HEALTH TECHNICAL MEMORANDUM 08-06

Pathology laboratory gas systems

2007

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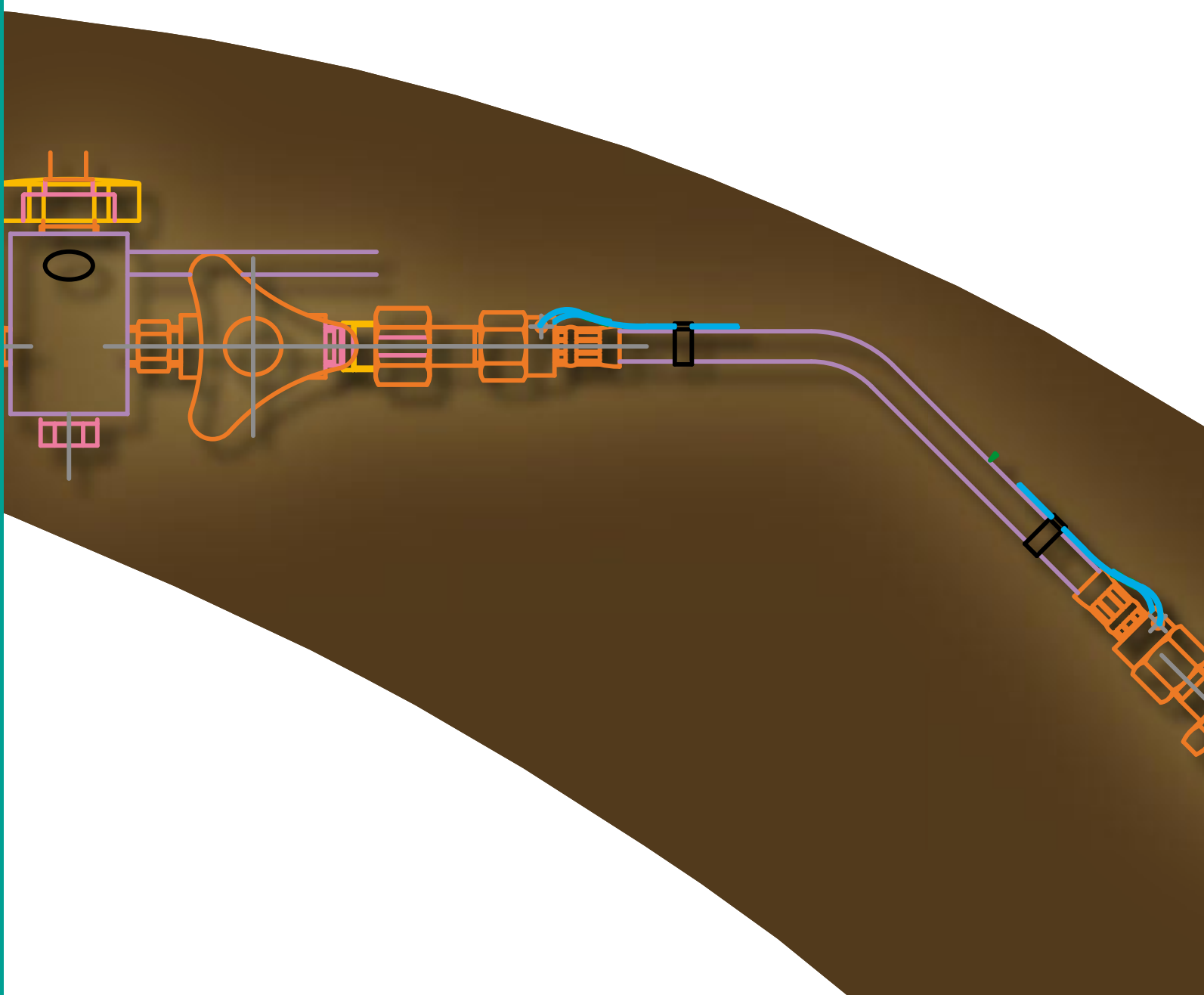
Specialist services
Health Technical Memorandum 08-06: Pathology laboratory gas systems



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Health Technical Memorandum
08-06: Pathology laboratory gas systems

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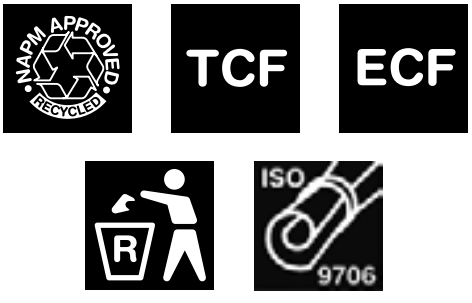


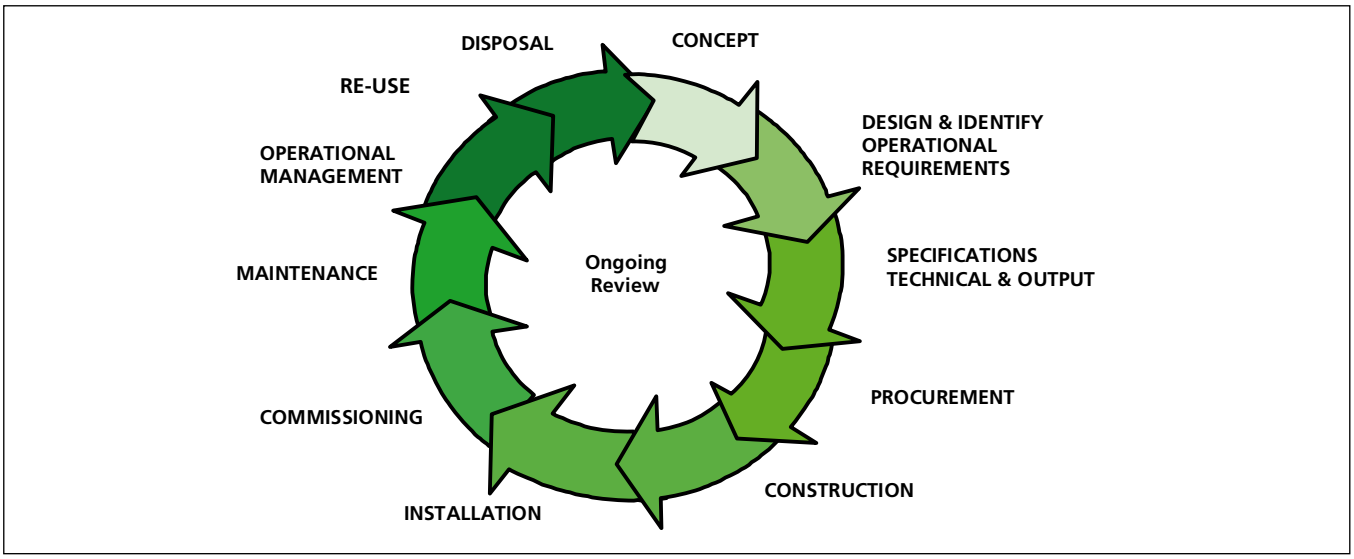
Preface

About Health Technical Memoranda

Engineering Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle.

Figure 1 Healthcare building life-cycle



Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of nine subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

Structure of the Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of nine core subjects:

Health Technical Memorandum 00
: Policies and principles (applicable to all Health Technical Memoranda in this series)

Health Technical Memorandum 01
: Decontamination

Health Technical Memorandum 02
: Medical gases

Health Technical Memorandum 03
Heating and ventilation systems

Health Technical Memorandum 04
Water systems

Health Technical Memorandum 05
Fire safety

Health Technical Memorandum 06
Electrical services

Health Technical Memorandum 07
Environment and sustainability

Health Technical Memorandum 08
Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Health Technical Memorandum 06-02 Part A will represent:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 will simply represent:

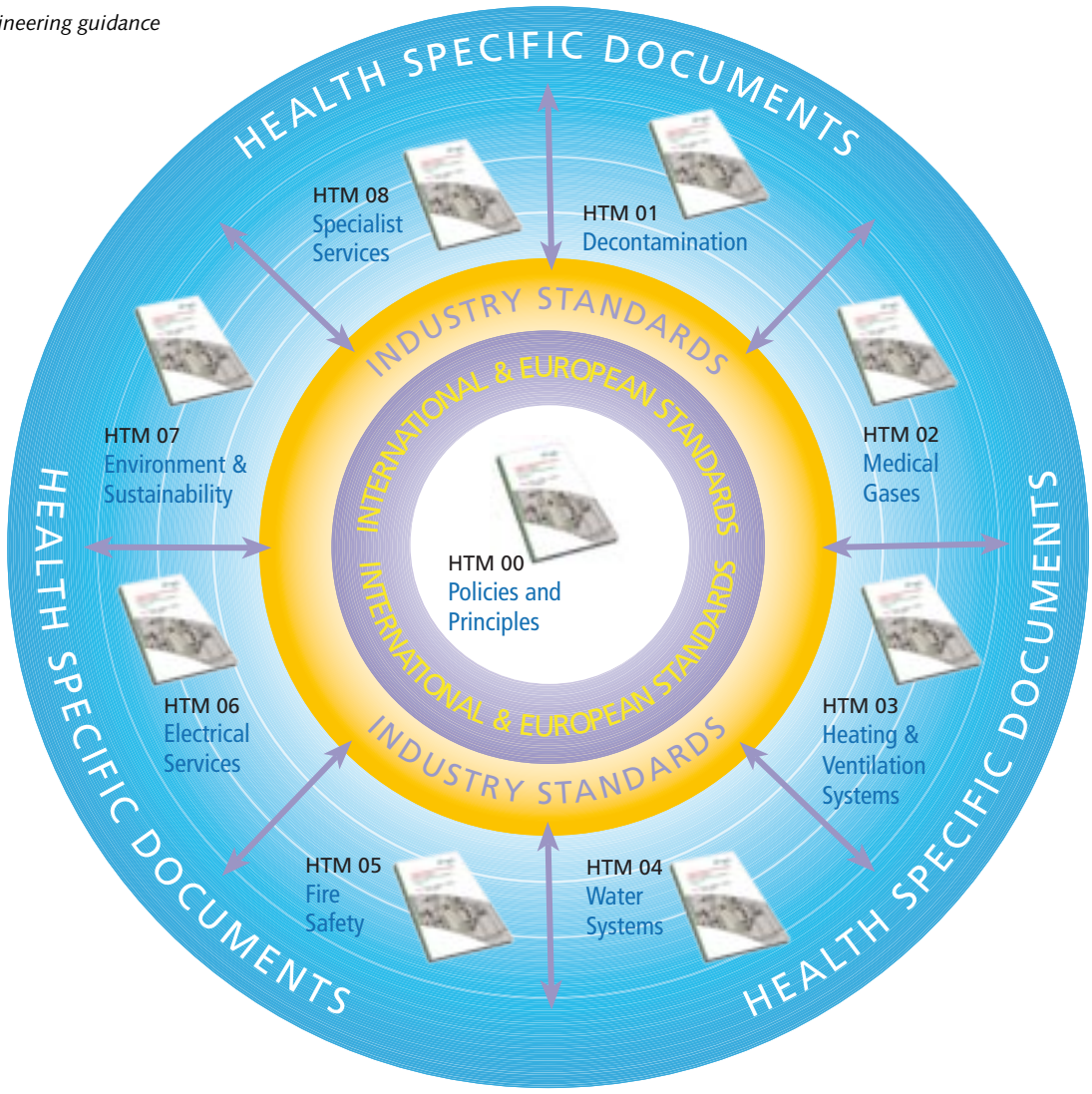
Environment and Sustainability – EnCO_2de.

All Health Technical Memoranda are supported by the initial document Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

DH Estates and Facilities Division wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.

Figure 2 Engineering guidance



Executive summary

Introduction

Pathology services provide a diagnostic service for clinicians and their patients. They offer high-quality, timely analysis of specimens to assist in clinical diagnosis, preventative medicine (for example screening programmes), research and epidemiological studies.

Pathology laboratory gas systems (PLGSs) are installed to support these activities by providing a distribution medium for gases.

The general provisions of Health Technical Memorandum 02-01 – 'Medical gas pipeline systems' and the British Compressed Gases Association's (BCGA) Code of Practice 4 (CP4) – 'Industrial gas cylinder manifolds & distribution pipework/pipelines (excluding acetylene)' apply to PLGSs, but certain gases will require additional safety measures as a result of their toxicity, flammability etc.

Aim of the guidance

The document aims to provide best practice guidance on the design, installation and testing of pathology laboratory gas systems. It can be applied to fixed gas pipeline systems, discrete plant, compressed gas cylinders and gas generators in a laboratory environment.

It also aims to improve system management by the introduction of defined planned maintenance tasks and a dedicated permit-to-work scheme.

Who should use this guidance

The document is intended to be used by system specifiers, designers, installers, testers, maintainers, analytical equipment suppliers, laboratory managers and/or their deputies, engineers and quality controllers who have a responsibility for pathology gas systems.

It will also be of use to those Authorising Engineers (MGPS), Authorised Persons (MGPS) and Competent Persons (MGPS) who have to take on responsibility for these systems.

