Review of Thermostatic Mixing Device Risk Assessment, Method Statements & Associated Processes

Gloucestershire Hospitals NHS Foundation Trust

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Service, maintenance and remedial activities undertaken on water assets or plumbed equipment within patient care areas, or locations where associated workflows could transmit waterborne organisms to the patient (e.g. kitchens, dirty utilities), present a risk to patient safety from poor hygiene practices, environmental contamination and contact contamination from unclean tools or hands.

Appointing a third-party contractor for critical tasks, such as thermostatic mixing device testing, maintenance and cleaning, may further increase risk if not properly managed. A full assessment must be undertaken by a multidisciplinary team to determine the critical aspects of task delivery, correct governance is needed for tender specification, procurement and onboarding training, clearly defined shared responsibilities and accountability must be understood by both parties, guaranteeing consistent levels of resource competency and compliance with agreed methodology for the contract duration is required, and ensuring seamless communication pathways for data capture as well as escalation of concerns or faults is necessary.

This document directs good practices supporting thermostatic control mixing device maintenance and service, raises concerns and presents a gap analysis for the provided Risk Assessment Method Statement (RAMS) and witnessed practices of the 3rd Party Contractor (Rock Compliance), and makes recommendations for improvement in this service for Gloucestershire Managed Services.

This report was requested by, and prepared for, Mark Johnston-Wood, Director of Estates & Facilities, Gloucestershire Managed Services by Dr Catherine Whapham, Water Hygiene Consultant, Harper Water Management Group Ltd.

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Introduction

For most people, the risk of hot water scalding during handwashing is minimal at outlets, provided that "Caution Hot Water" signage is displayed. However, vulnerable individuals (i.e. children < 5 years, adults > 65 years, and persons with cognitive or physical impairments) may be at increased risk of hot water scald injuries. Approximately 80% of domestic hot tap water scalds occur during immersion in bath or shower settings.

Within Gloucestershire Hospitals NHS Foundation Trust, hot water outlets (basins, showers and baths) predominantly used by patients for bathing or handwashing are typically risk assessed in favour of temperature control devices through the specification for a thermostatic mixing valve (TMV), thermostatic mixing shower body (TMS) or thermostatic mixing tap (TMT). The Trust is currently assessing and removing TMV/T from outlets, which have previously and historically been indiscriminately installed, where they are not predominantly for patient use.

For outlets predominantly used by staff, or not intended for handwashing or bathing (e.g. sinks within kitchen, dirty utility or cleaners' rooms), thermostatic control devices are generally not considered necessary, although display of "Caution Hot Water" signage is required to mitigate risk.

Thermostatic control devices (TMV, TMS, TMT) are complex assemblies containing polymeric and elastomeric materials, internal wetted surfaces and niches that may promote biofilm formation and support colonisation and proliferation of waterborne pathogens. Their installation may increase microbiological exposure risk to vulnerable users. The requirement for any water outlet presence, and for a thermostatic control device, must be risk assessed by a multidisciplinary Water Safety Group (WSG) prior to specification, procurement, installation, commissioning and operation.

Where installed, thermostatic control devices should preferably be integral to the outlet (TMT) or incorporated within a single mixed-temperature shower outlet (TMS). Where not integral, they must be installed as close to the outlet as possible to minimise the downstream blended water volume, stagnation, biofilm formation and microbial proliferation.

Thermostatic mixing valves used in healthcare facilities should be TMV3 approved and comply with the requirements of HTM 04-01 Supplement D08, which specifies enhanced installation, commissioning and maintenance requirements. Where risk assessment identifies TMV3 as appropriate (e.g. baths, showers and handwashing outlets predominantly used by vulnerable patients), the associated strainers and thermostatic mixing device should be inspected, cleaned, descaled and disinfected at least annually (outside of commissioning), or at a frequency determined by the WSG through risk assessment.

Thermostatic Control Device Maintenance & Service Critical Activity

Regular routine maintenance on thermostatic control devices (TMV/S/T), in accordance with the manufacturer's instructions and following Water Safety Group formally approved RAMS, must be carried out by trained and competent individuals

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(Competent Person, CP) in order to mitigate risk to patient safety. Non-maintained, failed or failing thermostatic control devices may contribute to increased scalding risk and poor waterborne pathogen control.

Following any routine TMV/S/T maintenance, remedial action or replacement, the outlet's return to service must include a hot water temperature "failsafe" check. Routine failsafe checks require isolating the cold water supply to verify that the thermostatic control valve will automatically shut down hot water flow within a maximum of 5 seconds (and a defined max limit of 120 mL 60 seconds thereafter), thus preventing user exposure to high hot water temperatures which could potentially scald.

Microbial verification on a proportion of maintained, remediated or replaced outlets, to confirm contamination has not been increased or introduced during the processes, is advisable, particularly when confirming changes to RAMS or CP(s) resources.

Trust Staff must ensure that all thermostatic control devices are readily and continuously accessible. Storage of items preventing access for this critical maintenance increases patient risk and must be reported urgently. Where access is not possible due to patient isolation, end of life or other clinical restriction, ward staff should document the access restriction for further communication and to ensure timely maintenance return.

Where opening and accessing ceiling voids and/or IPS panels to locate pipework isolation valves and to monitor hot and cold pipe temperatures, an environmental risk assessment must take into account any resulting particulate, spore and microbial exposure within the hospital room, surfaces and to the occupant patient(s). Competency in understanding the environmental impacts of airborne contamination is needed, and ward staff should support the CP(s) by confirming any higher risks or sensitivities associated with a patient, occupant or location.

Thermostatic control devices should be specified to be easily removable and disassembled with materials well suited to cleaning and disinfection. These installed items are commonly contaminated with particulates, debris and biofilms (see pictures below), which are formed following exposure to water during manufacturer wettesting, following system and component commissioning, operational exposure to influent hot and cold water, and on contact from splash, tools, brushes, cloths, hands and other surfaces. The componentry, outlet, associated sanitaryware and drain therefore must always be considered contaminated. Activity at the outlet must ensure hygienic workflows and respect adapted aseptic techniques in order to minimise contamination risk to the patient, healthcare environment, componentry and associated sanitaryware, and CP(s) undertaking the service works.
Competency to undertake these works can be evidenced by presentation of recent practical training records supporting environmental cleaning, water hygiene and aseptic techniques. The individual(s) must receive training on relevant approved Trust

RAMS and be witnessed as competent by the RP / Deputy RP (Water) and Infection Prevention.

