East Cheshire NHS
NHS Trust

POLICY AND PROCEDURES FOR THE ACCEPTANCE CHECKING OF MEDICAL DEVICES & EQUIPMENT ENTERING THE ORGANISATION

Medical Engineering Manager

V2 Aug 2012

Policy Title:	Policy and Procedures for the Acceptance Checking of Medical Devices & Equipment Entering the Organisation
Executive Summary:	Acceptance checks are defined as those tests and checks that are performed on newly delivered equipment and devices entering the organisation for the first time. These checks enable damaged, faulty or incorrectly supplied items to be identified at an early stage, thus minimizing any risk to the wellbeing of patients and staff before the items are used for the first time. This policy applies to ALL medical equipment and devices and includes equipment that is either purchased, leased, loaned, rented or on trial, whether they are electrically powered or not.
Supersedes:	V1
Description of Amendment(s):	References

This policy will impact on:

All users of medical equipment and devices.

Financial Implications:

Policy Area:	Corporate	**Document Reference:**	
Version Number:	**2**	**Effective Date:**	Jan 2013
Issued By:		**Review Date:**	Jan 2016
Author: **(Full Job title)**	Medical Engineering Manager	**Impact Assessment Date:**	Jan 2013

APPROVAL RECORD

	Committees / Group	**Date**
Consultation:	Medical Devices Group	Sept 2012
Approved by Committee:	Risk Management Sub-committee	Jan 2013
Received for information:		

Summary

Acceptance checks are recommended by the Medicines and Healthcare products Regulatory Agency (MHRA). They are defined as those tests and checks that are performed on newly delivered equipment and devices entering the organization for the first time.

These checks enable damaged, faulty or incorrectly supplied items to be identified at an early stage, thus minimizing any risk to the wellbeing of patients and staff before the items are used for the first time.

This policy applies to ALL medical equipment and devices and includes equipment that is either purchased, leased, loaned, rented or on trial, whether they are electrically powered or not.

IT IS IMPORTANT THEREFORE THAT NO MEDICAL EQUIPMENT AND/OR DEVICES MUST BE PUT INTO USE BEFORE SOME FORM OF ACCEPTANCE CHECKS HAVE BEEN PERFORMED.

For advice on medical equipment management issues, please contact any of the following:

Medical Engineering Department	Tel:	1930 MDGH
Medical Devices Co- Ordinator	Tel:	1981 MDGH
Infection Control Team	Tel:	1597 MDGH

CONTENTS

1. Introduction

Acceptance checks are defined as those tests and checks that need to be performed on newly delivered equipment and devices as they enter the organization for the first time. They enable damaged, faulty or incorrectly supplied items to be identified at an early stage before they are put into use.

Acceptance testing is recommended by the Medicines and Healthcare products Regulatory Agency (MHRA).It applies to all medical equipment and devices and includes equipment that is either purchased ,leased, loaned, rented or on trial, whether they are electrical or not.

There are risks to the wellbeing of patients and staff associated with not performing these tests before the items are put into use for the first time. Therefore to minimize these risks , medical equipment and devices must not be put into use before some form of acceptance checks have been performed.

2. Policy Statement

This “Policy and Procedures for the Acceptance Checking of Medical Devices & Equipment Entering the Organisation “describes the system to manage those risks identified above .It has been designed to satisfy the requirements of the Medical Devices and Equipment Management HSC2010 Controls Standard Framework, category: Accountability-Criterion 9 and 10.

The policy uses guidance published by the National Audit Office and the MHRA, formerly the Medical Devices Agency (MDA).

3. Background

The National Audit Office and the MHRA recommend some form of acceptance testing for all new medical equipment and devices entering a healthcare organization.

When a device is first put into service, records need to be created or updated, staff need training and maintenance regimes put into place. Potential users should also be made aware when they are first to use new equipment or devices.

Many tests specified in national or international standards are so called “type tests” which usually pose severe challenges to the equipment not normally associated with everyday use and are carried out by the manufacturer or a test house .Individual product items subjected to type tests are never put into service in case the test has caused some damage .Therefore, type tests must never be used by any employee of a Trust as a basis for its own pre- use tests.

Acceptance checks are used solely to minimize the risks associated with using newly delivered equipment, not to provide a belated critique of purchasing decisions .The quality,

suitability, conformity to standards, running costs, user training and maintenance of the device or equipment MUST be addressed before purchase.

4. Managerial and User's responsibilities

Chief Executive

Is ultimately accountable and responsible for the implementation of all policies within East Cheshire NHS Trust and to make sure an appropriate system is in place for the management and review of all policies in a given timeframe.

Medical Director

Where Directors are asked to ratify Trust policies, the Director is responsible for the review of the policy and the final ratification prior to its implementation. This ratification process will take place following the consultation and approval process. The Medical Director is the nominated Director on the Trust board.

Associate Director for Estates is responsible for ensuring that the appropriate policies and processes are in place within the Estates Team to provide assurance of compliance with statutory regulations and national guidance.

Head of Estates Operations is accountable for ensuring systems and processes are in place within the Medical Engineering Department that provides effective controls and assurances in relation to the operationalization of this policy within the Estates team.

Supplies Manager is responsible for ensuring that the correctly ordered equipment is delivered to the department undamaged, liaising between company and department on issues with orders and delivering to the medical engineering department or appropriate department for acceptance checking when appropriate. Any damage to packaging must be brought to the attention of the department who ordered the equipment or who are acceptance checking it.

The Medical Engineering Manager is responsible for managing the medical engineering team and ensuring that staff implement the policy and processes outlined within this document for equipment checked by the department prior to installation/delivery to the ward/ department. The Medical Engineering Manager is responsible for reviewing this policy every three years or when national guidance or regulations change.

Medical Engineering Team members are responsible for implementing the policy in practice and the completion of the appropriate documentation. When equipment is found to be substandard, damaged or faulty, they are responsible to highlight concerns to the Medical Engineering Manager.

Medical Devices Coordinator is responsible for updating the medical devices training log and central devices register following notification of receipt of new equipment to the Trust.

Associate Directors, Lead Nurses, Matrons and Ward or Departmental Managers of Business units have a responsibility to ensure that key clinical staff are identified to implement, monitor, and evaluate the policy within their clinical areas. Incidents relating to medical devices should be reported via the DATIX incident reporting system and any Risk Registers.

End – users (ward or departmental managers) are responsible for ensuring checklists for non-

portable equipment installed are completed and informing the Medical Devices Coordinator of the new equipment. Where NHS indemnity is required in the case of equipment that is loaned to the Trust or transferred free of charge, managers are responsible for ensuring that the appropriate indemnity forms are completed and appropriately stored within the respective testing department and copies kept on the department if required .Incidents relating to medical devices should be reported via the DATIX incident reporting system.