Recommendations

General

All pathology pressure gases should be piped, but small quantities may be supplied from portable cylinders, connected to specific equipment. Appropriate fire and safety requirements must be met if cylinders are to be used in this way.

Laboratory gas cylinders should be stored in a ventilated, secure external enclosure, similar to, but separated from, the medical gas storage area.

Manifolds and plant should be sited in dedicated plant and manifold rooms, generally constructed to the requirements in Chapter 14 of Health Technical Memorandum 02-01 (Part A).

Design

When designing PLGSs it is important to allow for repair, maintenance, inspection and extension with minimal disruption to the building user.

Systems should be as simple as possible, with adequate, safe, easy access provided to all parts of the installation.

Analytical equipment technology and procedures are continually changing, and consideration should be given to the need to allow for growth and change, irrespective of the scale of work and scientific disciplines involved.

The PLGSs should be readily accessible to modification and extension. However, plugged-tee outlets (for future change of use frequently fitted to early systems) should not be provided.

The recommended provision is for service outlets in a regular grid or pattern with service runs in floor ducts, above the ceiling or in vertical ducts, so that any work position is able to make use of the full range of services provided.

Pipeline systems

The greatest possible care should be taken in construction of the pipeline systems, for both general and local bench services. Installation, testing and maintenance should

be carried out by specialist contractors registered to ISO 9001/EN 13485 with documented competence in these areas.

Pipeline materials and components should be supplied suitable for oxygen service (cleaned, sealed and degreased), although at the discretion of the Laboratory Manager non-degreased outlet valves may be used on gases other than oxygen. (Greases used must be suitable for use with the gas controlled by the valve.)

Terminal point units of the type used for medical gases, medical compressed air and medical vacuum should not be used in a pathology laboratory.

Vacuum systems

Vacuum generated by locally-mounted vacuum pumps should be sufficient for most laboratory work, and therefore a piped vacuum system is not generally required. Care must be taken to ensure that vacuum pumps are compatible with the materials to be exhausted, as vapours may possess corrosive or explosive qualities.

Acknowledgements

Geoffrey Dillow (main author) Geoffrey Dillow and Associates

Medical Gas Association committee and members

Contents

1 Pathology department functions

General

1.1 This section provides a brief overview of the typical activities in a large pathology department and the application of pathology laboratory gas systems (PLGSs). Smaller departments may carry out commensurately fewer procedures.

1.2 Throughout the pathology department, compressed air and/or vacuum will be used for general filtration, emulsification of specimens, drying of specimens and glassware, powering and/or control of small analytical equipment, and as an oxidant for fuel gases.

Haematology

1.3 The following functions generally use automated analysers, some of which use compressed air as part of the analytical process or to actuate control systems:

- blood analysis – haemoglobin and platelet estimation and cell counting using automated blood cell counters.

  The blood cell counter is a screening instrument that analyses blood cells and measures haemoglobin for a variety of haematological and physiological disorders. The basic methodology involves the application of reagents to separate the different types of white and red blood cells.

  The method of analysis incorporating the whole blood count (WBC) measures several important parameters including blood cell structure and function. This is used to evaluate the adequacy of oxygen delivery to the tissues and to detect abnormalities in cell size and shape, which may provide clues to a variety of haematological conditions;

- assessment of red cell sedimentation rates;

- staining of blood cell specimens on slides for microscopic examination (staining is via automated processing);

- non-automated microscopic examination of blood specimens and bone-marrow preparations.

Clinical biochemistry

1.4 This involves the analysis of body fluids, such as serum, blood, cerebral cerebrospinal fluid (CSF) and urine. Identification and monitoring of physiological changes and detection for the presence of unusual substances are part of the discipline's remit.

1.5 Most of the frequently requested tests can be undertaken on automated equipment, some of which incorporate dedicated data processing systems.

1.6 Applications include the diagnosis of liver, bone and electrolyte complaints; the detection of foreign bodies (for example drugs of abuse); and success of therapeutic drugs.

1.7 Analytical equipment uses a variety of gases. Fuel gases such as propane and acetylene, possibly mixed with oxygen or air, are burned in a flame photometer, an instrument in which changes in flame coloration indicate the quantitative elemental composition of compounds injected into the flame.

Hospital bacteriology

1.8 This involves the examination of specimens to aid in the diagnosis of infection by bacteria, parasites and fungi and, where necessary, tests to gauge the sensitivity of organisms to antibiotics used to treat patients.

1.9 Serological tests are performed to demonstrate the presence of antigens and antibodies in specimens and to estimate the level of antibiotics in serum (from patients undergoing treatment). Some of this work is done in batches and may generally be regarded as less urgent.

1.10 Anaerobic atmospheres comprising various combinations of oxygen, carbon dioxide, hydrogen

and nitrogen are used to provide controlled atmospheres for the growth of sample cultures.

Hospital virology

1.11 This is concerned with the diagnosis of viral diseases. While the majority of specimens will undergo serological testing (see paragraph 1.9), virus isolation in cell cultures forms an important and specialist part of the work. Cell culture work will take place elsewhere.

1.12 Inoculated media must be incubated under highly controlled temperature and atmospheric conditions (for example aerobically in air or oxygen, or anaerobically in carbon dioxide atmospheres to obtain growth of organisms).

Histopathology

1.13 This is the morphological study of cells arranged in tissues that have been removed from the human body.

Cytopathology

1.14 This is the morphological study of dissociated cells. Cytopathology involves collecting cells by scraping the surface of an organ, from a secretion or excretion, or by needle aspiration from an organ or body cavity. It comprises two main areas:

a. gynaecological cytopathology, which screens cells from the female genital tract (for example cervical smears);

b. non-gynaecological cytopathology, which examines cells from other sites in the body for the diagnosis of malignancy, infectious or inflammatory diseases.

Support laboratories

1.15 Support laboratories include all areas that accommodate functions directly supporting both routine and specialised testing laboratories. No testing is carried out in these spaces, which comprise facilities such as equipment rooms, instrument rooms and preparation rooms.

Cryopreservation room

1.16 This may be required for accommodating liquid nitrogen freezers for the cryopreservation of biological specimens. The freezers come in a range of sizes and are refilled either via portable dewars or via a piped liquid nitrogen system from an external large-capacity tank.

1.17 Some units use freeze-drying equipment, requiring a dedicated high vacuum source.

Immunoassay laboratory

1.18 Certain immunoassay tests for haematology and clinical biochemistry can be carried out in the same room. They may use low-level radioisotopes and/or flammable solvents, in which case special facilities will be required.

1.19 Immunoassay involves the analysis of body fluids to monitor hormone imbalances (associated with thyroid and reproductive functions) and cancer and other tumour markers. Other applications include screening for drugs of abuse and infectious diseases.

1.20 Vacuum is employed generally in separation of compounds, usually by filtration. Specially constructed vacuum pumps (for example containing Teflon-coated internal parts) maintain performance while evacuating highly corrosive chemicals. In some instances, vacuum is generated by the use of water-driven ejector units.

Chromatography laboratory

1.21 Chromatography is a way of separating molecules based on differences in their structure and/or composition. It involves moving a preparation of the materials to be separated – the "test preparation" – over a stationary support.

1.22 Test molecules that display tighter interactions with the support will tend to move more slowly through the support than those molecules with weaker interactions. In this way, different types of molecule can be separated from each other as they move over the support material.

1.23 Highly toxic and, in some instances, carcinogenic chemicals may be used in the process, and these may be evacuated via dedicated vacuum pumps.

1.24 Gas liquid chromatography (GLC) involving passage of a gas (for example argon, nitrogen or hydrogen) through the substrate is also carried out to achieve similar objectives.

1.25 Compressed air is also used for substrate gel preparation and drying.

Cell culture room

1.26 Cell culture facilities may be required for the cultivation of tissues. Class II safety cabinets will be

required. Each room should be able to accommodate a bench-mounted microscope, under-bench refrigerator and freezer, bench-mounted centrifuge, a floor-standing incubator and a sink.

1.27 Inert gases may be used in combination with carbon dioxide to produce controlled atmospheres.

Mass spectrometer laboratory

1.28 Mass spectrometry equipment measures the exact molecular mass of molecules by measuring their flight path through a set of magnetic and electric fields. The equipment tends to be bench-mounted with an accompanying computer workstation, and requires dedicated ventilation above the equipment.

1.29 Atomic absorption spectrometry is an analytical technique that measures the concentrations of elements using wavelengths of light specifically absorbed by elements. It is used in pathology for analysing metals in biological fluids such as blood and urine.

1.30 Special dedicated plant generates the very high vacuum levels required for the spectrometer.

Polymerase chain reaction room

1.31 Molecular biology techniques are being used increasingly in pathology. Genetics is a fundamental discipline and one of the key techniques is the polymerase chain reaction (PCR). Used for amplifying DNA, this technique involves taking a single copy of a DNA molecule and creating millions of copies of it.

Electrophoresis room

1.32 Gel electrophoresis is one of the most common analytical methods in biochemistry and molecular biology and is being increasingly applied to pathology.

1.33 Electrophoresis is the separation of molecules according to how fast they move in an electric field. This is carried out in a gel (polymer matrix). Samples are put in at one end of a slab of polymer gel. An electric field across the gel pulls the molecules through it; smaller molecules move faster through the gel than larger; thus, molecules are separated according to size.

1.34 Carcinogenic compounds may be used in this process.

Flow cytometry room

1.35 Flow cytometry is a method of measuring certain physical and chemical characteristics of cells or particles as they travel in a suspension one by one past a sensing point. In certain respects, flow cytometers may be considered to be specialised fluorescence microscopes.

1.36 Modern flow cytometers consist of a light source, collection optics, electronics and a computer to translate signals to data. The light source is usually a laser that emits coherent light at a specified wavelength.

1.37 Two lenses (one set in front of the light source and one set at right-angles) collect scattered and emitted fluorescent light. Using a series of optics, beam splitters and filters, specific bands of fluorescence can be measured.

1.38 Physical characteristics such as cell size, shape and internal complexity and any other cell component or function that can be detected by a fluorescent compound can be examined.

Electron microscopy facilities

1.39 The scanning electron microscope (SEM) creates magnified images using electrons rather than light rays.

1.40 Samples have to be prepared carefully to withstand the vacuum inside the microscope. Biological specimens need to be dried in a way that prevents them from shrivelling. Since the SEM illuminates the specimen with electrons, it has to be able to conduct electricity. This is achieved by coating the sample with a thin layer of gold in a sputter coater.

1.41 The prepared specimen is placed inside the microscope's vacuum column through an airtight door. The air is pumped out of the column. An electron gun then emits a stream of high-energy electrons via a series of magnetic lenses onto the specimen.

1.42 The beam is moved across the specimen by a series of scanning coils. As the electrons hit each spot, secondary electrons are knocked loose and counted by a detector. The results are sent to an amplifier from which the final image is built up.

1.43 Again, the equipment uses a dedicated, very high vacuum source.

Blood grouping and cross-matching

1.44 Blood for transfusion is usually grouped by the time it is received from regional blood transfusion centres. It is tested in the hospital laboratory for compatibility with the blood of the patient undergoing the transfusion (whose blood group will also need to be determined).

1.45 The size and nature of pathology facilities may range from a large facility within an acute general hospital to a small satellite laboratory within a community healthcare building providing basic phlebotomy services and support for anti-coagulation, diabetes management and sickle-cell screening clinics.

2 Safety aspects of PLGS work

Hazards

2.1 Pathology laboratories present specific hazards for personnel working with PLGS. These include:

- physical hazards;
- infection hazards;
- chemical and gaseous hazards;
- electrical hazards;
- radiation hazards.

Physical hazards

2.2 Accidents and injuries may be associated with the use of sharp instruments; broken glassware; equipment; working in insufficient and badly-designed accommodation; slipping on wet floors; moving heavy loads; inadequate storage facilities; and cluttered benches and corridors. Additional care should be taken when working in the often-confined spaces of pathology departments.

Infection hazards

2.3 These arise from handling potentially infectious specimens of blood, serum, plasma, urine and other body tissues and other excretions. Infection may occur as a result of inhalation, ingestion, inoculation through the skin, or splashing into the eyes of infectious agents present in laboratory specimens. The laboratory safety manager should provide adequate warning of hazardous substances in use in the work area and advise on the use of suitable personal protective equipment (PPE).

Chemical and gaseous hazards

2.4 These are often associated with noxious and/or flammable gases and chemicals (for example fixatives, solvents, reagents, disinfectants) that have to be used in the laboratories during processing of specimens. Cryogenic liquids (for example liquid nitrogen) and asphyxiant gases (for example carbon dioxide) are commonplace in pathology departments. Appropriate PPE should be worn.

Electrical hazards

2.5 Arising from careless or improper use of electrical equipment, or incorrect or poorly maintained fittings and connections and long trailing leads, these hazards are particularly important in the conditions often present in laboratories using flammable or corrosive chemicals and water or other highly electrically conductive substances.

