ANNEX A

GOVERNANCE IN THE NEW NHS: BACKGROUND INFORMATION AND GUIDANCE ON THE DEVELOPMENT AND IMPLEMENTATION OF CONTROLS ASSURANCE FOR 1999/2000

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SUMMARY

This annex comprises two parts – Part I provides background information on the development of governance and controls assurance in the NHS. This will be useful background for those Chief Executives and Executive Directors with designated responsibility for implementing controls assurance covering risk management and organisational controls. Part II outlines work the NHS Executive is currently carrying out in support of its controls assurance initiative. This will be useful in assisting NHS organisations plan for controls assurance requirements during 1999/2000.

PART I – BACKGROUND AND INTRODUCTION TO GOVERNANCE AND CONTROLS ASSURANCE IN THE NEW NHS

Governance in the NHS

1. The Cadbury Committee reported on the *financial* aspects of *corporate* governance in 1992. In its report the committee defined corporate governance as "the system by which companies are directed and controlled" and identified three fundamental requirements for good corporate governance in organisations:

   • internal financial controls;

   • efficient and effective operations; and

   • compliance with applicable laws and regulations.

2. Subsequently, the Greenbury and Hampel Committees sought to improve upon the 'Cadbury Code'. The findings of these committees, together with the original Cadbury findings, have been consolidated into one 'Combined Code of Principles of Good Governance' published by the London Stock Exchange. Fundamental to these principles is the requirement that "the board should maintain a sound system of internal control to safeguard shareholders' investment and the company's assets" and that "the directors should, at least annually, conduct a review of the effectiveness of the group's system of internal control and should report to the shareholders that they have done so. The review should cover all controls, including financial, operational and compliance controls, and risk management."

3. The Turnbull Committee has recently published a consultation document containing further guidance on these principles. The final guidance is expected by late summer 1999. The Turnbull report reinforces the principle that all controls, including risk management, should be the subject of review. Reviewing the effectiveness of internal control is the responsibility of the board having regard to any information provided by the audit committee, or any other board committee. Internal audit's role is seen as evaluating the risk and monitoring the effectiveness of the system of internal control. The Turnbull report concludes that an objective and adequately resourced internal audit function should be in a position to provide the board with much of the assurance it requires regarding the effectiveness of the system of internal control.

4. The NHS has embraced the principles of good governance through its complementary corporate governance and clinical governance initiatives. Corporate governance in the NHS has been a carefully managed three stage process, which is on-going, involving the:

   • development of a framework of corporate accountability;

   • improvements in the organisation and staffing of internal audit; and

   • development of *controls assurance*, an innovative approach to governance built on world-wide best practice relating to all internal controls (not just finance) including risk management.

5.   Clinical governance is the lynchpin of the Government's strategy for ensuring that quality of care becomes the driving force for the development of health services in England. Clinical governance is defined as "a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (HSC(99)065). It aims to deliver a new approach to quality through the creation of a systematic set of mechanisms, or controls, many of which echo the principles of corporate governance. The task of implementing clinical governance is at this stage primarily developmental and will require a fundamental shift in the culture of many NHS organisations, a shift that may take several years to effect. During this period the interface between clinical governance and controls assurance will require careful handling to ensure that both initiatives proceed at a mutually acceptable level and pace.

Controls assurance

6.   Controls assurance is a holistic concept based on best governance practice. It is a process designed to provide evidence that NHS organisations are doing their "reasonable best" to manage themselves so as to meet their objectives and protect patients, staff, the public and stakeholders against risks of all kinds. This process is complementary to, and proceeds in tandem with, developments in clinical governance and risk pooling in the NHS.

7.   The cornerstone of the controls assurance process is the requirement on Boards of NHS organisations to produce statements of assurance that they are doing their "reasonable best" to manage their affairs efficiently and effectively through the implementation of internal controls to manage risk. Under EL(97)55 and HSC(98)70 health bodies are already required to produce controls assurance statements in respect of financial controls to accompany the Annual Accounts. This requirement is now extended to risk management and organisational controls covering non-financial, non-clinical risk areas by a controls assurance statement accompanying the Annual Report from 1999/2000 (paragraph 18).