Medical Devices Group is responsible for approving this policy and monitoring medical devices incidents reported across the Trust, including near misses where local procedures and staff actions have been reported as not complying with this policy.

Review

This policy will be reviewed on a 3 yearly basis by the Medical Engineering Manager and approved by the Medical Devices Group and the Risk Management Sub committee.

5. Suitable systems of work

It is essential that the Trust satisfies itself that newly delivered medical equipment and devices are checked to ensure that:

- The correct product , complete with user and, if applicable , maintenance manuals have been supplied.
- It has been delivered undamaged in good condition and in usable order.
- Risks associated with using the equipment for the first time have been minimized.

Additionally for re- usable equipment and devices it is necessary to:

- Ensure compliance with current legislation (Health & Safety at Work Act etc 1974, 1990).
- Record the details of the device onto the computer databases for maintenance and capital assets.
- Verify any user training needs.
- Verify maintenance requirements.
- Verify the technical support needs of the users.

The MHRA state that Trust's should keep records of any maintenance or safety tests of reusable medical equipment for a minimum of eleven years. Health and Safety Inspectors will expect to see evidence of these records upon request. The Medical Engineering Department manages the records for the reusable equipment that it maintains or acceptance checks it performs, on its computerised database. It is therefore essential that Medical Engineering is contacted before any medical equipment is used for the first time to ensure that the device can be checked and the records updated if they are to be held on their database.

The aims of these checks are relevant to all medical devices and equipment, not just those that are electrically powered.

Acceptance checks and tests are only effective when the individuals performing them have appropriate knowledge and skills required to carry them out. It is essential that all persons performing the checks have the necessary technical skills, where appropriate. A basic understanding of the Trusts' ordering and inventory systems and knowledge of the names and appearances of the medical equipment or devices undergoing the checks are also required.

The checks and tests that follow apply to products that are brand new and CE-marked under the Medicines And Healthcare products regulatory agency (MHRA). See the flowchart in Figure 1 below for guidance.

ACCEPTANCE PROCEDURE FLOWCHART

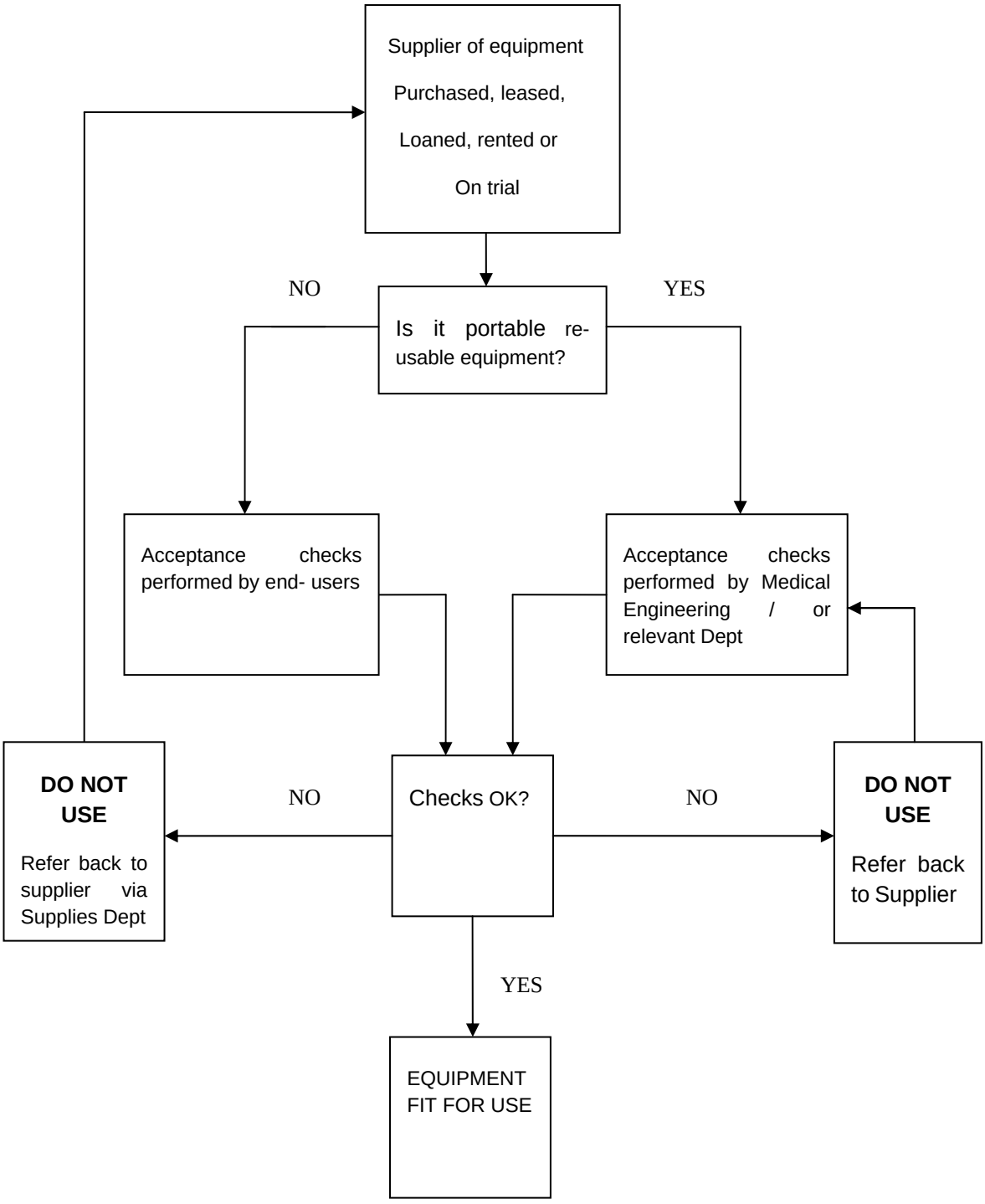

Fig. 1

6. Checks for portable electro-mechanical medical equipment and devices.

This task will normally be undertaken by the Trusts Medical Engineering Department and includes equipment such as infusion pumps, ECG recorders, defibrillators, pulse-oximeters, blood pressure monitors, patient monitors, ventilators, baby incubators, anaesthetic equipment, pressure care equipment, nebulisers, diagnostic laboratory equipment, etc.

