

Health and Safety Control of Substances Hazardous to Health (COSHH) Guideline



Health and Safety – Control of Substances Hazardous to Health (COSHH) Guideline

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1.0 Purpose

The purpose of this Guideline is to provide Line Managers who have responsibilities of complying with COSHH Regulations within their areas of responsibility with advice about how to implement the Health and Safety COSHH Policy and Procedure.

2.0 Scope

This Guideline applies primarily to all Line Managers when COSHH Regulations apply in their area of responsibility and all staff in those areas as part of their responsibilities under Section 7 of the Health and Safety at Work etc. Act 1974.

3.0 Definitions





3.1 Hazardous Substances under COSHH Regulations






“COSHH applies to a wide range of substances and preparations (mixtures of two or more substances) which have the potential to cause harm to health if they are ingested, inhaled, or are absorbed by, or come into contact with the skin, or other body membranes. Hazardous substances can occur in many forms, including solids, liquids, vapours, gases and fumes”
(The Control of Substances Hazardous to Health Regulations 2002 (as amended). Approved Code of Practice and Guidance. L5 (sixth edition), HSE).

It will include:


- **Substances with a specific danger of being very toxic, toxic, harmful, corrosive or irritant.** Check the Safety Data Sheet (SDS) of the chemical product where information about the classification of the product as hazardous can be found and the following table for further information.

Symbols used to indicate hazardous substances

Symbol	Hazard	Symbol	Hazard
	Explosive (Symbol: exploding bomb)		Hazardous to the environment (Symbol: Dead tree and fish)
	Flammable (Symbol: flame)		Health hazard/Harmful/Irritant (Symbol: Exclamation mark)

	Oxidising (Symbol: flame over circle)		Serious health hazard (Symbol: health hazard)
	Corrosive (Symbol: Corrosion)		Gas under pressure (Symbol: Gas cylinder)
	Acute toxicity (Symbol: Skull and crossbones)		

- **Substances with Workplace Exposure Limits (WELs).** WELs are British occupational exposure limits and are set in order to help protect the health of workers. WELs are concentrations of hazardous substances in the air, averaged over a specified period of time. For further information check document “EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). EH40 (Third edition), HSE Published in 2018”.
- **Biological agent/biohazards.** Micro-organisms, cell culture or human endoparasite whether or not genetically modified which can cause infection, allergy, toxicity or otherwise create a hazard to human health. The symbol of biohazard is in the following table but bear in mind that there are other sources of biological substances hazardous to health that do not have symbol such body fluids or sharp injuries. Reference should be made to NHS Lothian Policy “Working with Bloodborne Viruses”, National Infection Prevention and Control Manual and NHS Lothian “Clinical Sharps Devices” Policy.

	Bio Hazard	a pathogen, especially one used in or produced by biological research
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- **Medicines:** while the intentional administration of medicines to patients is exempt from COSHH, the exposures of staff (or the unintended exposures of patients) to medicines that have harmful properties are covered by the regulations.

COSHH Regulations do not cover asbestos, lead and clinical sharps which have their own regulations and substances that are hazardous to health because they are: radioactive, explosive, flammable or because they are used or stored at high or low temperature or high pressure.

3.2 Safety Data Sheet (SDS)

Safety Data Sheets are documents that provide information about the composition and physical, chemical and toxicological properties that help users to conduct COSHH Assessments. They identify the hazards the chemical products present and give information on handling, storage, disposal, personal protective equipment (PPE) required, transport and emergency measures in case of accidents and fire. Suppliers of chemical are required by law to provide an up to date safety data sheet if a substance is dangerous for supply. The SDS is not a COSHH Assessment itself.

3.3 Local Exhaust Ventilation (LEV)

Local Exhaust Ventilation (LEV) is an extract ventilation that takes dusts, mists, gases, vapour or fumes out of the air so that they cannot be breathed in. Properly designed LEV will:

- Collect the air that contains the contaminants,
- Make sure they are contained and taken away from people,
- Clean the air, if necessary and get rid of the contaminants safely

3.4 Personal Protective Equipment (PPE)

Personal Protective Equipment is equipment that will protect the user against health and safety risk at work. It can include amongst others items such as gloves, eye protection and respiratory protective equipment (RPE).

4.0 Roles and responsibilities

For implementation roles and responsibilities refer to the section 5 of the Health and Safety-Control of Substances Hazardous to Health (COSHH) Policy.

