Scottish Hospitals Inquiry Witness Statement of Questions and Responses Tom Makin

This statement was produced by the process of sending the witness a questionnaire with an introduction followed by a series of questions and spaces for answers. The introduction, questions and answers are produced within the statement.

Personal Details

- Please set out your professional background and qualifications. Please describe the activities of Makin and Makin Consultancy Limited and explain when and why you decided to set it up. What are its specialisms? Do they reflect your own?
- A Dr Thomas Makin BA, PhD, FIBMS, FRSPH, FWMSoc, CSci. I was employed from 1968 in the NHS initially as a Medical Laboratory Technician and subsequently as Biomedical Scientist. I worked in various hospitals in Liverpool - Newsham General Hospital, Mill Road Maternity Hospital, Broadgreen Hospital, Liverpool Royal Infirmary (LRI), and latterly at the Royal Liverpool University Hospital (RLUH).

After undergoing rotational training in all aspects of medical laboratory sciences (Haematology, Medical Microbiology, Clinical Chemistry and Histopathology) I specialised in Medical Microbiology while at Newsham General Hospital. I occupied posts of Senior Biomedical Scientist at LRI, and Chief Biomedical Scientist and Senior Chief Biomedical Scientist at RLUH. My last post in the NHS was Directorate Manager of Medical Microbiology at RLUH and I retired from this in 2010.

As a Biomedical Scientist in the department of Medical Microbiology at the RLUH I investigated an outbreak of Legionnaires' disease (LD) which occurred at the RLUH shortly after it opened in 1979. There was little known about this disease or the causative organism (Legionella) in the UK at this time as this was just 3 years after the first recognised outbreak of LD which occurred in the Bellevue Stratford hotel in Philadelphia in the USA in 1976 at an American Legionnaires' conference. This generated my interest in Legionnaires' disease and waterborne infection in general.

I have published several papers on Legionella and water quality in peer reviewed journals and technical journals and have presented many papers at various conferences and seminars in the UK, USA, Europe and Middle East. I submitted my thesis on Legionnaires' disease in the hospital environment and was awarded a PhD in 1995 by the Medical Faculty at the University of Liverpool.

I was invited by the UK Health and Safety Executive to participate as a co-author in producing the first Approved Code of Practice (ACoP) and Guidance (L8) on Legionnaires' disease: The Control of Legionella in Water Systems which was published in 2001, and I assisted the HSE in updating this document which was published as separate ACoP and guidance (parts 1 to 3) in 2014.

I have advised the Department of Health and many hospital Trusts on managing risks and complying with guidance and relevant regulations regarding water quality. I assisted in the production of NHS Estates Technical Memorandum on the Control of Legionella in Health Care Premises (HTM 2040) and was a member of the working party that produced the Department of Health Legionella guidance (HTM 04-01) which replaced the previous guidance (HTM 2040 and HTM 2027) in December 2006. I was a member of the steering group that produced the updated HTM 04-01 which was published in 2016. I assisted the Department of Health was published in 2016. I assisted the control of *Pseudomonas aeruginosa* in water systems in augmented care units which was released in March 2013.

I was a member of a committee of the Standing Group of Analysts (Environment Agency) which produced the technical guidance on the sampling of water systems for legionella bacteria BS: 7592:2008, this was in use until it was updated in 2022. I developed a procedure for the rapid detection of legionella bacteria in water systems, and using antibody techniques monitored the incidence of legionella infection in immuno-compromised patients and others in the Royal Liverpool University Hospitals (PhD thesis).

I managed a 3-year collaborative study for NHS Estates, which evaluated the efficacy of a biocide (chlorine dioxide) in controlling legionella bacteria in the hot and cold water system of a hospital where an outbreak of Legionnaires' disease had occurred. The outbreak was resolved following dosing of the potable water system with chlorine dioxide.

I have evaluated the efficacy of a variety of other measures for controlling legionella and other bacteria in hot and cold potable water systems, including regular flushing of outlets, self-purging showers, trace heating elements, automatic drain valves, ultra-violet light systems, re-circulating cold water systems, downward displacement v swan neck taps, and point of use filters.

I am a Fellow of the Institute of Biomedical Sciences, A Fellow of the Royal Society of Public Health, a Fellow of the Water Management Society and a Chartered Scientist.

Makin and Makin Consultancy Ltd was incorporated on 16th February 2007. It comprises me as Director and sole consultant and Ms S A Makin, microbiologist and company secretary. The company advises on a range of issues associated with the control of legionella and other microorganisms in a variety of water systems. It has advised on microbiological contamination of air, food and foodstuffs, and water used in industrial processes. Makin and Makin Consultancy Ltd can

undertake water quality audits and has provided services as expert witness, and Authorising Engineer (water) in healthcare premises advising Water Safety Groups.

Makin and Makin Consultancy Ltd has provided services to government agencies in the UK and other countries and municipalities, various large manufacturing companies, Estate and Facilities Management companies, water treatment companies, Metropolitan/Borough Councils, hospital Trusts and other health care premises, hotel chains, cruise lines and others. Currently, services are provided predominantly to healthcare premises.

I decided to set up Makin and Makin Consultancy Ltd because I was approaching retirement after 42 years as a medical microbiologist in the health service and felt that given the amount of knowledge I had acquired on water quality over many years and the time I had invested in ensuring that water systems were managed to prevent microbial contamination and associated waterborne disease, that it was inappropriate and wasteful to end my association with water systems when I retired. I enjoyed the link between environmental and clinical microbiology and wanted to keep on using the knowledge I had to provide practical advice and guidance on water quality particularly to health care premises.

Your Initial Involvement with QEUH/RHC

2. The Inquiry understands that you first became involved in the QEUH/RHC after being contacted in April 2018. Who made initial contact with you? What reasons were given at that time for your involvement? What were you told at that point about issues at the hospital for which your input might be useful? Was that sufficient to enable you form an understanding of what might be involved?

A I was first contacted via LinkedIn in April 2018 by Ian Storrar (IS) who I believe was Principal Engineer for Health Facility Scotland at that time. IS may have attended a lecture I gave on microbial aspects of water quality at a seminar in Scotland or one I gave in the Northeast of England. I was asked if I could assist at Queen Elizabeth University Hospital and the Royal Hospital for Sick Children (QEUH) with a water quality issue they had in their potable water system. IS didn't provide a lot of detail but asked me to contact Ian Powrie (IP), Deputy General Manager, Estates at QEUH to get more information and to arrange a visit to the hospital.

I contacted IP by email on 27th April 2018. He telephoned me on 30th April 2018 and provided me with more information, and that evening contacted me by email inviting me to attend QEUH to see the size and configuration of the water system. The email IP sent contained a plan of the site, a draft meeting report dated 25.04.18 produced by Dr Susanne Lee FAO Theresa Inkster **(A38271789 – Glasgow draft report)**, a report referred to as QEUH sanitisation paper (Rev 2) dated 26.04.18, a water services schematic diagram for QEUH, and a diagram showing the storage tank arrangement, filtration plant and booster pumps at QEUH.

Dr Susanne Lee's (SL) report outlined various factors contributing to microbial contamination of the potable water system. SL had attended QEUH in April 2018 and her report on microbial contamination of the water system focussed on the children's hospital. On the day I attended the first meeting at QEUH (10.05.18) IP emailed to me a spreadsheet of microbiology results from many water samples collected on 2nd and 3rd of May 2018.