8.   Fundamental to the principles of controls assurance is the effective involvement of people and functions within an NHS organisation to ensure objectives are met and risks are properly controlled in accordance with the dictum 'systems make things happen but people make it work'.

9.   Controls assurance has been well received by the service and others, including the National Audit Office, Audit Commission, Health and Safety Executive, British Association of Medical Managers and by an increasing number of international organisations.

Benefits of controls assurance

10.   Controls assurance underpins the development of clinical governance (paragraph 14) and will help minimise financial contributions to the new risk pooling schemes (see paragraphs 16 and 17). There are potentially significant *additional* benefits to be gained from implementing controls assurance in respect of risk management and organisational controls. These include:

reduction in risk exposure through more effective targeting of resources to address key risk areas;

improvements in economy, efficiency and effectiveness resulting from a reduction in the frequency and/or severity of incidents, complaints, claims, staff absence and other loss;

demonstrable compliance with applicable laws and regulations;

enhanced reputation through public disclosure of achievements in meeting objectives and managing risk; and, consequently,

increased public confidence in the quality of services provided by the NHS.

11. Controls assurance will help all Chief Executives of NHS organisations to discharge their duties, as accountable officers, effectively and efficiently. Controls assurance will also provide timely and reliable risk management and control information to enable the Chief Executive of the NHS Executive to provide assurance statements to Parliament and the public in accordance with best governance practice.

The controls assurance project

12.   The NHS Executive's controls assurance project is being managed by the Controls Assurance Team under the auspices of the Director of Finance and Performance and the NHS Corporate Governance Group. The project aims to help the NHS realise the benefits of effective risk management. The fundamental objectives of the project are to:

- develop and maintain a comprehensive 'control framework' comprising detailed risk management and organisational controls standards and assessment criteria (paragraphs 18 and 19);

- establish a system of regional and national reporting, monitoring and performance benchmarking based on the control framework;

- assist NHS organisations with implementation of the framework through the production of guidance, provision of training, development of web-based and other risk management networking, and identification of suitable computer software support systems (paragraphs 20-25); and

- establish a system of independent verification of organisational controls assurance statements required to be produced by NHS organisations from 1999/2000 (paragraphs 26-28).

Links between controls assurance and other policies

13.   Controls assurance is an 'over-arching' policy which aims to devise a clear framework of control encompassing a range of other key NHS policies. There are particularly close links between controls assurance, the development of clinical governance and the various risk pooling arrangements administered by the NHS Litigation Authority.

Clinical governance

14.   Controls assurance and clinical governance go 'hand-in-hand' linked principally through risk management processes. Clinical governance provides assurances on the mechanisms (or controls) in place to improve the quality of clinical care and manage clinical risk (HSC(99)65). Implementing and maintaining effective systems of internal financial and organisational control are essential to ensuring the success of clinical governance, providing a solid foundation upon which to build an environment in which quality care can be provided and clinical excellence can flourish.
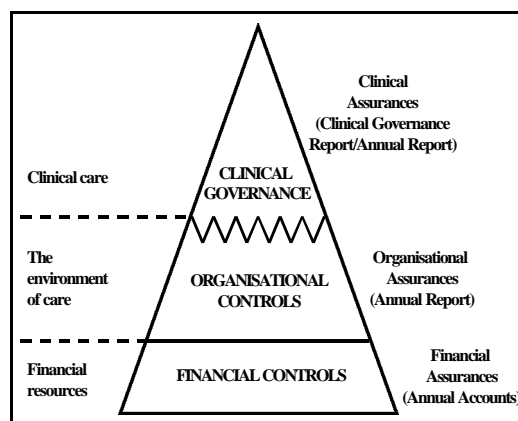

