

# Medicines management

## Health Building Note 14-01: Pharmacy and radiopharmacy facilities



# **Health Building Note 14-01**

## **Pharmacy and radiopharmacy facilities**

© Crown copyright 2013

Terms of use for this guidance can be found at <http://www.nationalarchives.gov.uk/doc/open-government-licence/>

# Preface

## About Health Building Notes

Health Building Notes give “best practice” guidance on the design and planning of new healthcare buildings and on the adaptation/extension of existing facilities.

They provide information to support the briefing and design processes for individual projects in the NHS building programme.

## The Health Building Note suite

Healthcare delivery is constantly changing, and so too are the boundaries between primary, secondary and tertiary care. The focus now is on delivering healthcare closer to people’s homes.

The Health Building Note framework (shown below) is based on the patient’s experience across the spectrum of care from home to healthcare setting and back, using the national service frameworks (NSFs) as a model.

## Health Building Note structure

The Health Building Notes have been organised into a suite of 17 core subjects.

**Care-group-based** Health Building Notes provide information about a specific care group or pathway but cross-refer to Health Building Notes on **generic (clinical) activities** or **support systems** as appropriate.

Core subjects are subdivided into specific topics and classified by a two-digit suffix (-01, -02 etc), and may be further subdivided into Supplements A, B etc.

All Health Building Notes are supported by the overarching Health Building Note 00 in which the key areas of design and building are dealt with.

### Example

The Health Building Note on accommodation for adult in-patients is represented as follows:

“Health Building Note 04-01: Adult in-patient facilities”

The supplement to Health Building Note 04-01 on isolation facilities is represented as follows:

“Health Building Note 04-01: Supplement 1 – Isolation facilities for infectious patients in acute settings”

Health Building Note number and series title	Type of Health Building Note
Health Building Note 00 – Core elements	Support-system-based
Health Building Note 01 – Cardiac care	Care-group-based
Health Building Note 02 – Cancer care	Care-group-based
Health Building Note 03 – Mental health	Care-group-based
Health Building Note 04 – In-patient care	Generic-activity-based
Health Building Note 05 – Older people	Care-group-based
Health Building Note 06 – Diagnostics	Generic-activity-based
Health Building Note 07 – Renal care	Care-group-based
Health Building Note 08 – Long-term conditions/long-stay care	Care-group-based
Health Building Note 09 – Children, young people and maternity services	Care-group-based
Health Building Note 10 – Surgery	Generic-activity-based
Health Building Note 11 – Community care	Generic-activity-based
Health Building Note 12 – Out-patient care	Generic-activity-based
Health Building Note 13 – Decontamination	Support-system-based
Health Building Note 14 – Medicines management	Support-system-based
Health Building Note 15 – Emergency care	Care-group-based
Health Building Note 16 – Pathology	Support-system-based

## Other resources in the DH Estates and Facilities knowledge series

### Health Technical Memoranda

Health Technical Memoranda give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare (for example medical gas pipeline systems, and ventilation systems).

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

All Health Building Notes should be read in conjunction with the relevant parts of the Health Technical Memorandum series.

### Activity DataBase (ADB)

The Activity DataBase (ADB) data and software assists project teams with the briefing and design of the healthcare environment. Data is based on guidance given in the Health Building Notes, Health Technical Memoranda and Health Technical Memorandum Building Component series.

1. Room data sheets provide an activity-based approach to building design and include data on personnel, planning relationships, environmental considerations, design character, space requirements and graphical layouts.
2. Schedules of equipment/components are included for each room, which may be grouped into ergonomically arranged assemblies.
3. Schedules of equipment can also be obtained at department and project level.
4. Fully loaded drawings may be produced from the database.
5. Reference data is supplied with ADB that may be adapted and modified to suit the users' project-specific needs.

### Note

The sequence of numbering within each subject area does not necessarily indicate the order in which the Health Building Notes were or will be published/printed. However, the overall structure/number format will be maintained as described.x

# Executive summary

This Health Building Note provides best practice guidance on the design and layout of pharmacy and radiopharmacy facilities in hospitals. In the case of hospitals with aseptic preparation facilities, it applies to those that do not/will not require a manufacturer's "specials" licence.

It describes facilities for the following:

- centralised bulk storage and stock distribution of medicines;
- medicines storage and dispensing, including automated dispensing, within the dispensary;
- aseptic preparation of medicines;
- non-sterile small-scale preparation and assembly of medicines;
- procurement of medicines and provision of consultative, administrative and information;
- services.

This document does not provide guidance on the following:

- medicines storage facilities in wards;
- medicines storage facilities in commonly occurring clinical spaces;
- GP-run or community pharmacies;
- retail pharmacy units;
- satellite dispensaries;
- pharmaceutical quality assurance services (which may be provided on hospital sites or externally).

## Key policy and standards

The guidance on pharmacy and radiopharmacy facilities takes into account the advice contained in:

- 'Aseptic dispensing for NHS patients';
- 'Guide to the preparation of non sterile extemporaneous products in NHS hospitals';

- 'Management issues for clinical trials of medicines in NHS hospitals with particular reference to the pharmacy';
- 'Pharmaceutical isolators. A guide to their application, design and control';
- 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors';
- 'The Safe and Secure Handling of Medicines: A Team Approach';
- 'Safe Management of Controlled Drugs: a guide to good practice in secondary care (England)';
- 'Quality Assurance of Aseptic Preparation Services'.

Reference should also be made to the following documents:

- 'A Spoonful of Sugar – Medicines Management in NHS Hospitals';
- 'A vision for pharmacy in the new NHS';
- 'Choosing health through pharmacy';
- 'Making a Difference – Reducing Burdens in Hospitals';
- 'Medicines management in NHS Trusts – hospital medicines management framework';
- 'The best medicine. The management of medicines in acute and specialist trusts'.

## Medicines preparation – licensed and unlicensed sites

The NHS has a requirement for unlicensed medicines that are essential to patient care but for which there are no licensed equivalents. The NHS sources unlicensed medicines from NHS manufacturing units and commercial companies, which require a manufacturer's "specials" licence from the Medicines and Healthcare products Regulatory Agency (MHRA) in order to operate.

However, some unlicensed medicines, including centralised intravenous additive (CIVA) injections/infusions, parenteral nutrition (PN) products, cytotoxic injections/infusions and radiopharmaceuticals, may be prepared on an individual patient basis under an exemption provided by Section 10 of the Medicines Act 1968.

‘Aseptic dispensing for NHS patients’ directs that unlicensed facilities should meet the same standards as licensed facilities.

Advice on design requirements for licensed sites should be obtained from the MHRA and the NHS pharmacy regional quality assurance specialist at an early stage in the planning process.

# Contents

Preface	About Health Building Notes The Health Building Note suite Health Building Note structure Other resources in the DH Estates and Facilities knowledge series Health Technical Memoranda Health Technical Memorandum Building Component series Activity DataBase (ADB) How to obtain publications	
Executive summary	Key policy and standards Medicines preparation – licensed and unlicensed sites	
<b>1 Introduction</b>	Scope of guidance Exclusions Status Policy context Medicines preparation – licensed and unlicensed sites	<b>1</b>
<b>2 Service context</b>	Purpose and role of the service Medicines information Clinical trials Procurement of medicines Centralised bulk storage and stock distribution Storage in wards and other clinical areas Dispensing Aseptic and non-sterile preparation of medicines	<b>3</b>
<b>3 General functional and design considerations</b>	Location Aseptic and non-sterile preparation facilities Storage requirements Infection control Radiation protection Access and security	<b>6</b>
<b>4 Centralised bulk storage and stock distribution facilities</b>	Spaces External goods entrance Stores office Goods reception and unpacking area Disposal hold Bulk storage area External flammables store Emergency medicines store	<b>8</b>
<b>5 Dispensary facilities</b>		<b>10</b>



Introduction	
Dispensing area	
Extemporaneous dispensing area	
Controlled drugs store	
Non-formulary drugs storage area	
Unlicensed medicines store	
Clinical trials material store	
Automated dispensing system (robot)	
Other dispensary spaces	
Waiting area	
Out-patient service counter	
Clinical checking area	
Final checking area	
Confidential counselling area	
Returned medicines store	
Secure store for controlled stationery	
Dispensary manager’s office	
<b>6 Aseptic preparation facilities</b>	<b>15</b>
Changing room(s)	
First-stage changing room	
Second-stage changing room	
Outer and inner support rooms	
Clean rooms	
Administration room	
General design requirements	
<b>7 Radiopharmaceutical preparation facilities</b>	<b>20</b>
Delivery and storage of generators	
<b>8 Non-sterile preparation facilities</b>	<b>22</b>
Materials/consumables store	
Ingredients weighing area	
Dry and liquid products	
Creams and ointments area	
Repacking and assembly facilities	
Visual inspection and labelling area	
Quarantine area	
<b>9 Staff support facilities</b>	<b>23</b>
Administration (continuous use) area	
Hot-desk area	
Clinical trials office	
Medicines information facilities	
Other staff support spaces	
<b>10 Glossary</b>	<b>25</b>
<b>11 References</b>	<b>27</b>

