ACIL ALLEN

17 May 2021

Report to New South Wales Ministry of Health

Public Health Regulation 2022

Regulation Impact Statement

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Executive summary

The health of New South Wales (NSW) residents is promoted and protected through the *Public Health Act 2010* (the Act). The Act is one of several Acts that deal with public health in NSW. It makes provisions for a range of matters, such as notification of diseases and conditions and the regulation of areas that have the potential to affect public health (for instance, drinking water, cooling water systems, skin penetration procedures and public swimming pools). The *Public Health Regulation 2012* (the Regulation) supports the Act by making provisions across these areas.

Under the provisions of the *Subordinate Legislation Act 1989*, the *Public Health Regulation 2012* is due for staged repeal on 1 September 2022. The NSW Ministry of Health (the Ministry) is proposing to remake the Regulation subject to a number of amendments set out in the *Public Health Regulation 2022* (the Draft Regulation).

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation.[1]

This draft regulatory impact statement has been prepared for public comment and the Ministry invites public submissions on its content and findings.

Objectives sought to be achieved by the Draft Regulation

The Act and the Draft Regulation are intended to provide a framework for adequate monitoring and control of risks to public health, prevention and control of infectious diseases, monitoring of conditions affecting public health and the protection of the health and safety of the public. The Draft Regulation provides legislative support and administrative detail for the operation of the Act and a framework for businesses, councils and individuals in the practical application of the Act.

The Regulation's overall objective is to give effect to the Act, which is achieved by providing provisions that apply to distinct regulatory areas. These areas of the Regulation include:

1. *Legionella* control (Part 2)
2. control of public swimming pools and spa pools (Part 3)
3. control of skin penetration procedures (Part 4)
4. safety measures for drinking water (Part 5)
5. notifications and record keeping requirements for scheduled medical conditions (Part 6)
6. disease control measures (Part 7)
7. disposal of bodies (Part 8)

[1] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 19 October 2020.

8. miscellaneous (Part 9) [2]
9. fees payable in relation to improvement notices, prohibition orders and inspection of premises.

Options considered

The Ministry has identified the following options to be considered in this RIS.

— **Base Case** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).

— **Option 1** — this option entails remaking the existing Regulation[3] without any changes (the *status quo* option). The Regulation makes provision for:
  - the installation, operating and maintenance requirements for air-conditioning systems and other regulated systems
  - operating requirements for public swimming pools and spa pools
  - the issuing of orders to temporarily close down public swimming pools or spa pools, or to take disinfection action, where there is a risk to public health
  - requirements for the carrying out of skin penetration procedures and for the premises where such procedures are carried out
  - quality assurance programs for suppliers of drinking water
  - disease control measures
  - the facilities and procedures for the handling of bodies of deceased persons, exhumations, cremations and other matters relating to the disposal of bodies
  - the code of conduct for certain health practitioners
  - fees payable in relation to improvement notices, prohibition orders and inspection of premises
  - notification and record-keeping requirements
  - fees and penalty notice offences.

— **Option 2** — this option entails making the Draft Regulation, which would involve remaking the existing Regulation with several proposed amendments. Table ES 1 summarises the main proposed amendments to different parts of the Regulation under this option. Notably, in addition to these amendments, the Regulation has been fully re-structured and re-numbered. During this process, some clauses have been re-worded, redundant text eliminated and some clarifications to the text have been made. Savings provisions that were no longer relevant have also been removed. These changes have no material effect on the obligations of industry.

[2] An impact assessment statement (IAS) for the code of conduct for non-registered health practitioners, and relevant health organisations, referred to in Part 9 of the Regulation, and set out in Schedules 3 and 4, has been excluded from the analysis in the RIS. The IAS will be published separately for consultation. A copy of the IAS will be published on https://www.health.nsw.gov.au/legislation/Pages/regulations.aspx.

[3] There are several provisions relating to COVID-19 and public health orders in the current Regulation. These provisions are continually under review. Changes may be made to the Current Regulation and draft Regulation due to developing public health risks associated with the COVID-19 pandemic.

Table ES 1 Summary of proposed changes to the Regulation under Option 2

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
Part 2 *Legionella* control		
Clause 13F (b)	Removing the reference to the Policy Directive entitled *Water – Requirements for the Provision of Cold and Heated Water* published by the Ministry of Health.	The standard referred to in Clause 13F(a) (AS/NZS 3666.2:2011) and the other clauses contained in Part 2, Division 5 of the Regulation are considered by the Ministry to be sufficient to safely maintain warm-water systems. Given this, it is considered that there is no need for additional obligations of a Policy Directive.
Clause 13J	– A new provision to require disinfection of cooling water systems that are assessed as a risk to public health (i.e., where the testing shows the level of *Legionella* in a cooling water system exceeds 10 colony-forming units per millilitre) with either a chlorine or bromine-based compound within 48 hours. – A new subclause defining free available chlorine and free available bromine.	Currently, where no outbreak has been declared and testing reveals that the level of *Legionella* in a cooling tower exceeds 10 colony-forming units per millilitre, enforcement action is limited to an improvement notice or a prohibition order and immediate disinfection is not a legal requirement for operators. Requiring disinfection of cooling water systems within 48 hours where unsatisfactory conditions/contamination are found would prevent conditions deteriorating further and risks of exposure and illness.
Clause 13O	A new subclause under Clause 13O (5) to require that a person undertaking an audit of risk assessment is not a person employed or engaged by the person who employed or engaged a person who: – undertook the risk assessment – installed, operated or maintained the cooling water system at any time in the previous 5 years – is the operator of a laboratory that carried out testing of the cooling water system at any time in the previous 5 years.	The proposed change would eliminate instances where a person undertaking an audit of risk assessment is employed by the employer of, or engaged by, the person who: – undertook the risk assessment – installed, operated or maintained the cooling water system at any time in the previous 5 years – is the operator of a laboratory that carried out testing of the cooling water system at any time in the previous 5 years. The aim of this change is to ensure that the auditor is truly independent in their assessment.
Clause 13S (1) and Clause 13T (2)	Penalty notice offences created for: – Failing to comply with Clause 13S (1) of the Regulation which requires the occupiers of premises on which a cooling water system is installed to have the required documents in relation to the system available for inspection on request by an authorised officer. – Failing to comply with Clause 13T (2) of the Regulation, which requires the occupier of premises on which a cooling water system is installed to notify the relevant local government authority of any change in the particulars provided about the system to the authority.	Public health units have reported that the four hour requirement to submit records upon request set in Clause 13S (1) of the Regulation is not being complied with by some occupiers of premises on which a cooling water system is installed. It is expected that these changes would increase compliance with the relevant clauses of the Regulation.
Part 3 Control of public swimming pools and spa pools		
Clause 14	A new clause is proposed to define a public swimming pool or spa pool for the purposes of Section 34 of the Act. Under this new definition, a water play park	This proposed change effectively excludes splash parks that do not recycle water from the definition of swimming pools for the purposes of Section 34 of the Act.

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
	or other recreational aquatic structure is declared not to be a public swimming pool or spa pool if it — (a) uses a public water supply, and (b) does not use a recirculation system, and (c) does not store water.	This change is unlikely to have an impact on the operations of these facilities because these types of parks are unable to comply with the requirements in the legislation (as they currently do not store or recycle water). Further, the Ministry considers that these facilities pose a low health risk.
Schedule 1 Requirements for public swimming pools and spa pools	All references and requirements related to Oxidation Reduction Potential Systems (ORP systems) would be removed from the Regulation.	Oxidation Reduction Potential (ORP) is a measure of the oxidizing capacity in water (i.e. it is not a measure of the level of chemicals/sanitisers in the water, but rather a measure of the potential a disinfectant – like chlorine - has to oxidize/clean the water). ORP systems are used to monitor and control water quality by measuring the oxidation reduction potential of disinfectants in pool water. Under the current Regulation, public pools in NSW fitted with ORP systems are required to maintain an ORP level of at least 720mV (if chlorine disinfected) or 700mV (if bromine disinfected), and if this is met are not required to measure or maintain minimum chlorine and bromine disinfection levels. This proposed change to the Regulation effectively removes ORP systems as an accepted alternate method for monitoring and controlling water quality in public swimming pools and spa pools. As a result of this change, public pools and spas currently fitted with ORP systems would be required to measure and maintain the same minimum chlorine and bromine disinfection levels set in the Regulation as any other pool.
Part 4 Control of skin penetration procedures		
Division 2 Clause 23(1)(d)	For premises where skin penetration procedures are carried out, clarifying that the separate sink required for cleaning equipment used in skin penetration procedures must only be used for cleaning equipment.	Under current Clause 23 of the Regulation, skin penetration premises are required to have (amongst other requirements): a) a hand basin that has a supply of clean, warm, potable water b) a separate sink that has a supply of clean, warm water for cleaning equipment (if equipment used in skin penetration procedures at the premises is cleaned at the premises). The intent of the Regulation under b) is that the sink for cleaning equipment is only used for this purpose. However, evidence from Public Health Units indicates that premises are using these sinks for other purposes, with consequent risk of cross contamination and poor availability. The purpose of this change is to clarify the intent of the Regulation.
Clause 26 (2) (a)	Removing the requirement to comply with the standard AS 2182-1998 (which sets the design and construction of the autoclave).	This standard has been rescinded and not replaced. The Ministry considers that the remaining requirements in the Regulation are sufficient for infection control and hygiene for skin penetration premises.

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
Clause 26	Amending this clause to add a requirement for premises that sterilise reusable articles off-site to keep for 12 months a copy of the report on the sterilisation by the person who sterilised the article.	This change is being proposed to ensure good record keeping and facilitate auditing of compliance with the requirements in the Regulation.
Clause 31 (1)	Amending this clause to clarify that the notice of the carrying out of skin penetration procedures must be given to the local government authority before skin penetration procedures are carried out at the premises.	This change is being proposed to clarify the intent of the Regulation.
Part 5 Safety measures for drinking water		
No major amendments proposed for this part of the Regulation		
Part 6 Scheduled Medical Conditions		
Clause 37 and 39	References to AIDS have been removed in these clauses.	Change is proposed to reflect changes in the Act, under which AIDS is no longer a notifiable condition under the Act.
Clause 39 (1)(a)	A refence to the conditions listed in Schedule 1A of the Act, alongside category 4 and 5 conditions has been included in this clause.	Change is proposed to reflect the introduction of this Schedule in the Act
Clause 39A	This clause has been expanded so that advice regarding measures to be taken, and activities to be avoided, in order to minimise the danger of a person suffering from a Category 2 or 3 condition passing the medical condition to another person, can be provided by a range of staff within public and private health services. This includes a person who provides any of the following services: a) medical, hospital, nursing or midwifery services, b) community health services, c) health education services, d) public and population health services, e) welfare services necessary to implement any services referred to in (a)–(d).	Change is proposed to better reflect the range of practitioners and staff that are appropriate to provide advice to patients regarding scheduled medical conditions.
Clause 39B (3)	This clause has been expanded so that the definition of 'relevant health practitioner' (who may notify a person who may have been in contact with a person suffering from a Category 2, 3 or 4 condition of measures to be taken, and activities to be avoided, in order to minimise the danger of the first person contracting the condition or passing it to a third person), includes a person who provides public and population health services.	Change is proposed to better reflect the range of practitioners and staff that should provide advice to patients regarding scheduled medical conditions.
Part 7 Other disease control measures		

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
Clause 44A	A new exemption from pre-enrolment immunisation requirements relating to childcare facilities to allow the principal of a childcare facility to permit enrolment of a child that meets the immunisation requirements for the purposes of section 6(1) of the *A New Tax System (Family Assistance) Act 1999* of the Commonwealth on the grounds set out in section 6(3)(c) or 6(4) or (6) of that Act.	The aim of this change is to ensure there is consistency between the exemptions to immunisation requirements allowed by the Commonwealth for the purpose of accessing some family assistance payments, and the exemptions allowed in NSW. In effect, the proposed new exemption would allow a child to be enrolled in childcare if the child meets the immunisation requirements set by the Commonwealth in the *A New Tax System (Family Assistance) Act 1999*, which establish that a child meets immunisation requirements if: 1. the child has been immunised 2. a general practitioner, a paediatrician, a public health physician, an infectious diseases physician or a clinical immunologist has certified in writing that the immunisation of the child: a) would be medically contraindicated, or b) is not required immunisation because the child has contracted a disease or diseases and as a result has developed a natural immunity, or c) the child is a participant in a vaccine study approved by a Human Research Ethics Committee registered with the National Health and Medical Research Council 3. the vaccines required for vaccination are temporarily unavailable 4. the chid has been vaccinated overseas and a recognised immunisation provider has that those vaccinations have provided the child with the same level of immunisation that the child would have acquired if the child had been vaccinated in accordance with a standard vaccination schedule 5. the Secretary determines in writing that the child meets the immunisation requirements. Notably, NSW already allows exemptions to the immunisation requirements for 2a and 4, so the new proposed exemptions relate to 2b (natural immunity), 2c (participation in a trial), 3 (vaccine not available) and 5 (Secretary's exemption).
Part 8 Disposal of bodies		
Division 3, Clause 57 (1)	Removing the requirement to comply with the guidelines specified in Part B of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* published by the National Health and Medical Research Council (NHMRC).	The NHMRC Guidelines have been updated and do not contain relevant requirements regarding bodies. The Ministry believes that the current general Workplace Health and Safety (WHS) obligations achieve the same result (the rescinded guidelines contained general infection control information).
Clause 54	Amend clause to increase the time that hospitals are allowed to retain bodies to up to 21 days.	Hospitals are currently allowed to retain bodies for up to 5 days. While funeral directors and families are encouraged to collect the body of a deceased person from hospital as soon as possible, there are circumstances where this is not possible (e.g. if relatives are overseas).

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
		Extending the retention time to 21 days would allow hospital, funeral directors and families more flexibility.
Clause 62 (2)	Amend clause to require mortuaries to register bodies immediately after the body is delivered to the mortuary for preparation (instead of after the body is prepared).	To improve the process of registration of bodies.
Clause 63 (a)	Amend clause to allow bodies to be buried in a shroud rather than only coffins (provided the shroud complies with the relevant Policy Directive).	Currently the Regulation requires that all bodies must be buried in a coffin unless otherwise approved for religious reasons under NSW Health Policy Directive Burials- Exemptions from Public Health Regulation 2012 for Community and Religious Reasons (PD 2013_048). This amendment would allow bodies to be buried in a shroud without the need to obtain an exemption. The change is proposed to ensure that adequate and proper provision is made for the interment practices and beliefs of all religious and cultural groups in our society and provide greater consumer choice for people interested in shroud burials for other non-religious reasons.
Clause 64	Amend clause to enable a general exemption, rather than just for specific burials, by the Secretary to approve burial of bodies shallower than 900 millimetres where they comply with the requirements of the exemption.	Currently, the Regulation only allows for approval for the shallow burial of a body at a depth of less than 900mm in a particular case. This approval is only granted upon application for individual grave sites that comply with the requirements set out in the NSW Health Policy Directive Shallow Burial (PD2013_045). The amendment would provide for a general exemption and allow for pre-approved methods for shallow burials. This would accommodate common situations, such as two burials in one grave, or geotechnical engineering work that is required in a cemetery (or cemeteries) with certain subsoil ground conditions (such as a high water table and shallow depth to a rock floater or bedrock).
Clause 67 (1) (a)	Amend clause to remove the requirement for the Secretary to approve the material to hermetically enclose a body in a coffin within a vault.	To be buried in a vault a body would still need to be embalmed and hermetically enclosed in a coffin, but the material used to hermetically enclose the body no longer needs to be approved by the Secretary.
Division 5 Cremation	Amending relevant clauses in this division to simplify the cremation process by: 1. substituting the requirement to provide a cremation certificate for the provision of:	Currently, to cremate a body, the following is required by the Regulation: 1. Application for Permission for Cremation — an application made in the approved form to a medical referee or coroner. 2. Cremation Certificate[4] — issued by an attending practitioner (as defined in Clause 81 of the Regulation)

[4] If the death is not examinable by Coroner.

Regulation area [a]	Proposed change	Purpose/rationale of the proposed amendment
	a) advice as to whether there is a cremation risk from a relevant medical practitioner. A relevant medical practitioner in this context is medical practitioner who: i) attended the person immediately before, or during the illness terminating in, the death of the person, or ii) has relevant knowledge of the dead person's medical history b) a death certificate, a Medical Certificate of Cause of Death (MCCD) or an order authorising the disposal of the remains of the dead person by a coroner under section 101 of the *Coroners Act 2009* 2. no longer requiring that the Medical Referee makes an external examination of the body as a condition to issue a cremation permit (however, a medical referee *may* conduct one if the Medical Referee considers it necessary).	3. Cremation Permit — issued by a medical referee.[5] To issue this permit the medical referee is required to make an external examination of the body The proposal is to: – substitute the Cremation Certificate for: – advice as to whether there is a cremation risk from a relevant medical practitioner (either the attending practitioner or a medical practitioner familiar with the deceased's medical history) – a death certificate, a MCCD or an order authorising the disposal of the remains of the dead person by a coroner under section 101 of the *Coroners Act 2009*. – no longer requiring a Medical Referee to undertake an external examination of the body as a condition to issue a cremation permit. These proposed changes are aimed at simplifying the cremation process, reducing the administrative burden for funeral directors and their clients and reducing cremation costs for families of deceased persons.
Part 9 Miscellaneous		
Clause 99	A new code of conduct prescribed for the purposes of section 100 of the Act for the provision of health services by a relevant health organisation.	Similar to the code of conduct for non-registered health practitioners in Schedule 3 of the Regulation, the proposed new code of conduct for health organisations has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.
Schedule 3		
N/A	This schedule is being review in whole. A new code for relevant organisations has been created in Schedule 4.	The code of conduct for non-registered health practitioners in Schedule 3 and a new code for relevant health organisations in Schedule 4 have been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.
Fees		
N/A	All fees have been increased by 2.5 per cent.	This is a standard increase in fees to reflect increases in the Consumer Price Index and the costs of administering the Regulation.

[a] All clauses refer to the current Regulation.

Source: Ministry of Health and ACIL Allen.

[5] Ibid.

Assessment of options

The following sections summarise the assessment of impacts of the regulatory options outlined above. The first section assesses the expected impacts of the Base Case (i.e. of letting the Regulation sunset) and the second section assesses the impacts of the proposed Draft Regulation (Option 2) against the status quo, i.e. the current Regulation (Option 1).

The benefits and costs associated with the alternative options have been analysed in this RIS qualitatively. This is because:

- the Ministry's advice that the RIS was to be prepared on a qualitative basis
- the benefits and costs associated with the alternative options are not amenable to easy quantification due to:
  - limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
  - the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

In addition, in preparing this RIS, selected stakeholder consultations were conducted with several organisations. Where relevant, comments by stakeholders have been included in the discussion. These views need to be further tested during the public consultation period before remaking of the Regulation.

Impacts of letting the Regulation sunset (the Base Case)

The Base Case option (discontinuing the Regulation) is not considered appropriate because of the following reasons:

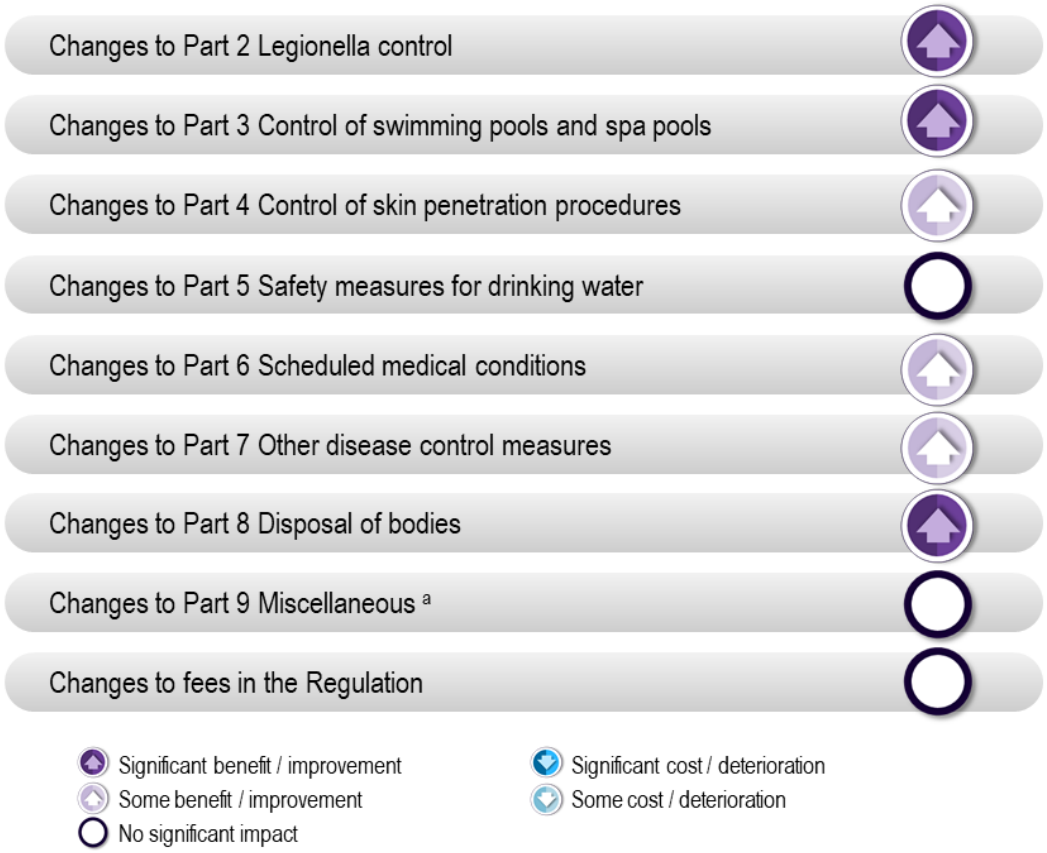
- it would mean that the Act would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates
- it would increase the risks to the health and safety of the public due to the lack of standards across a range of areas that have the potential to affect public health (for instance, drinking water, water cooling systems, skin penetration procedures and public swimming pools) and provisions for a number of measures to control the transmission of communicable diseases. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

Impacts of the proposed Regulation (Option 1 and Option 2)

The analysis of the impacts of the proposed amendments to the Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1) has been structured around the different areas of the Regulation, rather than around each of the options.