Radiation hazards

2.6 These are associated with ionising radiation from radioactive-labelled materials used in some techniques and non-ionising radiation from ultraviolet and other short-wavelength sources (including lasers). Reference should be made to the Ionising Radiations Regulations 1999. It is particularly important that rooftop vents exhausting small quantities of radioactive materials are properly labelled to indicate the potential hazard.

2.7 The design and layout of the facilities is important in encouraging safe working practices.

2.8 Gases should be handled and used with care and with knowledge of their hazardous properties, both individually and in combination with other materials to which they may be exposed. Some pathology laboratory gases are not only flammable but can form highly explosive mixtures with air and oxygen.

2.9 Provision should be made for the ready access and storage of PPE, first-aid products, chemical poison antidotes and eye-care items.

2.10 Fire risks in the laboratory do, however, merit some special mention, as the necessary presence of quantities of infectious materials, flammable solvents and gases and other reactive chemicals creates special hazards not generally encountered in other departments of the hospital. Electrical fires are another potential problem due to the large amount of powered equipment in use in the laboratory.

2.11 Extinguishers (for both electrical and chemical-based fires) should be strategically placed near to solvent stores, fume cupboards and at other key points throughout the laboratory. Fire blankets may also be necessary. Reference should be made to Health Technical Memorandum 05-03 Part G – 'Laboratories on healthcare premises'.

2.12 The British Compressed Gas Association (BCGA) Code of Practice 23 (CP23) – 'Application of the Pressure Systems Safety Regulations 2000 to industrial and medical pressure systems installed at user premises' – gives detailed requirements imposed by the Pressure Systems Safety Regulations 2000 on gas systems, containers and mobile systems installed at users' premises.

Gas-leak detection systems

2.13 Concerns over the safety of personnel exposed to various toxic agents, or fire risks associated with leakage of PLGS or attached equipment, have led to a rise in the number of gas-leak detection systems fitted in laboratories. These usually employ either a chemical detection type of sensor, which monitors the actual concentration of the hazardous agent, or oxygen concentration monitoring, intended to warn of oxygen depletion in a confined space.

2.14 Gas-leak detection systems are generally expensive compared with oxygen depletion monitors. However, recent concerns over the ability of the latter to accurately indicate oxygen levels in carbon dioxide atmospheres have led to increased interest in the former.

2.15 A risk assessment – based on the agents used and the volume and ventilation facilities of the area in which they are to be used – should be carried out.

2.16 "Second man" working has proved ineffectual in at least one case of oxygen depletion, and it is recommended that in areas where liquid nitrogen is being handled in a confined space, an oxygen depletion monitor be fitted.

2.17 The primary alarm level of this unit should not be less than 19% oxygen.

2.18 The area should also be subject to a strict, documented operating procedure, especially for filling and decanting processes, and all staff working with the liquid should be trained and issued with appropriate PPE.

3 System design

Termination (outlet) points

3.1 Medical gas terminal point units must not be used for PLGS services.

3.2 Terminations for oxygen should comprise degreased, non-ferrous valves, suitable for oxygen use.

3.3 Terminations for other gases and compressed air may comprise either colour-coded valves suitable for oxygen service or normal laboratory service valves, or a combination of these valves with a pressure regulator/flow controller as shown in Figure 1.

3.4 Vacuum terminations can be needle valves, integrated flow control valves or other laboratory service valves.

3.5 All outlets should be identified by valve colour-coding as illustrated in Appendix 1.

3.6 Vacuum pumps may be protected against inadvertent damage from corrosive or flammable vapours by fitting a scrubber vessel at the termination point.

Allocation of termination points

3.7 The previous practice of fitting additional plugged tees at bench points in order to facilitate future expansion of the system is no longer recommended. Terminations should be fitted in accordance with the requirements of the equipment quota for the laboratory and by liaison with the laboratory manager.

Equipment workshop

3.8 A facility may be provided within the department, where electronics and medical engineering technicians carry out minor scheduled or unscheduled servicing. Individual needs must be assessed, but outlets for oxygen, compressed air and vacuum are likely to be required.

Flow rates and pressures

3.9 It is difficult to prescribe system flow rates and supply-source capacities, as the mix of equipment varies from laboratory to laboratory. Also, technology is changing and gas demands change with it.

3.10 However, as a guide, Table 1 typifies flow and pressure requirements for common piped services. Where no flows are presented for a particular gas or gas mixture, this indicates that the gas is likely to be supplied from a locally sited discrete cylinder. In any event, the overall system demand should be calculated by analysis of the performance figures of the equipment to be attached.

Table 1 Examples of typical flow demands for PLGS

Gas/gas mixture	Nominal pressure at terminal point	Typical flow rate at each terminal point (L/min)
Oxygen	4 bar/400 kPa	4–10
Air	4 bar/400 kPa	10–80
Hydrogen	4 bar/400 kPa	2–10
Acetylene	0.6 bar/60 kPa	1–15
Propane	2 bar/200 kPa	2–10
Carbon dioxide	4 bar/400 kPa	5–10
Nitrogen (gaseous)	4 bar/400 kPa	5–10
Nitrous oxide	4 bar/400 kPa	1–5
Nitrogen (liquid)	N/A	N/A
Argon	4 bar/400 kPa	2–10
Oxygen + carbon dioxide	4 bar/400 kPa	5–10
Vacuum	400 mm Hg (~53 kPa)	6–20

Notes
Most equipment will be fitted with a pressure regulator offering output from 0 to 4 bar.
Vacuum controllers may also be added at terminal points and will comprise a vacuum gauge, regulating device and outlet coupling.
If it is intended to pipe acetylene at pressures above 0.6 bar, approval of the HSE Explosives Inspectorate must be sought.

Figure 1 Laboratory outlet point

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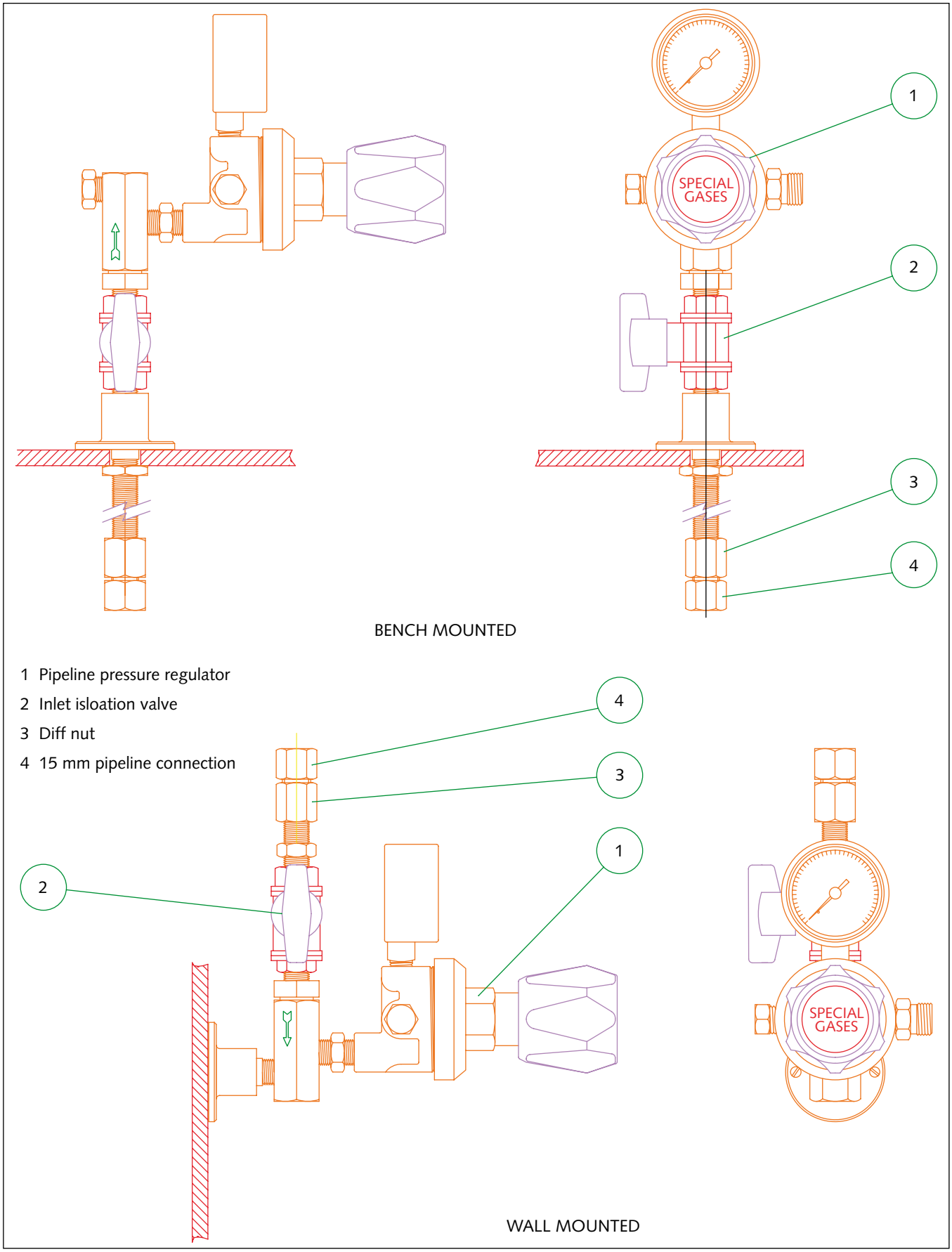

Pipe sizing

3.11 Given the comparatively low flow rates in the systems and their small extent by comparison with an MGPS, it is not expected that pipe sizes above 15 mm will be required.

3.12 Pressure drops greater than 10% from plant to the most distant terminal point at design flow are not likely to be experienced and, given the variety of equipment likely to be connected to the system, measurement of pressure drops is not generally undertaken. When sizing systems, this (10%) maximum allowable drop from plant outlet to the rear of the most remote terminal point should be taken into consideration.

3.13 The flow figures in Table 1 represent typical flow rates at the terminal points.

3.14 Most gases will be supplied from single- or twin-cylinder manual manifolds, or a two-cylinder automatic (or semi-automatic) unit.

3.15 These arrangements will suffice for most installations. If larger-capacity units are envisaged, auto-changeover manifolds, fitted with higher numbers of cylinders, will be required.

3.16 The need to ensure that pumps are not compromised by the passage of explosive or corrosive materials means that piped vacuum systems are not commonplace, whereas compressed air is generally piped.

3.17 It is not generally necessary to provide duplex air compressors or vacuum pumps for central air and vacuum supplies. Neither will a reserve supply be fitted.

3.18 Arrangements should be made for alternative supplies in the event of plant failure, but only if this is considered necessary.

Plant sizing

3.19 For sizing air and vacuum plant, diversity factors may be applied as follows:

a. **Compressed air:** 180 L/min for the first terminal point, plus 20 L/min for each additional terminal point outlet. This will allow for the connection of drying equipment (which uses higher flow rates than analytical equipment), while maintaining reasonable on/off times for the compressor plant.

b. **Vacuum:** 30 L/min for the first terminal point, plus 6 L/min for each additional terminal point.

4 Provision of plant and manifolds

General

4.1 Engineering services are a significant part of the capital cost of the laboratory. The project design engineer should therefore ensure economy in provision, consistent with meeting functional requirements and maintenance of clinical standards through effective risk management.

4.2 Identification of lifetime cost should be undertaken as part of the cost-benefit analysis.

Space required for plant and distribution systems

4.3 Sufficient space should be provided in suitable locations for all plant. The plant areas should provide convenient and safe access, arranged to prevent unauthorised entry.

4.4 Plant and equipment should be spaced to permit access for routine inspection and maintenance. The siting of plant areas should be such that removal and replacement of plant and components can be effected without disruption to laboratory services.

4.5 Infrastructures supporting specialist systems and equipment should avoid solutions that do not enable users to select alternative items of equipment in the future without extensive cost and disruption to the associated engineering services.

Spatial recommendations for engineering services are contained in Health Technical Memorandum 00 – 'Policies and principles'.

Accommodation considerations are also presented in Chapter 14 of Health Technical Memorandum 02-01 (Part A) (see paragraph 4.13).

Further information is provided in BSRIA Technical Notes:

- TN 17/95 – 'Rules of thumb';
- TN 9/92 – 'Inception stage design'; and
- TN10/92 – 'Detailed design stage'.

4.6 Wherever possible, the distribution of mechanical and electrical services to final points of use should be concealed in wall voids/casings and above false ceilings.

4.7 Services contained in the space above the false ceiling, with the exception of drainage, should be confined to those required for the pathology facility.

4.8 For economy, plant should be located as close as possible to the areas served.

4.9 Consideration needs to be given to the risks of noise and vibration, flooding and fire imposed by plant on the accommodation served. Methods of minimising these risks may be achieved by effective separation of the plant from the accommodation or by the introduction of additional measures (for example active fire suppression systems or additional acoustic shielding).

4.10 A risk assessment should be undertaken to explore the most appropriate solution.

Flexibility of design

4.11 PLGSs should be designed to facilitate changes in planning and services requirements. This is best achieved by distribution systems with vertical or horizontal service ducts and bench spines, readily accessible so that systems can be remodelled and maintained without undue disruption to the department.

