriate, investigated to determine underlying cause(s).

Verification *Policy/procedure*
Incident Report Form
Guidelines for completing incident form
Investigation reports

5.1.9 Implementation of incident reporting is operating in all areas of operation.

5.2.1 There is evidence of action arising from IR.

5.2.2 Person receiving IR's has written instructions on action to be taken.

5.3.1 All reported incidents are systematically analysed to identify trends and produce information for management review and action.

Verification *Quarterly hazard and untoward incident management report*
Risk Management Committee minutes
Board minutes

Evidence of staff awareness training concerning key hazards and untoward incidents
Evidence of correlation between hazards and untoward incidents reported and complaints, claims and staff absence data.

Standard 6 – Policy for rapid follow-up of significant non-clinical incidents

(The policy/procedure document will be assessed).

6.1.1 The policy covers responsibility for management of the follow-up to the incident.

6.1.2 A nominated person is responsible for disseminating the policy to staff.

6.1.3 The policy is explicit about responsibility for informing patient(s) and with their consent, where appropriate, relative(s).

6.1.4 The policy covers record keeping about the incident.

6.1.5 The policy is explicit about individuals within the Trust who must be informed.

6.1.6 The policy details which other interested parties need to be informed of the event, e.g. GPs, commissioners, LHCC's.

6.1.7 The policy makes it explicit that staff, patients and relatives must be notified before the media.

6.1.8 The policy covers media relations and who will be responsible for them.

6.1.9 For significant incidents, there is a strategy for dealing with multiple enquiries.

Standard 7 – Dealing with Complaints

7.1.1 The method of dealing with complaints is clear and meets current NHS guidelines.

Verification *Copy of complaints policy;*
Complaints Register;
Board reports
Evidence that the Chief Executive responds in writing to all written complaints.
Performance against NHS Guidelines

7.2.1 An audit system is in place to ensure complaints are reviewed and action taken.

7.3.1 There is evidence that all complaints are systematically analysed to ensure that remedial action is taken.

Verification *Evidence of quarterly complaints reports being prepared for the risk management group and Board*
Board minute which evidences review of the report
Evidence that the Chief Executive responds in writing to all written complaints.
Performance against NHS Guidelines

Standard 8 – Duty of care

8.1.1 There is a nominated person responsible for identifying all relevant new legislation.

8.1.2 All new legislation is adequately communicated to all staff, patients and other stakeholders, as appropriate.

8.1.3 The Trust have identified a 'competent person' to provide health and safety assistance to the organisation.

8.1.4 Employees, including managers and the board, are provided with adequate information, instruction and training.

8.1.5 There is an appropriate system in place to ensure that MELs are distributed to all relevant personnel.

Standard 9 – Standards, use, storage and retrieval of records

N.B. ***Trusts should be aware of the implications of the Data Protection Act 1998, which came into force on the 1st March 2000. Further guidance is available in the document produced in December 1999 by the Information & Statistics Division of the CSA (The Data Protection Act 1998: An Action Plan for the NHSiS).***

9.1.1 *The Trust should have identified/appointed someone to manage data protection compliance within the organisation.*

Verification *Document outlining the role and responsibilities*
Evidence of liaison between the nominated individual and records managers.

9.1.2 A Caldicott Guardian has been appointed and liases with local records managers.

Verification *Document outlining the role and responsibilities of the Caldicott Guardian.*
Evidence of liaison between the Caldicott Guardian and records managers.

9.1.3 Employees, including managers and the appointed Caldicott Guardian, are provided with adequate information, instruction and training on records management matters.

Verification *Training records*

9.1.4 The storage arrangements allow timeous retrieval.

9.1.5 There is clear evidence of audit of record-keeping standards.

Verification *Audit proformas, reports and action plans*
Internal audit report(s)

9.1.6 There is a mechanism for identifying records that must not be destroyed.

9.1.7 There should be a clear and acknowledged culling policy of records (*reference should be made to MEL (1993) 152: Guidance for the Retention and Destruction of Health Records).*

9.1.8 Records are held and transported securely and safely.

9.2.1 An author of an entry in a record is clearly and easily identifiable, and dated.

9.3.1 There is an organisation-wide records management strategy which is endorsed by the Board.

Verification *A sufficiently comprehensive strategy that demonstrates that all records management issues have been identified.*
A board minute which identifies endorsement of the strategy.

Standard 10 – Initial and Continuing Professional Competence

10.1.1 All staff must attend a general induction course on joining the Trust, which should include risk management, fire safety, health and safety and incident reporting, where appropriate.

Verification *Policy documents; course outline and content; records of attendance*

10.1.2 All staff must attend a specific induction appropriate to the area in which they are working.

10.1.3 A policy must be in place to ensure that all locum, agency or bank staff undergo appropriate induction training.

10.1.4 There is a locally managed system of CPD, as stated in 'Learning Together' and MEL (2000) 11.

10.1.5 There is a procedure to verify the registration of staff, where appropriate.

Verification *Human Resources procedures*
Evidence of monitoring compliance with the procedure

10.1.6 Criminal records are taken, where appropriate.

10.1.7 A Policy should be in place to ensure that appropriate references are taken for all new staff.

10.1.8 All staff should undergo induction / refresher training for incident reporting.

10.1.9 All Trusts must comply with the Action Plan contained in 'Towards a Safer Healthier Workplace'.

10.2.1 Non clinical risk management is included in the general induction arrangements for all healthcare staff.

10.2.2 There are policies for conduct, performance and for health screening of staff.