5.0 Main content

5.1 COSHH Regulations

The main requirements of the COSHH Regulations are as follows:

- Assess the risk.
- Prevention or Control of Exposure.
- Use of Control measures and maintenance, examination and test of control measures.
- Monitoring Exposure.
- Health Surveillance.
- Information, Instruction and Training.
- Arrangements to deal with accidents with accidents and emergencies.

5.2 COSHH Assessments

The Regulations prohibit carry out work which can expose any of their employees to any substance hazardous to health until a suitable and sufficient assessment of the risk has been made. A suitable and sufficient assessment of the risk is to:

- enable the Organisation to make a valid judgement of the severity of the risks.
- make valid decisions about the measures needed to prevent or adequately control the exposure and
- demonstrate that all relevant factors have been considered.

NHS Lothian as organisation is responsible for ensuring that the risk is assessed and that local managers are carrying out the assessments. Local managers must have the knowledge, training and experience to be able to complete this task. During the process staff must be involved and consulted and where appropriate their staff side H&S representatives. The person responsible for conducting the COSHH Assessment should start by making a list (COSHH Index) of the hazardous substances used in the department and registration of Local Exhaust Ventilation (LEV), is any. See section 6. Associated materials. NHS Lothian COSHH Index.

COSHH Assessments must contain the following elements:

- Identification of the hazardous substances, including:
 - Form of exposure, e.g. dust, vapour, mist, fume.
 - Whether they are used or produced.
 - In what amounts and how often they are used/produced.
- Task(s) which use or create the substance(s) and who may be harmed, including:
 - All the substances hazardous to health (including biological agents and simple asphyxiants) arising from the work (used, created as waste or by-products, or released from processes or during accidents, incidents and emergencies).
 - Work done by contractors, at the workplace that may expose employees to substances hazardous to health.
 - The ways in which, and the extent to which, any group of people, including member of the public such as visitors and patients could be exposed.
 - The need to protect particular groups of employees who may be at increased risk, trainees, pregnant workers, disables workers and any employees known to be susceptible to certain illnesses such as dermatitis, asthma or other diseases which may be caused or made worse by exposure to substances hazardous to health.
- Hazard Information. The usual source of this information is the safety data sheets (SDSs) that must be collated in its most updated version according to the European Regulation (EC) N1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) and the description of the task. This information should include:

- The physical, chemical and biological properties of the substances and the effects they could have on the body.
- Exposure limits (WELs).
- Routes of entry: Inhalation. Percutaneous, ingestion.
- Time of exposure.
- Possibility of eliminating or substituting this hazardous substance for a less hazardous material or use it in a different form. This is crucial when working with carcinogens, mutagens and asthmagens.
- Existing Precautions, including appropriate work processes, engineering controls such as Local Exhaust Ventilation (LEV), suitable work equipment and materials, adequate ventilation systems, appropriate organisational measures (reduction of the time of exposure, instructions in place, training provided), provision of suitable protective equipment.
- Information about storage, disposal, health surveillance, maintenance of equipment, personal protective equipment (PPE), first aid, emergency plans including spills procedure and other additional measures.
- Level of risk: Risk is the chance (low, medium, high or very high) that somebody could be harmed by considering likelihood and the consequence/impact in line with the NHS Lothian Risk Management Policy and its Risk Register Operational Procedure. The risk grade is given taking into account of the controls and other preventative measures that are in place and provide the residual or current risk grade. The resulting value will inform prioritisation and place the risk into one of 4 categories:
 - Low-Green-no issues or concerns, all controls in place
 - Medium-Yellow-all controls in place, but potential still exists for human error or failure to follow existing procedures and controls
 - High-Orange-some controls in place, but could be improved as potential for harm still exists
 - Very high-Red-Few, if any, controls, serious concerns over practice, consideration to stop practice
- Action Plan: It is necessary to summarise what precautions/further action(s) are needed to control exposures. The hierarchy of control demanded by the COSHH Regulations is described in the point “prevention or control of exposures”. The Action Plan must include responsible person and deadline for each action and date when this action is completed. Best practice should always be sought irrespective of the fact that the risk to health is thought already to be low.
- Review: Risk Assessments should be reviewed at least annually and whenever there is a reason to suspect they are no longer valid. For example, any substantial change in the way a task is undertaken would require a review in the Risk Assessment.