Figure 1 – Controls assurance and clinical governance

15.   Through close working between the Controls Assurance and Quality Management Teams, the synergies that exist between the two projects will be harnessed to best effect. A programme of joint research and development is planned for 1999/2000 and beyond. This will include:

- development of common standards for the recording, reporting, investigation and analysis of incidents, complaints and claims across 'clinical' and 'non-clinical' areas. This project will build on some of the experiences of the NHS in developing standards and computer software to enable both clinical and non-clinical incidents, complaints and claims information to be reliably recorded, reported, analysed and thoroughly investigated to determine underlying causes and enable lessons to be learned from experience. It is planned that these standards will be published during 1999/2000 to coincide with and complement the report by the Chief Medical Officer's Expert Advisory Committee on 'Learning from Experience'.

- development of standards aimed at integrating *systems* for 'clinical' and 'non-clinical' risk management. A holistic approach to clinical and non-clinical risk management is needed with mechanisms for prioritising the portfolio of risks being managed by NHS organisations, and in particular by NHS Trusts. It is planned that these standards will be available by 1 April 2000 and will form the basis of a wider controls assurance statement covering clinical standards from 2000/2001.

Risk pooling schemes

16.   The NHS Litigation Authority (NHSLA) administers the Clinical Negligence Scheme for Trusts (CNST). Trusts' contributions to this national risk pool are determined by their adherence to 'clinical' risk management standards which were published by the NHSLA in 1996. The NHSLA and the Controls Assurance and Quality Management Teams are working together to refine these standards as the basis for future developments in standards for clinical risk management to support clinical governance requirements (paragraph 15).

17.   From 1 April 1999 two new NHSLA-administered national risk pooling schemes for non-clinical areas, covering property and liabilities to third parties, have replaced the majority of commercial insurance cover currently taken out by NHS Trusts (HSC(99)21). Adherence to the risk management and organisational controls standards being developed for controls assurance will help to determine NHS Trusts' future contributions to these new risk pools. The NHSLA and the Controls Assurance Team, supported by specialist input from NHS Estates and other key stakeholders within the Department of Health and the NHS, are working together to ensure production of a uniform set of standards to meet the requirements of this circular and the new risk pooling schemes (paragraph 19).

PART II - IMPLEMENTING CONTROLS ASSURANCE COVERING RISK MANAGEMENT AND ORGANISATIONAL CONTROLS

The control framework

18.   Figure 2 outlines the key components of the NHS Executive's framework for controls assurance. From 1 April 2000 each NHS Trust and Health Authority will be required to sign a statement of assurance relating to 'organisational' controls, including risk managgement, contained within its Annual Report. A model statement is provided in Appendix 2 and further guidance on the production of an appropriate statement will be provided in the forthcoming 'Guidelines for implementing controls assurance in the NHS' (paragraph 21).
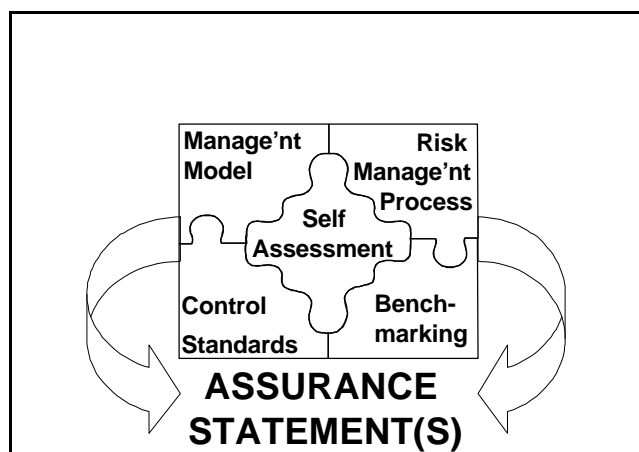
Figure 2 – Control framework

19.   The control framework is designed to provide boards of NHS Trusts and Health Authorities with the confidence needed to sign such a statement. At the heart of the framework is the concept of self assessment whereby NHS organisations will establish appropriate internal arrangements to continuously assess their performance in meeting their objectives and managing risk. The following tools are required to support self assessment. Additional, more detailed, guidance will be contained in 'Guidelines for implementing control assurance in the NHS'.