When placing the order with the supplier, the Trusts Supplies Department will usually arrange the delivery of the item(s) to the Medical Engineering Department, who will perform the checks or arrange for them to be performed on equipment and devices within this category. If potential users of new equipment have by-passed this procedure, it is essential to inform Medical Engineering on 01625 661930 before it is put into use for the first time.

The following procedure applies to equipment and devices that are either purchased, leased, loaned, or on trial. A checklist for this type of equipment is reproduced in Appendix A and may be photocopied use.

Upon receipt of the delivery it is essential to check that:

a. There is no damage to any outer packaging used for transit.

b. The product is undamaged, exactly as ordered, and corresponds with the delivery note.

c. It is complete with accessories and manuals.

d. Perform a visual inspection of the equipment for damage or incompleteness.

e. It has CE or any other relevant markings on the equipment case.

If there are any discrepancies, contact the supplier immediately to seek redress.

If the initial checks are satisfactory, proceed with the following:

f. Perform a function check.

g. Carry-out any calibration or measurement checks.

h. Perform electrical safety checks to IEC60601 standard.

i. Record the details on the Trust's computerised databases and allocate the equipment a unique asset number.

j. Arrange the planned preventative maintenance schedule according to the manufacturers

recommendations.

k. Inform the Trusts Medical Device Co-ordinator that device training will be required for all potential users of the new equipment.

7. Checks for all other medical devices (sterile & non-Sterile)

These items can be single-use items such as prostheses, surgical gloves, tongue depressors, catheters, IV infusion sets, syringes, dressings and any other item usually supplied in quantity.

These items should enter the organization via the Supplies and Distribution Centre at Macclesfield District General Hospital. From there, the goods are distributed to the wards and departments that originated the requisition.

Once these items have been delivered to the end-users, the following procedure should be used and applies to equipment and devices that are either purchased, leased, loaned, rented or on trial.

A checklist for these devices is reproduced in Appendix B and may be photocopied for use.

Fortunately, basic checks follow a common-sense approach.

Upon receipt of the delivery it is essential to check that:

a. There has been no damage to any outer packaging used for transit.

b. The product is undamaged, is exactly as ordered, and corresponds with the delivery note.

c. Check for CE and any other relevant markings on the device.

d. Visually inspect the device or equipment for damage or incompleteness.

If there are any discrepancies, it is vital that the supplier is contacted immediately via the Trust Supplies Department to seek redress.

Key issues to be addressed by users of these items are:

e. Stock rotation and use-by dates: use the oldest product first.

f. It is important to be able to trace batch numbers or lots in the event of a product recall. Ensure that records of stock can be easily accessed and understood.

g. Disseminate instructions and safety information when necessary.

h. Check for damaged or faulty product packaging before opening.

8. Non-portable electro-mechanical medical equipment

This category of equipment usually includes fixed items such as x-ray rooms, whole body scanners, laboratory diagnostic equipment or equipment used for sterilizing other medical devices.

In most cases, the manufacturer, supplier or their agent will be responsible for the complete installation and commissioning process.

However a designated member of the Trust's staff ideally from the clinical area where the equipment is to be installed, should oversee the commissioning process and take responsibility to ensure that it has been completed satisfactorily.

Under the Medical and Healthcare products Regulatory Agency (MHRA), suppliers must provide instructions for installing this type of equipment and bringing it into service. This will include the performance specification and safety information plus any calibration data or information required to maintain the designed specification during its lifetime.

9. Other device categories

Some equipment or devices may need to be used by the Trust which fall into other categories, see the table below If there is a need to use any of these devices or equipment, then a full risk assessment must firstly be made of the particular item in question.

CATEGORY	EXAMPLES
Medical devices manufactured outside the scope of the MHRA	Manufactured before the regulations came into force. Purchased by an individual outside the European Union. Manufactured "in-house".
Devices which have , or may have been used before.	Bought second-hand. Owned by the patient or member of staff.
Devices manufactured within the scope of the MHRA but not CE-marked.	Custom-made for a named patient. Under clinical investigation.

If the risks outweigh the possible benefits on whether to use a particular device or not, then the correct decision will be not to use the equipment.

10. Equipment loaned by manufacturers or other organizations.

As part of the Trust's risk management process it is important that before use, all equipment or devices supplied on loan by manufacturers, their suppliers, or other healthcare organizations (public and private sector), undergo the acceptance checking procedure as outlined above.

It is vital that any equipment or device loaned by manufacturers or commercial suppliers is

covered by the NHS Forms of Indemnity and NHS Delivery Notes.

The Forms of Indemnity provide protection to the Trust when in receipt of loaned equipment or goods from a supplier or where the ownership of goods is being transferred free of charge to the Trust. The forms seek to achieve this by placing on the supplier the financial risk arising from certain types of damage to the equipment/ goods or to people or property.

If the supplier is not registered with this scheme it can still be loaned under their own indemnity insurance policy, a copy of which must be presented for inspection at the time of the loan.

Appendix C has complete details and guidance for the NHS indemnity system.

Devices or equipment loaned from other healthcare organizations will also need to undergo the acceptance checking procedure before use.

Also if the equipment or device is not of the portable re-usable type it will still be necessary to satisfy the indemnity insurance requirements

Loaned medical equipment and devices must not be used before the following conditions have been satisfied:

A. The supplier must complete a standard NHS delivery note and indemnity form if applicable.

B. A certificate of decontamination must accompany the equipment.

C. An acceptance check must be performed (if the equipment is of the portable re-usable type, as part of the acceptance checking procedure, the Medical Engineering Department will check the indemnity issue at the same time as recording the details of the loan equipment).

D. Any user training required to operate the equipment has been delivered.

References

(a) The Management of Medical Equipment in NHS Acute Trusts in England, The National Audit Office, London, 1999.

(b) Medical Devices And Equipment Management HSC 2010.

(c) Medicines and Healthcare products Regulatory Agency (MHRA) Managing Medical Devices DB2006 (05).

APPENDIX A

SUGGESTED CHECKLIST FOR RE-USABLE ELECTRO-MECHANICAL MEDICAL EQUIPMENT AND DEVICES	
Supplier	
Device type / model	
Serial number	
DOCUMENTATION	
CE Marked?	
Goods as ordered?	
Outer packaging undamaged?	
User manuals supplied?	
Maintenance manual supplied?	
Final test certificate supplied?	
FUNCTIONAL CHECKS	
Equipment undamaged?	
Indicator lamps light?	
Display as described in user manual?	
Self test passed?	
Moving parts operate correctly?	
User controls act correctly?	
Equipment passes tests in user manual?	
ELECTRICAL CHECKS	
Check integrity of mains lead	
Perform electrical safety checks	
Allocate new asset number	
IF LOAN EQUIPMENT	
Decontamination certificate seen?	
Signed:	**Date:**
Print Name and Job Title	
Inform Medical Device Co-coordinator of equipment details/ location if new type to the Trust.	