The discussion with IP on the phone and the papers provided indicated that there was extensive microbial contamination of the potable water system with a range of different microorganisms, and that the water system appeared to be the source of infection in some immunocompromised patients in the haemato-oncology unit on wards 2a and 2b.

I first attended QEUH on 10th May 2018. I met with IP about 8.30am in his office in the Laboratory Medicine and FM centre. We talked for a while about the issues at QEUH and the extent of the microbial contamination and possible sources. I was then given a relatively brief tour around parts of the site focussing on the potable water systems. It was a very large site and I only saw part of it as I was required to attend a meeting at 11am with members of the Incident Management Team which I believe was specifically arranged for me to be introduced to the team and some of the issues they were dealing with regarding the contamination in the potable water system.

I also met with Dr John Hood Consultant Microbiologist that morning. I had met Dr Hood many years previously (circa 1995) when I was organising the first hospital-based trial of chlorine dioxide (CIO2) at Broadgreen Hospital in Liverpool. Dr Hood had heard of the trial and visited me to discuss it as I understand he had a Legionella contamination issue at that time at Glasgow Royal Infirmary (GRI) for which he was considering using CIO2.

Dr Hood subsequently published a paper in the American Journal of Infection Control (2000.28(1) p.86) entitled; *Six years' experience with chlorine dioxide in control of Legionella pneumophila in potable water supply of Glasgow Royal Infirmary* (A49541924 – Extract – American Journal of Infection Control – 4th Decennial International Conference on Nosocomial and Healthcare – Hood et al – Page 86) (A49542934 – Dr T Makin – Screen Shot – Reference list showing publication of Hood et al (2000) American Journal of Infection Control – Issue 28 Volume 1). I believe the paper reported that CIO2 had been effective in controlling the contamination. Dr Hood's knowledge and expertise in this area will have been of value to QEUH at this time. After being shown around parts of the site by IP, I attended a meeting and met with some of the members of the Incident Management Team. I believe this was attended by IP, Dr John Hood, Ian Storrar, Annette Rankin (Nurse Consultant IPC), Dr Teresa Inkster (Lead Consultant IPC), and Mary Anne Kane (Interim Director of PPFM).

I did not receive a formal contract or terms of reference for my engagement and as far as I can recall it was not explained to me how long my services would be required. I was invited to attend some of the Water Technical Group meetings (WTG) also referred to as the Water Review Meeting [Technical], and I was asked to produce two reports on Clorious2 and manual v automatic flushing of taps. Purchase orders for my services were provided as and when I was required to produce a report or attend a WTG meeting.

I was informed that I would not be required to attend all the WTG meetings, and my engagement did appear to be largely on an ad hoc basis. I normally inquired after each WTG meeting that I attended when I would next be required.

After one gap of three months without contact from QEUH I inquired if my services were still needed. I was informed by IP that they were but the next WTG meeting I attended was not for some months, a total of eight months between meetings. This raised initial concern for me because to maintain control of the water system I felt regular meetings were important, and I was not aware if WTG meetings occurred in my absence. From minutes I received of WTG meetings that I did attend I became aware that other WTG meetings were taking place, and from the minutes provided in the bundle it appears that these were frequent, which is reassuring.

Bundle 10 of the papers for this inquiry contain minutes from Water Technical Group / Water Review Group meetings from 6th April 2018 to 22nd April 2021 (A47395429). During this three year period there were 55 meetings and as far as I can recall from my diary and notes I attended 8 of these WTG meetings. It appears from the available minutes that the meetings were originally weekly but became biweekly, monthly, and then moved to approximately every two months. I attended WTG meetings on the following dates 27.06.18, 31.08.18, 26.04.19, 19.07.19, 16.08.19, 13.09.19, 17.04.20, and 18.09.20 which I believe was my last meeting at QEUH.

In attending these meetings and receiving correspondence and documents by email, mainly from IP, I believe the information I was given was adequate to enable me to form a reasonable understanding of the extent of the contamination at QEUH and what was involved in controlling it, although I was not involved in the detail of all of the various control measures.

I am now aware that there was information available at that time which I don't recall seeing until quite late into the period of my engagement e.g. the 2015 Legionella risk assessment which identified several deficient features of the water system and its management. This information would have been useful for me to see, but it wouldn't have made a significant difference to the advice I gave to the hospital.

As I understood it my role was to provide advice on the prospective measures for controlling microbial contamination of the water system to help reduce risk of nosocomial waterborne infection, rather than focussing on the possible causes of that contamination, although some knowledge of the latter was appropriate.

3. The Inquiry understands that that first contact led to a meeting at the hospital in May 2018. Who were you dealing with during that intervening period? Were you given further information prior to the meeting? Were you content that what you were provided with would be sufficient to address the issues that you understood at that time might be involved?

- A My main contact at the hospital until he left on 2nd July 2019 was lan Powrie (IP). Prior to my first meeting on 10th May 2018 IP provided me with various documents listed in Q2 above. I believe the information I was given was adequate to commence with as further information was revealed in the meetings with IP and the Incident Management Team. See my response to Q2.
- 4. Who was that meeting with, in May 2018? How was the then state of the water system at the QEUH/RHC described to you? What were you asked to do for NHS GGC? Did the issues raised at that meeting reflect the issues raised upon the initial contact? Did you have confidence at that time in the people with whom you were meeting, in terms of their knowledge of the water system?
- A See my response to Q2. I was informed by Ian Powrie (IP) before and at my meeting with him on 10th May 2018 that there was extensive contamination of the water system and that a wide variety of bacteria and some fungi had been detected in water samples. I can't fully recall when, but I understand that around the time of the first meeting or shortly afterwards I was informed that bacteria had been recovered in large numbers from tap flow straighteners.

As I recall, at the meeting with members of the Incident Management Team on 10th May 2018 I was asked to briefly give my opinion on the likely source of the contamination in the water system and suitable control measures. I mentioned my experiences at other hospitals and particularly regarding contamination following construction of new buildings and refurbishing of wards. I commented on my experience with chlorine dioxide and other biocides. Subsequently, on 8th June 2018 I was asked by IP to produce a report on an assessment of the biocide Clorious2 for the treatment of the hot and cold water system at QEUH, and on 27th June 2018 I was asked by IP to produce a report on manual v automatic flushing of taps. My initial contact at QEUH was IP and he remained my main contact until he left the hospital on 2nd July 2019. In my opinion he was very knowledgeable of the water system at QEUH, and he appeared thorough, effective, and keen to resolve the issue of the contamination in the water system. The members of the Incident Management Team (IMT) who I met on 10th May 2018 all appeared very competent and committed to resolving the problem of the contaminated water system. From the available minutes it was apparent that some of the IMT had been attending weekly meetings as members of the Water Technical Group (Water Review Meeting) since 6th April 2018 and had discussed many aspects of the water system and various remedial measures.

- 5. What did you discuss at the meeting? What role was decided upon for Makin and Makin?
- A Please see my responses to Q2 and Q4. On behalf of Makin and Makin I was to attend the WTG meetings to which I was invited and advise the hospital where I could on the contaminated water system and produce two reports on biocide dosing and manual v automatic taps.
- 6. When did you first get to see the water system? Please describe, to the best of your recollection, your initial thoughts about the issues raised? In particular, did you have any concerns about its size and complexity, its operation or its management?
- A I first saw the hospital and its water system on 10th May 2018. I do recall approaching it for the first time and discovering that it had been built next to a sewage treatment facility. I was shocked by this and did comment on it when I first met Ian Powrie (IP). I was very puzzled as to why it had been allowed given that the hospital contained very immunocompromised patients. I was concerned regarding the possible implications for the hospital and its patients arising from potential increased transmission of microorganisms from the sewage treatment facility. Airborne transmission of microorganisms from sewage treatment works is well documented.