4.12 Devices for the control and isolation of primary engineering services should be located in areas where they can be protected against unauthorised interference, ideally in plantrooms, engineering service spaces or circulation areas. They should not be located in working areas.

Plant and manifold accommodation – specific requirements

4.13 Accommodation for plant and manifolds should follow the guidelines for heating, ventilation,

lighting access and noise reduction given in Chapter 14 of Health Technical Memorandum 02-01 (Part A), taking into account the following requirements:

a. plant and manifolds should be housed separately from each other, and separately from MGPS plant and manifolds;

b. when a laboratory is intended to be routinely and frequently operated with flammable gases supplied from a manifold system, the manifold should be sited either:

   (i) in a separate manifold room with at least one wall fitted with a door having a fire-resistance classification of at least one hour, opening to the outside, and be ventilated in accordance with Chapter 14 of Health Technical Memorandum 02-01 (Part A); or

   (ii) outside of the building and connected to the laboratory equipment by a permanently installed pipework system;

Note

Pipework carrying flammable gases from source to point of use should be run outside buildings wherever possible. Where this is not possible, care must be taken to ensure that pipework can be easily accessed for the purposes of inspection and maintenance.

c. some gases may be fed directly to equipment from a discrete local cylinder/regulator combination within the laboratory. In these cases, the laboratory safety officer, or other authority having jurisdiction, must confirm that the volume and nature of the gas do not constitute a hazard. All cylinders must be secured in position;

d. rooms housing flammable gases should have a roof of lightweight construction or be provided with other means of explosion relief;

BCGA Guidance Note 7 (GN7) – 'The safe use of individual portable or mobile cylinder gas supply equipment' provides guidance on the safe use, inspection and maintenance of individual cylinder gas supplies, the gas being controlled by a single cylinder-mounted regulator, which is used to deliver industrial cylinder gases to gas-using equipment. It does not cover toxic or corrosive gases.

e. specialist advice should be sought for the installation of electrical systems installed in manifold rooms containing flammable gases (see paragraphs 11.42–11.46).

5 Manifold systems

5.1 Manifolds for PLGS are generally smaller and less complex than those used for MGPS.

5.2 Typical arrangements for single- and multiple-cylinder manual and auto-changeover manifolds are shown in Figures 2–8.

5.3 Fitting gas manifolds inside the laboratory is not advised but, if carried out, manifold size should not exceed 2 × 3 cylinders.

5.4 Care should be taken to ensure that all cylinders are well secured.

5.5 It is important that specialist suppliers and installers are used to ensure compatibility of equipment with the gases used (see Chapter 12).

5.6 BCGA Code of Practice 4 (CP4) – 'Industrial gas cylinder manifolds and distribution pipework/pipelines (excluding acetylene)' gives minimum safety standards for the design, installation, operation and maintenance of industrial gas supply manifolds, and associated distribution pipework up to 54 mm nominal bore. The manifold pressure is up to 300 bar, while the distribution pressure is limited to 40 bar.

5.7 BCGA Code of Practice 5 (CP5) – 'The design and construction of manifolds using acetylene gas from 1.5 bar to a maximum working pressure of 25 bar (362 lbf/in^2)' covers the design and construction of acetylene gas manifolds, working at pressures from 1.5 bar up to 25 bar. The statutory requirements of such systems are detailed. Also applicable is BCGA Code of Practice 6 (CP6) – 'The safe use of acetylene in the pressure range 0–1.5 bar (0–22 lbf/in^2)'.

5.8 Internal and external leakage of manifold components, which can lead to higher static pressures or depletion of cylinders and low line pressures, is addressed in BS EN 29090:1992/ISO 9090:1989 and BS EN 738-2:1998.

Figure 2 Manual-change manifold (with pressure reduction package) (for key see page 15)
Reproduced by kind permission of the Gas-Arc Group Ltd

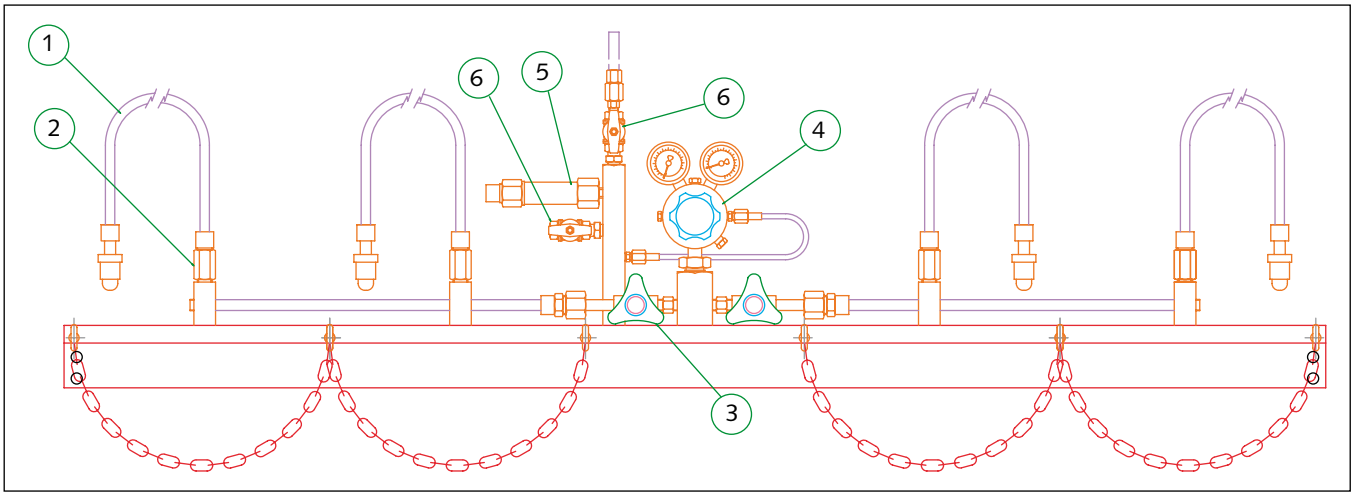

Figure 3 Single cylinder coupler (with pressure reduction package) (for key see page 15)
Reproduced by kind permission of the Gas-Arc Group Ltd

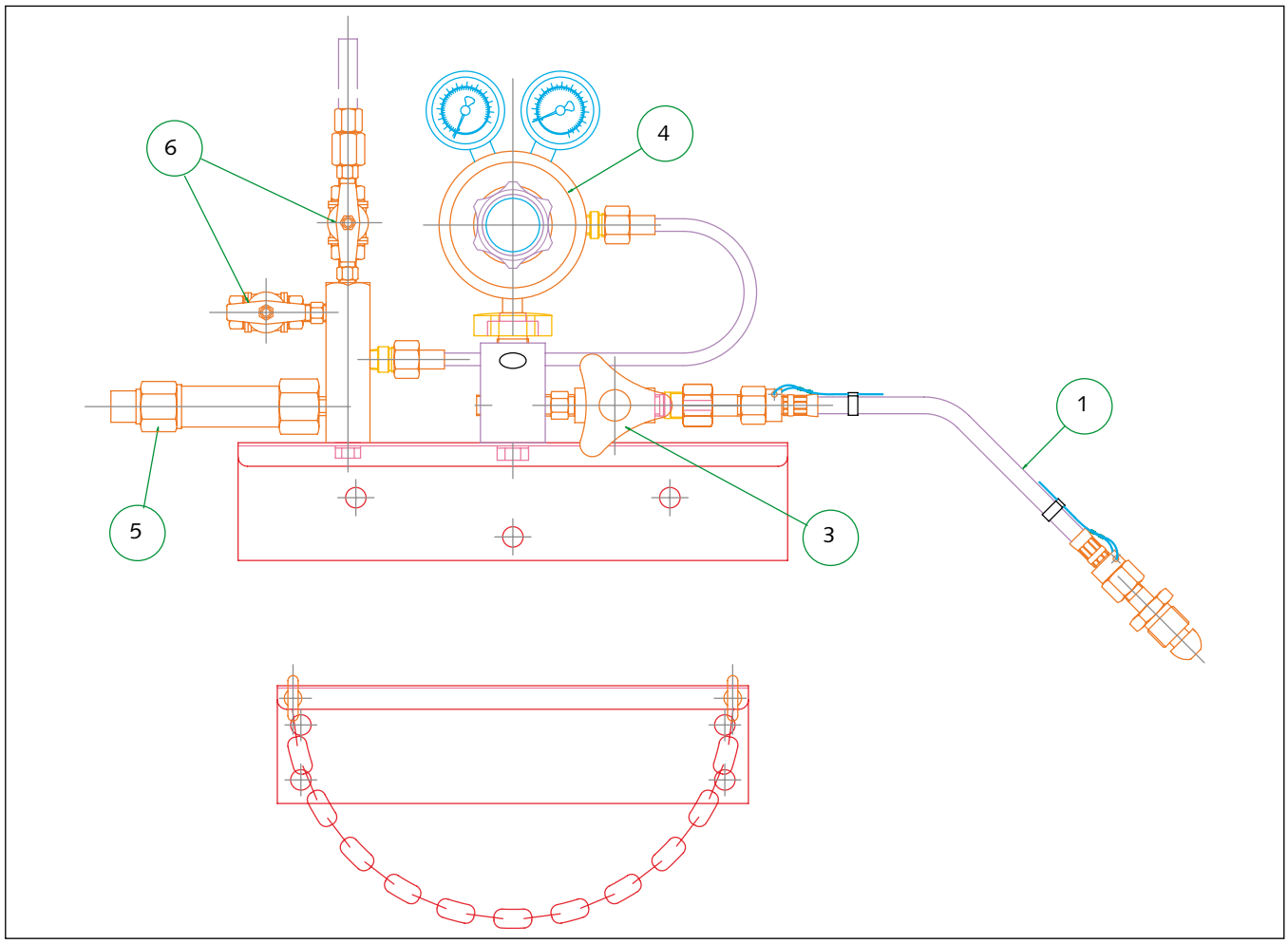

Figure 4 Manual-change manifold – multi-cylinder bank (with pressure reduction package) (for key see page 15)
Reproduced by kind permission of the Gas-Arc Group Ltd

