



Public Health Wales
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**Chemical, Explosive and
Microbiological Hazards
Division**

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Principal Inspector:
Dr Keith Stephenson

For the attention of Tracey Cooper (Chief Executive, Public Health Wales).

Dear Madam,

HEALTH AND SAFETY AT WORK ETC. ACT 1974 AND ASSOCIATED REGULATIONS

1. I am writing following my investigation of a dangerous occurrence that occurred in the Containment Level (CL) 3 laboratory at Wales Centre for Mycobacteria (WCM), Public Health Wales Microbiology, located at Llandough Hospital, on 16th May 2024. As part of my investigation, I met with various staff including Michelle Peters (Network Health and Safety Manager, Microbiology Division), Rachel Roper (Network Health and Safety Deputy Manager, Microbiology Division) and Rebecca Person (Regional Health and Safety Lead).
2. This letter is intended to raise matters that fell below the minimum legal requirements, and which must be addressed to ensure compliance with current health and safety legislation.
3. You are required to provide a written response to this letter by 26th September 2025. Please send the response by email to Kathryn.Howarth@hse.gov.uk

Details of the incident under investigation

4. Safe and effective decontamination of work surfaces and equipment is important when managing the risks associated with work involving infectious agents. Methods of disinfection include manual spray-and-wipe using liquid disinfectants; fogging techniques (which also use liquid disinfectants); and gaseous fumigation systems. The latter may comprise of true gases or vapour generated by heating source liquids, such as formaldehyde. At CL3, the laboratory must be capable of being sealed to allow it to be effectively disinfected. Ongoing programme of formal assessment, e.g. an annual test is recommended to make sure sealability is maintained. However, more frequent visual inspections should be undertaken, e.g. for cracks, or dust trails which may provide early indication of breaches in sealability of the facility. In this event, remedial work should be carried out and verified as effective.
5. Whilst reviewing the CL3 sealability report for CL3 Laboratory at Glangwili Hospital (Carmarthen), (provided by the external contractor (eLab)), during a pro-active inspection on 16th January 2025, I identified that the CL3 was not sealable to permit fumigation and during further discussion it became

evident that there were sealability issues across the network of Laboratories that warranted further investigation. I issued a verbal warning in relation to the lack of sealability including an instruction for PHW to undertake a review of the sealability reports (from the external contractor) across the network of Laboratories, to determine which Laboratories were sealable for disinfection. Public Health Wales (PHW) Microbiology undertook a review of the sealability reports from the external contractor and risk assessed all the CL3 laboratories within their network and identified which other laboratories were not sealable for fumigation. PHW provided me with a copy of the risk assessment to review, and further discussions were undertaken in relation to the measures PHW put in place for those Laboratories which were not sealable to permit fumigation.

6. Additionally, as a follow up to the PHW document review and risk assessment, I requested copies of the sealability reports for all the CL3 Laboratories and undertook my own review. I identified that Lab 35 at WCM Llandough Hospital which is the TB reference Laboratory was not sealable for fumigation on the report dated 16/5/2024. The report stated, 'excessive leak detected into the office above,' and the findings of the report state – 'recommended that the joint be filled with a grouting solution to seal the breach and overlaid with silicon to ensure an appropriate seal.' Further recommendations in the report stated 'In the event of an emergency fumigation the following recommendations must be adhered to: The laboratory and associated areas must be vacated due to leakage detected during the sealability study. The quantity and concentration of fumigant must be increased by 10% for fumigation to support Efficacy.' Yet despite the report stating the CL3 Laboratory was not sealable for fumigation, eLab issued a sealability certificate and work with high risk (HG3) biological agents continued within the Laboratory.
7. On 20/5/24 a maintenance request for the lab to be sealed as per the recommendation of the eLab report, was submitted to Cardiff and Vale estates by the Operations Manager, WCM. The MR portal shows the job was not completed until 16/7/24.
8. Additionally in June 2024 before the estates team had undertaken the repair, an in-house smoke pencil test was undertaken as part of a routine quarterly audit and this also identified that the laboratory was not sealable for fumigation, yet despite the evidence that the Laboratory was not sealable for fumigation, Lab 35 was not taken out of use.
9. Furthermore, when the Cardiff and Vale estates did complete the remedial work to seal Lab 35, PHW failed to verify that the work had been completed to a satisfactory standard to confirm that the laboratory was sealable for fumigation.