# 1 Introduction

## Scope of guidance

- 2.1 This Health Building Note provides best practice guidance on the design and layout of pharmacy and radiopharmacy facilities in hospitals. In the case of hospitals with aseptic preparation facilities, it applies to those that do not/will not require a manufacturer's "specials" licence.
- 2.2 It describes facilities for the following:
- centralised bulk storage and stock distribution of medicines;
  - medicines storage and dispensing, including automated dispensing, within the dispensary;
  - aseptic preparation of medicines;
  - non-sterile small-scale preparation and assembly of medicines;
  - procurement of medicines and provision of consultative, administrative and information services (see [Chapter 9, 'Staff support facilities'](#)).
- 2.3 The scale and exact nature of facilities will vary depending on local needs. Early and ongoing consultation with the relevant chief pharmacist is essential in order to establish requirements.
- 2.4 The guidance in this Health Building Note should be supplemented by reference to detailed technical guidance, manufacturers' information, the project brief and, most importantly, discussions between members of the full project team at the earliest opportunity and throughout the design, construction and commissioning phases of a scheme.
- 2.5 Specific requirements should be evaluated and specified from discussions between managers, clinicians, users and designers to ensure that the most effective design is achieved.
- 2.6 Some issues, particularly those related to radiation safety, may require specific and detailed discussions with other specialist professional consultants including the Radiation Protection Agency (RPA) and Health & Safety Executive (HSE).

- 2.7 The design and build of facilities for the preparation of medicines should be undertaken by specialist contractors.
- 2.8 For the purpose of this Health Building Note, the "pharmacy department" includes all facilities listed above. See paragraph 2.11.

## Exclusions

- 2.9 This Health Building Note does not provide guidance on the following:
- medicines storage facilities in wards;
  - medicines storage facilities in commonly-occurring clinical spaces;
  - GP-run or community pharmacies;
  - retail pharmacy units;
  - satellite dispensaries;
  - pharmaceutical quality assurance services (which may be provided on hospital sites or externally).

## Status

- 2.10 This Health Building Note replaces Health Building Note 29 – 'Accommodation for pharmaceutical services'. It also supersedes the information on radiopharmacies contained in Health Building Note 6 Volume 1 – 'Facilities for diagnostic imaging and interventional radiology'.

## Policy context

### Medicines preparation – licensed and unlicensed sites

- 2.11 The NHS has a requirement for unlicensed medicines that are essential to patient care but for which there are no licensed equivalents. The NHS sources unlicensed medicines from NHS manufacturing units and commercial companies, which require a manufacturer's "specials" licence from the Medicines and Healthcare products Regulatory Agency (MHRA) in order to operate.

- 2.12 However, some unlicensed medicines, including centralised intravenous additive (CIVA) injections/infusions, parenteral nutrition (PN) products, cytotoxic injections/infusions and radiopharmaceuticals, may be prepared on an individual patient basis under an exemption provided by Section 10 of the Medicines Act 1968.
- 2.13 'Aseptic dispensing for NHS patients' (DH, 1997) directs that unlicensed facilities should meet the same standards as licensed facilities.
- 2.14 Advice on design requirements for licensed sites should be obtained from the MHRA and the NHS pharmacy regional quality assurance specialist at an early stage in the process.

## 2 Service context

### Purpose and role of the service

- 2.1 The purpose of a hospital pharmacy service is to provide the overall lead and focus for the management of medicines within a hospital or number of hospitals and possibly to other NHS and/or private organisations.
- 2.2 The primary role is to promote and ensure best practice in all aspects of the handling and use of medicines. This includes procurement, through prescription validation, dispensing, supply and storage, to safe disposal.

### Medicines information

- 2.3 All hospital pharmacies require medicines information (MI) facilities capable of providing advice on the pharmaceutical care of individual patients and promoting effective medicines management. See [Chapter 9, 'Staff support facilities'](#).

### Clinical trials

- 2.4 Many hospitals are involved in clinical trials. This has significant implications for storage space, as clinical trials materials may need to be stored in refrigerators/ freezers, should be segregated from other pharmaceutical supplies, and should be kept with the associated trial material issues and documentation.
- 2.5 Significant space is also required for archived records. The location will depend on whole-hospital policy for storage of archived records.
- 2.6 Trials monitoring and MHRA inspection activities, as well as the need for facilities for processing questionnaires and stock reconciliation, will require the provision of office accommodation.
- 2.7 In terms of dispensing facilities for clinical trials, this guidance only covers facilities for adding dispensing information to trial packs. See [paragraph 5.4, 'Dispensing area'](#) and [Chapter 9, 'Staff support facilities'](#).

### Procurement of medicines

- 2.8 Medicines procurement is a major component of pharmacy activity and may be undertaken for a single hospital, by one site of a multi-site trust, or by one trust on behalf of several other trusts as part of a consortium or confederation.
- 2.9 Medicines procurement includes five distinct processes:
  - national and local contract management;
  - order placement;
  - goods receipt;
  - invoicing;
  - back-order pursuit.
- 2.10 With the exception of goods receipt, each process should take place in an office environment. For a multi-site trust or multi-trust grouping, the different processes may take place in separate offices.
- 2.11 Medicines may need to be quarantined pending the results of quality control (QC) assessments prior to release for general issue. A quarantine store will therefore be needed. This should be sited away from the main storage area, for example within the goods receipt area. See [Chapter 9, 'Staff support facilities'](#) and [Chapter 4, 'Centralised bulk storage and stock distribution facilities'](#).

### Centralised bulk storage and stock distribution

- 2.12 Facilities are required for the centralised bulk storage and distribution of medicines.
- 2.13 Storage capacity will be determined by local policies on stock ordering and delivery. Original packs require proportionately more space than other packs. See [Chapter 4, 'Centralised bulk storage and stock distribution facilities'](#).

## Storage in wards and other clinical areas

- 2.14 Wards and other clinical areas receive supplies of stock medicines via the pharmacy's "top-up" service.
- 2.15 It is important that adequate provision for medicines storage is made available in wards/clinical areas to ensure safe practice. The National Patient Safety Agency (NPSA) has reported that inadequate and insufficient medicines storage has led to deaths and serious harm due to overcrowding and selection errors.
- 2.16 Wards/clinical areas require considerable secure medicines storage. The amount of storage required for any ward/clinical area can be calculated by an inspection of the medicines stock list for that specific area or a similar area, which will be held by the hospital pharmacy.
- 2.17 Where required, the following medicines should be stored securely, with clear segregation of medicine types:
- oral medicines, for example capsules and tablets;
  - oral liquid medicines, nebuliser solutions and rectal medicines;
  - injectable medicines, for example ampoules, vials, pre-filled syringes and infusions of active medicines;
  - external medicines and dressings, for example creams, ointments, lotions and diagnostic reagents;
  - ready-to-administer epidural medicines, for example pre-filled syringes and infusion bags;
  - medicines to take home and patients' own medicines (where bedside medicines lockers are not in use);
  - bulk items, for example intravenous infusion fluids, sterile topical fluids and syringes.
- 2.18 Controlled drugs should be stored in lockable controlled drugs cupboards. Flammable materials should be stored in separate metal cupboards. Some medicines may require refrigeration.
- 2.19 Delivery of stock medicines is usually achieved by traditional portering. Electric or other vehicles may be required for the transportation of heavy and bulky items. The latter will affect access arrangements from the centralised bulk storage area.

- 2.20 Large pharmacy departments servicing remote or multiple sites may arrange for suppliers to deliver direct to clinical areas. This will reduce the storage requirement in the centralised bulk storage area. See [Chapter 3, 'General functional and design considerations'](#).