Individuals working on healthcare facility potable water pipes should hold an EUSR Water Hygiene Blue Card as a minimum, have experience of working in patient care environments, and preferably be a certified plumber through WaterSafe's approved schemes (such as via CIPHE, APHC, SNIPEF, WIAPS).





Photographs illustrating biofilms and particulate debris within installed operational thermostatic control devices

Witnessed Observations of Maintenance & Servicing Contractor (February 2026)

Witnessing was completed by Ade Olayiwola (Senior Estates Operations Officer,

Gloucester) and Dr Catherine Whapham (on behalf of Dr Susanne Surman-Lee, Leegionella Ltd), within a Staff Bathroom in the Maternity Unit, Gloucestershire Royal Hospital.

During this event, a Rock Compliance operative undertook TMV maintenance and service whilst being shadowed by another operative as part of onboarding to support TMV maintenance and service activity at both Gloucester and Cheltenham hospital sites.

Please see below photographs, key observations and proposed follow up activity.

Risk Recognition –Contractor TMV Maintenance & Fail-Safe Checks in Maternity/Birthing Staff Room Ensuite (1)









Observations

- No water hygiene awareness or aseptic techniques applied
- Dirty / rusted tools placed on bin lid – no clean tools nor products to clean tools with
- Shower Shine Plus (descaler) in a plastic jug used multiple times until solution is "black"
- Tap outlet scaled and presence of blue/green colour may indicate Pseudomonas colonisation
- Temperatures (pipe surface) taken for hot flow, return, cold supply and downstream flow from TMV. No measurement of time taken to achieve temperature
- Contractors are allowed 15 minutes by Rock Compliance to complete the task and therefore no time to find hidden isolation valves, move stored products to access panels/TMVs, to undertake this activity in a separate workshop/dirty area away from patient care areas

Follow Up

- Training for Rock Compliance contractors if they are to remain at site
- Method statement to be given by GMS/Trust
- Risk assessment for moving to alternative provider to be revisited
- Specification for critical tasks such as TMV Maintenance/Service/Fail-Safe must focus on patient safety and not cost or time
- Contractors working on the hospital water system should be plumbers with EU Blue Card and a WaterSafe certification
- Procedure for procurement of such services must be reviewed and risk recognised

Risk Recognition –Contractor TMV Maintenance & Fail-Safe Checks in Maternity/Birthing Staff Room Ensuite (2)






Observations

- No water hygiene awareness or aseptic techniques applied
- TMV components not submerged in the previously used descaler solution
- Scrubbing of components undertaken in sink on a previously used microfibre cloth with dispersal of contamination broadly cast in the surrounding area
- Clean componentry (tap handle) within the sink during cleaning procedure
- Dirty microfibre cloth used to wipe down the basin and tap following refitting, and rinsed before taking to the next water outlet
- Contractors confirmed this was the method from Rock Compliance

Follow Up

- Training for Rock Compliance contractors if they are to remain at site
- Method statement to be given by GMS/Trust
- Risk assessment for moving to alternative provider to be revisited
- Specification for critical tasks such as TMV Maintenance/Service/Fail-Safe must focus on patient safety and not cost or time
- Contractors working on the hospital water system should be plumbers with EU Blue Card and a WaterSafe certification
- Procedure for procurement of such services must be reviewed and risk recognised

Risk Recognition – Maternity/Birthing Staff Room Ensuite Bathroom with Bath, Shower, Toilet & Wash Hand Basin





Stethoscopes stored above the toilet in the splash zone



Access panel for Bath TMV

Observations

- Cluttered environment. Use of bathroom for lockers and storage
- 2 meter splash zone concerns, especially above the toilet
- Contractors unable to access TMV for Bath due to Christmas Decoration Boxes. Contractors confirmed this was not an isolated case at site
- Bath and Shower unused and stagnant
- Presence of scale

Follow Up

- Educate staff to recognize risk and splash zone management needs
- Remove all stored items from the bathroom
- Remove redundant Bath and Shower
- Create separate storage room and separate staff toilet and wash hand basin

Following assessment of Rock Compliance's RAMS (see appendix A), the document and processes within were not being followed at site by their operative. Additionally, several areas within the RAMS are considered inadequate, or subject to variation in operative behaviours. The methodology appears largely developed from an engineering and health and safety perspective rather than specifically for application within a healthcare environment requiring a targeted hygienic approach. Areas for review and improvement include:

"Disposable elbow length gloves – For healthcare these should be changed per TMV serviced." Gloves must be exchanged frequently during the process on a single TMV/outlet service in order to prevent recontamination of "clean" componentry and prior to hygienic reinstallation. There was no written instruction nor evidence of competent hygienic or aseptic technique witnessed, nor its relevance to this procedure. The use of disposable elbow length gloves is rare, although standard gloves are readily available and commonly used. The operator should be "bare below the elbow" to avoid any sleeve contamination.

"Disposable wipes" A well-used microfibre cloth was witnessed in use as a cover, a surface and to wipe-down the clinical basin and fitting at the end of the process. This action presents a risk of cross-contamination. Even if single use disposable wipes were present, the process to clean operative tools and critical areas, such as a patient wash hand basin or shower cubicle, requires specific "clean to dirty" procedure training. Spread of contamination from a multiple use cloth, contact from the drain to outlet, and outlet to outlet cross contamination is a recognised risk.

"Measuring jug with mL indicator capable of holding at least 500 mL." The jug or container for housing the thermostatic control device should be capable of completely containing and submerging the component, plus in addition, any splash or aerosolisation which may occur during the physical cleaning steps. This will minimise contamination spread into the surrounding environment and onto surfaces.

"Sealable Container" – there should be containers for dirty/used tools and clean/unused tools. Due to the amount of equipment and controlled workspace needed for this process, it is considered best practice to have a trolley with 2 shelves where one shelf is dedicated to clean items and processing, and the other for dirty items and procedures. This enables good user behaviours and a "dirty to clean" workflow which is supportive of hygienic techniques.