Issue 1: Sealability of Containment Level 3 Laboratories

10. Regulation 7(1) of the Control of Substances Hazardous to Health (COSHH) 2002, requires that every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled. Additionally, Schedule 3, Part II, containment measure 4 of COSHH requires Containment Level 3 Laboratories to be sealable to permit disinfection. Furthermore, Regulation 5(1) of the Management of Health and Safety at Work Regulations 1999 (MHSAW), requires that every employer shall make and give effect to such arrangements as are appropriate, having regard to the nature of his activities and the size of his undertaking, for the effective planning, organisation, control, monitoring and review of the preventive and protective measures.
11. The CL3 Lab (Lab 35) WCM Llandough Hospital was not sealable to permit disinfection with your chosen method, fumigation with gaseous formaldehyde. As a result, in the event of an incident/spillage with a biological agent which required fumigation of the CL3 laboratory, employees in the adjacent areas could have been exposed to formaldehyde vapour leaking from the laboratory or retained within a space not designed for fumigation.
12. Whilst the recommendation from the external contractor providing a Sealability testing service in recognition of the Sealability issues was to increase the concentration of formaldehyde used during fumigation of CL3 laboratory to compensate for the leakage, this is not appropriate, because the

adjacent spaces into which fumigant could leak are not designed or appropriate for gaseous fumigation, thereby increasing the risk of harm to people nearby or returning to work in that area, due to retained fumigant and/or off-gassing from soft absorbent furnishings/surfaces. Such an approach can also influence the effectiveness of the gaseous fumigant against the biological agent concerned because retention of the appropriate level of fumigant for the appropriate time within the CL3 laboratory cannot be guaranteed.

13. Despite the conclusion of the external contractor that the CL3 laboratory was not sealable for fumigation, PHW failed to act on the results and failed to cease work until Lab 35 could be confirmed as sealable for fumigation.
14. Furthermore, once remedial work was undertaken to reseal cracks, the remedial work was not verified as effective by undertaking a sealability check.
15. Therefore, by failing to ensure the sealability of the Containment Laboratories were in place, employees could be put at risk of harm if a situation had arisen that required the enactment of an emergency fumigation response. As a result, Public Health Wales have breached Regulation 7(1) of COSHH; Schedule 3, Part II, containment measure 4 of COSHH and Regulation 5(1) of MHSWA.

Action

In order to comply with the requirements of Regulation 7(1) of COSHH, Schedule 3, Part II, containment measure 4 of COSHH and Regulation 5(1) of MHSWA you must:

- a. **Review and revise your current arrangements in regard to reviewing the verification of the sealability of the CL3 (including where such tests are undertaken by external contractors), so that you can gain the necessary assurance that the facilities are sealable and therefore safe to operate after maintenance and testing activities.**
- b. **Implement a system to ensure that any remedial work carried out as result of sealability issues is verified as effective.**

In your written response you must describe how the above have been achieved and provide supporting documentary evidence.

Information for employees

16. Under section 28(8) of the Health and Safety at Work Etc Act 1974 I am required to bring factual information on the above matters to the attention of the employees and therefore I have sent a copy of this letter to Joanna Kronka, Unite Union representative.
17. If you have any questions, please do not hesitate to contact me.

Yours faithfully



Ms Kathryn Howarth

HM Specialist Inspector

CC: Michelle Peters (Network Health and Safety Manager, Microbiology Division);

Joanna Kondra (Unite Union Representative) and Keith Stephenson (HSE Principal Inspector).