- **Management model** – a range of management models exist which can help NHS organisations apply a logical, systematic management framework to the process of self assessment. These include the European Foundation Quality Model (EFQM), the Canadian Criteria of Control (CoCo) and the American Committee of Sponsoring Organisations (COSO). Both CoCo and COSO were referred to in previous guidance issued by the NHS Executive (FDL(97)22). The NHS Executive commends use of the European Excellence Model (Figure 3). This model is supported by the Cabinet Office, is widely applied in the public sector and is increasingly being used by NHS organisations. Guidance on application of this particular model will be contained, as an exemplar of use of such a model, in the forthcoming 'Guidelines for implementing controls assurance in the NHS'. It is stressed that NHS organisations are not bound to use this or any other model. They must use an approach which best satisfies their requirements. Further information on EFQM can be obtained from the European Foundation for Quality Management (http://www.efqm.org).

- **Risk management process** – the generic process proposed for risk management is that documented in the Australian/New Zealand Standard (paragraph 20).
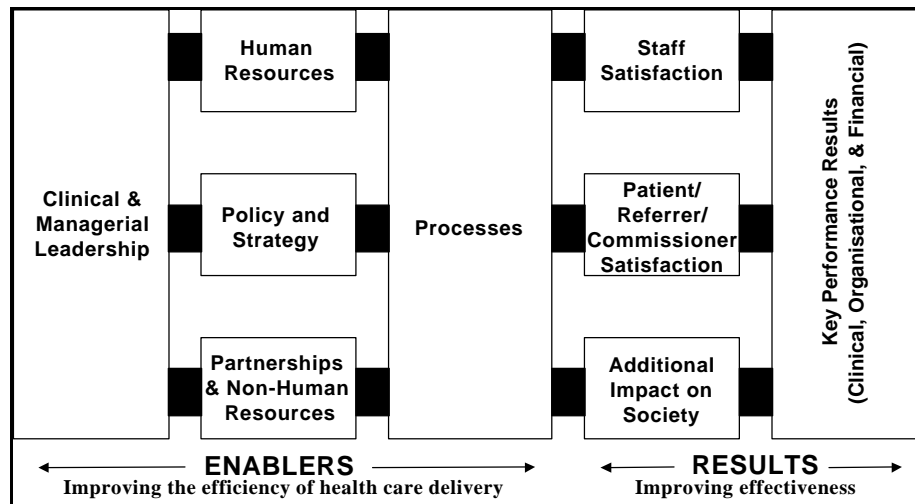
Figure 3 – European Excellence Model applied to health care

- **Standards and criteria** – the Controls Assurance Team, in association, where relevant, with the NHSLA, Quality Management Team, NHS Estates and other stakeholders, is developing a coherent set of risk management standards and supporting criteria arranged into key modules as follows:

  - **Risk management –** standards and criteria covering the key requirements of a system which should be in place to manage risk. These are outlined in Appendix 1 and will be issued separately with the forthcoming 'Guidelines on implementing controls assurance in the NHS' (see also paragraph 15).

  - **Financial controls –** standards and criteria covering the key requirements for managing risks associated with financial resources. These standards are referred to as the Internal Financial Control Evaluation standards and are contained in HSC(98)70.

  - **Organisational controls –** standards and criteria covering key areas of organisational risk. Seventeen standards are currently under development and are listed in Appendix 1. These will be issued separately including guidance on interpretation of the criteria and outlining verification requirements.

  - **Clinical controls** – standards and criteria for managing risks associated with clinical processes (clinical risk management) are being developed by the Quality Management and Controls Assurance Teams, in conjunction with relevant stakeholders, based on the existing NHSLA standards used in respect of the CNST (see also paragraph 15).