## Dispensing

- 2.21 The modern dispensing process comprises five activities:
- receipt of prescriptions from out-patients or clinical areas;
  - clinical checking;
  - dispensing;
  - final accuracy/product quality check;
  - temporary storage and issue of dispensed items to out-patients or clinical areas.
- 2.22 All these activities take place in the dispensary, which should be physically configured to maximise workflow efficiency.
- 2.23 The issue of dispensed items is usually via a combination of the dispensary reception counter, pneumatic tube system and traditional portering. Facilities should reflect the transportation systems to be used.
- 2.24 Automated dispensing systems (robots) are an integral part of the modern dispensing service. Potential benefits include improvements in stock management, pick speeds and accuracy, and reductions in dispensing times and staff movement thereby allowing a greater focus on clinical care.
- 2.25 Robots provide compact storage for suitable packs. Although they occupy a large footprint, their use will result in an overall reduction in storage space requirements compared to conventional shelving.
- 2.26 The majority of medicines are dispensed as original packs and, therefore, automated systems may be used.
- 2.27 A minimum size of operation is needed for a robot to be cost-effective. For example, robots may not be appropriate in small community hospitals or mental health hospitals where a large proportion of dose units are dispensed. Alternative unit dose dispensing systems are available and may be appropriate in such circumstances.
- 2.28 Adequate storage provision should be made for the storage of containers from which dose units are

manually dispensed. See [Chapter 5, 'Dispensary facilities'](#).

## Aseptic and non-sterile preparation of medicines

- 2.29 Preparation and assembly activities should take place in dedicated areas which have controlled access and comprehensive environmental management systems.
- 2.30 Separate areas may be required for different types and stages of preparation and assembly, depending on the materials and processes used.
- 2.31 Very specific environments are required for the preparation of aseptic products.
- 2.32 Designated space may be required for quarantined stock whilst awaiting the results of QC assessments prior to issuing stock. Raw materials for use in preparation should be stored separately from finished products. See [Chapter 6, 'Aseptic preparation facilities'](#) and [Chapter 7, 'Radiopharmaceutical preparation facilities'](#).

## 3 General functional and design considerations

### Location

- 3.1 The pharmacy department should be located on the ground floor, as many of its functions are dependent on receiving, storing and distributing goods.
- 3.2 It should be readily accessible from the hospital's main horizontal and vertical circulation routes for the convenience of patients and staff and to facilitate distribution of medicines to wards and other clinical areas.
- 3.3 Pneumatic tube systems (small bore diameter) may be used for the delivery of small quantities of medicines throughout the hospital provided that collection/ dispatch stations are secured against theft.
- 3.4 The design of the pharmacy department should take into account the supplies distribution system for the whole hospital.

### Aseptic and non-sterile preparation facilities

- 3.5 The size, configuration and location of any aseptic or non-sterile preparation facilities will depend on the scale and organisation of the workload and will be influenced by mechanical and electrical engineering requirements.
- 3.6 Aseptic facilities should be designed so that the preparation processes can be physically supervised by a pharmacist or should include facilities for remote supervision, for example high-quality CCTV.
- 3.7 Facilities for the preparation of radiopharmaceuticals should provide easy access to the diagnostic imaging and interventional radiology departments or be located within or close to the nuclear medicine department.

### Storage requirements

- 3.8 A controllable environment is required to ensure that all pharmaceutical products and raw materials are stored at a temperature not exceeding 25°C.
- 3.9 All storage should be raised above the floor.
- 3.10 Certain groups of pharmaceutical products and raw materials require more stringent storage conditions in terms of security, temperature control and/or protection from light.
- 3.11 The construction and installation of controlled drugs cabinets/stores should comply with the requirements laid down in the Misuse of Drugs (Safe Custody) Regulations 1973. This is a legal requirement for pharmacies registered with the Royal Pharmacy Society of Great Britain (RPSGB).
- 3.12 See [paragraph 5.18, 'Controlled drugs store'](#).
- 3.13 Where medicines require refrigeration, consideration should be given to the use of a centralised walk-in cold store (for bulk storage) incorporating appropriate measures to minimise heat gain when the store door is opened.
- 3.14 Where refrigerators are used, these should be of the following specification:
  - constructed of impervious, cleanable materials both internally and externally;
  - single cooler panel without a freezer box;
  - maintain the temperature between 2°C and 8°C;
  - automatic defrost;
  - use grille-type shelving;
  - integral air circulating fan;
  - fitted with glass doors to minimise the length of time that the door needs to be open whilst selecting the correct medicine;
  - permanent external display of current fridge temperature;
  - lockable.

- 3.15 Freezers may be required for the storage of vaccines, sera and other biological products. Freezers should be maintained below  $-15^{\circ}\text{C}$ .
- 3.16 Constant temperature monitoring and recording with 24-hour remote visual and audible alarming is required on all medicines storage, including refrigerated and frozen storage.

## Infection control

- 3.17 The pharmacy department (including air intakes) should be sited away from potential sources of contamination including the pathology department, mortuary, kitchens and waste disposal area.
- 3.18 Mechanical and electrical services serving other parts of the hospital should not be routed through the pharmacy department.
- 3.19 Pipework and other services should not be routed through the aseptic preparation facilities except those serving the facilities or within the ceiling void above the facilities. Aseptic preparation facilities should not be located where there are toilets, washrooms etc immediately above.

## Radiation protection

- 3.20 The design of facilities for the preparation of radiopharmaceuticals should take into account the particular hazards associated with the radioactive nature of radiopharmaceuticals. It is therefore important to consult with the hospital radiation protection advisor.
- 3.21 Project teams should take into consideration the requirements and recommendations of the following:
- ‘Medical and dental guidance notes. A good practice guide on all aspects of ionising radiation protection in the clinical environment’ (DH 2002);
  - the Ionising Radiations Regulations 1999;
  - the Ionising Radiation (Medical Exposure) Regulations 2000;
  - the Radioactive Substances Act 1993;
  - the Radioactive Material (Road Transport) Regulations 2002.

## Access and security

- 3.22 The trust’s nominated local security management specialist (LSMS) should be consulted for advice

and guidance on the implementation of security measures to ensure the safety of staff and security of premises.

- 3.23 The whole pharmacy department should be planned as an integrally secure area with controlled and segregated staff, public and goods receipt entrances, and a separate medicines distribution exit.
- 3.24 The total number of entrances from the exterior should be minimised, with CCTV monitoring, where appropriate, to deter unauthorised access. Corridors traversing the pharmacy department should not be used as links to other departments.
- 3.25 It is essential that an accessible environment is provided for disabled people.
- 3.26 All entrances should have steel doors and be fitted with security locks. Mechanical locks should be used to provide “out of hours” security in preference to electromagnetic devices, since the latter will release in the event of activation of the fire alarm.
- 3.27 The provision of retractable or rising bollards at the external goods entrance should be considered to deter “ram raiding”.
- 3.28 Partitioning to the perimeter of the department should be taken full height to structural soffit/roof level and constructed to offer high resistance to determined attack.
- 3.29 External doors should not incorporate visible ironmongery and windows, and should be lockable, alarmed, and glazed using laminated toughened glass. Consideration should be given to the provision of external electrically-operated security shutters to windows.
- 3.30 Arrangements for out-of-hours or emergency access to the pharmacy department should be agreed locally.
- 3.31 An intruder alarm system for the department complying with BS 4737 as appropriate should be installed. It should be linked to the main hospital switchboard.
- 3.32 Consideration should be given to the provision of personal alarms or other means to summon help for staff, for example for a lone worker in the department delivering an out-of-hours on-call response. See ‘Not Alone: A Guide for the Better Protection of Lone Workers in the NHS’ for guidance on protecting lone workers in the NHS.



## 4 Centralised bulk storage and stock distribution facilities

### Spaces

#### External goods entrance

- 4.1 An external goods entrance with an associated access road and vehicle parking/ turning area, designed to accommodate the maximum number, weight and dimension of delivery vehicles expected at one time, is required.
- 4.2 The entrance area may be grouped with the general external goods entrance for the whole hospital, although there should be direct access to the pharmacy department.
- 4.3 A protected loading dock with tailboard access should be provided. Some deliveries may require mechanical handling using a pallet truck/stacker. Space may be required for storage of pallet trucks/stackers.
- 4.4 A dedicated refrigerator should be provided near the external goods entrance for outgoing medicinal products that need to be stored between 2°C and 8°C.

#### Stores office

- 4.5 A stores office is required at the external goods entrance to permit supervision of the area. The stores team will carry out general clerical duties associated with receiving and storage of supplies. A desk and chair, space for a computer, shelving and storage for files should be provided.

#### Goods reception and unpacking area

- 4.6 An area within the pharmacy department will be required for the reception and unpacking of pharmaceutical supplies.
- 4.7 The goods reception/unpacking area should be adequately ventilated to minimise airborne dust produced when unwrapping parcels.
- 4.8 Benches should be fitted at a comfortable standing working height, and space provided for holding

parcels that cannot be unwrapped immediately on delivery.

