SWEDISH
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AUTHORITY

AFS 2001:7

Anaesthetic Gases

Provisons of the Swedish Work Environment Authority on Anaesthetic Gases, together with General Recommendations on the implementation of the Provisions

Translation
In the event of disagreement concerning the interpretation and content of this text, the printed Swedish version shall have priority

The Work Environment Authority's Statute Book

The Swedish Work Environment Authority was formed through a merger of the Swedish National Board of Occupational Safety and Health and the Labour Inspectorate, on 1st January 2001.

Provisions adopted by the Swedish Work Environment Authority are published in the Statute Book of the Swedish Work Environment Authority. Provisions earlier published in the Statute Book of the Swedish National Board of Occupational Safety and Health simultaneously still apply. Both Statute Books' names are abbreviated AFS.

Please note that references to statutes always give the original number of the document concerned, regardless of any subsequent amendments and reprints.

Concerning amendments to and reprints of Provisions of the Swedish National Board of Occupational Safety and Health and of the Swedish Work Environment Authority, reference is made to the latest Statute Book Register (in Swedish). A list of Ordinances, General Recommendations, Directions and Notices is also published in English.

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AFS 2001:7

Provisions of the Swedish Work Environment Authority on Anaesthetic Gases

Adopted 27th September 2001 Published 6th November 2001

The following Provisions are issued by the Swedish Work Environment Authority pursuant to Section 18 of the Work Environment Ordinance (SFS 1977:1166) and in consultation with the National Board of Health and Welfare and the Medical Products Agency.

Scope

Section 1

These Provisions apply to all activities involving the use of anaesthetic gases.

Section 2

For the purposes of these Provisions, anaesthetic gas is defined as a medical product administered in gaseous form through the respiratory tract for the purpose of achieving anaesthesia or pain relief.

Section 3

The following terms are used in these Provisions with the meanings indicated below.

Local scavenging An scavenging device removing air contaminants at or near their source.

Anaesthetic gas machine scavenging A scavenging device removing anaesthetic gases from the excess valve or exhalation valve of the anaesthetic gas equipment.

General stipulations

Section 4

Work with anaesthetic gas shall only be carried out by a person having sufficient knowledge of the risks which the work entails and how to prevent them.

Section 5

The written handling and safety instructions necessary for the work shall be available at the workplace.

Work using anaesthetic gas equipment

Section 6

Work with anaesthetic gases shall be carried out in such a way and with such equipment as to minimise the amount of anaesthetic gas escaping into the surroundings when used as intended.

Section 7

During work with anaesthetic gas equipment, there shall be an anaesthetic gas scavenging system, the capacity of which is sufficient to capture and remove from the premises any excess gas from the equipment. Means shall be provided to continuously verify that the gas flow of the scavenging system is the intended.

Section 8

Anaesthetic gas equipment shall be controlled before being taken into service and shall thereafter be technically overhauled at least once every twelve months. Among other things the control and overhaul shall include adjustment of the equipment, aiming at minimising discharge of anaesthetic gas during the intended use, and measurement of the leakage flow. The results of that measurement shall be documented. The documentation shall be available for examination on request by a supervisory authority. The method of measurement and other particulars with a bearing on the results shall be recorded.

Section 9

The tightness of the breathing system of the anaesthetic gas equipment shall be controlled by a suitable method prior to every occasion of use. If when controlled the breathing system turns out to be insufficiently leak-proof, the system shall be readjusted and the control shall be repeated.

The results of the control and the measures taken shall be documented. The documentation shall be available for examination on request by a supervisory authority.

Section 10

The person carrying out overhaul, adjustment and control according to Sections 8 and 9 shall have sufficient knowledge and access to necessary equipment.

Central distribution of nitrous oxide

Section 11

Before work is undertaken on any part of a medical gas pipeline system for nitrous oxide, the pressure shall be relieved in such a way that exposure to the gas is prevented.

Section 12

Terminal unites for nitrous oxide shall be controlled regularly for leaks, at least once every twelve months and in connection with replacement of tubing. The results of the control shall be documented. The documentation shall be available for examination on request by a supervisory authority.

Liquid anaesthetic agents

Section 13

Work with liquid anaesthetic agents intended for inhalation in gaseous form shall be conducted in such a way that the occurrence and spread of air contaminants is prevented. Residues of liquid anaesthetics shall be disposed of in such a way as to minimise the risk of exposure.

If a receptacle containing a liquid anaesthetic agent intended for inhalation in gaseous form does not constitute a closed, unbroken original packaging or is part of a closed system, it shall be stored in a particular, separately ventilated space.

Ventilation

Section 14

If anaesthesia with a mask or other work is to be carried out in such a way that anaesthetic gases are leaking or are released in such quantities that exposure can endanger the health of the persons working there, a local scavenging device shall be provided on the premises. The scavenging device shall have sufficient capacity for evacuating the anaesthetic gases.

The capacity of the local scavenging device shall be controlled on installation and following changes to the installation. The results of the control shall be documented. The documentation shall be available for inspection on request by a supervisory authority.

Any malfunction of the local scavenging device, when in operation, shall be monitored by a control system.

Entry into force and transitional stipulations

These Provisions enter into force on 1st April 2002. The Ordinance of the National Board of Occupational Safety and Health (AFS 1983:11) containing Provisions on Anaesthetic Gases is repealed with effect from the same date.

