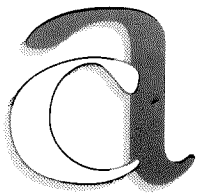
DEPARTMENT OF HEALTH

MEDICAL DEVICES DIRECTORATE

COMPETENT AUTHORITY

CODE OF PRACTICE ON ENFORCEMENT



THE MEDICAL DEVICES COMPETENT AUTHORITY (UK)

The Competent Authority is the body authorised to act on behalf of the government of an EC Member State to ensure that the requirements of the medical devices Directives are carried out. In the UK, the Competent Authority is the Secretary of State for Health who has delegated responsibility for day to day running of the Authority to the Medical Devices Directorate.

The main purpose of the Competent Authority is to safeguard the public health by ensuring that medical devices and equipment for sale or use in the UK meet appropriate standards of safety, quality and performance, and that they comply with the relevant European Community Directives.

Although patients and users of medical devices are the primary beneficiaries of its services, in the context of this Code of Practice, the Competent Authority's other main customers are manufacturers and suppliers of medical devices, and Notified Bodies, etc.

How the Competent Authority will help it's customers

OUR CUSTOMERS ARE ENTITLED TO EXPECT THE COMPETENT AUTHORITY:

TO BE FAIR AND EVEN HANDED

- *By handling your enquiries impartially*
- *By treating all our customers in the same manner without favour or discrimination*

TO HELP YOU

- *To understand how and when the regulations apply to your business and when certain requirements are not obligatory*
- *By keeping your enquiries strictly confidential within the bounds of Open Government and the requirements of the Directives which the regulations implement*
- *By providing clear information and advice*
- *By being polite and courteous at all times*

TO PROVIDE AN EFFICIENT SERVICE

- *By publication of standards we want to meet*
- *By enforcing the regulations only when it is necessary to do so thus helping you to minimise the costs of complying with them*

IF YOU ARE NOT SATISFIED

- *You can ask us to look at your complaint*
- *We will tell you how to make a complaint*
- *If you are dissatisfied with our response, you can ask an independent adjudicator to consider whether your complaint is justified.*

FOREWORD

by Alan Kent, Director of the Medical Devices Directorate

On 20 July 1993, as part of the Government's deregulation initiative, the Prime Minister set out the fundamental principles to be adopted by public sector enforcement bodies whose customers are businesses. In a DTI leaflet entitled "Working with Business: a Code for Enforcement Agencies", the Prime Minister made it clear that while the Government's review and sensible reduction of regulation will continue unabated, those bodies responsible for enforcing regulations have a duty to discharge their responsibilities in an open, even handed and helpful manner to develop an atmosphere of mutual respect.

The Code, which brings together Citizen's Charter and deregulation principles, requires each enforcement body to publish, by 1 January 1994, a Code of Practice on Enforcement that clearly demonstrates how those principles are to be put into effect.

This document is the Medical Devices Directorate's response to the Prime Minister's initiative. In our role as Competent Authority for the purposes of the European medical devices Directives, this Code sets out the guiding principles for our dealings with the UK medical device industry and addresses its main concerns; it describes how we intend to carry out our responsibilities for enforcing regulations relating to the EC medical devices Directives; and the level and standard of service we will provide. We regard the medical device industry as a primary customer.

IN BROAD TERMS, THE COMPETENT AUTHORITY'S MAIN CUSTOMER GOALS ARE TO:-

- *help you to comply with the regulations thereby providing access to the European market;*
- *provide you with easy access to simple guidance about the regulations; and*
- *enable you to complain without fear of discrimination if you are dissatisfied with the way particular regulations have been enforced.*

THE CODE OF PRACTICE THEREFORE SEEKS TO BENEFIT YOU BY:-

- *helping you to cut the overall cost of complying with the regulations;*
- *reducing any uncertainty as to whether you are taking the right approach; and*
- *assuring you that all our customers are being treated on level terms.*

NOTE
The Medical Devices Directorate will be established as an Executive Agency of the Department of Health.
Alan Kent is the Chief Executive of the Medical Devices Agency (designate).