- 4.9 Unwrapping creates an accumulation of used packaging materials, and facilities will be required for the regular disposal of waste packaging material.
- 4.10 If required, a quarantine store should be located here for holding medicines pending the results of QC assessments prior to release for general issue.

#### Disposal hold

- 4.11 A room will be required for holding segregated waste prior to disposal. See 'Facilities management' in Health Building Note 00-03 – 'Clinical and clinical support spaces'.

#### Bulk storage area

- 4.12 Products will be held in a bulk storage area, prior to onward distribution. Adequate floor space and spacious adjustable racking are needed.
- 4.13 High-usage and bulky items such as intravenous infusion fluids may be delivered and stored on pallets. To facilitate safe handling, materials delivered on pallets should be stored at low level. This requirement will have a significant impact on the area required for storage.
- 4.14 If a working stock of flammable materials is required, cabinets with spillage trays should be provided.
- 4.15 The bulk storage area should be adjacent to, but physically separate from, the goods reception/unpacking area, with close and easy access to the dispensary.
- 4.16 Where an automated dispensing system (robot) is located in the dispensary, consideration should be given to the use of a conveyor link between the bulk storage area and the robot for stock picking. Alternatively the robot may be located within the bulk storage area with a conveyor link to the dispensary. Short conveyor runs are essential to

maintain efficiency. Noise generated by conveyor systems should be considered in planning.

- 4.17 Designated (and in some cases, segregated) storage areas will be required for certain products. In order to optimise the use of space and to minimise travel distances between the various stores, these specialised stores should form part of the bulk storage area.

#### *Temperature-controlled storage*

- 4.18 A number of refrigerators and freezers may be required within the bulk storage area. A walk-in cold store may be provided in place of the refrigerators.

#### *Consumables storage area*

- 4.19 A designated area of shelving will be required for the storage of containers, sterile supplies and equipment used in the preparation and assembly of pharmaceutical products.
- 4.20 Storage areas for starting materials and components for use in aseptic preparation should be pharmaceutically clean and not located in a main circulation route, to reduce potential sources of contamination.

#### *Ward stock distribution area*

- 4.21 Standard pharmaceutical items are delivered to wards and other clinical areas in ward boxes and/or delivery trolleys.
- 4.22 An area is required for holding empty ward boxes and/or trolleys. Trolleys will require plenty of space for parking and manoeuvring.
- 4.23 Space for packing, checking and holding filled ward boxes and/or trolleys prior to issue should also be provided. The use of roller conveyors for handling boxes and loading trolleys should be considered.

- 4.24 Separate medicines distribution exit(s) providing easy access to the hospital's main horizontal and vertical circulation routes, and to any area from which supplies are dispatched to satellite facilities, should be provided from the ward stock distribution area. For security reasons, the number of such exits should be kept to the minimum.
- 4.25 If electric or other vehicles are to be used to transport heavy and bulky items, the exits will require heavy-duty protection to minimise the risk of physical damage.

#### **External flammables store**

- 4.26 Bulk flammable materials should be kept away from user areas. The provision of an external isolated store for flammable materials is therefore essential. Local policy may require the pharmacy department to be responsible for holding stocks of flammable materials for other departments as well, which will affect the size of the store.
- 4.27 The store should be sited away from any entrances, including the external goods entrance, and emergency fire exits.

#### **Emergency medicines store**

- 4.28 The supply of medicines when the pharmacy is closed will be determined by local policy. A store for holding emergency stocks will be required. It should include a refrigerator, an index system and a means of recording items taken. A panel for displaying notices should be provided.
- 4.29 Ideally the store should be close to the pharmacy department (for ease of checking and restocking) and, for security reasons, should be near to the main thoroughfare of the hospital or an area which is constantly manned. However, it should not have direct communication with the pharmacy department.

## 5 Dispensary facilities

### Introduction

- 5.1 This chapter describes facilities for dispensing and issuing medicines to out-patients and dispensing to wards and other clinical areas.
- 5.2 The dispensary is the hub of the pharmacy department. It should be located close to the bulk storage area.
- 5.3 It should also be near to the out-patients department. If this is not possible, an adequate system for the transfer of medicines to out-patients should be provided. This may be by pneumatic tube. See Health Technical Memorandum 2009 – ‘Pneumatic air tube transport systems’.

### Dispensing area

- 5.4 Shelves, cupboards and drawers should be provided for working stocks of medicinal products, bottles, lids, cartons and other packaging.
- 5.5 If a working stock of flammable liquids is to be kept in the dispensary, a suitable lockable steel flammable storage cabinet should be provided.
- 5.6 Storage units should not be located close to heat sources, for example pipes and radiators, as this may cause medicines to deteriorate.
- 5.7 It is advisable to minimise the number of wall-mounted or fixed units to allow maximum future flexibility.
- 5.8 The need for refrigerated storage in the dispensing area will depend on local needs. For reasons of efficiency and economy, consideration should be given to the provision of a single cold store accessible from both the dispensary and the bulk storage area.
- 5.9 Work surfaces should be well-lit, level, stable and fixed at a suitable height. They should be non-reflective and easily cleanable, with no fissures or jointing. White benches provide a difficult background on which to see white packaging and

medication, and should be avoided. A colour that contrasts with white should be chosen.

- 5.10 A dedicated work surface with an adjacent sink with integral drainer should be provided to allow for the preparation of small quantities of “wet” products including antibiotic mixtures.
- 5.11 Dedicated clinical hand-washing facilities should be provided close to the work areas.
- 5.12 Computer workstations should be provided within the dispensing area for ordering supplies, stock control, and the recording and labelling of prescriptions.
- 5.13 If a pneumatic tube system is installed, a collection/dispatch point should be provided in the dispensary close to the clinical checking area.
- 5.14 Pipework and all items of equipment should be installed so that they may be readily cleaned and, if necessary, sanitised.

### Extemporaneous dispensing area

- 5.15 If there is a requirement for on-demand extemporaneous dispensing of ointments, lotions, mouthwashes, syrups, suppositories etc, a dedicated area within the dispensary should be provided equipped with work surfaces. A suitably-sized sink should be provided nearby.
- 5.16 Ideally, any work involving hazardous material should not be undertaken in the dispensary. However, where this is unavoidable, an extract safety cabinet will be required.
- 5.17 The design of extemporaneous dispensing areas should comply with the ‘Guide to the preparation of non sterile extemporaneous products in NHS hospitals’ and should take account of the nature and scale of the work undertaken.

### Controlled drugs store

- 5.18 Controlled drugs required in the dispensary should be held on open shelving in a separate secure

(lockable) store and equipped with audio-visual alarms connected to a continually manned location.

- 5.19 A work surface and computer(s) for counting items and recording supplies issued should be provided in the store. Space will be required for storing a ledger or PC.

### Non-formulary drugs storage area

- 5.20 If required, a segregated area of shelving for the storage of those medicines not included in the hospital formulary should be provided within the dispensary.

### Unlicensed medicines store

- 5.21 A dedicated store is required for holding unlicensed drugs. A dedicated refrigerator will be required.

### Clinical trials material store

- 5.22 A dedicated store is required for holding clinical trials material. A dedicated refrigerator/freezer will be required.

### Automated dispensing system (robot)

- 5.23 If a robot is to be installed in the dispensary, the layout should be configured around the equipment to optimise the use of space and minimise travel distances for dispensary staff.
- 5.24 Where drop chutes (without a conveyor system) are used, dispensing stations should be located by the side of the robot, but conveyor belts (with drop chutes as necessary) may be used to reach dispensing stations conveniently positioned within the dispensary.
- 5.25 Care is needed to ensure sufficient space is provided for the loading of the robot, any associated (manual) computer checking system, and to accommodate the trolleys on which the medicinal products to be loaded are delivered.
- 5.26 Floor strength and ceiling height are critical considerations when planning automated systems. A 3000–3500 mm high robot is likely to achieve the optimum storage solution. The ceiling may be recessed above the robot only in order to reduce the overall ceiling height requirement.



Medicines storage for use with dispensing robot



Medicines storage for use with dispensing robot



Dispensing robot

## Other dispensary spaces

### Waiting area

- 5.27 Seating is required for out-patients and visitors. There should be space for wheelchairs and those using walking aids.
- 5.28 Notice boards should be provided for displaying health educational material. Consideration may be given to the provision of television and video facilities for health promotional material and to help alleviate the boredom of waiting.
- 5.29 A wheelchair-accessible public telephone should be provided in or near to the waiting area.
- 5.30 A supply of chilled filtered drinking water should be available for those waiting and for patients needing to take tablets.
- 5.31 Doors from the waiting area to non-public areas of the department should be fitted with an electronic access control system.

