

Use of Formalin Policy

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Summary

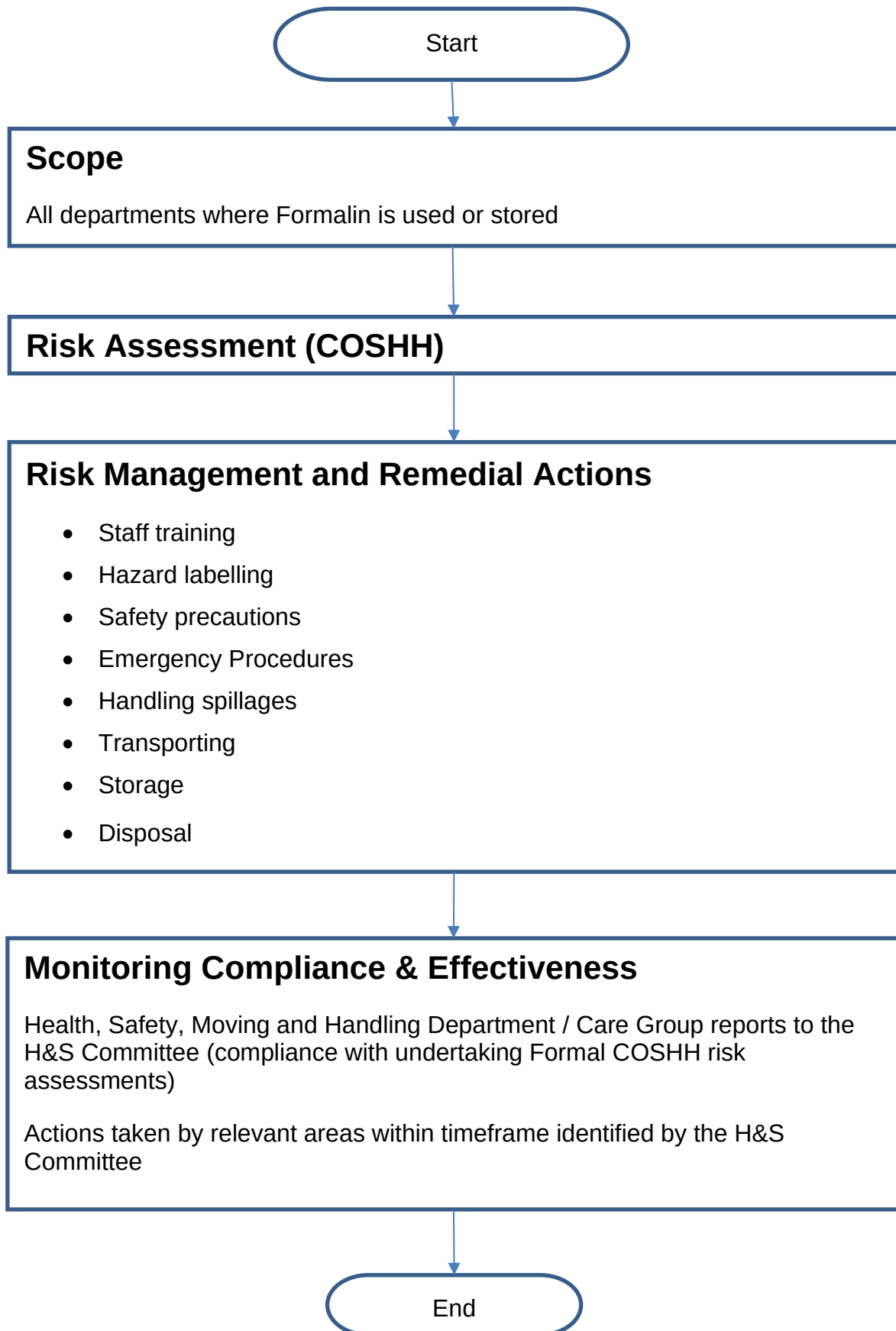


Table of Contents

Summary	2
1. Introduction.....	5
2. Purpose of this Policy/Procedure	5
3. Scope.....	5
4. Definitions / Glossary.....	6
5. Ownership and Responsibilities	6
5.1. RCHT Staff.....	6
5.2. Role of the Trust Board	7
5.3. Role of the Chief Executive Officer	7
5.4. Role of the Executive Director	7
5.5. Role of Care Group managers (CGM)	7
5.6. Role of Heads of Department.....	7
5.7. Role of Health and Safety.....	7
5.8. Role of All Staff	7
6. Standards and Practice	8
6.1. Formalin	8
6.2. Risk Assessment.....	9
6.3. Hazards.....	9
6.4. Formalin Hazard labelling	10
6.5. Safety Precautions	11
6.6. Emergency Procedures.....	14
6.7. Handling Formalin Spillages.....	16
6.8. Transport.....	19
6.9. Storage	21
6.10. Disposal.....	21
6.11. Summary of Recommendations for Managers	22
6.12. Training and Education.....	22
7. Dissemination and Implementation	23
8. Monitoring compliance and effectiveness	23
9. Updating and Review	24
10. Equality and Diversity	24
Appendix 1. Governance Information	25
Appendix 2. Equality Impact Assessment	27
Appendix 3. Instructions for Histology Containers	30

