

Dear

FREEDOM OF INFORMATION – FORMALDEHYDE MONITORING

I write in response to your request for information in relation to formaldehyde monitoring in NHS Lothian.

Question:

1. Please provide the current COSHH risk assessment(s) relating to formaldehyde (formalin) exposure for staff working in operating/surgical theatres, produced to meet the Trust's duties under COSHH Regulation 6.

Answer:

The relevant COSHH risk assessments are enclosed.

Questions:

2. Please provide copies of all formaldehyde (formalin) exposure monitoring data held by the Trust for operating/surgical theatre staff for the last 12 months, including: Fixed/static air monitoring results; Personal exposure or badge monitoring results (with personal data redacted as appropriate)

This includes monitoring undertaken for any purpose, including baseline, verification, and/or investigation monitoring, in line with COSHH Regulation 10. It is noted that COSHH Regulation 10(5)(b) requires such records to be kept for a minimum of five years.

3. How does the Trust prevent or control employee exposure to formaldehyde (formalin) in its operating/surgical theatres, including but not limited to engineering, procedural, and/or organisational controls?

4. Does the Trust undertake regular scheduled formaldehyde (formalin) exposure monitoring in operating/surgical theatres? If so, please state the frequency.

5. Please state the total number of occasions on which regular scheduled formaldehyde (formalin) exposure monitoring has been undertaken in operating/surgical theatres in the last 12 months.

6. If regular scheduled formaldehyde (formalin) exposure monitoring is **not** undertaken, please provide documentation held by the Trust that demonstrates the effectiveness of current controls and supports the decision that routine monitoring is not required. If no such documentation is held, please confirm how the Trust assures compliance with COSHH Regulations 7 and 10 in the absence of routine exposure monitoring.

Answer:

Monitoring is not undertaken in operating theatres. Based on the COSHH ACOP (Reg 10), exposure monitoring is only required where there is a risk that exposure could exceed the WELs (2 ppm long term / 2 ppm STEL). For areas only conducting brief handling of prefilled formalin pots, in designated rooms compliant with the SHTM ventilation standards, the risk of exposure to concentrations approaching the WELs would generally be low unless a large spillage were to occur.

In the event of a large spillage, staff are expected to follow the local formalin spillage procedure which should incorporate the use of a formaldemeter to ensure that environmental concentrations of formaldehyde are at a safe level before the area is re-opened. This is reactive spill monitoring, rather than proactive monitoring falling under the Reg 10. Designated staff members are also fit tested to a suitable re-usable chemical respirator to wear when clearing the spillage, and this will be stored within the department as part of the local spill kit.

This all forms part of the wider COSHH assessment for the theatres and laboratories. NHSL have robust engineering controls in place through adherence to the relevant SHTM ventilation standards for theatres and laboratories and a hierarchy of control in relation to the handling/use of chemicals and relevant Standard Operating Procedures.

The relevant Standard Operating Procedures are enclosed.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at <https://www.foi.scot/appeal>. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.



If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: <https://org.nhslothian.scot/FOI>

Yours sincerely

ALISON MACDONALD
Executive Director of Nursing Midwifery and AHPs
Cc: Chief Executive

