

L.N. 5 of 2006

**PUBLIC HEALTH ACT, 2003
(ACT NO. XIII of 2003)**

Control of Legionella Regulations, 2006

IN exercise of the powers conferred by article 26 (i) of the Public Health Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

1. The title of these regulations is the Control of Legionella Regulations, 2006. Title.

2. In these regulations, unless the context otherwise requires:- Definitions.

“accredited laboratory” means a laboratory which takes part in an external quality assessment scheme for the isolation of legionella from water and where the interpretation of any results is carried out by an experienced microbiologist;

“the Act” means the Public Health Act;

“authorised officer” means any duly qualified person authorised by the Superintendent to carry out any functions under these regulations and includes any nominated officer;

“biocide” means a physical or chemical agent capable of killing micro-organisms, including Legionella;

“clean” means to render free from visible sludge, foam, slime (including algae and fungi), rust, scale, dirt, and any deposit or accumulation of impurities or other foreign material;

“cold water system” means an installation of plant, pipes and fittings in which cold water is stored, distributed and subsequently discharged;

“cooling tower systems” includes:-

(a) a cooling tower, or a number of interconnected cooling towers that use the same recirculating water; and

(b) any machinery that is used to operate any such tower; and

(c) any associated tanks, pipes, valves, pumps or controls;

“cooling tower” means a device whose main purpose is to cool water by direct contact between that water and a stream of air;

“designated area” means any premises or part thereof to which the public or a section of the public has access, whether on payment or otherwise;

“disinfect” means to carry out a process which is intended to kill or remove pathogenic micro-organisms;

“drift” means the water aerosol which emerges from the airflow outlet of a cooling system;

“evaporative condenser” means a device whose main purpose is to cool a fluid by passing that fluid through a heat exchanger which is itself cooled by the contact of water passing through a stream of air;

“guidelines” means the European Guidelines for Control and Prevention of Travel Associated Legionnaires’ Disease produced by the European Working Group for Legionella Infections (EWGLI) and endorsed by the Committee for the Epidemiological Surveillance and Control of Communicable Diseases in the Community, instituted by Decision 2119/98/EC of the European Parliament and the Council;

“heat exchanger” means a device for transferring heat between fluids which are not in direct contact with one another;

“heterotrophic colony count” means an estimate of the number of viable units of bacteria per millilitre of water made using the pour plate, spread plate or membrane filter test (also known as the total bacterial count, total plate count or viable bacterial count test) method;

“legionella” means bacteria belonging to the genus *Legionella*;

“premises” includes all non-domestic premises used for or in connection with the carrying on of a trade or business (whether for profit or not) and should include any healthcare facility and schools;

“responsible person” includes the person who owns, manages or controls the cooling tower systems, or evaporative condensers, or hot and cold water systems, or water fountains or a number of these systems in the same premises;

“sentinel taps”, in relation to a hot water system, means the first and last taps on a recirculating system. For cold water systems (or non-recirculating hot water systems), the nearest and furthest taps from the storage tank. The choice of sentinel taps may also include taps which are considered to represent a particular risk;

“spa pool” includes a bath or a small pool where warm water is constantly recirculated, through high velocity jets or with the injection of air to agitate the water;

“the Superintendent” means the Superintendent of Public Health.

“warm water system” means a piped water supply, including any thermostatic mixing valve, which is designed to supply water at a temperature of between 30°C and 60°C;

“water” means water supplied through the main water distribution system or water supplied by an authorised private water supplier or through a water supply approved by the Superintendent or by the relevant competent authorities;

“water fountain” means any water feature located in a designated area.

3. (1) Cooling tower systems and evaporative condensers are prohibited to be newly installed on healthcare facilities and schools.

Installation of new cooling tower systems and evaporative condensers.

(2) Installation of new cooling tower system or evaporative condenser on any other premises should be restricted to those cases only where no other suitable dry cooling facility is possible as an alternative.

4. (1) At the stage of installation of cooling tower system or an evaporative condenser, inspection shall be carried out by competent persons so that the cooling tower and evaporative condenser pose minimal health risk to occupants of the premises and members of the public.

Design and construction of cooling tower system and evaporative condenser.

(2) Cooling systems shall be designed and constructed so as to minimise the release of drift and to aid safe operation, regular cleaning and disinfection.

Location of cooling towers and evaporative condensers.

5. The cooling tower or evaporative condenser shall be located at least five metres away from air circulating and ventilating inlets, open windows and occupied areas, pedestrian thorough fares, traffic areas, areas of public access, exhaust discharge from kitchens, air handling systems or other areas where nutrients conveyed from these systems could assist in the growth of legionella.