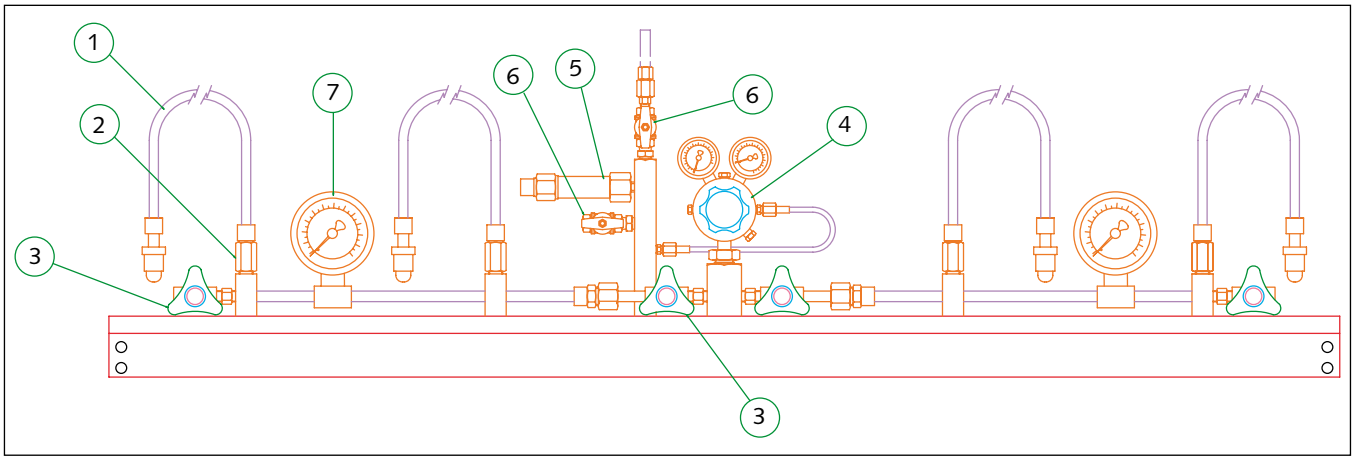

Figure 5 Auto-changeover manifold (with pressure reduction package) (for key see page 15)
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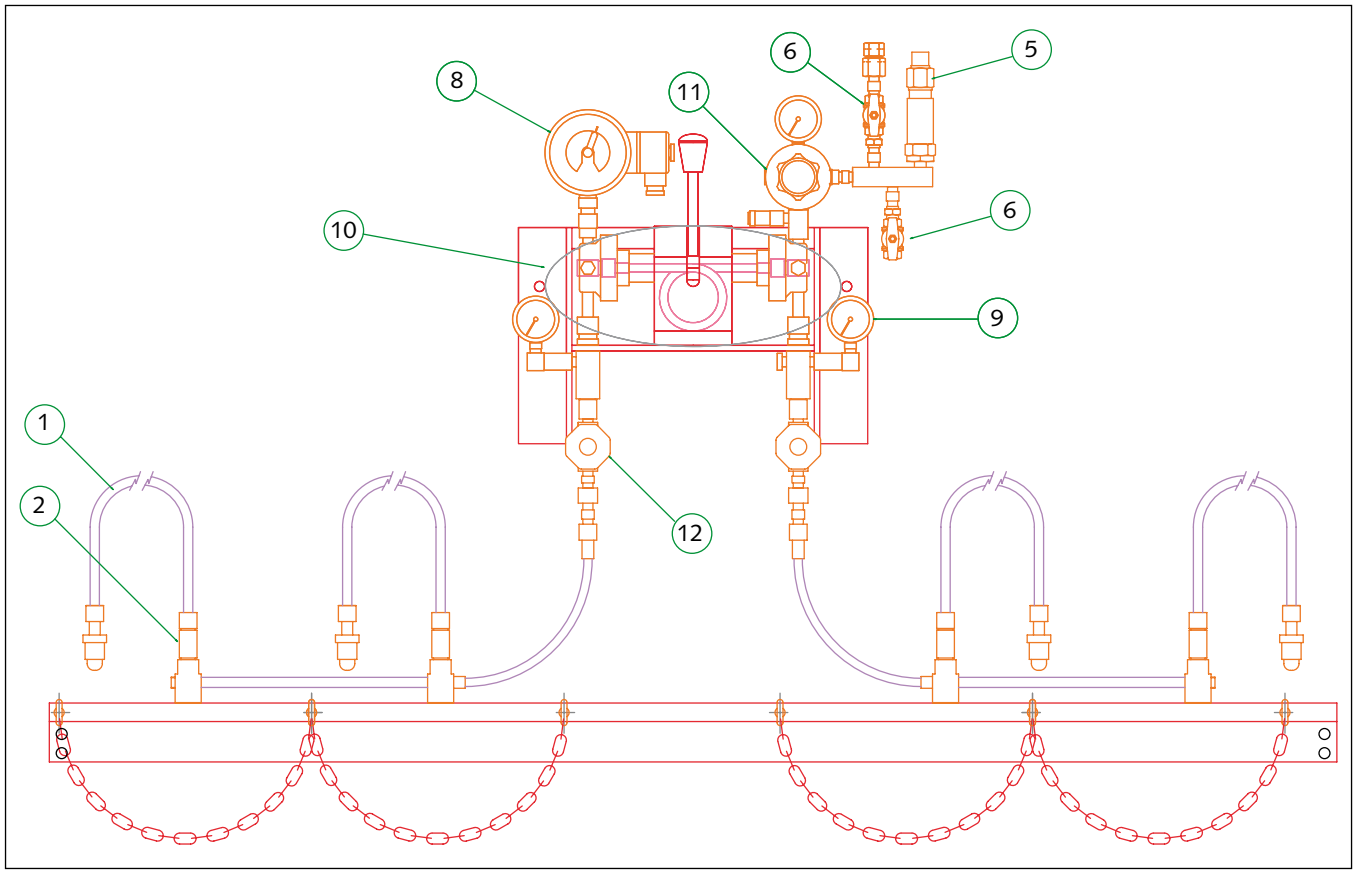

Figure 6 Auto-changeover manifold – multi-cylinder bank (with pressure reduction package) (for key see page 15)
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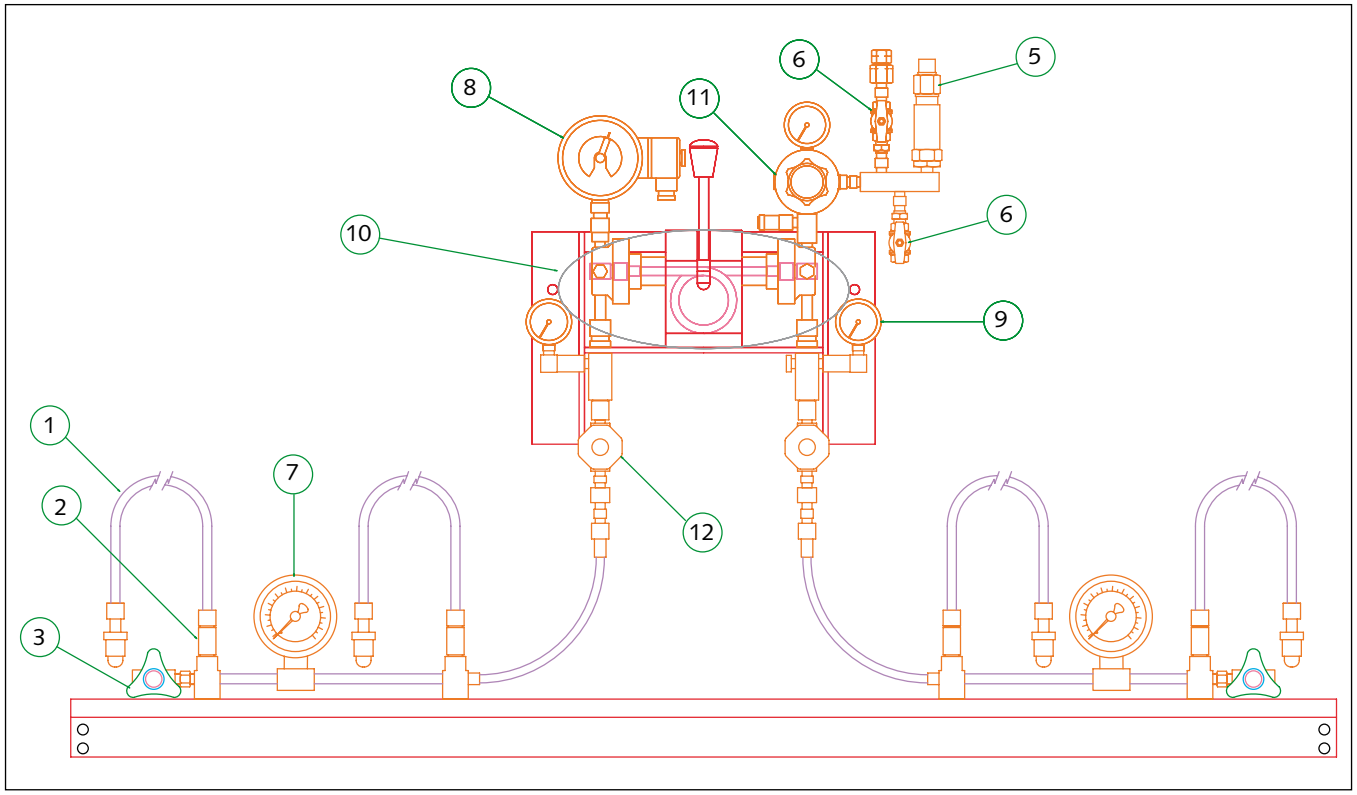


Figure 7 Acetylene manual-change manifold (for key see below)
Reproduced by kind permission of the Gas-Arc Group Ltd

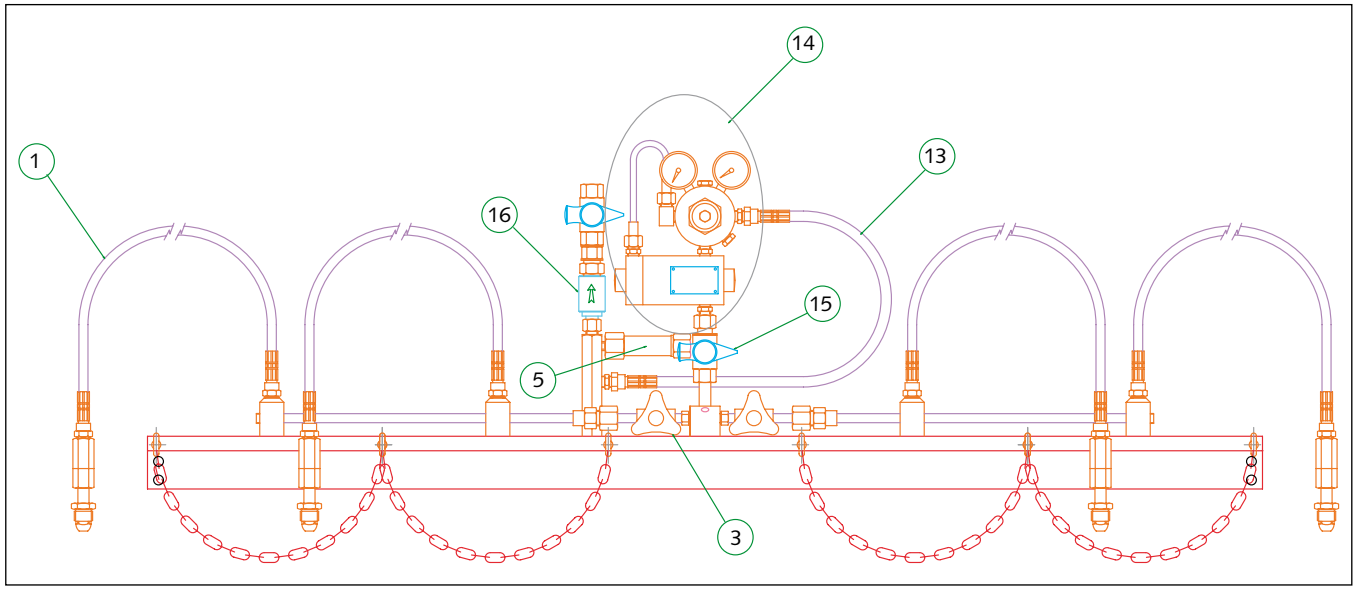
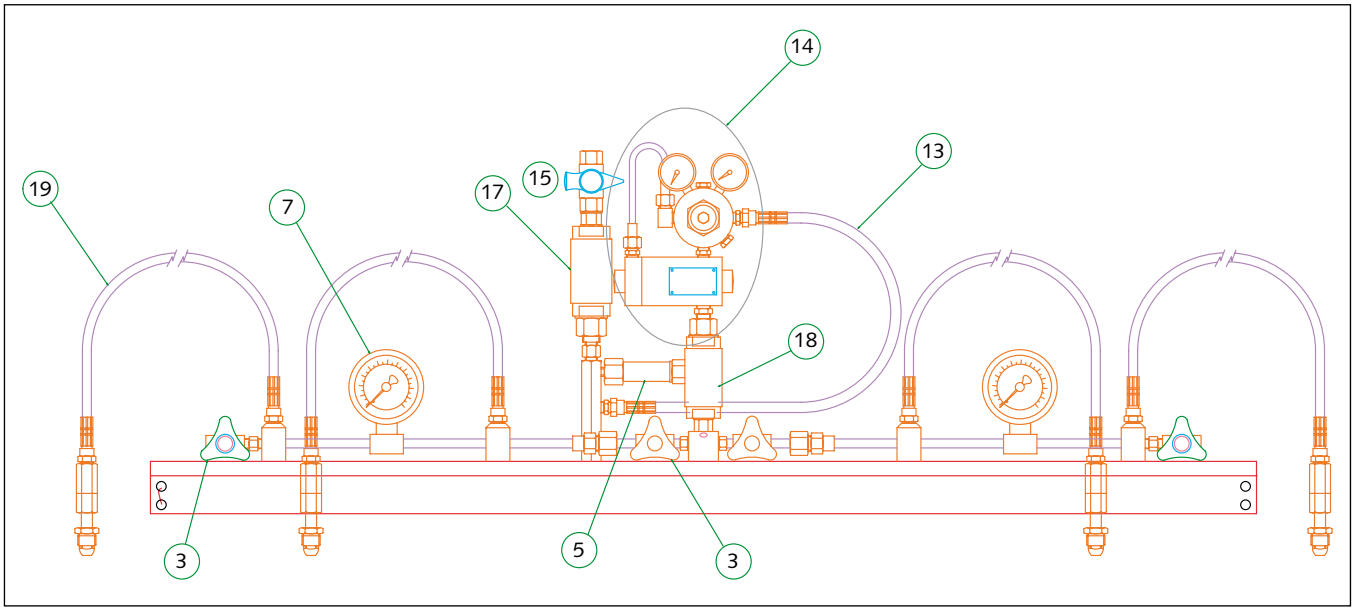


Figure 8 Acetylene manual-change manifold – multi-cylinder bank (for key see below)
Reproduced by kind permission of the Gas-Arc Group Ltd



Manifolds – Key to Figures 2–8

1. 600/1800 mm high pressure tailpipe
2. High pressure non-return valve
3. High pressure needle isolation valve Type A
4. Multi-stage regulator
5. Pipeline relief valve
6. ¼-turn ball isolation valve
7. 100 mm contents gauge
8. Contact alarm gauge
9. 50 mm contents gauge
10. Primary regulator (auto-change assembly)
11. Auto-change line regulator
12. High pressure needle isolation valve Type B
13. Low pressure flexible hose (acetylene)
14. Multi-stage acetylene regulator with slam-shut unit
15. Quick-action manual isolation valve
16. Flashback arrestor Type A
17. Flashback arrestor Type B
18. Quick-action automatic shut-off valve
19. 600/1800 mm high pressure tailpipe with non-return valve (acetylene)

6 Compressed air systems

6.1 Simplex plant is generally sufficient to meet the needs of the laboratory.

6.2 Any type of plant able to produce output to the laboratory design specification can be used, but care must be taken to ensure that the quality of the air delivered is able to satisfy the requirements of all types of equipment likely to be connected to the system.