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General Recommendations of the Swedish Work Environment Authority on the implementation of the Provisions on Anaesthetic Gases

The following General Recommendations are issued by the Swedish Work Environment Authority on the implementation of the Authority's Provisions (on Anaesthetic Gases (AFS 2001:7). The National Board of Health and Welfare and the Medical Products Agency have been consulted.

General Recommendations have a different legal status from Provisions. They are not mandatory. Instead they serve to clarify the meaning of the Provisions (e.g. by providing information on suitable ways of meeting the requirements, by exemplifying practical solutions and procedures) and to provide recommendations, background information and references.

Background

The Provisions of AFS 2001:7 are a revised edition of the Provisions in AFS 1983:11. A project aimed at evaluating AFS 1983:11 was carried out in 1997 by the National Board of Occupational Safety and Health and the Labour Inspectorate. Their findings are presented in Arbetarskyddsstyrelsens rapport 1999:12 (Report 1999:12 from the National Board of Occupational Safety and Health).

The substances used as anaesthetic gases are nitrous oxide (dinitrogen oxide, N_2O) and halogenated organic compounds such as halothane, enflurane, isoflurane, desflurane and sevoflurane. The halogenated organic compounds are liquids at room temperature. Nitrous oxide (dinitrogen oxid N_2O) is a colourless gas and is stored under pressure in liquid form in gas cylinders.

During inhalation anaesthesia, the gas mixture is administered through the respiratory tract to achieve the intended effect. This can be done by placing a mask over the region of the nose and mouth. For dental surgery the mask is secured over the nose with a tape. Anaesthetic gas can also be administered by intubation, i.e. by placing a tube (of plastic or rubber material) in the trachea. The tube is sealed against the trachea by means of an inflatable balloon – a cuff. Other methods of achieving a leak-proof connection with the respiratory tract have been developed in recent years. They include the laryngeal mask, which is inserted down to the epiglottis but not into the trachea itself. The laryngeal mask normally will cause less leakage than a conventional mask. When the patient is to be given a general anaesthesia, the anaesthetic gas mixture normally consists of nitrous oxide mixed with at least 30 per cent oxygen by volume and additionally, of an organic anaesthetic, usually up to 10 per cent by volume. For pain relief (analgesia) the gaseous

mixture consists of equal parts of nitrous oxide and oxygen, 50 per cent by volume of each. The liquid halogenated organic anaesthetic agents are transferred to a vaporiser which forms part of the anaesthetic gas equipment. The liquid when used is vaporised and a mixture of oxygen and nitrous oxide/oxygen is used as carrier gas. Normally the anaesthetic gases are administered in a larger quantity than the patient is capable of inhaling. Excess gases are removed though a valve in the equipment. This valve is connected to a gas scavenging system which transfers the excess gases to a terminal unite connected to the atmosphere, either directly or by the exhaust air duct of the ventilation system. The anaesthetic gas mixture can also be returned to the patient through a feedback (“circle”) system after passing through a container with carbon dioxide absorbing substance. This arrangement is termed a closed system.

Normaly, nitrous oxide is delivered in gas cylinders to the hospital medical gas centre, and distributed from there to various premises in the hospital by pipelines. From a terminal unit in a wall or, a medical supply unit, an anaesthetic gas equipment can be connected. In addtition to terminal unites for nitrous oxide, terminal unites for oxygen and air to be supplied with the nitrous oxide are also installed. Furthermore, portable gas cylinders are commonly used in hospitals. E.g. anaesthetic gas machines, can be provided with spare cylinders for oxygen and nitrous oxide.

Health hazards

Starting at the end of the 1960s adverse health effects were observed in medical personnel, mainly nurses, who had been working with anaesthetic gases, e.g. nitrous oxide and halothane. A probable connection between exposure and miscarriage frequency was observed. Since then a number of studies all over the world have been published, showing daily exposure to anaesthetic gases to be associated with health hazards.

In connection with the administration of anaesthetic gases and the care of patients immediately after anaesthesia, personnel can be exposed by inhaling the air which has been contaminated by anaesthetic gases from air exhaled by patients. The anaesthetic gases can affect various organs, e.g. the nervous system and the liver, either directly or following breakdown in the body. The usefulness of anaesthetic gases is due to their capacity for influencing the nervous system. The properties of nitrous oxide causes persons with manifest or latent vitamin B_{12} deficiency to be a group at risk.

Several studies have shown that women exposed in their profession to anaesthetic gases are running an increased risk of miscarriage (spontaneous abortion), and risks of foetal injury are also suspected. In some studies this has also been reported for women whose husbands were exposed to anaesthetic gases in their profession. As compared to other medical personnel, those handling anaesthetic gases more frequently are complaining of suffering from concentration and remembering difficulties and from headache, nausea, tiredness and other symptoms. Balance problems and impaired precision motor skills have also been reported. The introduction of stricter safety precautions at the beginning of the 1980s and, to some extent, the development of new medical drugs with improved clinical properties have helped to reduce the adverse effects reported previously.

Reports have appeared concerning the unhealthy working environment of anaesthetists. A survey conducted by the Swedish Work Environment Authority in the spring of 2001 showed that, presently, there are no indications that exposure to anaesthetic gases was the cause of this.