After my initial meeting with IP he showed me around parts of the hospital water system. The hospital was very large, one of the biggest I had encountered in my career, and it became increasingly clear to me given its size and complexity that the contamination of the water system could prove difficult to control. I recall considering that new hospitals often suffer from contamination of the water system arising during the construction phase and how it can be difficult to manage the quality of the potable water following occupation of the building as higher levels of biocide used to control the contamination can't readily be used.

It was reported that large numbers of different types of bacteria had been recovered from various parts of the water system and some of these had been associated with infection in immunocompromised patients. The presence of such a variety of bacteria suggested to me the presence of established biofilm within the system and as bacteria were detected in various locations it indicated the contamination was widespread.

I was concerned that biofilm may have been allowed to develop during construction of the building after the hot and cold water systems had been filled, because in my experience once biofilm becomes established early in the development of a building it can prove very difficult to control, and it is not unusual to encounter microbial contamination in the water systems of newly opened hospitals due to the problems that can occur during construction.

Dr Susanne Lee's report (SL) dated 25.04.18, noted that the water system had been filled during construction and remained so for over 12 months prior to it receiving patients. If regular flushing did not occur during this period, then water in the cold water system in particular would effectively stagnate or remain relatively static and this would encourage heat gain and associated biofilm development in different parts of the cold water system. The hot water system is designed to continuously circulate even in the absence of tap outlets opening, so providing this circulation is properly balanced it should not stagnate except for the areas after thermostatic mixing valves where hot and cold water is blended immediately prior to a tap or shower outlet.

I am not aware if regular flushing of water outlets did take place during this period. However, in a system as big as QEUH even regular flushing of outlets prior to occupation would probably be insufficient to control the buildup of microorganisms in various parts of the water system, and in my opinion additional measures such as continuous dosing with a biocide as soon as the water system is filled, combined with regular flushing of all the outlets would have been necessary. SHTM 04-01 (part B section 7.6) states that continuous dosing with appropriate biocides that have proven efficacy should be considered during construction to prevent the accumulation of biofilm.

SL's report also noted there was no data available on water temperatures as the hospitals computerised Building Management System had been faulty. This raised other concerns because the main microbial control measure in most hot water systems is maintaining hot water from calorifiers at >60degC and at outlets at >55degC. Failure to maintain these temperatures can allow microorganisms to survive in the water system and can even encourage their growth and development if temperatures between 20 and 45degC persist.

I had no immediate concerns at the time that I was engaged by QEUH regarding how the contamination of the water system was being managed, at least by the people who I met at QEUH, because it was evidently an issue of high importance to the hospital and involved a large multidisciplinary group who appeared capable and met regularly to discuss the various findings and options, and who sought the advice of various external experts in the field of water quality.

I recall being impressed around the time of the first meeting with how much work had been done in identifying the extent of the contamination and the various possible causes such as the discovery of the contaminated tap flow straighteners, and the consideration given to appropriate control measures.

I did have concerns about how the water system had been managed and operated after it had been filled during construction and if outlets had been flushed regularly up to the point where the hospital received patients. It also concerned me that biocide treatment did not appear to have been used during construction as soon as the water system had been filled, and it wasn't clear if the hot water temperatures recommended in guidance had been achieved throughout the hot water system. These and other factors mentioned when I was assisting QEUH would have contributed to the microbial contamination detected in the water system.

- 7. Had you at that time seen the 2015 DMA Canyon Risk Assessment report 'L8 Risk Assessment (Pre-Occupancy) NHS Greater Glasgow and Clyde South Glasgow University Hospital 29th April 2015'? please refer to Bundle 6, Miscellaneous Documents, Document No. 29, Page 122 When did you first see this document?
- A I don't recall seeing the DMA Risk Assessment report (29.04.15). The documents I saw when I was first engaged are listed in my response to Question 2
- 8. Who showed it to you and when? What were your immediate thoughts?
- A I don't recall when I first saw the DMA Risk Assessment report
 (29.04.15) but I don't believe it was around the time of my first meeting at QEUH.
- Are you aware of further DMA Reports in 2017 and 2018, please refer to Bundle 6, Miscellaneous Documents, Document 30, Page 416. When did you see those? Please describe your views on them (taking time to read them if not already seen).
- A I don't recall seeing DMA reports 2017 / 2018 prior to this inquiry.

I was able to access the 2017 DMA report from the inquiry bundle. It is a Legionella risk assessment (LRA) which took place predominantly in September/October 2017 with follow up analysis taking place in January 2018. The LRA identified several risk areas at QEUH that could support the growth of Legionella and other waterborne microorganisms. Some of the more significant risks listed in the LRA include:

- Filtration units unable to fill other tank under fault conditions. (2015 LRA noted filtration system was bypassed during the initial occupation phase)
- Cold water tank 2B was not turning over as well as others with evidence of heat gain
- Debris in the cold water tank indicates the filtration system may not be working or is bypassed
- Debris and washers in the tank in 2015 and 2017LRA suggest they are not inspected and not cleaned/disinfected and queries competency of staff doing inspection
- Water tanks (1A and Trades water tank) valved off and creating a deadleg. Trade tank isolated for approx 3 years = deadleg with no evidence of flushing
- Expansion vessels not flushed, not insulated, not flow through
- Calorifier drains no evidence of flushing, dirty water increase flushing
- Calorifier return temperatures consistently below recommended 55 deg
 C
- Numerous dead legs on the domestic water system within plantrooms and risers
- Evidence of heat gain on the cold water system up to 30 deg C
- TMV's limited evidence of TMVs being serviced in high risk areas and no evidence of this in non-high risk areas
- Showers unable to confirm service history
- Written scheme provided by DMA in 2015 not updated. Legionella management structure and PPM program not updated.

 Authorised Person (water) – no training in the control of Legionella or other bacteria has limited knowledge of the water systems on site and the requirements of L8, HSG 274 and SHTM 04-01.

There are several significant concerns from the 2017 LRA, which would all have to be rectified within a suitable time scale as indicated in the LRA.

Particularly notable risks are:

- the AP (water) had received no training on the control of Legionella/other microorganisms,
- no service history for the showers and most TMVs were not serviced,
- evidence of significant heat gain in the cold water system,
- inadequate calorifier return temperature,
- same debris in the CWS tanks in the 2015 and 2017 LRA indicates not cleaned and not inspected properly,
- various and numerous dead legs on the hot and cold water system,
- expansion vessels not flushed

It of significant concern that the 2017 LRA report by DMA summarises with the following statement - *The information gathered highlights significant gaps in the Legionella (and potentially other bacterial) control on site both in terms of management processes and the implementation of the recommended planned preventative maintenance tasks.*

This LRA highlighted that management and processes to control risks in the potable water system, particularly planned preventative maintenance, were not in place and that parts of the water system were conducive to the development of Legionella and other microorganisms in September/October 2017 and in some cases there had been no change regarding these risks since 2015. The LRA indicates that these risks were not being adequately addressed and they probably contributed to the widespread contamination of the potable water system that was monitored effectively for the first time in February and March 2018 following initial testing of outlets. During this initial testing 77% of 98 water samples collected from the children's haemato-oncology unit tested positive for the indicator bacterium *Cupriavidus pauculus* (T. Inkster et al. JHI 111.2021.53-64).