### Out-patient service counter

- 5.32 A service counter is required for receiving prescriptions and issuing dispensed items. Consideration should be given to the provision of separate counter sections for “prescriptions in” and “medicines/issues out” to aid workflow and promote patient confidentiality. The counter should be welcoming with good signage.
- 5.33 At least one section of the counter should be at a height suitable for a person in a wheelchair. The provision of vertical privacy screens between sections of the counter should be considered.
- 5.34 Consideration should be given to designating one section of the counter for the use of hospital staff and visitors to the department itself. If the counter is sectionalised, each function should be clearly signed.
- 5.35 Induction loop facilities for those with hearing impairment should be provided, but the need for privacy in conversations conveyed by such means should be ensured.
- 5.36 Facilities for the collection of prescription charges, including a cash till and a computer, should be provided. Project teams should consider the provision of a visual and audible numbered ticket system for patient recall.
- 5.37 The need for staff security should be borne in mind. Consideration should be given to the

installation of “bank teller” style screens or automatic security shutters that provide staff security but do not adversely impact upon patient confidentiality.

- 5.38 The need for CCTV surveillance of the service counter will depend on the type of physical security provided. A security alarm actuating switch or button (“panic button”) should be located unobtrusively at the service counter. It should be connected to a continuously staffed area such as the hospital telephone switchboard or the porters’ room.
- 5.39 The counter should be adjacent to the waiting area. There should be direct access for staff behind the counter to the dispensary and confidential counselling area. The dispensary should not be visible or audible for patients/visitors at the counter.

### Clinical checking area

- 5.40 A number of computer workstations and telephones should be provided close to the service counter for use by staff involved in clinical checking. Storage space for a small amount of reference material will be required.

### Final checking area

- 5.41 A number of workstations should be provided for staff involved in final checking. To aid staff concentration, the workstations should not be sited near telephones or other distractions nor in direct view of the service counter.
- 5.42 A storage area, close to the out-patient service counter, is required for holding items pending issue.

### Confidential counselling area

- 5.43 A discrete part of the dispensary, accessible from both the waiting area (for patients/visitors) and dispensary (for staff), should be provided for confidential discussions between pharmacy staff and patients, relatives and carers.
- 5.44 It should be furnished comfortably, with a fixed desk acting as a security barrier between the dispensary and waiting area. Seating for two people and space for a wheelchair should be provided on the waiting side.
- 5.45 The entry door from the waiting area should be under staff control but free to exit. The dispensary side of the facility should be visually and

acoustically screened yet open to the dispensary to allow staff to withdraw quickly and safely in the event of a threat to their security. A “panic button” should be provided.

- 5.46 The counselling area should be equipped with a computer.
- 5.47 An induction loop facility for those with hearing impairment should be provided.

#### **Returned medicines store**

- 5.48 A dedicated store is required for holding returned or recalled medicines, prior to them being dispatched for disposal or recycling. A refrigerator will be required in this store.

#### **Secure store for controlled stationery**

- 5.49 Controlled stationery should be stored securely in the dispensary or in an alternative secure location within the pharmacy department.

#### **Dispensary manager's office**

- 5.50 The dispensary manager's office should contain one workstation, and seating for two or three other people. See 'Offices' in Health Building Note 00-03 – 'Clinical and clinical support spaces'.

## 6 Aseptic preparation facilities

- 6.1 This chapter describes aseptic preparation facilities operating under Section 10 of the Medicines Act 1968, which may be used to prepare:
- parenteral nutrition (PN) products;
  - centralised intravenous additive (CIVA) injections/infusions;
  - cytotoxic injections/infusions.
- 6.2 The specific requirements associated with radiopharmaceuticals (including radiation protection) dictate that these should be prepared in dedicated facilities (see ‘Radiopharmaceutical preparation facilities’ for details).
- 6.3 Gene therapy products may also require dedicated facilities, depending upon their risk classification under the Genetically Modified Organisms (Contained Use) Regulations 2000. Expert advice should be sought.
- 6.4 The design of aseptic preparation facilities should comply with the guidance laid down in ‘Rules and Guidance for Pharmaceutical Manufacturers and Distributors’ (the so-called “Orange guide”) and ‘Quality Assurance of Aseptic Preparation Services’.
- 6.5 Aseptic preparation facilities should comprise:
- changing facilities;
  - outer and inner support rooms (including storage facilities for starting materials, components and finished products);
  - clean rooms containing laminar flow cabinet(s) and/or isolator(s) and/ or class 2 safety cabinet(s);
  - an administration room.
- 6.6 See **Chapter 7, ‘Radiopharmaceutical preparation facilities’**; the Genetically Modified Organisms (Contained Use) Regulations 2000; and ‘Quality Assurance of Aseptic Preparation Services’.

### Changing room(s)

- 6.7 The inner support room and clean rooms should be accessed through dedicated changing facilities. The size of the changing room(s) will depend on the number of staff changing concurrently.

### First-stage changing room

- 6.8 The first-stage changing room will be the sole point of entry into the changing facilities.
- 6.9 The room should be divided into “dirty” and “clean” zones, with a step-over bench marking the boundary between the two zones.
- 6.10 It should be designed as an airlock with its own supply of filtered air from a ceiling-mounted terminal HEPA filter at the clean end of the room. An audible and visual warning system should be provided to indicate failure of the air supply. Air pressure differences should be monitored continuously and recorded regularly.
- 6.11 Storage facilities for outer garments should be provided in the dirty zone and for clean room clothing in the clean zone. A shelf below the step-over bench should be provided for storage of footwear.
- 6.12 A foot-operated bin for disposal of used clean room clothing should be provided in the dirty zone. If used clean room garments are to be reprocessed, a suitable container should also be provided here.
- 6.13 If the procedure requires full change (that is, down to underwear), “in use” and “male/female” warning indicators under control of the room occupant will be required.
- 6.14 An electronic interlocking system should be installed to prevent the simultaneous opening of the entry and exit airlock doors. A visual and/or audible warning system may also be required to indicate if both doors are allowed to open (in the event of failure of the interlocking system).
- 6.15 Clinical hand-washing facilities should be provided immediately outside the entry door.



## Second-stage changing room

- 6.16 The second-stage changing room may be accessed from the clean side of the first-stage changing room or via the inner support room. There should be no direct access between the inner support room and aseptic clean rooms.
- 6.17 Clean rooms containing laminar flow cabinets or class 2 safety cabinets should be accessed via at least a first- and second-stage changing room (as defined in this manual). Clean rooms containing isolators may be accessed via a dedicated changing room or a second-stage changing room accessed via the support room. The inner support room may be accessed via the first-stage changing room or a dedicated changing room.
- 6.18 The design of the second-stage changing room should be similar to the first-stage changing room without the requirement for storage of outer garments. Protective sterile clothing and gloves should be stored on the clean side of the room.