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

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1. Introduction

- 1.1. The Royal Cornwall Hospitals NHS Trust (RCHT) recognises and is committed to meeting or exceeding its legal duties under the Health and Safety (H and S) at Work etc. Act 1974 and the Control of Substances Hazardous to Health Regulations 2002 (CoSHH) (as amended 2005).
- 1.2. This document is particularly concerned with the safe transport, storage, use and disposal of formalin solutions.
- 1.3. This document should be read in conjunction with the Trust Health and Safety Policy and the incident Reporting policy.
- 1.4. The successful implementation of this policy requires the total co-operation and commitment of all members of the Trust's management and staff.
- 1.5. The special duties of staff detailed herein are in addition to those detailed in the Trust Health and Safety Policy.
- 1.6. This policy and procedure will be reviewed bi-annually.
- 1.7. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

- 2.1. The Trust aims to achieve or exceed current statutory requirements and strive for excellence of best practice.
- 2.2. The aim of the policy is to establish roles and responsibilities for various levels of management compliance with statutory obligations and to promote timely reporting of relevant incidents.
- 2.3. Formaldehyde is a naturally occurring organic compound and at room temperature it is a colourless gas with a pungent irritating odour ⁽¹⁾.
- 2.4. Formalin solution at 37% concentration is produced from the gas Formaldehyde and is used as a disinfectant or for preserving biological tissue specimens. The term formalin will be used throughout this policy.
- 2.5. In view of its widespread use, toxicity and volatility, exposure to formaldehyde is a significant consideration for human health and in 2015 Formaldehyde was re-classified as a carcinogen as well as skin, eye and respiratory irritant.
- 2.6. These guidelines exist to inform all personnel involved in the transport, storage, use and disposal of formalin in line with Health and Safety policies and procedures.

3. Scope

- 3.1. This document covers the safe transport, storage, use and disposal of formalin. It sets the standards expected within the Trust.
- 3.2. This document is applicable to all sites, care groups, departments and wards, within the Trust.

4. Definitions / Glossary

For the purposes of this document the following terms will, unless otherwise stated, apply:-

The Trust	The Royal Cornwall Hospitals NHS Trust.
RCHT	Royal Cornwall Hospitals Trust.
Trust Sites	All areas, sites, buildings, or premises owned, occupied or controlled by the Trust.
CEO	Chief Executive Officer.
CGM	Care Group Managers.
PPE	Personnel Protective Equipment.
SOP	Standard Operating Procedure.
COSHH	Control of Substances Hazardous to Health Regulations 2002 (as amended 2005). (CoSHH)
Incident	“An unplanned, uncontrolled event which has led to or could have led to injury to people, damage to plant, machinery or the environment and/or some other loss”.
HSE	The Health and Safety Executive. They are the enforcing authority for the Trust on Health and Safety matters.
SDS	Safety Data Sheet.
Exposure Limit	Maximum allowable airborne concentration of a chemical (vapour, fumes or dust) to which a worker may be exposed.
MEL	Maximum exposure limit.
OEL	Optimum exposure limit.
WEL	Workplace exposure limit.
CLP	Classification, labelling and packaging.
EC	European Community.

5. Ownership and Responsibilities

5.1. RCHT Staff

Trust Board managers and staff are responsible for establishing, maintaining and supporting a holistic approach to H and S management, in all areas of their responsibility. They should comply with the Trust H and S management in all areas of their responsibility. They should comply with the Trust H and S Policies and Procedures and ensure effective risk management mechanisms are

implemented in accordance with these. Some members of Staff and Committees have specialist functions in relation to H and S management as described below.

5.2. Role of the Trust Board

The Trust Board is ultimately responsible for fulfilling all Health and Safety duties as an employer, including all statute H and S Law requirements.

5.3. Role of the Chief Executive Officer

The Chief Executive Officer (CEO) has overall responsibility to The Trust Board for ensuring that appropriate and effective Health and Safety management systems are in place.

5.4. Role of the Executive Director

The Chief Executive delegates responsibility for Health and Safety to the Chief Operating Officer. The Chief Operating Officer deals with the matters of Health and Safety in close association with Executive Directors, clinical directors, senior managers and the Head of Health and Safety.

5.5. Role of Care Group managers (CGM)

The Care Group Managers (CGM) are responsible for ensuring that day-to-day activities of the care group are conducted in a safe and suitable manner and this policy is effectively and correctly employed within their own care group.

5.6. Role of Heads of Department

Heads of Department and Departmental Safety Officers should establish local procedure guidelines specific to their own departments. They should ensure that CoSHH and formalin risk assessments and standards operating procedures (SOP) are in place.

5.7. Role of Health and Safety

5.7.1. The Head of Health and Safety is the designated safety management advisor for the Trust. They are responsible for advising all staff throughout the organisation on issues relating to areas of risk and adverse incident management.

5.7.2. The Head of Health and Safety has overall responsibility for liaising with relevant external agencies, including, but not restricted to, the H and S Executive, Fire and Rescue Service, Local Authority, Environment Agency and other enforcement authorities etc. where their involvement is indicated in respect of adverse incident issues.

5.8. Role of All Staff

5.8.1. All employees are expected to take reasonable care to ensure the safety of themselves, their colleagues, patients and members of the public. Members of staff are responsible for complying with all CoSHH/Risk assessments and policies.