A brief summary of the principles of COSHH risk assessment and how to complete the form can be found in the How to complete a COSHH Assessment.

5.3 Prevention or Control of Exposure

The COSHH Regulations are very stringent with regard to control. The legal duty is to prevent exposure if it is reasonably practicable. If not, it must be 'adequately controlled'.

Elimination or substitution should be undertaken so far as is reasonably practicable by replacing the use of a hazardous substance with a substance or process which, under the conditions of use, either eliminates or reduces the risk.

Sometimes, when elimination or substitution for a safer substance is impracticable, the risk can be reduced by substituting the form of a material. For example, the application of a disinfectant with a wipe will produce much less airborne contamination than the use of a spray; the pouring or weighing-out of a toxic solid will also produce less airborne contamination if it is in granular form rather than a powder; exposures to cytotoxic drugs are less likely if they are prepared for administration in the controlled conditions of the pharmacy by comparison with the more fallible preparation on the ward. The same logic can be applied in many situations.

Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, NHS Lothian shall apply protection measures appropriate to the activity and consistent with the COSHH Assessment.

Measures to control exposures that are inherently effective and reliable are always to be preferred to those that are prone to failure through equipment failure or human error. This choice of more inherently safe precautions could be enforced by HSE inspectors.

The regulations set an order of preference for different approaches to controlling exposure (hierarchy of control):

- Design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials.
- Control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and
- Provision of suitable personal protective equipment

To be effective in the long term, control measures must be practical, workable and sustainable. The COSHH Regulations provide a summary of the eight key principles for Good Practice in the Control of Exposure to substances hazardous to health. The approach implemented should incorporate the following principles as far as possible.

- a) Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.
- b) Take into account all relevant routes of exposure — inhalation, skin and ingestion- when developing control measures.
- c) Control exposure by measures that are proportionate to the health risk.
- d) Choose the most effective and reliable control options that minimise the escape and spread of substances hazardous to health.

- e) Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.
- f) Check and review regularly all elements of control measures for their continuing effectiveness.
- (g) Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.
- h) Ensure that the introduction of control measures does not increase the overall risk to health and safety.

5.4 Use of control measures and maintenance, examination and test of control measures

NHS Lothian (via the management chain) must take all reasonable steps to ensure that control measures, including PPE are properly used. This control should be undertaken with the implementation of working procedures/protocols including:

- Visual checks and observations at appropriate intervals.
- Supervising members of staff to ensure that the established methods of work are being followed.
- Monitoring the implementation of the established precautions and prompting remedial action where necessary.

When the use of personal protective equipment (PPE) is required, NHS Lothian must ensure that they are suitable for the purpose, fit the person and are adequately maintained (or disposed). When the task requires the use of a tight-fitting face-pieces (masks) the employee is required to be face fit tested regularly to ensure that they are actually being protected.

Employees have a duty to make full use of the control measures provided and report promptly to the line manager any defects discovered in any control measure.

Furthermore, NHS Lothian must ensure that every element of a control measure performs as originally intended and, continues to adequately control the exposure of employees to substances hazardous to health. The frequency of any check carried out will depend on the likelihood of significant deterioration of that particular element of the control measure and its importance.

Engineering controls must be checked when they are installed to ensure that they meet the specified technical performance and in combination with other control measures are capable of providing adequate control and subsequently must be thoroughly examined and tested at suitable or specified intervals. Records of this thorough examination must be kept for at least 10 years in line with the NHS Lothian Records Management Policy. Specifically, for LEV these thorough examinations must be conducted at least once every 14 months by a competent person and records of these examinations must be kept at least 5 years. This will normally be undertaken by arrangement with the Estates Department or a contractor. Information of the installed LEV system must be in place to confirm that it provides adequate protection which should be kept for the life of the equipment.

The maintenance, examinations and tests of respiratory protective equipment (RPE) should be in accordance with the manufacturer's instructions and should be made at suitable intervals.

The frequency should increase where the health risks and conditions of exposure are particularly severe. The maximum maintenance interval is 3 months. Records of this thorough examination must be kept for at least 10 years in line with the NHS Lothian Records Management Policy.

5.5 Monitoring exposure

NHS Lothian must ensure that the exposure of employees to substances hazardous to health is monitored following a suitable procedure when the COSHH Assessment indicates that this is a requisite for ensuring the maintenance of adequate control of the exposure or it is a requisite for protecting the health of employees.