"Equipment to be inspected daily and any defects to be reported and appropriate remedial action taken. Operatives will be instructed in the correct use of equipment." Clean tools must be a priority. Tools were witnessed to be rusty and appeared dirty. Tools were set down on inappropriate surfaces such as the clinical waste bin lid and the wash hand basin. Tools must be cleaned by a verified method which may include being washed in a surfactant solution and subsequently disinfected at the end of the

day, stored dry in a clean container, wiped down thoroughly with a single use disposable wipe (e.g. Clinell Universal Wipe) at the end of each disassembly and prior to reassembly of any cleaned componentry.

"Carry out site specific safety risk assessment including taking into account waste disposal routes and special precautions." It is critical that GMS and the Trust have agreed appropriate locations for used fluids (e.g. Showerhead Plus) and wipes to be disposed of safely. This location, for example, may be in a Dirty Utility with used fluid disposed of in a macerator and single use wipes placed in correct clinical waste bins.

"Mix a solution of 1 part Showerhead Plus to 3 parts water as per manufacturers specifications. This should be stored within a sealable container while being used on site to prevent spillage. When the product colour changes from yellow to blue/green, fresh solution should be used." Fresh solution, made up in a clean dispensing container, should be used for each component to avoid crosscontamination from one outlet to another. The water for making up the solution should be of a known quality, ideally either 0.2 micron sterile filtered water or made up with bottled sterile water, to avoid introducing contamination.

"Turn on cold tap until a suitable flow rate is reached, allow outlet to run but for no longer than 2 minutes. A calibrated thermometer and penetration probe required to be placed under running water and temperature should be continuously recorded until temperature stabilises at which point temperature is to be recorded. Outlet temperatures required to be less than 20 °C to comply with requirements of HSG 274." The instructions within the RAMS for hot and cold temperature data collation is good. However, the written process was not followed nor witnessed: no timer was used, no details on temperature stabilisation or fluctuations. It is also important to recognise that new build or refurbishment projects following NETB 2024/3 should have stable, compliant hot and cold water temperatures reached within 30 seconds. There is no mention of NETB 2024/3 within the RAMS which suggests the document is outdated.

"Turn on the hot tap until a suitable flow rate is reached, allow outlet to run but for no longer than 1 minute. A calibrated thermometer and surface probe requires the temperature to be taken from prior to the TMV, but as close to the TMV as possible and the temperature should be continuously recorded until temperature stabilises at which point temperature is to be recorded. The temperature correction should be made in line with Table 1 in section 14 below. Outlet temperature required to be greater than 55 °C in healthcare premises to comply with the requirement of the HSG 274."

The instructions within the RAMS for hot and cold temperature data collation is good. However, the written process was not followed nor witnessed: no timer was used, no details on temperature stabilisation or fluctuations. It is also important to recognise that new build or refurbishment projects following NETB 2024/3 should have stable,

compliant hot and cold water temperatures reached within 30 seconds. There is no mention of NETB 2024/3 within the RAMS which suggests the document is outdated.

Temperature corrections (as illustrated in table 1 within RAMS document) are dubious, and also very dependent on the pipe materials, the level of scale build up within the pipe and contact of the probe with the pipe. Where continuous remote monitoring sensors are used, the difference between water and pipe surface temperatures has been evidenced as minimal, even with thicker rolled copper, older installations or plastic pipework, and is generally less than 1 ^{o}C variable to the water temperatures.

"Table 1 in section 14" allows for large temperature variations from -7 ^{o}C - + 39 ^{o}C. For copper pipework, variations are adjusted for -2 to + 2 ^{o}C. This table is not referenced correctly, but is believed to be from an elderly BSRIA document (September 1994) which is no longer available.

To avoid potential false temperature passes or failures, our recommendation is that the raw temperature data should be captured, without adjustment, with any failed or borderline temperatures investigated, and where necessary remediated and verified by the respective Estates Officers or their CP(s).

Risk Assessment Section:

"Chemical / Biological Exposure – If possible, carry out works away from the area of potential exposure, or use an alternative material that the hazardous substance. If this is not possible, then ensure that all the information relating to the hazard is available from the Safety Data Sheets and carry out a COSHH assessment of the material in the proposed usage. If PPE/RPE is stipulated in the assessment then ensure that this is work at all times during exposure. Appropriate training and information must be evidenced for all operatives as well as appropriated inspection records. For biological hazards, consult the appropriate information sources e.g. Legionella, Leptospirosis etc." Ideally there would be a separate and suitable workshop area for completing these tasks, away from the patient care environment. However, removing a potentially contaminated component from a location requires risk assessment for safe handling and transit. Biological hazard recognition is inadequate within this RAMS, and should include *Pseudomonas*, non-tuberculous mycobacteria and reflect the importance of managing potential contact with antimicrobial resistant organisms. Risk ratings should be adjusted to reflect these well recognised hazards. There is no indication that competence in handling AMR contaminated componentry is included within the specific task training.

"Housekeeping - Poor housekeeping during working can cause problems relating to slips, trips and falls. Chemical exposure due to spillages can result. All working areas must be kept clean and tidy." Inadequate recognition of microbiological hazards, with focus on chemical spillage. Attention to the critical "clean to dirty" cleaning processes

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are not included which may risk cross contamination in the healthcare environment. Healthcare environmental contamination events were witnessed during the observed session, and immediately escalated by Ade Olayiwola.

"Tools & Equipment – Most tasks will require the use of appropriate tools and equipment. All equipment must be inspected regularly, particularly before use. There must be recorded operative inspection and recorded inspections by suitable competent staff." There is no mention that tools must be clean, stored in a clean container, nor regularly cleaned throughout the process of maintenance and service. No mention of the cloths or brushes used for cleaning, nor how frequently they should be disposed of (single use) or decontaminated.

"Behavioural & Human Factors – Ensure that those elements of human behaviour and other human factors are considered in each of the individual assessments listed above, particularly those dealing with training and competency. Only those persons having received the correct training and competency assessments should carry out the specific task." This section is critical for risk recognition. Despite training/competency, behavioural and human factors impact thermostatic control device maintenance and service tasks thus creating potential risk in the patient environment.