A survey concluded in 2001 indicates an elevated risk of MS (multiple sclerosis) in anaesthetic nurses. The nurses affected had been exposed to anaesthetic gases between 1963 and 1987, i.e. at a time when more toxic anaesthetics were being used in hospitals when, generally, exposure was higher.

Pollution by anaesthetic gases and preventive measures

Section 4 of the Provisions of the National Board of Occupational Safety and Health on Occupational Exposure Limit Values and Measures against Air Contaminants, AFS 2000:3, requires that work shall be organized, conducted and followed up in such a way as to make the concentration of air contaminants in the respiratory zone as low as is practically possible.

If leaking of anaesthetic gases and pollution of the premises cannot be avoided, preventive measures are needed to be taken so as to keep exposure to a very low level, thus minimising the risks of untoward effects and ill-health among the employees. The preventive measures are mainly of a technical nature, but organisational measures are also involved. It has been shown that work under stress often entails a greater risk of leakage and, accordingly, exposure to anaesthetic gases. A suitable choice of working methods prevents anaesthetic gases from being released unnecessarily. A good result is achieved if working methods are jointly devised by different personnel categories such as anaesthetists, anaesthetic nurses, surgical staff, dentists, dental nurses, veterinary surgeons and veterinary assistants, with medical technicians, operating theater personnel etc. also involved. It is appropriate that safety delegates take part to in the planning of preventive measures. The occupational health services can also be consulted in the planning context.

Anaesthetic gases can leak to the premises from anaesthetic gas equipment due to technical defects and leaks in connectors, hoses, reservoir bags, valves etc. This can be avoided, for example, by

– carrying out maintenance and care in the correct manner and at sufficiently frequent intervals,
– assembling the equipment properly,
– only using connectors which are not worn, are close-fitting and gas-specific and belonging to specific anaesthetic gas equipment,
– replacing parts which are damaged or of inferior design,
– having leakage detection routines.

Anaesthetic gas can escape in large quantities while being transferred from anaesthetic gas equipment to the patient. Working procedures are highly important in this connection. Mainly the induction, but also the ending, of anaesthesia will entail heavier exposure than the anaesthesia itself. Intubation can also involve leakage. If anaesthetic gas is allowed to escape freely to the premises, the air can become heavily contaminated, submitting the employees to high exposure. This can, for example, be avoided by

– checking the tightness of the breathing system with air or oxygen before use,
– having local scavenging at all exhaust points,
– having the local scavenging device turned on before the anaesthetic gas is administered,
– not turning on anaesthetic gases until the mask or the tracheal tube, as the case may be, has been closely fitted to the patient and the gas scavenging disposal system is operative,
– by leaving the patient connected to the anaesthetic gas equipment for a reasonable length of time after the flow of anaesthetic gas has been turned off at the end of anaesthesia, while at the same time supplying oxygen and/or air to the patient. Part of the inhaled anaesthetic gases uptake will then be transferred to the scavenging device an evacuated. Keeping the anaesthetic mask in place until excess gases have been ventilated off, will reduce the risk of anaesthetic gases from being transmitted into the room.

Nitrous oxide, when used for pain relief, is often administered directly by the patient. If so, it is important that the patient will be instructed to also exhale in the mask, so that the gas mixture can be carried away by the scavenging system.

Measurements have shown that using a mask anaesthesia almost invariably entails heavier exposure of personnel to anaesthetic gases than does anaesthesia with an intubated patient. The reason being that, although there are modified mask sizes, keeping the mask closely fitted to the patient’s face can be difficult. As a mean towards minimising pollution by anaesthetic gases, new types of anaesthetic masks (“double masks”) have been developed, incorporating a local scavenging device.

Low flow systems entail less leakage than high flow ones and are preferable from a work environment point of view. Use of local scavenging reduces the risk of exposure. An effective and adequate ventilation system with a capacity to effectively remove contaminants in combination with appropriate routines for changing patients, will help to keep pollution by anaesthetic gases at a low level. Inducing anaesthesia in children often causes more leakage of anaesthetic gases, since children may show more anxiety than adult patients in this situation. In paediatric anaesthesia special care should be taken to choose a method entailing minimum leakage of anaesthetic gases.

Following the finish of anaesthesia, the patient exhales the anaesthetic gas into the environment, thus increasing the risk of personnel exposure. The anaesthetic gases remaining in the patient’s expiratory air for a considerable length of time after surgery can result in elevated concentrations of anaesthetic gases occurring in recovery rooms. Therefore it is important that these rooms have general ventilation of such capacity that the anaesthetic

gases are effectively removed from the ambient air. If general ventilation does not have such capacity, it may need supplementing with local scavenging. Effective scavenging will be achieved if the captive part of the local scavenging device is placed at a distance exceeding 15 cm from the patient's face.

Risk assessment and survey of air contaminants

Stipulations on risk assessment prior to work with chemical substances are contained in the Provisions of the National Board of Occupational Safety and Health on Chemical Hazards of the Working Environment. In anaesthesiology, risk assessment is needed in order, for example, to investigate the extent of exposure. Risk assessment is especially important when new activities are being introduced and when changes are made to existing ones. Stipulations on continuous and recurrent inspection of the working environment are contained in the Provisions of the Swedish Work Environment Authority on Systematic Work Environment Management.

Occupational exposure limit values have been defined for nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane. Special stipulations on occupational exposure limit values and measures to limit air contaminants are contained in the Provisions of the National Board of Occupational Safety and Health on Occupational Exposure Limit Values and Measures against Air Contaminants.