Although the application of this Code of practice will be particularly helpful to the Medical Device Industry, I believe patients and users of medical devices will also benefit from its introduction through ensuring that the regulations achieve their intended objectives. At the same time reasonable enforcement of the regulations will reduce burdens on our customers and the taxpayer. I hope to improve the Code as we learn from experience and as the new Medical Devices Agency becomes established after its launch in April 1994.

Alan Kent

ALAN KENT Director

PREFACE

This Code of Practice provides information and guidance to the medical device industry on the Competent Authority's role and responsibilities for enforcing the regulations implementing the EC medical devices Directives in the UK. It also lays down the minimum level and standards of service the Competent Authority will provide for all its customers.

The Code has been approved by the Department of Health for the purpose of providing practical guidance relating to the relevant provisions of the EC medical devices Directives and the UK legislation (such as the Active Implantable Medical Devices Regulations 1992) which implements the Directives.

The Code has been drawn up by the Competent Authority (UK) after consultation with representatives of the UK medical device industry, Trade Associations, patients and users organisations and other interested parties in the healthcare sector.

The Code is a guidance document only and has no legal status. Its contents must not therefore be treated as an authoritative statement of the law in any particular case. You should consult the relevant Directive and appropriate regulations before taking action in respect of any of the matters referred to in this document. If you are unsure about how the regulations affect your business, contact the Competent Authority for advice. An organisation chart and a list of some of the people who will be able to help you is given on pages 14 and 15 of this Code. If you require a legal interpretation of the regulations however, you must consult your own legal advisers.

THE CODE IS DIVIDED INTO 3 PARTS:

PART 1 gives a brief overview of the current position on all three **EC MEDICAL DEVICES DIRECTIVES**

PART 2 explains the role and responsibilities of the **COMPETENT AUTHORITY (UK)**

PART 3 describes the level and standard of service provided for the customer by the **COMPETENT AUTHORITY**

Part 1 EUROPEAN COMMUNITY MEDICAL DEVICES DIRECTIVES

From 1 January 1993, a series of three Directives regulating the safety and marketing of medical devices throughout the European Community started to come into effect in the UK. These are:

- *The Active Implantable Medical Devices Directive*
- *The Medical Devices Directive*
- *The In Vitro Diagnostic Medical Devices Directive*

The Active Implantable Medical Devices Directive (90/385/EEC)

This Directive covers all powered medical devices implanted and left in the human body, such as heart pacemakers, cochlear implants, implantable drug infusion pumps, implantable defibrillators and implantable neuromuscular stimulators.

The Directive also covers implanted passive parts of active implants (eg. pacemaker leads and adaptors) and external parts that are an essential part of the systems (eg. pacemaker programmers). The Directive took effect in the UK on 1 January 1993 through the Active Implantable Medical Devices Regulations 1992 (SI 1992 No 3146) Copies can be obtained from Her Majesty's Stationery Office by Telephoning 071 873 9090, quoting the SI reference number.

The Directive also provides a transitional period which runs from 1 January 1993 until 31 December 1994, during which time manufacturers will have the choice of following existing national controls or the requirements of the Directive. However, the transitional period does not apply to medical devices intended for clinical investigation. The clinical investigation procedures defined in the Directive therefore apply from 1 January 1993.

From 1 January 1995, all active implantable medical devices will have to carry the CE marking.

Medical Devices Directive (93/42/EEC)

This Directive covers a wide range of products from, for example, first aid bandages through to CT scanners. The Directive was agreed at the Council of Ministers Internal Market Council (IMC) on 14 June and the formal adoption process was completed on 12 July 1993 with its publication in the Official Journal of the European Communities (OJ No L169/1). Copies can be obtained from Her Majesty's Stationery Office by telephoning 071 873 9090, quoting the Journal reference number L/169 and the date of publication (12 July 1993).

Although implementing legislation is expected to be laid before Parliament early this year, its provisions will not take effect in the UK until 1 January 1995 with a transitional period until 13 June 1998. As for the first Directive, the transitional period does not apply to investigational devices. From 14 June 1998 therefore, all devices covered by this Directive will have to carry the CE marking.