COSHH Assessment Form

Name of Assessor(s): Posts Held:	Vicki Elliot Lily Goodpatrick Gillian Thomson Jennifer Anderson Carolyn Kear Arthur Brady (Lauren Keriouh)	Date of Original Assessment:	18/06/2020																		
Manager Responsible:	Janine Fletcher																				
Department:	Theatres/Anaesthetic/Recovery																				
Hazardous Substance – include form e.g. solid, gas, liquid etc, amount used (Ensure that the SDS is updated to the CLP Regulation).																					
Formaldehyde (Formalin)																					
Tasks which use the substance and who will be exposed:																					
Decanting of substances from one container to another to fix specimens in large pots. Handling of specimens. All Staff exposed.																					
Hazard Information (Harmful properties, exposure limits etc) from Safety Data Sheet include route of entry, hazard type e.g. sensitiser etc and how long exposure is likely to be for																					
<ul style="list-style-type: none"> - Carcinogenic - Toxic by inhalation - Toxic by ingestion - Toxic through skin absorption - Flammable <p>H302 Harmful if swallowed H332 Harmful if inhaled H317 May cause an allergic skin reaction H341 Suspected of causing genetic defects H350 May cause cancer</p> <p>Up to date ventilation rates within theatre sluices:</p> <table> <tbody> <tr> <td>TH 1 - 20-0-100</td> <td>0.121 m3/s or 40.3 AC/Hr</td> </tr> <tr> <td>TH 2 - 20-0-91</td> <td>0.100 m3/s or 35.7 AC/Hr</td> </tr> <tr> <td>TH 3 - 20-0-83</td> <td>0.096 m3/s or 32 AC/Hr</td> </tr> <tr> <td>TH 4 - 20-0-75</td> <td>0.139 m3/s or 46.3 AC/Hr</td> </tr> <tr> <td>TH 5 - 20-0-60</td> <td>0.120 m3/s or 40 AC/Hr</td> </tr> <tr> <td>TH 6 - 20-0-52</td> <td>0.106 m3/s or 35.3 AC/Hr</td> </tr> <tr> <td>TH 7 - 20-0-48</td> <td>0.057 m3/s or 20 AC/Hr</td> </tr> <tr> <td>TH 8 - 20-0-40</td> <td>0.117 m3/s or 39 AC/Hr</td> </tr> <tr> <td>TH 9 - 20-0-32</td> <td>0.118 m3/s or 39.3 AC/Hr</td> </tr> </tbody> </table>				TH 1 - 20-0-100	0.121 m3/s or 40.3 AC/Hr	TH 2 - 20-0-91	0.100 m3/s or 35.7 AC/Hr	TH 3 - 20-0-83	0.096 m3/s or 32 AC/Hr	TH 4 - 20-0-75	0.139 m3/s or 46.3 AC/Hr	TH 5 - 20-0-60	0.120 m3/s or 40 AC/Hr	TH 6 - 20-0-52	0.106 m3/s or 35.3 AC/Hr	TH 7 - 20-0-48	0.057 m3/s or 20 AC/Hr	TH 8 - 20-0-40	0.117 m3/s or 39 AC/Hr	TH 9 - 20-0-32	0.118 m3/s or 39.3 AC/Hr
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Can this substance be Eliminated or Substituted? If not, please explain why:																					
Cannot feasibly be eliminated as used routinely to fix specimens.																					
Existing Precautions																					

Staff must wear:

- Nitrile gloves
- Surgical masks, for routine handling (not spillages)
- Spill kits within department (Combined stores cupboard)
- Staff training in place
- Ventilation rates within sluice rooms of each theatre have been investigated

Storage

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition.

Disposal

Is there a requirement for Health Surveillance? Yes/no and what type e.g. skin health etc

Staff to report any adverse reactions/effects to line manager and referred to occupational health. RIGGOR HSE involvement.
Skin surveillance.

Maintenance of equipment - including LEV test, maintenance and inspections

Ventilation rates assessed annually and staff training recorded.

Is there a need for Personal Protective Equipment? YES/NO and what type

- Nitrile gloves
- Surgical masks to be used routinely when handling substance

First Aid Measures

Remove from exposure
Irrigate with water
DO NOT induce vomiting

Eye contact – rinse immediately with plenty of water, also under eye lids for at least 15 minutes – seek medical advice
Skin contact – Wash off immediately with lots of water for at least 15 minutes. Immediate medical attention is required
Inhalation – If breathing becomes difficult, give Oxygen. Move to fresh air and seek immediate medical attention if required
Ingestion – Do not induce vomiting. Seek medical advice or call poison control centre immediately

Emergency Plans - including spills procedures

Spill kits available (stored in community store cupboard)
Adequate PPE – Personal face fitted masks with filters. (Kept in box with spill kits)
Weaver box for disposal of absorbed spillages.