Almost invariably, work with anaesthetic gases entails leakage of anaesthetic gases. According to Section 7 of the Provisions of the National Board of Occupational Safety and Health on Occupational Exposure Limit Values and Measures against Air Contaminants, AFS 2000:3, it is the duty of the employer to investigate the extent of exposure. When an occupational exposure limit value is suspected to be exceeded, investigation by measuring exposure is required in Section 13 of the same Provisions.

Stipulations on exposure measurement procedures are contained in Sections 9-11 of the Provisions of the National Board of Occupational Safety and Health on Occupational Exposure Limit Values and Measures against Air Contaminants, AFS 2000:3. During these measurements it is important to take into account both level limit value and short-term value. Foremost, attention should be given to initially measure exposure where anaesthetic gases are handled. In cases where employees are exposed indirectly by another employee's work with anaesthetic gases, the need for measurements must be decided from case to case.

A preliminary investigation, e.g. in the form of a random sample measurement, is appropriate for deciding where and to what extent more detailed measurement is needed.

It is highly important that measurements are planned, conducted and assessed by or in consultation with a person who has had good training in occupational hygiene. Often the hospital's own medical technicians can be engaged. Occupational health services and county council occupational and environmental medicine divisions can render assistance. The Work Environment Inspectorate and the National Institute for Working Life can be consulted. It is important that planning and procedures for air sampling are based on consultations with employees and safety delegates at the workplace.

The frequency of use of anaesthetic gases, the type of equipment and working methods employed etc. can decide the need for measurements. If no measurements have been carried out before, a more comprehensive measurement may be necessary as compared to a recurrent check of the continuing acceptability of exposure.

Changes rendering previous measurements inapplicable include, for example, change of premises, change of equipment and structural alterations. In activities where anaesthetic gases have not been used previously, e.g. in connection with work with magnetic resonance imaging equipment, frequent follow-ups are especially important as a means of ensuring that the concentration of anaesthetic gases is safely below the occupational exposure limit value.

It is important that all activities likely to entail exposure should be included in measurements, e.g. filling of vaporisers or the induction of anaesthesia. It is also important that measurement should be carried out when there is reason to suspect the occurrence of brief but heavy exposures, e.g. in connection with anaesthesia to uncooperative patients. Measurement shall also clarify exposure in relation to the short-term value.

The concentration of anaesthetic gases in recovery rooms should also be checked. It is inappropriate to start anaesthesia or to have patients recover from anaesthesia in corridors and other spaces which have inadequate general ventilation and are not equipped with local scavenging facilities.

Stipulations on measures to be taken and on recurrent controls

In Section 18 of the Provisions of the National Board of Occupational Safety and Health on Occupational Exposure Limit Values and Measures against Air Contaminants, AFS 2000:3, requirements are given concerning immediate action to be taken to reduce exposure to an acceptable level, if air pollution tests show exposure to anaesthetic gases to be unacceptable. Actions should be aimed at reducing activities entailing high, although brief exposure to anaesthetic gases. Following these actions, in the same Provisions requirements are given concerning new exposure measurement to be carried out at the earliest possible opportunity, at the latest within three months unless obviously unnecessary. Rules on the documentation of exposure measurement are contained in Section 19 of the same Provisions.

Information

According to Chap. 3, Section 3 of the Work Environment Act, the employer has a duty to inform his employees of the risks which may be associated with the work and how to guard against them.

According to Section 23 of the Provisions of the National Board of Occupational Safety and Health on Chemical Hazards in the Working Environment, AFS 2000:4, the employer has to provide information on occupational exposure limit values for substances currently used and on other Provisions applying to the work. The employer shall ascertain that the employees concerned have understood the information.

It is important that employees who do not work directly with anaesthetic gases but who nonetheless are running the risk being exposed to them, e.g. personnel taking part in surgical operations or who are for other reasons present on premises where work using anaesthetic gases is undertaken, should be informed of the risks associated with such gases.

Application of standards

In all cases where the General Recommendations refer to an applicable standard, the Swedish Work Environment Authority wishes to emphasise that standards are voluntary undertakings, whereas mandatory product requirements are given in the applicable EC legislative acts in this field.

Guidance on individual Sections

Guidance on Section 1

These Provisions apply wherever anaesthetic gas is administered to humans or animals, e.g. in medicine, dentistry, veterinary medicine or animal experiments. They apply to all handling in an activity where anaesthetic gases are used. For example, in addition to surgery and obstetric care, activities of this kind include postoperative recovery in hospitals and in veterinary medicine. In medical care, anaesthetic gases are used for certain examinations, e.g. those including magnetic resonance imaging (MRI), cardiovascular radiology and for pain relief, e.g. in ambulances and ambulance helicopters. Emergency medical vehicles may also be provided with anaesthetic gas equipment.

The Provisions also apply to anyone performing service and maintenance on anaesthetic gas equipment and calibrating vaporisers and thus are exposed to anaesthetic gases. In addition they apply to persons doing work on medical gas pipeline systems and thus exposed to nitrous oxide.

The Provisions do not apply to production of anaesthetic agents, wholesale storage or transport to and from users, etc.