In summary, exposure monitoring is necessary if:

- The COSHH Assessment shows that an initial exploratory monitoring exercise is necessary to reach an informed and valid judgement about the risk.
- Failure or deterioration of the control measures could result in a serious health effect, either because of the toxicity of the substance or because of the extent of potential exposure or both.
- Measurement is required to be sure that a WEL or any self-impose (in house) exposure standard is not exceeded.
- Any change in the conditions affecting employees' exposure means that adequate control of exposure is no longer being maintained.
- It is needed as an additional check on the effectiveness of any control measure provided.

The most commonly used methods are monitoring the air in the employee's breathing zone, background air monitoring, wipe sampling of the skin, biological monitoring and biological effect monitoring.

The Health and Safety Department will assist in determining if monitoring exposure is necessary and if this is the case in establishing a scheme of regular exposure monitoring.

Records of this monitoring must be kept. Wherever an exposure monitoring record contains the personal exposure monitoring data of an individual employee, the record should be kept for at least 40 years and all other types of exposure monitoring records must be kept for at least 10 years in line with the NHS Lothian Records Management Policy.

5.6 Health surveillance

Where it is appropriate for the protection of the health of the employees who are working with substances hazardous to health, the organisation shall ensure that such employees are under suitable health surveillance.

The objectives of health surveillance are to:

- Check the health of individual employees by detecting as early as possible, adverse changes which may be caused by exposure to substances hazardous to health.

- Collect keep up-to-date and use data and information for determining and evaluating hazards to health.
- Check control measures are working effectively.

Health surveillance must be taken regularly, annually for Skin Surveillance and always in line with the NHS Lothian Health Surveillance Policy and Health Surveillance Procedure for Managers (Skin Surveillance). Records must be kept for 40 years in line with the NHS Lothian Records Management Policy.

The Occupational Health and Safety Department will assist in the implementation of the Health Surveillance within the organisation.

5.7 Information, Instruction and Training

Unless suitable and sufficient information, instructions and training are given to staff, all efforts to comply with the COSHH Regulations are pointless. They shall include:

- details of the substances hazardous to health to which staff is liable to be exposed.
- the significant findings of the COSHH Assessment.
- the appropriate precautions and actions to be taken.
- the results of any monitoring of exposure carried out in the workplace
- the collective (anonymous) results of any health surveillance.

Managers should consider what information, instructions and training their staff will need following the completion of the COSHH assessments within the department. The best means of providing this will depend on the nature of the department and on the type of information to be provided and managers must ensure that the information, instruction and training are:

- adapted to take into account of significant changes in the type of work carried out or methods of work used, and
- provided in a manner appropriate to the level, type and duration of exposure identified by the COSHH Assessment.

The methods available include:

- simple verbal instructions.
- Tool box talks.
- formal training sessions (suitable for high risk or complex tasks / skills, thorough, likely to be remembered). The Health and Safety Department delivers regularly Health and Safety training for managers and one module within this training is specifically about COSHH.
- written procedures.
- formal written instructions with signature by recipient (gives written record).

Providing information, instruction and training is not a one-off exercise and should be reviewed and updated whenever significant changes are made to the type of work carried out or to the work methods used.

Staff should also be made aware of the organisational arrangements for COSHH compliance so they can play an active part in improving health and safety standards. Without the active participation of members of staff and their representatives, there is a danger that the implementation of the process will be unsuccessful. Managers must ensure and have evidence that staff, within their remit, have a knowledge and understanding of the Health and Safety COSHH Policy and all its related documents.

When working with staff of other departments and with contractors, channels of communication must be established to ensure that they are properly informed. In this respect, NHS Lothian Control of Contractors must be followed.

Records of the training given to individual employees or specific groups of named employees must be kept for 10 years in line with the NHS Lothian Records Management Policy.

5.8 Arrangements to deal with adverse events and emergencies

NHS Lothian must ensure that procedures (including the provision of appropriate first-aid facilities and relevant safety drills) have been prepared and are ready to be in place in the event of adverse events and emergencies and that suitable warning and other communication systems are established to provide an appropriate response.

Staff must promptly report through DATIX all adverse events in relation to the use, storage, disposal or accidental release of substances hazardous to health and managers must ensure that all COSHH adverse events are reported and investigated in line with the NHS Lothian Adverse Event Management Policy and Procedure. If the adverse event meets the RIDDOR criteria, managers must report it to HSE within the deadline.