APPENDIX B

SUGGESTED CHECKLIST FOR MEDICAL EQUIPMENT AND DEVICES OTHER THAN RE-USABLE TYPES	
Supplier	
Device type / model	
DOCUMENTATION	
CE marked?	
Goods as ordered?	
Outer packaging undamaged?	
Inner packaging intact?	
Goods clean?	
User instructions supplied?	
Stock rotation procedures followed?	
IF LOAN EQUIPMENT	
Decontamination certificate seen?	
Signed :	**Date :**
Print Name and Job Title	
Inform the Medical Device Coordinator of equipment details/ location if new type to the Trust.	

APPENDIX C

GUIDANCE NOTES FOR SUPPLIERS FOR NHS FORMS OF INDEMNITY AND NHS DELIVERY NOTES

Part A Forms and Delivery Notes

1. The Forms of Indemnity provide protection to a trust when the trust is in receipt of equipment or goods from a supplier in cases where the equipment is being loaned to the trust or where the ownership of goods is being transferred free of charge to the trust. However the trust will remain liable for the cost of repairing accidental damage (except where caused by the Supplier).

2. NHS Form of Indemnity A ("Form A") is to be used for equipment on loan from a supplier to a trust. Only one Form A needs to be executed by a Supplier.

3. NHS Form of Indemnity B ("Form B") is to be used for goods in which the legal rights of ownership are to be transferred by the Supplier to the trust (namely, when the trust is the beneficiary of a gift from a Supplier). Only one Form B needs to be executed by a Supplier.

4. The forms may be executed by the trust or by PASA on behalf of all the trusts. The Forms are therefore drafted so that either the trust or PASA is the party and need to be completed and executed accordingly.

5. Before executing Form A or B, it is advisable that proof of the Supplier's public and product liability insurance is seen. The indemnity insurance must be in the name of whoever signs Form A or B. This will usually be the Supplier. Alternatively, where a Supplier is acting as an agent for a manufacturer and the manufacturer has signed Form A or B, the indemnity insurance must be in the name of the manufacturer. On expiry of the insurance, proof of renewal should be obtained from the Supplier (or manufacturer, where the Supplier is acting as an agent).

6. Form A states that the loan of the equipment shall not be deemed to be a contract for the hire of goods as per the Supply of Goods and Services Act 1982.

7. As the Sale of Goods Act 1979 (as amended) does not automatically apply to Form B (because the trust is not paying for the goods of which it is likely to become the owner), certain parts of it have been incorporated.

8. Forms A and B are to be executed as deeds to avoid the supplier's undertakings not being enforceable because of a lack of consideration (that is, a promise given by the trust, which prevents the supplier's promises from being purely gratuitous).

9. An NHS Delivery Note must be completed and signed by the Supplier and the Authority or the user of the equipment upon delivery of the goods or equipment.

10. The NHS Delivery Note contains different sections for completion according to whether the Delivery Note is being used in conjunction with Form A or Form B. In either case – i.e. use of Form A or B - the reference number given to the Form of Indemnity must be recorded on the Delivery Note so that it is clear which goods or items of equipment relate to which Form of Indemnity.

11. The NHS Delivery Note must record the details of the equipment including model/make, serial number, value and description. If appropriate, diagrams should accompany the Delivery Note. It should also state the intended purpose of the equipment, as the supplier is warranting that the equipment is fit for this stated purpose. For Form A the period of the loan should also be specified on the Delivery Note and trusts should ensure that they amend the expiry date should the original loan be extended. For Form A the Delivery Note will also need to state the premises at which the loaned equipment will be kept.

12. Provided that the transaction is one entered into at trust level, each Form of Indemnity and NHS Delivery Note, once entered into, should be retained by the trust. The NHS Purchasing and Supply Agency will not require a copy of either document.

13. If in doubt about any aspect of the Forms of Indemnity or the NHS Delivery Note you should contact PASA's purchasing helpdesk in the first instance.

14. If for any reason the equipment remains on the premises after the period of loan (covered by the indemnity) has expired then it remains at the Supplier's risk. In the absence of any agreement replacing that applicable during the term of the loan, the supplier should ensure that the equipment is removed as soon as the term ends.

Part B Completing the forms

15. Instructions

15.1 On the indemnity forms A and B on the first page, the company's name will need to be completed. Please leave the space for the date blank.

15.2 Two signatures by the supplier's director(s)/company secretary are required at the back of each indemnity form in the second block of signatures. The upper block is used for endorsement of the agreement by appropriate trust or PASA signatories (whichever is applicable).

15.3 Forms A and B bearing original signatures should be passed (normally by post) to PASA or the trust (whichever is applicable).

15.4 Proof of insurance for both public and product liability will also be required, showing a minimum of £5,000,000 cover for each.

15.5 Once the agreement has been checked, and signed by both parties, a copy will be posted to the supplier for retention.

15.6 Details will be included in the indemnity agreement list of suppliers published on the PASA website at http://www.pasa.nhs.uk/MIA/

15.7 Every time an insurance cover is about to expire, a letter will be issued to remind suppliers to send proof of the extended or new cover as promptly as possible. No new agreement needs to be signed at the expiry of the policy. Also, no confirmation of the update will be sent, as all details can be checked on the website (web address as in 15.6 above).

15.8 An NHS Delivery Note must be completed in relation to all goods and equipment delivered under indemnity forms A and B. This should be signed by an Authority representative and a Supplier representative upon delivery, to confirm delivery and acknowledge receipt.

15.9 For goods and equipment delivered under indemnity form A, the NHS Delivery Note can also be signed by an Authority representative and a Supplier representative upon collection, to confirm collection and acknowledge receipt.