Guidance on Section 2

An anaesthetic/analgesic agent intended for inhalation is called an inhalation anaesthetic/analgesic agent. Halogenated organic anaesthetics are medicinal products approved by the Swedish Medical Products Agency. A description of them will be found in FASS, the joint catalogue of the pharmaceutical industry, published by LINFO, Läkemedelsinformation AB. Nitrous oxide and medical gas consisting of 50 per cent nitrous oxide and 50 per cent oxygen by volume, e.g. Kalinox® and Medimix®, meets the requirements of the current pharmacopoeia and conforms to the regulations of the Swedish Medical Products Agency concerning medical gases.

Guidance on Section 3

A local extraction device removes anaesthetic gases in the vicinity of the patient's face. There are various designs of local extraction device coupled to the mask ("double masks"). For dental use there is a nose and chin mask of corresponding design. Similar masks also exist for veterinary use.

Guidance on Section 4

The employer has to meet the requirements in Chap. 3, Section 3 of the Work Environment Act on ensuring that the employee has received sufficient training to enable the work to be safely undertaken. Adequate knowledge of safety and health matters should at least comprise the content of these Provisions and recognition of the risks associated with work with anaesthetic gases and the precautions needed to be taken. It is very important that knowledge should be kept updated, and regularly recurrent training should therefore be provided. Some personnel categories – e.g. anaesthetists, anaesthetic nurses, assistant nurses, theatre personnel, midwives, dentists, dental nurses, veterinary surgeons, veterinary assistants and ambulance crews – being particularly exposed to anaesthetic gases and the reasons to this exposure are due to the handling of anaesthetic gas equipment, creates a need to organise annually recurrent training, among other subjects, covering the following:

– preventive measures,
– working methods entailing the least possible exposure,
– care and maintenance of the equipment,
– correct control of tightness,
– leakage elimination,
– functional principles of the anaesthetic gas scavenging system and local scavenging devices and control of their capacity,
– the importance and function of room ventilation,
– handling of liquid anaesthetic agents, the vapour from which is intended for inhalation,
– protective measures.

A special need for training is entailed by changes of personnel and workplace, the hiring of temporary personnel, introduction of new equipment and new agents, and changes of routines.

It is important that midwives, veterinary surgeons and dentists, as well as nurses, veterinary assistants and dental nurses, undergoing specialist

anaesthesiology training, as early as possible during the training should learn working methods aimed at minimising exposure to anaesthetic gases.

Guidance on Section 5

According to Section 11 of the Provisions of the National Board of Occupational Safety and Health on Chemical Hazards in the Working Environment, AFS 2000:4, the employer has the main responsibility for providing employees with the handling and safety instructions they need in order to minimise exposure to anaesthetic gases and to take preventive safety measures. The task of designing handling and safety instructions can be transferred to another person, e.g. the supervisor. Instructions for use and a product description from the supplier can make a suitable basis for establishing handling and safety instructions. It is important that instructions concerning anaesthetic gas equipment and the control methods for care and maintenance should be adapted to suit the personnel category for which they are intended.

It is important that the instructions should be adapted to local conditions regarding equipment, working methods etc., and that they should be readily intelligible to the employees concerned. It is appropriate to go through the written handling and safety instructions when they are issued to the employees.

The written instructions need to be available near the place where the work is done, and they need to cover every element of risk involved with the work. The content of the instructions may, for example, include the following.

– Information as to how a certain anaesthetic gas equipment is to be assembled, checked for leaks, cared for and used.
– An explanation of the procedure for reading off control functions, e.g. flow meters, and the values with which readings are to be compared.
– A description of the procedure for filling and emptying a vaporiser so as to minimise exposure.
– A statement of the intervals at which the equipment is to be controlled and who is responsible for the controls being done.

Personnel supervising recovery and medical technicians servicing equipment etc. are among the employee categories normally needing written instructions on handling and safety.

It is appropriate for the instructions to be made up on the basis of joint consultations between the employer and the employees, safety delegates and somebody closely familiar with conditions at the workplace and who has experience of the work. According to Chap. 3, Section 4 of the Work Environment Act it is the duty of the employee to comply with current Provisions and to co-operate in achieving the best possible working enviroment.

Guidance on Section 6

Anaesthetic gas equipment used for administering anaesthetic gas includes, for example, anaesthesia workstations, gas equipment for providing analgesia (used for example in obstetrics, in ambulances and in dental practice) and a ventilator.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices was transferred to Provisions and General Recommendations of the National Board of Health and Welfare on Medical Products in Health Care, SOSFS 1994:20. Through an amendment of 1st September 2001 concerning, the allocation of responsibilities between the National Board of Health and Welfare and the Medical Products Agency for the supervision of medical devices in health care, these Provisions have been transferred to the Statute Book of the Medical Products Agency, Provisions on Medical Devices , LVFS 2001:6. The regulations on responsibility for the use of medical devices in health care is governed by the Provisions and General Recommendations of the National Board of Health and Welfare on the Use and In-house Manufacture of Medical Devices in Health Care SOSFS 2001:12. The Provisions and General Recommendations of the National Board of Health and Welfare on Quality Systems in Health Care SOSFS 1996:24 include, for example, Provisions on responsibility, competence, procurement, identification of defects and non-compliance and documentation in connection with the handling of medical equipment.

One way of meeting the requirements of Directive 93/42/EEC concerning medical devices is given in the Swedish Standard SS-EN 740, Anaesthetic workstations and their modules – Particular requirements. There may be other ways of meeting the requirements of the Directive besides those described in the Swedish standards.