As discussed before, the benefits and costs associated with the alternative options are not amenable to quantification. However, Figure ES 1, provides a summary of the relative nature of the benefits and costs of the changes proposed under Option 2 across the areas outlined in Table ES 1 (except Schedule 3 which is outside the scope of the RIS), with respect to Option 1 (i.e. the *status quo*).

Figure ES 1 Summary of potential relative impacts of the proposed Draft Regulation across key areas of change (relative to the status quo)



[a] Other than rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (and hence no significant costs or benefits associated with these), the only other change proposed for this part of the Regulation is a new code of conduct for health organisations. This proposed new code of conduct, and changes to the existing code of conduct for health practitioners in Schedule 3, has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.

Source: ACIL Allen.

In summary, in relation to the proposed changes to the Regulation across its main areas:

1. Overall, it is considered that the proposed changes to the *Legionella* provisions in Part 2 of the Regulation could contribute to a reduction in the frequency, severity and impact of legionellosis outbreaks at a marginal cost to occupiers of premises on which cooling systems are installed.
2. The proposed changes to Part 3 of the Regulation related to the removal of ORP systems as an accepted alternate method for monitoring and controlling water quality in public swimming pools and spa pools are likely to result in:
   - a reduction in risks to people's health and safety when using a public swimming pool
   - possible reductions in the frequency, severity and impact of diseases facilitated by improperly maintained pools
   - a possible marginal reduction in the costs of maintaining ORP systems for some industry operators who may decide to discontinue the use of ORP systems due to the proposed change.

   Overall, it is considered that the above benefits are likely to outweigh the additional compliance costs related to the proposed changes for facilities with ORP systems that do not already conduct the required tests separately.

3. The proposed changes to Part 4 of the Regulation can potentially reduce cross contamination risks in skin penetration premises and improve record keeping of sterilisation reports at a marginal cost. Accordingly, these changes are expected to be beneficial.
4. The only amendments proposed for Part 5 of the Regulation (safety measures for drinking water) are rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry. Given this, there are no significant costs or benefits associated with these changes.
5. To the extent that the proposed changes to Part 6 of the Regulation (scheduled medical conditions) result in are better alignment of the Regulation and the Act and improved clarity of the Regulation, the changes are expected to be beneficial.
6. Overall, it is considered unlikely that the new proposed exemptions from pre-enrolment immunisation requirements, relating to childcare facilities in Part 7 of the Regulation for children with certified natural immunity, participating in an approved vaccine study or who cannot be vaccinated due to temporary vaccine unavailability, would significantly increase risks of transmission of communicable diseases in childcare facilities because:
   - the rate of vaccination of children 5 years and under in NSW is very high (over 91 per cent), so the number of children which would fall within the three new exemptions is expected to be very low
   - anecdotal evidence indicates that children who fall within the proposed new exemptions are already being allowed to enrol in childcare as they are deemed to comply with the Commonwealth immunisation requirements, so formalising this practice is unlikely to create *additional* risk for the community compared to the status quo
   - while achieving higher vaccination coverage for children in childcare settings is desirable, the increased risk for unvaccinated children is considered to be slight and related principally to the situation where vaccines are temporarily unavailable. These risks are outweighed by the benefits of enabling those children to participate in the education system.

   The proposed exemptions would ensure consistency between Commonwealth and state requirements (which could result in some administrative costs for childcare providers) and would result in children who fall within the proposed new exemptions but who were previously excluded from enrolling in childcare services, being able to attend (although, as noted above, there is anecdotal evidence that these children are already being allowed to enrol in childcares). Under this scenario, the benefit of the proposed changes would be cost savings to parents/carers, childcare providers and regulators who would not have to spend time negotiating enrolment of children under these circumstances).

   To the extent that the proposed new exemptions could improve equity of access to early education for children who cannot reasonably be (or need to be) immunised and improve consistency between Commonwealth and state requirements, without increasing the overall health risks to children in childcare settings, the proposed change is expected to be beneficial.
7. To the extent that the changes proposed to Part 8 of the Regulation (disposal of bodies) do not significantly increase cremation risks (including the risk of cremating bodies where death should be subject of other investigation) or health and safety risks for people handling bodies, and result in compliance and administrative cost savings (both for industry and government), increased consumer choice, more efficient burial and cremation operations and better utilisation of cemetery land and burial space, then the proposed change is expected to be beneficial .

   Given that the proposed changes for this part of the Regulation would be subject to Policy Directives/Guidelines produced by the Ministry with the aim of continuing to adequately protect public health by setting appropriate infection control standards and procedures and

providing for the appropriate documentation in relation to cremations, then the proposed changes in this area of the Regulation are expected to be overall beneficial.

8. The proposed changes for Part 9 of the Regulation involve:
   - rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry, government or consumers (and hence no significant additional costs or benefits)
   - a new code of conduct for health organisations. This proposed new code of conduct has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.
9. The proposed increase in fees to reflect inflation rates are not considered a cost of Option 2 because this change leaves the *real* level of fees unchanged.

Considering the above, the Ministry would like to receive submissions on whether the proposed changes in the Draft Regulation are appropriate before a final decision is made regarding pursuing the proposed changes.

Next steps

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft Regulation and respond accordingly. Key issues on which stakeholder views are sought include the following:

- Are there additional measures that could be included in the Regulation to more effectively identify, manage or control the growth and spread of Legionella in cooling water systems? For example, reducing the threshold for reportable test results to a level that would improve identification and response to Legionella detections.
- Are there any costs and benefits of the Draft Regulation that have not yet been considered, and how material are these impacts?
- Are there any risks of the Draft Regulation that have not yet been considered?
- Are there any additional amendments which could have a net positive impact on the proposed Regulation?
- Could the results of the proposed Regulation be achieved through any alternative options?
- Are the matters covered in the Regulation appropriate to be dealt with by the Public Health Regulation, and by NSW Health? Or, are there more appropriate mechanisms (including other legislation), or bodies, to manage any of the matters in the Regulation?

Consistent with the *Subordinate Legislation Act 1998*, the Draft Regulation and RIS will be open for public consultation for a period of at least 21 days. Submissions must be received 22 April 2022.

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
ST LEONARDS NSW 1590

Submissions may also be made via email to NSWH-LegalMail@health.nsw.gov.au.

Individuals and organisations should be aware that generally any submissions received will be publicly available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry of Health, in considering the submissions received, may also circulate submissions for further comment to other interested parties or publish all, or parts, of the

submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

1 Introduction

1.1 Overview

The health of New South Wales (NSW) residents is promoted and protected through the *Public Health Act 2010* (the Act). The Act is one of several Acts that deal with public health matters in NSW and it makes provisions for a range of matters, such as notification of diseases and conditions and the regulation of areas that have the potential to affect public health (for instance, drinking water, cooling water systems, skin penetration procedures and public swimming pools). The *Public Health Regulation 2012* (the Regulation) supports the smooth operation of the Act by making provisions across these areas.

Since 2012 there have been a few changes to the Regulation. The most significant changes were made to the Legionella control provisions in 2018 which imposed additional installation, operational and maintenance requirements relating to cooling water systems (including monthly sampling of cooling towers). The NSW Ministry of Health (the Ministry) is proposing to remake the Regulation subject to a number of amendments. The proposed remake of the Regulation is set out in the Draft Public Health Regulation 2022 (Draft Regulation).

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation[6]. ACIL Allen Consulting (ACIL Allen) has been engaged by the Ministry to prepare the RIS for the remake of the Regulation.

The primary purpose of a RIS is to ensure that the costs and benefits of regulatory proposals are fully examined so that affected stakeholders can be satisfied that the benefits of the regulation exceed the costs. To achieve these ends, the *Subordinate Legislation Act 1989* requires a RIS to contain certain information including:

- an analysis of the nature and extent of the problem sought to be addressed by the regulation and establishing the need for regulation
- a statement of the objectives sought to be achieved by the regulation
- the identification of the alternative options by which those objectives can be achieved
- an assessment of the costs and benefits of the impacts of the alternative options
- an assessment as to which of the alternative options involves the greatest net benefit or the least net cost to the community
- a statement of the consultation program to be undertaken.

[6] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 19 October 2020.

In addition to the *Subordinate Legislation Act 1989*, the introduction of regulations in NSW is also governed by Better Regulation Principles. The principles (outlined in Box 1.1) are a best practice guide for policy development and regulatory design process and must be followed in the development of every regulatory proposal.

Box 1.1 The Better Regulation Principles

- **Principle 1:** The need for government action should be established. government action should only occur where it is in the public interest, that is, where the benefits outweigh the costs.
- **Principle 2:** The objective of government action should be clear.
- **Principle 3:** The impact of government action should be properly understood, by considering the costs and benefits (using all available data) of a range of options, including non-regulatory options**.**
- **Principle 4:** Government action should be effective and proportional.
- **Principle 5:** Consultation with business, and the community, should inform regulatory development.
- **Principle 6:** The simplification, repeal, reform, modernisation or consolidation of existing regulation should be considered.
- **Principle 7:** Regulation should be periodically reviewed, and if necessary reformed, to ensure its continued efficiency and effectiveness.

Source: NSW Treasury 2019, NSW Government Guide to Better Regulation, tpp19-01.

1.2 Scope of the RIS

The evaluation of costs and benefits of the alternative options analysed in this RIS has been undertaken on a qualitative basis. This is because:

- the Ministry's advice that the RIS was to be prepared on a qualitative basis
- the benefits and costs associated with the alternative options are not amenable to easy quantification due to:
  - limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
  - the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

In addition, following advice by the Ministry, proposed changes to the existing Code of Conduct for non-registered health practitioners in Schedule 3 of the current Regulation and the proposal to create a new Code of Conduct for health organisations have been excluded from the RIS as these require a separate Impact Assessment Statement.

1.3 Structure of the RIS and the proposed Regulation

The chapters in this report are structured around the *Subordinate Legislation Act 1989's* RIS content requirements and the application of the Better Regulation Principles.

While all the provisions in the Regulation are essentially concerned with preserving and promoting public health, they deal with a range of different, and in many cases largely independent matters. Given this, the approach taken in the RIS is to separately analyse each of the substantive Parts of the proposed regulations. This approach will allow the reader to form an understanding of the purpose and merits of each of the key elements of the proposed Regulation.

The Regulation is divided into 9 Parts:

1. Part 1 — Preliminary matters
2. Part 2 — *Legionella* control

3. Part 3 — Control of public swimming pools and spa pools
4. Part 4 — Control of skin penetration procedures
5. Part 5 — Safety measures for drinking water
6. Part 6 — Scheduled medical conditions
7. Part 7 — Other disease control measures
8. Part 8 — Disposal of bodies
9. Part 9 — Miscellaneous.

Nature and extent of the problem 2

When conducting a review of a Regulation due to be repealed, it is important to clearly demonstrate that the Regulation is still relevant. This consists of two steps. First, it is necessary to identify that a problem exists. Second, the RIS should demonstrate that the problem is amenable to a government intervention and that a regulatory response is appropriate.

This chapter addresses the first requirement through outlining the nature and extent of the problem that the Regulation intends to address. Chapter 3 will assess the case for government intervention.

The assessment of the problem is based on the main areas of risk that the Regulation seeks to address. These are:

— *Legionella* risk
— transmission of disease in public swimming pools and spa
— infection risk through skin penetration procedures
— safety of drinking water
— transmission and management of certain medical conditions and infectious diseases
— immunisation of children in childcare facilities and primary schools
— disposal of bodies.

2.1 *Legionella* risk

Legionnaires' disease is an infection of the lungs (pneumonia) that occurs when a person breathes in bacteria that are commonly found in the environment (in contaminated water vapour or dust). Although there are many different species of *Legionella* bacteria, the two that most commonly cause disease in NSW are: [7]

— *Legionella pneumophila* — these bacteria can grow to high numbers in warm, stagnant water. Outbreaks are sometimes associated with contaminated cooling towers that are part of air conditioning systems in large buildings. Regular inspections, disinfection and maintenance of cooling towers and plumbing systems limits the growth of the bacteria.
— *Legionella longbeachae* — these bacteria are common in soil and potting mix.

Around 10 per cent of people with Legionnaires' disease die despite treatment.[8]

[7] Ministry of Health (MoH) NSW 2016, *Legionnaires' disease factsheet*, https://www.health.nsw.gov.au/Infectious/factsheets/Factsheets/legionnaires-disease.pdf, accessed 26 October 2020.

[8] Ministry of Health (MoH) NSW 2020, *Legionnaires' disease - frequently asked questions,* https://www.health.nsw.gov.au/Infectious/alerts/Pages/legionnaires-faq.aspx#5, accessed 26 October 2020.

Epidemiological evidence suggests that the risks from *Legionella* arise mainly from systems in the built environment which allow the growth of these microorganisms to numbers much greater than those normally encountered in the natural environment, thereby becoming a source of infection.[9] Water supplies can contain very small and often undetectable levels of *Legionella* which could multiply given favourable conditions. Indeed, the Ministry notes that, although 10 per cent or more of cooling towers may be contaminated in a city, most are never found to cause outbreaks of disease.[10]

Cooling water systems allow the survival and proliferation of *Legionella* bacteria due to their operating temperature, unless an effective system of disinfection is installed, maintained and correctly operated.[11] While it is not practicable to eliminate *Legionella* completely, measures to reduce the levels of *Legionella* to levels not posing a public health risk are important to minimise the risks of outbreaks and deaths due to this disease.

In 2020 there were 164 cases of Legionnaires' disease reported in NSW, with 72 due to *Legionella longbeachae*, 89 due to *Legionella pneumophila* and three not specified. As shown in Figure 2.1, over the last few years there have been about 140 cases of Legionnaires' disease reported in NSW each year (except in 2018 where there was a slight spike in notifications due to an outbreak), with about 50 to 60 per cent of cases caused by *Legionella pneumophila*. Figure 2.2 shows the rates of *Legionella* notifications per 100,000 population.

The following factors have been identified by the Ministry as contributing to the increase in notifications of Legionnaires' disease over recent years:[12]

— the development of more sensitive tests and the more widespread use of these tests, which has contributed to better diagnoses and reporting of cases

— recent increased awareness of the disease among clinicians, in part thanks to NSW Health's media alerts and direct communication to GPs and hospitals, is also likely to have increased the diagnoses of previously unrecognised cases.

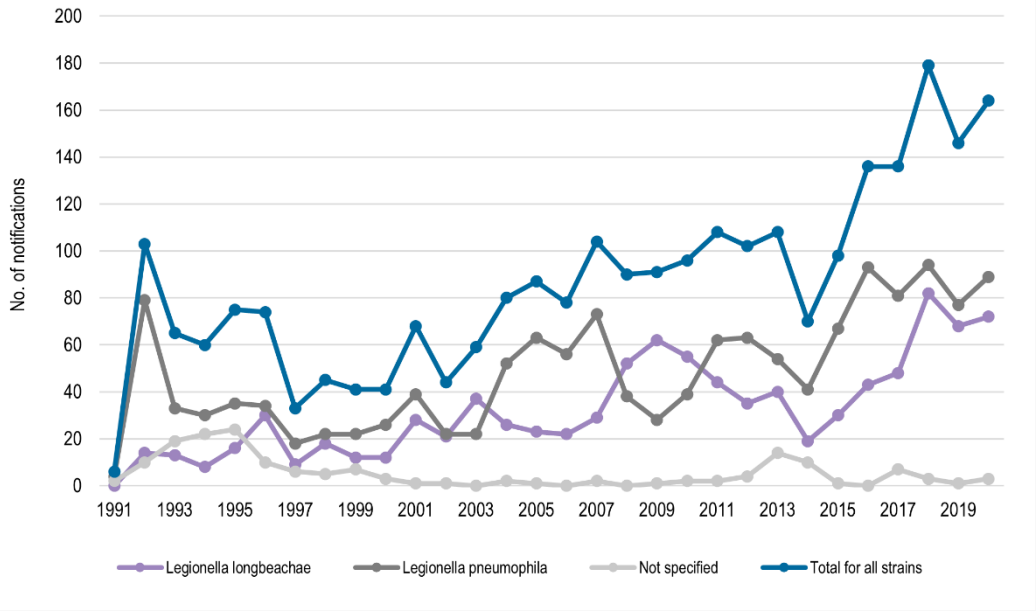
[9] Ministry of Health (MoH) NSW 2011a, *Public Health Regulation 2011 Regulatory Impact Statement*.

[10] Ministry of Health (MoH) NSW 2020, *Legionnaires' disease - frequently asked questions,* https://www.health.nsw.gov.au/Infectious/alerts/Pages/legionnaires-faq.aspx#5, accessed 26 October 2020.

[11] Ministry of Health (MoH) NSW 2011a, *Public Health Regulation 2011 Regulatory Impact Statement*.

[12] Ministry of Health (MoH) NSW 2020, *Legionnaires' disease - frequently asked questions,* https://www.health.nsw.gov.au/Infectious/alerts/Pages/legionnaires-faq.aspx#5, accessed 26 October 2020.

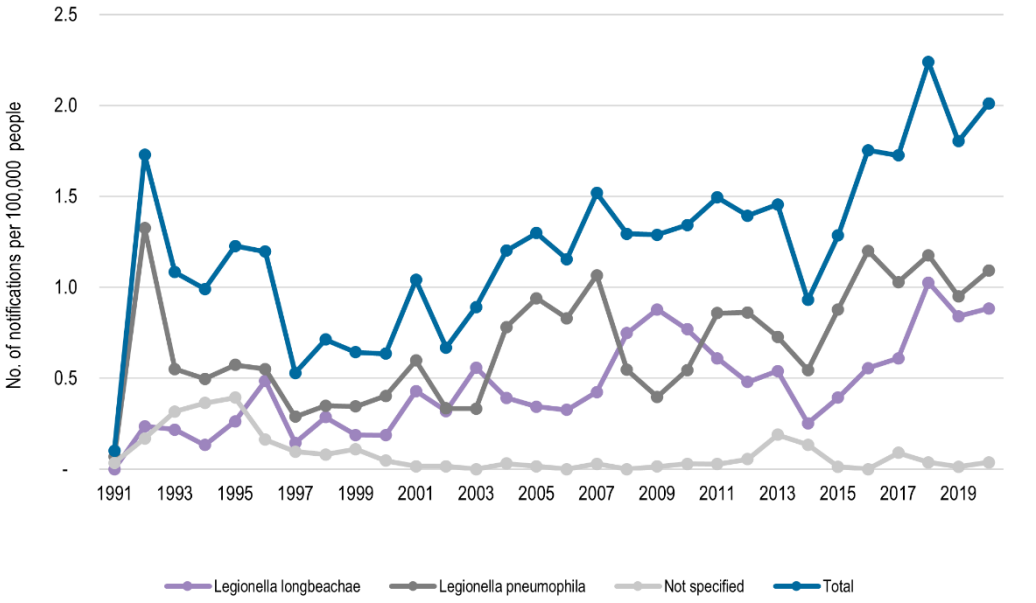
Figure 2.1 *Legionella* notifications in NSW residents, by year of disease onset, 1991-2020



Note: Based on onset - the earlier of patient-reported onset, specimen, or notification date. Became notifiable November 1991. Data excludes persons whose age or gender was unknown, or who were not NSW residents.

Source: NSW Health Notifiable Conditions Information Management System (NCIMS), Communicable Diseases Branch and Centre for Epidemiology and Evidence, NSW Health.

Figure 2.2 *Legionella* notifications per 100,000 population, by year of disease onset, 1991-2020



Note: Based on onset - the earlier of patient-reported onset, specimen, or notification date. Became notifiable November 1991. Data excludes persons whose age or gender was unknown, or who were not NSW residents.

Source: NSW Health Notifiable Conditions Information Management System (NCIMS), Communicable Diseases Branch and Centre for Epidemiology and Evidence, NSW Health.

2.2 Transmission of disease in public swimming pools and spa pools

Water in public swimming pools and spas is an ideal medium for the transmission of disease and these facilities have been associated with cases and outbreaks of illness due to harmful microorganisms.

There are a number of infections that may be spread through inadequately maintained swimming pools and spas. These are summarised in Table 2.1. While a number of these infections are relatively minor and easily treated (such as athlete's foot), other infections, such as cryptosporidiosis and giardiasis can be serious or life threatening in extreme cases, particularly for certain sections of the public such as those with immune deficiencies.

Table 2.1 Diseases facilitated by improperly maintained pools and spas

Group	Pathogen	Disease
Bacterial	*Pseudomonas aeruginosa*	– Eye infections – Ear infections (Otitis externa) – Skin infections (Folliculitis) – Urinary tract infections
	Legionella spp	– Legionnaires' disease – Pontiac fever
	Mycobacterium marinum	Swimming pool granuloma
Protozoan	*Cryptosporidium parvum*	Cryptosporidiosis
	Giardia	Giardiasis
	Naegleria fowleri	Primary amoebic menigo-encephalitis
Viral	Enteroviruses	Gastroenteritis
	Adenoviruses types 3 and 4	Pharyno-conjunctival fever
	Herpes simplex	Cold sores
	Papovavirus	Plantar warts
Fungal	Trichophyton mentagrophytes	Athlete's foot
	Candida albicans	– Urino-genital infections – Skin infections – Nail infections

Source: Ministry of Health (MoH) NSW 2011a, Public Health Regulation 2011 Regulatory Impact Statement.