5.8.2. All personnel involved in the filling, handling, use or transportation of formalin shall:

- Be aware of, and trained in the hazards and handling of formalin (see section 6.12).
- Wear appropriate hand, eye, feet and body protection when handling containers of formalin.
- Not fill, use or transport any containers that are damaged or leaking.
- Only use containers which are correctly and clearly labelled.
- Only transport containers of formalin in a sealed chemical trolley or original cardboard box packaging on a flatbed trolley correctly labelled for transport.
- Know what actions to take in the event of a formalin spillage.
- Know what actions to take if an incident results in contamination of clothing, skin, eyes, ingestion or inhaling of formalin solution or fumes.

6. Standards and Practice

6.1. Formalin

Formaldehyde is a naturally occurring organic compound ^(1,2) and at room temperature it is a colourless gas with a pungent irritating odour.

Formalin solution at 37% concentration is produced from the gas Formaldehyde and is used as a disinfectant or for preserving biological tissue specimens.

Formalin is a colourless liquid and should be stored at a temperature of 15-25°C in a dry well-ventilated area.

In view of its widespread use, toxicity and volatility, exposure to formaldehyde is a significant consideration for human health and is possible carcinogen which may cause cancer, as well as being a skin, eye and respiratory irritant. In RCHT establishments, 10% (4% w/v) buffered formalin (formalin and phosphate buffer) is currently used as a preservative (fixative) for histology tissue samples, to preserve them so a reliable pathological diagnosis can be made.

Once tissue is removed from the human body it starts to autolyze and decomposes, due to the enzymes and host microorganisms naturally present in/on human tissue. Formalin stops this process and preserves the tissue.

In the process of fixation, formaldehyde forms cross links with the proteins of tissues. The reaction is mild and relatively short. The process is reversible once the tissue is removed from the formalin solution and placed in water, but this process does depend on how long the tissue has been in formalin.

All departments that use or store formalin should carry out a CoSSH risk assessment and audit processes of use annually.

All staff that use formalin must receive appropriate training in its safe handling and use.

Small amounts of formalin (<50mls) must only be used in well-ventilated areas.

When using larger quantities greater than 50mls, mobile or local exhaust fume extraction units must be available in which decanting of formalin can be undertaken safely.

6.2. Risk Assessment

The precautions that need to be taken will depend to some extent on individual circumstances of each department and should be decided following a risk assessment, as required by both the Management of H and S at Work Regulations 1999 and the Control of Substances Hazardous to Health Regulations 2002 (as amended 2005) (CoSHH). As discussed below, some of the hazards and precautions are common to all users.

6.3. Hazards

- 6.3.1. Formalin is colourless with an irritating pungent odour (1,3).
- 6.3.2. In 2015 formaldehyde was re-classified from a potential carcinogen to a known carcinogen, as well as skin, eye and respiratory irritant.
- 6.3.3. Formalin is toxic by inhalation, and extremely irritating on contact with skin or eyes and if swallowed even on brief exposure.
- 6.3.4. The current workplace exposure limit (WEL) for formalin is two parts per million (2ppm), time weighted average over eight hours.
- 6.3.5. Formalin can cause percutaneous skin burns and there is the possibility of irreversible effects.
- 6.3.6. Formalin has a low flammability and is completely miscible with water.
- 6.3.7. Formalin must not come into contact with oxidizing agents, acid solutions or combustible materials.
- 6.3.8. Under certain conditions of temperature and humidity formalin vapour may react with Hydrochloric Acid to form Bis-Chloromethyl Ether vapour. A potent human carcinogen.
- 6.3.9. Where formalin is in use, the room must have a good air supply maintaining 4-12 air changes per hour.
- 6.3.10. Depending on quantity/ concentration of formaldehyde solutions, local exhaust ventilation systems may be required to regulate vapor exposure.
- 6.3.11. **Formaldehyde is a category 3 carcinogen, but working below the MEL will virtually eliminate any carcinogenic risk.**

6.4. Formalin Hazard labelling

6.4.1. CoSHH

- 6.4.1.1. European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures came into force on 20 January 2009 in all EU Member States, including the UK. It is known by its abbreviated form, 'the CLP Regulation' or just plain 'CLP' (Chemical classification, labelling and packaging (CLP) updated in UK 2021).
- 6.4.1.2. Classification is very important and provides the starting point for the controls needed to protect us.
- 6.4.1.3. Labels can help you identify the more hazardous chemicals; tell you what the hazards are and how to avoid them.
- 6.4.1.4. A hazard label is made up of specific symbols (known as 'pictograms') and warnings. These pictograms and the wording that supports them are set out in law and chemical suppliers/users must use them where hazardous properties have been identified.
- 6.4.1.5. It is important to make sure you understand, classify, label and package chemicals according to the Manufacturers Safety Data Sheet (MSDS)⁽³⁾.
- 6.4.1.6. The following COSHH hazard symbols should be visible on any containers containing formalin solutions between 1-20%: -



Serious Health Hazard



Health Hazard

Formalin solutions greater than 20% should **also** display the following symbol: -



Acute Toxicity

6.4.2. Specimen Labelling

Any histology samples placed in formalin solution must be placed in a sealable container with the following label on it:-

HISTOLOGICAL SPECIMEN
Neutral Buffered Formaldehyde 10% (Formaldehyde 3.8-4% w/v UN2283)

Name: _____ DoB: _____ REF 3802075E
Specimen: _____ Hosp. No.: _____ LDT
Surgeon/Consultant: _____ Date: _____

WARNING! Causes skin irritation. Suspected of causing cancer. May cause an allergic skin reaction. Causes serious eye irritation. Wear protective gloves/eye protection.