The Swedish Standard SS-EN 740 gives the following values for the maximum permissible leakage from anaesthetic gas equipments.

Maxmum leakage from a flow control system (between the anaesthetic gas flow control valve and fresh-gas inlet to the breathing system) 50ml/min at 3 kPa and 20^{o} C.

Maximum leakage from an anaesthetic breathing system (between the anaesthetic gas flow inlet to the breathing system and the patient connection port) 150 ml/min at 3 kPa and 20^{o} C.

Maximum leakage from the anaesthetic gas scavenging system 100 ml/min mixed gas under test conditions as per requirements in clause 111.

In Sweden, however, for quite some time, it has been possible to maintain the following leakage values, which are lower than those allowed by the standards:

Flow control system: 10 ml/min mixed gas at 3 kPa and 20^{o} C.

Breathing system: 100 ml/min mixed gas at 3 kPa and 20^{o} C.

At several Swedish hospitals it has been shown that in practice the level of leakage from breathing systems can easily be kept down to 25 ml/min, not only in type testing but also in equipment which has been in service for several years.

As a supplement to the above values, the following maximum leakage values are recommended.

High pressure systems: (between the connecting point to the gas cylinder and/or the gas pipeline system and the valve for anaesthetic gas flow control) 5 ml/min nitrous oxide at the maximum normal gas distribution pressure and 20^{o} C.

If the anaesthetic gas system cannot be divided in the above systems, the following values can be used, where applicable:

High pressure and flow control systems constituting a technical unit: 15 ml/min nitrous oxide at the maximum normal gas distribution pressure and 20^{o} C.

When flow control and breathing systems constitute a technical unit: 110 ml/min mixed gas at 3 kPa and 20^{o} C.

Dimensional requirements for the avoidance of misconnections for breathing systems are given in the Swedish Standard SS-EN 1281-1, Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.

Dimensional requirements for terminal unites and quick connectors are given in the Swedish Standard SS-875 24 30, Connectors for medical gases.

It is appropriate to devise routines for discarding used equipment. Care should be taken not to use equipment which has been discarded by a medico-technical department of a hospital for another type of activity, e.g. in dental care or veterinary medicine.

Guidance on Section 7

The gas scavenging system may be integrated with the anaesthetic gas equipment or may be installed on the premises where the anaesthetic gas equipment is used. It is recommended that documentation, accompanying the equipment when delivered and when returned from technical overhaul, should be stored together with the equipment at the workplace.

It is important that the user should be able to monitor the capacity of the gas scavenging system to ensure that it stays within the intended values while in use. Different equipment can impose different loads on the scavenging system, which, as well as like contaminants from scavenged particles, can affect suction capacity.

Requirements for the capacity of the scavenging system and for testing procedures are given in the Swedish Standard SS-EN 737-2, Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements and amendment 1 – A1, clause 8. According to this standard, the flow capacity shall not exceed 50 l/min measured at a flow

resistance with a pressure drop of 1 kPa and shall not be less than 25 l/min measured at a pressure drop of 2 kPa.

Differently powered types of scavenging systems exist. In Sweden, however, ejector driven systems, using compressed air, are the most common. Excess gas from the anaesthetic gas system is then evacuated to the exhaust air duct of the ventilation system or to the outside of the building in a way which, in practice, creates a minimum of leakage. The most common breathing system is the circle system in which the greater part of the carbon dioxide-contaminated anaesthetic gas mixture is passing through a container filled with carbon dioxide absorbing substance. Gas is then recirculated in the system.

It is important that the outlet part of the scavenging system should be sufficiently large to impose the least possible load on the scavenger's ejector. It is important that the drive power source (the scavenging ejector) is provided with a device for adjusting the extraction flow. The function indicator of the scavenging system should clearly indicate to the user whether the system is turned off or operative. It is important that the scavenging system, pipeline disposal system included, is controlled with regard to tightness and functional efficiency before it is taken into service. The volume of gas (sampling gas) extracted for controls in equipment for monitoring anaesthetic gases should be safely collected and fed to, e.g. to the scavenging system, or fed back to the breathing system. Dimensions of connectors for connection to sampling hoses are given in the Swedish Standard SS-EN 13014, Connections for gas sampling tubes to anaesthetic and respiratory equipment.

Anyone using the scavenging system should have a thorough knowledge of its working mode and should be aware of the importance to connect it properly prior to every occasion of use.

One way of meeting the requirements of Directive 93/42/EEC concerning medical devices as regards leakage from the receiving part of the scavenging system is indicated in the Swedish Standard SS-EN 740, Anaesthetic workstations and their modules – Particular requirements, section 111.2 R. There may be other ways of meeting the requirements of Directive 93/42/EEC concerning medical devices besides those indicated in the Swedish standard.

Guidance on Section 8

As a rule the manufacturer will have given instructions as to how the technical control is to be carried out and documented. The purpose of these controls is to minimise leakage. The manufacturer's instructions is an appropriate basis for those controls; see LVFS 2001:6 Provisions of the Medical Products Agency on Medical Devices, App. 1, point 13:6. The investigation and documentation requirements contained in the Provisions of the Swedish Work Environment Authority on Systematic Work Environment Management should also be borne in mind. These controls should be in accordance with the quality system for medical care; see Section 31 of the Health and Medical Services Act (1982:763) and SOSFS 1996:24 on Quality Systems in Health Care. Preferably, the technical overhaul should be performed by a person with technical competence, e.g. from a medico-technical department. Manufactures or suppliers, if considered suitable, can also carry out the technical overhaul. The technical overhaul will correct any defects present. At the completed technical overhaul, a careful tightness check and measurement

of the leakage flow should be carried out. Equipment to patient leakage is not normally included in the measurement. Particulars of measuring method and other data are obtainable from the supplier of the anaesthetic gas equipment.