- 10. Were you shown the Intertek Reports, please refer to Bundle 18, Volume 1 of 2, Documents 3 and 4 at pages 82 and 91 respectively; and individually in the Objective Connect file entitled "Water Technical Group Intertek Investigation into Contamination of Flow Straighteners 11 July 2018? When were they shown to you and by whom? What were your thoughts?
- A The Intertek (interim) report (ITSS-0718-0001W) dated 11.07.18 was emailed to me by Ian Powrie (IP) on 25.07.18. It provided results of laboratory analysis carried out on17 flow straighteners removed from taps in various wards around the hospital, and results of analysis on drains from hand wash basin, and analysis for biofilm in two sponges recovered from one of the hospital's cold water storage tanks. The full Intertek report, also dated 11.07.18, is more extensive and in addition to the analysis in the interim report it evaluated microbial contamination in unused flow straighteners over time. I received a copy of this report in an email from IP on 30.08.18 and it was an agenda item to be discussed at the WTG meeting the following day.

Both reports show that very large numbers of a wide range of bacteria were recovered from all flow straighteners. These were mostly common environmental organisms (heterotrophs) that would not be regarded as harmful for most people, but some of these may cause infection in severely immunocompromised patients. The presence of large numbers of a wide variety of heterotrophic bacteria indicates that conditions in the water system were also likely to be conducive to the presence of waterborne pathogens. *Stenotrophomonas maltophilia* was detected in two flow straighteners and this is recognised as an opportunistic waterborne pathogen that has been recovered from infections in hospitalised patients.

Of the 17 flow straighteners tested, 9 showed heavy visual fouling and 12 produced a strong instant reaction for biofilm. These results indicate that the flow straighteners were heavily contaminated with bacteria and were colonised with biofilm to various extents.

The full Intertek report provided in the bundle contains the results of analysis of 25 unused flow straighteners that were fitted to taps and were tested for bacteria over time. Prior to installation in taps these flow straighteners contained only small numbers of bacteria and no biofilm was detected. The flow straighteners were tested over a period of more than a month and the results show they contained increasing numbers of a wide range of bacteria and after a month showed a 500,000 fold increase in bacteria. At this stage all flow straighteners tested positive for biofilm and over 70% were heavily positive for biofilm.

The Intertek report also analysed results of water testing (provided by QEUH) for each floor of the hospital, and this showed that an average of around 40% of the samples collected from each floor (basement to 11th floor) were positive for bacteria and 60% of samples were positive on the 5th floor. It is not clear if this section of the report is referring to Cupriavidus or general bacteria.

Further analysis showed that 12 of 16 expansion vessels were contaminated with Cupriavidus and the report noted these vessels have a high potential to contaminate the water system. The sponges recovered from the cold water storage tank also contained biofilm but the report does not indicate if they underwent quantitative testing for bacteria. One of the two drains analysed gave a strong reaction for biofilm. Drain samples are normally colonised with biofilm.

The main findings from this Intertek report are that flow straighteners and expansion vessels in QEUH were heavily contaminated with a wide range of bacteria, and newly installed flow straighteners became heavily contaminated with bacteria and with biofilm after a month in situ. Analysis of 60 water samples taken from the cold-water storage tanks revealed 5 positive samples (8%) and 3 of these samples were positive for *Cupriavidus* spp, which indicates the organism was present at the entrance to the water system.

Intertek report (01.10.18) Bundle 18 vol 1, doc 3, p82

I don't recall previously seeing this report. It may have been discussed at a WTG soon after it was received. The report is dated 01.10.18 and after the meeting I attended on 31.08.18, as far as I can recall, the next WTG meeting I attended was eight months later on 26th April 2019 so it may have been discussed at one of the meetings held during this period to which I wasn't invited.

Analysis of flow straighteners showed they were comprised of 8 parts, 6 internal plastic parts and 2 rubber gaskets. Flow straighteners were removed from taps fitted to the water system at QEUH at various times (1 week, 1 month, 2 months, 3 months, > 3 years) and were tested for total bacteria (TVC) and biofilm. At one month in the water system TVC's had increased from 10^2 c fu/straightener to 10^6 cfu/straightener, and after 3 months and 3 years in situ TVC counts exceeded the maximum of 10^8 cfu/straightener. The number of different species of bacteria detected in flow straighteners also increased with time, from 3 species at one month to 6 species after more than three years in situ. After 3 months in situ over 50% of flow straighteners tested positive for biofilm.

These results confirm that flow straighteners fitted to taps in the water system at QEUH support increasing numbers and diversity of bacteria with time. *Cupriavidus pauculus* and *Stenotrophomonas maltophilia* were recovered from flow straighteners along with other genus of bacteria.

Intertek report (08.07.19) Bundle 18 vol 1, doc 4, p91

This report may have been discussed at the WTG meeting I attended on 19th July 2019 as Intertek reports are mentioned in the minutes of that meeting, but no detail is recorded. The minutes note that the reports possibly support the need for replacement of components in the system.

I don't recall receiving the report before the WTG meeting. Ian Powrie was my main contact at QEUH and he sent me most documents I received regarding QEUH particularly relevant documents prior to any WTG meetings I attended. As I understand IP left the employ of QEUH on 02.07.19 and as far as I can see from my email records, I received no more emails or documents from him after 28.06.19.

The Intertek report (08.07.19) comments on visual inspection and microbiological/biofilm analysis of several component parts of valves, pumps, calorifiers and expansion vessels removed from the water system at QEUH. Bacteria and biofilm were detected in all components and heavy levels of biofilm detected in some parts particularly the expansion bladder metal holding plate which was badly corroded.

The results of analysis show all the components tested, particularly from the expansion vessel, were colonised with bacteria and these would have been contributing to the microbial contamination detected in the QEUH water system.

- 11. In respect of each of the above documents, were you in your view informed of them at an appropriate time during the work for which you were instructed?
- A I was first engaged and attended site at QEUH on 10th May 2018. I received the interim and full Intertek reports (both dated 11.07.18) on 25.07.18 and 30.08.18 respectively. The interim report was discussed at the WTG meeting on 27.07.18, and the full report was discussed at a meeting of the WTG on 31.08.18.

Although both reports are dated 11.07.18 I presume the full report was delayed and not available for discussion until the August WTG meeting and was distributed the day before this meeting. I believe I was informed of these reports within a reasonable period of time considering the need to discuss the reports with the WTG and given the scheduling of these meetings. I don't recall receiving the Intertek reports dated 01.10.18 and 08.07.19 prior to WTG meetings that I attended but they may have been discussed at WTG meetings shortly after the dates of the reports.

I recall being impressed with the initial observation by QEUH that the flow straighteners may have been a source of microbial contamination and that the hospital engaged Intertek to carry out a full physical and microbiological analysis of the flow straighteners. This led to them being recognised as a significant source of microbial contamination in the potable water system and to a programme where they were removed from the hospital particularly from areas occupied by immunocompromised patients where they presented the biggest risk. This work was initiated before I was engaged by the hospital.

I felt it was also notable that Intertek were further engaged by QEUH to undertake similar analysis of component parts of the water system which identified they, particularly expansion vessels, were contaminated with biofilm and would contribute to the contamination of the water system.