Any activity which relies on human intervention is subject to behavioural and human factors, with training, SOPs and use of PPE recognised as being the least effective methods of control (Hierarchy of Control Matrix). Residual risk calculations should reflect this well evidenced matrix. The Trust's strategy to remove water sources (i.e. adoption of a "Waterlite" approach) and reduce the number of thermostatic control devices based on updated scalding risk assessment will support the more effective methods of control – Elimination.

Governance of 3rd Party Contractor Service Provision

Gloucestershire Managed Services (GMS) should determine how this 3rd Party Contractor's competence, to undertake a critical task within the patient environment, was assured prior to tender award and as part of onboarding at site. Evidence for the process followed, the approvals and governance must be sought to avoid similar concerns now and in the future. Questions to confirm include:

- What detail and expectation of service delivery and operative competency was included in the tender?
- How was the technical quality of the bidders measured?
- What training was delivered to the service provider following the contract award and prior to commencement of works?
- Who reviewed and approved the RAMS?
- What checks were made to verify that approved RAMS were being followed and that thermostatic control device testing aligns with, or is an improvement on, guidance (HTM 04-01 D 08)?
- As the Trust remains accountable for water quality and patient safety, how would GMS evidence and provide assurance to the Trust for this (or other services undertaken by 3rd Party contractors) critical service activity?

Gaps remain regarding communication, site intelligence and strategic alignment, which should be reviewed by GMS in risk assessing the suitability of any contractor to deliver service at site as opposed to trained and competent in-house engineering resources. For example:

- How are the failures found in the field reported, escalated and resourced for corrective action?
- There is important feedback to the Trust – both IPC and Clinical teams - where storage of clinical and non-clinical items prevent access to thermostatic control devices for their needed maintenance. How is this reported, escalated and resourced for corrective action?
- If an outlet is taken out of service, how is that communicated to the patient/ward staff/GMS/Water Safety Group?
- What is the typical duration of an "out of service" outlet, and what mitigations are implemented to prevent the outlet becoming a dead leg, and thereby increasing conditions conducive for microbial amplification?
- How do GMS measure risk when activities are completed by operatives under 3rd party contractors at site?

In this example, how was the change in contractor (from Neptune to Rock Compliance) risk assessed to ensure their procedures did not introduce infectious risk?

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- Did the contract stipulate which operatives are allowed to complete the works at site, or could there potentially be a regular burden of both training and witnessing placed on the RP/DRP (Water) at each site?
- How do GMS ensure that the EPIC records (Rock Compliance) are reconciled with internal systems (Zetasafe, Helpdesk, Quality Reporting) and how is this audited?
- What oversight exists over replacement of duty decisions? Was quality vs cost included in that assessment to ensure the maintenance and service processes plus subsequent environmental cleaning did not introduce infection risk?
- How have costs been calculated, and does that bring risk to the process? Where contractors are under time pressures to complete a number of processes within a set period, the unintended consequences are that where isolation valves are difficult to access, where IPS access is restricted due to inappropriate storage of items, or other restrictions, outlets are missed. Delays in maintenance and service would lead to increased water quality ussies and patient risks

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Suggested Best Practice Methodology for Thermostatic Control Device Maintenance & Servicing

(compliant with and aligned to HTM 04-01, British Standard 7942: 2011, Infection Prevention & Control and Water Hygiene practices)

The following maintenance and remedial activities should be planned for, appropriately resourced (CP) and documented:

- *New TMV/T componentry installations:* 1st service 6-8 weeks post commissioning; 2nd service 12-15 weeks post commissioning. 3rd service to align with routine service installations
- *Routine Service Installations:* regular (dependent on WSG risk assessment and manufacturer's instruction) and minimally annual full maintenance and service
- *Routine TMV/T Outlet Temperature Monitoring:* regular (dependent on WSG risk assessment and manufacturer's instructions) and minimally 6 monthly "Failsafe" checks
- *TMV/T Replacement:* at lifecycle exchange, or on failure where performance cannot be restored or maintained, or following persistent positive water sampling results (see New TMV/T componentry installations above)
- *TMV/T Remedial Action:* Following receipt of a failed microbiological sample, the outlet undergoes an investigative, remedial and verification step which includes ○ Lifecycle assessment to determine if a new tap fitting or component should be installed. Where a new fitting is determined appropriate a multidisciplinary team risk assesses:
    - *if the outlet is needed at all*
    - *whether the outlet requires a thermostatic mixing control device or if a non-TMV/T is better suited as the replacement* ○ TMV componentry remedial cleaning which requires asset removal, disassembly within a protected non-patient and clean workshop environment, physical (scrub) cleaning, descaling, disinfection, sterile rinsing, reassembly and hygienic reinstallation. Verification sampling completed a minimum of 5 days post re-installation will determine if remediation activity has been effective

Task training must include perspectives from infection prevention and the patient environment. All outlets and their drains should be considered as hazardous, contaminated items. Any processes involving interactions with outlets and their drains must focus on hygienic workflow and the principles of aseptic technique to avoid cross contamination.

- Ensure any tools required are inspected and confirmed as "clean", having undertaken a verified decontamination procedure prior to commencement of activity.

- Tools should be stored in a clean container following decontamination and undergo a cleaning step between activities and between each outlet to avoid transfer of contaminants between dirty to clean components and outlet locations.
- Tools should be handled in the workflow from "clean" to "dirty" zones, only returning to the clean zone following a cleaning step. Whilst working within patient environments, decontamination steps may include a physical wipe down process with a single use alcohol based wipe followed by an alcohol based spray. One wipe should be used per tool or surface. The wipe must be disposed of immediately within an appropriate waste container. The item should be allowed to air dry following use of alcohol based spray prior to returning to a clean container.
- Ensure any descaling, disinfectant or rinsing fluids are freshly made (minimally every 3 hours), with a known quality water source (e.g. 0.2 micron sterilizing grade filtered water). Fluids should be risk assessed to exchange for new fluid volumes on each item processed.
- The use of a trolley should be supported to carry needed equipment, arranged to support "Clean" and "Dirty" workflows, enable appropriate worksurfaces to be present within the patient environment and provide assurance of safe practice whilst onsite. The trolley should be cleaned and disinfected at the end of each day, or as determined by the Clinical team on exit from a patient (isolation) room.