Some activities, e.g. in veterinary medicine, do not have a medico-technical department of their own. In such cases, a medical technician from a hospital can be engaged, or else the veterinary practitioner can leave the overhaul to a servicing company. It is important to ensure that the person carrying out the overhaul is competent to assess an anaesthetic gas equipment.

Furthermore, the stipulations apply when acquiring/borrowing used equipment.

Guidance on Section 9

Breathing systems consist of various parts, e.g. mask, connectors, breathing tubes, reservoir bags, carbon dioxide absorbers etc. Usually, the equipment manufacturer has recommended a suitable method for controlling the breathing system. It is important that the method used for checking the tightness of the equipment should be sufficiently accurate. Controls to ensure that the equipment is sufficiently tight for the patient's safety do not always ensure that the equipment is free from major leaks. A quantitative flow measurement may be needed in order to check that the equipment is sufficiently tight. Presently, some products are equipped with integrated units for checking the tightness of the breathing system of the anaesthetic gas equipment. In the absence of a tightness control unit or a method recommended from the manufacturer, the "constant flow method" can be used. A protocol, for example, can be used for documenting the controls. At all times, this protocol should be kept together with the anaesthetic gas equipment.

Guidance on Section 10

In order to facilitate controls and adjustment, knowledge should be kept up to date and the equipment should be in full working order.

Guidance on Section 11

Pressure should never be relieved directly to the premises in such a way that the room air becomes contaminated with nitrous oxide. When cylinders are changed in a central gas installation, some nitrous oxide usually escapes. This quantity will be reduced by having a check valve between each gas cylinder and the central unit's manifold regulator. The pressure can also be relieved with a permanent excess valve opening onto the atmosphere. When terminal unites for nitrous oxide are being repaired, the pressure can be relieved by means of a hose from the nitrous oxide terminal unit to the exhaust air duct of the ventilation system. It is important that the person carrying out this relief should have the training and knowledge for the task and be familiar with the necessary safety precautions to be taken. See Section 4.

The Swedish Standards Institution (SIS) has issued general recommendations, SIS, Technical Report 370, Safety rules for medical gas pipeline systems. Stipulations, among other things, on the handling of medical gases in gas pipeline systems, are contained in the Swedish Pharmaceuticals Standard (Svensk Läkemedelsstandard).

Rules are also contained in the Provisions of the National Board of Occupational Safety and Health on Gases and in the Provisions of the Swedish Work Environment Authority on Gas Cylinders.

Test methods for measuring leakage from medical gas pipeline systems are given in the Swedish Standard SS-EN 737-3, Medical gas pipeline systems – Part 3: Pipelines for compressed medical gases and vacuum and in SIS, Technical Report 370, Safety rules for medical gas pipeline systems.

Guidance on Section 12

If the gas terminal unites are not leak-proof, the air in the room can be continuously contaminated with considerable quantities of nitrous oxide and other gases. The maximum acceptable leakage is given in the Swedish Standard SS-EN 737-1, Medical gas pipeline systems – Part 1: Terminal units for compressed medical gases and vacuum, section 5.4.15. Detailed recommendations on operational control of gas pipeline systems, including tightness testing of terminal units, and recommendations on gas scavenging disposal systems are contained in SIS, Technical Report 370, safety rules for medical gas pipeline systems.

Guidance on Section 13

Considerable air contamination can occur in connection with the filling and emptying of vaporisers unless a completely closed filling and emptying system is used. If filling of vaporisers with liquid anaesthetic agents in vaporisers cannot be performed using completely closed systems, the safest course is to work in a safety cabinet or in conjunction with a local scavenging device. The efficiency of the closed system should be checked regularly, and there should be routines for technical overhaul.

Requirements for the filling systems for liquid anaesthetic agents are given in the Swedish Standard SS-EN 1280-1, Agent specific filling systems for anaesthetic vaporizers.

Liquid anaesthetic agents should not be stored in the safety cabinet used for filling vaporisers. Anaesthetic containers placed in the safety cabinet can disrupt air movements in the bench and thus impair its efficiency.

Since liquid anaesthetic agents are volatile solvents, receptacles containing liquid agents and not forming part of a closed system can easily emit fumes to the ambient air. This risk is especially great if a receptacle (e.g. bottles) has been opened (unsealed). Accordingly, Section 13 requires that a receptacle not forming part of an entirely closed system shall be stored in a specially delimited, ventilated space. A special storage room, cabinet or similar device, connected to an exhaust air outlet, are examples of such spaces.

It is advisable that routines should be devised for disposing of residues and unused anaesthetic liquid. Central collection of liquid residues from emptying of vaporisers etc. for further distribution for destruction is recommended.

Alternatively the drug dispensary can take care of this kind of residues. It is often prohibited, and always inappropriate, to pour residues of anaesthetic liquid down a sink or similar receptacle, thus enabling those residues to enter the municipal sewer network.