The diseases which are most likely to be transmitted in poorly maintained pools are skin infections, ear nose and throat infections, and gastro-intestinal infections. Serious diseases which may be transmitted through public swimming pools and spas are rare in Australia and the risk of such diseases is negligible in properly maintained pools. Nevertheless, fatalities due to primary amoebic meningitis and Legionnaires' disease transmitted through inadequately treated public swimming pools or spas could occur. [13]

Each year there are sporadic outbreaks of illness associated with public pools (particularly in the summer months), with the most common pathogen spread being *Cryptosporidium.* Ingesting pool water contaminated with *Cryptosporidium* oocysts can lead to illness, commonly presenting as gastroenteritis. Symptoms of the disease usually include watery diarrhoea associated with cramping abdominal pain, dehydration, weight loss, fever, nausea and vomiting. Symptoms can

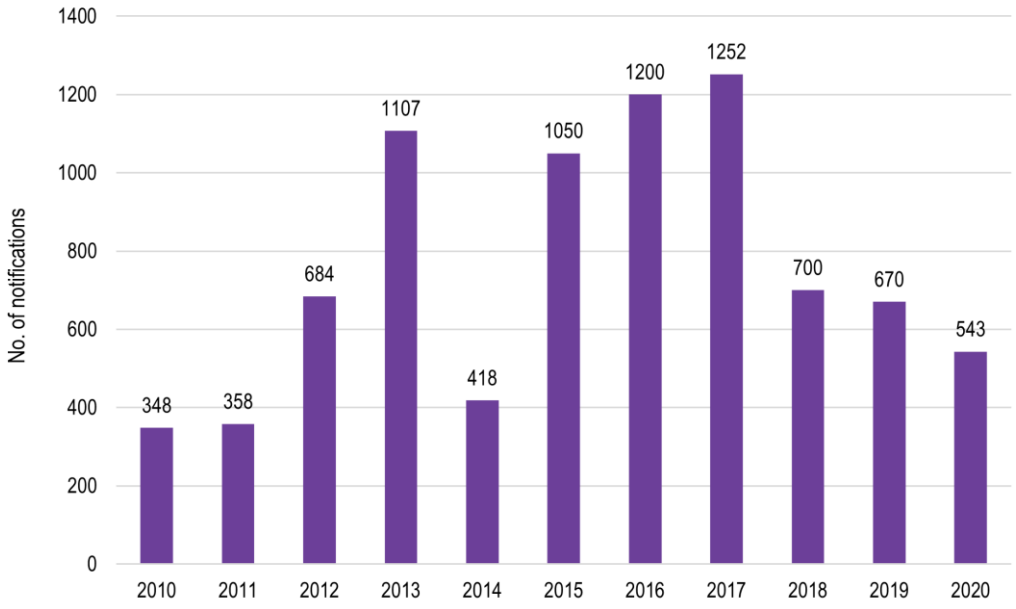
[13] Ministry of Health NSW 2011, *Public Health Regulation 2011 Regulatory Impact Statement*.

last for four to 21 days. Less commonly the infection may involve the lungs, gall bladder and pancreas.[14]

The annual number of Cryptosporidiosis notifications in NSW residents over the last ten years is presented in Figure 2.3. This shows the overall levels of Cryptosporidiosis affecting the community throughout the year (not only those associated with aquatic facilities). As noted above, each year sporadic outbreaks of illness are associated with swimming pools and are typically detected in the warmer months of the year.

A high proportion of children use public swimming pools and they are more likely to contract Cryptosporidiosis than the broader population due to their immature immune systems and likelihood of ingesting more pool water. Analysis of notifications in NSW by age from December 2010 to December 2020 shows a higher number of cases in young children, particularly those under five years of age (around a third of all case notifications over the 10-year period, see Figure 2.4).

Figure 2.3 Cryptosporidiosis notifications in NSW residents, by year of disease onset, 2010 to 2020.

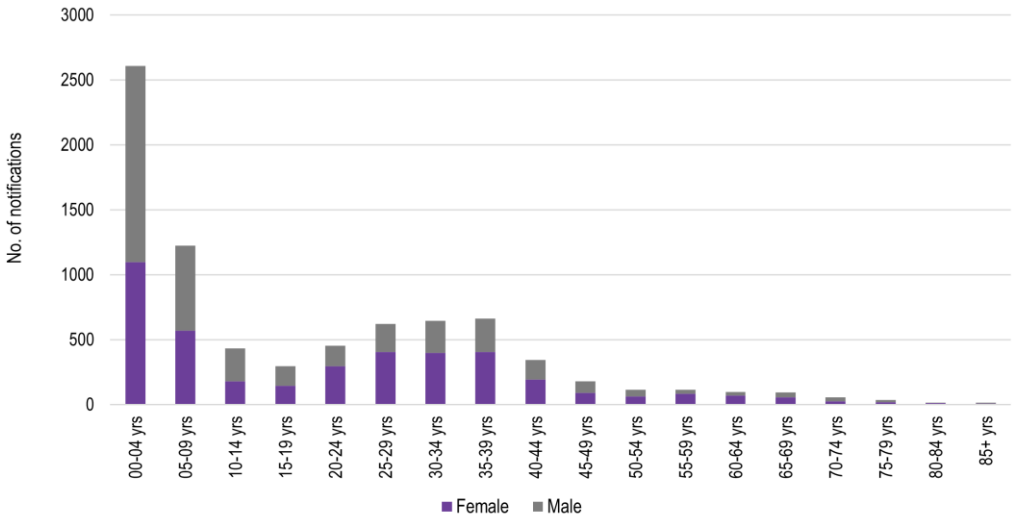


Note: As of 25 October 2020. Based on onset - the earlier of patient-reported onset, specimen, or notification date. Became notifiable December 1996. Data excludes persons whose age or gender was unknown, or who were not NSW residents.

Source: NSW Health Notifiable Conditions Information Management System (NCIMS), Communicable Diseases Branch and Centre for Epidemiology and Evidence, NSW Health.

[14] Department of Health and Human Services (Victoria) 2019, *Public Health and Wellbeing Regulations Sunset Review, Regulatory Impact Statement*, August.

Figure 2.4 Cryptosporidiosis notifications in NSW residents, by five year age group and gender, December 2010 to December 2020



Note: As of 25 October 2020. Based on onset - the earlier of patient-reported onset, specimen, or notification date. Became notifiable December 1996. Data excludes persons whose age or gender was unknown, or who were not NSW residents.

Source: NSW Health Notifiable Conditions Information Management System (NCIMS), Communicable Diseases Branch and Centre for Epidemiology and Evidence, NSW Health.

Public swimming pools and spas can amplify the risk of infection if their water is not properly treated or if the facility is not well managed and unhygienic. Chemical treatment of pools, using either chlorine or bromine, and filters minimise the presence of pathogens and thereby assist in preventing disease transmission through pools and spas. Thus, ensuring that pools and spas are appropriately treated and that facilities are maintained in a hygienic condition is necessary to promote and protect public health.

2.3 Infection risk through skin penetration procedures

The Act and the Regulation regulate body decorating and grooming practices carried out by people who are not registered as health professionals. The regulated body decorating and grooming industries include[15]:

- acupuncture
- beauty treatments
- body, nose and ear piercing
- cosmetic enhancements
- colonic lavage
- tattooing
- blood cholesterol and glucose measurement.

Hairdressing and other body decorating and grooming practices which do not deliberately pierce the skin, are not regulated under the Act or the Regulation.

While there is no current data on the number of skin penetration premises in NSW, a RIS undertaken by the (then) NSW Department of Health[16] estimated that there were approximately

[15] Ministry of Health NSW 2018a, *Skin penetration industry*, https://www.health.nsw.gov.au/environment/skinpenetration/Pages/default.aspx, accessed 26 October 2020.

[16] Ministry of Health NSW 2011, *Public Health Regulation 2011 Regulatory Impact Statement*.

3,500 skin penetration businesses in 2011 (this number is likely to have increased since then) and that around 50 per cent of these businesses carried out skin penetration procedures on a full-time basis, and for the rest of the premises conducing skin penetration procedures were only a part of the occupier's business.

Skin penetration procedures provide a pathway for the spread of infection if the procedures are done in an unhygienic way. For instance, the use of unsterilised needles may result in the transmission of blood borne pathogens such as HIV and hepatitis B and C and viral and bacterial infections. These kinds of procedures carry a greater risk of spreading disease because microorganisms (germs) can easily enter the body when the skin barrier is broken.

While there is little data regarding the number or type of blood borne and other infections that may occur through skin penetration procedures, outbreaks of diseases such as hepatitis B and C have been caused by using dirty instruments in skin penetration procedures[17]

The RIS undertaken by the (then) NSW Department of Health in 2011 estimated that the risk of infection for blood borne diseases (which are the most serious of medical conditions that may be passed on through skin penetration procedures) is significant. Using health care worker needle stick injuries as a guide, it was estimated that where a needle stick injury occurs and the needle contains infected blood, the rate of transmission is 0.3 per cent for HIV, 1 per cent to 5 per cent for hepatitis C, and between 2 per cent and 40 per cent for hepatitis B, depending upon the viral load and the nature of the penetration.[18] While the risk of transmission for some of these diseases is relatively low, there is currently no vaccination against the HIV or hepatitis C and the consequences of being infected with the viruses hepatitis B or C or HIV are long term and may result in debilitating illness. For example, hepatitis B or C may result in chronic hepatitis, and cirrhosis of the liver. In a proportion of cases this will progress to cancer, which is often fatal.

The Communicable Diseases Intelligence (CDI) journal published by the Office of Health Protection reports on the source of exposure for cases of communicable diseases and found that in 2015 skin penetration procedures were recorded as an exposure factor in 13 per cent of the notifications of newly acquired hepatitis B infections and in 14 per cent of the notifications of newly acquired hepatitis C infections (see shaded rows in Figure 2.3). [19]

Unhygienic skin penetration procedures, such as use of unsterilised needles, may result in the transmission of blood borne pathogens such as HIV and hepatitis B and C, as well as bacterial infections such as *Staphylococcus* aureus. As such, ensuring that skin penetration procedures are conducted in accordance with appropriate infection controls provides a measure of protection against the transmission of disease.

[17] Ministry of Health NSW 2018b, *Beauty treatment - hygiene standards*, https://www.health.nsw.gov.au/environment/factsheets/Pages/beauty-treatment.aspx, accessed 26 October 2020.

[18] Ministry of Health NSW 2011, *Public Health Regulation 2011 Regulatory Impact Statement*.

[19] Communicable Diseases Intelligence 2019, *Australia's notifiable disease status, 2015: Annual report of the National Notifiable Diseases Surveillance System*, Australian Department of Health, https://www1.health.gov.au/internet/main/publishing.nsf/Content/629317B6B9941F1FCA257BF000217BA7/$File/australia%E2%80%99s_notifiable_disease_status,_2015_annual_report_of_the_nndss.pdf, accessed 5 November 2020.

Table 2.2 Enhanced risk factor data on notifications of newly acquired Hepatitis B and C cases in selected jurisdictions, 2015, by risk factors

Exposure category	Hepatitis B [a]		Hepatitis C [b]	
	Total number of exposure factors reported	Percentage of total cases (n=97) [c]	Total number of exposure factors reported	Percentage of total cases (n=433) [c]
Sexual exposure	**35**	**36**	**63**	**15**
Sexual contact (hepatitis B/C partner status unknown) – opposite sex	14	14	1	0
Sexual contact (hepatitis B/C positive partner) – opposite sex	9	9	39	9
Sexual contact - no further classified	5	5	6	1
Sexual contact (hepatitis B/C partner status unknown) – same sex	4	4	2	0
Sexual contact (hepatitis B/C positive partner) – same sex	3	3	15	3
Skin penetration procedure	**13**	**13**	**61**	**14**
Tattoos	6	6	46	11
Ear or body piercing	2	2	14	3
Acupuncture	5	5	1	0
Injecting drug use	30	31	258	60
Household contact	5	5	38	9
Major dental surgery work	4	4	5	1
Imprisonment	3	3	166	38
Surgical work	2	2	20	5
Needlestick/biohazardous injury	3	3	7	2
Perinatal transmission	1	1	41	9
Other	9	9	15	3
Undetermined	6	6	11	3
Unknown (not recorded)	15	15	70	16
Non-IDU remote risk (>24 months prior to diagnosis)			11	3
Total exposure factors reported	**105**		**350**	
Total number of cases	**97**		**433**	

[a] Includes cases from New South Wales, South Australia, Tasmania, Victoria and Western Australia. While these 5 jurisdictions provided enhanced data on risk factors, not all cases had this information recorded.

[b] Includes cases from the Australian Capital Territory, New South Wales, the Northern Territory, South Australia, Tasmania, Victoria and Western Australia. While these 7 jurisdictions provided enhanced data on risk factors, not all cases had this information recorded.

[c] The denominator used to calculate the percentage is based on the cases with recorded enhanced data. As more than one exposure category for each notification could be recorded, the total percentage does not equate to 100 per cent.

Note: More than one exposure category for each case could be recorded. Analysis and categorisation of these exposures are subject to interpretation and may vary between reports

Source: Communicable Diseases Intelligence 2019, Australia's notifiable disease status, 2015: Annual report of the National Notifiable Diseases Surveillance System, Australian Department of Health.

2.4 Safety of drinking water

Drinking water of poor quality presents a threat to public safety and can lead to illnesses, and in some cases fatalities. There is a wide range of potential biological, chemical and physical contaminants in the water that present a health risk. These include:

- Microorganisms and biological contaminants, most commonly:
  - *Escherichia coli* (E. Coli), a bacterium whose virulent strains can cause bloody diarrhoea, and sometimes haemolytic uraemic syndrome.[20]
  - Cyanobacteria, sometimes known as blue-green algae which can produce hepatotoxins, neurotoxins, and cylindrospermopsin which can damage various parts of the body, although no deaths have been attributed to consumption of Cyanobacteria.[21]
  - *Cryptosporidium*, a parasite which infects the intestine and can cause diarrhea, stomach cramps, vomiting, nausea, and fever. [22]
- Chemical contaminants, which in recent years have included:
  - uranium
  - arsenic
  - excessive chlorine, after machine or human error.
- Physical contaminants, including:
  - vermin in a reservoir — which can lead to the introduction of microorganisms and chemical contaminants
  - turbidity, particularly after storms and flood.

A larger list of contaminants can be found in the Australian Drinking Water Guidelines (ADWG).

There is little data on the number of infections directly linked to poor quality water in Australia, however, a couple of incidents overseas can be used to illustrate the potential magnitude of the problem caused by contaminated drinking water.

- In 2000 there was a serious outbreak of waterborne illness following the contamination of the community drinking water supply in Walkerton, Canada. This incident resulted in over 2,000 cases of illness and seven deaths and is estimated to have cost the economy more CA$64 million. There was a range of causes identified for the outbreak, including that there was little effort to protect the source water from faecal contamination, deficient chlorination practice and a failure to respond to poor test results, as well as limited training and breakdowns in regulatory action.[23]
- In April 1993 there was a major outbreak of illness in the city of Milwaukee, Wisconsin due to *Cryptosporidium*. More than 400,000 people became ill after drinking contaminated water from the city water supply system. Most of these people recovered on their own, but those with compromised immune systems were sometimes unable to fight off the disease. It is now believed that as many as 100 people may have died as a result of this incident.[24]

While events where diseases are spread through contaminated drinking water are very rare in Australia, occasionally there are incidents that affect drinking water quality (these may include changing source water conditions such as flooding, operational problems, detection of *Escherichia coli* bacteria and/or blooms of cyanobacteria).

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[20] Ministry of Health (MoH) NSW 2017, *Shiga Toxigenic Escherichia coli (STEC) Infection and Haemolytic Uraemic Syndrome (HUS)*, https://www.health.nsw.gov.au/Infectious/diseases/Pages/shigatoxigenic.aspx accessed 26 April 2021

[21] National Health and Medical Research Council (NHMRC) 2021, *Australian Drinking Water Guidelines 6 2011, version 3.6 update March 2021* Section 5.3.5, accessed 24 April 2021

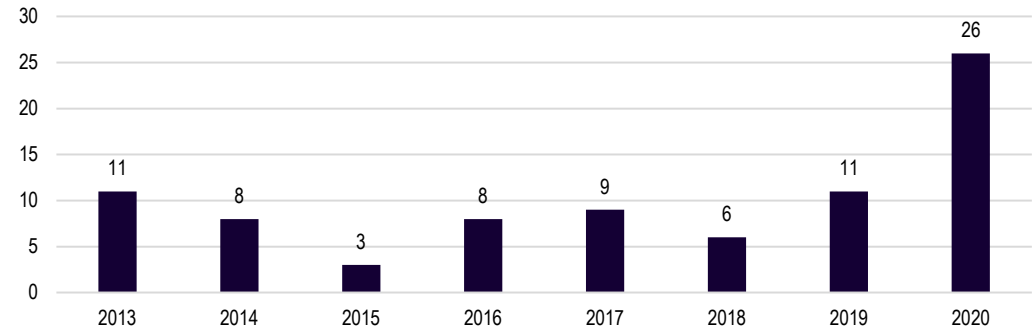
[22] Ministry of Health (MoH) NSW 2018, *Cryptosporidiosis fact sheet,* https://www.health.nsw.gov.au/Infectious/factsheets/Pages/cryptosporidiosis.aspx Accessed 26 April 2021

[23] Ministry of Health NSW 2011, *Public Health Regulation 2011 Regulatory Impact Statement*.

[24] Minnesota Department of Health, 2020, *Cryptosporidium page,* https://www.health.state.mn.us/communities/environment/water/factsheet/cryptosporidium.html, accessed 1 May 2021.

In 2020 there were 26 water notices issued by NSW water suppliers advising that drinking water was contaminated. Many of these notices were accompanied by instructions to boil the water before consumption. However, the number of these notices have varied significantly over time, with 2015 having as low as three reports (see Figure 2.5).

Figure 2.5 Number of drinking water incidents in NSW by date placed



Source: NSW Health Drinking water quality and incidents, 2021

Although rare, serious outbreaks of gastroenteritis have occurred as a result of people drinking contaminated water from suppliers of drinking water associated with camp centres, caravan parks and other facilities not receiving a town water supply. Problems have also been experienced by water carters drawing water from a contaminated source. Thus, ensuring that drinking water suppliers adopt quality assurance programs, implement risk-based management plans and keep appropriate records relating to managing the safety of its drinking water supply is necessary to promote and protect public health.

2.5 Transmission and management of certain medical conditions and infectious diseases

The Act and Regulation provide a requirement for the notification of the Secretary if a patient at a hospital has or is suspected of having had a notifiable disease. The Regulation currently contains over 40 notifiable diseases. These include both communicable and non-communicable diseases such as cancer, COVID-19, syphilis and the plague.[25]

Communicable diseases can have serious consequences for the community if their spread is not managed by public health interventions and access to timely and reliable information about the spread of such diseases is essential to coordinate any public health response.[26] Where a disease or condition is not communicable, information about the number and distribution of affected people can help with the identification and addressing of the causes of such diseases.

It is challenging to determine to what extent communicable notifiable diseases would spread in a counterfactual scenario absent of the public health protections in place because of the uncertain nature of disease spread. Given the number of communicable diseases and the different ways and rates by which they propagate, it is difficult to quantify the nature of the problem and its impact. Further, some diseases have a very low likelihood of entering or spreading in NSW but would have a very high cost if they were to spread unchecked.

One contemporary example to consider is the spread of COVID-19. Diagnoses of COVID-19 are recorded and tracked used by the Ministry to measure the spread of the virus, including infection

[25] Schedule 2 Notifiable diseases, *Public Health Act (2010) No 127.*

[26] Health Vic, *Notification procedures for infectious diseases* https://www2.health.vic.gov.au/public-health/infectious-diseases/notification-procedures, accessed 26 April 2021.

sites and times which inform mandatory quarantine orders and direct testing efforts. Without this mandatory notification, the virus may have spread unchecked through the community, leaving the state to rely on less reliable and timely metrics and less well targeted interventions.

A requirement for notification is a low-cost way to provide timely and reliable information to the Ministry that enables monitoring, managing and/or prevention of some diseases and conditions affecting public health, and hence public risk. Indeed, notification of diseases and conditions prescribed in the regulations:[27]

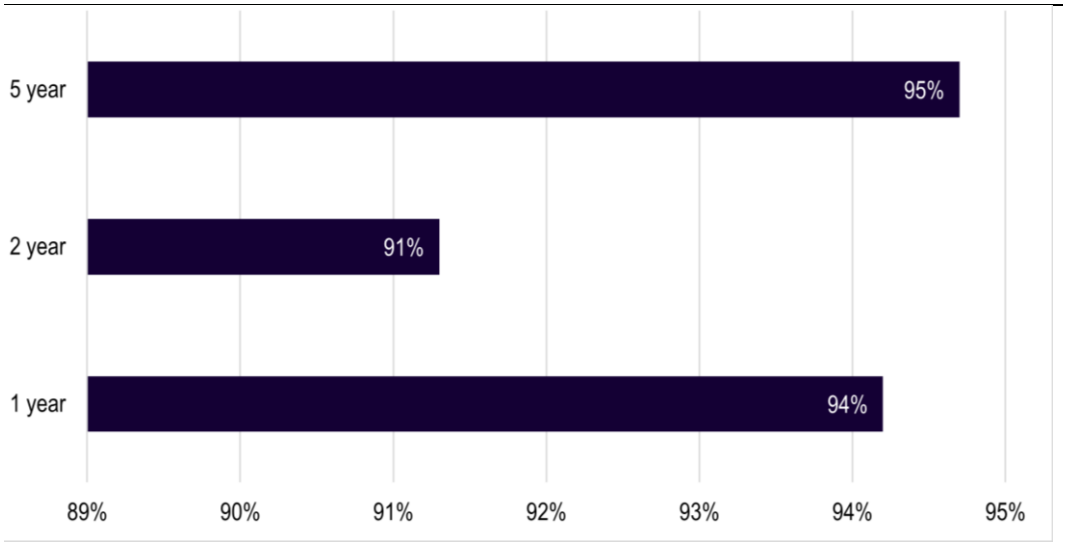
- provides a crucial early warning of a potential threat to public health
- enables the Ministry to respond to prevent or control the spread of disease and prevent further illness
- allows emerging trends to be identified and appropriate policy responses and public health interventions and policies to be implemented (for instance, immunisation, legislation or education programs).

2.6 Immunisation of children in childcare facilities and primary schools

Childcare centres and primary schools are high risk environments for the transmission of communicable diseases, as students are in close proximity, have underdeveloped hygiene habits and are more susceptible to infections due to their developing immune system.[28]

Data regarding the rate of illnesses suffered and propagated by children in childcare centres and primary school are scarce. However, the rate of vaccinations amongst children aged one, two and five are recorded in the Australian Immunisation Register (AIR). As shown in Figure 2.6, more than nine in ten young children in these age groups are fully vaccinated for diphtheria, tetanus, whooping cough, polio, hepatitis B, Haemophilus influenzae type b and pneumococcal disease in NSW. However there remains at least one in twenty students at risk in each of the studied age groups.