The response to an emergency should be proportionate to the risk and the emergency procedures should be reviewed and updated in the light of changing circumstances. Information about emergency arrangements and procedures must be available.

6.0 Associated materials

- NHS Lothian COSHH Policy.
- NHS Lothian COSHH Operational Procedure.
- NHS Lothian COSHH Index.
- NHS Lothian How to complete a COSHH Assessment.
- NHS Lothian COSHH Assessment Form.
- NHS Lothian Health & Safety Policy
- NHS Lothian Adverse Event Management Policy and Operational Procedure.
- NHS Lothian Risk Management Policy and Risk Register Operational Management Procedure.
- NHS Lothian Health Surveillance Policy.
- NHS Lothian Health Surveillance Procedure for Managers (Skin Health).
- NHS Lothian Working with Bloodborne Viruses Strategic Policy and Procedures.
- National Infection Prevention and Control Manual.
- NHS Lothian Clinical Sharps Devices Policy.
- NHS Lothian Records Management.

- NHS Lothian Control of Contractors Policy.
- NHS Lothian Guidelines for the safe use of systemic Anti-Cancer Therapies (SACT) v2.4.

7.0 Evidence base

- The Control of Substances Hazardous to Health Regulations 2002 (as amended) (S.I.2002/2677).
- European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Control of Substances Hazardous to Health (COSHH) HSE website <http://www.hse.gov.uk/coshh/>
- Control of substances hazardous to health Regulations 2002 (as amended). Approved Code of Practice and Guidance. L5 (Sixth Edition), HSE Published 2013 <http://hse.gov.uk/pubns/priced/l5.pdf>
- EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). EH40 (Third edition), HSE Published 2018 <http://www.hse.gov.uk/pubns/priced/eh40.pdf>
- Management and Operation of microbiological containment laboratories (Advisory Committee on Dangerous Pathogens). HSE Published 2018 <http://www.hse.gov.uk/biosafety/management-containment-labs.pdf>
- The Approved list of biological agents (Advisory Committee on Dangerous Pathogens). Third Edition, HSE Published 2013 <http://www.hse.gov.uk/pubns/misc208.pdf>
- Respiratory Protective Equipment at work. A practical guide. HSG53 (Fourth edition), HSE Published 2013 <http://www.hse.gov.uk/pubns/priced/hsg53.pdf>
- Controlling airborne contaminants at work. A guide to local exhaust ventilation (LEV). HSG258 (Third edition), HSE Published 2017 <http://www.hse.gov.uk/pubns/priced/hsg258.pdf>
- Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy, CEL (2012), The Quality Unit, Planning & Quality Division, The Scottish Government.

8.0 Stakeholder consultation

All departments referenced in this Guideline have been consulted in the content.

The COSHH Policy and related documents were displayed on consultation zone for a 4 week period for all NHS Lothian staff to comment on.

9.0 Monitoring and review

For monitoring and review refer to the section 9 of the Health and Safety-Control of Substances Hazardous to Health (COSHH) Policy.

Appendix 1: Carcinogens and mutagens

According to the CLP Regulations, carcinogens mean substances or mixtures of substances which induce cancer or increase its incidence. This will include:

- Category 1: Known or presumed human carcinogens.
- Category 2: Suspected human carcinogens.

In the healthcare environment this definition will mainly cover substances and mixtures with the risk phases H350 (May cause cancer), H350i (May cause cancer by inhalation) and H351 (Suspected human carcinogens) in the Safety Data Sheets and medicines classified as carcinogens.

Mutagens mean substances or mixtures of substances that may cause mutations in the germ cells of human than can be transmitted to the progeny. This will include:

- Category 1: Known to induce heritable mutations in the germ cells of humans.
- Category 2: Substances which cause concern for human owing to the possibility that may induce heritable mutations in the germ cells of humans.

In the healthcare environment this definition will mainly cover substances and mixtures with the risk phases H340 (May cause genetic defects) and H341 (Suspected of causing genetic defects) in the Safety Data Sheets and medicines classified as mutagens.