6.3 Equipment manufacturers often state "oil-free" air as an essential, but non-quantitative, requirement. If this is the case, the minimum requirement for compressed air treatment is the fitting of:

- automatic drains on the compressor receiver;
- an oil trap (also with automatic drain);
- an oil mist filter; and
- a bacteria filter with charcoal element to medical air standards (see Chapter 7 of Health Technical Memorandum 02-01 (Part A)).

6.4 A suitable alternative would be an oil-free compressor of suitable capacity and fitted with bacteria and charcoal filtration as above.

6.5 Frequently, this basic level of oil removal and air filtration is the only treatment given for air delivered to most equipment quoted as requiring dry air.

6.6 Dry air is generally specified without recourse to dew-point specifications (although an atmospheric dew-point of –20°C has been quoted as sufficiently dry for most equipment).

6.7 Given that adding a desiccant dryer will easily produce the medical air atmospheric dew-point of –46°C, there is little to be gained by specifying the lower value.

6.8 Therefore, some installers are fitting small simplex units delivering medical air quality in the interests of good practice. Using air of this quality is recommended in this Health Technical Memorandum and has the added advantage of extending the life of equipment and control systems by reducing the likelihood of condensation within the pipeline and equipment.

7 Central vacuum plant

7.1 The fitting of centrally provided laboratory vacuum is rare owing to possible damage to the plant from chemicals passing through the system. Separate pumps, dedicated to individual equipment items, are recommended.

7.2 Hazardous agents vented via these pumps should be disposed of to safe areas via terminations carrying appropriate warning signs. Any pump type capable of meeting the disposal requirements of hazardous agents may be used.

7.3 In some circumstances, scrubbing or washing systems may have to be installed between equipment and terminal points. A duplex bacteria filtration system of at least the standard used for medical vacuum plant should be fitted before the receiver. Condensation traps should be fitted where required.

7.4 The bacteria filters should have an efficiency (when tested by the sodium flame test in accordance with BS 3928:1969) of greater than 99.995% at the system design flow (see Chapter 7 of Health Technical Memorandum 02-01 (Part A)).

7.5 Exhaust terminations of central plant should be above roof level, and constructed and signed in accordance with Health Building Note 15 – 'Accommodation for pathology services'.

7.6 Internally-sited plant must be fitted with exhausts constructed and ducted in accordance with the health and safety requirements of the specific processes serviced.

8 Gas generators

8.1 Gas generators provide a simple and reliable alternative to piped cylinder gas supplies and are available as both bench-top generators and high-capacity systems, replacing gas cylinders as a source of calibration standard.

8.2 Such generators generally have low electricity consumption and, in the case of those using air as a source gas, low driving-medium consumption.

8.3 Gas generators are easy to install and require only minimal annual maintenance. They are commonly available for:

- nitrogen and zero nitrogen,
- air and zero air, and
- hydrogen,

although other units are available to special order for less frequently used gases.

8.4 Bench-top units produce flow rates in the typical range of 10–30 L/min.

Nitrogen and zero nitrogen

8.5 Using a compressed air supply, which may be provided from an integral oil-free compressor, nitrogen is produced using a pressure-swing adsorption system (zeolite molecular sieve).

8.6 The purity of the nitrogen produced is usually described in terms of its residual oxygen content, which varies with the application. A range of 10 ppm to 3% oxygen content is typical of these generators.

8.7 Oxygen produced by the unit is usually exhausted to its surroundings.

8.8 So-called zero nitrogen is produced when the high-purity nitrogen is passed over a heated catalyst (also integral to the unit), reducing the hydrocarbon content to less than 1 ppm.

8.9 Other gaseous contaminants such as carbon monoxide and oxides of nitrogen, as well as particulates, are also removed during this process.

8.10 Drying of the gas to an atmospheric dew-point of –40°C is typical, and some of the units are designed to produce clean air in addition to the nitrogen.

Air and zero air

8.11 Air generators produce laboratory-grade purified air for the most demanding techniques (for example for gas analysers and other types of analytical instrument such as gas chromatography with a flame ionisation detector (GC-FID) etc).

8.12 The units either purify an existing compressed air supply or may use an integral compressor.

8.13 First-stage purification removes oil, water and dirt particles using a 1–10 µm coalescing filter (depending on the manufacturer).

8.14 A further membrane dryer may be used to remove moisture. A portion of the air produced may be used as purge for the dryer.

8.15 Hydrocarbons, including methane, are then removed by passing the air over a heated catalyst, or activated carbon filter, leaving a typical residual total hydrocarbon level of <0.1 ppm.

8.16 Catalysts are also used to convert any carbon monoxide (CO) into carbon dioxide (CO_2) and remove any oxides of nitrogen.

8.17 A 0.01–0.1 µm particle removal filter (depending on manufacturer) completes the purification process.

8.18 As part of the process, some units are fitted with an integral ultraviolet sterilization chamber. The ultraviolet light also oxidises any nitric oxide (NO) into nitrogen dioxide (NO_2).

Hydrogen

8.19 These units are often used with gas analysers, as a fuel gas.

8.20 Hydrogen generators generally use membrane technology for electrolytic production of pure hydrogen gas.

8.21 Electrolytic membrane technology is clean and requires less maintenance than, for example, generators using caustic solutions.

8.22 Distilled or deionised water is required for operation, and there is no need to store and use other chemicals.

8.23 Some units are fitted with an automatic shut-off if gas quality specifications are not met, and adjustable alarms allow the user to be warned whenever operating conditions vary from the set point.

9 Cylinder storage and management

9.1 The general guidelines given in Chapter 8 of Health Technical Memorandum 02-01 (Part B) should be followed for pathology gas cylinder storage and management.

9.2 It is important to maintain separation between medical and pathology gas cylinders and oxidising and flammable gases when stored.

9.3 Ventilation and electrical installation requirements for flammable gas storage areas are also important.

9.4 Staff handling the cylinders must be trained in manual handling techniques and be made aware of the properties and hazards of the compounds contained within. In particular, training should be given in procedures for dealing with defective cylinders and emergency situations (for example rapid release of flammable gases).

9.5 BCGA Guidance Note 3 (GN3) – 'Safe cylinder handling and the application of the Manual Handling Operations Regulations to gas cylinders' defines the principles of safe practice for the handling of compressed and liquefied gas cylinders. It explains how compliance with the Manual Handling Operations Regulations 1992 may be achieved.

9.6 Personal protective equipment must be provided and used where appropriate. This is particularly relevant to the decanting process for cryogenic gases (for example liquid nitrogen) where additional precautions against liquid spillage and consequent oxygen depletion must be taken.

Cylinders stored within the laboratory for "ready use"

9.7 Cylinders should be in racks or secured in an upright position in designated "parking" areas known to all staff.

9.8 The aggregate accumulation of cylinders at any one bench position/workstation should not exceed one extra cylinder for each cylinder actually connected for use.

9.9 BCGA Guidance Note 2 (GN2) – 'Guidance for the storage of transportable gas cylinders for industrial use' defines the principles of safe practice for the storage of gases in cylinders, or liquid containers less than 1000 L, on industrial premises. It is relevant to the use of these gases in pathology laboratories.

9.10 BCGA Code of Practice 30 (CP30) – 'The safe use of liquid nitrogen dewars up to 50 litres' and BCGA Technical Information Sheet 6 (TIS6) – 'Cylinder identification, colour-coding and labelling requirements' are also applicable. In particular, CP30 contains valuable information on the safe transport of small dewars on healthcare premises.

10 Alarm systems

General

10.1 MGPS alarm systems may be used for monitoring PLGSs. However, pressure switches of a type suitable for use with flammable gases (for example zener barrier types) must be used where appropriate.

10.2 Cabling and isolating devices may also need protection against ingress of flammable gases (see the safety note "acetylene pipeline installations" at paragraph 11.39).

10.3 A separate electrical earth cable (with a cross-sectional area (CSA) of ≥4 mm^2) should be taken back to the consumer's main earth point in order to protect against possible loss of earth continuity arising from a damaged distribution board.

Indications

10.4 If alarms are fitted to compressed air and vacuum plant, indications of pump and line pressure failure should be provided.

10.5 Alarms fitted to manifolds will give the following indications for a single cylinder manual manifold and an automatic (or semi-automatic) manifold:

Indication	Single cylinder manual manifold	Automatic or semi-automatic manifold
"Change cylinders"	Activated by a pressure switch or contact gauge at approximately 10% of cylinder contents	Activated by manifold changeover
"Line pressure low"		Activated by a line pressure switch, or contact gauge, at 10% below nominal line pressure

Location of panels

10.6 Traditionally, PLGS alarm panels have been sited close to the source of supply. This has led to instances of inadvertent supply failure and consequent disruption of analytical services.

10.7 It is strongly recommended that alarm panels be sited where they can be monitored for at least the period of occupation of the laboratory (for example in a portering office or the laboratory manager's office, or some other readily observable location within the laboratory).

11 Installation practice

General

11.1 General guidance on installation given in Chapter 13 of Health Technical Memorandum 02-01 (Part A) should be followed, taking particular care with respect to the following.

11.2 It is important that specialist suppliers and installers are used, to ensure compatibility of equipment and processes with the gases used, including all regulators, valves, pipeline materials and jointing techniques.

11.3 Installers must be registered under ISO 9001/ EN 13485 with a defined scope of work in PLGS design, installation, testing or maintenance.

11.4 Phosphorus deoxidised, non-arsenical copper to BS EN 1412:1996 grade CW024A (Cu-DHP) in metric outside diameters and to BS EN 13348:2001 – R250 (half hard) for sizes up to 54 mm is the recommended material for pipelines carrying oxygen, nitrous oxide, helium, compressed air, hydrogen, carbon dioxide, nitrogen, carbon dioxide/oxygen mixtures and carbon dioxide/ nitrogen/hydrogen mixtures.

11.5 Pipe jointing fittings should be end-feed capillary fittings to BS EN 1254-1:1998.

11.6 All pipes must be cleaned and degreased for oxygen service and be free of particulate matter and toxic residues in accordance with BS EN 13348:2001. They must be individually capped at both ends during delivery.

11.7 These pipelines should be joined using the inert gas brazing technique described in Chapter 13 of Health Technical Memorandum 02-01 (Part A).

11.8 Acetylene should not be piped in copper (see the safety note "acetylene pipeline installations" at paragraph 11.39).

11.9 If a piped vacuum system is to be installed, particular care should be taken with choice of pipeline materials, as compounds such as acetone will attack copper.

11.10 Sleeving of hydrogen pipelines passing through a roof space will prevent accumulation of the gas in the event of pipeline fracture or leakage.

11.11 Sleeving should be applied to all pipelines carrying flammable gases through unventilated roof, ceiling or other spaces.

11.12 Where sleeving is impracticable, the unventilated area should be classified as a duct, and appropriate mechanical ventilation provided.

11.13 Leakage of natural gas, which is often supplied to a pathology department (frequently in the same duct as an oxygen pipeline), must be addressed in the same way.

11.14 Consideration should also be given to sleeving or ventilation of inert-gas-carrying pipelines, where the risk of leakage could result in severe oxygen depletion and a consequent danger of asphyxiation (see BS 8313:1997).

11.15 As an alternative to roof/ceiling mounting, suitably protected outside runs of pipework are acceptable. Tappings from this pipeline should be taken into the building at convenient points.

Change of use of a gas system

11.16 Pipework systems should not be used for gases other than those for which they are designed and identified.

11.17 If a system is to be converted for use with a gas other than that for which it was originally installed, it should be inspected for suitability for the proposed gas, purged with an inert gas (such as nitrogen), cleaned if necessary, and pressure-tested.

11.18 Each outlet of such a system should be identified by suitable colour-coding and written labelling and specifically converted for use with the successor gas.

Labelling and colour-coding

11.19 Labelling of pipework and colour-coding of terminal points (gas taps) should be in accordance with Appendices 1 and 2. As many taps have interchangeable handles, the name of the service should be posted adjacent to the tap.

11.20 Additional signage, highlighting specific hazards, may be posted adjacent to outlet points at the discretion of the laboratory manager.

11.21 Functions of alarm panels and main isolating valves and the areas the latter control, along with any identification number(s) for the valves/valve keys, should be posted near the valves.

System isolation provision

11.22 Each system should be provided with a method of complete isolation for use in the event of fire. It will be necessary to consult with the relevant authority on this requirement, as isolation of a system may be effected in three ways:

a. An isolating valve for each system, sited near the main entry point to the building;

b. Isolation of the shut-off valve of each manifold system. This method can be used when the manifolds are sited outside the building, or in an adjacent but separate manifold room. The advice of the fire officer should be sought as to the adequacy of this method of isolation, as in most cases it cannot be used as an alternative to (a), since manifold systems will be in secured locations – hence delaying isolation;

c. Isolation by a solenoid valve that is operated by a fire detection system. Such systems exist, but the possibility of nuisance tripping and its effects on laboratory throughput must be taken into account. Such a method will therefore only be installed on a client's written request.