## Outer and inner support rooms

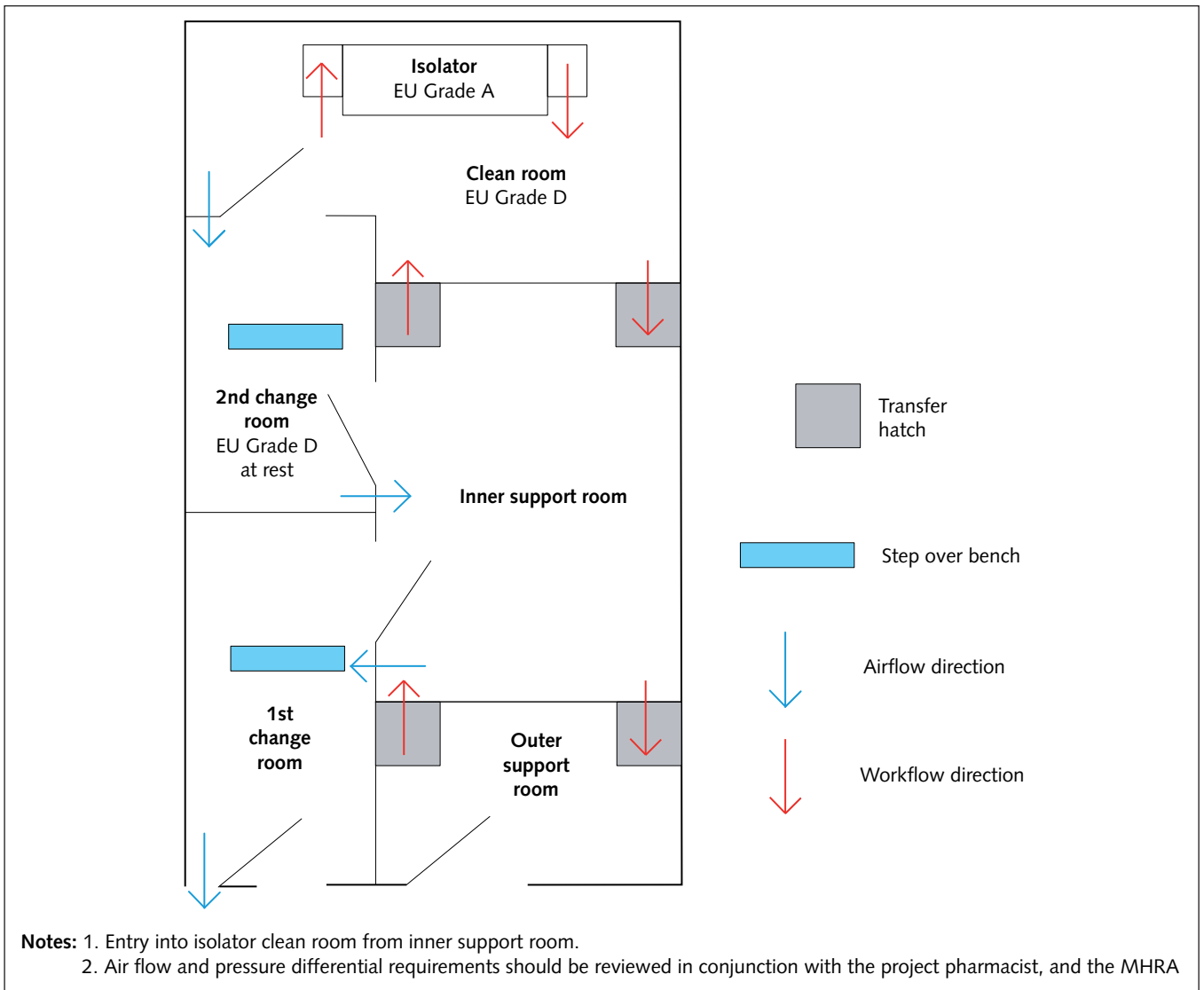
- 6.19 Materials and small items of equipment to be used in the aseptic preparation facilities will be transferred between the outer support room and the inner support room via two airlock pass-through hatches (that is, separate “in” and “out” hatches). The wall between the support rooms should incorporate observation screens.
- 6.20 The inner support room is used for the assembly of starting materials and components prior to transfer to the clean rooms and the checking and labelling of finished products.
- 6.21 Dedicated work surfaces with a suitable contrasting colour and an illuminated magnifier attached are required at a suitable height and adjacent to the pass-through hatches between the inner and outer support rooms for the assembly and final checking operations.
- 6.22 Materials and equipment will be passed between the inner support room and the clean rooms via separate airlock pass-through hatches (that is, there will be an “in” and “out” hatch serving each clean room).
- 6.23 In busy units, localised air extraction may be provided adjacent to each “in” hatch, depending on a risk assessment, to extract alcohol vapour from surface disinfection solutions.

- 6.24 Separate storage areas will be required for the temporary holding of starting materials/ components and finished products. Storage areas may include wall-mounted shelving, cupboards and drawers as well as refrigerators with glass doors.
- 6.25 A dedicated cleaners’ room should be provided close to the entry door to the changing facilities.

## Clean rooms

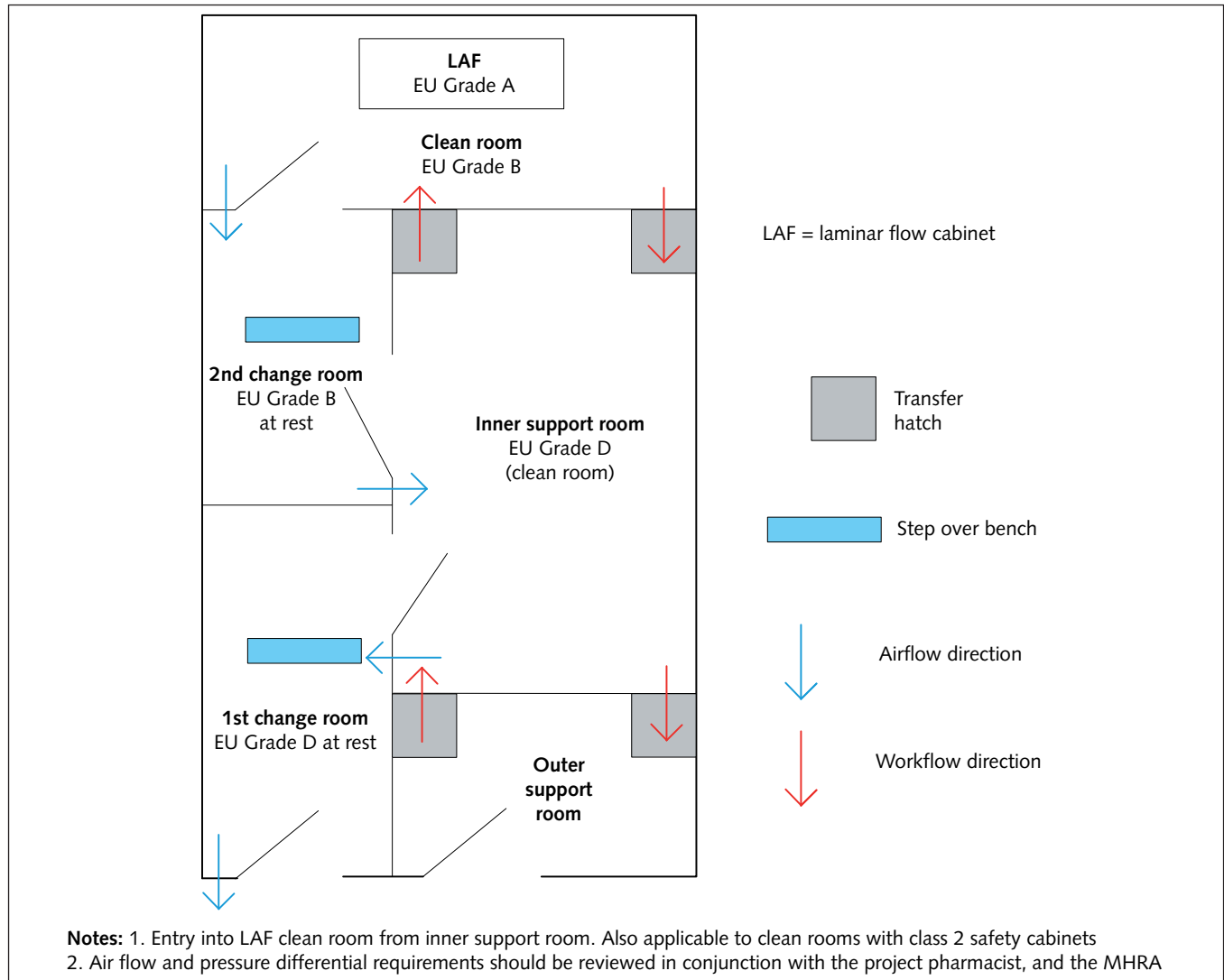
- 6.26 Requirements for the clean rooms will vary depending on the type of product being prepared.
- 6.27 In many instances, the focus will be on product protection, achieved through the use of laminar flow cabinets or positive pressure isolators that recirculate filtered air. However, in the preparation of cytotoxics, both the operator and product require protection. This is often achieved through the use of negative pressure isolators or class 2 safety cabinets both ducted to atmosphere. Positive pressure isolators ducted to atmosphere may also assist in the protection of operators where medicines such as antibiotics are handled.
- 6.28 The number of clean rooms and laminar flow cabinets/isolators/class 2 safety cabinets should be established on a local basis with advice from the relevant pharmaceutical quality assurance advisor. See the two figures below for example layouts of aseptic facilities.
- 6.29 If common clean rooms are used for the preparation of different products, care should be taken to segregate activities by time and, where appropriate, specific cleaning arrangements so that cross-contamination is avoided. If specific product types are routinely required, consideration should be given to the provision of dedicated clean rooms or dedicated isolators within clean rooms.
- 6.30 Laminar flow cabinets should meet BS EN ISO 14644 standards and class 2 safety cabinets should meet BS EN 12469:2000 standards. Both should be located in clean rooms complying with EU GMP Grade B.
- 6.31 Isolators should meet standards given in ‘Pharmaceutical Isolators: A guide to their application, design and control’, and should be located in clean rooms complying with at least EU GMP Grade D.
- 6.32 All cabinets and isolators should be provided with a visual indication of airflow, with the minimum safe airflow clearly shown. There should be an audible

Figure 1 Isolator suite (example layout)



Isolator clean room

Figure 2 LAF suite (example layout)



and visual warning if the flow falls below the safe level.