Figure 2.6 Percentage of children fully vaccinated by age group, 2019



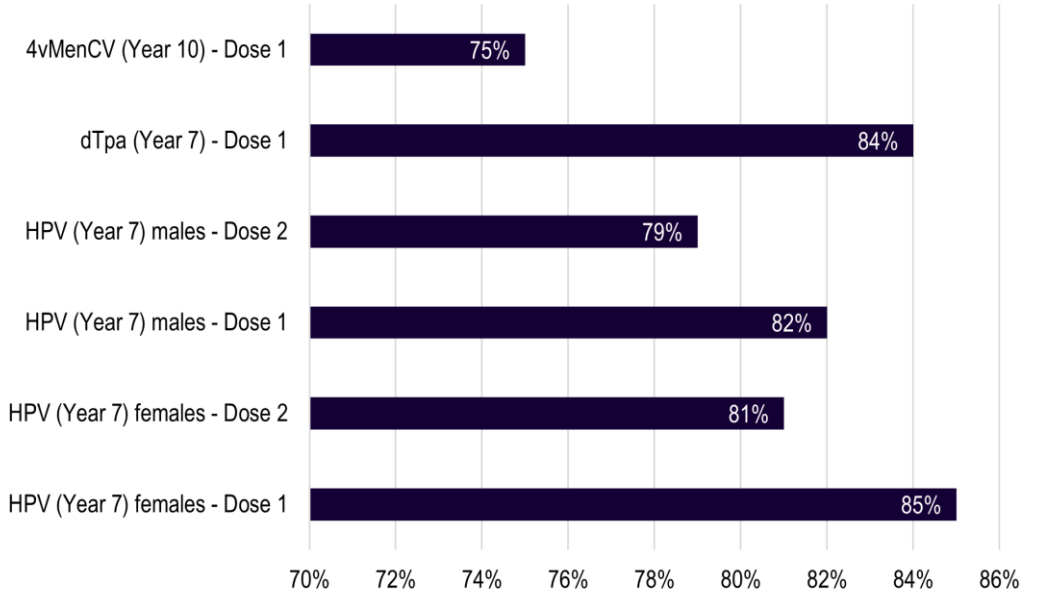
Source: HealthStats NSW, 2019

[27] Department of Health and Human Services (Victoria) 2019, *Public Health and Wellbeing Regulations Sunset Review, Regulatory Impact Statement*, August.

[28] Ministry of Health NSW 2021, *Immunisation requirements in primary and secondary schools,* https://www.health.nsw.gov.au/immunisation/Pages/immunisation-in-schools.aspx, Accessed 26 April 2021.

There are lower rates for follow up vaccinations amongst older students, particularly of the Meningococcal ACWY vaccine, which only 75 per cent of eligible students had received.

Figure 2.7 Percentage of students vaccinated by school year and vaccine type, eligible school students, NSW 2019



Source: Health Protection NSW, 2020.

In the event of an outbreak of a vaccine preventable communicable disease in a childcare or school setting, keeping unvaccinated students at home is essential to minimise the spread of disease, as the unvaccinated children are at higher risk if exposed and may infect others. Keeping those students home serves to protect them and the broader community by preventing the spread of disease to the wider population. This approach relies on being able to access accurate records of the immunisation status of children attending these facilities. Without this information, if there is an outbreak of a vaccine preventable disease, public health authorities would be unaware of which children in the school or childcare centre are unimmunised and therefore at risk to themselves and others.

2.7 Disposal of bodies

There are several risks associated with the disposal of bodies. Some of these can be largely considered occupational health and safety risks which can be managed through risk reduction strategies (for instance, risks related to the management of a body when transferring to a coffin or when lowering into a grave). These risks, while important, are unlikely to affect general public health. However, some risks associated with the disposal of bodies can affect general public health.

General public health risks associated with the disposal of bodies may arise via:

— the inappropriate disposal of waste products and human remains

— unhygienic practices in the handling and disposal of bodies (including inadequate infection control practices), which may result in the transmission of blood borne or other pathogens to those people manipulating infectious bodies.

After death, bodies can become vectors for infection through human waste products and remains, particularly if the deceased person had a communicable disease at the time of death. Bloodborne

diseases such as HIV and hepatitis C are of particular concern as there may be risk of exposure if the body is improperly handled.[29] As such, efforts to mitigate the seeping of bodily fluid and the decomposition of bodies before burial are required. To achieve this, bodies are usually refrigerated after death and stored in a coffin, although in some instances, the body is shrouded.

There is little recorded data on the transmission of diseases related to the disposal of bodies, however a RIS undertaken in 2011 by the Ministry noted the following regarding the potential health risks associated with the disposal of bodies (these points relate to the autopsy-related literature which relies on studies of occupational transmission of HIV and hepatitis C virus in the broader health care setting, with specific reference to needlestick injury): [30]

- There is broad agreement that the risk of transmission of HIV after occupational exposure is around 0.3 per cent following a percutaneous injury.
- Estimates of the risk of transmission of hepatitis C virus (HCV) after occupational exposure vary widely:
  - a study by Jagger et al[31] integrating 14 different occupational exposure studies undertaken between 1992 and 2002, covering more than 11,000 HCV-exposed health care workers across six countries, found a simple average transmission for all reports of 0.5 per cent
  - a 2003 review of 25 longitudinal studies of health care workers' occupational risk for HCV infection[32] following parenteral exposure to blood from individuals infected with HCV found an average infection risk of 1.9 per cent. The author concluded that the risk associated with an occupational exposure is likely to be less than 1.9 per cent but somewhere between 1 per cent and 2 per cent.

Importantly, even if the risk of transmission of communicable diseases through the handling of bodies for disposal is low, the consequences of that transmission could be catastrophic and lead to the need for extended treatment, decreased quality of life and loss of life at the worst. Indeed, as noted in Section 2.3 above, there is currently no vaccination against HIV or hepatitis C and the consequences of being infected with the viruses of hepatitis B or C or HIV are long term and may result in debilitating illness. For example, hepatitis B or C may result in chronic hepatitis, and cirrhosis of the liver. In a proportion of cases this will progress to cancer, which is often fatal.

To provide some perspective of the magnitude of the potential problem:

- In 2018 there were 53,456 deaths recorded in NSW (68.7 per cent of these bodies were cremated and 31.3 per cent were buried). Those who died with diseases would present a risk of transmission if bodies were disposed of improperly.
- According to the HCV Mapping National Report 2016, there were an estimated 77,083 residents in NSW suffering from chronic HCV infection, representing 0.94 per cent of the population. The Kirby Institute estimated that there were approximately 11,721 people living with HIV in NSW, representing 0.1 per cent of the NSW population in 2019. Given these rates, expected number of deaths of individuals with either HIV or HCV would be over 500 per year.

[29] Ministry of Health NSW 2011, *Public Health (Disposal of Bodies) Regulation 2011 Regulatory Impact Statement.*

[30] Ministry of Health NSW 2011, *Public Health (Disposal of Bodies) Regulation 2011 Regulatory Impact Statement.*

[31] Jagger J, Puro V, De Carli G. 2002, Occupational transmission of hepatitis C virus, *Journal of American Medical Association* 2002; 288(12): 1469-70.

[32] Henderson K. 2003, Managing occupational risks for hepatitis C transmission in the health care setting. [Review] *Clinical Microbiology Reviews* 2003;16(3):546-568.

Considering this, ensuring that the funeral industry follows appropriate infection control standards and procedures to dispose of bodies in an adequate and safe manner is necessary to promote and protect public health.

3 The case for Government intervention

Establishing that a problem exists is not sufficient to justify government intervention. Rather, the case for action must be established on the basis of market failure, regulatory failure, or in order to achieve societal or environmental outcomes that would not be delivered by the market alone. Further, in building the case for government action, it is important to demonstrate that the problem could not be solved by the market itself or through alternative quasi or non-regulatory responses.[33]

The remainder of this chapter explores the various types of market failure that are related to the protection of public health and the control of infectious diseases and whether there are non-legislative means for addressing them.

3.1 Market failure

Generally, a competitive market is the most efficient means of allocating resources across a society, ensuring that the goods and services demanded by consumers are produced efficiently and promoting innovation as well as consumer choice. A situation when a market fails to perform these functions is commonly known as market failure.

The presence of market failure implies that there is potential for the government to improve outcomes for consumers, businesses, the economy and society as a whole. However, government action is not always warranted, and poorly designed regulations may create further inefficiencies or impose administrative and compliance burdens for businesses, consumers and government.

The four main types of market failure accepted by governments and regulators are public goods, externalities, information asymmetries and natural monopolies. These are described further in Box 3.1.

In the context of regulations related to the protection of public health and the control of infectious diseases, the economic and policy rationale for government intervention is most likely to be justified on the grounds of information asymmetries and externalities. These are discussed in the following sections.

Box 3.1 Examples of Market Failure

Information asymmetries

In some markets it can be difficult for consumers to be certain about the quality of a good or service before they consume it. This can disadvantage suppliers of better quality products because they will find it difficult to convince customers to pay the higher prices, which are necessary to cover any additional costs the producers have incurred.

[33] NSW Treasury 2019, *NSW Government Guide to Better Regulation*, TPP19-01, January

Another way in which information asymmetry may manifest is when consumers purchase/consume a good or service without fully being aware of the consequences of their decisions/actions. High sugar diets and obesity-related health issues are good example, where the quantity of unhealthy food consumed by an individual may be more than they otherwise would if they were aware of the illnesses such diets are known to cause.

Externalities

Externalities exist when the welfare of some agent, or group of agents, is affected by the actions of another and this is not reflected in market prices. When the effects of one economic agent on another are not taken into account, market prices will not reflect the true marginal cost/benefit of the good or service traded. A common example is pollution, where unless a producer is required to compensate society for the pollution they generate (by internalising the cost of mitigating/remediating in their production cost), they would produce more of that good than at the socially optimum level.

Public goods

Examples of public goods include roads, public parks, national security, public schools and other intangible goods such as clean air and waterways. These goods are unique in that they are both non-excludable and non-rivalrous. Unlike private goods where non-paying consumers can be prevented from accessing it, both paying and non-paying consumers can access a public good. The non-rivalrous nature of public goods also means that use/consumption of the good by one agent (typically) does not reduce the ability for others to use/consume it. As a result, an unregulated market will lead to an undersupply of public goods at the detriment of social welfare, and thus, require governments to intervene in their provision.

Natural monopolies

Natural monopolies exist in industries that are more efficient when only one (or few) firm(s) produces a good rather than multiple firms. This typically occurs where there are large initial costs associated with setting up the infrastructure needed for production and delivery; for example, water and energy networks. Where there is a single monopoly firm, governments may also choose to regulate market power more directly – for example, through ex-ante price controls.

Source: ACIL Allen.

3.1.1 Information asymmetry

It has been well-established that information asymmetries regarding health exist. Medical knowledge is complex, and as a result a physician is likely to possess greater information in relation to treatment possibilities and consequences than the patient.[34]

In a public health context, consumers likely possess a lesser understanding of the risks of certain activities. This is due to both the specialised knowledge of the activity, and the private knowledge of suppliers – the extent the service abides by public health standards or regulations may not be visible to consumers.

An example of the former effect may occur when consumers receive a tattoo, being unaware of the risk of certain diseases. In these circumstances there might be a higher level of demand amongst consumers than there would be if the risks were well understood. Probabilities compound over time, so that even if the likelihood of a negative outcome associated with any service is small, the risk increases the more it is undertaken.

An example of the effect of private knowledge is that consumers of tattoo services will generally not know to what extent the equipment used during the procedure is sterilised and maintained to mitigate the risks. Where consumers cannot distinguish between the services which mitigate public health risks effectively and those that do not, there is generally insufficient market-driven incentive to operate services which provide an adequate level of safety. Further, businesses that meet higher

[34] Arrow, K. J. 1963, Uncertainty and the Welfare Economics of Medical Care, *American Economic Review*, 53(5), pp. 941-973.

safety standards may be undercut by those who do not, making businesses that take safety measures uncompetitive. This may lead to consumers being placed at greater risk.

In cases where reputational damage is suffered by suppliers, consumer demand for the whole market of services may shrink if the private knowledge is not communicable to consumers.[35].

Instances of asymmetric information occur across the range of activities covered by the Regulation, including the maintenance of public pools, cooling towers, safety measures for the disposal of bodies and provision of drinking water.

3.1.2 Externalities

As discussed before, externalities are costs and benefits arising from a transaction incurred by third parties. In relation to activities and services that can pose a risk to public health (e.g. public pools, cooling towers, etc.), failures to meet adequate standards can impose burdens on both users and not users of these services and/or the health system.

Infectious disease outbreaks can occur or be exacerbated as a result of the failure of individuals and organisations to adopt adequate preventative measures that will affect many, as these individuals do not bear the cost incurred by their behaviours. One example of this is the externality effects related to the control of Legionnaires' disease, which is largely spread by aerosols emanating from cooling water systems, causing infection of passers-by. The difficulty in identifying infection sources, together with the difficulty in obtaining redress from a cooling water system owner means that this group faces inadequate incentives to control these risks in the absence of regulatory intervention.

3.2 Can the problem be addressed by non-regulatory means?

Having established a justification for government action arising from market failure and the presence of an equity outcome likely not delivered by the market alone, it is necessary to consider whether there are non-regulatory or quasi-regulatory responses the government could pursue, or whether the market may self-correct through its normal functioning.

3.2.1 Is there scope for self-regulation, quasi-regulation or market self-correction?

Self-regulation

According to the *Australian Government Best Practice Regulation Handbook,* self-regulation is typically characterised by the industry formulating rules and codes of conduct, with industry itself being solely responsible for monitoring and enforcing them.[36]

Box 3.2 outlines the circumstances in which self or quasi-regulation may be appropriate. As shown in this box, self-regulation in the area of public health is appropriate when the health and safety concerns are relatively low, when the problem has low impact or significance and where the cost of compliance and regulatory structure would be so onerous as to be undesirable. Further, self-regulation may be feasible if the market is capable of stepping in to develop a solution, for instance in order to ensure industry survival or where there is a particular market advantage to a proactive response. Self-regulation is likely to be successful where a sufficient proportion of the industry participates, the industry is cohesive and there is evidence that a voluntary approach can work.

[35] Akerlof, George A 1970, The Market for 'Lemons': Quality Uncertainty and the Market Mechanism, *The Quarterly Journal of Economics*, vol. 84, no. 3, pp. 488–500. JSTOR, www.jstor.org/stable/1879431.

[36] Commonwealth of Australia 2007, *Best Practice Regulation Handbook*.

Box 3.2 Checklist for assessment of self-regulation

Self-regulation should be considered where:

- there is no strong public interest concern, in particular, no major public health and safety concern
- the problem is a low-risk event, of low impact or significance
- the problem can be fixed by the market itself.

Proposed approaches under self-regulation should not restrict competition.

Source: Best Practice Regulation Handbook (Commonwealth of Australia, 2007).

It is possible that some of the activities currently covered under the Regulation could be addressed by self-regulation. Current examples of self-regulation in Australia include the Australian Association of National Advertisers' Code of Ethics and the Australian Press Council's Standards of Practice. These examples work because the outputs of these industries are mostly public by their nature, which shrinks the cost of identifying breaches. While pools, for example, are public facing and there is a reputational incentive for these areas to uphold quality, breaches of any code of conduct may not be known until someone gets sick and as such some industry participants may have an incentive to disregard breaches that do not result in people getting sick. Furthermore, the standards used by industry to review pool water quality may vary or diminish. Similar issues could be present for other industries covered by the Regulation.

Quasi-regulation

Quasi-regulation includes a wide range of rules and/or arrangements where governments influence businesses/industry to comply, but which do not form part of explicit government regulation.[37] Examples of quasi-regulation include accreditation schemes and codes of conduct/practice developed with government involvement. Box 3.3 outlines the circumstances in which self or quasi-regulation may be appropriate.

This approach is likely to be successful when government is not convinced of the need to develop or mandate a code for the whole industry. In these situations, flexible, tailor-made solutions and less formal mechanisms bring cost advantages, particularly when the industry is capable of engaging in a cohesive response.

Quasi-regulation can take many forms such as government endorsed codes of practice, industry-initiated programs, negotiating standards of behaviour and making compliance with a code a condition of procurement.

This approach is not considered appropriate for the industries covered by the Regulation, as failing to meet standards would put the public at risk of illness, and in some cases death. While quasi-regulation can affect the behaviour of businesses (and sometimes impose a burden similar to explicit government regulation), in contrast with government regulation, there is no mechanism for the government to legally enforce quasi-regulatory arrangements and ensure public health risks are minimised. Government provided codes of practice may be a useful tool for industry participants looking to achieve best practice, however they will not ensure that less scrupulous organisations meet minimum safety standards, nor will they provide incentives to ensure compliance.

While quasi-regulatory approaches may have a role supporting the regulations and providing for greater public safety, they cannot replace the core safety standards that are ensured by a regulatory approach.

[37] Ibid.

Box 3.3 Checklist for assessment of quasi-regulation

Quasi-regulation should be considered where:

- there is a public interest in some government involvement in addressing a community concern and the issue is unlikely to be addressed by self-regulation
- there is a need for an urgent, interim response to a problem in the short term, while a long-term regulatory solution is being developed
- government is not convinced of the need to develop or mandate a code for the whole industry
- there are cost advantages from flexible, tailor-made solutions and less formal mechanisms
- there are advantages in the government engaging in a collaborative approach with industry, with industry having substantial ownership of the scheme. For this to be successful, there needs to be:
  - a specific industry solution rather than regulation of general application
  - a cohesive industry with like-minded participants, motivated to achieve the goals
  - a viable industry association with the resources necessary to develop and/or enforce the scheme
  - effective sanctions or incentives to achieve the required level of compliance, with low scope for benefits being shared by non-participants
  - effective external pressure from industry itself (survival factors), or threat of consumer or government action.

Proposed approaches under both quasi-regulation should not restrict competition.

Source: Best Practice Regulation Handbook (Commonwealth of Australia, 2007).

Self-correction

In some industries, consumer protections and the threat of litigation is sufficient to ensure satisfactory industry behaviour. However, this approach is not appropriate for public health measures which prevent the spread of disease.

In some of the regulated activities, such as *Legionella* control, it may be difficult for a complainant to find the cooling water system responsible for infecting them. Similarly, while some of the regulated activities put consumers at risk of specific diseases, consumers may not know what it was that infected them. Other illnesses may not be severe enough to make litigation appropriate, while fatalities may not be litigated through the courts by the deceased person's family.

Given these requirements, self-correction is inappropriate to ensure adequate safety measures are taken in the activities covered by the Regulation.

Summing up

The conditions for relying in market self-correction, quasi-regulation or self-regulation do not exist in the industries covered under the Regulation. There is strong public interest in the quality and safety of these industries as events can, in the worst case scenario, result in loss of life.

The relatively disparate nature of the sectors covered in the Regulation as well as the information asymmetries and externalities discussed above, mean that industry-owned schemes would be unlikely to deliver the desired public safety objectives.

Therefore, due to the risks arising from inadequate safety and quality standards among currently regulated activities, these non-regulatory responses are not considered to be sufficient to minimise the risks to public health and protect the health and safety of the public.

3.2.2 Provision of information

A possible non-regulatory response by government to problems arising from information asymmetry could be to provide more information to consumers so that they are more informed. However, this approach is unlikely to be effective in relation to public health risks. While requiring industry to disclosure information to consumers/users about the health risk associated with the

goods and services they supply could form an important part of a regulatory response, information provision by government on its own is not sufficient to address the problem.

4 Objectives of proposed regulation

An important goal of a RIS is to clearly identify the objective of the regulatory intervention.

The current and Draft Regulation have been designed to give effect to particular provisions of the Act that seek to protect the health and safety of the public.

The objectives of the Draft Regulation remain the same as the *Public Health Regulation 2012.* These are to make provisions with respect to:

a) the installation, operating and maintenance requirements for air-handling systems, hot water systems, humidifying systems, warm-water systems and cooling water systems for *Legionella* control
b) minimum public health standards for public swimming pools and spa pools and the issuing of orders to temporarily close down public swimming pools or spa pools, or to take disinfection action, where there is a risk to public health
c) minimum public health standards for the carrying out of skin penetration procedures and for the premises where such procedures are carried out
d) quality assurance programs and record-keeping requirements for suppliers of drinking water
e) control measures for infectious diseases
f) the facilities and procedures for the handling of bodies of deceased persons, exhumations, cremations and other matters relating to the disposal of bodies
g) the code of conduct for certain health practitioners, and in the proposed new Regulation, health organisations
h) fees payable in relation to improvement notices, prohibition orders and inspection of premises
i) notification and record-keeping requirements
j) penalty notice offences relating to the Act and Regulation.

Overall, the key objectives of the Draft Regulation are to provide:

- legislative support and administrative detail for the operation of the Act
- a framework for:
  - adequate monitoring and control of risks to public health
  - adequate prevention and control of infectious diseases
  - adequate monitoring of conditions affecting public health
  - protection of the health and safety of the public.

5 Options considered

A RIS should identify and assess the policy options that could achieve the objectives of government action outlined in Chapter 4. The options that have been identified by the Ministry are the following.

- ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).
- ***Option 1*** — this option entails remaking the existing Regulation without any changes (the *status quo* option).
- ***Option 2*** — this option entails making the Draft Regulation, which would entail remaking the existing Regulation with several proposed amendments.

Each of these options are discussed in more detail in the sections below.

5.1 Base case: letting the Regulation sunset

This option entails letting the Regulation sunset, which means that the Regulation would be repealed and not replaced.

In considering this option it is useful to outline a view of the likely general implications of such a regulatory change, as this will provide a basis for assessing the range of potential costs and benefits under this scenario.

If the Regulation were discontinued, the *Public Health Act 2010* would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates. A brief discussion about the potential impacts of this scenario for the different areas for which the Regulation makes provisions is provided below.

5.1.1 *Legionella* control

In the absence of the Regulation, there would be no minimum standards for the design, installation, maintenance or operation of air-handling systems, hot water systems, humidifying systems, warm-water systems or cooling water systems as these are prescribed in the Regulation.