It is important that ventilation should be adequate and properly designed in spaces where liquid anaesthetic agents and their waste are stored.

Guidance on Section 14

When anaesthetic gas is spreading from a certain point, e.g. in the event of leakage round the mask, the personnel in the vicinity, e.g. the anaesthetic nurse and theatre staff, can be exposed to high concentrations of anaesthetic gas. Concentrations of anaesthetic gas in their respiratory zone may then be considerably greater than the average concentration in the room. There is a serious risk of the occupational exposure limit value for the present anaesthetic gas in question being exceeded. Certain procedures create a particularly great risk of leakage, e.g. anaesthesia by intubation when the tracheal tube does not fit closely. During induction of anxious patients, e.g. children, the leakage from round the mask can be greater than normal. If a local scavenging device is used, most of the anaesthetic gases will be removed and will not be polluting the room. Similarly, it is important to use a local scavenging device when dealing with patients which are undergoing complicated treatment, and also when treatment time may be considerable. In dentistry the use of a local scavenging device is essential, because the dentist/dental surgeon is working in the mouth, making the use of a close-fitting mask impossible. In veterinary medicine as well, when anaesthetic gases are administered to animals, a local scavenging device should be used so as to avoid the risk of exceeding the occupational exposure limit value. A local scavenging device connected to an anaesthetic mask can be used.

Before a new model of anaesthetic mask is introduced, a check should normally be made to ensure that there is no leakage. It is important that leakage checks should be made regularly.

General rules on the ventilation of working premises are contained in the Provisions of the National Board of Occupational Safety and Health on Workplace Design. The National Board of Health and Welfare has issued General Recommendations on Supervision pursuant to the Environmental Code – Ventilation (SOSFS 1999:25).

The quality of general ventilation is of great importance and is an important part of the interaction with scavenging generally and scavenging devices. When planning facilities, it is advisable that dimensions of ventilation systems and local scavenging devices are designed for maximum loads. For the maintenance of good air quality and to minimise the concentrations of anaesthetic gases, it is important to have routines for regular overhaul and

maintenance of scavenging and ventilation systems. This work has to be carried out by an expert.

Concentrations of anaesthetic gases are likely to be high in hospital recovery rooms, and veterinary recovery rooms, etc. If the general ventilation is not sufficient, local scavenging devices with sufficient scavenging capacity should be installed.

Information published by the Swedish Work Environment Authority

Current rules

Legislation and Ordinances

The Work Environment Act (SFS 1977:1160)*
The Work Environment Ordinance (SFS 1977:1166)*
The Health and Medical Services Act (SFS 1982:763)
The Medicinal Products Act (SFS 1992:859)
The Medicinal Products Ordinance (SFS 1992:1752)

Statute Book of the National Board of Occupational Safety and Health (AFS)

Use of Work Equipment (AFS 1998:4)
VDU Work (AFS 1998:5)
Workplace Design (AFS 2000:42)
Gases (AFS 1997:7)
Pregnant and Breast-feeding Employees (AFS 1994:32)
Occupational Exposure Limit Values and Measures against Air Contaminants (AFS 2000:3)
Chemical Hazards in the Working Environment (AFS 2000:4)*

Statute Book of the Swedish Work Environment Authority (AFS)

Gas Cylinders (AFS 2001:4)
Systematic Work Environment Management (AFS 2001:1)*

Statute Book of the Medical Products Agency

Current Ordinance of the Medical Products Agency concerning the Swedish Medicinal Products Standard (Svensk Läkemedelsstandard)
Provisions of the Medical Products Agency concerning Medical Devices (LVFS 2001:6)

* Available in English

Statute Book of the National Board of Health and Welfare

General Recommendations of the National Board of Health and Welfare on Medical Gas Installations (SOSFS 1991:13)
General Recommendations of the National Board of Health and Welfare on Supervision Pursuant to the Environmental Code – Ventilation
(SOSFS 1999:25)
Provisions and General Recommendations of the National Board of Health and Welfare on the Use and Original Manufacture of Medical Devices in Health Care (SOSFS 2001:12)
Provisions and General Recommendations of the National Board of Health and Welfare on Quality Systems in Health Care (SOSFS 1996:24)

Standards relating to anaesthetic gas equipment and medical gas pipeline systems

SS-EN 737-1	Medical gas pipeline systems – Part 1: Terminal units for compressed medical gases and vacuum
SS-EN 737-2	Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements and amendment 1–A1
SS-EN 737-3	Medical gas pipeline systems – Part 3: Pipelines for compressed medical gases and vacuum
SS-EN 740	Anaesthetic workstations and their modules – Particular requirements
SS-EN 1280-1	Agent specific filling systems for anaesthetic vaporizers
SS-EN 1281-1	Anaesthetic and respiratory equipment – Conical connectors Part 1: Cones and sockets
SS-EN 13014	Connections for gas sampling tubes to anaesthetic and respiratory equipment
SS 875 24 30	Connectors for medical gases

Current literature

Rapport 1999:12, Anestesigaser, Arbetarskyddsstyrelsen
Handbok för sjukvårdsarbete, Landstingsförbundet
FASS, Läkemedel i Sverige, LINFO, Läkemedelsinformation AB
SIS, Teknisk rapport 370, Säkerhetsnorm för medicinska gasanläggningar