In Vitro Diagnostic Medical Devices Directive

The third Directive will cover diagnostic test kits, certain instruments, equipment and self-test products. The European Commission is expected to publish a formal proposal for a Directive early this year but it is not expected to take effect in the UK before 1996.

Part 2 COMPETENT AUTHORITY (UK)

What is the Competent Authority (UK)'s role?

Put simply, our most important function is to ensure that all medical devices used in the UK meet the essential requirements laid down in the Directives and in so doing, do not compromise the health and safety of patients, users and, where appropriate, any other persons.

How does the Competent Authority do this?

The regulations

We ensure that the requirements of the regulations are observed and that appropriate administrative arrangements are made for this purpose.

Advice

We will offer advice, for example on the conformity assessment routes available and opinions on the classification rules for medical devices. We will also help with advice to manufacturers and Notified Bodies, for example when disagreements cannot be satisfactorily resolved between the parties concerned.

Monitoring

We monitor the effectiveness of the regulations and their possible burdens on business.

Enforcing the regulations

We have a specific duty to enforce the regulations using powers under The Consumer Protection Act 1987. In so doing, we must take whatever action is necessary to withdraw unsafe devices from the market, or, when necessary, prohibit or restrict their being placed on the market.

Adverse incidents

We provide the administrative 'arrangements' needed to facilitate the reporting of adverse incidents within the appropriate timescales and ensure that these are recorded and evaluated centrally.

Clinical investigations

We process applications for the pre-clinical assessment of devices intended for clinical investigations including their evaluation by expert assessors within a statutory time limit of 60 days.

Notified bodies

We designate Notified Bodies in the UK to carry out the conformity assessment procedures laid down in the medical devices Directives.

Devices carrying the CE marking

NOTE:
Although custom-made devices and those intended for clinical investigation will not carry the CE marking, they must nevertheless meet the essential requirements laid down in the Directives.

THE COMPETENT AUTHORITY MUST ENSURE THAT:-

- *all devices that carry the CE Marking meet the Essential Requirements, and*
- *only devices carrying the CE Marking are placed on the market.*

Manufacturer and Product Registration

From 1 January 1995, when the Medical Devices Directive takes effect, the Competent Authority will have a duty to start maintaining registers of:-

- *manufacturers of Class 1 devices*
- *manufacturers of custom-made devices*
- *those involved in placing system or procedure packs on the market*
- *those involved in the process of sterilisation of medical devices*

A manufacturer or his authorised representative will be required to inform the Competent Authority of the country in which he has his registered place of business of his registered address and provide a description of or the category of the devices concerned.

Liaison with EC and other Member States

We are required to inform the EC Commission of any enforcement action taken within the UK and we must also provide observations on any notifications received from the Commission about enforcement action taken in other Member States. Countries in the European Free Trade Area (EFTA) have agreed to accept the provisions of the Directives and implement them in their national legislation.

Liaison with Trading Standards Departments

We will retain overall control and responsibility for enforcing the regulations for all medical devices in the UK. In addition, Trading Standards Officers (TSOs) will also monitor and enforce the regulationsfor those medical devices which can be defined as consumer products (eg first aid bandages, thermometers, spectacles), within the meaning of the Consumer Protection Act 1987, sold in high street stores and other retail outlets.

Any action taken by TSOs involving a breach of the regulations under the Act will be taken in consultation with the Competent Authority bearing in mind the latter's responsibility for informing the EC Commission and other Member States.

Are Notified Bodies bound by this Code of Practice?

No. Although the Competent Authority is responsible for designating them in the UK, Notified Bodies are independent, self-financing organisations. The Competent Authority will nevertheless encourage them to develop their own Codes of Practice, based on the principles set out in this document.