Task risk assessment must include Clinical team input and support prior to the commencement of works for:

- Consideration for patient safety and environmental contamination risk: assessing patient/occupant exposure to particulates, spores and microbial contamination through completion of all stages of maintenance and service activity, including access to isolation valves (ceiling voids, behind IPS panels).
- A clear 2 meter working zone surrounding the outlet, free from patient items, clinical equipment etc., in order to minimise contamination risk during *in-situ* access, flushing and necessary cleaning activities.
- Agreement on access to appropriate waste disposal (e.g. spent fluids and single use wipes)

Temperature monitoring prior to commencement of service works: The domestic hot water supply must achieve ≥ 55 ^{o}C at the outlet (or thermostatic mixing valve inlet) within one minute of opening the outlet, or within 30 seconds if the area has been designed in accordance with NETB 2024/3. In areas which have not been designed in accordance with NETB 2024/3, a temperature reading at 30 seconds is helpful to recognise areas with poor hydraulic balance.

The hot water return pipe surface temperature must be recorded first, and without opening the outlet (otherwise hydraulic circulation cannot be verified). The hot water

return temperature should continuously achieve ≥ 55 °C at a monitoring point close to the outlet.

The cold supply pipe should be ≤ 20 °C, with ≤ 2 °C heat gain from the mains cold influent source. This temperature should be reached within two minutes of opening the outlet, or within 30 seconds if the area has been designed in accordance with NETB 2024/3. In areas which have not been designed in accordance with NETB 2024/3, a temperature reading at 30 seconds is helpful to recognise areas with excessive stagnancy or potential cross-connections.

As mains influent cold water has a seasonally variable temperature, an appropriate BMS reading should be confirmed at the start and conclusion of each day for the areas undergoing service works. This gives a representative Baseline temperature to assure and compare outlet temperatures. An understanding of heat gain, and whether this is predominantly at the cold water storage tank or within the supply pipe network. Concerns raised regarding cold water temperatures and excessive heat gain should be investigated, remediated and verified in order to reduce risk from microbial amplification

Outlets which are controlled via thermostatic mixing devices should discharge hot water as per the summary table below:

Outlet Location	Maximum Water Temperature @ Point of Discharge
TMV/T Basin Mixer Tap	41 °C
TMV/S Shower Head	41 °C
TMV/T Bath Tap (non-assisted fill)	44 °C
TMV/T Bath Tap (assisted fill)	46 °C

Any TMV/T controlled outlets which are discharging hot water below 39 °C should be considered “failed” and adjusted, or investigated further.

Thermostatic Control Device Failsafe Checks: Isolation valves should be found fully open, closed for the duration of the “FailSafe” testing and opened fully post testing, service or recommissioning

After restoring the cold water supply, continuously record the mixed hot water temperature immediately on opening, after 15 seconds, 30 seconds and 1 minute of opening the tap.

Measure and record the temperature of the mixed hot water discharged at the maximum available flow setting

Verify that these temperatures do not differ by more than 2°C from the initial discharge temperature and by no more than 2°C from the set temperature.

If temperatures vary by more than 2°C from the set temperature, recheck the isolation valves and the supply conditions, readjust the thermostatic control following the manufacturer's instructions for use, and recommission.

If the thermostatic control cannot be adjusted to meet the correct temperatures, risk assess the outlet and its peripheral supply and waste pipeworks for complete removal, replacement with a new outlet fitting or component with or without thermostatic control and recommission in accordance with the manufacturer's instructions.

If the outlet is an elbow operated tap, ensure the tap handle position is aligned as per manufacturer's instructions enabling easy elbow operation and not pushed back to make contact with the wall behind.

Failsafe Check Data Capture Checklist

Test Description	**Measure**	**Pass / Fail**	**Follow Up Action**
Location	**e.g. Zetasafe ID**		
Surface and probe thermometers serial numbers and in-date calibration certificates			
Hot water outlet temperature at maximum flow	**ºC**		
Volume water from outlet post isolation of the cold water supply	**mL**		
Hot water outlet temperature after cold water supply restored	**ºC**		
Deviation of temperature from set temperature	**ºC**		
Isolation valves left fully open	**visual**		

Thermostatic Control Device Maintenance & Service must be carried out once every six months in high-risk or vulnerable patient environments and minimally annually within other healthcare areas to ensure risk from bacterial colonisation and amplification, and potential patient scalding is kept to a minimum.

In addition to the FailSafe Testing described above, the inline and/or integral strainers within and immediately prior to the fittings, plus TMV are physically cleaned and disinfected. This is to mitigate microbial contamination of the water delivered to patients or occupants, and in particular to reduce the presence of waterborne

pathogens such as Legionella, Pseudomonas and non-tuberculous mycobacteria (NTM). The filters/ strainers either from the 'Y' strainers, unions on the TMV or from the tap body and the TMV/T should be accessed and disassembled as per manufacturers schematic diagrams and instructions. Pictorial (photographic) steps are helpful to reinforce training and behavioural actions for the common components and fittings installed within the Trust facilities

When descaling filters/strainers/TMV/T the items must be submerged in the active fluid within a suitable clean container and full contact time made (e.g. Shower head Plus at 1 part in 3 parts water, with 15 minutes contact time)

Physically rub/soft brush the components, containing any splash or "flickage" within the container to avoid environmental contamination, to ensure removal of any stubborn scale or embedded particulates.

Once cleaned, submerge the components in a disinfectant (typically per acetic acid or chlorine) and allow sufficient contact time to meet the disinfectant manufacturer's recommendations having assured material compatibility of the componentry

Ensure gloves are changed before handling the clean and disinfected items. Using clean tools, reassemble any components and reinstall

TMT/TMV Temperature adjustment should follow manufacturers' instruction for use and ideally be supported with pictorial (photographic) steps to reinforce training and behavioural actions for the most common components and fittings installed within the Trust facilities . Critical to this activity is the use of clean tools, hygienic workflow and the activity should adopt the principles of aseptic technique

Non Return Valves (NRV): Checks must be made after works are completed to ensure that NRVs are working properly and as intended. Ensures the cold water supply is not bleeding into the hot water supply and vice versa.