Source of water.

6. Make-up water shall be supplied either through the main distribution system or by an authorised water supplier or through a water supply approved by the Superintendent.

Discharge of water.

7. (1) Effluent water from cooling towers and evaporative condensers shall be discharged into the public sewers as approved by the respective competent authorities.

(2) The concentration of chemicals in the effluent shall be within the limits established by the respective competent authorities.

Commissioning and operation.

Cap. 321.

8. (1) Cooling towers and evaporative condensers shall be commissioned, approved and certified by a competent warranted engineer in terms of the Engineering Profession Act before use to ensure that they operate correctly and safely.

(2) The entire air-conditioning system shall be clear of any construction debris and dirt, and cleaned before operation starts.

(3) Precautions shall be taken to control the risks during commissioning, start up and during the normal operation of the system as per guidelines.

Maintenance and testing of cooling tower systems and evaporative condensers.

9. (1) It shall be the duty of the responsible person to ensure that:

(a) any cooling tower system or evaporative condenser in use is maintained and tested in accordance with the guidelines;

(b) the water of the cooling tower system or evaporative condenser is maintained in a clean condition;

Water quality and treatment.

(c) the water of the cooling tower system or evaporative condenser is continuously treated with:

i. one or more biocides to effectively control the growth of micro-organisms, including Legionella; and

ii. chemicals or other agents to minimise scale formation, corrosion and fouling;

(d) a chlorine-compatible bio-dispersant is added to the recirculating water of the cooling tower system or evaporative condenser, and that the system is then disinfected, cleaned and re-disinfected:

Disinfection,
cleaning and re-
disinfection.

i. immediately prior to initial start up following commissioning, or any shut down period of greater than one month; and

ii. at intervals not exceeding six months;

(e) the cooling tower system or the evaporative condenser are inspected in accordance with the guidelines and Schedule 1;

Routine inspections
and testing.

(f) at least once every month take a sample of the recirculating water of the cooling tower system and the evaporative condenser to an accredited laboratory for testing for heterotrophic colony count and once every six months for legionella;

Microbiological
sampling frequency.

(g) a water sample shall be taken before the dosing of biocide and in accordance with the guidelines.

Water sampling.

10. (1) The responsible person must ensure that the actions following microbiological monitoring of cooling towers and evaporative condensers is in accordance with the procedures laid down in Schedule 2 to these regulations.

Action levels
following
microbiological
monitoring of
cooling tower
systems and
evaporative
condensers.

(2) The responsible person shall immediately inform the Superintendent of any situation provided for in Schedule 2 of these regulations.

(3) The responsible person shall carry out any further monitoring and remedial actions as may be directed by the Superintendent.

(4) The Superintendent may require the systems or part thereof to be shutdown until all necessary remedial actions have been taken by the responsible person and until microbiological sampling results of any system would have returned within the recommended acceptable levels as indicated in Schedule 2 to these regulations.

11. (1) The responsible person shall ensure that:

Maintenance of hot
and cold water
systems.

(a) unless the system is shut down or drained of water or is otherwise not in use, any hot and cold water system that the responsible person owns, manages or controls is maintained and

tested in the manner set out in these regulations and according to the guidelines;

Start up procedures.

(b) the hot and cold water system is disinfected by heat or chlorination and cleaned immediately prior to initial start up following commissioning, or any shut down period of greater than one month;

Routine disinfection.

(c) the hot and cold water system is disinfected by one or more of the following methods:

- i. at least once each month by heat or chlorination; or
- ii. continuously by means of automatic low level chlorination; or
- iii. continuously by means of ultra-violet light treatment; or
- iv. a method approved in the guidelines;

Routine inspections and testing.

(d) the hot and cold water system is inspected and that the hot and cold water systems are maintained at all times in accordance with the guidelines and Schedule 1 and 3;

Biocide treatments.

(e) when biocides are used to treat water systems, they are meticulously controlled and checked at least weekly or as otherwise indicated to ensure that it is operating correctly;

Microbiological sampling frequency.

(f) at least once every six months a sample of the water from the hot and cold water system is taken and delivered to an accredited laboratory for testing and reporting on Legionella.

Action levels following microbiological monitoring.

12. (1) The responsible person must ensure that the actions following microbiological monitoring of hot and cold water systems are in accordance with the procedures laid down in Schedule 4 of these regulations.

(2) The responsible person shall immediately inform the Superintendent of the situation provided for in Schedule 4 of these regulations.