COSHH Regulations include special provisions, apart from those indicated in section 5, for preventing or adequately controlling exposure to category 1 carcinogens and mutagens (H340, H350 and H350i and medicines classified as such). If the complete elimination of exposure to these substances is not reasonably practicable, then the following measures in addition to the general requirements of COSHH must be applied:

- Total enclosure of process and handling systems, unless this is not reasonably practicable.
- Use, storage, labelling and disposal:
 - Keep carcinogenic and mutagenic substances to be used in the workplace to the minimum needed.
 - Store and transport them on site in closed containers, clearly labelled and with clearly visible warning and hazard signs.
 - Clearly label and securely store carcinogenic or mutagenic waste products until they are removed safely in line with NHS Lothian Waste Policy.
 - Clearly identify the areas in which exposure to carcinogens or mutagens may occur and take measures to prevent the spread of contamination within and beyond these areas.
 - Limit the number of people likely to be exposed to carcinogenic or mutagenic substances and the duration of their exposure.
- Precautions against contamination
 - Prohibition of eating, drinking, smoking and cosmetics in affected areas.

- Designation of affected areas and use of suitable warning signs to demarcate areas.
- Appropriate hygiene measures in place including cleaning procedures to remove any contamination from walls, doors, tools, equipment, clothing, PPE and other surfaces.
- Adequate washing facilities to facilitate a high standard of personal hygiene.

Cytotoxic chemotherapy is known to be potentially carcinogenic and mutagenic as defined by the COSHH Regulations. Treatment involving cytotoxic chemotherapy must follow the COSHH Principles. Check Appendix 3 for additional information.

Appendix 2: Biological Agents

In terms of the COSHH Regulations biological agents include:

- micro-organisms such as bacteria, viruses, fungi, and the agents that cause transmissible spongiform encephalopathies (TSEs)
- cell cultures, if the cell being cultured is itself hazardous, and
- Parasites that live inside their host which may cause infection, allergy, toxicity or otherwise create a hazard to human health.

COSHH Regulations cover both:

- incidental exposure to biological agents that can occur when an employee's work brings them into contact with material which contains infectious agents, eg blood, body fluids, contaminated water or waste material and,
- deliberate planned work with a biological agent in microbiological containment facilities eg research or diagnosis.

Biological agents are classified into four hazard groups according to:

- Their ability to cause infection.
- The severity of the disease.
- The risk that the infection will spread to the community
- The availability of vaccines and effective treatment.

When assessing the risk for exposure to biological agents apart from what have been indicated in section 5.2., the following information must be taken into account:

- Hazard groups of any biological agents that may be present and what form they may be present.
- How and where they are present, how they are transmitted and the diseases they cause.
- The likelihood of exposure and consequent disease, including the identification of job positions and non-workers such as patients.

In addition to the general principles of controlling the exposure to hazardous substances (section 5) when it is not reasonably practicable to prevent exposure to a biological agent, the following additional measures should be put in place. However, for incidental exposure, if the COSHH Assessment concludes that exposure to a biological agent is unavoidable and the risk is low, then not all these additional measures will need to be adopted:

- Displaying suitable and sufficient warning signs, including the biohazard sign.



- Specifying appropriate decontamination and disinfection procedures.
- Implementing means for the safe collection, storage and disposal of contaminated waste.
- Testing where it is necessary and technically possible, for the presence, outside the primary confinement, of biological agents used at work.
- Specifying procedures for working with, and transporting at the workplace, a biological agent or material that may contain a biological agent.
- If the COSHH assessment concludes there is a risk of exposure to biological agents for which effective vaccines are readily available, they should be offered to those employees who are not already immune to the biological agent to which they are exposed or are liable to be exposed. Records of the vaccination must be kept.
- Promoting hygiene measures including the provision of washing facilities and the prohibition of eating, drinking, smoking and the application of cosmetics.
- Deliberate work with a biological agent should be carried out in contained-use facilities and the level of containment and therefore containment measures will be based on the classification of the biological agent into:
 - Group 1: Unlikely to cause human disease
 - Group 2: Can cause human disease and may be a hazard to employees: it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available
 - Group 3: Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available
 - Group 4: Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.
- For Group 3 or 4 biological agents
 - List of employees exposed to biological agents: A list of employees exposed to Group 3 or Group 4 biological agent must be kept for deliberate work. The list should include the type of work done and where known, the biological agent to which they have been exposed and records of exposures, accidents and incidents. This list must be kept for at least 40 years from the date of the last entry made in it.