    Within each standard the criteria are being arranged into three levels (1, 2 and 3) broadly reflecting the current CNST approach. Level 1 is concerned with ensuring that relevant policies and procedures are in place and being implemented. Level 2 requires evidence that policies and procedures are being implemented successfully throughout the organisation. Level 3 requires evidence of the existence of a continual improvement process based on self assessment with benchmarking arrangements in place and working effectively for the benefit of the organisation.

- **Benchmarking** – a comprehensive national and regional benchmarking scheme is currently under development and planned for implementation on the controls assurance website (http://www.doh.gov.uk/riskman.htm) from 1 April 2000. Initially this will focus on incidents, complaints and claims together with compliance with key standards and criteria as outlined above. A feature of this scheme will be electronic collection of relevant data from existing risk management software in common use in the NHS (paragraphs 24-25).

Australia/New Zealand Standard 4360:1999 – Risk management

20.   AS/NZS 4360:1999 provides a generic non-prescriptive standard for managing any type of risk in any organisation. The principles outlined in the standard are universal and can be applied in any health care risk management context – financial, organisational or clinical. Figure 4 provides an overview of the risk management process documented in the standard. This process is an integral component of the control framework outlined above. It is anticipated that the standard will be made available along with the planned 'Guidelines for implementing controls assurance in the NHS' document.
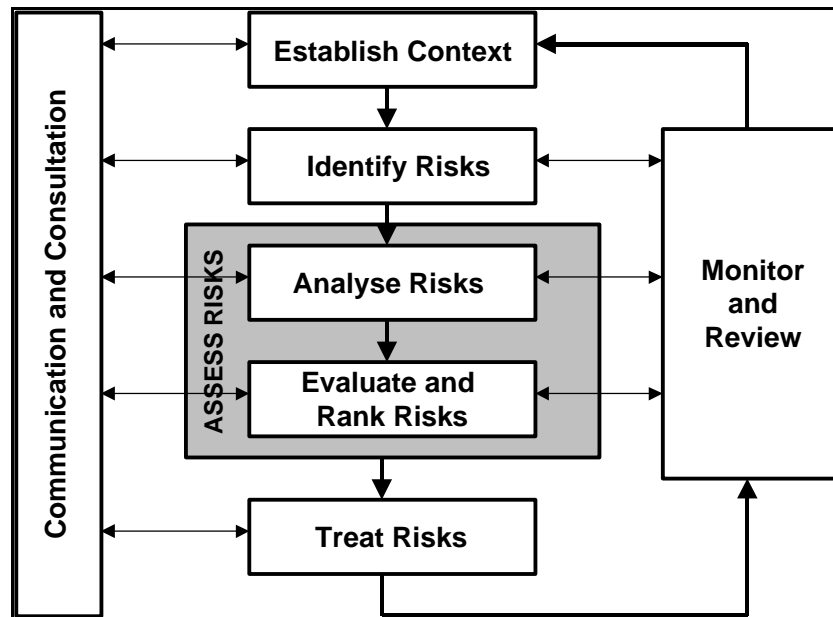
Figure 4 – Risk management overview
(from AS/NZS 4360:1999 – Risk management)

Guidance

21.   The NHS Executive's 'Risk management in the NHS' document, published in December 1993, has served the NHS well but needs updating. To meet the requirements of governance in 'The new NHS', the NHS Executive, in collaboration with a number of NHS organisations, is developing 'Guidelines for implementing controls assurance in the NHS'. This publication will be based on the concept of self assessment using the European Excellence Model as an exemplar, together with the risk management process outlined in the Australian/New Zealand risk management standard. The guidelines will be supplemented by the standards and criteria contained in the NHS Executive's control framework. The guidelines will replace the 'Risk management strategy evaluation guide' referred to in HSC(98)70 and will be issued separately in October 1999. The publication will also be available in electronic format on the controls assurance website (http://www.open.gov.uk/doh/riskman.htm).