6.33 All cabinets and isolators should incorporate checks against extraneous air flow, with automatic alarms if such air flow occurs. Isolators should be able to undergo a pressure leak test according to 'Pharmaceutical Isolators'. Equipment should possess capacity for the safe changing of filters if hazardous material is handled.

6.34 Each clean room should:

- be designed for easy cleaning, with self-covered skirtings, coved ceiling/wall and wall/wall junctions and the minimum number of projecting ledges, shelves, cupboards and items of equipment;
- incorporate an observation panel in the wall to the inner support room but not have opening windows;

- have a sealed ceiling in order to prevent potential contamination from the void above.

## Administration room

6.35 An administration room is required, sized according to the number of staff who will be working in the aseptic preparation facilities. The design, environmental standards, finishes, fixtures and fittings will need to be appropriate to an aseptic environment.

## General design requirements

6.36 Separate access to engineering services should be provided to ensure that the clean environment is not compromised by the need to carry out regular or essential maintenance. Advice should be sought from the relevant pharmaceutical quality assurance advisor.

- 6.37 The design of the ventilation and environmental systems should be developed in conjunction with the project pharmacist, and through them the MHRA, to suit the type of products being prepared.
- 6.38 Sinks and drains should be excluded from areas where aseptic operations are carried out.
- 6.39 Fittings and finishes should be smooth, impervious, jointless and easily cleaned.
- 6.40 Ventilation systems and airflow through cabinets should be designed for continuous operation and should only be shut down for the purposes of maintenance or emergency isolation.

## 7 Radiopharmaceutical preparation facilities

- 7.1 This chapter describes dedicated and self-contained aseptic preparation facilities (operating under Section 10 of the Medicines Act 1968) for the assembly and storage of radiopharmaceuticals.
- 7.2 The procedures undertaken are similar to those used in aseptic preparation facilities generally, and the principles set out in that section should be employed. The need to protect the operator and local environment from ionising radiation means that the design of the radiopharmaceutical preparation facilities should meet requirements for radiation protection.
- 7.3 Radiopharmaceutical preparation facilities should comprise:
- a support room (including storage facilities for consumables);
  - changing facilities;
  - clean room(s) containing laminar flow cabinet(s) or isolator(s);
  - a room for the storage and decay of waste radioactive substances;
  - a separate area for undertaking radiochromatographic quality control procedures;
  - an administration room;
  - a room for storage of the old generator and receipt of the new generator.
- 7.4 Consumables (for example syringes, needles, vials etc) will be transferred between the support room and each clean room(s) via separate airlock pass-through hatches (that is, there will be a pair of hatches serving each clean room).
- 7.5 The support room and clean room(s) should be accessed from dedicated changing facilities.
- 7.6 Each cabinet/isolator should have its own individual exhaust system incorporating effective precautions against blow-back and providing safe dispersal to atmosphere.
- 7.7 Air extracted from areas where radioactive products are handled should not be recirculated.
- 7.8 To cope with the risk of an accident or spillage outside cabinets, a clearly labelled “panic button” should be provided. Its function is to switch off the air supply to that space whilst providing extract only. The controls should provide for all air extracted to be discharged to atmosphere. This should display a warning sign at point of discharge.
- 7.9 A dedicated clean room with dedicated changing facilities will be required if radiolabelling of blood products is to be carried out. This is to prevent cross-contamination of products.
- 7.10 All finished preparations should be assayed for content of radioactivity (dose calibration). This may take place in the clean room(s) or support room.
- 7.11 The equipment for performing these assays should be shielded to exclude background readings, and may require strengthened benching support.
- 7.12 Preparations that are stable at 2–80°C should be stored in a refrigerator (in the support room) until required. There may be a requirement for shielded refrigerators.
- 7.13 All potentially contaminated materials (including syringes, needles and operatives’ gloves) should be collected and stored in a separate shielded room (with controlled access) until safe. A number of rooms may be required for different categories of waste. Alternatively, separate shielded cupboards may provide sufficient segregation.
- 7.14 The environment within radiopharmaceutical preparation facilities should be monitored for radioactive contamination after each working session and decontaminated when appropriate. Its design and construction should allow for chemical and physical decontamination methods.

## Delivery and storage of generators

7.15 Preparation of radiopharmaceuticals requires the delivery of molybdenum generators to the clean room(s) in order to provide the necessary radioisotopes. Generators are heavy and radioactive,

and thus require specialised storage and transportation.

7.16 A small room, accessible from both outside and inside the building, should be provided for out-of-hours delivery. Access should be by key entry only.

## 8 Non-sterile preparation facilities

8.1 This chapter describes non-sterile facilities for the preparation of pharmaceutical products from raw materials and/or other commercially available pharmaceutical products.

### Materials/consumables store

8.2 Once passed for use in preparation, raw materials are transferred from the quarantine area into a materials store until required. A refrigerator(s) should be provided. Storage will also be needed for other materials involved in preparation, for example small quantities of consumables such as filters and cleaning materials as well as empty containers, which need a great deal of space.

### Ingredients weighing area

8.3 Raw materials taken from stores are weighed in the weighing area before being passed directly into the preparation areas.

8.4 The weighing area should be fitted with enclosed balances set up on a level (slate) table with a completely firm base. There will also need to be provision for recording the weighings on batch documentation.

### Dry and liquid products

8.5 Since both solid and liquid products will be prepared in this area, it should allow for sufficient flexibility of use in response to demand. Workbenches will be required for preparing smaller batches of liquids.

8.6 Depending on the nature and quantity of materials produced, safety cabinets that are capable of handling flammable vapours may be required. Mechanical ventilation may also be required.

8.7 See Health Technical Memorandum 03-01 – ‘Specialised ventilation for healthcare premises’.

### Creams and ointments area

8.8 The preparation of creams and ointments, which may be particularly susceptible to microbial and other contamination during manufacture, should be carried out in a dedicated area that satisfies the air supply criteria of Grade D. Small batches can be prepared on an electrically heated slab mounted on or inset into a worktop.

### Repacking and assembly facilities

8.9 The function of this support area is to repackage items in a form suitable for patient use. It is assumed that only bought-in products will be repackaged.

### Visual inspection and labelling area

8.10 Finished products are moved into a separate area for visual inspection and labelling. A bench may provide a convenient boundary, and assists hand-labelling. Products may then be transferred to the quarantine store to await pharmacist or QC clearance.

### Quarantine area

8.11 Items may need to be quarantined pending the results of quality control (QC) assessments prior to use or general issue. The quarantine area should be large enough to accommodate raw materials, components, finished products and returned materials, each of which should be held in a separate area of the store. Refrigerators will be required for some products.

## 9 Staff support facilities

- 9.1 This chapter describes office accommodation for procurement of medicines, consultative, administrative and information services. It also outlines other staff support spaces associated with a pharmacy department.
- 9.2 Office accommodation will be required for the following staff:
- clerical and secretarial staff, including those performing purchasing duties;
  - pharmacists and technicians, including those with managerial duties;
  - clinical pharmacists, working throughout the hospital but requiring a base within the pharmacy department.
- 9.3 A mixture of administration (continuous use) and hot-desk areas may be provided.

### Administration (continuous use) area

- 9.4 The administration area should be open-plan or a mixture of open-plan and individual offices.
- 9.5 Individual workstations/desks should be designated to office-based staff and used on a continuous basis over a day/shift.
- 9.6 Where open-plan space is provided for senior staff with managerial duties, consideration should be given to providing:
- quiet rooms (one for every six staff) for confidential discussions;
  - interview room(s) for employment interview, staff reviews etc.
- 9.7 Individual offices may be required for the chief pharmacist and a number of senior pharmacists with managerial duties.
- 9.8 Office accommodation for the chief pharmacist should be sited close to staff and visitor entrances. See 'Offices' in Health Building Note 00-03 – 'Clinical and clinical support spaces'.

### Hot-desk area

- 9.9 The hot-desk area should be open-plan. Individual workstations/desks should be shared for use by clinical and non-clinical staff (including clinical pharmacists) on an ad hoc basis (that is, not continuous usage over a day/shift).
- 9.10 There should be one workstation/desk for every two to six people (on average one for every four people) depending upon average user occupation. The overall number should be based on the maximum demand for desks at any one time.
- 9.11 Where a hot-desk area is provided, associated quiet rooms and breakout spaces will be required. These should be located nearby. There should be one quiet room and one breakout space for every six hot desks. See 'Offices' in Health Building Note 00-03 – 'Clinical and clinical support spaces'.