Document revision control

File ref: Indemnity form guidance notes for Suppliers October 2008

Version	**Author/editor**	**Notes**	**Date published**
October 2008	David Brassington	Section 2 of Indemnity Form B revised to refer to current *NHS Conditions of Contract for the Purchase of Goods* (July 2007 edition)	October 2008
October 2007	David Brassington	Indemnity Form A, NHS Delivery Note and Guidance Notes revised: to discontinue use of suppliers' own delivery notes; to provide for signature of NHS Delivery Note by authorised representative of the Supplier; and to	1 October 2007

		provide for NHS Delivery Note to be used to confirm/acknowledge collection where Indemnity form A is used	
March 2004			March 2004

NHS Form of Indemnity – A **Reference Number [ ]**

Equipment on loan

Supplier:

Company Name			
Address			
		Postcode	
Contact name			
Contact e-mail			
Tel			

A DEED made the ……day of …….. …...201_ **BETWEEN:**

EITHER*

NHS Trust/NHS Foundation Trust/Health Authority*

("the Authority");

OR

The Secretary of State for Health ("the Department");

AND

Supplier

("the Supplier")

WHEREAS

The Supplier is the owner of equipment (the "Equipment") and wishes to make the Equipment available directly to the Authority or through the Department to NHS Trusts, NHS Foundation Trusts, Health Authorities and other users ("Users") agreed by the parties for a specified period in accordance with the terms of this Deed. The Equipment and the period for which the Equipment will be on loan to the Authority or the relevant User(s) shall be specified in an NHS Delivery Note completed by the Supplier and the Authority or the relevant User(s) at the outset of the loan. For the avoidance of doubt, there shall be no limit on the number of NHS Delivery Notes which may be completed pursuant to this Deed. "Equipment" shall be deemed to include any part or parts of the Equipment and all replacements and additions supplied by the Supplier during the continuance of this Deed.

IT IS HEREBY AGREED that the Supplier shall make the Equipment available to the Authority or the relevant User(s) by way of loan free of charge for the period agreed between the Authority or the relevant User(s) and the Supplier, at the premises ("the Premises") specified in the relevant NHS Delivery Note on the terms set out in this Deed:-

1. For the avoidance of doubt, this Deed is not a contract for hire pursuant to the Supply of Goods and Services Act 1982.

2. Title to the Equipment shall remain for all purposes fully vested in the Supplier.

*__Delete as appropriate__

3. The Equipment (other than Equipment which the Authority or relevant User(s) has taken on loan for the purposes of trial or evaluation at the request of the Supplier) shall at all times after its delivery to the Authority or the relevant User(s) be at the sole risk of the Authority or relevant User(s) as regards damage, loss or destruction. The Authority or the relevant User(s) shall be liable for the repair or replacement of any such Equipment which is damaged, destroyed or lost whilst in its possession or control.

4. Subject to Clause 5, Equipment which the Authority or relevant User(s) has taken on loan for the purposes of trial or evaluation at the request of the Supplier shall at all times after its delivery to the Authority or the relevant User(s) be at the sole risk of the Supplier as regards damage, loss or destruction and neither the Authority nor the relevant User(s) shall be under any obligation to keep the Equipment insured. For all pieces of Equipment on loan to the Authority at any one time the Supplier shall keep a record of the purpose of the loan and, when requested by the Authority upon reasonable notice, communicate the purpose of the loan to the Authority within a reasonable time.

5. The Authority or the relevant User(s), as the case may be, shall be liable for the repair of:

   5.1. any damage to the Equipment occurring at the Premises (or during transit in the event that the Authority or relevant User collects the Equipment pursuant to Clause 6) and caused by the Authority or the relevant User(s) failing to use or operate such Equipment in accordance with the express instructions of the Supplier; and

   5.2. any damage to the Equipment occurring at the Premises (or during transit in the event that the Authority or relevant User collects the Equipment pursuant to Clause 6) and caused by the act or omission of the Authority or the relevant User(s) their employees, agents or contractors or any third party beyond reasonable control of the Supplier.

6. The Supplier shall use its reasonable endeavors to deliver the Equipment to the Premises on a date agreed between the Supplier and the Authority or the relevant User(s). Except where carried out solely by the Authority or the relevant User(s), delivery shall be effected by the Supplier delivering the Equipment to the Premises or (if otherwise agreed) by the Authority or the relevant User(s) collecting the Equipment from the Supplier's premises or any other premises agreed by the parties. Unless otherwise agreed, the Authority or relevant User(s) shall be responsible for installation of the Equipment at the Premises such that it is in working order for use by the Authority or the relevant User(s). The Authority's responsibility shall also extend to any and all costs and damage caused by or arising out of the failure to correctly install the Equipment, provided always that it is the Authority which has installed the Equipment. For the avoidance of doubt, should the Supplier be responsible for installing the Equipment, the Authority shall have no responsibility to meet any costs and damage caused as a result of the installation.

7. Subject to Clauses 7.1 and 7.2 below, the Supplier shall indemnify and hold harmless the Authority, the relevant User(s) and the Secretary of State for Health against all losses suffered by the Authority, the relevant User(s) or the Secretary of State for Health:

   (i) in connection with any defect in the design or manufacture of the Equipment; or

(ii) arising directly as a result of the provision by the Supplier of negligent training or instruction in the use, or preparation for use, of the Equipment to the Authority, the relevant User(s) or the Secretary of State for Health

7.1. The Supplier shall not be liable for any loss suffered by the Authority, the relevant User(s) or the Secretary of State for Health to the extent that such loss was caused by the negligent acts or omissions of or breach of statutory duty by the Authority, the relevant User(s) or the Secretary of State, save where such acts, omissions or breaches were occasioned as a result of following the instructions of the Supplier or the Supplier's agents, employees or contractors. For the avoidance of doubt, but without prejudice to the generality of the foregoing, the following circumstances shall amount to negligent acts:

(i) a failure to use or operate the Equipment in accordance with the operating instructions and other relevant information of which the Authority or relevant User(s) has been made expressly aware by the Supplier; including failure to observe requirements for the safe disposal or reprocessing of the Equipment;

(ii) a failure by the Authority or relevant User(s) to ensure that the Equipment is operated by persons who have been made aware of the method of operation in accordance with Clause 9; and

(iii) use of the Equipment for a use or in a manner for which it was not intended.

7.2. The Supplier shall be liable for physical damage to the Premises resulting from its negligence up to a maximum of five million pounds (£5,000,000.00) (in respect of any one event or series of connected events).

(i) Nothing in this Deed shall exclude or limit the Supplier's liability for death or personal injury caused by its negligence or any liability the Supplier may have pursuant to the Consumer Protection Act 1987 to a person who has suffered damage caused by defective Equipment.

(ii) The Supplier shall not be liable for any loss of profit, income, business, revenue or goodwill or any indirect or consequential losses.

(iii) Without prejudice to Clauses 7.2 and 7.2(i) above, the Supplier's maximum aggregate liability arising in connection with (a) any defect in the design or manufacture of the Equipment or (b) the provision of negligent training or instruction in the use of, or preparation for use, of the Equipment, whether arising in contract, tort (including negligence) or otherwise, shall in no circumstances exceed five million pounds (£ 5,000,000.00) (in respect of any single event or series of connected events).