Training

22.   Perhaps the most crucial 'success factor' for the controls assurance project will be delivery of

high quality, accredited training on implementing the control framework. The Controls Assurance Team, in association with the NHSLA and NHS Estates, is working closely with the Institute of Risk Management (IRM) to develop and accredit suitable training courses with a view to commencing a programme of regional training in October 1999. The IRM is the foremost risk management education and training accreditation body with an annual examination programme with more than 1800 papers covering 10 subjects examined in 35 countries world-wide. The chairman of the IRM's education and training committee has been appointed to develop an appropriate training syllabus and accreditation arrangements. Training courses will also meet the requirements of the new non-clinical risk pooling schemes. Specialist accredited training courses will be developed for Internal Audit practitioners wishing to provide specialist services relating to the verification of organisational controls assurance statements (paragraphs 26-28). The service will be notified no later than 31 August 1999 on the content and arrangements in respect of these training courses.

Risk management networking

23. Many groups concerned with various aspects of risk management can be found across the NHS. A compendium of known groups has been compiled by a number of NHS risk management professionals and will be sent separately to those with designated responsibility for overseeing implementation of controls assurance in respect of risk management and organisational controls by 31 July 1999. It will also available on the controls assurance website (http://www.doh.gov.uk/riskman.htm).

Software

24. Interest has been expressed across the service in relation to providing a common computer-based system or systems for controls assurance. Such a system should enable NHS organisations to conduct an electronic assessment against standards, produce and maintain a risk register, and robustly plan and prioritise the implementation of risk controls with responsibilities clearly assigned. A common system would help ensure that the requirements of controls assurance are met and benefits are achieved in the most efficient and effective manner. A common system would also enable assurances to be aggregated regionally and nationally and would facilitate benchmarking and networking.

25. The NHS Executive has commissioned an independent review of software packages for controls assurance. The results of this review, including any recommendations, will be sent to those with designated responsibility for controls assurance as soon as it is available.

Independent verification of the organisational controls assurance statement

26. The draft guidance contained in the Turnbull report (paragraph 3) advocates internal audit as the key function to provide the board with much of the assurance it needs regarding the effectiveness of the system of internal control. In addition, the results of consultation in relation to HSC(98)70 combined with other studies strongly indicate the need for internal audit to take the lead in the independent verification of organisational controls assurance statements. It is planned, therefore, to provide specialist training to selected internal auditors to complement their existing financial systems audit skills with risk management systems audit expertise.

27. It is not the intention to train internal auditors to become risk professionals. Rather it is intended to impart the knowledge necessary for internal auditors to work closely with relevant technical specialists (e.g. NHSLA, NHS Estates, Health and Safety advisers, risk managers/advisers, estates and facilities professionals etc.) in order that they can be reasonably assured that the relevant technical standards are in place and working effectively. In this way internal audit can share its systems audit expertise with other colleagues so as to offer an integrated approach to boards in the review of internal controls. It is anticipated that a 'Chief Internal Auditor Report on Risk Management and Organisational Controls' will be produced annually in relation to the auditee's statement and this report will be submitted to the relevant committee or group (e.g.

audit committee, clinical governance committee, risk management committee, etc). Guidance on the independent verification of organisational controls assurance statements together with a model Chief Internal Auditor Report will be published to coincide with the introduction of appropriate training courses for internal auditors.