REV A

These labels are available from RCHT Procurement

6.5. Safety Precautions

6.5.1. Safe Systems of Work and Risk Assessment

- 6.5.1.1. Equipment and systems of work should be designed, operated and maintained to reduce the risk of an accidental spillage.
- 6.5.1.2. The volume of formalin used or stored should be kept to a minimum and the measure to safely control a potential spillage, should be proportionate to this volume.
- 6.5.1.3. To this end a risk assessment of the dangers posed must be undertaken in each area where formalin is either used, transported or stored.

6.5.2. Personal Protective Equipment

- 6.5.2.1. The following Personal Protective Equipment (PPE) must be worn when handling formalin⁽³⁾:
 - Eyes: face visor or safety goggles (to protect both the face and the eyes respectively) depending on activity being performed, to protect from splashes. Safety glasses must be made to EN166 standard.

Eyewash stations must be available where formalin is in use.

- Hands: Nitrile (9 newton) disposable gloves, or gloves made from butyl rubber or polyethylene Viton rubber (fluor rubber).

Latex gloves are not permitted for general use within the Trust, however some specialized and risk assessed procedures do retain the use of specific latex gloves. Do not use latex gloves when dealing or handling formalin.

- Body: wear appropriate clothing to prevent skin contact (overalls, theatre scrubs, Howie style laboratory coat, disposable apron or similar as recommended). To avoid collection of liquid, such clothing should preferably not have pockets, and trousers should not be tucked into boots or have

turn-ups. Open footwear **must not** be worn, and legs should be covered.

- Respirators: should be worn at all times when there is no mechanical ventilation in place ensuring exposure is below work place optimum exposure limit. Respirator must be fitted with formalin dedicated filters. Please contact RCHT Health and Safety services for advice / supply on respirators currently in use.

6.5.2.2. When decanting formalin always ensure safety glasses, disposable gloves and respirator are used if no mechanical ventilation is available.

6.5.2.3. Always wear appropriate gloves when handling anything that is, or may have been, in immediate contact with formalin.

6.5.3. Ventilation

6.5.3.1. Ventilation of formalin storage depends on several factors e.g., the volume of the room, amount of formalin stored and evaporation rates.

6.5.3.2. In areas where formalin is in use it is the responsibility of the Trust to ensure the optimum ventilation is present and maintained, to ensure the optimum exposure limit for formalin is not exceeded.

6.5.3.3. For general handling of small storage containers of formalin less than 50mls, natural ventilation is generally sufficient so long as the sealed containers are only open for a matter of seconds in order to place a histology specimen in them.

6.5.3.4. Laboratories, theaters, and any other areas within the Trust where formalin is in use should have two separate systems of ventilation. One for general air ventilation (often combined with heating and air conditioning) and the other for local removal of hazardous fumes (local exhaust ventilation)⁽¹⁾.

6.5.3.5. Properly designed chemical fume hoods enclose the emissions area structurally and functionally from the rest of the room. Preferably a motor somewhere in the duct work moves air directly to the outside. A device removing air from a workplace must have a supply to draw on. This is in addition to the amount required by the general venting system to perform the required air room changes per hour. Number of air changes needs to be confirmed with estates department as this is dependent on size and use of room.

6.5.3.6. Ventilation hoods other than fume hoods may be used but must be fit for purpose. When deciding on type of fume extraction ensure the following are considered: -

- Cross currents.
- Degree of vapor level will dictate frequency of replacing filters.

- Room design/activities.
 - Filter for formaldehyde/formalin (activated carbon).
- 6.5.3.7. Such fittings and units must be serviced every 14 months as per COSHH regulations.
- 6.5.3.8. Servicing must be undertaken by a company who have experience in carrying out servicing of such equipment. This may be by an experienced contractor or the company from where the mechanical extraction/ventilation unit(s) were purchased from. Contact the RCHT estates department /RCHT ventilation group to get advice as regards which companies are Trust approved for servicing ventilation units. Standalone equipment should be serviced by manufacturer.

Air purifiers based on ozone must not be used as they can generate a chemical more hazardous than most of the fumes found in histology labs.

6.5.4. Medical Surveillance

- 6.5.4.1. Environmental monitoring of formalin fumes must be undertaken on a regular basis to ensure that the optimal working exposure limit (OEL) is not exceeded in the working area ^(1,2). Frequency will depend on activity and periods of exposure but always when changes in practice are to be considered. The Departmental safety officer is responsible for ensuring this requirement is met. Monitoring equipment is available ranging from one stop monitoring to continuous monitoring equipment with software packages, from which reports can be downloaded giving an up-to-date record of exposure limits.
- 6.5.4.2. Employees working in an environment where formalin is used must undergo personal monitoring for exposure to formaldehyde fumes on a regular basis to ensure they are working well within the OEL limit. Frequency will depend on activity and periods of exposure but always when changes in practice are to be considered. The Departmental safety officer is responsible for ensuring this requirement is met.
- 6.5.4.3. An exposure limit is the maximum allowable airborne concentration of a chemical (vapour, fume or dust) to which a worker may be exposed. Exposure limits are the properties of the worker and the workplace combined. The exposure limit is usually measured as a time weighted average (TWA) over an 8-hour period.
- 6.5.4.4. The OEL for formalin is in two parts per million (2ppm) TWA over an 8-hour period of work (as defined in HSE publication EH40).