Addressing the Water System

- 12. The Inquiry is aware of your report 'An assessment of Clorious2 for the Treatment of Hot and Cold Potable Water Systems in the Queen Elizabeth University Hospital Glasgow 30 June 2018' (A44311678 – Assessment of the suitability of Clorius2). Please describe what led you to produce that report.
- A Ian Powrie (IP) contacted me by email on 8th June 2018 and asked if I would review the properties of Clorious2 and prepare a report for NHS GG&C whether it would be safe to adopt this product over traditional chlorine dioxide (ClO2) and if so, what were the benefits and risks associated with the use of the product. IP asked for my opinion on the preferred selection of Clorious2 or traditional ClO2. IP informed me in his email that the Water Technical Group (WTG) had agreed to use ClO2 as the preferred biocide, as opposed to copper/silver ions which had also been considered with ClO2 in a discussion paper on potable water sanitisation prepared by IP and dated 24th April 2018.

IP had been introduced to Clorious2 by Dennis Kelly who was the hospital's Authorising Engineer (water). IP had reviewed the benefits of Clorious2 and had proposed to the WTG that it was adopted due to benefits which he listed as:

- a stabilised solution,
- not prone to gassing off in the hot water system,
- low odour with higher efficacy,
- minimal impact on pipework corrosion as there is no acid used in the production of the CIO2,
- minimal chlorate levels due non reversion of the stabilised solution.

IP stated that while they were keen to accept the benefits of this product the WTG were hesitant to adopt this system without expert advice, to this end he was asked to seek my support in reviewing the properties of this product and preparing a report. I agreed to do this and reviewed all the material provided on the product and other information I accessed through literature searches. My report was completed on 30th June 2018.

- 13. Please describe the Chlorine Dosing strategy which you proposed, and how it was intended to work. Why did you propose this particular strategy? Was there any work required within the hospital to enable it to be carried out?
- A I didn't propose a chlorine dosing strategy. The hospital had already taken the decision to use continuous dosing with chlorine dioxide (CIO2). QEUH asked me to produce a report on a new form of CIO2 which is Clorious2 and the merits of this compared to traditionally generated CIO2.

Clorious2 is a CIO2 based biocide manufactured by Brenntag who refer to it as Clorious2_care. With traditional CIO2, sodium hypochlorite or strong acid is used in the reaction with sodium chlorite to generate CIO2 on site and this is dosed directly into the water system. Clorious2 used sodium peroxydisulfate to generate CIO2 from sodium chlorite and Brenntag claim that this reaction produces a stable solution of CIO2 which needs no further activation and achieves 100% conversion of chlorite to CIO2 with negligible chlorite, chlorate and chlorine byproducts.

In 2018, when I produced my report on Clorious2, to me this was a novel means of generating ClO2. I was not aware of this product or its benefits as claimed by the manufacturer, and I wasn't aware of it being used for microbial control in potable water systems in either healthcare or non-healthcare buildings. I am still not aware today of its use, particularly in healthcare premises, other than the example cited by Brenntag of a small healthcare facility in the north of England and four hospitals in the Czech Republic. Efficacy data on Clorious2 were not provided from any of these locations.

It was reported by the manufacturer Brenntag that Clorious2 is a stable solution of CIO2 with a good shelf life (6 months), efficient conversion from precursor chemicals and little residual precursor chemical sodium chlorite or chlorate, which guidance indicates can be harmful to neonates and renal dialysis patients. Brenntag also claimed that diluted Clorious2 does not contribute to higher corrosion rates, even at higher dosages, and it apparently exhibits a lower corrosion tendency towards brass and copper, than chlorine dioxide generated by reacting strong acid with sodium chlorite.

In his email to me dated 8th June 2018, Ian Powrie reported that Clorious2 was also not prone to gassing off, and it had low odour and higher efficacy. My report commented on its efficacy in controlling test bacteria in laboratory-based studies and in my opinion it did not appear to have a higher efficacy but it did seem to be a stable solution with a good conversion rate from the reaction of precursor chemicals

I felt that consideration of the use of Clorious2 was reasonable as it was CIO2 based and QEUH had already decided to use CIO2 as the preferred biocide for continuous dosing of the potable water system. Also, it had some benefits as claimed by the manufacturer which could be advantageous in QEUH.

However, having assessed the various information available to me at that time, in my opinion it was not appropriate to choose Clorious2 over traditionally activated ClO2 which had been used extensively in healthcare premises for some time with efficacy evaluated in peer reviewed publications and was supported in current guidance (HTM 04-01, SHTM 04-01 and HSG 274. Furthermore, I didn't feel it appropriate to trial a relatively unknown biocide such as Clorious2, in QEUH where the water system was widely contaminated and was associated with waterborne infection in patients.

The strategy of continuous dosing with CIO2 was originally proposed by QEUH. I supported this strategy but advised that it should be preceded by shock dosing with a higher level of chlorine dioxide over a shorter contact period (hours). Shock dosing is used to effectively 'soften up' any established areas of colonisation and biofilm before continuous dosing with CIO2 at much lower levels (normally 0.5ppm) commences. Shock dosing can help improve the efficacy of continuous dosing and can produce an earlier reduction in levels of microbial contamination.

The disadvantages of shock dosing are the significant disruption it can cause in a busy hospital as tap and shower outlets must be put out of use during the disinfection process, and shock dosing can result in the sudden release of large amounts of biofilm into the water system as it detaches from colonised surfaces. This risk can be mitigated by ensuring the system is well flushed after shock dosing to remove residual biocide and detached biofilm, and POU filters can be fitted for additional protection in areas occupied by immunocompromised patients.

Shock dosing with CIO2 prior to implementing continuous dosing with CIO2 was considered by QEUH but this was ruled out as I believe it was considered to be too disruptive to the normal functioning of the hospital, and the manufacturers of the stainless steel water pipes informed the hospital that it would have a deleterious effect on the pipes. There may have also been some objection from the tap manufacturer to using high level CIO2 because of damage it may cause to tap components.

Continuous dosing with CIO2 was eventually implemented at QEUH without shock dosing with CIO2.

Regarding works required in the hospital to enable dosing with CIO2, whenever disinfection is planned, liaison with specialist departments (such as renal units and neonatal units) should take place first. I noted in my report on Clorious2 that SHTM04-01 (part B section 7.8, Note 9) states: *CIO2 and its breakdown products chlorite and chlorate can be deleterious to neonates and renal dialysis patients, and should be removed from the water supply to these units.* I confirmed this in my paper on Clorious2.

In my opinion it is preferable to have a dedicated cold water supply to these units in case the water system to the rest of the hospital requires treating with biocides such as CIO2 or hydrogen peroxide. I am not aware if a separate water supply for the renal unit was introduced at QEUH, but I understand that the Renal Association guidelines indicate that chlorite and chlorate can be removed using either granular activated carbon (GAC) or powdered activated carbon (PAC). I recall from various discussions at the WTG's I attended that appropriate risk assessments were carried out before continuous dosing with CIO2 was implemented. e.g. at the WTG meeting on 31.08.18, which I attended, the agenda included:

CIO2 Impact Renal Dialysis/Endoscopy Impact Clinical Equipment Impact Status Satellite Lab Impact Neonatal – Supply Transfer Status

Also on the agenda at this meeting was an update on the status of the purchase of the dosing equipment. This had to go through a tendering process and when the equipment was acquired considerable works were required to install it. I understand several dosing units were sourced to expedite penetration of CIO2 throughout such a large water system.

A strategy for flushing all outlets on the water system had to be produced which involved flushing all outlets at least twice daily. This was implemented to ensure satisfactory levels of CIO2 reached all peripheral parts of the system. Regular flushing of outlets is crucial for the success of a biocide treatment programme. I am not aware how rigorous the outlet flushing programme has been at QEUH but it has been discussed at some of the WTG meetings.