Note

BCGA Code of Practice CP4 also recommends isolation at every departmental branch line, and this philosophy is supported by this Health Technical Memorandum. The client must assess the risks of provision less than this recommendation.

11.23 It is not normal practice to employ MGPS-type area valve service units (AVSUs) as main line isolating valves, as these will be specific to medical gases. Ball-type line valves will usually suffice, but specifically designed AVSUs/line valve assemblies (LVAs) may be installed at the laboratory manager's discretion.

11.24 Care should be taken to ensure that AVSU/valve seals and blanking spades are compatible with the gases carried. AVSUs containing non-interchangeable screw thread connector (NIST) fittings for medical gases must not be used.

11.25 System security should also be considered. Either the main line isolating valve should be locked and subject to an appropriate key control system, or an appropriate lockable numbered valve box should be fitted.

11.26 If a locked line valve is used, an emergency break-glass-type key box should be sited near the valve for use in the event of fire.

Drain cocks

11.27 Drain cocks are not normally fitted to PLGSs, but if desired may be fitted at the bottom of main risers.

11.28 It is not necessary to fit drain bottles to these cocks on pressure gas systems, but they should be fitted to vacuum systems.

11.29 All cocks should remain capped off when not in use, by means of either the drain bottle or a suitable end cap.

Pressure safety valves

11.30 Pressure safety valves must be vented to a safe position by means of pipework suitable for the medium carried. All exhaust terminations should be signed to indicate their function and associated hazards, and all but compressed air exhausts should terminate externally, away from windows, air intakes etc. Lightning protection may be needed for rooftop terminations.

Purge and test points

11.31 A test point to facilitate engineering and quality-control testing, comprising a lockable valve and suitable connector (for example a ⅜ inch BSP male fitting), should be fitted to all plant and manifolds upstream of the plant/manifold isolating valve.

11.32 Additional purge points used to facilitate system-testing (for example at isolating valves) may be fitted at the discretion of the laboratory manager.

11.33 Some manifolds are supplied with valved-off purge points, and these offer an acceptable alternative to fitting a specific test point.

Jointing techniques

11.34 Copper pipelines should be joined, where applicable, using the inert brazing technique described in Chapter 13 of Health Technical Memorandum 02-01 (Part A).

11.35 Oxygen-free nitrogen should be used as the inert gas shield.

11.36 For very small systems, it will not be practicable to cut out sample joints, but the technique can be applied to larger systems at the discretion of the Authorised Person (MGPS) and/or laboratory manager.

11.37 Degreased mechanical couplings can be used as an alternative to brazed joints, but the fire integrity and material compatibility of such joints should be appropriate to the gas service and installation environment.

11.38 It is recommended that any mechanical joints used should have a fire integrity equivalent to that of a copper-to-copper brazed joint.

11.39 Couplings at terminal points and valves will usually be of the compression type, depending on the design of the terminal/valve.

Safety note: terminal point connections

In some instances, terminal points have been connected to rigid pipework using flexible connecting hoses (for example nylon). This method of connection is not recommended, particularly where such material could lead to gas escape in the event of failure during a fire.

For this reason, all terminal points should be connected directly to the rigid pipework.

Safety note: acetylene pipeline installations

Acetylene gas, in the presence of moisture, will react with copper and silver compounds to produce mechanically unstable compounds known as acetylides. If these compounds have formed within the system, physical impact on, or dismantling of, system components can cause explosive decomposition of the acetylides, with potentially fatal results.

For this reason, acetylene systems must not be installed using copper or silver-containing components.

Mild or stainless steel can be used for acetylene pipeline installations, the latter being the preferred material.

Jointing methods must be appropriate to the material (for example tungsten inert gas (TIG) welding for stainless steel). Mechanical jointing methods must produce joints exhibiting characteristics of a welded joint (for example by the use of twin-ferrule mechanical couplings).

If acetylene or other flammable gases are to be passed through a mixing device, together with an oxidising gas (for example oxygen), it is normal practice to fit a combined non-return valve and flame arrestor to both flammable and oxidising gases. However, it will be necessary to consult with specialist installers and equipment manufacturers on exact requirements for fitting non-return valves and flame arrestors/automatic quick-acting shut-off valves.

BCGA Code of Practice 6 (CP6) gives guidance on the safe distribution of acetylene at pressures between 0 and 1.5 bar.

Both fixed and mobile systems are included, as are the statutory requirements.

Safety note: liquid nitrogen pipeline installations

Liquid nitrogen is usually supplied to a laboratory in small dewars, refilled by decanting from a larger, static cryogenic storage vessel. There are also some installations where liquid nitrogen is piped from the main vessel to terminations in the laboratory. Specialist contractors must be used for this type of installation, as it may well involve the use of vacuum-insulated pipework, which is not only expensive but also difficult to install without damage to the vacuum seals.

Where the use of vacuum-insulated pipework is envisaged, the design layout of the installation should ensure that the distance from the storage vessel to the termination point is kept to a minimum in order to avoid excessive gassing-off on start up of laboratory processes.

See also BCGA Code of Practice 30 (CP30).

Removal of pipework

11.40 Because of the nature of the agents carried, removal and cutting out of redundant PLGS

pipelines and equipment can present significant hazards.

11.41 All such work – including inert gas purging before cutting into existing pipelines, capping off, and removal of redundant equipment and pipework – should only be carried out by specialist PLGS contractors. It should not be carried out by demolition contractors.

Electrical installations

11.42 Appropriate protection against ignition must be provided for all electrical apparatus in contact with the gas stream (for example pressure switches and contact gauges).

11.43 BS EN 60079-10:2003 and BS EN 60079-14: 2003 cover the classification of hazardous areas where flammable gas or vapour risks may arise. The standard also gives details of the protective measures that need to be applied to reduce the risk of explosions.

11.44 BS EN 60079-10:2003 supports the Dangerous Substances and Explosive Atmospheres Regulations 2002 and provides information on obligations with respect to hazardous zones within establishments.

11.45 The separation between flammable-gas carrying pipework and electrical equipment that is not classified as "gas-proof" (for example laboratory ring main and lighting circuits) must not be less than 25 cm.

11.46 For hydrogen pipelines, care should be taken to ensure that the pipeline is sited above electrical equipment and sockets, and that the separation distance is greater than 50 cm.

12 Validation and verification

12.1 The extent of testing of pathology gas systems is considerably less than that of MGPS. Nevertheless, because of the hazardous nature of some of the gases carried, all tests should be carried out in a conscientious manner to ensure installation of a safe working system.

12.2 Carcass and complete systems will not generally be tested separately; rather, testing of pipework sections between plant/manifolds and terminal points, with the latter fitted, will be expected.

Engineering tests

Pressure (leak) testing of systems

12.3 Using oxygen-free nitrogen, each system (with all termination points fitted and isolated) must be tested at a pressure of at least 1.5 times its working pressure. By implication, a maximum test pressure of 6 bar will be required, and it is common practice to test all systems, including those such as propane (which will run at 2 bar), at this pressure. If terminal control devices would be compromised by this pressure, they should be removed for the duration of the test. The pipeline would then be plugged at the terminal.

12.4 The test gas should be applied at the manifold connection in the case of cylinder sources and at the plant connection in the case of compressed air.

12.5 Plant and manifolds should be disconnected for the duration of the test.

12.6 Using suitable measuring equipment, no leaks should be detected during a two-hour test period.

12.7 Vacuum system pipework is also tested to this standard. No additional testing under vacuum is performed other than the functional test of the plant.

Note

Plant and manifolds will be leak-tested by suppliers, but may also be tested for leaks by installers during functional tests.

Use of helium as a leak-proving medium

12.8 For most systems, oxygen-free nitrogen is acceptable as a test gas during pressure and other testing. However, there are (infrequent) occasions when helium has been requested as a leak-proving medium, because of its small atomic size and hence its superior ability to permeate very small leaks. It is perfectly acceptable to employ helium as the test gas, but detection equipment is expensive and requires careful calibration if any advantage is to be gained by its use.

12.9 However, helium should always be used as the test gas for hydrogen systems, as both gases can pass through joints that have proved leak-tight with nitrogen.

Annual leak test

12.10 Laboratory managers may request annual leak-testing of some (usually flammable) gas systems. For this test to take place, the system must be depressurised by venting off gas in a safe manner, and purged of the working gas by the use of oxygen-free nitrogen. The latter is then used as the test gas.

Cross-connection test

12.11 PLGSs are generally smaller in extent than MGPSs, and any cross-connection is usually revealed during installation. However, it is essential that there is no cross-connection between oxidising and flammable gas systems.

12.12 It is also important that acetylene is not allowed to contaminate copper pipework, although the chance of this is small as differences in pipeline material should be self-evident.

12.13 A cross-connection test must be performed using the test gas.

12.14 The test method in the format below has been used successfully to confirm absence of cross-connection between systems, and follows guidance previously issued in Health Technical

Memorandum 2022 – 'Medical gas pipeline systems' (1997).

Note

Health Technical Memorandum 02-01 (2006), the revised edition of Health Technical Memorandum 2022 (1997), describes an alternative method of test in Chapter 15 of Part A, whereby two systems – starting with oxygen and vacuum – are tested simultaneously. Subsequent tests are carried out without the need to return each system to atmospheric pressure. For those installers familiar with the requirements of Health Technical Memorandum 02-01 (2006), either method of testing for cross-connection may be used.

a. Using the test gas at working pressure, the oxygen (or other defined pressure gas) system is pressurised first.

b. All other systems are at atmospheric pressure, with line valves etc open.

c. A check is made to ensure that there is a flow at every oxygen (or other defined gas) terminal point: there must be no flow at any other terminal point on other gas systems.

d. The oxygen (or other defined gas) system is then brought down to atmospheric pressure, and all valves/terminal points are left open and the test gas is applied to another system.

12.15 This process is repeated for other systems in turn. In all cases there must be no gas flow from any system, other than the one under test.

Notes

- The tests can be carried out on a total-system, departmental or sub-departmental basis, having previously checked for cross-connection up to the appropriate line valves.
- During the cross-connection test, the identity of terminal-unit colour-coded taps should be confirmed, as not all manufacturers use the ISO colour-coding scheme shown in Appendix 1. The veracity of labelling on/near the terminal point should also be confirmed during this test (see paragraphs 11.19–11.21).
- This test must be repeated in full if any subsequent modifications are made to the pipeline system.

Design flow and pressure-drop tests

12.16 A formal flow and pressure-drop test as for MGPSs is not normally required, unless requested by the laboratory manager, although it should be confirmed that all terminal points operate correctly.

Functional tests

12.17 Each system should be tested to ensure that all plant, manifold and alarm and indicating systems are functioning as specified in the contract.

Performance testing of modified systems

12.18 Formal flow and pressure drop tests are not required, as it is unlikely that addition of extra terminal points will significantly affect the performance of the system.

12.19 However, consideration must be given to additional and significant demands created by connection of high flow equipment such as drying cabinets. Such additions could warrant a change, for example, from cylinder- to compressor-supplied air.

12.20 In addition, when gas generators are installed, care should be taken to ensure that they are rated to cope with any additional load.

12.21 Discussion with end-users, manufacturers and installers should take place to determine the service requirements of specialist equipment.

12.22 Infection control issues will require detailed discussion with other professionals (for example microbiologists).

Particulate contamination

12.23 A test analogous to that in Chapter 15 of Health Technical Memorandum 02-01 (Part A) can be used (that is, a 75 L sample of test gas taken at a flow rate of 150 L/min for 30 seconds), although it is doubtful whether many systems will be required or able to achieve this high flow. The highest flow possible should be used and a sampling filter size of 0.8 µm chosen.

12.24 The test should be carried out at all terminal points on the system.

Odour test

12.25 The pipelines are not intended for patient use. Therefore an odour test is not normally performed and is not advised as it is of little value.

12.26 However, if requested by the laboratory manager, the test can be performed on all systems when filled with the inert shield gas.

12.27 The test must not be performed on any working systems other than oxygen and compressed air.

Filling with the working gases

12.28 The small volumes associated with PLGSs mean that purging the test gas from the system can be completed efficiently and quickly.

12.29 Each terminal point should be purged to allow exhaustion of the test gas. On most systems, this can be achieved easily with a two-minute purge.

12.30 Great care must be taken to ensure safety when disposing of the purging gases, particularly those that are flammable.

Pipelines left before filling with the working gas

12.31 Time may elapse between initial construction and filling with the working gas.

12.32 During this period, systems should be left filled with the inert shield gas at working pressure.

12.33 Repurging with the shield gas before filling with the working gas will be necessary if there is any doubt that a system has been depressurised in the interim.

12.34 This is especially important in the case of flammable gases, where ingress of air could lead to the formation of explosive mixtures.