(3) The responsible person shall carry out any further monitoring and remedial actions as may be directed by the Superintendent.

(4) The Superintendent may require the systems or part thereof to be shut down until all necessary remedial actions have been taken by the responsible person and until microbiological sampling results have returned within the recommended acceptable levels in Schedule 4 of these regulations.

13. (1) It shall be the duty of the responsible person to ensure that: Maintenance and testing of water fountains.

(a) any water fountain under his responsibility is maintained and tested in accordance with the guidelines and Schedule 1;

(b) water in a water fountain is sampled: Microbiological sampling.

i. at least once a month for the purpose of determining the heterotrophic colony counts; and

ii. at least once every six months for the purpose of detecting legionella bacteria.

(2) The responsible person shall immediately inform the Superintendent of the situation provided for in Schedule 2 of these regulations.

(3) The Superintendent may require the responsible person to carry out tests and maintenance of water fountains as he may deem necessary. Notice to carry out inspection, test or maintenance of water fountains.

14. (1) It shall be the duty of the responsible person to ensure that any spa pool and any other type of water system under his responsibility is maintained and tested in accordance with the guidelines and Schedule 1. Maintenance and testing of other risk systems.

(2) Spa pools on display in retail outlets or exhibitions shall be treated in the same manner as if they were being used.

15. (1) The responsible person shall: Risk assessment.

(a) carry out a risk assessment to identify and assess the risk of exposure to legionella bacteria from work activities and the water systems on the premises under his control as identified in the guidelines; and

(b) identify any necessary precautionary measures which may need to be adopted; and

(c) review the assessment either annually or when the situation changes or when the original assessment may no longer be valid; and

(d) keep a fully documented record of the risk assessment.

Control measures.

(2) When the risk assessment reveals that there is a foreseeable risk which cannot be eliminated, the responsible person shall adopt a scheme specifying the measures to be taken to minimise the risk of exposure.

External audit.

(3) The risk assessment and operation of the control measures shall be audited by an independent competent person at least every two years.

(4) All maintenance and risk assessment records shall be retained for at least five years.

Action plan for an outbreak.

16. (1) The responsible person shall inform the Superintendent of an outbreak of legionnaire's disease or if it is suspected to have occurred.

(2) In the event or on the suspicion of an outbreak of legionnaires' disease, the responsible person shall implement all instructions which may be issued by the Superintendent.

Duties of the Superintendent.

17. (1) It shall be the duty of the Superintendent to investigate any case or suspected case of Legionnaires' disease at any premises and to cause the sampling and analysis of any samples required to investigate such case or suspected case.

Initial investigations.

(2) The expenses incurred for the elevation, transportation, preparation and analysis of samples in case of initial investigation of a case or suspected case of legionnaire' disease shall be encumbered by the Superintendent.

Follow-up investigations.

(3) If the results of the initial samples indicate the presence of Legionella species, or if the investigation is within 24 months of the first notified case or suspected case, the expenses of follow-up samples or initial samples, as the case may be, shall be encumbered by the responsible person:

Provided that the responsible person of the premises shall sign *a priori* the declaration attached as Schedule 5 to these regulations confirming his acceptance to pay any fees due to the Superintendent.

(4) Any person who fails to comply with sub-regulation (3) of this regulation shall be guilty of an offence and the court, besides awarding punishment, shall oblige the accused to pay the due fees.

18. (1) In the event that the responsible person fails to follow the instructions referred to in the preceding regulations, or the Superintendent considers that the risk of infection with legionella from that particular premises is significant, he may order that the premises, part of the premises or any water related system, be immediately closed until the risk of infection is controlled. Closure of premises.

(2) The Superintendent shall issue an enforcement notice to the responsible person and shall be in the form specified in Schedule 6 to these regulations, or in any other modified form as the Superintendent may deem appropriate in the particular circumstances may deem. Enforcement notice.

(3) Once the premises, part of the premises or any water related system has been closed by an enforcement notice issued by the Superintendent, same enforcement notice may be lifted only after it is confirmed by the Superintendent that the risk of infection has been controlled.

(4) Any person who fails to comply with the enforcement notice issued under sub regulation (2) of this regulation shall be guilty of an offence under the Act. Failure to comply with the enforcement notice.

19. Any person who contravenes any of the provisions of these regulations shall be guilty of an offence under the Act. Offences.