CIO2 dosing units require ongoing maintenance and calibration of dosing equipment and regular monitoring of CIO2 at the dosing unit and at outlets to ensure it achieves a minimum level (0.1ppm) and where appropriate does not exceed drinking water limits at outlets (0.5ppm). I understand regular monitoring of CIO2 was in place at QEUH, but I have not witnessed it.

- 14. How successful, in your view, has that strategy proved to be?
- A I am not aware of how effective the CIO2 dosing proved to be at QEUH as I have had no contact with the hospital in almost 4 years. I attended a total of eight WTG meetings in two years and four months and I normally didn't receive minutes of the meetings to which I wasn't invited to attend, so I am not up to date on all issues at QEUH. The last WTG meeting I attended was on 18th September 2020.

The CIO2 dosing took longer to roll out than anticipated. As far as I am aware, it was originally planned to go live with continuous dosing from around the early part of November 2018. There was some slippage with this due to installation issues and I believe from the minutes of the WTG provided in the bundle CIO2 dosing started around February 2019.

From the minutes of the meeting on 26th April 2019, microbiology results were showing a significant improvement in line with expected control. Weekly manual CIO2 residual samples reports were reviewed, confirming that residual levels of CIO2 in cold water were above target

and generally between 0.2 - 0.3 ppm, while CIO2 in hot water was low at 0.02 to 0.06 ppm. A software upgrade to the CIO2 dosing unit was raised at this meeting to increase the overall average in hot water.

It was reported in the WTG minutes from the meeting on 22nd April 2021 that robust CIO2 results were being produced and the minutes implied excellent water quality.

The efficacy of continuous dosing of a potable water system with a biocide such as CIO2 is particularly dependant on regular use of the outlets to draw biocide into all peripheral parts of the system. If this is not sustained it can impact on the effectiveness of this control measure. For this purpose, a protocol for flushing all taps and showers was produced by Ian Powrie which required all outlets to be flushed twice daily for one minute. The contractor DMT was engaged to assist cleaners with this process (WTG minutes 26.04.19). I am not aware how well flushing was implemented at QEUH.

The efficacy of any biocide treatment is also affected by how well the water system is being maintained through planned preventative maintenance. For example, it is necessary to ensure that TMV's and associated strainers and shower heads and hoses are regularly cleaned and disinfected, and that expansion vessels and calorifier drains are regularly purged to reduce conditions that can impede the effectiveness of biocide treatment and support microbial growth.

It is also important to ensure that hot water consistently flows through all parts of the distribution pipework, that there is no excessive heat gain in the cold water system or heat loss from the hot water system. Ensuring that maintenance of the system takes place in accordance with guidance (e.g. SHTM 04-01) will enable biocide treatment to be more effective. In my experience, long term use of POU filters can also reduce the effectiveness of biocide treatment in peripheral parts of water systems. Continuous dosing of a biocide requires regular attention and the dosing equipment needs to be frequently checked, maintained and calibrated. It is noted in the WTG minutes of 20.09.18 that there are no guarantees that any biocide dosing system will be effective in eradicating bacteria from all aspects of a water system, but it has been shown in trials that CIO2 can be an effective control measure for microorganisms in potable water. In my experience it is an effective biocide and as far as I am aware it is the biocide most widely used for treating potable water in healthcare premises.

It is worthy of note that the movement in healthcare premises towards single bedrooms each with separate en-suite facilities, as occurs in QEUH, increases the complexity of water systems and the opportunity for more tap and shower outlets to become underused, which increases the opportunity for them to be colonised with waterborne microorganisms and can affect the efficacy of biocide treatment. The risk of transmission of microorganisms from even reasonably managed water systems in healthcare premises is now becoming increasingly recognised and has induced some augmented care units to become waterless. Where this has been implemented there are reports of an associated reduction in the incidence of nosocomial infection.

- The Inquiry is also aware of your report 'Manual v Automatic flushing of Taps' (A44312301 – Manual vs Automatic – July 2018). Please describe what led you to produce that report.
- A On behalf of the Water Technical Group (WTG) Ian Powrie (IP) emailed me on 27th June 2018 to seek my advice on flushing requirements to maintain chlorine dioxide levels at all outlets with respect to the proposed continuous water treatment process. Regular flushing of outlets on a potable water system is crucial for the success of a continuous dosing programme with a biocide. IP asked if I would provide a written assessment of the pro's & cons of automated sensor tap flushing against a manual flushing programme.

IP said that the current manual flushing programme used in the hospital was based on the guidance where domestic staff flush showers and taps as part of their daily cleaning regime and record this activity by exception. I produced the report on 1st July 2018, and it was circulated to the WTG. IP was responsible for ensuring cleaning staff and contractors recruited to assist with the flushing were aware of the flushing protocol. This was discussed at a few WTG meetings

I am not aware what training staff received regarding flushing of outlets, but I emphasised the need for such training in my report and the need to keep records on when flushing took place

Concluding

- 16. You are included among the authors of a paper published in the Journal of Hospital Infections 11 (2021) 53-64 entitled "Investigation and control of an outbreak due to contaminated hospital water system, identified following a rare case of Cupriavidus pauculus bacteraemia". Please refer to Inkster T, Peters C, Wafer T, Holloway D and Makin T "Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of Cupriavidus pauculus bacteraemia" Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of Cupriavidus pauculus bacteraemia" Journal of Hospital Infection 111 (2021) Bundle 6, Document 41, Page 1236) Does this paper set out your opinion and does it remain your opinion?
- A Dr Theresa Inkster is the lead author of this paper, and for my part I can't claim making any significant contribution to it apart from some proof reading, and corrections of a few misspelt names of microorganisms. As I didn't play any real part in shaping the paper I felt I should have perhaps just been mentioned in acknowledgements, but Dr Inkster very kindly and unexpectedly included me amongst the list of authors. I proposed very few amendments to the paper and thought it was an excellent document that provided invaluable information which could help prevent similar situations occurring in other healthcare premises.

At the time the paper was completed (23.12.20) I was no longer engaged at QEUH, and I was unaware of some of the information included in the paper e.g. the commissioning data from before the hospital opened, and that taps were pressure tested at the factory.

The paper does largely reflect my opinion regarding the likely cause of the contamination of the water system at QEUH and appropriate control measures. However, given my experience of water systems in healthcare premises I do not entirely concur with the statement that as a new-build hospital it was unexpected to find well-established biofilm and systemic contamination in a building which had been open for less than three years, but I can understand why this was the view of Dr Inkster and others at QEUH.

My expertise is predominantly required by healthcare premises that have problems with their water systems, which is why QEUH engaged me, and so in my rather more directed experience of new hospitals it's not unusual for me to encounter contaminated water systems, or for biocide treatment to be considered shortly after the opening of a new or refurbished hospital.

In my experience, most problems with contaminated water systems in new buildings arise during the construction of the building and before handover to the users. Dr Susanne Lee stated in her report (25.04.18): *In new buildings in particular the highest risk time for contamination is during the build and installation and commissioning.*

This is because the conditions that support contamination of the new water system are often created during construction e.g.:

- dead legs in the water distribution system,
- inappropriate use of materials to seal pipe joints,
- the presence of EPDM flexible hoses,

- inadequate balancing and distribution of hot water,
- hollow supports in cold water tanks,
- inadequate insulation of pipework,
- proximity of heat sources to cold water systems,
- oversized cold water storage tanks,
- outlets not flushed regularly after the water system is filled
- inadequate disinfection of the water system prior to handover.

In my experience, various combinations of these and other factors commonly occur in new healthcare buildings despite there being extensive information available on these matters in guidance and standards.