7.3. The Supplier does not accept and hereby excludes, any liability for negligence save as provided in this Clause 7.

8. The Supplier shall take out and maintain insurance cover with an insurer reasonably acceptable to the Authority or the relevant User(s) on terms sufficient to cover its liability to the Authority or the relevant User(s) and the Secretary of State for Health under this Deed and in any event with a minimum indemnity cover of £5 million in any year (or such other amount as may be agreed by the Authority or the relevant User(s) in writing). On request the Supplier shall provide documentary evidence of such insurance cover to the Authority or the relevant User(s). If at any time the Supplier shall default in its obligations to insure as aforesaid then the Authority or the relevant User(s) shall hereby be irrevocably appointed by the Supplier as the Supplier's agent to effect such insurance cover as the Supplier would have taken out and maintained and accordingly the Authority or the relevant User(s) shall recharge to the Supplier (who hereby undertakes to make payment to the Authority or the relevant User(s) promptly on demand) the full cost of effecting such insurance cover together with such sum as shall cover all costs reasonable incurred by the Authority or the relevant User(s) in effecting such insurance provided that such sum shall not exceed an amount equivalent to five per cent (5%) of the cost of the policy effected.

9. The Supplier shall provide to the Authority or the relevant User(s) instructions for use relating to the Equipment and detailed instructional manuals (where available) for the intended purpose stated by the Supplier, including any information and documents required by the Control of Substances Hazardous to Health Regulations 1999. The instruction manual shall accompany the Equipment and shall be in the English language and contain appropriate directions as to the operation of the Equipment. The Supplier shall provide a telephone number to the Authority which telephone line shall be manned during normal working hours by those of the Supplier's staff who are trained and qualified to deal properly with any enquiries the Authority or the relevant User(s) may have in relation to the operation of the Equipment. The Authority or the relevant User(s) will notify Supplier promptly of any fault or safety issue arising with or damage to the Equipment and will use its reasonable endeavours to ensure that the Equipment is not used until such fault or damage has been repaired or the safety issue resolved.

10. Where appropriate, the Supplier warrants and represents that the Equipment complies with the Essential Requirements of the Medical Devices Directive (93/42) and is CE marked. The Supplier further warrants that the Equipment is fit for the intended purpose for which the Equipment is supplied.

11. The Supplier and the Authority or the relevant User(s) shall complete and sign an NHS Delivery Note in relation to each item of Equipment to be covered by this Deed.

12. This Deed shall continue in force from the date hereof until it is terminated by either party in accordance with this clause. For the avoidance of doubt, the parties' obligations under this Deed shall apply only to Equipment which is in the possession of the Authority or the relevant User(s) from time to time and shall not apply to Equipment which has been returned to the Supplier in accordance with Clause 16. This Deed will terminate if either party serves on the other party not less than 3 months' written notice to expire at any time.

13. Upon termination of this Deed for whatever reason the Authority or the relevant User(s) shall forthwith provide the Supplier with written particulars of any contamination or other hazard including any safety hazard that has arisen in respect of the Equipment during the period in which the Equipment was on loan to the Authority or the relevant User(s)

sufficient to facilitate compliance by the Supplier with statutory and other reasonable requirements to make safe the Equipment, the contamination and any other hazard so that it may be maintained, repaired, removed, transported or otherwise dealt with by the Supplier as may be appropriate provided that the Authority or the relevant User(s) shall accept no liability whatsoever for any failure by the Supplier to make safe the Equipment or to deal with any contamination or other hazard in accordance with any statutory or other requirements whether or not such failure has arisen out of or is connected with any written particulars provided by the Authority or the relevant User(s) under this condition, except that the Authority or the relevant User(s) shall be responsible for any and all costs where Equipment is returned to the Supplier with insufficient or incorrect information of a hazard or contamination. If such contamination or other hazard has resulted from the failure of the Authority or the relevant User(s), their servants or agents to use the Equipment for the Supplier's intended purpose, the Authority or the relevant User(s) shall bear the reasonable cost of making safe the Equipment, the contamination and any other known hazard.

14. The Equipment shall not be modified or repaired by the Authority or the relevant User(s) without the prior written agreement of the Supplier.

15. Neither the Authority nor the relevant User(s) shall be liable for any charge for maintenance, repair, consumable materials or accessories required for the operation of the Equipment during the period in which the Equipment is on loan to the Authority or the relevant User(s) or for any carriage or installation charges except as provided in this Deed or by agreement and the issue of an official purchase order by the Authority or the relevant User(s).

16. Upon receipt of a written request at any time from the Authority or the relevant User(s) or at the end of the loan period specified in the relevant NHS Delivery Note, the Supplier shall remove the Equipment from the Premises with all practicable speed, free of charge, and at that time shall provide the Authority or the relevant User(s) with a receipt for the Equipment, and shall have the right to enter onto the Authority's or relevant User(s) premises to exercise such removal.

17. The Supplier shall provide the Authority or the relevant User(s) with reasonable written notice of the time at which it intends to remove the Equipment from the Premises in accordance with Clause 16.

18. The Supplier shall be solely responsible for the cost of making good and reinstating the Premises to the reasonable satisfaction of the Authority or the relevant User(s) following the removal of the Equipment provided always that if the Equipment is free-standing and not in any way attached to the fabric of the Premises then there shall be no obligation on the Supplier under this clause.

19. Nothing in this Deed shall create any obligation on the Authority or the relevant User(s) to purchase or take on paid hire either during the period of this Deed or at any time thereafter any quantity of the Equipment and the Supplier acknowledges that it has not relied on any representation on behalf of the Authority or the relevant User(s) as to any future business between the Supplier and the Authority or the relevant User(s) (except that nothing in this clause shall exclude the Authority's liability for fraudulent misrepresentations) and the Supplier warrants that neither the Authority nor any relevant User(s) is under any obligation to the Supplier in connection with the Equipment (save as expressly set out herein) or future orders therefore.

20. Each party, and its employees and agents, shall at all times keep confidential and secret and shall not (without the prior written consent of the disclosing party) disclose to any person any information or other matters acquired by the receiving party in connection with this Deed save where required to comply with the requirements of any regulatory or other competent authority or as otherwise required by law.

21. Nothing in this Deed is intended to confer on any person any right to enforce any term of this Deed which that person would not have had but for the Contracts (Rights of Third Parties) Act 1999. The parties acknowledge that the provisions of this Clause 21 shall not affect any right or remedy which exists or is available, whether express or implied, apart from the Contracts (Rights of Third Parties) Act 1999.