SCHEDULE 1**RECOMMENDED INSPECTION FREQUENCIES FOR RISK SYSTEMS****CHECKLIST 1: COOLING WATER INSTALLATIONS**

SYSTEM/SERVICES	TASK	FREQUENCY
Cooling towers and evaporative condensers	Monitor water quality, water use and biocide/chemical use to assess and ensure effectiveness of water treatment regime, including key chemical and microbiological parameters and observations of internal condition of pond, pack and water	6 monthly
	Central control function, conductivity sensor calibration, blow down function, uniformity of water distribution, condition of sprays/troughs, eliminators, pack, pond, immersion heater, fan and sound attenuators	Monthly to 3 monthly, according to risk
	Clean and disinfect cooling towers/evaporative condensers, make up tanks and associated systems, including all wetted surfaces, descaling as necessary. Packs should be removed and cleaned where practicable.	6 monthly

CHECKLIST 2: HOT AND COLD WATER SERVICES

SERVICE	TASK	FREQUENCY
Warm water services	Arrange for samples to be taken from hot water heaters, in order to note condition of drain water	6 monthly
	Check temperatures in flow and return at calorifiers	Daily
	Check temperature up to 1 minute to see if it has reached 50°C in the sentinel taps	Weekly
	Visual check on internal surfaces of water heaters for scale and sludge	Annually
	Check representative taps for temperature as above on a rotational basis	Monthly
Cold water services	Check tank water temperature remote from ball valve and mains temperature at ball valve. Note maximum temperatures recorded by fixed max/min thermometers where fitted	6 monthly
Note: This temperature may not be reached during the summer months in Malta	Check that temperature is below 20°C after running the water for up to 2 minutes in sentinel taps	Weekly
	Visually inspect cold water storage tanks and carry out remedial work where necessary	6 monthly
	Check representative taps for temperature as above on a rotational basis	Monthly
Shower heads	Dismantle, clean and descale shower heads and hoses	Quarterly, or as necessary, whichever comes first
Little used outlets	Flush through and purge to drain	Weekly

CHECKLIST 3: OTHER RISK SYSTEMS

SYSTEM/SERVICE	TASK	FREQUENCY
Spray humidifiers, air washers and wet scrubbers	Clean and disinfect spray humidifiers/air washers and make up tanks including all wetted surfaces, descaling as necessary	6 monthly
	Confirm the operation of non chemical water treatment (if present)	Weekly
Water softeners	Clean and disinfect resin and brine tank – check with manufacturer what chemicals can be used to disinfect resin bed	As recommended by manufacturer
Emergency showers and eye wash sprays	Flush through and purge to drain	6 monthly or more frequently if recommended by manufacturer
Sprinkler and hose reel systems	When witnessing tests of sprinkler blow down and hose reels ensure that there is minimal risk of exposure to aerosols	Quarterly
Lathe and machine tool coolant systems	Clean and disinfect storage and distribution system	6 monthly
Spa baths	Check filters - sand filters should be backwashed daily	Daily
	Check water treatment – pools should be continuously treated with oxidising biocide	3 times daily
	Clean and disinfect entire system	Weekly
Horticultural misting systems	Clean and disinfect distribution pipe work, spray heads and make-up tanks, including all wetted surfaces, descaling as necessary	Annually
Fountains and water features (particularly indoors)	Clean and disinfect ponds, spray heads and make-up tanks, including all wetted surfaces, descaling as necessary	Weekly

SCHEDULE 2
ACTION LEVELS FOLLOWING MICROBIOLOGICAL MONITORING FOR
COOLING TOWER SYSTEMS AND EVAPORATIVE CONDENSERS

HETEROTROPHIC COLONY COUNT¹ CFU/ML AT 30°C (Minimum 48 hours incubation)	LEGIONELLA BACTERIA CFU/LITRE²	ACTION REQUIRED ON SYSTEM	NOTIFICATION TO SUPERINTENDENT
≤10,000	≤1000	System under control	None
>10,000 and up to 100,000	>1000 and up to 10,000	Review programme operation – The count should be confirmed by immediate re-sampling. If similar count is found again, a review of the control measures and risk assessment should be carried out to identify any remedial actions.	Following resampling and similar counts are confirmed, the Superintendent is to be informed in writing within 24 hours of receiving the laboratory report and should include copies of laboratory results together with the control measures being taken by the responsible person to remedy the situation.
>100,000	>10,000	Implement corrective action – The system should immediately be re-sampled. It should then be 'shot dosed' with an appropriate biocide, as a precaution. The risk assessment and control measures should be reviewed to identify remedial actions.	Once microbiological results indicate these levels of bacterial counts, the responsible person within 24 hours of receiving the laboratory report shall inform the Superintendent by phone and in writing within 48 hours which report should include copies of the laboratory results together with the control measures being taken to remedy the situation.