- 6.5.4.5. If this limit is exceeded work must cease or the use of formalin cease in that area, until the corrective action is undertaken (e.g., correct ventilation and fume extraction installed).
- 6.5.4.6. There are a wide range of direct reading detectors tubes and handheld devices for monitoring of formaldehyde available on the market. Some of these may suffer from interferences from other chemicals in the surrounding environment so before purchasing always check specification. Direct reading formaldehyde sensors are usually available with computer software so a continuous recording of vapours levels can be monitored. These can be purchased through Cornwall Procurement and should be validated for the area they are to be used in.
- 6.5.4.7. Personnel monitoring can be undertaken using Vaportest badges which are lightweight devices that collect gas and airborne contaminants in the workplace. Badges are made from a plastic housing that contains a permeable, absorbent membrane that can be lab tested. Badges, depending on manufacturer's specification can be used to measure a single independent vapour or a variety of substances helping to assess the exposure level of the gases and vapours in the workplace. These badges are obtainable from Solmedia or CellPath and are obtainable through Cornwall Procurement. Exposure time is anything from 15 minutes to 24 hours which must be recorded on the Analysis Request Form which accompanies the badges, in order to be valid for analysis.
- Please contact RCH Estates or RCH Health and Safety services for current advice on monitoring formaldehyde vapours.
- 6.5.4.8. Personal monitoring is undertaken bi-annually or when any practices in the use of formalin or change in ventilation / extraction units is undertaken.
- 6.5.4.9. Any changes in practice must immediately warrant environmental and personnel monitoring.

6.6. Emergency Procedures

Emergency procedures should be prepared by the Department Head, taking into account possible spillages and venting/leaking.

6.6.1. Writing An Emergency Procedure:

The following should be considered when formulating such a procedure:

- Raising the alarm.
- Summoning help and emergency services where necessary. This will depend on volume split and destination of spillage. Risk assessments must be undertaken to identify any risks involving spillages and action plans put in place. Advice for individual situations may be sought from Health and Safety Services.

- Isolating the source of leakage if appropriate and where it is safe to do so, evacuation of persons from the danger area and preventing access. Remember persons in pits, basements, cellars, stairwells, lower floors etc.
- Ventilation of the area by opening exterior doors and windows, where safe to do so. This will allow the formaldehyde vapours to evaporate naturally.
- Alert neighboring wards or departments to possible dangers from vapours and evacuate where necessary.
- Preventing reoccupation of the area until spillage and vapours have been cleaned up and dispersed respectively. If the spillage occurs in an area other than the laboratory or theatre, then contact the H and S Services and Histopathology Laboratory for advice and assistance in cleaning up the spillage.
- Staff likely to be involved in cleaning up spillages must be clear about the actions required to minimise any adverse effects or risk to themselves.
- The best method of checking if the formaldehyde vapour is below the optimal exposure limit (2ppm) is to operate a handheld electronic device specific for formaldehyde vapours and undertake continuous monitoring if possible.

6.6.2. **Spillage Kit**

6.6.2.1. The following are the minimum requirements for a departmental spillage kit where quantities less than 100mls of formalin are in use: -

- Respirator (as advised by RCHT Health and Safety Services).
- Formalin dedicated filters for respirator.
- Splash proof glasses / visor.
- Disposable apron.
- Nitrile disposable gloves.
- SPILL-XF formalin spillages granules.
- Paper towels.
- Yellow clinical waste bag.

6.6.2.2. The following are the minimum requirements for a departmental spillage kit where quantities greater than 100mls of formalin are in use:-

- Respirator (as advised by RCHT Health and Safety services).
- Formalin dedicated filters for respirator.
- Splash proof safety glasses.
- Face shield.
- Disposable apron.
- Rubber or nitrile gloves.
- Absorbent booms to soak up spillage.
- SPILL-XF formalin spillages granules.
- Dustpan and brush.
- Broom.
- Mop and bucket.
- Yellow clinical waste bags.

(All items are available through Cornwall NHS procurement Team).

6.6.2.3. The spillage kit must be accessible at all times and regularly checked for contents during quarterly H and S audits.

6.6.2.4. The positioning of the spillage kit should be near the area of use or preferably near the exit of the room, so the spillage can be dealt with ensuring it is contained and all staff can be evacuated.

6.6.2.5. Any items which need replacing should be replaced immediately.

6.6.2.6. The provision of the spill kit is the responsibility of the Head of Department/Departmental H and S Officer.

6.6.2.7. Advice in making up spillage kits for purpose can be obtained from RCHT Health and Safety or RCHT Histopathology.

6.7. Handling Formalin Spillages

6.7.1. Small Spillages

6.7.1.1. Staff likely to be involved in cleaning up spillages must be clear about the actions required to minimise any adverse effects or risk to themselves.

6.7.1.2. In areas where 30-60mls pots of buffered formalin are used for

histology specimens, the amount of spillage is minimal and can be cleared up using paper towels, in conjunction with suitable PPE.

- 6.7.1.3. Retrieve spillage kit and place on respirator, safety spectacles and apron.
- 6.7.1.4. Ensure room is ventilated by switching on any ventilation / extraction systems, opening windows or doors, so long as it does not lead out into a public / clinical enclosed area.
- 6.7.1.5. Put on disposable gloves and ensure that any specimen placed in the pot prior to the spillage is retrieved, as histology samples are classed as irretrievable specimens.
- 6.7.1.6. Try to stop spillage spreading and neutralise the fumes by sprinkling decontaminant granules around periphery of spillage and then infill.
- 6.7.1.7. Allow spillage granules to soak in and neutralise spillage for a few minutes (2-5 minutes) before clearing up with paper towels and dispose of them in a clinical waste container (place used towels and gloves in a sealed hazardous waste bag prior to disposal so any vapours are contained).
- 6.7.1.8. Once the spillage has been soaked up wash the area with general cleaning detergent and warm water.