Part 3 STANDARDS OF SERVICE

This part of the Code of Practice sets out our aim to provide our customers with an acceptable level and standard of service based on broad principles relating to each of the following:

- *Publication of Standards of Performance*
- *Information and Openness*
- *Consultation and Communication*
- *Courtesy and Helpfulness*
- *Complaints*
- *Value for Money*

Standards of Performance

OUR AIM IS TO PROVIDE A CLEAR STATEMENT OF THE LEVEL AND STANDARD OF SERVICE OUR CUSTOMERS SHOULD RECEIVE

As a way of measuring how we intend to help manufacturers to comply with the medical devices regulations, the standards we set will include the time taken to respond to enquiries and the provision of an adequate and effective complaints procedure. We will also publish each year, the results of our performance against the standard set. The first Annual Report will be published in April 1995 and will cover the financial year ending 31 March (94/95 year).

How we will achieve this

We will deal with your enquiries in a prompt, efficient and business-like manner.

All letters and business correspondence will be logged on the day they are received and receipt will be acknowledged within 3 working days.

All written enquiries will receive a full reply within 21 days of receipt unless there are special reasons where it is impracticable to do so (for example where complex and exhaustive enquiries are necessary). Where a full reply cannot be sent, an interim response will be issued within this timescale.

Enquiries of a vital or urgent nature will receive priority over all other general correspondence.

Telephone enquiries

Telephone enquiries will be dealt with in a courteous and efficient manner. Our staff will identify themselves by name and try to ensure that, where appropriate, your enquiry is directed to the appropriate person with a minimum of avoidable delay.

What we expect from our customers

In return, you are asked to set out your enquiries in a clear, concise and logical manner and to answer promptly, any requests for additional or further information needed to help with our reply.

Our customers are asked to remember however, that the Competent Authority can only provide professional advice to the best of its ability; it is not qualified to offer a legal interpretation in any particular case.

Publication of performance standards

Shortly after the end of each financial year, we will publish the results of our performance against the standards of service set out in this document and about your perception of the effectiveness of our complaints procedure.

Performance target (94/95)

For 94/95 financial year, the Competent Authority will aim to answer 95% of all enquiries received within 21 days of receipt. This target will, of necessity, include interim responses where a full reply cannot be sent within 21 days.

The results in terms of standards achieved will be issued in the form of a Performance Indicator. This will be expressed as a percentage of individual items of correspondence answered within 21 days against the total number of such enquiries received.

Performance areas

Performance results will cover 2 main areas, the time taken to respond to written enquiries and a summary of the outcome of complaints dealt with under the new complaints procedures.

THESE WILL NORMALLY BE DEALT WITH IN THE FOLLOWING FORMAT:

Correspondence

- *Number of enquiries received during financial year*
- *Number where reply sent within 21 days*
- *Number outstanding at end of year*
- *Percentage of enquiries answered within 21 days*

Complaints

- *Number of complaints received during year*
- *Type of complaint (brief summary)*
- *Average time taken to deal with complaint*
- *Summary of conclusions*

Customer satisfaction

With the issue of each Annual Report and as an integral part of the reporting process, our customers will have an oppourtunity to comment on our performance and the standards of service we seek to achieve (including the effectiveness of our complaints procedure) and will be invited to offer constructive suggestions for improving our overall service.

Confidentiality

We will respect the confidentiality of all the correspondence we enter into and action we may take within the bounds of Open Government.

Information and Openness

We will provide accurate and helpful advice to all our customers on the enforcement of the regulations and keep any charges which may be introduced for our services to a reasonable minimum, consistent and commensurate with the level of service provided.

YOU MAY NEED TO GET IN TOUCH WITH US FOR A NUMBER OF REASONS. FOR EXAMPLE:

- *To make an application for a pre-clinical assessment of a medical device intended for the purposes of a clinical investigation. We will help you to understand the regulations which manufacturers need to comply with by providing application forms and guidance documents that are easy to understand. We will also explain which requirements are obligatory and those which, although helpful to us, are optional.*
- *To ask us for advice or information, for example about a particular aspect of the regulations and how this may affect your manufacturing process, or what guidance we have published or what we are doing about a particular matter that affects your business, or about some matter connected with the work we do.*
- *To tell us about some matter on which you are knowledgeable, or have views on our policies.*
- *To discuss the content of our Information Bulletins and suggest topics for new ones.*
- *To apply to become a Notified Body for the purposes of the Directives. We will explain the criteria that must be met before a Notified Body can be designated.*
- *To report medical devices that are not CE marked or incorrectly marked or subject to Vigilance reports.*

Charges

We have the responsibility of reducing the burden of taxation in respect of our activities as a Competent Authority. Hence, important policy decisions on the principle of charging our customers for certain services provided by us are being considered in preparation for the establishment of the Medical Devices Agency as an Executive Agency of the Department of Health from April this year.