Environmental cleaning will be necessary after an invasive engineering procedure such as FailSafe checks and thermostatic control device maintenance and service, which involve activity and surface contract of wash hand basins, showers, baths and outlet fittings within patient care areas

No works or storage of items should occur on or within the basin, sink or shower tray. This is to avoid any cross contamination and prevent debris (scale, broken seals, rubbers, sealant) from being washed into the drain and ubend.

In some circumstances the Domestic Services team may be required to complete a full cleaning process after the maintenance and service works have been completed. This should be agreed with the clinical and domestic teams.

For the majority of outlets, it will be necessary to remove any visible debris or contamination created during the works. The CP may not necessarily have been trained to undertake the cleaning protocols adopted by the Trust; there must be a level of cleaning knowledge which would include a sequence for wiping down an area with single use wipes. This must reflect movements from clean to dirty areas, frequent changing of wipes, not touching the outlet nor the drain. Poor cleaning techniques at the completion of maintenance and service works can spread contamination and potentially increase risk of microbial exposure to users.

A pictorial guide, illustrating best cleaning practice practical steps at common outlet types, would be an important support piece for those CP individuals undertaking the task at site

Risk Reduction: Whilst the 3rd Party Contractor (Rock Compliance) RAMS could be improved and the updated methodology trained into their Competent Operative(s) approved to be at site, there remains a need for regular witnessing and verification of works to be completed by GMS and the Trust IPC to assure this critical activity.

Proposed Next Steps & Actions

- Arrange an online meeting with Mark Johnston-Wood to present a summary of document content
- Review this document in detail with Ade Olayiwola, Brett Cameron and the inhouse Estates teams, and develop a detailed RAMS supporting FailSafe checks and thermostatic control device maintenance and service for fittings installed at Gloucestershire Royal Hospital and Cheltenham General Hospital. Include discussion on needed competencies and training for individuals undertaking these critical tasks.
- Present the subsequent developed method statement and updated risk assessment to the Trust Water Safety Group and request multidisciplinary (particularly IPC) review, comment and feedback.
- Collate feedback and review an updated RAMS with the Trust Water Safety Group for formal approval .
- Recruit and train either in-house employed resource, or ensure the Procurement team and any 3rd Party service provider are updated, trained and are witnessed to follow the approved Trust RAMS. (NB: The current 3rd Party provider may need to (re)quote against the updated RAMS process)

Concluding Remarks

Service, maintenance and remedial work on water assets or plumbed equipment in patient care areas, or locations where workflows may transmit waterborne organisms (e.g. kitchens and dirty utilities), pose patient safety risks through poor hygiene, environmental contamination, and contamination from unclean tools or hands.

In reviewing the third-party contractor RAMS and witnessing their operative at site undertaking critical tasks, illustrates an increase in patient risk. A multidisciplinary assessment should define task requirements, supported by robust governance for procurement, tendering and contractor onboarding. Clear roles, responsibilities and accountability, competent resources, compliance with agreed methodologies, and effective communication for data capture and fault escalation are essential.

This document outlines good practice for thermostatic mixing device maintenance, identifies gaps in the contractor's activity, and provides recommendations to strengthen governance, improve service delivery, and reduce patient safety risks for Gloucestershire Managed Services.

Thank you for the opportunity to complete this analysis and we look forward to your availability to review and discuss this content at a convenient date.

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Supporting References & Abstracts

- NHS Never Events List. https://www.england.nhs.uk/wpcontent/uploads/2020/11/2018-Never-Events-List-updated-February-2021.pdf *(accessed June 2026)*
- Yetiş Ö, Ali S, Karia K, Bassett P, Wilson P. Enhanced monitoring of healthcare shower water in augmented and non-augmented care wards showing persistence of *Pseudomonas aeruginosa* despite remediation work. J Med Microbiol. 2023 May;72(5).

Introduction. *Pseudomonas aeruginosa* in healthcare shower waters presents a high risk of infection to immunesuppressed patients; identifying the colonization-status of water outlets is essential in preventing acquisition. **Hypothesis/Gap Statement.** Testing frequencies may be insufficient to capture presence/absence of contamination in healthcare waters between sampling and remediation activities. Standardization of outlets may facilitate the management and control of *P. aeruginosa*. **Aim.** This study aims to monitor shower waters and drains for *P. aeruginosa* in augmented and non-augmented healthcare settings every 2 weeks for a period of 7 months during remedial actions. **Methodology.** All shower facilities were standardized to include antimicrobial silverimpregnated showerhead/hose units, hose-length fixed to 0.8 m and replaced every 3 months. Standard hospital manual decontamination/disinfection occurred daily. Thermostatic-mixer-valves (TMVs) were replaced and disinfected if standard remediation unsuccessful. **Results.** Of 560 shower and drain samples collected over 14 time-points covering 7 months, *P. aeruginosa* colonized 40 %(4/10; non-augmented) and 80 %(8/10; augmentedcare) showers in the first week. For each week elapsed, new outlets became contaminated with *P. aeruginosa* by 18-19 % (*P*<0.001) in shower waters (OR=1.19; CI=1.09-1.31) and drains (OR=1.18; CI=1.09-1.30). *P. aeruginosa* occurrence in shower water was associated with subsequent colonization of the corresponding drain and vice versa (chi-square; *P*<0.001) with simultaneous contamination present in 31 %(87/280) of areas. TMV replacement was ineffective in eradicating colonisation in ~83 % of a subset (6/20; three per ward) of contaminated showers. **Conclusions.** We demonstrate the difficulties in eradicating *P. aeruginosa* from hospital plumbing, particularly when contamination is no longer sporadic. Non-augmented care settings are reservoirs of *P. aeruginosa* and should not be overlooked in outbreak investigations. Antimicrobial-impregnated materials may be ineffective once colonization with *P. aeruginosa* is established beyond the hose and head. Reducing hose-length insufficient to prevent cross-contamination from shower drains. *P. aeruginosa* colonization can be transient in both drain and shower hose/head. Frequent microbiological monitoring suggests testing frequencies following HTM0401 guidelines are insufficient to capture the colonization-status of healthcare waters between samples. Disinfection/decontamination is recommended to minimize bioburden and the effect of remediation should be verified with microbiological monitoring. Where standard remediation did not remove *P. aeruginosa* contamination, intensive monitoring supported justifying replacement of showers and contiguous plumbing.