Do not use any bleach based cleaning products.

6.7.2. Large Spillages

- 6.7.2.1. Staff likely to be involved in cleaning up spillages must be clear about the actions required to minimise any adverse effects or risk to themselves.
- 6.7.2.2. These types of spillages are most likely to occur in theatres, histology or during transport by the NHS couriers.
- 6.7.2.3. Ensure all patients, visitors and staff are evacuated from the area.
- 6.7.2.4. Isolate area by calling for assistance from the Health and Safety ext 2266 / RCHT Porters ext 2468 / Histology ext 2550 / or switch board ext 0.
- 6.7.2.5. Ensure the area is well ventilated. Open windows and doors where possible so long as no patients, visitors or staff are put at risk from the spillage or fumes.
- 6.7.2.6. Retrieve spill kit and ensure appropriate PPE is put on (respirator with formalin dedicated filters attached, safety spectacles, gloves, apron and boots).

- 6.7.2.7. Extinguish all ignition sources and avoid flames, heat and smoking.
- 6.7.2.8. Retrieve spill kit and ensure appropriate PPE is put on (respirator with formalin filters attached **MUST** be put on along with safety spectacles, gloves, apron/laboratory coat, boots).
- 6.7.2.9. If the container from which the spillage came from contained a histology specimen (human tissue) then this must be retrieved before spillage is cleared up.
- 6.7.2.10. Try to stop spillage spreading by sprinkling decontaminant granules around periphery of spillage and then infill. Use spillage booms to also stop spread of fluid from spillage.
- 6.7.2.11. The granules will neutralise the vapour (5-10 minutes) which will make the cleaning up process more comfortable and accessible.
- 6.7.2.12. The granules will result in a green sticky sludge which will need to be cleaned up using the dust pan and brush from the spillage kit.
- 6.7.2.13. The spillage booms and green sludgy waste must be disposed of in a yellow clinical waste bag which is then double bagged. The bag must be labelled as per waste disposal policy (e.g., complete addressograph label on yellow bags).
- 6.7.2.14. Area then needs to be cleaned using general hospital detergent and warm water. **Never use cleaning compounds containing chlorine (e.g., bleach, chlorsept) as this will react with any residual formalin generating the carcinogenic compound Bis-Chloromethyl Ether vapour.**
- 6.7.2.15. All formalin spillages must be reported on the Trust Datix system.

6.7.3. First Aid

- 6.7.3.1. **Eyes:** Wash eyes immediately with plenty of water/eye wash while lifting eye lids. Seek medical attention immediately (individual must attend RCHT A and E/ Ophthalmology day care unit).
- 6.7.3.2. **Skin:** Remove affected person from the source of contamination and immediately flush contaminated skin with plenty of water. Remove any contaminated clothing and wash before reuse. If irritation persists, seek medical attention (visit RCHT A and E / Dermatology Day care unit).
- 6.7.3.3. **Ingestion: Never** make an unconscious person vomit or drink fluid. **Transport to RCHT Emergency Department immediately.**

- 6.7.3.4. **Inhalation:** Move the exposed person to fresh air immediately. If breathing has stopped perform CPR immediately without rescue breaths. Keep affected person warm and rested while seeking urgent medical attention – contact ext 2222 for the Crash team.

6.7.4. **Medical Symptoms**

- 6.7.4.1. Extreme irritation of eyes and mucous membranes including burning and tearing. Repeated exposure may cause chronic eye irritation.
- 6.7.4.2. Irritation of nose due to vapour / dust contact. Rhinitis (inflammation of the nasal mucous membranes).
- 6.7.4.3. Upper respiratory irritation. General respiratory distress, unproductive cough.
- 6.7.4.4. May cause suffocation.
- 6.7.4.5. Severe skin irritation. Allergic rash. Acute eczematous dermatitis, contact type erythema, oedema, papules, vesicles, bullae, crust, desquamation.
- 6.7.4.6. Nausea, vomiting, severe abdominal pain. Swallowing concentrated chemical may cause severe internal injury.
- 6.7.4.7. Dizziness.

6.8. **Transport**

- 6.8.1. Only use closed 'transport' carriers when moving containers of formalin.
- 6.8.2. Small histology specimen pots (30-100mls) can be transported between clinics or from courier collections using the following approved pathology specimen transport boxes which are available through RCHT Procurement:



- 6.8.3. When transporting larger quantities of formalin and when using lifts, this task must be undertaken using a closed transport trolley for the patients samples contained in formalin (see sample below), or original closed cardboard packaging when transporting stock formalin solutions: -



- 6.8.4. These trolleys should be labelled with the universal pathology sample label UN3373 with COSHH label for formalin (Serious Health Hazard and Health Hazard).
- 6.8.5. Always keep containers of formalin solution upright. Tipping the container or laying it on its side can cause spillage of formalin. It may also damage the container and any materials stored in it.
- 6.8.6. Under no circumstances must formalin be transported in lifts if there is any risk of spillage.
- 6.8.7. Large boxes and specimen containers are heavy enough to cause personal injury, if proper lifting and handling techniques are not used.
- 6.8.8. Avoid transport on vehicles where the load space is not separated from the driver's compartment (e.g., a car). Ensure the vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
- Before transporting containers or specimens containing formalin, ensure they are firmly secured and lids are fitted correctly. For instructions in use in these pots please see appendix 1.
- 6.8.9. **Under no circumstances must containers of formalin be transported on public transport, including taxis.**
- 6.8.10. Formalin is a hazardous chemical and vehicles have to be labelled with Hazchem code 2T; ADR class is 8; and transport classification is Corrosive substance. Vehicles should have a sign plate on the outside at the back of the vehicle with a test tube dripping onto hand (black and white plate).