EXECUTED AND DELIVERED AS A DEED BY AND ON BEHALF OF: -

Name of NHS Trust/ NHS Foundation Trust/ Health Authority:-

[ ]

OR The Secretary of State for Health *

acting by:

Name:

Position:

Signature:

EXECUTED AND DELIVERED AS A DEED BY, FOR AND ON BEHALF OF: -

Supplier Name:

acting by:

1st Signatory

Name:

Position: Director/Company Secretary**

Signature:

2nd Signatory

Name:

Position: Director/Company Secretary**

Signature:

*****Delete as appropriate (the form should be executed by the Authority OR by The Department – see Guidance Notes)

** Delete as appropriate

Form of Indemnity – B **Reference Number [ ]**

Free issues

Supplier:

Company Name			
Address			
		Postcode	
Contact name			
Contact e-mail			
Tel			

A DEED made the ……day of …….. …...201_ **BETWEEN:**

EITHER*

NHS Trust/NHS Foundation Trust/Health Authority*

……. (“the Authority”);

OR

The Secretary of State for Health ("the Department");;

AND

Supplier …… ("the Supplier").

WHEREAS

The Supplier is the owner of goods (the "Goods") and wishes to transfer the legal and equitable title in the Goods to the or to NHS Trusts, NHS Foundation Trusts, Health Authorities and other users agreed with the Department in accordance with the terms of this Deed. The Goods shall be specified in an NHS Delivery Note completed by the parties at the time of the transfer. For the avoidance of doubt, there shall be no limit on the number of NHS Delivery Notes which may be completed by the parties pursuant to this Deed.

IT IS HEREBY AGREED that the Supplier shall transfer the legal and equitable title in the Goods to the Authority or the relevant User(s) free of charge on the terms set out below:

1. Sections 12 to 15 of the Sale of Goods Act 1979 (as amended) are to be implied into this Deed.

2. Clause 16 (Limitation of liability) and Clause 17 (Insurance) of the *NHS Conditions of Contract for the Purchase of Goods* (July 2007 edition) shall be incorporated into this Deed.

***Delete as appropriate**

EXECUTED AND DELIVERED AS A DEED BY AND ON BEHALF OF: -

Name of NHS Trust/ NHS Foundation Trust/ Health Authority:-

[ ]

<u>OR</u> The Secretary of State for Health *

acting by:

Name:

Position:

Signature:

EXECUTED AND DELIVERED AS A DEED BY, FOR AND ON BEHALF OF: -

Supplier Name:

acting by:

1st Signatory

Name:

Position: Director/Company Secretary**

Signature:

2nd Signatory

Name:

Position: Director/Company Secretary**

Signature:

*__Delete as appropriate (the form should be executed by the Authority OR by Secretary of State for Health – see Guidance Notes)__

__ Delete as appropriate__**

Form of Indemnity – B **Reference Number [ ]**

Free issues

Supplier:

Company Name			
Address			
		Postcode	
Contact name			
Contact e-mail			
Tel			

A DEED made the ……day of …….. …...201_ **BETWEEN:**

EITHER*

NHS Trust/NHS Foundation Trust/Health Authority*

…… (“the Authority”);

OR

The Secretary of State for Health ("the Department");

AND

Supplier …… ("the Supplier").

WHEREAS

The Supplier is the owner of goods (the "Goods") and wishes to transfer the legal and equitable title in the Goods to the or to NHS Trusts, NHS Foundation Trusts, Health Authorities and other users agreed with the Department in accordance with the terms of this Deed. The Goods shall be specified in an NHS Delivery Note completed by the parties at the time of the transfer. For the avoidance of doubt, there shall be no limit on the number of NHS Delivery Notes which may be completed by the parties pursuant to this Deed.

IT IS HEREBY AGREED that the Supplier shall transfer the legal and equitable title in the Goods to the Authority or the relevant User(s) free of charge on the terms set out below:

3. Sections 12 to 15 of the Sale of Goods Act 1979 (as amended) are to be implied into this Deed.

4. Clause 16 (Limitation of liability) and Clause 17 (Insurance) of the *NHS Conditions of Contract for the Purchase of Goods* (July 2007 edition) shall be incorporated into this Deed.

***Delete as appropriate**

EXECUTED AND DELIVERED AS A DEED BY AND ON BEHALF OF: -

Name of NHS Trust/ NHS Foundation Trust/ Health Authority:-

[ ]

OR The Secretary of State for Health *

acting by:

Name:

Position:

Signature:

EXECUTED AND DELIVERED AS A DEED BY, FOR AND ON BEHALF OF: -

Supplier Name:

acting by:

1st Signatory

Name:

Position: Director/Company Secretary**

Signature:

2nd Signatory

Name:

Position: Director/Company Secretary**

Signature:

***Delete as appropriate (the form should be executed by the Authority OR by Secretary of State for Health – see Guidance Notes)**
****** Delete as appropriate**

NHS Delivery Note

Date _____ day of _____ 200_____

Supplier _____

Form of Indemnity Reference Number _____

Authority _____

This NHS Delivery Note specifies the Equipment provided under the NHS Form of Indemnity with the reference number shown above.

Model/make _____

Serial Number _____

Value _____

Description _____

Purpose _____

Form of Indemnity A

Period of loan:

[ ] years and [ ] months commencing on [ ] day of [ ] 200[ ]

The trial/testing to be undertaken by the Authority (if any) _____

_____

Premises at which the Equipment will be kept:

_____

The Authority acknowledges receipt of the Equipment detailed above on the terms of the Form of Indemnity detailed above:

SIGNED on behalf of the Authority _____

The Supplier confirms delivery of the Equipment detailed above to the Authority for loan on the terms of the Form of Indemnity detailed above:-

SIGNED on behalf of the Supplier _____

Form of Indemnity B

The Authority acknowledges receipt of the Goods detailed above from the Supplier on the terms of the Form of Indemnity detailed above:-

SIGNED on behalf of the Authority _____

The Supplier confirms delivery of the Goods detailed above and transfer of the legal and equitable title to those Goods to the Authority as from the date hereof on the terms of the Form of Indemnity detailed above:-

SIGNED on behalf of the Supplier _____

Form of Indemnity A – collection at the end of the loan period

The Authority confirms collection by the Supplier of the Equipment detailed above:

SIGNED on behalf of the Authority _____

The Supplier acknowledges receipt of the Equipment detailed above:

SIGNED on behalf of the Supplier _____

DATE: _____

APPENDIX D – EQUALITY AND HUMAN RIGHTS IMPACT ASSESSMENT FORM

Part 1 – AIMS AND IMPLEMENTATION OF THE POLICY/PROCEDURE/STRATEGY/SERVICE SPECIFICATION

1.1 What is being assessed? Name of the policy, procedure, strategy or service specification (hereafter referred to as 'DOCUMENT'):

POLICY AND PROCEDURES FOR THE ACCEPTANCE CHECKING OF MEDICAL DEVICES & EQUIPMENT ENTERING THE ORGANISATION

1.2 Details of person responsible for completing the assessment:

- *Name: R Broadhurst*
- *Job title: Medical Engineering Manager*
- *Team: Estates*

1.3 What is the main purpose or aims of the document?

(*this is usually the first paragraph of what you are writing – cut and paste it here. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)*

Acceptance checks are recommended by the Medicines and Healthcare products Regulatory Agency (MHRA).They are defined as those tests and checks that are performed on newly delivered equipment and devices entering the organisation for the first time.