- Hutchins CF, Moore G, Webb J, Walker JT. Investigating alternative materials to EPDM for automatic taps in the context of Pseudomonas aeruginosa and biofilm control. J Hosp Infect. 2020 Nov;106(3):429-435.

Background: Automatic taps use solenoid valves (SVs) which incorporate a rubber (typically EPDM) diaphragm to control water flow. Contaminated SVs can be reservoirs of opportunistic pathogens such as Pseudomonas aeruginosa; an important cause of healthcare-associated infection. **Aims:** To investigate the attachment and biofilm formation of P. aeruginosa on EPDM and relevant alternative rubbers to assess the impact on water hygiene in a laboratory model. **Methods:** Biofilm formation on EPDM, silicone and nitrile rubber coupons was investigated using a CDC biofilm reactor. SVs incorporating EPDM or nitrile rubber diaphragms were installed on to an experimental water distribution system (EWDS) and inoculated with P. aeruginosa. P. aeruginosa water levels were monitored for 12-weeks. SVs incorporating diaphragms (EPDM, silicone or silver ion-impregnated silicone rubber), pre-colonized with P. aeruginosa, were installed and the effect of flushing as a control measure was investigated. The concentration of P. aeruginosa in the water was assessed by culture and biofilm assessed by culture and microscopy. **Findings:** Bacterial attachment was significantly higher on nitrile (6.2×10^5 cfu/coupon) and silicone (5.4×10^5 cfu/coupon) rubber than on EPDM (2.9×10^5 cfu/coupon) ($P<0.05$, $N = 17$). Results obtained in vitro did not translate to the EWDS where, after 12-weeks in situ, there was no significant difference in P. aeruginosa water levels or biofilm levels. Flushing caused a superficial reduction in bacterial counts after <5 min of stagnation. **Conclusion:** This study

did not provide evidence to support replacement of EPDM with (currently available) alternative rubbers and indicated the first sample of water dispensed from a tap should be avoided for use in healthcare settings.

- Quick J, Cumley N, Wearn CM, Niebel M, Constantinidou C, Thomas CM, Pallen MJ, Moiemen NS, Bamford A, Oppenheim B, Loman NJ. Seeking the source of Pseudomonas aeruginosa infections in a recently opened hospital: an observational study using whole-genome sequencing. BMJ Open. 2014 Nov 4;4(11):e006278.

Objectives: Pseudomonas aeruginosa is a common nosocomial pathogen responsible for significant morbidity and mortality internationally. Patients may become colonised or infected with P. aeruginosa after exposure to contaminated sources within the hospital environment. The aim of this study was to determine whether wholegenome sequencing (WGS) can be used to determine the source in a cohort of burns patients at high risk of P. aeruginosa acquisition. **Study design:** An observational prospective cohort study. **Setting:** Burns care ward and critical care ward in the UK. **Participants:** Patients with >7% total burns by surface area were recruited into the study. **Methods:** All patients were screened for P. aeruginosa on admission and samples taken from their immediate environment, including water. Screening patients who subsequently developed a positive P. aeruginosa microbiology result were subject to enhanced environmental surveillance. All isolates of P. aeruginosa were genome sequenced. Sequence analysis looked at similarity and relatedness between isolates. **Results:** WGS for 141 P. aeruginosa isolates were obtained from patients, hospital water and the ward environment. Phylogenetic analysis revealed eight distinct clades, with a single clade representing the majority of environmental isolates in the burns unit. Isolates from three patients had identical genotypes compared with water isolates from the same room. There was clear clustering of water isolates by room and outlet, allowing the source of acquisitions to be unambiguously identified. Whole-genome shotgun sequencing of biofilm DNA extracted from a thermostatic mixer valve revealed this was the source of a P. aeruginosa subpopulation previously detected in water. In the remaining two cases there was no clear link to the hospital environment. **Conclusions:** This study reveals that WGS can be used for source tracking of P. aeruginosa in a hospital setting, and that acquisitions can be traced to a specific source within a hospital ward.

- Yui S, Karia K, Ali S. Evaluation of novel disinfection methods for the remediation of heavily contaminated thermostatic mixing valves and water systems with Pseudomonas aeruginosa biofilm: considerations for new and existing healthcare water systems. J Hosp Infect. 2024 Sep;151:195-200.

Background: Pseudomonas aeruginosa is a leading cause of nosocomial Gram-negative bacteraemia. Water systems are a well-documented source of P. aeruginosa and established biofilms are difficult to remove. **Aim:** To evaluate the efficacy of regular flushing, peracetic acid disinfection, in-tap thermal disinfection, and in-line thermal disinfection to eradicate P. aeruginosa biofilm in a colonized tap model. **Methods:** A simulated tap system was constructed and inoculated with a reference and an environmental strain of P. aeruginosa to form biofilm. Water samples were collected from the taps and P. aeruginosa levels enumerated following disinfection methods. To simulate regular flushing, taps were flushed for 5 min, five times per day with water tested daily. Peracetic acid (4000 ppm) was manually injected into the system and flushed through the system with a pump. Thermal flushing at 60 °C was performed in-line and with an in-tap bypass valve. Tests were conducted with cross-linked polyethylene (PEX) piping and repeated with copper piping. **Findings:** Regular flushing and peracetic acid applied with a pump did not reduce P. aeruginosa levels. A limited reduction was observed when manually injecting peracetic acid. In-tap thermal flushing eradicated P. aeruginosa in copper piping but not PEX. In-line thermal flushing was the most effective at reducing P. aeruginosa levels; however, it did not eradicate the biofilm. **Conclusion:** In-line thermal flushing was the most effective method to remove P. aeruginosa biofilm. Results vary significantly with the strain of bacteria and the composition of the plumbing. Several methods used in combination may be necessary to remove established biofilm.