When water is first introduced into a potable water system to check for leaks etc prior to occupation of the building, inadequate flushing of the water system and delays in the normal operation of the water system can lead to stagnation or reduced flow which can support the accretion and development of biofilm comprising a wide range of waterborne microorganisms in various parts of the system.

Regular flushing around the whole site is required during this critical phase in new builds and in my experience this is frequently not carried out correctly or recorded. SHTM 04-01, part A (Design, installation, testing) which applies to healthcare premises under construction, recommends flushing hot and cold outlets every 3 days for one minute. SHTM 04-01 part B, (operational management) recommends sporadically used outlets should be flushed at least twice weekly. This guidance is predominantly based on the control of Legionella in water systems. Legionella is a relatively slow growing bacterium. Other waterborne bacteria can multiply faster so more frequent flushing of outlets would be necessary to help prevent these bacteria from colonising a water system.

Dr Susanne Lee noted in her report dated 25th April 2018 that there was at least 12 months delay between filling the water system at QEUH and occupation of the building. Water systems should be filled with water as close to occupation as possible. They should be disinfected just prior to handover, flushed and kept flowing as if in full operational use to avoid stagnation. In my opinion, too much reliance is put on the final disinfection of the water system to control bacterial contamination that may have accumulated after the water system has been filled. If biofilm has been allowed to become established during this period e.g. because regular flushing wasn't implemented, then this final disinfection prior to handover will not be fully effective.

I am not aware if regular flushing occurred at all outlets during this period at QEUH, but in my experience it is unlikely for it to be done correctly. It is doubtful however that flushing alone would be sufficient to control contamination of the water system in such a large building as QEUH. Water systems should be filled with water as late in the build as possible. They should be disinfected, flushed and kept flowing as if in full operational use to avoid stagnation.

Continuous dosing with an effective biocide in conjunction with regular flushing of outlets would have been appropriate at QEUH throughout the period that the system was filled with water and prior to occupation of the building. During this period, when patients are not present, biocide levels can be increased, providing that the higher levels of biocide are not damaging to the fabric of the water system. SHTM 04-01 (part B section 7.6) states that continuous dosing with appropriate biocides that have proven efficacy should be considered during construction to prevent the accumulation of biofilm.

Dr Inkster's paper advises that in hospitals housing high-risk areas, such as haemato-oncology units, consideration should be given to additional precautions for these high-risk groups and amongst other measures lists the application of long-term point of use filters. I have some concern with this view and recall commenting on this at a QEUH WTG meeting. POU filters provide effective and immediate control for transmission of waterborne bacteria, and at QEUH they appeared to be installed rapidly after recognition of the contaminated water system as a source of infection. They are an important control measure while engineering works and other remedial measures are put in place such as biocide treatment.

However, while POU filters are very effective at protecting patients from exposure to a contaminated water system, their long-term use should be avoided where possible, as noted in guidance, as they can exacerbate further microbial colonisation of the water system and this may cause issues for other areas of the hospital where POU filters are not fitted. POU filters can also sometimes contribute to contamination of outlets as fitted filters can reduce the gap between the tap outlet and the drain in the hand wash basin leading to biofilm disruption and likely aerosolisation from biofilm commonly present in drains. This point was highlighted in Dr Inkster's paper.

I especially agree with the recommendation in the paper that Infection control teams (ICT) should play an active role in Water Safety Groups (WSG) and be involved in the planning, and commissioning of hospital water systems from the outset. I don't see this happening in many healthcare premises. However, I would add that ICT need to be well supported by the WSG, particularly the Responsible Person (water) and the Authorising Engineer (water) who should have a more in-depth knowledge of the design and operation of water systems and how to reduce their contamination with microorganisms.

17. What, in your opinion, is the cause or origin of the issues or problems with the water system at the QEUH/RHC that led to your being asked to provide your help and assistance in 2018?

A In my experience of water systems in large healthcare premises contamination normally occurs during the building phase from shortly after the system has been filled with water. Small numbers of microorganisms already in fitted pipework (particularly uncapped pipes), and in water storage vessels, taps/showers etc will be supported when the system is filled with water.

Mains water supplies are not sterile and the number of microorganisms present in this water often show seasonal variation with larger numbers detected in warmer summer months. Mains water is treated with a biocide (usually chlorine or monochloramine), so the number of microorganisms entering buildings in mains water should normally be small.

In QEUH this water is passed through filters (0.5 micron according to DMA 2015 LRA, and 0.2 micron according to Dr Walker expert report 21.12.24) before entering potable water bulk storage tanks. Both filters would remove particulate matter, 0.5 micron would remove most bacteria and 0.2 micron would remove all bacteria.

It was noted during the April 2015 Legionella Risk assessment (LRA) that the filters were being bypassed during the LRA and unfiltered water was allowed to enter the system. This took place during the period after handover (26.01.15), and prior to occupation of the building by patients, which I understand commenced from 24.04.15 for the main building and from 10.06.15 for the children's hospital. The bypass of the filters appears to have taken place when QEUH was operating the building rather than during the construction phase.

Taps installed throughout the building were fitted with flow straighteners and these became contaminated with a range of waterborne bacteria after installation or were contaminated prior to installation as shown by analysis carried out by Intertek (11.07.18), or both of these events occurred. Some of these bacteria were similar to types recovered from infected patients. Unused flow straighteners contained small numbers of bacteria on receipt from the manufacturer and when they were installed in taps fitted to the water system analysis by Intertek established the presence of biofilm and large numbers of bacteria after just one month in situ.

It was reported in Dr Inkster's paper that the taps were pressure tested in a factory before they were delivered to the hospital. Pressure testing normally uses water and if this becomes contaminated it can result in bacterial contamination of the internal parts of the tap which may persist up to installation. I have personally encountered this problem with another tap manufacturer where contaminated water in a pressure testing facility left bacteria inside the taps.

In my opinion the water system was probably contaminated with bacteria from when water first entered the system during the construction phase and prior to the hospital being occupied, and this contamination originated from contaminated taps/flow straighteners, contaminated pipework or other fittings such as expansion vessels, and ingress of bacteria present in the mains water supply particularly when the filtration system was bypassed. Once bacteria gained access to the water system at QEUH conditions must have been conducive to their development in various parts of the system as testing showed they were widespread, particularly at tap outlets, and there were many different types of bacteria detected.

Dr Lee noted in her report that the water system was filled with water for over 12 months before occupation of the building. If the outlets were not regularly flushed prior to occupation this would effectively produce stagnant water conditions particularly in the cold water system. Stagnant or low flowing cold water is susceptible to heat gain and concomitant microbial growth and it has no shearing force to help remove biofilm. Lack of flushing also supports the accretion and development of microorganisms at tap and shower outlets. In my opinion, in addition to regular flushing of outlets, a water system as large as QEUH would require continuous dosing with an effective biocide until the building was occupied. SHTM 04-01 supports both continuous dosing with a biocide and regular flushing of outlets during construction. If these control measures were not in place from when the water system was first filled, and there are some indications that they were not, then I believe this is the period when widespread microbial contamination became established in the water system at QEUH.