Under this scenario:

- the offence provisions and improvement notice and prohibition order provisions in Part 3, Division 2 of the Act would have no effect
- the Ministry would have no power to act or intervene in circumstances where a facility is causing a risk to the public or is not meeting the minimum installation, maintenance or operating requirements (as there would be none)

— building owners and occupiers of premises with the above systems installed would adopt whatever standards they deem appropriate. It is also likely that some owners/occupiers would still adopt the relevant standards mentioned in the Regulation[38] (which would still be available) to avoid negligence claims for damages for loss or injury suffered as the result of infection due to inadequately maintained systems.

5.1.2 Control of public swimming pools and spa pools

If the Regulation were discontinued:

— There would be no minimum operating requirements for public swimming pools and spas.

— Occupiers of premises at which a public swimming pool or spa pool is situated would still be required by the Act to disinfect their pools/spas to minimise the transmission of disease to users, but there would be no minimum disinfection standards to meet.

— The Secretary would not have power to order the temporary closure of public swimming pools and spa pools where the pool/spa is a risk to public health.

— In the absence of the Regulation, and of standards to be met by premises at which a public swimming pool or spa pool is situated, public pool and spa operators would be at liberty to deal with the risk of disease transmission in any way that they consider appropriate. Under this scenario it is likely that there would be an increase in disease rates, which would result in a cost to the community and, if legal action was pursued by consumers, operators would be liable for legal costs to defend claims for damages and potentially for additional cost if claims for damages where awarded. It is also possible that under this scenario the industry would become self-regulated and develop voluntary health and safety guidelines. However, the Ministry would have no ability to penalise the owner of these premises for non-compliance with the standards (as there would be none) or close public pools or spa pools that are a risk to public health. This would result in an ineffective enforcement and compliance regime.

Under this scenario the Secretary would still have a power to establish an inquiry into public health risks under Section 106 and Part 8 of the Act. However, these provisions only apply to a risk that has occurred, while the Regulation is aimed at preventing the risk. arising in the first place.

5.1.3 Control of skin penetration procedures

If the Regulation were discontinued, there would be:

— no minimum health and safety requirements for:
  — premises where skin penetration procedures are carried out (including no requirements in terms of the minimum equipment and facilities that need to be available at these premises or the sterilisation of equipment used for the procedures)
  — carrying out skin penetration procedures (including no requirements for the use of needles, sharps, protective equipment, inks, pigments, wax and other articles)

— no requirements to notify the carrying out of skin penetration procedures or to register premises where skin penetration procedures are carried out.

Similar to the case of swimming pools and spas, in the absence of the Regulation, and of standards to be met by facilities where skin penetration procedures are carried out, the Ministry would have

[38] AS/NZS 3666.1:2011 Air-handling and water systems of buildings—Microbial control, Part 1: Design, installation and commissioning; AS/NZS 3666.2:2011 Air-handling and water systems of buildings—Microbial control, Part 2: Operation and maintenance; AS/NZS 3666.3:2011 Air-handling and water systems of buildings—Microbial control, Part 3: Performance-based maintenance of cooling water Systems; AS/NZS 3666.4:2011 Air-handling and water systems of buildings—Microbial control, Part 4: Performance-based maintenance of air-handling systems (ducts and components).

no ability to penalise the owner of these premises for non-compliance with the standards (as there would be none), resulting in an ineffective enforcement and compliance regime.

Under this scenario, facilities where skin penetration procedures are carried out could become self-regulated and follow voluntary industry guidelines (if available/developed). Facilities may seek to differentiate on the basis of quality, cost or competitive advantage. While these drivers, as well as liability and insurance concerns, may promote safety and quality of these facilities, there would be no power for the NSW Government to act or intervene in circumstances where a facility is causing a risk to the public or is not meeting the voluntary standards.

5.1.4 Safety measures for drinking water

Under a scenario where the Regulation were discontinued, suppliers of drinking water would still be required by the Act to have quality assurance programs and provide relevant records to the Secretary if directed, but there would be no specification about:

- the matters that are required to be included in a quality assurance program (including in relation to different requirements by types of suppliers)
- the records that need to be kept by suppliers of drinking water.

In the absence of the Regulation, and of minimum requirements for quality assurance and record keeping for drinking water suppliers, it is likely that there would be a wide-range of methods/standards used for compliance with the Act and the Ministry would have no ability to require certain matters to be included in quality assurance programs or certain records to be maintained. This would result in an ineffective enforcement and compliance regime.

5.1.5 Scheduled medical conditions

In the absence of the Regulation:

1. Any death arising from the scheduled conditions included in the Act would still need to be notified. However, some particular details not detailed in the Act would not be included in the notification (date of birth and sex of the deceases; date, place and cause of death; and the address of the person who certified the cause of death).
2. Medical practitioners would still be required to notify the Secretary of Category 1 and 2 conditions, but there would be:
   - no specific requirements prescribed about the details required to be recorded concerning the person's medical conditions
   - no specific period prescribed for keeping records of the person's medical conditions.
3. An authorised medical practitioner would still be able to make a public health order in respect of a person with a Category 4 or 5 condition. However, the authorised medical practitioner would not be required to take into account the following matters outlined in the Regulation when deciding whether or not to make a public health order (which have been included to ensure that orders are only made in appropriate circumstances):
   - whether reasonable attempts have been made to provide the person with information about the effects of the Category 4 or 5 condition the person has and the risks to public health of hat condition
   - the options other than a public health order that are available to deal with the risk to public health posed by the person
   - if the proposed public health order will require the person to undergo treatment — the availability and effectiveness of the proposed treatment and the likely side effects of the proposed treatment on the person
   - if the proposed public health order will require the person to be detained — the likely social, economic, physical and psychological effects of the detention on the person

- if the proposed public health order relates to a person with tuberculosis — the guidelines entitled Tuberculosis Management of People Knowingly Placing Others at Risk of Infection published by the Ministry of Health
- if the proposed public health order relates to a person with HIV or AIDS — the guidelines entitled HIV — Management of People with HIV Infection Who Risk Infecting Others published by the Ministry of Health.

4. Due to privacy reasons, the Secretary and relevant medical practitioners may not be able to provide:
   - advice to Category 2 or 3 patients of measures to be taken, and activities to be avoided, to minimise the danger of passing the medical condition to another person
   - advice to contacts of a person suffering from a Category 2, 3 or 4 condition of measures to be taken, and activities to be avoided, to minimise the danger of the first person contracting the condition or passing it to a third person.
5. Information relating to a Category 5 condition may not be able to be disclosed even under a court order. The removal of this provision to disclose information relating to Category 5 conditions under a court order would create uncertainty.

Under this scenario, the likely result of:

- 1) and 2) above would be that there would be less information recorded to help the Ministry monitor and manage some diseases and conditions affecting public health, and hence public risk
- 3) above would be that there could be instances where public health orders are made in inappropriate circumstances
- 4) above would be that the Secretary and relevant medical practitioners would not be able to provide the advice required by patients to manage the potential risks of certain conditions.

5.1.6 Other disease control measures

Under a scenario where the Regulation were discontinued:

1. Medical practitioners who suspect that a person has a sexually transmitted infection would still be required to provide information concerning the infection, but there would be no specific requirements about the information to be provided. This *may* result in less relevant information for the control of these diseases being provided to the infected person and potentially an increased risk of transmission.
2. The Chief Executive Officer (CEO) of a hospital that suspects that a patient at the hospital has a notifiable disease, or a former patient has had a notifiable disease while a patient at the hospital would still be required to notify the Secretary, but there would be no specific requirements about the information to be provided. This *may* result in less information being recorded to help the Ministry monitor some diseases and conditions affecting public health.
3. 'Child' and 'authorised practitioner' for the purposes of Section 85 (1) of the Act would not be prescribed. This could result in:
   - uncertainty for a principal of a school or childcare facility regarding what group of children they are responsible for ensuring are vaccinated
   - uncertainty about the people who are authorised to give vaccinations.
4. An immunisation certificate would still be required by the Act before enrolment at a childcare facility, and schools would still be required to request an immunisation certificate at enrolment. However, there would be no specific requirements for:
   - when updated certificates need to be provided

- the period of time for which the principal of a school must retain an immunisation certificate or the period of time for which the principal of a child care facility must retain information about a child in the immunisation register
- exemptions from the pre-enrolment immunisation requirements relating to child care facilities.

In the absence of the Regulation it is possible that the records kept by schools and child care facilities in relation to the immunisation status of children could be out of date or not available after enrolment. Without this information, if there is an outbreak of a vaccine preventable disease, the Ministry would not be aware about which children in the school or child care centre are unimmunised and therefore at risk to themselves and others.

5. There would be no provisions to ensure that correctional centres are not public health risks (which could therefore result in increased health risks in this type of facilities). In particular, there would be no:
   - requirements regarding standards and sizes for rooms and cubicles
   - mechanism to enable the Chief Health Officer to direct a correctional centre to appropriately deal with a public health risk.
6. There would be:
   - No requirements for an occupier of premises to take reasonable measures to keep the premises free from fleas, other disease-carrying insects, rats and mice.
   - No requirements for an occupier of premises to avoid overcrowding or unreasonable sleeping space ratios. This could increase the potential risks of contracting an infectious disease through the spread of respiratory particles.
   - No prohibitions regarding the sale, use, transfer or receipt of animals (or parts of an animal) that are suffering or have died from anthrax. This could result in increased risks to public health.

5.1.7 Disposal of bodies

If the Regulation was discontinued, there would be no prescribed requirements for:

- premises handling bodies, body preparation rooms and vehicles used for transporting bodies
- the retention, embalming, handling and viewing of bodies (including bodies infected with prescribed infectious diseases)
- the registration of bodies prepared in a mortuary
- the burial and transportation of bodies (including requirements for the use of coffins, the minimum depth at which coffins must be buried and requirements to place bodies in a vault)
- exhumations, cremations or cremated remains
- registration of mortuaries.

In addition, under a scenario where the Regulation were discontinued:

- the Minister would not be able to order the closing of a crematory whose operations are directed by the cremation authority
- authorised offices would not have power to inspect mortuaries (or premises that the officer has reason to suspect are mortuaries), crematories, cemeteries or holding rooms or their records.

In summary, if the Regulation was discontinued and not replaced there would be no public health regulation in this area. Although the funeral industry would still be partially regulated via the *Work Health and Safety Act 2011*, the *Fair Trading Act 1987,* the *Cemeteries and Crematoria Act 2013* and other related regulations, none of these Acts and regulations are focused on minimising the spread of infectious diseases or regulating cremations. In this situation it is possible that the industry would develop voluntary health and safety guidelines and become self-regulated. It is also

possible that public liability insurance issues could exert some influence on how funeral operations function. However, without specific regulation in respect to public health and cremations:

- it is likely that funeral operators would lower their standards and the risks associated with the transmission of infectious diseases would increase
- there would be no incentive for operators to ensure that proper documentation was obtained prior to cremating a body. In such a case, unidentified bodies may be cremated and bodies may be cremated even where the death was the result of suspected foul play.

5.1.8 Other matters prescribed in the Regulation

In addition to the areas outlined in the sections above, the Regulations make a number of provisions under the general regulation making power or other specific provisions of the Act. If the Regulation were repealed and not replaced, these provisions would cease to exist. As summary of the implications of this are briefly outlined in the points below.

- There would be no prescribed corresponding interstate prohibition orders to give effect to section 101 (1) of the Act. This would result in prohibition orders from other states not being recognised in NSW and hence, health practitioners that have been de-registered in other states being able to continue to provide the health services from which they have been de-registered in NSW.
- Public or disease registers could only be established for the purposes outlined in Section 97 of the Act and not for the purposes outlined in Clause 93D of the Regulation. Without Clause 93D of the Regulation, the data that could be compiled regarding diseases and public health would be limited. The likely result of this would be that there would be less ability to create public health and disease registers in relation to a range of public health matters.
- De-registered health practitioners or health practitioners who are subject to a prohibition order would still be required to notify the person to whom the health practitioner intends to provide a health service (or their parent or guardian if that person is under 16 years) that their registration has been cancelled or that they are subject to a prohibition order. However, there would not be set requirements as to what information this notification should include. This may result on patients or employers not being made fully aware of the limitations of a practitioner's practice, which in turn may result in an increase in risks to public health.
- There would be no minimum qualifications requirements set out for the person appointed as the director of nursing at a nursing home. This may result in persons that are not sufficiently experienced and qualified being appointed as directors of nursing, which could potentially increase risks on residents' safety.
- There would be no requirements for local government authorities to notify the Secretary of improvement notices and prohibition orders. This may result in less relevant information for the control of these diseases and public health risks being provided to the Secretary and potentially increased risks to public health.
- There would be no prescribed:
  - fees for improvement notices, prohibition orders or for re-inspection of premises subject to prohibition order
  - penalties for offences against the Act.
- There would not be a Code of Conduct for the provision of health services by not registered health practitioners.[39]

[39] As noted in Chapter 1, the Code of Conduct for non-registered health practitioners in Schedule 3 of the Regulation has been excluded from the impact assessment in this RIS.

5.2 Option 1: remaking the existing Regulation without changes (status quo)

This option entails remaking the existing Regulation without any changes, which means that the obligations across all the areas that have the potential to affect public health would remain unchanged.

5.3 Option 2: remaking the existing Regulation with changes

Option 2 entails remaking the Regulation with several amendments contained in the Draft Regulation. Generally, the amendments proposed for the remaking of the Regulation fall within one or more of the following areas. [40]

1. Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).
2. Changes to clauses to clarify the intent of the Regulation and reflect changes in the Act. These include:
    a) For premises where skin penetration procedures are carried out, clarifying that the separate sink required for cleaning equipment used in skin penetration procedures must only be used for cleaning equipment (Part 4 Control of Skin Penetration Procedures, Division 2 Clause 23(1)(d)).
    b) In Part 6 Scheduled Medical Conditions:
        - removing references to AIDS in Clause 37 and 39 (AIDS is no longer a notifiable condition under the Act)
        - including a reference in Clause 39 (1)(a) to the conditions listed in Schedule 1A of the Act, alongside category 4 and 5 conditions to reflect the introduction of this Schedule in the Act.
3. Removal of references to standards and guidelines that have been rescinded or are no longer relevant. These include:
    a) In Part 2 *Legionella* Control, Clause 13F (b), removing reference to the document entitled *Water—Requirements for the provision of cold and heated water* published by the Ministry of Health.
    b) In Part 4 Control of Skin Penetration Procedures, Clause 26 (2) (a), removing the requirement to comply with the standard AS 2182-1998 as this standard has been rescinded and not replaced.
    c) In Part 8 Disposal of bodies, Division 3, Clause 57 (1), removing the requirement to comply with the guidelines specified in Part B of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* published by the National Health and Medical Research Council (NHMRC).
4. Minor changes to better reflect current practice and ensure good record keeping. These include:
    a) Changes to clauses to better reflect the range of practitioners and staff that should provide advice to patients regarding scheduled medical conditions (Part 6 Scheduled Medical Conditions, Clause 39A and 39B (3)).
    b) In Part 4 Control of Skin Penetration Procedures:
        i) A change in Clause 26 to add a requirement for premises that sterilise reusable articles off-site to keep for 12 months a copy of the report on the sterilisation by the person who sterilised the article.
        ii) A change in Clause 31 (1) to clarify that the notice of the carrying out of skin penetration procedures must be given to the local government authority before skin penetration procedures are carried out at the premises.

[40] All clauses refer to the current Regulation.

5. Updated fees to reflect increases in the Consumer Price Index and the costs of administering the Regulation.
6. Changes to the requirements for cooling water systems.
7. Additional exemptions from pre-enrolment requirements relating to childcare facilities in relation to immunisation.
8. Changes to the disposal of bodies.
9. Changes to the control of public swimming pools.
10. Creation of penalty notice offences for failing to comply with the requirements of the Regulation.

Additional details about the proposed changes under each of these areas are provided in Table 5.1 below. The impacts of these changes are explored in more detail in the following chapter.

Table 5.1 Summary of amendments proposed for the regulation

Area of change	Proposed change (all clauses refer to the current Regulation)
1) Rewording, renumbering, restructuring and clarifications	The Regulation has been fully re-structured and re-numbered. During this process some clauses have been re-worded, redundant text eliminated and some clarifications to the text have been made. Savings provisions that were no longer relevant have also been removed. These changes have no material effect on the obligations of industry.
2) Changes to clauses to further clarify the intent of the Regulation and reflect changes in the Act	**Part 2, Division 6 *Legionella* Control** The inclusion of a definition of free available chlorine and free available bromine in Clause 9 of the Regulation. **Part 4, Control of Skin Penetration Procedures, Clause 23(1)(d)** For premises where skin penetration procedures are carried out, clarifying that the separate sink required for cleaning equipment used in skin penetration procedures must only be used for cleaning equipment. **Part 6 Scheduled Medical Conditions** – Clause 37 and 39 — references to AIDS have been removed as AIDS is no longer a notifiable condition under the Act. – Clause 39 (1)(a) — a refence to the conditions listed in Schedule 1A of the Act, alongside category 4 and 5 conditions has been included in this clause to reflect the introduction of this Schedule in the Act.
3) Removal of references to standards and guidelines that are no longer relevant	**Part 2 *Legionella* Control, Clause 13F (b)** Removing reference to the document entitled *Water—Requirements for the provision of cold and heated water* published by the Ministry of Health . **Part 4 Control of Skin Penetration Procedures, Clause 26 (2) (a)** Removing the requirement to comply with the standard AS 2182-1998 as this standard has been rescinded and not replaced. **Part 8 Disposal of bodies, Division 3, Clause 57 (1)** Removing the requirement to comply with the guidelines specified in Part B of the Australian Guidelines for the Prevention and Control of Infection in Healthcare published by the National Health and Medical Research Council (NHMRC). The NHMRC Guidelines have been updated and do not contain relevant requirements regarding bodies.
4) Minor changes to better reflect current practice and ensure good record keeping	**Part 4 Control of Skin Penetration Procedures** Clause 26 A change to add a requirement for premises that sterilise reusable articles off-site to keep for 12 months a copy of the report on the sterilisation by the person who sterilised the article. Clause 31 (1) A change to clarify that the notice of the carrying out of skin penetration procedures must be given to the local government authority before skin penetration procedures are carried out at the premises.

Area of change	Proposed change (all clauses refer to the current Regulation)
	Part 6 Scheduled Medical Conditions The following changes are proposed to better reflect the range of practitioners and staff that should provide advice to patients. – Clause 39A — this clause has been expanded so that advice regarding measures to be taken, and activities to be avoided, in order to minimise the danger of a person suffering from a Category 2 and 3 condition passing the medical condition to another person can be provided by a range of staff within public and private health services. This include a person who provides any of the following services: (a) medical, hospital, nursing or midwifery services, (b) community health services, (c) health education services, (d) public and population health services, (e) welfare services necessary to implement any services referred to in (a)–(d). – Clause 39B (3) — expand definition of relevant person to include one who provides public and population health services **Part 8 Disposal of Bodies** Removing the requirement for the Secretary to approve material to be used for hermetically enclosing an embalmed body in a coffin buried in a vault in Clause 67 (1) (a).
5) Updated fees	Fees for different matters in the Regulation have been increased by 2.5%.
6) Changes to the requirements for cooling water systems	**Part 2 *Legionella* Control, Division 6 Cooling Water Systems** <u>Clause 13J</u> A new provision to require disinfection of cooling water systems that are assessed as a risk to public health (i.e. where the testing shows the level of *Legionella* in a cooling water system exceeds 10 colony-forming units per millilitre) with either a chlorine or bromine based compound within 48 hours. Currently, where no outbreak has been declared enforcement action is limited to an improvement notice or a prohibition order and immediate disinfection is not a legal requirement for occupiers. <u>Clause 13O</u> A new subclause under Clause 13O (5) to require that a person undertaking an audit of risk assessment is not employed by the employer of the person who undertook the risk assessment, the duly qualified person who installed, operated or maintained the cooling water system in the previous 5 years, the operator of a laboratory that carried out testing of the cooling water system any time in the last 5 years, to ensure independence of auditors.
7) Additional exemptions from immunisation requirements	**Part 7 Other Disease Control Measures, Division 2 Immunisation of Children** A new exemption from pre-enrolment immunisation requirements relating to child care facilities to allow the principal of a child care facility to permit enrolment of a child that meets the immunisation requirements for the purposes of section 6(1) of the *A New Tax System (Family Assistance) Act 1999* of the Commonwealth on the grounds set out in section 6(3)(c) or 6(4) or (6) of that Act. In effect, this exemption allows a child to be enrolled in childcare if the child meets the immunisation requirements set by the Commonwealth in the *A New Tax System (Family Assistance) Act 1999*, which establish that a child meets immunisation requirements if: 1. the child has been immunised 2. a general practitioner, a paediatrician, a public health physician, an infectious diseases physician or a clinical immunologist has certified in writing that the immunisation of the child: a) would be medically contraindicated, or b) is not required immunisation because the child has contracted a disease or diseases and as a result has developed a natural immunity, or c) the child is a participant in a vaccine study approved by a Human Research Ethics Committee registered with the National Health and Medical Research Council

Area of change	Proposed change (all clauses refer to the current Regulation)
	3. the vaccines required for vaccination are temporarily unavailable 4. the child has been vaccinated overseas and a recognised immunisation provider has certified in writing that those vaccinations have provided the child with the same level of immunisation that the child would have acquired if the child had been vaccinated in accordance with a standard vaccination schedule 5. the Secretary determines in writing that the child meets the immunisation requirements.
8) Changes to the disposal of bodies	**Part 8 Disposal of Bodies** <u>Proposed changes to Division 3 Handling of bodies</u> – Amend Clause 54 to increase the time that hospitals are allowed to retain bodies to up to 21 days (hospitals are currently allowed to retain bodies for up to 5 days). – Amend Clause 62 (2) to require mortuaries to register bodies immediately after the body is delivered to the mortuary for preparation (instead of after the body is prepared). – Amend Clause 63 (a) to allow bodies to be buried in a shroud rather than only in a coffin (provided the shroud complies with the relevant Policy Directive/Guideline). – Amend Clause 64 to provide a general exemption, rather than just for specific burials, by the Secretary to approve burial of bodies shallower than 900 millimetres where they comply with the requirements of the exemption. – Amend Clause 67 (1) (a) to remove the requirement for the Secretary to approve the material to hermetically enclose a body in a coffin within a vault <u>Proposed changes to Division 5 Cremation</u> Amending relevant clauses in this division to simplify the cremation process by: 1. substituting the requirement to provide a cremation certificate for the provision of: a) advice as to whether there is a cremation risk from a relevant medical practitioner. A relevant medical practitioner in this context is a medical practitioner who: i) attended to the person immediately before, or during the illness terminating in, the death of the person, or ii) has relevant knowledge of the dead person's medical history b) a death certificate, a Medical Certificate of Cause of Death (MCCD) or an order authorising the disposal of the remains of the dead person by a coroner under section 101 of the *Coroners Act 2009* 2. no longer requiring that the Medical Referee makes an external examination of the body as a condition to issue a cremation permit (however, a medical referee *may* conduct one if it is considered necessary).
9) Changes to the control of swimming pools	**Part 3 Control of public swimming pools and spa pools, Clause 14** A new clause is proposed to define a public swimming pool or spa pool for the purposes of Section 34 of the Act. Under this new definition, a water play park or other recreational aquatic structure is declared not to be a public swimming pool or spa pool if it — (a) uses a public water supply, and (b) does not use a recirculation system, and (c) does not store water. **Schedule 1 Requirements for public swimming pools and spa pools** All references and requirements related to Oxidation Reduction Potential Systems (ORP systems) would be removed from the Regulation. This change effectively removes ORP systems as an accepted alternate method for monitoring and controlling water quality in public swimming pools and spa pools.
10) Creation of PIN offences	**Part 2 *Legionella* Control, Division 6 Cooling Water Systems** Penalty notice offences created for failing to comply with the requirements in the following clauses of the Regulation: – Clause 13S (1) Availability of records and other information – Clause 13T (2) Notification of installation of cooling water systems.