6.9. Storage

- 6.9.1. The location for the storage and use of formalin must be well ventilated. Preferably and external chemical store. If stored in departments room must be well ventilated and preferably by a local exhaust system.
- 6.9.2. Store buffered formalin at sufficiently high temperature (15-25°C) in dry, well-ventilated area to avoid the formation of polymer and crystallization of buffer salts.
- 6.9.3. Keep away from oxidizers, hydrochloric acid, heat and flames.
- 6.9.4. Solutions can cause corrosion and be subsequently discoloured by iron, copper, nickel and zinc alloys.
- 6.9.5. Recommended materials for equipment use should be made of stainless steel, polyethylene or polypropylene.
- 6.9.6. Solutions of formalin containing high amounts of methanol can form explosive mixtures on exposure to air at elevated temperatures. Formaldehyde gas can also be evolved at high temperatures and can form explosive mixtures.

6.10. Disposal

- 6.10.1. Currently the South West Water (SWW) Board allow general disposal of 10% (4% formaldehyde) formalin solutions used in medical and laboratory practice, into mains drainage so long as it is accompanied with copious amounts of water.
- 6.10.2. The histology laboratory at RCHT is probably the main user of formalin in the Trust. The histology department annually check the anticipated amount of formalin for disposal with the SWW board to ensure RCHT is complying with the current local disposal regulations.
- 6.10.3. If for any reason there were quantities of concentrated formalin for disposal this would be returned to the supplier.
- 6.10.4. Currently formalin supplies are purchased through Cornwall NHS procurement team from: -
 - Genta Medical
Unit 17D
Marston Business Park
Tockwith
York YO26 7QFAlternatively supplies can be obtained from: -
 - Cellpath
80 Mochdre Enterprise Park
Newton
Powys SY16 4LE

or

- Leica Microsystems (UK) Ltd
Larch House
Woodlands Business Park
Milton Keynes MK14 6FG

6.11. Summary of Recommendations for Managers

- 6.11.1. A Trust wide surveillance assessment will be carried out annually by the Health and Safety department in accordance with the Management of Health and Safety at Work Regulations ⁽¹⁾.
- 6.11.2. Departments must carry out annual risk-assessments and ensure any actions resulting from these are completed.
- 6.11.3. Ensure staff are aware of the hazards of formalin and that standard operating procedures are in place and followed.
- 6.11.4. Ensure that optimal ventilation and fume extraction is provided in areas where formalin is in use or stored.
- 6.11.5. Ensure that procedures are in place for the transportation of formalin within the premises, particularly in respect to the use of lifts and stairs.
- 6.11.6. Ensure that manual handling assessments have been carried out on all activities involving the handling of histology specimens containing formalin.
- 6.11.7. Ensure that labelling meets all regulatory requirements especially with secondary containers (histology sample pots).
- 6.11.8. Ensure that emergency procedures are in place in the event of a liquid spillage including those spillages containing histology samples.
- 6.11.9. Ensure that a sufficient number of personnel are trained in First Aid.

6.12. Training and Education

- 6.12.1. Training will be facilitated by the employees department through Learning and Development and be accessible to all employees handling formalin solutions. Type of training will depend on staff role.
- 6.12.2. Advice on training can be sought from the Health and Safety services, Learning and Development or from RCHT Histopathology.
- 6.12.3. All personnel handling formalin and those directly involved in the use of formalin must be fully informed regarding the hazards.
- 6.12.4. Ensure all staff using formalin have received respirator 'FIT' Test training (available through the Face Fit team based in the Health and Safety departments).

- 6.12.5. The training must be arranged to cover those aspects and potential hazards that the particular person is likely to encounter. Training should cover, but not necessarily be confined to, the following subjects for all personnel: potential hazards of formalin handling procedures e.g., method of dispensing, sample retrieval, transportation, use of protective clothing/apparatus including use of respirators in emergency procedures and first aid treatment for spillages.
- 6.12.6. All training must be formally recorded with refresher training undertaken annually.
- 6.12.7. Staff competency records must contain a section to record evidence of training in the use and handling of formalin.

7. Dissemination and Implementation

- 7.1. Once consultation has been undertaken the final published document will be held centrally within the online Document Library and be available to staff.
- 7.2. Upon publication, awareness to all staff will be raised by notification within the Trust “Daily Bulletin” and through H and S Committee feedback from both management and staff representatives.
- 7.3. Care Group Managers will ensure that the contents of this document are highlighted to staff through regular care group meetings.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with undertaken Formalin (COSHH) risk assessments.
Lead	H and S Committee.
Tool	Care Group Reports to the H and S Committee.
Frequency	H and S Advisors report and Care Group reports to the H and S.
Reporting arrangements	Reports received by the H and S Committee as detailed above and reported in accordance with the Committee Terms of Reference.
Acting on recommendations and Lead(s)	H and S Committee will request action from Care Group Representatives and escalate to Governance Committee as required.
Change in practice and lessons to be shared	Where issues are identified within reports all such comments will be fed back to the relevant area by the appropriate representative on the committee within a timeframe identified by the Committee.