Contamination of the hot and cold water system would be further exacerbated by the other deficient factors identified in the Legionella risk assessments (LRA) carried out by DMA Canyon in 2015 and 2017 and referred to in Provisional Position paper 11 in the inquiry bundle. Some of the more significant risk factors that were identified and were likely to exacerbate contamination within the water system at QEUH are:

- the hot water system was not achieving recommended temperatures as indicated in the 2015 LRA.
- Heat gain in the cold water system and inadequate operation and cleaning of storage tanks
- the installation of expansion vessels that were not recommended for hospital water systems and which contained stagnant water and were colonised with bacteria.
- Numerous dead leg sections of pipe and non-operational calorifier and cold water storage tanks acting as a dead leg
- No servicing history for showers and many TMVs

Once bacteria and associated biofilm became established in the water system this would prove very difficult to control and would justify the use of various control measures including continuous dosing with chlorine dioxide, regular flushing of outlets to encourage the distribution of the biocide to all parts of the system, and the fitting of point of use filters to protect more susceptible patients while these control measures and other remedial works were being implemented.

- 18. Do you have any additional comments to make regarding these matters, or any other matters that you consider to be of significance?
- A No standards or guidance I believe it is of relevance that there are no standards or guidance on the control of bacteria being detected in the water system at QEUH such as *Cupriavidus* spp,
 Stenotrophomonas spp and other waterborne opportunistic pathogens. I am not aware of any benchmarks for permitted levels of these bacteria in water systems, as there are for Legionella bacteria and *Pseudomonas aeruginosa*.

Background environmental bacteria are present in many water systems but have only relatively recently been able to be routinely identified with improved laboratory techniques. They are generally regarded as not harmful to health, but it is becoming increasingly evident that some can cause infection in particularly vulnerable patients e.g. those receiving augmented care and notably patients with immune systems that are compromised due to immuno-suppressive therapies.

As far as I am aware, there wasn't a requirement in the Scottish HTM 04-01 (2014) to test water samples routinely for the presence of *Pseudomonas aeruginosa* in augmented care facilities as occurs in HTM 04-01 which applies in England. This requires routine six monthly testing of all relevant water outlets in all augmented care units in healthcare premises. SHTM 04-01 (2014) part B note 16 does not advise routine testing for *P. aeruginosa* and only requires testing of water in certain circumstances such as suspected or confirmed outbreaks or a series of sequential cases. In my opinion, if a requirement for routine testing for *P. aeruginosa* had been in place from when the hospital opened in April 2015 it may have helped to identify the presence of widespread bacterial contamination of the water system earlier. In my opinion, routine testing of water outlets for *P. aeruginosa* should be considered at the next review of SHTM 04-01.

Although testing for *P. aeruginosa* can assist as a marker organism in revealing general bacterial contamination in water systems, it is a selective procedure focussed on the detection of *P. aeruginosa* and not designed to identify the presence a wide range of other waterborne bacteria. A large proportion of background bacteria in water systems are detected during conventional testing for total heterotrophic bacteria (TVC). In addition to routine *P. aeruginosa* testing in augmented care facilities I believe consideration should be given to including TVC testing which is a simple test that can help indicate if conditions in the water system are generally conducive to the presence of waterborne bacteria including opportunistic pathogens.

Water quality regulations require water delivered to consumers taps to be wholesome. This is based on compliance with Prescribed values and Indicator parameters which from a microbiological perspective effectively means the absence of *E. coli*, Enterococci and coliform bacteria (Prescribed values). TVC testing is included in Indicator parameters but there are no numerical values set for TVCs. The regulations state that TVC's at consumers taps should show no abnormal change.

This criterion based on trend analysis could be adopted if TVC testing is undertaken routinely in augmented care units to detect underlying bacterial contamination. Where TVCs increase on previous results of analysis, or on levels in incoming mains water supplies, then this should initiate further investigation that could lead to the identification of opportunistic pathogens such as *Cupriavidus pauculus*, *Stenotrophomonas maltophilia* and others. The BSI standards publication PD 855468:2015* uses TVC results in excess of a 2 log difference above that found in incoming water as an indicator for further investigation of microbial contamination of potable water systems. (*PD855468:2015 Guide to the flushing and disinfection of services supplying water for domestic use within buildings and their curtilages)

Sewage treatment facility - I recall my first visit to the hospital and discovering that it had been built next to a sewage treatment facility. I was astonished by this, and it was the first point I raised when I met Ian Powrie, my main contact at QEUH. I asked why it had been allowed given that the hospital contained some very immunocompromised patients, and I was particularly concerned about potential transmission of microorganisms from the sewage treatment facility, as airborne transmission of microorganisms from sewage treatment works had been well documented.

I'm not aware if the impact of the proximity of QEUH to the sewage treatment works has been fully investigated e.g. if air sampling for airborne microorganisms has been carried out at appropriate times and places and if the possibility of airborne and waterborne contaminants gaining access to the water system at QEUH has been properly considered.

Continuous dosing with a biocide - It is regrettable that biocide dosing equipment for treatment of the water system at QEUH was not installed earlier than it was. As far as I am aware, continuous dosing with chlorine dioxide (CIO2) was being discussed at the hospital from early in 2018 and the hospital appeared to be already in favour of continuous dosing with CIO2 before or shortly after I was engaged on 10th May 2018. I advised the hospital on continuous dosing with CIO2, and on an alternative CIO2 dosing unit (Clorious2).

As far as I am aware from information provided in the inquiry bundle, the CIO2 dosing units became operational around November 2018 with reasonable levels of CIO2 at outlets not being achieved until 2019. I am not aware if this water treatment system could have been implemented any sooner, but the water system at QEUH is very large and complex

and the hospital was fully operational, all of which would influence when the CIO2 dosing system was eventually installed.

In my opinion if shock dosing with an effective biocide had been carried out in accordance with the appropriate standard just prior to occupation of the building, and if continuous dosing of the water system with ClO2 had been installed during construction and activated as soon as water entered the system along with regular flushing of all outlets, and if the system had been operated in accordance with guidance in SHTM 04-01 then I believe this is likely to have significantly reduced the risk of widespread contamination of the water system detected at QEUH.

Both measures i.e. continuous dosing with a biocide during construction and regular flushing of outlets are contained in SHTM 04-01 current guidance. This states: *Continuous dosing with appropriate biocides that have proven efficacy should be considered during construction to prevent the accumulation of biofilm. A regular flushing programme for all outlets should also be implemented.* Further explicit guidance or standards on this matter may be needed to help mitigate similar microbial contamination of potable water systems in the future.

Declaration

- 19. I believe that the facts stated in this witness statement are true. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.
- 20. The witness was referred to specific documents in the following bundles associated with the questions asked within their questionnaire. (Appendix A)

21. The witness verbally / physically introduced the following document/s to the Scottish Hospital Inquiry for reference when they completed their questionnaire statement (Appendix B)

Appendix A

A43293438 – Bundle 6 – Miscellaneous Documents
A47395429 – Bundle 10 – Water Technical Group/Water Review Group Minutes
A48235836 – Bundle 18 – Documents referred to in the export report of Dr J.T. Walker
A44312301 – Manual vs automatic flushing of Taps – Tom Makin
A44311678 - An assessment of the suitability of Clorious2 for the treatment of hot and
cold potable water systems in Queen Elizabeth University Hospital, Glasgow – Tom
Makin
A42303223 - Water Technical Group Intertek Investigation into Contamination of Flow
Straighteners - 11 July 2018

Appendix B

A38271789 – Draft meeting report - 25/4/2018 - NHS Greater Glasgow & Clyde A49541924 – Extract – American Journal of Infection Control – 4th Decennial International Conference on Nosocomial and Healthcare – Hood et al – Page 86 A49542934 – Dr T Makin – Screen Shot – Reference list showing publication of Hood et al (2000) American Journal of Infection Control – Issue 28 Volume 1