¹ Colony count determined by pour plate method according to ISO 6222(20) or by spread plate method on yeast extract agar

² Determined in accordance with ISO 11731(19)

SCHEDULE 3
TEMPERATURE CONTROL FOR HOT AND COLD WATER SYSTEMS

FREQUENCY	CHECK	STANDARD TO MEET		NOTES
		COLD WATER	HOT WATER	
Weekly	Sentinel taps	The water temperature should be below 20°C or less after running the water for up to two minutes	The water temperature should be at least 50°C within a minute of running the water	This check makes sure that the supply and return temperatures on each loop are unchanged i.e. the loop is functioning as required
Monthly	If fitted, input to thermostat mixer valves (TMV) on a sentinel basis		The water supply to the TMV temperature should be at least 50°C within a minute of running water	One way of measuring this is to use a surface temperature probe
	Water leaving and returning to the water heater		Outgoing water should be at least 60°C, return at least 50°C	If fitted, the thermometer pocket at the top of the hot water storage heater and on the return leg are useful points for accurate temperature measurement. If installed, these measurements could be carried out and logged by a building management system.
Six monthly	Incoming cold water inlet (at least once in the winter and once in summer)	The water should preferably be below 20°C at all times		The most convenient place to measure is usually at the ball valve outlet to the cold water storage tank
Six monthly	Representative number of taps on a rotational basis	The water temperature should be 20°C or less after running the water for two minutes	The water temperature should be at least 50°C within a minute of running the water. The difference between the highest and lowest temperature recorded at the taps after one minute should not be greater than 10°C	This check makes sure that the whole system is working properly

SCHEDULE 4
ACTION LEVELS FOLLOWING MICROBIOLOGICAL MONITORING FOR
HOT AND COLD WATER SYSTEMS

LEGIONELLA BACTERIA CFU/LITRE ¹	ACTION REQUIRED ON SYSTEM	NOTIFICATION TO SUPERINTENDENT
≤1000	System under control	None
>1000 and up to 10,000	Either: (i) If only one or two samples are positive, systems should be re sampled. If a similar count is found, then review of the control measures and risk assessment should be carried out to identify any remedial actions; (ii) If the majority of samples are positive, the system may be colonised, albeit at a low level, with Legionella. Disinfection of the system should be considered but an immediate review of control measures and risk assessment should be carried out to identify any other remedial action required.	Following resampling and similar counts are confirmed, the Superintendent is to be informed in writing within 24 hours of receiving the laboratory report, and should include copies of laboratory results together with the control measures being taken by the responsible person to remedy the situation.
>10,000	The system should be re-sampled and an immediate review of the control measures and risk assessment carried out to identify and remedial actions, including possible disinfection of the system.	Once microbiological results indicate these levels of bacterial counts, the responsible person within 24 hours of receiving the laboratory report shall inform the Superintendent by phone and in writing within 48 hours which report should include copies of the laboratory results together with the control measures being taken to remedy the situation.

¹ Determined in accordance with ISO 11731(19)

SCHEDULE 5

CONFIRMATION DECLARATION OF FEES DUE TO THE SUPERINTENDENT OF PUBLIC HEALTH

The Superintendent of Public Health
Health Division

I, the undersigned, in my capacity of(**position**) of(**premises name**) hereby declare that I will pay, within one month's time of receipt of invoice, all the expenses that the Health Division will incur in the sampling, transportation, preparation and analysis of(**number**) of samples, which have been taken from(**premises name and address**) on the(**date of sampling**) as part of the investigation of a case or suspected case of Legionnaire's disease.

(Sgd)

Name and Surname :
o.b.o. :
I.D. No. :
Date of Birth :
Place of Birth :
Parent's Name and Surname :
Residential Address :
Billing Address :
VAT No. :

Date :

SCHEDULE 6

HEALTH AUTHORITY

ENFORCEMENT NOTICE

(As per regulation 18(2) of the Control of Legionella Regulations, 2005)

Date:

To:
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.....

1. Following investigations carried out by the Superintendent of Public Health, it was found that the risk of infection from Legionnaire's Diseases is significant at
.....
.....

2. The risk of infection from Legionnaire's Diseases relates to
.....
.....

3. Without prejudice to the Superintendent's right to take action in accordance with the provisions of the Control of Legionella Regulations, 2005, you are hereby requested to IMMEDIATELY close down the until further notice.

Superintendent of Public Health