Area of change	Proposed change (all clauses refer to the current Regulation)

Source: Ministry of Health and ACIL Allen.

6 Impact analysis

This chapter assesses the impacts of the regulatory options outlined in Chapter 5. It first assesses the expected impacts of the Base Case (i.e. of letting the Regulation sunset) and then assesses the impacts of the proposed Draft Regulation (Option 2) against the *status quo*, i.e. the current Regulation (Option 1).

Notably, the benefits and costs associated with the alternative options have been analysed in this RIS qualitatively. This is because:

- the Ministry's advice that the RIS was to be prepared on a qualitative basis
- the benefits and costs associated with the alternative options are not amenable to easy quantification due to:
  - limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
  - the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

Further, in preparing this RIS, selected stakeholder consultations were conducted with several organisations.[41] Where relevant, comments by stakeholders have been included in the discussion. These views need to be further tested during the public consultation period before remaking of the Regulation. Comments received from stakeholders about areas of the Regulation for which changes are not being proposed are presented for future consideration by the Ministry in Appendix A.

6.1 Impacts of letting the Regulation sunset (the Base Case)

As noted in Section 5.1, the likely general implications of letting the Regulation sunset are as follows.

- The Act would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates.
- There would be no minimum standards for the design, installation, maintenance or operation of air-handling systems, hot water systems, humidifying systems, warm-water systems or cooling water systems. Building owners and occupiers of premises with these systems installed would adopt whatever standards they deem appropriate. It is likely that some owners/occupiers would still adopt the relevant standards mentioned in the Regulation (which would still be available) to avoid negligence claims for damages for loss or injury suffered as the result of infection due to inadequately maintained systems. Facilities would meet safety and quality standards based on insurance and liability and reputational concerns.

[41] Further information about the stakeholder consulted can be found in Appendix A.

- There would be no minimum operating requirements for public swimming pools and spas. Public pool and spa operators would be at liberty to deal with the risk of disease transmission in any way that they consider appropriate. It is possible that under this scenario the industry could become self-regulated and develop voluntary health and safety guidelines. However, all the swimming pools stakeholders consulted for the RIS suggested that self-regulation is not a likely option for this industry. As above, facilities would meet safety and quality standards based on insurance and liability and reputational concerns.
- There would be no minimum health and safety requirements for premises where skin penetration procedures are carried out or for carrying out skin penetration procedures. Facilities where skin penetration procedures are carried out could become self-regulated and follow voluntary industry guidelines (if available/developed). Facilities may seek to differentiate on the basis of quality, cost or competitive advantage. These drivers, as well as liability and insurance concerns, may promote safety and quality of these facilities, but there would be no power for the NSW Government to act or intervene in circumstances where a facility is causing a risk to the public or is not meeting the voluntary standards.
- There would be no minimum requirements for quality assurance and record keeping for drinking water suppliers. As suppliers of drinking water would still be required by the Act to have quality assurance programs and provide relevant records to the Secretary if directed, it is likely that there would be a wide-range of methods/standards used for compliance with the Act.
- There would be no minimum requirements for reporting and record keeping of certain medical conditions and immunisation status, which would result in less information recorded to help the Ministry monitor and manage some diseases and conditions affecting public health. In addition, due to privacy reasons, certain medical conditions would not be able to be disclosed (even under a court order) and medical practitioners would not be able to provide advice to patients with certain conditions to minimise the danger of passing the medical condition to another person.
- There would be no:
  - requirements regarding standards and sizes for rooms and cubicles in correctional centres and no mechanism to enable the Chief Health Officer to direct a correctional centre to appropriately deal with a public health risk
  - requirements for an occupier of premises to:
    - take reasonable measures to keep the premises free from fleas, other disease-carrying insects, rats and mice
    - avoid overcrowding
  - prohibitions regarding the sale, use, transfer or receipt of animals (or parts of an animal) that are suffering or have died from anthrax. This could result in increased risks to public health.
- There would be no prescribed requirements for the handling of bodies of deceased persons, exhumations, cremations and other matters relating to the disposal of bodies. While the funeral industry would still be partially regulated via other Acts and regulations[42], none of these are focused on minimising the spread of infectious diseases or regulating cremations. Under such a scenario it is possible that the industry would develop voluntary health and safety guidelines and become self-regulated. It is also possible that public liability insurance issues could exert some influence on how funeral operations function.
- There would be:

[42] The *Work Health and Safety Act 2011*, the *Fair Trading Act 1987* and the *Cemeteries and Crematoria Act 2013*.

- no provisions to recognise prohibition orders from other state in NSW to stop de-registered health practitioners providing services from which they have been de-registered in other states
- no provisions to establish public or disease registers for the purposes outlined in Clause 93D of the Regulation and to collect relevant data on certain diseases
- no set requirements as to what information de-registered health practitioners or health practitioners who are subject to a prohibition order would be required to provide to the person whom the health practitioner intends to provide a health service
- no minimum qualifications requirements set out for the person appointed as the director of nursing at a nursing home
- no requirements for local government authorities to notify the Secretary of improvement notices and prohibition orders
- no prescribed fees for improvement notices, prohibition orders or for re-inspection of premises subject to prohibition order, or penalties for offences against the Act.

Benefits

Broadly, the benefits of discontinuing the Regulation would include:

- elimination/reduction of compliance and administrative costs for a range of industry sectors
- reduced regulatory costs for the NSW Government in administering the regulatory regime, including administrative, monitoring and enforcement costs
- a potential increase in:
  - the number of facilities in NSW providing the services currently regulated by the Regulation (given the lower barriers to entry and regulatory costs associated with the provision of these services)
  - competition in the industries providing the services that are currently regulated, and associated impacts on the pricing of services.

Costs

The costs associated with eliminating the Regulation and relying on industry self-regulation include:

- increased risk to the health and safety of the public and a potential increase in disease rates and associated costs to the community
- a potential increase in cremation of unidentified bodies and bodies where the death was a result of suspected foul play
- having an enforcement and compliance regime that is unable to operate properly
- inconsistent standards applying across premises/facilities/businesses
- increased information asymmetries due to lack of information recorded regarding some infectious diseases and conditions affecting public health.

Conclusion

Overall, letting the Regulation sunset is not considered appropriate as the risks and costs associated with eliminating minimum standards in relation to a variety of premises, services and the management of certain medical conditions and relying on industry self-regulation are considered to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

The NSW Government requires the visibility to detect public health risks and the certainty provided by legal sanctions to meet its broader social welfare responsibilities to the current and future generations.

It is noted that all stakeholders consulted for the RIS agreed that letting the Regulation sunset is not an appropriate option as the Regulation is central to maintaining adequate standards for monitoring, preventing and controlling risks to public health and protecting the health and safety of the public.

6.2 Impacts of the proposed Regulation (Option 1 and Option 2)

This section qualitatively assessed the impacts of the Draft Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1). This analysis has been structured around the impacts on each of the substantive Parts of the Regulation.

6.2.1 Part 2 — *Legionella* control

The amendments proposed for Part 2 of the Regulation under Option 2, and the views of stakeholders in the industry consulted about these changes are summarised in Table 6.1. The costs and benefits associated with these amendments are outlined in the sections below.

Benefits

The main benefits of the proposed changes to Part 2 of the Regulation under Option 2 are as follows.

— By requiring disinfection of cooling water systems that are assessed as posing a risk to human health within 48 hours, the proposed changes to the Regulation would prevent conditions deteriorating further and reduce the risks of people becoming ill from exposure to the *Legionella* bacteria (and the health burden associated with additional legionellosis cases that could have occurred due to these deteriorating conditions).

— The proposed introduction of provisions in the Regulation to ensure that the audit of a risk assessment for a cooling tower is truly independent would provide greater confidence in the *Legionella* monitoring and response system and could contribute to a reduction in the frequency, severity and impact of legionellosis outbreaks.

— The introduction of penalty notice offences for occupiers of premises for failing to comply with certain requirements in the Regulation provides a practical means of addressing noncompliance (including public health risk).

Costs

— The proposed new requirement to disinfect cooling water systems that are assessed as posing a risk to human health within 48 hours could have a resource cost to conduct the treatment in a shorter period of time than under the status quo. However, consultation with water treatment stakeholders suggested that cooling water systems found to have 10 or more colony-forming units of *Legionella* per millimetre are already disinfected within 24 hours. Given this, it is unlikely that this proposed change would have a material cost for industry or occupiers of premises.

— The proposed new penalties are not considered a cost of the proposed Regulation (Option 2) because non-compliance costs (including penalties for failing to comply with a Regulation and legal fees, including costs incurred in court and tribunal processes) are not considered a regulatory burden as these are avoidable costs caused by deviant behaviour[43].

[43] Office of Best Practice Regulation (OBPR) (2014), Regulatory Burden Measurement Framework, Department of the Prime Minister and Cabinet, Australian Government, https://www.pmc.gov.au/sites/default/files/publications/005_Regulatory_Burden_Measurement_Framework_4.pdf.

Conclusion

The proposed changes to the *Legionella* provisions in the Regulation could contribute to a reduction in the frequency, severity and impact of legionellosis outbreaks at a marginal cost. Given this, the proposed changes are expected to be overall beneficial.

Table 6.1 Proposed amendments for Part 2 *Legionella* Control

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).	Improved clarity of the Regulation.	Stakeholders support improving clarity of the Regulation.
Clause 13F (b)	Removing the reference to the Policy Directive entitled *Water – Requirements for the Provision of Cold and Heated Water* published by the Ministry of Health.	The standard referred to in Clause 13F(a) (AS/NZS 3666.2:2011) and the other clauses contained in Part 2, Division 5 of the Regulation are considered by the Ministry to be sufficient to safely maintain warm-water systems. Given this, it is considered that there is no need for additional obligations of a Policy Directive.	Stakeholders did not raise any objections with regards to this change.
Clause 13J	– A new provision to require disinfection of cooling water systems that are assessed as a risk to public health (i.e., where the testing shows the level of *Legionella* in a cooling water system exceeds 10 colony-forming units per millilitre) with either a chlorine or bromine based compound within 48 hours. – A new subclause defining free available chlorine and free available bromine.	Currently, where no outbreak has been declared and testing reveals that the level of *Legionella* in a cooling tower exceeds 10 colony-forming units per millimetre, enforcement action is limited to an improvement notice or a prohibition order and immediate disinfection is not a legal requirement for operators. Requiring disinfection of cooling water systems within 48 hours where unsatisfactory conditions/contamination are found would prevent conditions deteriorating further and risks of exposure and illness.	Water treatment industry stakeholders argued that disinfection at high levels of contamination is already required to be completed within 24 hours by the Australian Standards called in the Regulation. Given this, it was suggested that the proposed change to the Regulation would not change current practice. A council stakeholder suggested that disinfection should be required within 24 hours (not 48) to avoid further risk of infection.
Clause 13O	A new subclause under Clause 13O (5) to require that a person undertaking an audit of risk assessment is not a person employed or engaged by the person who employed or engaged a person who: – undertook the risk assessment – installed, operated or maintained the cooling water system at any time in the previous 5 years – is the operator of a laboratory that carried out testing of the cooling water system at any time in the previous 5 years.	The proposed change would eliminate instances where a person undertaking an audit of risk assessment is employed by the employer of, or engaged by, the person who undertook the risk assessment, operated or maintained the cooling water system in the previous 5 years, or operated a laboratory that carried out testing of the cooling water system in the previous 5 years to ensuring that the auditor is truly independent in their assessment.	Water treatment industry stakeholders indicated that, while in their view independence of risk assessments was not an issue, if this change is made in the Regulation, additional clarity about the definition of 'employed' should be provided (e.g., does this definition include contractors). A council stakeholder consulted noted that they have had several instances where risk assessments were clearly not providing independent risk advice. It was suggested that in addition to the proposed change to the Regulation, there should be strong penalties for auditors and risk assessors that are found to not provide independent advice. Removal of licence was suggested as an option.

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Clause 13S (1) and Clause 13T (2)	Penalty notice offences created for: – Failing to comply with Clause 13S (1) of the Regulation which requires the occupiers of premises on which a cooling water system is installed to have the required documents in relation to the system available for inspection on request by an authorised officer. – Failing to comply with Clause 13T (2) of the Regulation, which requires the occupier of premises on which a cooling water system is installed to notify the relevant local government authority of any change in the particulars provided about the system to the authority.	Public health units have reported that the four hour requirement to submit records upon request set in Clause 13S (1) of the Regulation is not being complied with by some occupier of premises on which a cooling water system is installed. It is expected that these changes would increase compliance with the relevant clauses of the Regulation.	Water treatment industry stakeholders noted that these offences are related to owner occupier requirements so they had no comment. A council stakeholder strongly supported the introduction of these offences and noted that there are not enough penalties they can use to incentivise occupiers of premises to comply with some aspects of the Regulation. Councils are able to issue improvement notices, but there are no penalties for not complying with these notices. The only recourse that councils have if a property manager does not comply is to take them to court, but this is suggested to be an unrealistic course of action for already resource constrained councils.

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

6.2.2 Part 3 — Control of public swimming pools and spa pools

The amendments proposed for Part 3 of the Regulation under Option 2, and the views of stakeholders in the industry consulted about these changes are summarised in Table 6.2. The costs and benefits associated with these amendments are outlined in the sections below.

Benefits

The main benefits of the proposed changes to the regulation of public swimming pools and spas relate to the removal of the exemption to measure and maintain minimum chlorine and bromine disinfection levels in pools fitted with ORP levels.

While limited, the available evidence about the effectiveness of ORP systems for monitoring and controlling water quality in public swimming pools in NSW suggests that setting a standard single reference ORP level as an approach to managing public health risks is inappropriate. Indeed:

- A study undertaken by the Northern Sydney Public Health Unit (NSPHU) about the performance of ORP systems in local swimming pools found that[44]:
  - Public swimming pools with the same ORP levels had substantial differences in Free Available Chlorine (FAC) concentrations despite pH levels being within the prescribed range. FAC levels were often below the minimum concentration prescribed by the Regulation for pools operating without ORP systems with pH within the range of 7.0- 7.8.
  - Meeting a standard reference ORP level does not necessarily result in satisfactory levels of FAC after adjusting for pH. However, once a satisfactory level of FAC level is reached in an individual pool, and its corresponding ORP level established, this ORP level can be used to maintain a satisfactory disinfection level for the pool. This suggests that achieving satisfactory levels of FAC would require individualised ORP levels for different pools rather than setting a standard level to be used across pools.
  - Implementing a standard reference ORP level across all public swimming pools (as it is currently set in the Regulation) is problematic and challenging for pool operators, regulators and/or pool service companies as ORP cannot be relied upon to ensure a suitable FAC level after adjusting for pH.
- A study undertaken by a student from Western Sydney University on behalf of Shoalhaven City Council explored the effectiveness and reliability of various types of disinfectant dosing systems and found that:[45]
  - Automated ORP systems showed to be the least effective and least reliable at maintaining compliance with public health regulations, with a 46 per cent failure rate.
  - On average, compared to other systems studied, automated ORP systems (and continuous metered saltwater chlorinators):
    - operate at a higher, less effective pH level regarding disinfection power
    - operate at higher free and total chlorine levels.
  - 12.5 per cent of ORP systems (and 10.29 per cent of continuous metered salt chlorinator systems) exceeded the maximum allowable total chlorine level of 10mg/L as prescribed in the Regulation (compared to 0 per cent of the other types of systems studied).
  - Within Shoalhaven both automated ORP and combination systems controlled by ORP on average operate below the minimum required 720 mV prescribed in the Regulation. It was also shown that some ORP controlled systems operating at or above the required 720 mV, with compliant pH levels, can have questionably low free chlorine levels, less than 1.0mg/L.

[44] Ives, N. and Prendergast G. 2018, *Investigating Oxidation Reduction Potential in Public Swimming Pools*, Journal of Environmental Health Australia (WA), Summer Vol 24 No 2.

[45] Sneesby, Mark 2018, The reliability and effectiveness of disinfectant dosing system within the Shoalhaven at maintaining pool chemistry in compliance with the NSW Public Health Regulations 2012, October.

In light of the evidence above, the main benefit of the proposed changes to Part 3 of the Regulation under Option 2 would be a reduction in risks to people's health and safety when using a public swimming pool. Improved water safety in public swimming pools would contribute to a reduction in the frequency, severity and impact of diseases facilitated by improperly maintained pools (e.g. skin infections, ear nose and throat infections and gastro-intestinal infections).

The proposed changes could also result in a marginal reduction in the costs of maintaining ORP systems for some industry operators who may decide to discontinue the use of ORP systems due to the proposed change.

Costs

The main costs related to the proposed changes in this part of the Regulation are the cost of the additional testing (both labour and materials) that facilities with ORP systems would have to do to measure the levels of chlorine and bromine and the cost of the additional chemicals that would need to be used to maintain the minimum levels of chlorine and bromine set in the Regulation.

Conclusion

Overall, it is considered that the benefits from reduced risks to public swimming pool users from stemming from improved testing to maintain water quality are likely to outweigh the additional compliance costs related to the proposed changes for facilities with ORP systems that do not already conduct the required tests separately.

As noted above, all stakeholders consulted for the RIS supported the proposed changes as a way to improve water quality management in public swimming pools in NSW.

Table 6.2 Proposed amendments for Part 3 Control of public swimming pools and spa pools

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).	Improved clarity of the Regulation.	Stakeholders support improving clarity of the Regulation.
Clause 14	A new clause is proposed to define a public swimming pool or spa pool for the purposes of Section 34 of the Act. Under this new definition, a water play park or other recreational aquatic structure is declared not to be a public swimming pool or spa pool if it — (a) uses a public water supply, and (b) does not use a recirculation system, and (c) does not store water.	This proposed change effectively excludes splash parks that do not recycle water from the definition of swimming pools for the purposes of Section 34 of the Act. This change is unlikely to have an impact on the operations of these facilities because these types of parks are unable to comply with the requirements in the legislation (as they currently do not store or recycle water). Further, the Ministry considers that these facilities pose a low health risk.	Stakeholders did not raise any objections with regards to this change.
Schedule 1 Requirements for public swimming pools and spa pools	All references and requirements related to Oxidation Reduction Potential Systems (ORP systems) would be removed from the Regulation.	Oxidation Reduction Potential (ORP) is a measure of the oxidizing capacity in water (i.e. it is not a measure of the level of chemicals/sanitisers in the water, but rather a measure of the potential a disinfectant – like chlorine - has to oxidize/clean the water). ORP systems are used to monitor and control water quality by measuring the oxidation reduction potential of disinfectants in pool water. Under the current Regulation, public pools in NSW fitted with ORP systems are required to maintain an ORP level of at least 720mV (if chlorine disinfected) or 700mV (if bromine disinfected), and if this is met are not required to measure or maintain minimum chlorine and bromine disinfection levels. This proposed change to the Regulation effectively removes ORP systems as an accepted alternate method for monitoring and controlling water quality in public swimming pools and spa pools. As a result of this change, public pools and spas currently fitted with ORP systems would be required to measure and maintain the	All the stakeholders consulted for the RIS agreed that ORP systems on their own are an unreliable mechanism to control water quality in swimming pools and none of them relied solely in ORP to monitor and maintain water quality of the pools they operate (indeed, a large operator noted that they have removed all ORP systems from their pools due to their poor reliability). However, it must be noted that most of the stakeholders consulted are large operators of public swimming pools. The following was also noted during these consultations: – For the stakeholders consulted, this proposed change to the Regulation would not change their current water testing regime. However, it was noted that it is likely that for small operators/owners of swimming pools this may not be the case. – The cost of additional tests is marginal. However, the labour required to undertake these tests may be a significant additional expense for owners/operators or smaller pools. While large operators of swimming pools already have the people/resources to conduct these tests (some also have aquatic consultants to

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
		minimum chlorine and bromine disinfection levels set in the Regulation as any other pool.	help manage their pools), a small caravan park operator with one single pool (for instance) may have to incur additional costs to have someone do the additional testing. – The benefits of ensuring water safety in public swimming pools are significantly higher than any additional testing costs that the proposed change might impose in pool operators.

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

6.2.3 Part 4 — Control of skin penetration procedures

The amendments proposed for Part 4 of the Regulation under Option 2, and the views of some public health units and a council official[46] consulted about these changes are summarised in Table 6.2 (no industry stakeholders were consulted regarding the changes proposed to this part of the Regulation, but the Ministry would welcome submissions on whether the proposed changes are appropriate). The costs and benefits associated with these amendments are outlined in the sections below.

Benefits

The main benefits of the proposed changes to Part 4 of the Regulation under Option 2 are as follows.

— Increased clarity to operators and regulators about the regulatory requirements for skin penetration premises.