These checks enable damaged, faulty or incorrectly supplied items to be identified at an early stage, thus minimising any risk to the wellbeing of patients and staff before the items are used for the first time.

This policy applies to all medical equipment and devices and includes equipment that is either purchased, leased, loaned, rented or on trial, whether they are electrically powered or not.

1.4 Who is this document intended for?

Who will need to do something differently because of this document? Who will be affected by what this document covers? All staff or just a team? All patients or just those who use a particular service? Any other group?

Staff responsible for or involved with any medical devices.

How will the document be put into practice and who will be responsible for it?

(Who defined the document? Who implements the document? Does this document cover a particular team/Unit or does it link to another team, agency or contractor? If external parties are involved then what are the measures in place to ensure that they comply with the Trust's Equality and Diversity Policy?

Implementation

- **Chief Executive, General Managers and Heads of Department** – to appoint the appropriate personnel identified in Roles and Responsibilities.
- **Medical Devices Group-** to consider the full implications of Medical Devices and equipment entering the organisation.
- **Infection Prevention and Control** – To provide the trust with basic decontamination information and advice.

Part 2 – CONSIDERATION OF DATA AND RESEARCH

To conduct the assessment you will need information about service users, and the staff that provide the service. This section is to help you identify the sort of information that will needed to help you assess whether there may be barriers to different groups who are affected by this document.

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document (*include information where appropriate from other teams/units, census, patient or staff monitoring etc. Please note that in some cases data may not exist or be available and you may therefore have to undertake additional research. In this case, contact Adrian Barrowdale (01925 664425) or Lyn Bailey for support))*

Staff responsible for or involved with any Medical Devices and Equipment entering the organisation.

2.2 Profile of users or beneficiaries

What have you found out using this information? Are there any key groups of people who will be affected, or who have been over/under represented?

All Staff responsible for Medical Devices and Equipment entering the organisation.

2.3 Relevant consultation

Having identified key groups, how have you made sure that the document will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Medical Devices Group , Risk Management

2.4 Evidence of complaints relating to this document on grounds of discrimination. (Is there any evidence of complaints either from patients or staff (grievance) relating to the document or its effects on different groups?)

No.

2.5 Does the information gathered from 2.1 – 2.4 indicate any negative impact as a result of this document?

No.

Part 3 – ASSESSMENT OF IMPACT

Now that you have looked at the purpose, etc. of the document (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the document on each of the strands listed below. Only complete the boxes which are relevant to the data you have looked at – for any other boxes, you can write "N/A"

RACE – testing of disproportional and adverse impact

a. How are racial groups reflected in the numbers of people affected by this document? **N/A**
b. From the evidence available does the document affect, or have the potential to affect, racial groups differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

GENDER (INCLUDING TRANSGENDER) – testing of disproportional and adverse impact

a. How are different gender groups reflected in the numbers of people affected by this document? N/A
b. From the evidence available does the document affect, or have the potential to affect, different gender groups differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

DISABILITY – testing of disproportional and adverse impact

a. How are disabled people reflected in the numbers of people affected by this document? N/A
b. From the evidence available does the document affect, or have the potential to affect, disabled people differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

AGE – testing of disproportional and adverse impact

a. How are different age groups reflected in the numbers of people affected by this document? N/A
b. From the evidence available does the document affect, or have the potential to affect, age groups differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

LESBIAN, GAY, BISEXUAL – testing of disproportional and adverse impact

a. How are people with different sexual orientations reflected in the numbers of people affected by this document? **N/A**
b. From the evidence available does the document affect, or have the potential to affect, LESBIAN, GAY AND BISEXUAL people differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

RELIGION/BELIEF – testing of disproportional and adverse impact

a. How are people with different RELIGIONS OR BELIEFS reflected in the numbers of people affected by this document? N/A
b. From the evidence available does the document affect, or have the potential to affect, RELIGIOUS/BELIEF groups differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

CARERS – testing of disproportional and adverse impact

a. How are people with caring responsibilities reflected in the numbers of people affected by this document? N/A
b. From the evidence available does the document affect, or have the potential to affect carers people differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

OTHER – Additional factors that may affect impact (including Human Rights) - testing of disproportional and adverse impact

a. How are OTHER groups reflected in the numbers of people affected by this document? **N/A**
b. From the evidence available does the document affect, or have the potential to affect, OTHER groups differently? **Yes** ☐ **No** **x**
c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? *Reason/evidence/comment*

Part 4 - Safeguarding Assessment

For advice on completing this section, contact the Named Nurse for Safeguarding Children and Young People

CHILDREN - testing of disproportional and adverse impact

a. Is there a direct or indirect impact upon children? Yes ☐ No ☐ N/A
b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:
c. If no please describe why there is considered to be no impact / significant impact on children
The acceptance checking of medical devices & equipment entering the organization has no direct impact upon children.

Part 5 – CONSULTATION WITH EQUALITY AND DIVERSITY LEAD AND NAMED NURSE FOR SAFEGUARDING

At this point, you should forward the template to:

- **The Trust's Equality and Diversity Lead**
- **The Named Nurse for Safeguarding Children**

and arrange a meeting or telephone call. You will be asked a number of final questions based on your responses to date.

You can record the results of those conversations here:

Equality and Diversity: Impact assessment agreed
Safeguarding Children:

Part 6 - CONCLUSIONS AND RECOMMENDATIONS

6.1 Summary of changes implemented

VERY briefly, list changes made as a consequence of conducting this assessment

6.2 Is there anything which you think may have an adverse impact but which you have not been able to address in writing your document?

6.3 Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

List all actions (large and small) that have been identified during the assessment and include a named person and date for completion.

Action	**Name Lead**	**Date to be Achieved**

6.4 When will the document be reviewed*? (Include dates for completion and officer(s) responsible.)*

Date completed:

Signed by (Manager)……

The Trust's Equality and Diversity Lead:…

……..

The Named Nurse for Safeguarding Children:…… Melanie Barker