28. External verification of risk management and organisational controls assurance statements (Figure 5) needs to be considered carefully, particularly in the light of the proposed establishment of the Commission for Health Improvement (CHI) towards the end of 1999 (subject to Parliamentary legislation) and plans to encourage joint working between the CHI and the Audit Commission. The Controls Assurance Team is working closely with the Quality Management Team and the Audit Commission to identify an optimum external verification methodology. The Controls Assurance Team plans to invite the Health and Safety Executive (HSE), the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) to participate. The results of this exercise will be published by April 2000.
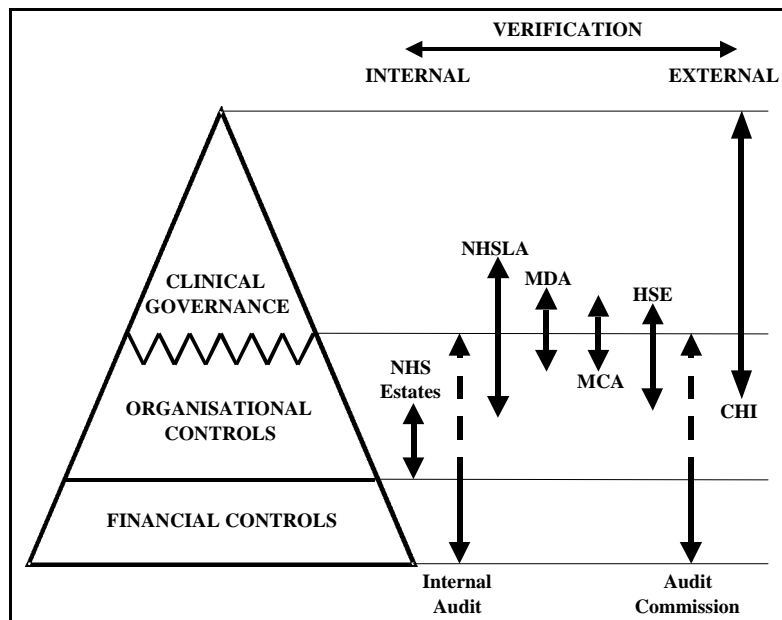
Figure 5 – Independent verification

Consultation with the health service

29. The NHS Executive and the NHS Corporate Governance Group would be pleased to receive views and comments on any aspect of this guidance addressed to:

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APPENDIX 1 – RISK MANAGEMENT AND ORGANISATIONAL CONTROL STANDARDS

RISK MANAGEMENT
Leadership and commitment
Policy and strategy
Planning, organising and resourcing
Risk management process
Incident reporting and investigation
Complaints handling
Claims management
Measurement and evaluation
Audit
Review and improvement

ORGANISATIONAL CONTROL STANDARDS
Buildings, land, plant and non-medical equipment
Catering and food hygiene
Contracts and contractor control
Emergency preparedness
Environmental management
Fire safety
Health and safety
Human resources
Infection control
Information management and technology
Medical equipment and devices
Medicines management
Professional and product liability
Records management
Security
Transport
Waste management

APPENDIX 2 – Model controls assurance statement covering organisational risks and controls

The following model statement is based on the consultation guidance issued by the Turnbull Committee (paragraph 3) together with earlier work carried out by the Devon and Cornwall Audit Confederation. It is intended to be a helpful indication of the kind of assurance a Board might reasonably be expected to make in its 1999/2000 Annual Report. Further guidance on the production of controls assurance statements will be provided in the forthcoming 'Guidelines for implementing controls assurance in the NHS'.

Model Statement

The Board of [Dingley Dell NHS Trust] acknowledges and accepts its responsibility for the organisation's system of internal control and for reviewing its effectiveness in providing reasonable assurance against material misstatement or loss.

"I, as the Chief Executive of [Dingley Dell NHS Trust], confirm for the period [1 April 1999] to [31 March 2000] that the Board has:

- established a system to ensure compliance with Level 1 of the NHS Executive's standards and criteria for risk management and organisational controls (Note 1);
- begun a process of self assessment involving the board and staff in identifying key strategic and operational risks;
- established a system of regular reporting to the Board in respect of the same; and
- ensured that there are proper arrangements for the independent verification of the above by Internal Audit on a continuous basis."

During this period there have been no significant events or situations requiring disclosure.

Signed: _____ Chief Executive   Date: _____

Note 1:   Risk management
          Buildings, land, plant and non-medical equipment
          Catering and food hygiene
          Contracts and contractor control
          Emergency preparedness
          Environmental management
          Fire safety
          Health and safety
          Human resources
          Infection control
          Information management and technology
          Medical equipment and devices
          Medicines management
          Professional and product liability
          Records management
          Security
          Transport
          Waste management