### Clinical trials office

- 9.12 Separate office accommodation is required for managing clinical trials.
- 9.13 The office should contain a workstation/desk for administrative work and a separate workbench for reconciling drugs.
- 9.14 Space is required for storing records, books, files and other documents. See 'Offices' in Health Building Note 00-03 – 'Clinical and clinical support spaces'.

### Medicines information facilities

- 9.15 Medicines information facilities are required for the provision of evidence-based information regarding pharmaceutical products.
- 9.16 The facilities should be located in the pharmacy department, preferably adjacent to the dispensary. They should be accessible to all pharmacy staff.
- 9.17 The facilities should comprise an office with computer workstations/desks with telephones and



space for storage of reference material and report writing.

9.18 It should conform to the minimum standard of accommodation and resources as determined by the national body (UKMI).

9.19 In smaller trusts, the clinical trials office and medicines information facilities may be located within one office space.

### **Other staff support spaces**

9.20 The following support spaces will also be required:

- staff changing area (general), including showering and toilet facilities;
  - staff rest room, including facilities for preparing and consuming beverages and snacks;
  - meeting space;
  - cleaners' room.
- 9.21 See Health Building Note 00-02 – 'Sanitary spaces' and Health Building Note 00-03 – 'Clinical and clinical support spaces'.

## 10 Glossary

**Ampoules:** Sealed glass containers containing sterile solutions or emulsions for injection. Typical volumes: 1–20 ml

**Automated dispensing systems (robots):** Mechanised systems that store and dispense original pack medicines. They offer very compact storage, improved stock handling and facilitate more accurate and rapid picking than manual methods

**Aseptic preparation:** The preparation of medicines within an aseptic (sterile) environment

**Aseptic products:** Medicines prepared to be free from microbial contamination

**Bulk intravenous infusion fluids:** Large volume infusion fluids, typically boxes of 10 × 1000 ml bags, weighing 10 kg per box

**Centralised intravenous additive (CIVA) injections/infusions:** A range of injectable medicines prepared within the pharmacy aseptic facilities in a ready-to-use format for example pre-loaded syringes

**Clinical areas:** A generic term for hospital wards, clinics, operating theatres etc

**Clinical checking:** The process of assessing the suitability of a prescription to enter the dispensing process, validating legality, clinical appropriateness and the presence of all required information

**Clinical trials:** Medicines that are undergoing strictly controlled assessment for their safety and efficacy before being licensed for UK use by the Medicines and Healthcare products Regulatory Agency (MHRA) and released onto the market. Also trials that compare licensed products

**Starting materials and components (also known generically as raw materials):** Medicinal substances and devices that will be combined to form a new medicinal entity. Used in aseptic and non-sterile preparations

**Controlled drugs:** A class of medicines including morphine, diamorphine and methadone whose usage and handling are strictly controlled under the Misuse of Drugs Act 1971

**Controlled stationery:** Prescription forms and similar stationery that requires secure storage and documented supply

**Cytotoxic medicines:** Medicines that kill living cells, used primarily in the treatment of cancers. They are generally administered orally, topically or by injection

**Dispensing:** A term that covers a range of techniques whereby medicines or raw materials are manipulated to produce a final entity that fulfils the prescribed requirement for an individual patient

**Emulsions:** Aqueous solutions containing emulsified fatty materials for injection or oral administration

**Epidural medicines:** Injection solutions specially configured for injection into spinal areas

**Extemporaneous dispensing:** A medicine that is not available commercially and should be freshly prepared in a small quantity on demand for example a special ointment or mouthwash

**Final accuracy/product quality check:** The analysis of dispensed items to confirm dispensing accuracy to the prescription specifications and other quality aspects that renders them suitable for issue to a patient/carer

**Gene therapy:** Medicinal products incorporating genetic material to supplement or replace non-functioning material in the patient

**Infusions:** Sterile solutions for injection – administered over a defined period of time for example a volume of 1 litre over eight hours

**Intravenous:** Injecting directly into a patient's veins

**Licensed facilities:** Facilities used for the preparation or assembly of medicines that are required to hold a Manufacturer's "Specials" Licence from the Medicines and Healthcare products Regulatory Agency (MHRA)

**Local security management specialist:** Person nominated by their NHS health body and who is trained and accredited by the NHS Security Management Service to undertake security management work in the NHS

**Medicines management:** A term that encompasses all aspects of the management of medicines – procurement, storage, prescribing, preparation, supply, administration and disposal

**MHRA:** The Medicines and Healthcare products Regulatory Agency – national body with responsibility for medicines licensing in the UK

**Molybdenum generator:** A radioactive device used in the preparation of radiopharmaceuticals

**Nebuliser:** A device for creating a mist of droplets for inhalation from a water-based medication solution. Nebulisers are driven by compressed medical air or medical oxygen

**Non-formulary medicines:** Medicines defined in the hospital's medicines formulary as not being available for routine use, for example prescribing restricted to consultant medical staff only

**Non-sterile medicines:** Medicines that are not required to be free from microbial contamination

**Non-sterile preparation and assembly:** The bringing together of two or more starting materials or components as one entity that will then be administered or used by another person, for example combining one ointment with another to form a new, single product

**NPSA:** National Patient Safety Agency. National body responsible for promoting risk reduction and safety in patient care

**Original packs:** A medicine that is packed by the manufacturer in a ready-to-use format and contains a quantity suitable for a fixed period or single course of treatment

**Parenteral nutrition (PN) products:** Nutritional solutions/emulsions administered by injection to replace orally-administered foods

**Pharmacist:** Person holding a degree in pharmacy and registered with the Royal Pharmaceutical Society of Great Britain

**Pharmacy technician:** Person holding an NVQ level 3 qualification in pharmacy services and registered with the Royal Pharmaceutical Society of Great Britain

**Quarantined stock:** Stocks of newly-prepared medicines that are set aside pending the result of quality assurance tests, before being released for issue

**Radiopharmaceuticals:** Medicinal products that are radioactive in nature

**Suppositories/enemas:** Medication provided in a semi-solid (suppositories) or liquid (enemas) form suitable for rectal administration

**Topical:** Of a medicine, applied directly to the skin

**UKMI:** National NHS body responsible for the support and governance of NHS hospital medicines information facilities

**Unlicensed facilities:** Facilities used for the preparation or assembly of medicines that operate under a Section 10 exemption of the Medicines Act 1968

**Planning and design manual 1061:0.2:England**

**Unlicensed medicines:** Medicines that do not have a current licence for use within the UK from the Medicines and Healthcare products Regulatory Agency (MHRA)

# 11 References

- Management issues for clinical trials of medicines in NHS hospitals with particular reference to the pharmacy.
- Pharmaceutical isolators. A guide to their application, design and control.
- The Safe and Secure Handling of Medicines: A Team Approach.
- Safe Management of Controlled Drugs: a guide to good practice in secondary care (England).
- Quality Assurance of Aseptic Preparation Services.
- A Spoonful of Sugar – Medicines Management in NHS Hospitals.
- A vision for pharmacy in the new NHS.
- Choosing health through pharmacy.
- Medicines management in NHS Trusts – hospital medicines management framework.
- Medicines and Healthcare products Regulatory Agency (MHRA).
- Health Building Note 6 Volume 1 – ‘Facilities for diagnostic imaging and interventional radiology’.
- Medicines Act 1968.
- Aseptic dispensing for NHS patients. DH, 1997.
- Misuse of Drugs (Safe Custody) Regulations 1973.
- Medical and dental guidance notes. A good practice guide on all aspects of ionising radiation protection in the clinical environment. DH 2002.
- Ionising Radiations Regulations 1999.
- Ionising Radiation (Medical Exposure) Regulations 2000.
- Radioactive Substances Act 1993.
- Radioactive Material (Road Transport) Regulations 2002.
- Not Alone: A Guide for the Better Protection of Lone Workers in the NHS.
- Health Building Note 00-03 – ‘Clinical and clinical support spaces’.
- Health Technical Memorandum 2009 – ‘Pneumatic air tube transport systems’.
- The Genetically Modified Organisms (Contained Use) Regulations 2000.
- Aseptic preparation facilities.
- Health Technical Memorandum 03-01 – ‘Specialised ventilation for healthcare premises’.
- Health Building Note 00-02 – ‘Sanitary spaces’.