Appendix 3: Medicines

Medicines are potent materials and many have harmful properties in addition to their therapeutic effects. While the intentional administration of medicines to patients is exempt from COSHH, the exposures of staff (or the unintended exposures of patients) are covered by the regulations although there are no safety data sheets for them. Therefore, they must be assessed and suitable precautions applied. The precautions detailed in standard procedures for administration are largely for patient safety and the COSHH assessment must therefore ensure that they account adequately for the potential for harm to the staff administering the drugs.

The side effects and contraindications of medicines are documented but they mainly refer to clinical risks to the patient. Furthermore, evidence of risk to staff is scarcer and: a) the route of exposure may be different, b) the pattern and duration of exposure are different, and c) the risk balance is different as the staff member is not being treated for a condition for which the risk of unwanted side effects may be tolerable. For the patient, the tolerability of unwanted effects is a matter for clinical judgement. For staff, the COSHH assessment is the process which confirms that the risk of effects on staff is eliminated or is adequately controlled. The greater the potential of the drug to cause harm, the more stringent and carefully managed the safeguards for staff must be. For most clinical areas, the COSHH assessment can conclude the risk is 'Green' or 'Yellow' assuming there is a thorough communication and application of all the correct administration procedures.

The information provided in this appendix must be used in conjunction with the NHS Lothian Safe Use of Medicines Policy and Procedures and the NHS Lothian Guidelines for the safe use of systemic Anti-Cancer Therapies (SACT) v2.4. If there are problems in relation to any specific drugs, the person responsible for conducting the COSHH Assessment should consult their pharmacist for further support.

1.0 Administration Methods

1.1 Oral – tablets

Good practice for tablets dictates the use of gloves, specific cups, and avoidance of skin contact. These standard precautions are adequate for preventing exposure to tablet medicines (including the most potent) which come in blister packs. Those which are supplied loose in containers will create some powder by abrasion. There will be some exposure by inhalation despite good practice. The most potent medicines (cytotoxics, immunosuppressants, others identified by pharmacist) should not be supplied in this form.

Dividing or crushing tablets creates dust which may be inhaled or ingested by indirect contamination. It also produces imprecise doses for the patient. It is always preferable to

acquire tablets of the correct dose and, if a powder is required, to ensure it is dispensed in this form. If dividing or crushing is unavoidable, try to ensure it is an interim practice only, not used for potent medicines, done very carefully with approved equipment and discussed with the pharmacist.

1.2 Oral – suspensions

Suspensions are somewhat more likely to create accidental exposures by splashing and spillage. Good handling is essential for the more potent medicines and this must be reinforced locally through reminders and monitoring. Contingency spillage procedures should be made known to all relevant staff together with the materials required for cleaning up spillages.

Suspensions which are made up outside pharmacy create the potential for exposure by inhalation of powder during mixing. The most potent medicines should not be supplied for making up on the ward or clinic. Those which are made up from powder require the application of correct technique for opening and mixing – consult pharmacist if in doubt.

1.3 Injection and Infusions

Specific information about cytotoxic medicines is provided later on under high hazardous medicines.

Other medicines administered by these routes require similarly rigorous techniques for the protection of the patient although the small quantities that may cause exposure of staff through extravasation, spillage etc are less likely to cause such a high risk as with cytotoxics.

Although the correct methodology for injections and infusions are part of the training of clinical staff, the supervision, reminders, and special adaptations will be required in some circumstances and is more likely to be needed for the more potent medicines. Training in the correct use of specific infusion devices is a pre-requisite for all infusion devices and all medicines.

1.4 Inhaled and Nebulised Medicines

Administration by inhalation is required for a few drugs. Because the emission of some of the drug (by leakage or uncontrolled exhalation) is inevitable, and with it the exposure of staff, other routes of administration are preferable if they are clinically acceptable.

When using this administration method with medicines known or suspected of having serious side effects, control measures (apart from the standard ones) such as scavenger systems and room air changes must be considered.

However, no special precautions are required for those, such as normal prescribed inhalers, where there are no serious side effects.