Pharmaceutical tests

Important safety information

12.35 Quality-control testing of systems carrying flammable agents such as pure acetylene, hydrogen and propane is not recommended.

12.36 Some anaerobic mixtures contain small quantities of hydrogen gas and, if these are to be tested, attention should be given to the following:

a. disposal of flammable, toxic etc gases requires particular care if hazards to personnel are to be avoided. Disposal routes and methods should be examined before testing is attempted, to ensure total safety;

b. if there is any doubt as to the compatibility of test equipment with the gases to be tested, testing should not be carried out. This applies particularly to the use of electrically powered test equipment and its associated sampling and disposal tubing with gases that may be highly flammable or corrosive.

Quality-control testing routines

12.37 For reasons given in paragraph 12.35, comprehensive pharmaceutical quality-control testing of PLGS is rare.

12.38 Frequently, no quality-control testing of PLGS takes place and, hence, many Quality Controllers have no experience of such systems.

12.39 Users should be encouraged to ensure that adequate testing of systems has taken place before use, as the consequences of using contaminated gases can be serious in terms of equipment damage and/or performance.

12.40 Employing a Quality Controller with experience of MGPS testing is essential, and the Quality Controller chosen should be on the MGPS National QC Register as recommended in Chapter 15 of Health Technical Memorandum 02-01 (Part A).

Particulates and oil

12.41 The particulate and oil tests described above may have been carried out by the installer before a Quality Controller is invited to test the system. Repetition of these tests is therefore at the discretion of the Quality Controller.

Water

12.42 Leaving pipework open to the elements can lead to water vapour ingress. In extreme cases, liquid water will collect in unprotected pipework. If at all possible, a moisture test carried out before filling with working gases will ultimately save time and cut down on wastage of expensive gases.

Other tests

12.43 The laboratory manager may request additional tests, and the Quality Controller will be able to give advice on relevant tests when required. These tests will include:

a. **Compressed air system:**
Air quality can be tested to European Pharmacopoeia (Ph. Eur.) specifications if a suitable dryer system is fitted. Otherwise, a test to ensure oil levels are below 0.1 mg/m^3 will ensure protection of the system against oil contamination. Dew-point levels of an "oil

separator plus filter" only system are difficult to predict, but values can be recorded in order to aid detection of trends in plant performance. Users should be made aware of potential damage to expensive equipment that can result from condensation of water vapour.

b. Vacuum system:
Presence of suction only, although actual vacuum may be recorded if desired.

c. Other gases:
Tests are usually based on:

(i) proving the absence of inert shield purge gas (although this will be difficult when analysing gas mixtures containing nitrogen);

(ii) proving the absence of excessive amounts of moisture (as described above).

Mixtures of oxygen, carbon dioxide, nitrogen and hydrogen in varying proportions can be tested for presence of water vapour, oxygen, carbon dioxide and monoxide, nitrous oxide, nitric oxide, nitrogen dioxide and sulphur dioxide, as appropriate to the mixture and in accordance with the gas suppliers' specifications.

Gases of very high purity may also warrant initial testing of pipelines for specific contaminants in very low concentrations. In such instances, the advice of the laboratory manager, and the specialist gas and equipment suppliers, should be sought.

Requirements before a PLGS is taken into use

General

12.44 Before a system is used, the appropriate persons must certify in writing that all tests have been completed and that all systems comply with the requirements. This must include certification that all drawings and manuals required by the contract have been supplied and as-fitted drawings are correct.

12.45 All certificates must be dated and signed by the appropriate witnesses, by the contract supervising officer, and by the representative of the contractor.

12.46 All construction labels and signage should be removed from the system.

Operational policy

12.47 If the Authorised Person (MGPS) is to assume responsibility for the PLGS, the MGPS operational policy can be amended to include operational requirements for the PLGS.

12.48 If the Authorised Person (MGPS) has no responsibility for the PLGS, the laboratory manager, or delegated representative, will assume responsibility for the PLGS.

12.49 It will then be the responsibility of the laboratory manager or his/her delegated representative to prepare, or arrange for preparation of, a separate operational policy for the PLGS.

12.50 Arrangements for policy implementation and monitoring should be documented and a regular review carried out.

12.51 Guidance on operational policy content and preparation is given in Chapter 5 and Appendices A and B of Health Technical Memorandum 02-01 (Part B).

13 PLGS permit-to-work system

13.1 In the absence of a formal permit-to-work system for PLGSs, some Authorised Persons (MGPS) have amended MGPS permit forms to manage PLGS work. However, as the MGPS permit is intended for use with patient-connected systems, its use on a PLGS is not appropriate.

13.2 An alternative permit form is reproduced in Figure 9 and should be used for work on the PLGS.

13.3 There may be other permits applicable to work on a PLGS, for example "confined spaces" and "hot work". These should be referenced on the PLGS permit document.

13.4 Copies of the permit should be retained by the Authorised Person (MGPS) and/or the laboratory manager.

13.5 If pharmaceutical testing has taken place, a copy of the quality control test results should be signed by the Quality Controller and appended to the completed permit.

13.6 The Quality Controller may retain a copy of the permit by request.

Figure 9 Sample permit-to-work form for work on a PLGS

Pathology laboratory gas systems permit-to-work form

Establishment name _____ Permit No 00000

Location of work _____

Permission is given by:

Name (print) _____ Title _____

Signature _____ Date _____

for the following work to take place on:

Date _____ between the hours of _____ and _____

Laboratory Gas system(s) affected _____

The system will/will not be isolated at valve No _____ Location _____

Description of work: _____

_____

Hazards identified (circle as appropriate):

Flammable, toxic, corrosive, oxidising, asphyxiating, microbiological, radioactive

Other (please describe): _____

Appropriate protective equipment will be used.

I understand and accept responsibility for the work described above. I have been informed of and understand all relevant safety hazards and procedures. No other work will be carried out under this authorisation.

Name (print) _____ Company _____

Signature _____ Date _____ Time _____

Other Permits in use for this work No _____
No _____

It has been necessary to extend the work beyond the allotted time. The system(s) remain safe to work on and all hazards and precautions have been explained to the person taking over.

The expected time of completion of the work is now _____ hours on _____ (date)

Name (print) _____ Company _____

Signature _____ Date _____ Time _____

All work described has been completed and tested in accordance with Health Technical Memorandum 08-06 Chapter 13. A copy of the test results/service report attached to this Permit has/have been left with the Authorised Person (MGPS)/ Laboratory Manager.

Name (print) _____ Company _____

Signature _____ Date _____ Time _____

Following successful test results, I accept the above system(s) back into use.

Name (print) _____ Title _____

Signature _____ Date _____

14 PLGS maintenance

General

14.1 To facilitate effective maintenance, it is expected that all plant will be located within plantrooms designed to the criteria in Chapter 14 of Health Technical Memorandum 02-01 (Part A).

14.2 Wherever possible, main services distributions should be routed above corridors and other circulation spaces so that access from user accommodation is not required for maintenance. This applies to pipework routes where, in addition to routine inspection and maintenance, it is inevitable that modifications, additions and renewals will be required periodically.

14.3 In clean areas it is important to ensure that plant and equipment is arranged so that access to the space is only required for terminal point outlets.

14.4 Devices for the control and safe isolation of engineering services should be:

a. located in circulation rather than working areas to avoid disruption;

b. protected against unauthorised operation;

c. clearly visible at all times;

d. accessible to facilities staff.

14.5 It is important to ensure that engineering services are readily maintainable. Within the pathology facility, services should be arranged so that they are secure; yet maintenance access should not be impeded.

14.6 As a general principle, with the exception of drainage, only those services which serve the facility should be located above false ceilings and, wherever possible, they should be installed over corridors and other circulation spaces.

14.7 In clean areas and other areas requiring non-accessible ceiling voids, the design of engineering services should ensure that access for terminal point filters etc is from below.

14.8 The use of specialist contractors, registered under ISO 9001/EN 13485, with a documented scope of registration, is recommended.

Compressor and central vacuum plant

14.9 This should follow the guidelines given in Chapter 10 of Health Technical Memorandum 02-01 (Part B).

14.10 For plant providing a discrete service to equipment items, the manufacturer's maintenance schedules should be followed.

14.11 Special safety restrictions may apply to the servicing of central vacuum plant, particularly with respect to microbiological contamination.

Manifold systems

14.12 Guidance given in Chapter 5 of Health Technical Memorandum 02-01 (Part A) applies generally to MGPS manifolds.

14.13 The schedule below applies more specifically to PLGSs:

- obtain permit-to-work to carry out all work, including leak tests if necessary;
- inform customer/client of alarm conditions to be expected during maintenance work.

14.14 On all single-cylinder-served pipelines:

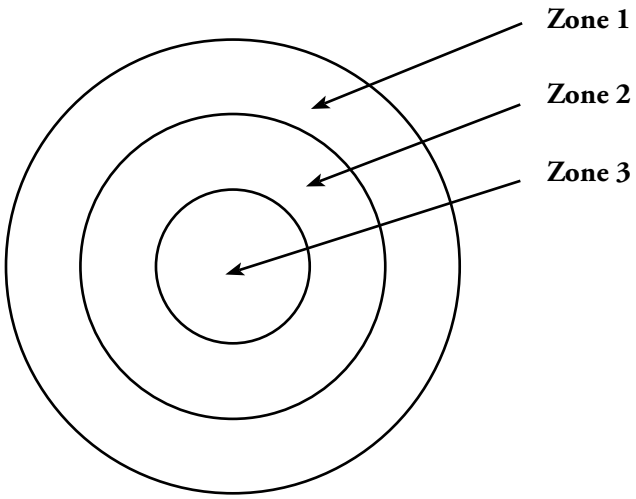
- carry out full flow test through regulator at working pressure to ensure continued capability of multi-stage regulator;
- test regulator against closed outlet valve to check for creep;
- carry out leak test using recognised leak detector (Snoop/Teepol etc);
- inspect all tailpipes/non-return valves for leakage/damage;
- inspect all signage/labelling for permanence and legibility.

14.15 On all auto-changeover manifolds:

- check both inlet valves for full shut-off;
- re-balance both left- and right-hand primary regulators to manufacturer's recommended settings and carry out full flow test through integral line regulator;
- test regulator against closed outlet valve (where fitted) to check for creep;
- carry out leak test using recognised leak detector (Snoop/Teepol etc);
- inspect all tailpipes/non-return valves for leakage/damage;
- if an annual pressure drop is to be carried out, ensure all safety relief valves are removed and blanked unless testing at statutory 1.2 times the working pressure;
- check all equipment for signs of five-year replacement with reference to the guidelines given in BCGA Code of Practice 7 (CP7) – 'The safe use of oxy-fuel gas equipment (individual portable or mobile cylinder supply)' and BCGA Guidance Note 7 (GN7) – 'The safe use of individual portable or mobile cylinder gas supply equipment';
- upon completion of all works, inform customer/client of alarm reinstatement to normal conditions and sign off any permit-to-work issued.

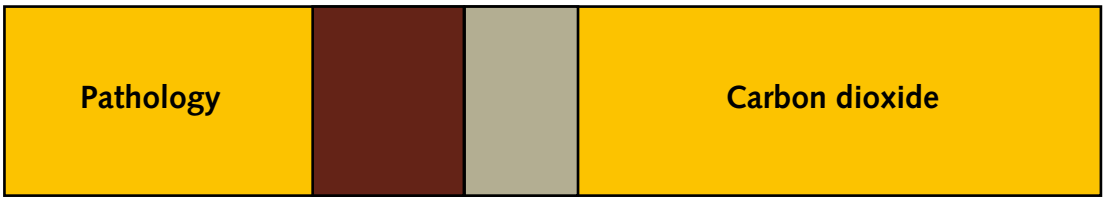
Recommended service intervals	
Single regulator systems	Once per annum
Auto-changeover manifolds	Twice per annum
Leak tests (if required)	Once per annum

Appendix 1 – Colour-coding of laboratory gas termination point taps in accordance with BS EN 13792:2002



Gas	Abbreviation or formula	Zone 1	Zone 2	Zone 3
Oxygen	O_2	Blue	Blue	Blue
Carbon dioxide	CO_2	Blue	Blue	Black
Hydrogen	H_2	Red	Red	Red
Acetylene	C_2H_2	Yellow	White	Green
Butane	C_4H_{10}	Yellow	Blue	Blue
Propane	C_3H_8	Yellow	Blue	Red
Natural gas	G	Yellow	Yellow	Yellow
Compressed air	CA	Blue	Blue	Yellow
Argon	Ar	Blue	Grey	Grey
Sulphur dioxide	SO_2	Black	Blue	Yellow
Helium	He	Blue	Grey	White
Chlorine	Cl_2	Black	White	White
Carbon dioxide + oxygen	CB	Blue	Black	Blue
Low vacuum 10^5–100 Pa	V	Grey	Grey	Black
Fine vacuum 100–0.1 Pa	VF	Grey	Grey	Grey
High vacuum 0.1–10^{-5} Pa	VH	Grey	Grey	White

Appendix 2 – Examples of pipeline colour-coding labels



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