Although decisions on charging have still to be made, our customers are assured that the scope, timing, extent and level of charging will be subject to a formal consultation process before any such decisions are finally made.

SOME EXAMPLES OF THE ACTIVITIES FOR WHICH CHARGES ARE BEING CONSIDERED ARE:

- *Accreditation of Notified Bodies*
- *Audit and inspection of Notified Bodies*
- *Processing applications for pre-clinical assessment of devices intended for clinical investigation*

Consultation and Communication

Apart from our statutory duty to consult interested parties under the Consumer Protection Act 1987, we will consult and continue to meet our customers on an ad hoc basis to discuss a wide range of matters such as compliance failures, adverse incidents or other difficulties.

Consultations will be of benefit to both of us as they will help us to understand your concerns better and, at the same time, they will help you to

recognise and understand the need for good regulation.

Our commitment to consultation and communication also extends to regular and ad hoc meetings with Trade Associations and other interested private bodies and it formalises existing practices.

We will continue to issue EC Medical Devices Directives bulletins as and when appropriate and desirable.

Courtesy and Helpfulness

Under this Code of Practice, we aim to provide a service that is courteous, efficient and positively helpful to our customers. Staff involved in enforcing the regulations will identify themselves by name at all times.

A list of Competent Authority officials engaged (inter alia) on enforcement duties is given in the Annex to this document which will of course be updated from time to time.

Complaints

We are introducing a complaints system under this Code of Practice. This should help our customers to seek a swift and effective resolution of any complaints they may have about the way we deal with their enquiries.

The overall purpose of the system will be to ensure that our customers will be able to complain without fear of discrimination and that we will carry out our duties impartially.

If you want to complain, you should ask the person you have been dealing with for their senior officer's name. You can then telephone or write to that person.

Internal review

If you complain to us about the way in which we have handled your enquiry, your complaint will be investigated by a senior official within the Medical Devices Directorate. If we are at fault, we will tell you what we will do to put matters right.

IF YOU WISH, YOU CAN SEND YOUR COMPLAINT TO:

The Director
Medical Devices Directorate
14 Russell Square
London
WC1B 5EP

Independent review

If you are dissatisfied with the outcome of an internal review, you can ask for your complaint to be investigated by an independent adjudicator who has considerable experience in the healthcare sector but who no longer has any direct contact with, or allegiance to, either the Competent Authority or the medical device industry.

A list of adjudicators is being drawn up following consultation with interested parties. It is intended that they will have had considerable experience in the healthcare sector (eg Trade Associations or former medical device. A list of consultants). adjudicators will be made available on request.

A copy of all the documents placed before the independent adjudicator will be sent to you. If you are dissatisfied with his decision, you can also, if you wish, write to your MP and ask him to take the matter up on your behalf, or to refer your complaints for review by the ombudsman.

There is no further right of redress against an independent adjudicator's decision.

Value for Money

It is also our policy to ensure that the costs to our customers of compliance with the regulations (for example audit and inspection costs) are kept to a minimum.