Specifically, Nitrous oxide/oxygen inhalation is commonly used for sedation of dental outpatients and patients in labour administered via a small fitted mask over the patient's nose. Specific precautions should be established in these circumstances such as:

- Monitoring the nitrous oxide levels regularly is recommended to ensure that the exposure is lower than the workplace exposure limit (WEL).
- The use of a scavenging system that is connected to the mask and that uses vacuum to collect all expire or waste anaesthetic gases prior to exhaust via a filter to the external environment is crucial and this scavenging system should be maintained according to manufacturer's recommendation.
- Ensure selection of the correct mask size for each patient and that the mask seal to the patient's face during treatment.
- Turn off the nitrous oxide supply well in advance of removing the nasal mask.
- Inspect the system each use.
- Keep the concentration of nitrous oxide as low as possible.
- Ensure that the general ventilation provides good room-air mixing.

2.0 High Hazardous Medicines

The description above of the main methods of administration is sufficient to cover most medicines, but some require particular attention whichever administration method applies. The person responsible for conducting the COSHH assessment should check what medicines are administered in the categories below, then ensure that effective safeguards are implemented and that the information and training given to staff are adequate and meet the appropriate standards.

1. Cytotoxic agents, Immunosuppressants and some anti-virals.
2. Sensitising Agents – Antimicrobials, antivirals, steroids
3. Other drugs with potentially serious effects which are not covered adequately by the general procedures for administration.

2.1 Cytotoxics, Immunosuppressants, Anti-virals

These materials are among the most potent chemical agents and many are known to have serious harmful effects. The aim of the precautions for cytotoxic, immunosuppressant agents and some of the anti-virals is not only to prevent all contact and emission to the air but to make the systems of administration as reliable as possible to minimise the chances of small errors, or departures from best practice, resulting in accidental exposure.

Cytotoxic agents are designed to destroy human tissue and many are carcinogenic – staff must be safeguarded against these effects by the most effective and reliable precautions in line with the Control of Substances Hazardous to Health regulations (COSHH). The precautions required are documented in the NHS Lothian Guidelines for the safe use of systemic Anti-

Cancer Therapies (SACT) v2.4. and must be carefully implemented wherever cytotoxic agents are administered.

All Anti-cancer medication must be supplied from a pharmacy controlled facility and dispensed for the individual patient in a ready to administer form. Specific systems and procedures following the principles of COSHH Regulations must be in place to minimise occupational exposure including:

- receipt of the medicine,
- transportation in a safe and secured manner,
- safe handling,
- safe disposal of unused doses and all patient waste potentially contaminated and,
- reporting and investigation of adverse events including spillage and potential exposure to these agents.

These medicines must be stored securely and safely in locations separate from other medicines and clearly marked. Personal protective equipment, appropriate to the level of handling of cytotoxic agents, must be available to all staff. Cytotoxic spill kits must be available and prominently displayed in all areas where this kind of medicines is stored or handled. All staff involved in the use of cytotoxic agents must have appropriate skills, knowledge and training in their field of practice, including: principles of safe use and relevant national guidance, local policy and procedures on safe use and safe handling of cytotoxic chemotherapy.

Immunosuppressants are used when the normal activity of the immune system would be harmful to the patient and therefore needs to be suppressed. While the effect of such drugs may be required in the patient, it is inherently harmful to staff and strict adherence to correct administration methods must be applied, and staff members informed of the nature of the hazard.

Viral infections are difficult to treat with drugs. Some of those that have been developed to tackle serious viral conditions also have serious harmful effects. Ganciclovir and Valganciclovir should be treated in the same way as for cytotoxic agents. Others should be checked with the pharmacist if required.

2.2 Sensitising Agents

Most antibiotics, many steroids and a few others (eg ranitidine – used in the treatment of ulcers) are sensitising agents. When a person has become sensitised to a particular substance, subsequent exposure will result in allergic reactions. These can include asthmatic attacks, dermatitis, allergic rhinitis, and anaphylaxis. The precise reaction depends on the substance, the nature of the contact, and the sensitivity of the person.

The aim is to prevent staff becoming sensitised and to protect those who have become sensitised from further harm. Prevent exposure by avoiding generation of dusts from tablets or powders or aerosol from poor injection techniques. Sensitised individuals may require their work to be altered so they have no further contact with the substance. The precautions required for their safety are set following referral to Occupational Health.

2.3 Other drugs with potentially serious effects

If there is evidence that any other drug has the potential to cause serious harm, the responsible person in the ward for conducting COSHH assessments should discuss it with their pharmacist and ensure that precautions are effective and reliable, and that staff is fully informed. The general guidelines for each route of administration should be carefully established, any complicating factors noted and staff instructed accordingly.