— A potential reduction in risk of cross contamination associated with using equipment washing sinks for other purposes.

— Improved record keeping of sterilisation reports (which increases the capacity to conduct tracing if ever necessary) could result in improved public health outcomes.

Costs

The proposed changes to the retention of records for 12 months may result in an increase in administrative costs for skin penetration facilities that sterilise reusable articles off-site. It is considered that this increase in costs would be small.

It is considered that the clarification of the requirement to use equipment sinks solely for the purpose of cleaning equipment used in skin penetration procedures would not impose additional costs on businesses — that is, the proposed change is not a requirement to install an additional sink to clean equipment, as such a sink should already be provided by skin penetration premises as part of the requirements of the current Regulation.

Conclusion

To the extent that the proposed changes to Part 4 of the Regulation reduce the potential risk of cross contamination and improve record keeping of sterilisation reports at a marginal cost, the changes are expected to be overall beneficial.

[46] Only the council official was consulted directly by ACIL Allen, public health units provided feedback for the RIS through the Ministry.

Table 6.3 Proposed amendments for Part 4 Control of skin penetration procedures

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).	Improved clarity of the Regulation.	Council official consulted supported improving clarity of the Regulation.
Division 2 Clause 23(1)(d)	For premises where skin penetration procedures are carried out, clarifying that the separate sink required for cleaning equipment used in skin penetration procedures must only be used for cleaning equipment.	Under current Clause 23 of the Regulation, skin penetration premises are required to have (amongst other): a) a hand basin that has a supply of clean, warm, potable water b) a separate sink that has a supply of clean, warm water for cleaning equipment (if equipment used in skin penetration procedures at the premises is cleaned at the premises). The intent of the Regulation under d) is that the sink for cleaning equipment is only used for this purpose. However, evidence from Public Health Units indicates that premises are using these sinks for other purposes, with consequent risk of cross contamination and poor availability. The purpose of this change is to clarify the intent of the Regulation.	The council official consulted supported this change. Public health units and a council official also suggested the following additional changes to the Regulation: – hand wash basins must be conveniently located close to the procedure area and available at all times for hand washing to promote good hand hygiene (the Regulation currently has no location requirements for hand basins) – for premises where there are several rooms where skin penetration procedures are being carried out, a hand washing basin should be required for each room. A stakeholder suggested that, if a person conducting a procedure has to go into another room with a client to use the basin, they most likely would not wash their hands.
Clause 26 (2) (a)	Removing the requirement to comply with the standard AS 2182-1998 (which sets the design and construction of the autoclave).	This standard has been rescinded and not replaced. The Ministry considers that the remaining requirements in the Regulation are sufficient for infection control and hygiene for skin penetration premises.	No comment was provided about this change.
Clause 26	Amending this clause to add a requirement for premises that sterilise reusable articles off-site to keep for 12 months a copy of the report on the sterilisation by the person who sterilised the article.	This change is being proposed to ensure good record keeping and facilitate auditing of compliance with the requirements in the Regulation.	No comment was provided about this change.

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Clause 31 (1)	Amending this clause to clarify that the notice of the carrying out of skin penetration procedures must be given to the local government authority before skin penetration procedures are carried out at the premises.	This change is being proposed to clarify the intent of the Regulation.	No comment was provided about this change.

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

6.2.4 Part 5 — Safety measures for drinking water

There only amendments proposed for this part of the Regulation are rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry. Given this, there are no significant costs or benefits associated with these changes.

6.2.5 Part 6 — Scheduled medical conditions

The amendments proposed for Part 6 of the Regulation under Option 2 are summarised in Table 6.4 (no stakeholders were consulted with regards to these proposed changes). The costs and benefits associated with these amendments are outlined in the sections below.

Table 6.4 Proposed amendments for Part 6 Scheduled Medical Conditions

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).	Improved clarity of the Regulation.
Clause 37 and 39	References to AIDS have been removed in these clauses.	Change is proposed to reflect changes in the Act, under which AIDS is no longer a notifiable condition under the Act.
Clause 39 (1)(a)	A refence to the conditions listed in Schedule 1A of the Act, alongside category 4 and 5 conditions has been included in this clause.	Change is proposed to reflect the introduction of this Schedule in the Act
Clause 39A	This clause has been expanded so that advice regarding measures to be taken, and activities to be avoided, in order to minimise the danger of a person suffering from a Category 2 or 3 condition passing the medical condition to another person can be provided by a range of staff within public and private health services. This includes a person who provides any of the following services: a) medical, hospital, nursing or midwifery services, b) community health services, c) health education services, d) public and population health services, e) welfare services necessary to implement any services referred to in (a)–(d).	Change is proposed to better reflect the range of practitioners and staff that are appropriate to provide advice to patients regarding scheduled medical conditions.
Clause 39B (3)	This clause has been expanded so that the definition of 'relevant health practitioner' (who may notify a person who may have been in contact with a person suffering from a Category 2, 3 or 4 condition of measures to be taken, and activities to be avoided, in order to minimise the danger of the first person contracting the condition or passing it to a third person), includes a person who provides public and population health services.	Change is proposed to better reflect the range of practitioners and staff that should provide advice to patients regarding scheduled medical conditions.

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

Benefits

The main benefits of the proposed changes to Part 6 of the Regulation under Option 2 are better alignment of the Regulation and the Act and improved clarity of the Regulation.

Costs

The proposed changes are unlikely to result in additional costs for government, industry or the community.

Conclusion

To the extent that the proposed changes increase clarity of the Regulation at no cost, the changes are expected to be overall beneficial.

6.2.6 Part 7 — Other disease control measures

The amendments proposed for Part 7 of the Regulation under Option 2, and the views of a stakeholder from the NSW Department of Education consulted about these changes are summarised in Table 6.5 (no childcare providers or carers were consulted regarding the changes proposed to this part of the Regulation, but the Ministry would welcome submissions on whether the proposed changes are appropriate). The costs and benefits associated with these amendments are outlined in the sections below.

Benefits

The main benefits of the proposed changes to Part 6 of the Regulation under Option 2 are as follows.

- Consistency between Commonwealth and state requirements, which could result in some administrative costs for childcare providers.
- Children who fall within the proposed new exemptions would not be excluded from enrolling in childcare services. The significance of early childhood education for all children for all children in terms of socialisation and educational attainment, regardless of vaccination status, has long being recognised. Notably, while this is a significant potential benefit, anecdotal evidence suggests that children who fall within the proposed new exemptions may already be allowed to enrol in childcares, as they are deemed to comply with the Commonwealth immunisation requirements. Under this scenario, the benefit of the proposed changes would be instead cost savings to parents/carers, childcare providers and regulators who would not have to spend time negotiating enrolment of children under these circumstances (our understanding from discussions with the Ministry is that the number of these children in NSW is very small).

Costs

The main costs related to the proposed changes to Part 6 of the Regulation under Option 2 are as follows.

- The Ministry would incur a small cost in informing stakeholders of this regulatory change. No financial cost is expected to be incurred by childcare operators or parents/carers.
- There could be a potential increase in the risk of transmission of communicable diseases in a childcare setting due to the enrolment of children who would fall under the new exemptions and who would not be fully immunised. However, this risk is considered to be small because:
  - the rate of vaccination of children 5 years and under in NSW is very high (over 91 per cent, see Figure 2.6), so the number of children which would fall within the three new exemptions (natural immunity, participation in a trial and vaccine not available) is expected to be very low
  - as mentioned above, anecdotal evidence indicates that children who fall within the proposed new exemptions may already be allowed to enrol in childcares, so formalising this practice is unlikely to create *additional* risk for the community compared to the status quo

- NSW already allows exemptions to the immunisation requirements for 2a and 4 above, so the new proposed exemptions relate to 2b (natural immunity), 2c (participation in a trial), 3 (vaccine not available) and 5 (Secretary's exemption)
  - the risk for children with natural immunity will not change with the new regulation
  - there would be societal benefits associated with properly supervised trials which would outweigh the costs associated with keeping a child away from school
  - the lack of availability of a vaccine is likely to be temporary (and uncommon), otherwise all children would be unvaccinated. This may result in a small risk but with no alternative but to keep the child out of school. Overall, the benefits of allowing the child to attend would outweigh the costs of denying access until the vaccine is available again.

Conclusion

To the extent that the proposed new exemptions could improve equity of access to early education for children who cannot reasonably be (or need to be) immunised and improve consistency between Commonwealth and state requirements, without increasing the overall health risks to children in childcare settings, then the proposed change is expected to be beneficial.

Table 6.5 Proposed amendments for Part 7 Other disease control measures

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry.	Improved clarity of the Regulation.	No comment was provided about this change.
Clause 44A	A new exemption from pre-enrolment immunisation requirements relating to childcare facilities to allow the principal of a childcare facility to permit enrolment of a child that meets the immunisation requirements for the purposes of section 6(1) of the *A New Tax System (Family Assistance) Act 1999* of the Commonwealth on the grounds set out in section 6(3)(c) or 6(4) or (6) of that Act.	The aim of this change is to ensure there is consistency between the exemptions to immunisation requirements allowed by the Commonwealth for the purpose of accessing some family assistance payments, and the exemptions allowed in NSW. In effect, the proposed new exemption would allow a child to be enrolled in childcare if the child meets the immunisation requirements set by the Commonwealth in the *A New Tax System (Family Assistance) Act 1999*, which establish that a child meets immunisation requirements if: 1. the child has been immunised 2. a general practitioner, a paediatrician, a public health physician, an infectious diseases physician or a clinical immunologist has certified in writing that the immunisation of the child: a) would be medically contraindicated, or b) is not required immunisation because the child has contracted a disease or diseases and as a result has developed a natural immunity, or c) the child is a participant in a vaccine study approved by a Human Research Ethics Committee registered with the National Health and Medical Research Council 3. the vaccines required for vaccination are temporarily unavailable 4. the child has been vaccinated overseas and a recognised immunisation provider has certified in writing that those vaccinations have provided the child with the same level of immunisation that the child would have acquired if the child had been vaccinated in accordance with a standard vaccination schedule	The NSW Department of Education stakeholder consulted supported this change (as noted above, no other stakeholders were consulted regarding this proposed change).

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
		5. the Secretary determines in writing that the child meets the immunisation requirements. Notably, NSW already allows exemptions to the immunisation requirements for 2a and 4 above, so the new proposed exemptions relate to 2b (natural immunity), 2c (participation in a trial), 3 (vaccine not available) and 5 (Secretary's exemption).	

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

6.2.7 Part 8 — Disposal of bodies

The amendments proposed for Part 8 of the Regulation under Option 2, and the views of stakeholders in the funeral industry consulted about these changes are summarised in Table 6.6. The costs and benefits associated with these amendments are outlined in the sections below.

Benefits

The main benefits of the changes proposed for the Regulation under Option 2 would be as follows.

- The extension of the time a hospital can retain a body would provide additional flexibility to hospitals, funeral directors and families when organising a funeral.
- A reduced risk of misidentification of bodies at mortuaries (due to the proposed change to Clause 62 (2)).
- Allowing bodies to be buried in a shroud would:
  - provide increased consumer choice for burials, regardless of faith
  - result in improved environmental outcomes as there would be no need to use a coffin for the burial
  - reduced regulatory costs for the Ministry in reviewing/granting individual applications for shrouded burials.
- A general exemption for pre-approved shallow burial methods would have a number of benefits, including:
  - increased certainty about the requirements for shallow burials
  - more efficient burial operations as an exemption would not be needed in a case by case basis
  - increased cemetery land utilisation and burial space, which would assist with cemetery renewal and sustainability. This is particularly important given the critical shortage of burial space in the Greater Sydney Metropolitan Area noted by the recent review of the *Cemeteries and Crematoria Act 2013*[47]
  - reduced regulatory costs for the Ministry in reviewing/granting individual applications for shallow burials.
- The removal of the requirement for the Secretary to approve the material to hermetically enclose a body in a coffin within a vault would allow the use of innovative sealing materials and potentially increased consumer choice. Eliminating this requirement would also lower the costs for the Ministry in administering the Regulation as approvals for materials to hermetically enclose a body would not be necessary.
- Depending on the final requirements and form of the proposed 'cremation risk advice', the proposed changes to the cremation requirements in the Regulation could:
  - simplify the cremation process
  - reduce the administrative burdens for funeral directors and families
  - lower the cost of cremation for families.

Costs

The main costs related to the changes proposed to for Part 8 of the Regulation under Option 2 are the following.

[47] Whitella Consulting 2020, *The 11th Hour Solving Sydney's Cemetery Crisis, Cemeteries and Crematoria Act 2013 Statutory Review*, https://www.industry.nsw.gov.au/__data/assets/pdf_file/0008/353087/Statutory_Review_of_the_Cemeteries_Crematoria_Act.pdf.

- Allowing bodies to be buried in shrouds could:
  - Result in increased risks to the health and safety of people handling the body of the deceased[48] due to potential leakage of fluids, staff exposure to shrouded bodies and the physical management of the body without a coffin. While it is not possible to quantify the magnitude of this potential increase in risk, it is worth noting that:
    - A considerable number of burials are already being done in a shroud. For instance, it was noted during stakeholder consultations that around 25 per cent of burials in Rookwood General Cemetery (which undertakes approximately 30 per cent of Sydney's burials[49]) are shrouded. Anecdotal evidence noted by stakeholders suggest that these burials have been conducted without any negative outcomes. However, it is important to note that these shroud burials are done for religious reasons and hence, shrouded bodies are lowered into the grave by a family member.
    - Funeral directors and cemetery staff do not *have* to be exposed to these potential risks. If there are significant safety issues with a body (e.g. significant leakage), a funeral director does not have to agree to bury the body in a shroud. The alternative may be that the family of the deceased chooses to take the body to be buried somewhere else, but ultimately the funeral director and staff do not *have* to be unnecessarily exposed to these matters if they do not wish to do so.
    - Stakeholders consulted for the RIS suggested that a detailed policy directive for industry to guide the handling of bodies in shrouds throughout the burial process could help ameliorate any potential health and safety issues associated with an increased in shroud burials.
    - The Ministry noted the need to provide advice and guidance to address potential concerns about the conveyance of deceased persons in respect to minimising leakage and their dignified and respectful treatment during viewing, ceremonies and management at grave sites.
  - Result in increased burial costs for consumers choosing this option for non-religious reasons, as not having family members involved in the handling of the body (e.g. in lowering the body into a grave), may in practice require the use of additional equipment or labour. However, this is an additional cost that consumers would factor into their decision making and would choose to incur if they choose a shrouded burial (which would reflect their willingness pay extra to be buried in a manner they prefer), and as such, it is not a cost that could be attributed to the proposed regulatory change.
- A general exemption for shallow burials could potentially increase the incidence of cases where subsidence occurs causing the coffin to deteriorate, decomposition odours to escape, and attraction of rats and feral animals to the grave site. However, given that the amendment would only allow for pre-approved shallow burial methods designed to avoid (or minimise) these risks, it is unlikely that this proposed change would result in increased risks to health and safety.
- The removal of the requirement that a Medical Referee undertakes an external examination of the body of the deceased person as a condition to issue a cremation permit could result in Medical Referees approving cremations that may not (or should not) have been approved if the body was seen. These circumstances could include deaths from non-natural processes or bodies that pose a risk to cremate.

[48] And indirect risks to the general public through the possibility of workers infected through the handling of shrouded bodies on-transmitting infections to other members of the public.

[49] Whitella Consulting 2020, *The 11th Hour Solving Sydney's Cemetery Crisis, Cemeteries and Crematoria Act 2013 Statutory Review*, https://www.industry.nsw.gov.au/__data/assets/pdf_file/0008/353087/Statutory_Review_of_the_Cemeteries_Crematoria_Act.pdf, accessed 30 April 2021.

Conclusion

To the extent that the changes to Part 8 of the Regulation do not significantly increase cremation risks (including the risk of cremating bodies where death should be subject of other investigation) or health and safety risk of people handling bodies, then the proposed changes are likely to result in compliance and administrative cost savings (both for industry and government), increased consumer choice, more efficient burial and cremation operations and increased cemetery land utilisation and burial space.

The proposed changes in this part of the Regulation would be subject to Policy Directives/Guidelines produced by the Ministry with the aim of continuing to adequately protect public health by setting appropriate infection control standards and procedures and providing for the appropriate documentation in relation to cremations. These Policy Directives/Guidelines are likely to reduce potential risks associated with the proposed changes in this area of the Regulation.

Table 6.6 Proposed amendments for Part 8 Disposal of bodies

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
Various	Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (including removal of savings provisions that are no longer relevant).	Improved clarity of the Regulation.	Stakeholders support improving clarity of the Regulation.
Division 3, Clause 57 (1)	Removing the requirement to comply with the guidelines specified in Part B of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* published by the National Health and Medical Research Council (NHMRC).	The NHMRC Guidelines have been updated and do not contain relevant requirements regarding bodies. The Ministry believes that the current general Workplace Health and Safety (WHS) obligations achieve the same result (the rescinded guidelines contained general infection control information).	Stakeholders did not raise any objections with regards to this change.
Clause 54	Amend clause to increase the time that hospitals are allowed to retain bodies to up to 21 days.	Hospitals are currently allowed to retain bodies for up to 5 days. While funeral directors and families are encouraged to collect the body of a deceased person from hospital as soon as possible, there are circumstances where this is not possible (e.g. if relatives are overseas). Extending the retention time to 21 days would allow hospital, funeral directors and families more flexibility. Greater storage time may also be required by persons during pandemics, such as the current COVID-19 pandemic.	Stakeholders were supportive of this change and did not raise any issues related to risks or unintended consequences of this proposed change.
Clause 62 (2)	Amend clause to require mortuaries to register bodies immediately after the body is delivered to the mortuary for preparation (instead of after the body is prepared).	To improve the process of registration of bodies.	Stakeholders were supportive of this change and did not raise any issues related to risks or unintended consequences of this proposed change.
Clause 63 (a)	Amend clause to allow bodies to be buried in a shroud rather than only coffins (provided the shroud complies with the relevant Policy Directive).	Currently the Regulation requires that all bodies must be buried in a coffin unless otherwise approved for religious reasons under NSW Health Policy Directive Burials-Exemptions from Public Health Regulation 2012 for Community and Religious Reasons (PD 2013_048). This amendment would allow bodies to be buried in a shroud without the need to obtain an exemption.	Stakeholders generally supported the need for shrouded burials for religious reasons, to meet the changing needs of society in respect to more environmental/sustainable burials and to provide greater consumer choice regardless of faith. However, some health and safety concerns were raised by some stakeholders regarding: – leakage of fluids

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
		The change is proposed to ensure that adequate and proper provision is made for the interment practices and beliefs of all religious and cultural groups in our society and provide greater consumer choice for people interested in shroud burials for other non-religious reasons.	– staff exposure to shrouded bodies – the physical management of a body in a shroud (including securing it for transport) – lowering of bodies into graves, particularly when the family of the deceased is not involved in lowering the body into the grave (where, for instance, the shroud burial is not related to religions reasons) and there is an expectation that the cemetery would take care of this. Some stakeholders also raised concerns about dignified and respectful viewing and ceremonies at churches and other locations. With respect to the above concerns, it was noted that if the proposed change is made to the Regulation, that a detailed policy directive should be prepared for industry to guide the handling of bodies in shrouds throughout the burial process to avoid any health and safety issues. Stakeholders also raised the need to more adequately define 'shroud', particularly how a layer is of material is defined (e.g. is a garment a layer or a layer needs to be covering the body from head to toe). A request to not limit the shroud to specific materials (e.g. cotton or linen) was made, as sometimes wool can also be used for shrouds.
Clause 64	Amend clause to enable a general exemption, rather than just for specific burials, by the Secretary to approve burial of bodies shallower than 900 millimetres where they comply with the requirements of the exemption.	Currently, the Regulation only allows for approval for the shallow burial of a body at a depth of less than 900mm in a particular case. This approval is only granted upon application for individual grave sites that comply with the requirements set out in the NSW Health Policy Directive Shallow Burial (PD2013_045). The amendment would provide for a general exemption and allow for pre-approved methods for shallow burials. This would accommodate common situations, such as two burials in one grave, or geotechnical engineering work that is required in a cemetery (or cemeteries) with	Stakeholders were supportive of this change, provided clear guidelines are provided about how shallow burials should be conducted to ensure health and safety (particularly for shroud burials). Notably, as mentioned in the previous column, there is currently a Shallow Burial Policy Directive produced by the Ministry, which would be updated to reflect the proposed change in the Regulation. Stakeholders noted that this change would have a number of benefits, including: – increased certainty about the requirements for shallow burials

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
		certain subsoil ground conditions (such as a high water table and shallow depth to a rock floater or bedrock).	– more efficient burial operations as an exemption would not be needed in a case by case basis – increased burial space, which would assist with cemetery renewal and sustainability.
Clause 67 (1) (a)	Amend clause to remove the requirement for the Secretary to approve the material to hermetically enclose a body in a coffin within a vault.	To be buried in a vault a body would still need to be embalmed and hermetically enclosed in a coffin, but the material used to hermetically enclose the body no longer needs to be approved by the Secretary.	Stakeholders were supportive of this change. It was noted that this is a positive change given that it would allow the use of innovative sealing materials being developed over time.
Division 5 Cremation	Amending relevant clauses in this division to simplify the cremation process by: 6. substituting the requirement to provide a cremation certificate for the provision of: a) advice as to whether there is a cremation risk from a relevant medical practitioner. A relevant medical practitioner in this context is medical practitioner who: i) attended the person immediately before, or during the illness terminating in, the death of the person, or ii) has relevant knowledge of the dead person's medical history b) a death certificate, a Medical Certificate of Cause of Death (MCCD) or an order authorising the disposal of the remains of the dead person by a coroner under section 101 of the *Coroners Act 2009* 7. no longer requiring that the Medical Referee makes an external examination of the body as a condition to issue a cremation permit (however, a medical referee *may* conduct one if the Medical Referee considers it necessary).	Currently, to cremate a body, the following is required by the Regulation: 8. Application for Permission for Cremation — an application made in the approved form to a medical referee or coroner. 9. Cremation Certificate[50] — issued by an attending practitioner (as defined in Clause 81 of the Regulation) 10. Cremation Permit — issued by a medical referee.[51] To issue this permit the medical referee is required to make an external examination of the body The proposal is to: – substitute the Cremation Certificate for: – advice as to whether there is a cremation risk from a relevant medical practitioner (either the attending practitioner or a medical practitioner familiar with the deceased's medical history) – a death certificate, a MCCD or an order authorising the disposal of the remains of the dead person by a coroner under section 101 of the *Coroners Act 2009.*	Stakeholders were generally supportive of substituting the cremation certificate for cremation risk advice and a death certificate, provided that there are still enough 'checks and balances' to ensure that: – bodies are properly identified – the body is safe to cremate (with regards to implanted devices and prior medical treatments). It was further highlighted that it is essential for crematoria to receive all the required documentation prior to cremation. Stakeholders also suggested additional changes to the MCCD that would further simply the cremation process. These are detailed in Appendix A. Some stakeholders were concerned about no longer requiring that the Medical Referee makes an external examination of the body as a condition to issue a cremation permit. This examination was highlighted as an important fail-safe procedure.