9. Updating and Review

- 9.1. This document will be reviewed bi-annually and/or in the event of any significant change with the organisational structure/management arrangements and subject to consultation via the Trust H and S Committee.
- 9.2. Appendices and the associated documentation regarding this policy may be reviewed / revised in consultation with the H&S Team without formally being undertaken by the H&S Committee, provided that the amendments do not impact upon the general arrangements made within the policy.
- 9.3. Where the revisions are minor, e.g., amended job titles or changes in the organisational structure, approval can be sought from the Executive Director responsible for signatory approval, and can be re-published accordingly without having gone through the full consultation and ratification process.
- 9.4. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

- 10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Inclusion and Human Rights Policy'](#) or the [Equality and Diversity website](#).

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Use of Formalin Policy HSP 010.4 V3.0
This document replaces (exact title of previous version):	Use of Formalin Policy V2.0
Date Issued/Approved:	March 2023
Date Valid From:	March 2023
Date Valid To:	March 2026
Directorate / Department responsible (author/owner):	Stephen Davison, Head Biomedical Scientist Diagnostic and Molecular Pathology Clinical Support Care Group
Contact details:	01872 25 2550
Brief summary of contents:	To inform all personnel involved in the transport, storage, use and disposal of formalin in line with H and S policies and procedures
Suggested Keywords:	Formalin, Formaldehyde
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Pathology, RCHT Health and Safety Committee
General Manager confirming approval processes:	Gavin Griffiths, Head of Health, Safety, Moving and Handling
Name of Governance Lead confirming approval by specialty and care group management meetings:	Natasha Quick, Service Improvement and Business Lead (Health)
Links to key external standards:	⁽¹⁾ www.hse.gov.uk/pubns/iacl88.htm

Information Category	Detailed Information
Related Documents:	(2) www.gov.uk/government/HPA/Formaldehydegeneralinformation (3) Material Safety Data Sheet Neutral Buffered Formalin Concentrate, Genta Issue AMJ 4.0 25/1/2015 RCHT Health and Safety Policy and Guidance for the Use and Management of Hazardous Substances
Training Need Identified?	Yes
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Chief Operating Officer/Health and Safety

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
14 Oct 2015	V1.0	Initial issue	Valerie Rodd Chief Biomedical Scientist
18 Oct 2018	V2.0	Updated with minor changes of wording only. Amendments to the Care Group Structure and governance sheets.	Valerie Rodd Chief Biomedical Scientist Natasha Quick Senior H and S Advisor
23 December 2022	V3.0	Full review updated with minor changes in 6.5.4 Medical Surveillance.	Valerie Rodd, Lead Biomedical Scientist

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team

rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Use of Formalin Policy HSP 010.4 V3.0
Directorate and service area:	Chief Operating Officer/ Health and Safety
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Valerie Rodd, Lead Biomedical Scientist
Contact details:	01872 252550

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To protect guidance on the use of formalin throughout the Trust.
2. Policy Objectives	To provide advice on safe use of formalin for Trust Staff in the working environment.
3. Policy Intended Outcomes	Effective use and understanding of the safe use of formalin.
4. How will you measure each outcome?	Through incident reporting and Annual surveillance by Health, Safety, Moving and Handling.
5. Who is intended to benefit from the policy?	All RCHT staff, visitors and patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	- Workforce: Yes - Patients/ visitors: No - Local groups/ system partners: No - External organisations: No - Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Health and Safety Committee.
6c. What was the outcome of the consultation?	Approved
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys: No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	It is expected that any one working in a health care situation is of employment age.
Sex (male or female)	No	The policy does not make any reference to gender.
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	The policy does not make any reference to gender reassignment.
Race	No	The policy does not make any reference to race or Ethnic groups.
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	The policy does not make any reference to user disabilities.
Religion or belief	No	The policy does not make any reference to religion or belief.

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	This policy does not make any reference to relationship status.
Pregnancy and maternity	No	Exposure of a pregnant mother to formaldehyde is not expected to cause damage to the unborn child at amounts below that which cause significant health effects to the mother ⁽²⁾ .
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	This policy does not make any reference to sexual orientation.

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:

Valerie Rodd, Lead Biomedical Scientist

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
[Section 2. Full Equality Analysis](#)

Appendix 3. Instructions for Histology Containers

HOW TO



OPENING

When removing the lids, it is important that the lip is folded back **all the way round** for the lid to then effortlessly lift off. Failure to do this by tugging, tearing or pulling the lid off will damage the lid and rim of the container, often weakening the flange and losing its water-tight seal.



CLOSING WITH LIP TURNED DOWN (for the first time)

When sealing the containers with the lid, ensure that the rim is pushed down firmly. Then to complete the watertight seal, place the container on a level that you are able to lean over it and using your upper body weight through your arms place your hands side by side with thumbs touching and press down hard on the rim in a sharp movement with the balls of your hands until a "snap" is heard. This forms the watertight seal. However this must be done **all the way round** the rim. It is advisable to start at one point with both hands and then work, either all the way round the circumference in a circle, or if well used to the procedure, work both hands away from each other until they meet at the far side.



CLOSING WITH LIP TURNED UP

When sealing the containers with the lip turned up on the lid, fold the lip down and then repeat the closing process detailed above.

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