Other Additional Measures

Staff training
Documentation of understanding from staff of importance of spillage awareness and handling precautions

Level of Risk

Select the level which indicates the current risk level:

Green	Yellow	Orange	Red
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Action Plan			
What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)
Spill Kit training for staff fitted with PPE	Team lead	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date
Detail	Name	Date	Date

Review Table			
Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
24/09/2025	L Keriouh	Annual review – updated safety data sheet	Name & Date
Date	Name	Detail	Name & Date
Date	Name	Detail	Name & Date

COSHH Risk Assessment

Name of Assessor(s): Posts Held:	Kathryn Pearce/Carol Hutchison	Date of Original Assessment:	15/06/2022
Manager Responsible:	Suzanne Crawford/Claire O'Neill, Darren Haddow/Evia Mamvura/Sharlene Philp/Steven Elder/Joanne Scott/Cath Green		
Department:	Theatres and Anaesthetics		
Hazardous Substance:			
<ul style="list-style-type: none"> • 200mls – 5litres Formaldehyde Spillage Kit - Contents include: • 4 x 950ml FNC neutraliser, 4 x 50ml activator, 1 x 200gm absorbent and immobiliser, 1 x absorbent pad, 1 x dustpan and brush, 6 x disposal bags with ties, 1 x pair of gloves, facemask and 1 x pair of safety goggles • Absorbency capacities 950ml of Vytac FNC and 50ml activator will neutralise approximately 670ml of Formaldehyde @ 37%, 2500ml of Formaldehyde @ 10%, 6000ml of Formaldehyde @ 4% 			
Tasks which use the substance and who will be exposed:			
Spillage of Buffered Formalin (Formaldehyde) used for fixing pathology specimens. Pouring the fluid from one container into another to preserve tissue for investigation may rarely result in large spillage of buffered formalin where a large spillage kit would be required.			
Hazard Information (Harmful properties, exposure limits etc) from Material Safety Data Sheet:			
<p>The contents of the spillage kit itself is minimally hazardous and very safe to use - the formaldehyde neutralizing granules completely immobilizes concentrated solutions (15 - 37%) within 3 - 10 minutes and eliminates vapour emissions. The resulting residues are environmentally harmless and safe to handle. but knowledge of formaldehyde gas produced by the spillage of buffered formalin 4% prior to use of the granules should be known and are as follows:</p> <ul style="list-style-type: none"> • Max 0.75 ppm 8 hours TWA • Short Term Exposure Limit (STEL) 2ppm over 15 mins, LTEL 2ppm. <p>When present in the air at a concentration above 0.1 parts per million, formaldehyde can cause watery eyes, nausea, coughing, chest tightness, wheezing, skin rashes, allergenic reactions, and burning sensations in the eyes, nose, and throat. Formaldehyde has been shown to cause cancer in laboratory animals and may cause cancer in humans. It also may cause birth defects. It is highly toxic if swallowed, inhaled, or absorbed through skin or mucous membranes. Formaldehyde reacts vigorously with oxidizers and, at its highest concentrations, is a combustible liquid. In addition, formaldehyde reacts with hydrochloric acid (HCl) to produce bis (chloromethyl) ether vapour, a very potent carcinogen.</p> <p>Formaldehyde is corrosive, and the eyes are especially vulnerable. An air concentration of two parts per million (2 ppm) is quickly irritating to the eyes, and 20 ppm can cause permanent clouding of the cornea after only one exposure. Formaldehyde is also a sensitising agent. Subsequent exposures can produce symptoms more quickly and at lower concentrations. Symptoms of exposure may include coughing, eye or skin irritation, allergic reactions, vomiting, and diarrhoea.</p> <p>Exposure to concentrations of formaldehyde in air greater than 25 ppm can cause severe injury, including fatal pulmonary oedema (water in the lungs). Cal/OSHA limits employees' exposure to airborne concentrations of formaldehyde to an average of 0.75 ppm over an 8-hour workday. Formaldehyde's odour threshold (the lowest concentration you can smell) is about 1 ppm. As a sensitiser, subsequent formaldehyde exposures can produce symptoms more quickly and at lower concentrations, while olfactory fatigue can significantly raise the odour threshold concentration. Symptoms of exposure may include coughing, allergic reactions, difficulty breathing, vomiting, and diarrhoea.</p>			
Can this substance be Eliminated or Substituted? If not, please explain why:			
No – no alternative. Staff are recommended to use small pre-filled containers for specimens where possible.			
PRECAUTIONS.			
<ul style="list-style-type: none"> • Only staff who have been fitted for 3M series 6000 masks and trained in formaldehyde spillage kit use may perform this procedure. • Ventilation Formaldehyde should always be used with adequate ventilation, preferably in a fume hood, to minimize inhalation of vapour formaldehyde. In theatres the specimen should be taken into the sluice and the specimen fixed there using PPE. • PPE please see below. • All incidents and health problems should be reported • 			

Is there a requirement for Health Surveillance?