- Prokopenko M, Reed AJM, Chicco M, Issa F. Preventable Burns from Domestic Tap Water. Eur Burn J. 2022 May 9;3(2):362-369.

Tap water scalds from domestic outlets can afflict large body surface areas. Such injuries are preventable and carry significant associated morbidity, mortality, and economic burden. Previously identified risk factors include age (<5

or >65 years old) and the presence of physical or mental disabilities. Education campaigns and advances in legislation mandating the restriction of tap water temperature at user outlets have been employed in an attempt to prevent such injuries. Nonetheless, the incidence of these injuries persists, and further mitigating measures must be implemented to minimize their occurrence. The purpose of this study was to determine the groups at risk for such injuries and whether this has recently changed. A retrospective observational study was carried out to include patients admitted with tap water scalds to a regional burn's unit from October 2016 to September 2020. Twenty-three patients were included, and their incidence was 5.75 cases per year, equating to 5.1% of all scalds requiring inpatient treatment. The very young (<5 years old) and elderly (>65 years old) accounted for the majority of admissions (65.2%), 26.1% had a mental disability, and 30.4% had a physical disability. Tap water scalds continue to cause preventable injuries affecting all ages, and in particular, the elderly and patients with pre-existing disabilities.

- Meda M, Gentry V. TMVs in health care: Pseudomonas aeruginosa HCAI vs scalding risk - more can be done. J Hosp Infect. 2022 Nov;129:113-114.

Thermostatic mixing valves (TMVs) are an integral part of taps and showers in many UK healthcare settings, and are commonly used globally to regulate water temperatures, primarily designed to preventing scalding incidents. These are recommended as part of engineering controls to prevent water of temperature >44 °C being discharged from outlets by the Health and Safety Executive, UK.

At Frimley Health National Health Service (NHS) Foundation Trust, the majority of taps have been fitted with TMVs. During 2018, high levels of *Pseudomonas aeruginosa* were detected persistently from a few taps in one neonatal intensive care unit (NICU). All attempts at eradication, including advising staff regarding appropriate use of handwash basins, monitoring practices of use and cleaning, disinfection of outlets, use of acetic acid in drains, and changing taps, were unsuccessful. Following this, a risk assessment was made in conjunction with the NICU matrons, and a decision was made to change all outlets in the NICUs to non-TMV outlets. Immediately after this, the problem with recurrent *P. aeruginosa* detection reduced to minimal levels. Following this incident and successful implementation of non-TMV taps in the NICUs, the Water Safety Group agreed that all taps in augmented care units and 'staff-only' areas should be replaced with non-TMV taps following a risk assessment led by matrons in the respective areas. Subsequently, this has been rolled out to other areas of the Trust where the scalding risk of vulnerable patients was assessed to be low. This has led to an overall reduction in the number of outlets that have tested positive for *P. aeruginosa* in the Trust, and hence an overall reduction in the costs associated with repeat water testing and remedial works when such outlets detect these pathogens. Based on this, the current process of the Water Safety Group for taps that have persistent detection of *P. aeruginosa* is, firstly, to risk assess the need for handwash basins and remove them when they are unnecessary, and, secondly, to risk assess and replace TMV taps with non-TMV taps, working closely with the clinical teams for the area. Since 2018, nearly one-third of the 3439 taps present in the Trust have been replaced with non-TMV taps. No scalding incidents have been reported to date.

Health Technical Memorandum (HTM) 04–01: Supplement – Performance Specification D 08 suggests that a risk assessment should be carried out, and the 'application for washbasin use is included for those situations where the risk assessment shows that a greater level of protection is necessary'. Also, Health Building Note (HBN) 00–01 – Part C recommends that the water temperature at the point of delivery should be controlled by manual control (separate hot and cold water taps or blending valves controlled manually by the user), and suggests that 'assemblies that use manual control should be subject to a "duty of care" risk assessment'. Furthermore, HBN 00–09 – Infection Control in the Built Environment suggests the use of non-TMV taps in kitchens and clean/dirty utility rooms to allow user control of water temperature, as well as in intensive care units and other critical care areas, where patients are unlikely to be able to use handwash basins following a risk assessment. This recommendation also exists in HTM 04-01 Part C: *Pseudomonas aeruginosa* – Advice for Augmented Care Units In addition, the recently published British Standard 8580–2 emphasizes that a scalding risk assessment should be performed for ascertaining the requirement for TMVs where the risk of scalding by whole body immersion is present.

However, current practice with newbuild contracts in NHS England from the authors' experience and noted elsewhere is that taps with TMVs are default fixtures throughout these newbuild projects, unless this is recognized and amended during the commissioning process.

A patient 'scalded by water used for washing/bathing' is required to be reported as a 'never event' in the NHS. Scalds from water being used for purposes other than washing/bathing (e.g. from kettles) was introduced as a 'never event' by NHS England in 2011. From data available on these 'never events' in England, five events relating to scalding have been reported (patient scalded in bath, patient scalded in shower, small area of redness to buttock

as bath water temperature not checked, water temperature increased during use, burns to feet from soaking in a bowl of water). No data are available on scalding incidents prior to 2011. The low numbers may be due, in part, to the presence of engineering controls, such as the presence of TMVs in most water outlets in healthcare settings. Scalding from tap water is unlikely to result in life-threatening outcomes in non-vulnerable patient groups. Although it is difficult to establish exactly how many healthcare-associated infections (HCAIs) related to *P. aeruginosa* and other water-related pathogens occur each year in the NHS, there have been high-profile incidents that have caught the attention of the media and the public, including the death of four babies in a neonatal care unit in Northern Ireland in 2011–2012. It is likely that many HCAIs, such as pneumonia/surgical site/wound infections due to *P. aeruginosa,* from water sources in healthcare settings go unrecognized and underreported, and are therefore under-investigated. Techniques such as whole-genome sequencing have made it possible to link such infections to TMVs.

Is it time for a mandate in the NHS, especially in newbuild contracts, for all taps in areas which are risk assessed to be low risk for scalding to be of non-TMV type?

- Health Technical Memorandum 04-01: Supplement Performance specification D 08: thermostatic mixing valves (healthcare premises). 2017