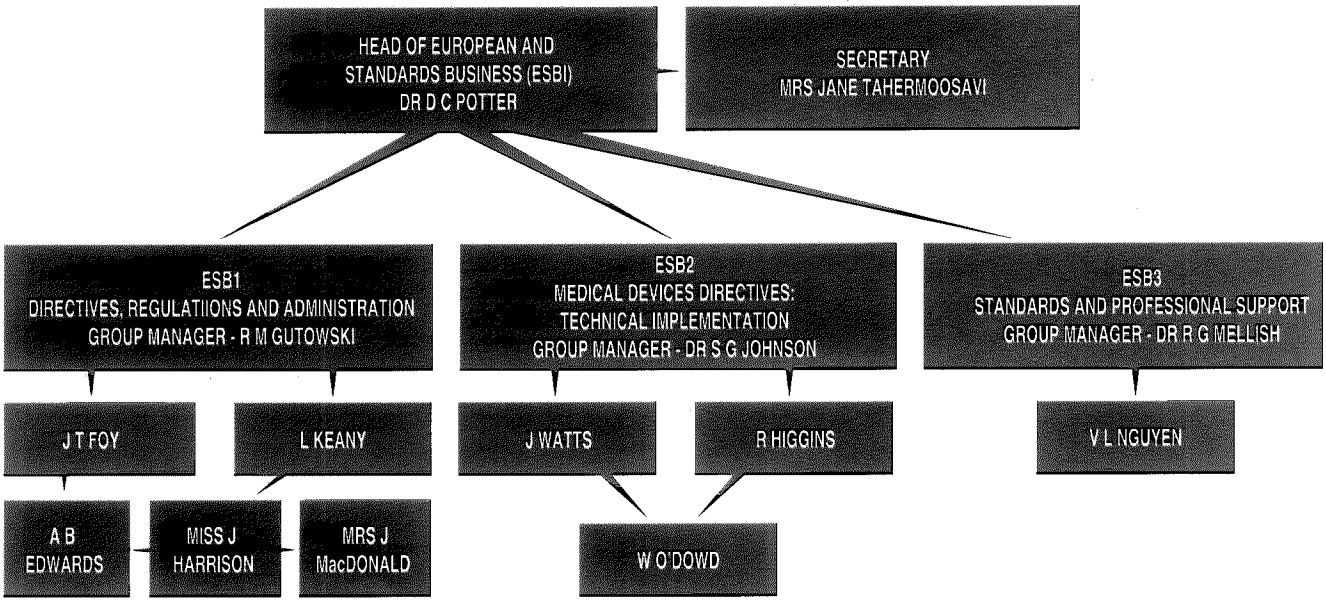
We will ensure, as far as possible, that these are proportionate to the costs of conformity assessment and take account of the particular circumstances of smaller businesses within the medical device industry. The principles of better and sensible enforcement set out in this document are designed to ensure better value for money for our customers.

Further information

IF YOU REQUIRE ANY FURTHER INFORMATION ABOUT THIS CODE OF PRACTICE OR IF YOU HAVE ANY PRACTICAL SUGGESTIONS FOR IMPROVING THE CODE, PLEASE SEND THESE TO:

Mr Richard Gutowski
Medical Devices Directorate
14 Russell Square
London
WC1B 5EP

ANNEX 1; MEDICAL DEVICES DIRECTORATE, EUROPEAN AND STANDARDS BUSINESS



Active Implantive Medical Devices (AIMD) Regulations

Enforcement of regulations and legal activities

Business Administrative support

Processing of Notified Body applications

Liaison with NATRIC

Standards administration and budgets

Phone:
071 972 8253

Negotiation of In-Vitro Diagnostic Medical Devices Directive

Other EC Matters relating to medical devices

Overlap with other Directives

Communication with EC, other Member States and other Government Departments

Publicity for Directives and Competent Authority

Implementation of Medical Devices Directives:

(1)
Technical matters relating to the Competent Authority

(2)
Harmonised Standards for active implantable devices

Phone:
071 972 8282

Standards Programme, priorities, policies and professional aspects

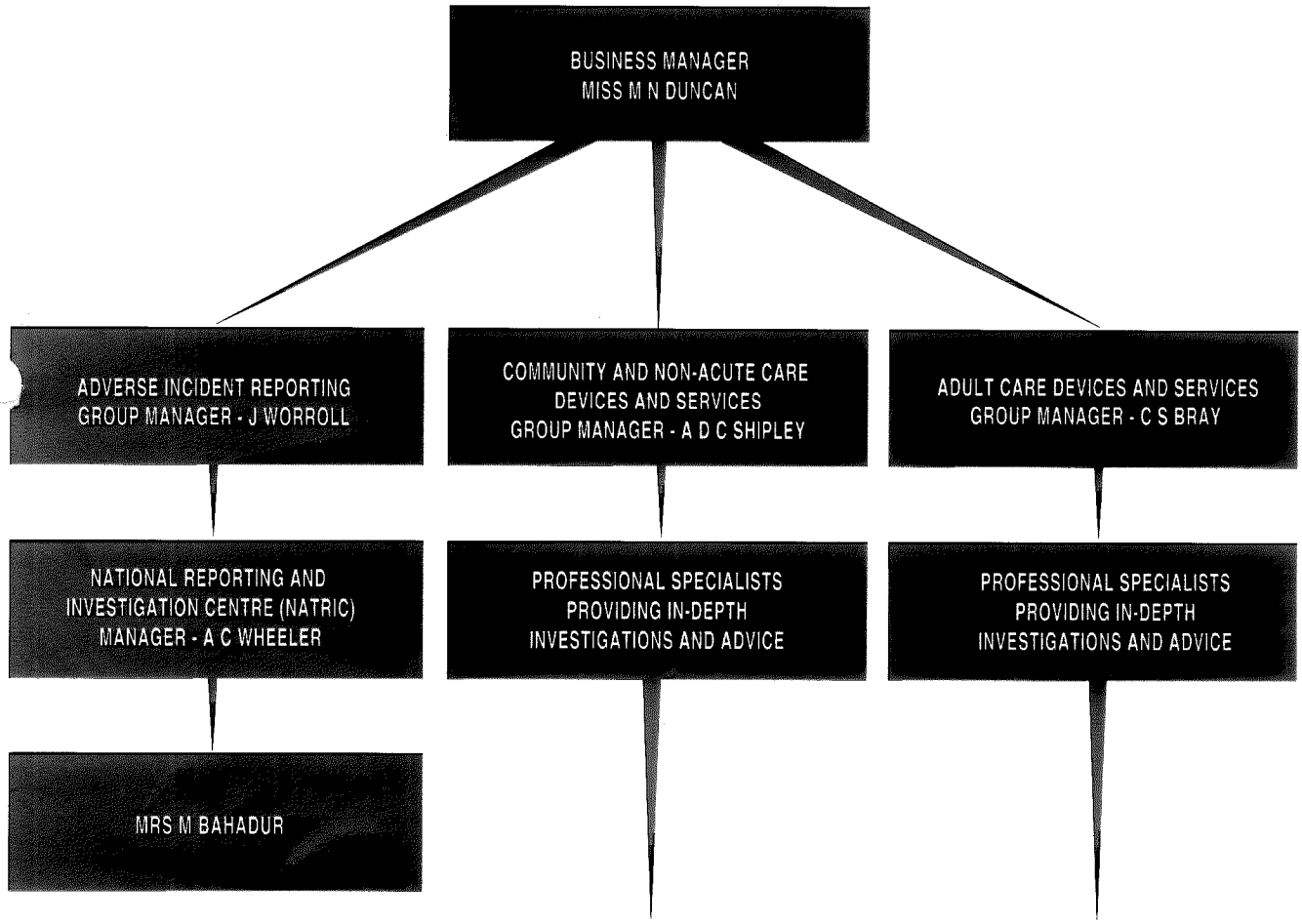
Participation in standards policy and safety committees

Approval procedures for Notified Bodies

General Safety Issues

Phone:
071 972 8247

ANNEX 2; MEDICAL DEVICES DIRECTORATE, DEVICE TECHNOLOGY AND SAFETY (DTS)



Phone: 071 972 8220

MEDICAL AND
NURSING ADVICE

DR S LUDGATE
DR SP VAHL
MRS P A COLLINSON

Community and non-acute care devices

Mobility aids and equipment

Non-Acute care diagnostic imaging and measurement devices

Phone: 071 972 8179

External life support devices

Implants and toxicology

Acute service therapy, surgical devices and in-vitro diagnostic devices

Phone: 071 972 8275