- Yes.
- Skin surveillance.
- Lung function testing where appropriate.

Maintenance of equipment:

Dates on kits should be checked monthly and replaced in good time. Kits should be reordered once used as are a once only use.

Is there a need for Personal Protective Equipment?

Yes:

- Nitrile Gloves.
- Goggles/Eye protection.
- Wear appropriate clothing that offers protection against splashing.
- Plastic apron.
- Respirator for major spillage (see below).

If spillage is greater than 5 litres:

- Close all doors.
- Block doorways with absorbent socks from kit.
- Evacuate area.
- Call fire service to deal with spillage.
- Inform Theatre Coordinator Bleep 2118 or Bleep 100.

First Aid Measures

Always remove patient from exposure

Inhalation:

1. Remove from exposure
2. Rest and keep warm
3. Seek Medical Advice if serious or if the patient continues to deteriorate after removal from exposure

Skin Contact

1. Continually wash with water
2. Seek medical advice if appropriate

Eye Contact

1. Irrigate eye for at least 10 mins with water
2. Seek Medical attention

Ingestion

1. Irrigate mouth with water
2. Do not induce vomiting
3. Give water to drink if the patient is conscious
4. Seek medical advice.

Emergency Plans, including spills procedures

Spillage

Formalin releases formaldehyde; the rate of release depends on the surface area of formalin exposed to the air, the concentration, and the temperature. Formaldehyde is a highly irritant gas. The threshold of effects on the eye is less than 1ppm; concentrations above 2ppm produce discomfort in the eyes and respiratory tract. Brief exposure to 50ppm will produce very serious lung damage. Formaldehyde has a Maximum Exposure Limit of 2ppm (15 minute average).

Spillage could occur during the filling of a tub for biopsy fixing, or during the subsequent handling of the tub. The most likely quantity is a fraction of one of the 1-litre bottles of 4% formalin. The worst case would be the entire contents of a large biopsy tub – 5 litres.

- **Procedure Outline**

When it is practicable and safe, spillages should be dealt with by the theatre staff following this procedure. If this is not possible (see level 3 below) the Fire Brigade should be called and the affected area evacuated.

Safe use of the spillage kit depends on the determination of the severity of the spill (see levels 1-3 below) and on its use by trained staff. Only those who know how to use the contents of the spill kit and its limitations may do so. Anyone who has not been fit-tested and trained in the use of the respirator should use not use the respirator.

- **On Discovery of a Spill**

Any member of staff who discovers a leak or spillage should report it immediately to the charge nurse, who will decide what level of response is required.

If required use spillage kit.

Formaldehyde gives good warning by smell of excessive concentrations, although the nose can, however, become de-sensitised after a while. Sense of smell can be used to distinguish level 1 from level 2.

- **Level 1: A few millilitres**

The smell of formaldehyde may be strong, but if it is very strong and beginning to cause irritation, go to level 2.

1. Wear Nitrile gloves.
2. Wear plastic apron, and face protection if splashing is likely during mopping up.
3. Mop up spilled material using absorbent pads in spillage kit.
4. Seal used absorbent in double plastic bags
5. Arrange for repair of damaged, leaking equipment as required.
6. If at Royal Infirmary, request uplift as hazardous waste: by Haden.
7. If at other sites, inform Maintenance Manager (31436) and arrange to transport to WGH.
8. Complete incident report

- **Level 2: Larger Spills:** 1 litre or more, not significantly affecting personnel in theatre.

The smell of formaldehyde may be definitely irritant but still tolerable without respiratory protection. If the smell is intolerable, or the spill is causing a very strong smell in the operating theatre during a surgical procedure, go to level 3.

1. Evacuate the sluice room.
2. Use full protective gear including respirator from spillage kit. Only those trained in its use and fit tested for the respirator may use it.
3. Follow procedure for level 1 from point 3 onwards.
4. Complete incident report

- **Level 3: Large Spills** where the smell of formaldehyde is intolerable without a respirator, or where the theatre is badly affected during a surgical procedure.

1. Can the theatre be evacuated?
2. If yes, go to point 4.
3. If no, (surgical procedure is underway and cannot be suspended) the concentration of formaldehyde in theatre from a 5-litre spill is most unlikely to cause severe acute effects. Follow spillage procedure above using full protective kit, including respirators. Speed is very important.
4. Activate the fire alarm
5. Inform Fire Brigade of the nature of the spillage (quantity of formalin, breathing apparatus required for formaldehyde, large quantity of absorbent material will be required)
6. Prepare to assist Fire Brigade by ensuring a responsible person can indicate the source of the problem without delay.
7. Complete incident report

Other Additional Measures

Level of Risk

Current risk level



See accompanying guidance: [Health and Safety](#) (RIGHT CLICK TO OPEN LINK)

Step 4: Action Plan			
What further action is necessary?	Action By Whom	Action by when (dd/mm/yy)	Action completed. (dd/mm/yy)

Step 5: Review Table			
Date (dd/mm/yy)	Reviewer	Reasons for review	Approved/Not Approved by (dd/mm/yy)
15/06/2022	Kathryn Pearce/Carol Hutchison		15/06/2022

FORMALIN SPILLAGE STANDARD OPERATING PROCEDURE

Formalin is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Formalin releases formaldehyde, rate of release is dependent on concentration, surface area exposure to air and temperature

HAZARD	CATEGORY
Flammable liquids	Category 4
Skin Corrosion/irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 1
Skin Sensitization	Category 1
Germ Cell Mutagenicity	Category 2
Carcinogenicity	Category 1A
Specific target organ toxicity (single exposure) Target Organs - Respiratory system, Central nervous system	Category 1

SPILLAGE	CATEGORY	ACTION
≤ 200mls	Minor	Spillage procedure using formaldehyde neutralising/absorbent granules
200 – 5litres	Large	Formaldehyde spillage kit
≥ 5 litres	Major	Fire service involvement

Category	Action
Minor ≤ 200mls Simple spillage procedure	<ul style="list-style-type: none"> • use PPE- gloves, standard eye protection • use formaldehyde neutralising/ absorbent granules to cover spill, leave for recommended time to allow neutralisation to occur • scrape up granules • clean area with detergent wipes, place all waste in clinical waste bags, seal & dispose of as clinical waste
Large 200mls – 5litres Formaldehyde spillage kit	<ul style="list-style-type: none"> • Evacuate all non essential staff from area • Outside the area, put on appropriate mask with formaldehyde filter, eg 3M series 6000 with formalin filter • Use appropriate PPE, long nitrile gloves, standard apron, etc • Minimal number of staff to be involved with spill and enter area with exposure. • On entering area, Open formaldehyde spillage kit • Place sock around formalin to contain spill • Use formaldehyde neutralising/absorbent granules to soak up spillage, cover with absorbent mat, leave for recommended time to allow neutralisation to occur • Scrape up granules & [place in clinical waste bag. • Clean area with detergent wipes, place all waste in double bags from kit, seal & dispose of as clinical waste
	NB only staff who have been fitted for 3M series 6000 masks and trained in formaldehyde spillage kit use may perform this procedure
Major ≥ 5 litres	<ul style="list-style-type: none"> • Close all doors • Block doorways with absorbent socks from kit • Evacuate area • Call fire service to deal with spillage • Inform coordinator or bleep 100
NB speed is essential to reduce levels of formalin being released into the area, placing staff/patients at risk	
To avoid unnecessary spills Use prefilled formalin pots where possible Specimens that require larger volumes of formaldehyde must be treated in an area with adequate ventilation Place pots in sink with plug in situ or in a deep sided tray on a trolley to contain any potential spillage – Apply tight fitting lid and secure well to prevent spillage during transportation, place in double bag.	

FORMALIN SPILLAGE STANDARD OPERATING PROCEDURE