[50] If the death is not examinable by Coroner.

[51] Ibid.

Clause [a]	Proposed change	Purpose/rationale of the proposed amendment	Stakeholder comment
		– no longer requiring a Medical Referee to undertake an external examination of the body as a condition to issue a cremation permit. These proposed changes are aimed at simplifying the cremation process, reducing the administrative burden for funeral directors and their clients and reducing cremation costs for families of deceased persons.	

[a] All clauses refer to the current Regulation.

Source: ACIL Allen.

6.2.8 Part 9 — Miscellaneous

Broadly, there are two amendments to this part of the Regulations:

1. Rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry. There are no significant costs or benefits associated with these
2. A new code of conduct prescribed for the purposes of section 100 of the Act for the provision of health services by a relevant health organisation in Schedule 4. Similar to the code of conduct for non-registered health practitioners in Schedule 3 of the Regulation, the proposed new code of conduct for health organisations has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.

6.2.9 Fees in the Regulation

Fees in the Draft Regulation have been increased to reflect increases in the Consumer Price Index and the costs of administering the Regulation. The proposed increase in fees are not considered a cost of Option 2 because this change leaves the *real* level of fees unchanged.

7 Conclusion

The NSW Ministry of health has identified the following options to be considered in this RIS.

— ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).

— ***Option 1*** — this option entails remaking the existing Regulation without any changes (the *status quo* option).

— ***Option 2*** — this option entails making the Draft Regulation, which would entail remaking the existing Regulation with several proposed amendments.

The Base Case option (discontinuing the Regulation) is not considered appropriate because of the following reasons:

— it would mean that the Act would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates

— it would increase the risks to the health and safety of the public due to the lack of standards across a range of areas that have the potential to affect public health (for instance, drinking water, water cooling systems, skin penetration procedures and public swimming pools) and provisions for a number of measures to control the transmission of communicable diseases. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

The analysis of the impacts of the proposed amendments to the Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1) has been structured around the following areas of the Regulation, rather than around each of the options.

1. *Legionella* control (Part 2)
2. Control of public swimming pools and spa pools (Part 3)
3. Control of skin penetration procedures (Part 4)
4. Safety measures for drinking water (Part 5)
5. Notifications and record keeping requirements for scheduled medical conditions (Part 6)
6. Disease control measures (Part 7)
7. Disposal of bodies (Part 8)
8. Miscellaneous (Part 9)
9. Fees payable in relation to improvement notices, prohibition orders and inspection of premises.

As discussed before, the benefits and costs associated with the alternative options have been analysed qualitatively because:

— the Ministry's advice that the RIS was to be prepared on a qualitative basis

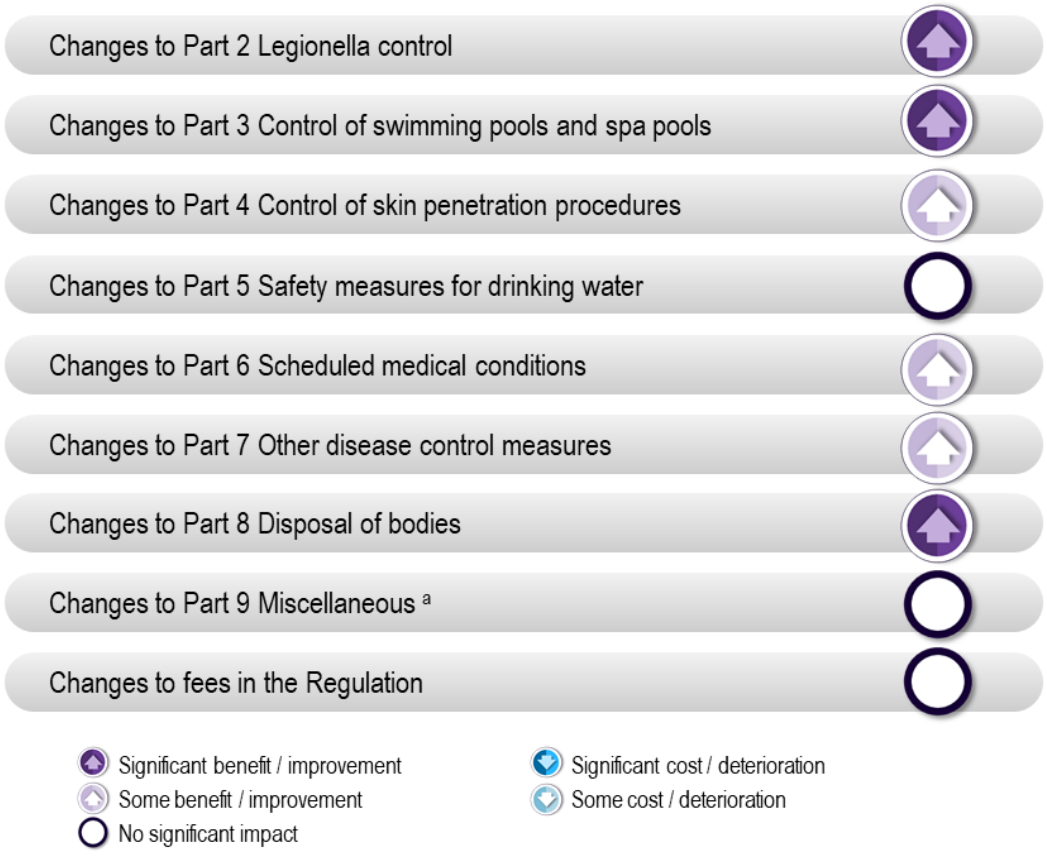
— the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

  — limited data available to comprehensively demonstrate the effectiveness of the existing Regulation

  — the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

However, Figure 7.1 provides a summary of the relative nature of the benefits and costs of the changes proposed under Option 2 across the eight areas outlined above, with respect to Option 1 (i.e. the *status quo*).

Figure 7.1 Summary of potential relative impacts of the proposed Draft Regulation across key areas of change (relative to the status quo)



[a] Other than rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry (and hence no significant costs or benefits associated with these), the only other change proposed for this part of the Regulation is a new code of conduct for health organisations. This proposed new code of conduct, and changes to the existing code of conduct for health practitioners in Schedule 3, has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.

Source: ACIL Allen.

In summary, in relation to the proposed changes to the Regulation across its main areas:

1. Overall, it is considered that the proposed changes to the *Legionella* provisions in Part 2 of the Regulation could contribute to a reduction in the frequency, severity and impact of legionellosis outbreaks at a marginal cost to occupiers of premises on which cooling systems are installed.
2. The proposed changes to Part 3 of the Regulation related to the removal of ORP systems as an accepted alternate method for monitoring and controlling water quality in public swimming pools and spa pools are likely to result in:

- a reduction in risks to people's health and safety when using a public swimming pool
- possible reductions in the frequency, severity and impact of diseases facilitated by improperly maintained pools
- a possible marginal reduction in the costs of maintaining ORP systems for some industry operators who may decide to discontinue the use of ORP systems due to the proposed change.

Overall, it is considered that the above benefits are likely to outweigh the additional compliance costs related to the proposed changes for facilities with ORP systems that do not already conduct the required tests separately.

3. The proposed changes to Part 4 of the Regulation can potentially reduce cross contamination risks in skin penetration premises and improve record keeping of sterilisation reports at a marginal cost. Accordingly, these changes are expected to be beneficial.
4. The only amendments proposed for Part 5 of the Regulation (safety measures for drinking water) are rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry. Given this, there are no significant costs or benefits associated with these changes.
5. To the extent that the proposed changes to Part 6 of the Regulation (scheduled medical conditions) result in are better alignment of the Regulation and the Act and improved clarity of the Regulation, the changes are expected to be beneficial.
6. Overall, it is considered unlikely that the new proposed exemptions from pre-enrolment immunisation requirements, relating to childcare facilities in Part 7 of the Regulation for children with certified natural immunity, participating in an approved vaccine study or who cannot be vaccinated due to temporary vaccine unavailability, would significantly increase risks of transmission of communicable diseases in childcare facilities because:
   - the rate of vaccination of children 5 years and under in NSW is very high (over 91 per cent), so the number of children which would fall within the three new exemptions is expected to be very low
   - anecdotal evidence indicates that children who fall within the proposed new exemptions are already being allowed to enrol in childcare as they are deemed to comply with the Commonwealth immunisation requirements, so formalising this practice is unlikely to create *additional* risk for the community compared to the status quo
   - while achieving higher vaccination coverage for children in childcare settings is desirable, the increased risk for unvaccinated children is considered to be slight and related principally to the situation where vaccines are temporarily unavailable. These risks are outweighed by the benefits of enabling those children to participate in the education system.

   The proposed exemptions would ensure consistency between Commonwealth and state requirements (which could result in some administrative costs for childcare providers) and would result in children who fall within the proposed new exemptions but who were previously excluded from enrolling in childcare services, being able to attend (although, as noted above, there is anecdotal evidence that these children are already being allowed to enrol in childcares). Under this scenario, the benefit of the proposed changes would be cost savings to parents/carers, childcare providers and regulators who would not have to spend time negotiating enrolment of children under these circumstances).

   To the extent that the proposed new exemptions could improve equity of access to early education for children who cannot reasonably be (or need to be) immunised and improve consistency between Commonwealth and state requirements, without increasing the overall health risks to children in childcare settings, the proposed change is expected to be beneficial.

7. To the extent that the changes proposed to Part 8 of the Regulation (disposal of bodies) do not significantly increase cremation risks (including the risk of cremating bodies where death should be subject of other investigation) or health and safety risks for people handling bodies, and result in compliance and administrative cost savings (both for industry and government), increased consumer choice, more efficient burial and cremation operations and better utilisation of cemetery land and burial space, then the proposed change is expected to be beneficial .

   Given that the proposed changes for this part of the Regulation would be subject to Policy Directives/Guidelines produced by the Ministry with the aim of continuing to adequately protect public health by setting appropriate infection control standards and procedures and providing for the appropriate documentation in relation to cremations, then the proposed changes in this area of the Regulation are expected to be overall beneficial.

8. The proposed changes for Part 9 of the Regulation involve:
   - rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of industry, government or consumers (and hence no significant additional costs or benefits)
   - a new code of conduct for health organisations. This proposed new code of conduct has been excluded from the impact assessment in this RIS as it requires a separate Impact Assessment Statement.
9. The proposed increase in fees to reflect inflation rates are not considered a cost of Option 2 because this change leaves the *real* level of fees unchanged.

8 Consultation

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a RIS and a period of public consultation.

Consistent with the *Subordinate Legislation Act 1998*, the Draft Regulation and RIS will be open for public consultation for a period of at least 21 days

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
ST LEONARDS NSW 1590

Submissions may also be made via email to NSWH-LegalMail@health.nsw.gov.au.

Individuals and organisations should be aware that generally any submissions received will be publicly available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry of Health, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft Regulation. Key issues on which stakeholder views are sought include the following:

- Are there additional measures that could be included in the Regulation to more effectively identify, manage or control the growth and spread of Legionella in cooling water systems? For example, reducing the threshold for reportable test results to a level that would improve identification and response to Legionella detections.
- Are there any costs and benefits of the Draft Regulation that have not yet been considered, and how material are these impacts?
- Are there any risks of the Draft Regulation that have not yet been considered?
- Are there any additional amendments which could have a net positive impact on the proposed Regulation?
- Could the results of the proposed Regulation be achieved through any alternative options?
- Are the matters covered in the Regulation appropriate to be dealt with by the Public Health Regulation, and by NSW Health? Or, are there more appropriate mechanisms (including other legislation), or bodies, to manage any of the matters in the Regulation?

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Appendices

Stakeholder consultations A

A.1 Consultations undertaken as a part of this RIS

As part of the development of this RIS, ACIL Allen undertook informal consultations during April 2021 with a limited number of stakeholders to gather stakeholder views about the impacts of potential amendments to the Regulation.

In addition to their views about potential amendments to the Regulation, through these consultations, stakeholders shared their views about a number of other issues related to the Regulation (noting that there will be no regulatory changes associated with these issues at this time). These issues are outlined for future consideration in the following section.

The stakeholders consulted through these workshops are outlined in the table below.

Table A.1 Stakeholders consulted during preparation of this RIS

Organisation	Date
Carlile Swimming (Brookvale)	8 April 2021
YMCA NSW	7 April 2021
Country Pool Managers Association	6 April 2021
Integra Water Treatment Solutions	12 April 2021
Hydrochem	12 April 2021
SAS Water Solutions	12 April 2021
Ecolab	12 April 2021
A council from the Greater Metropolitan Sydney Region	12 April 2021
Australian National Imams Council (ANIC)	13 April 2021
NSW Funeral Directors Association	14 April 2021
Australian Funeral Directors Association	14 April 2021
Cemeteries and Crematoria Association of NSW	14 April 2021
Cemeteries and Crematoria NSW	14 April 2021
NSW Department of Education	8 April 2021

Source: ACIL Allen Consulting.

Belgravia Leisure was asked to participate in the consultations, but were not available to participate.

A.2 Issues raised by stakeholders for future consideration

Stakeholders consulted for this RIS suggested a number of other refinements to the overall regulatory framework around the areas dealt with by the Regulation. These are presented below for future consideration by the Ministry where feasible. It is important to note that some of these suggestions fall outside the remit of the Regulation and/or the Ministry.

***Legionella* control**

Water treatment service providers raised the following issues in relation to the overall regulatory framework for *Legionella* control:

- Councils interpret the regulatory requirements differently, resulting in inconsistencies in the application of the regulatory framework and the requirements for industry. It was suggested that a single team within the Ministry in charge of *Legionella* control (similar to the *Legionella* team within Victoria Health) would provide more consistency in the application of the Regulation and more certainty to industry.
- In instances where additional guidance is required about the intent and application of the Regulation, this guidance is not always provided in a swift manner. An example was raised when it took two years to receive guidance about a requirement related to corrosion tests.
- Industry stakeholders noted that there are some inconsistencies between the standards called in this part of the Regulation[52] and the NSW Guidelines for *Legionella* Control in Cooling Water Systems. It was also noted that these standards are currently being reviewed and so clarity about the version of the standard that industry would be required to follow is necessary.
- The format of the Risk Management Plans (RMP) required by the Regulation is unclear (stakeholders noted that some councils require RMPs to be provided in the exact format of the Risk Management Plan approved form in the Ministry's website, and other councils advise that RMPs can be provided in the company's own format).

A council consulted for the RIS made the following comments in relation to the overall regulatory framework for *Legionella* control:

- The *Legionella* requirements introduced in 2018[53] have significantly increased the administrative burden on councils, without a corresponding increase in resources to administer these regulatory changes. These resource constraints have resulted in some councils having limited ability to conduct proactive inspections of cooling towers, as resources are focused in administering the new requirements.
- The council stakeholder consulted suggested that there are not enough penalties they can use to incentivise industry to comply with some aspects of the Regulation. Councils are able to issue improvement notices, but there are no penalties for not complying with these notices. The only recourse that councils have if a property manager does not comply, is to take them to court, but it is known that this is an unrealistic course of action for already resource constrained councils. As noted in the body of this report, some two additional penalty infringement offences have been included as part of the proposed changes to the Regulation.

[52] AS/NZS 3666.1:2011; AS/NZS 3666.2:2011; AS/NZS 3666.3:2011 and AS/NZS 3666.4:2011.

[53] From 10 August 2018, building occupiers are required to ensure that there are six key safeguards in place for their cooling water systems: (1) risk assessment of Legionella contamination, documented in a Risk Management Plan (RMP) every five years (or more frequently if required) (2) independent auditing of compliance with the RMP and Regulation every year; (3) providing certificates of RMP completion and audit completion to the local government authority; (4) sampling and testing for Legionella and heterotrophic colony count every month; (5) notifying reportable laboratory test results (Legionella count ≥1000 cfu/mL or heterotrophic colony count ≥5,000,000 cfu/mL) to the local government authority; and (6) displaying unique identification numbers on all cooling towers.

— There should be strong penalties for auditors and risk assessors that are found to not provide independent advice. Removal of licence was suggested as an option.

Swimming pools

Stakeholders consulted suggested the following with respect of the requirements for swimming pools in the Regulation.

— Clarifying the scientific basis for the requirement to keep alkalinity of the water between 80 mg/L and 200 mg/L.
— Considering eliminating the requirement to keep alkalinity of the water between 80 mg/L and 200 mg/L.
— Considering reducing the maximum level of cyanuric acid in the water to 25 mg/L.
— Considering including a requirement in the Regulation for people who handle/dose/mix chemicals for pool operation to have minimum qualifications.

Stakeholders in this industry also raised the following issues in relation to the 'Public Swimming Pool and Spa Pool Advisory Document', which is not required to be followed by the Regulation (this document is provided for information and guidance to pool operators and is not called out in the Regulations and a requirement to be met):

— There is a need to clarify the text under Section 5.2.6 to ensure it is clear that a pool can operate continuously for 24 hours as recommended in Section 8.6.
— Section 5.3.1 of this document recommends adding soda ash 'slowly and gradually over an extended period when the pool is closed to the public or through the balance tank', however, stakeholders noted that pool operators using chlorine gas add soda ash through a metering pump as required and cannot do this when the pool is closed to the public.
— Section 6.51 notes that 'Under no circumstances should backwash wastewater be directly discharged to the environment or to the stormwater system. The wastewater is extremely harmful to the environment and promotes weed growth in natural bushland areas.' However, a stakeholder noted that some pool builders are installing cartridge filters in preference to sand filters, which contain the same pollutants as a sand filter, but these filters are cleaned by washing them with a hose and the pollutants are discharged into the stormwater system or the environment. In light of this, the stakeholder argued that cartridge filters are unsuitable for use in a public facility and should not be allowed to be installed.
— There are inconsistencies round the frequency of testing required in the Regulation and recommended in the advisory document.
— There seems to be a level of confusion about whether pools need to comply with the advisory document or whether they are just a guide.

Skin penetration procedures

A council consulted for the RIS made the following comments in relation to the overall regulatory framework for skin penetration procedures:

— Under current Clause 23 (c), skin penetration premises are required to have a hand basin that has a supply of clean, warm, potable water. However, for premises where there are several rooms where skin penetration procedures are being carried out, a hand washing basin should be required for each room. It was noted by the council that, in reality, if a person conducting a procedure has to go into another room with a client to use the basin, they most likely would not wash their hands.

- While there are guidelines and factsheets available from the Ministry about disinfection of surfaces in skin penetration premises, these are not required by the Regulation. It was recommended that these requirements are added to the Regulation.

Disposal of bodies

As noted in Table A.1, several stakeholder groups from the funeral services sector were consulted for this RIS. In addition to their views about the proposed changes in the Regulation, these stakeholders provided the following comments in relation to the disposal of bodies in NSW.

- Stakeholders suggested the following changes to the regulatory framework for the disposal of bodies:
  - Under Clause 50 of the Regulation, a person must not, without the approval of the Secretary, use any premises other than a mortuary for the embalming or other preparation of bodies for burial or cremation or for the placing of bodies in coffins for burial or cremation. Some stakeholders suggested amendments to this area of the Regulation to:
    - Allow for bodies to be coffined at home, as this would save cost to the families of the deceased, and it was argued would not impose any health risks.
    - Allow for bodies to be prepared at home. This was raised in the particular context of people whose religious beliefs require them to wash the body of the deceased at home. While it was noted that health and safety procedures would still need to be followed, it was argued that these could be clarified in the Regulation or through guidelines.
  - Allow cremation in shrouds. It was argued by some stakeholders that any health and identification risks related to this can be minimised through appropriate guidelines/policy directives and/or workplace health and safety regulation and policies.
  - Allow the identification of deceased persons via video link for a cremation certificate to be issued. It was noted that this is already common practice, but that it should be formalised into policy. Allowing this would avoid having to transport bodies to doctors for the purpose of identification, which results in increased costs to the family and delays in the interment. This is particularly important for regional areas where in-person identification may require the body of the deceased to be driven long distances.
  - Allow medical practitioners to email death certificates to funeral directors. It was noted that currently the NSW Coroner, the Ministry and the NSW Registry of Births Deaths and Marriages all accept emails, but some Doctors are reluctant to email a Death Certificate.
  - Set standard maximum fees for:
    - death certificates (anecdotal evidence was provided of private medical practices charging unreasonable fees for providing a death certificate)
    - cremation certificates (in the case the proposed changed to the regulation in this respect are not adopted)
    - medical referees.
  - Increase the length of time that a crematorium is allowed to retain a body before cremation to 72 hours to allow crematoria more flexibility when circumstances do not permit bodies to be cremated within the currently specified period (e.g. during bushfires and floods).
  - Amend the Medical Certificate of Cause of Death (MCCD) to include the following key elements missing from it:
    - time of death
    - how soon after death did the medical practitioner examine the body
    - cremation risk and whether the risk was addressed (when present).
- The following issues relating cremation were raised by stakeholders:

  - It was noted that currently there is no 'simple' mechanism to cremate people who died overseas. The current process requires the NSW Coroner to provide the required documentation for cremation. Stakeholders suggested that the Ministry should consider whether overseas documentation is sufficient without needing NSW coronial certification to simplify the process. It was also suggested that forms for the cremation of bodies be standardised across Australian jurisdictions.
  - The identification requirements for the cremation of organs are unclear and these should be clarified to support operators.
  - Advice is required on whether micra transcatheter pacemakers present a risk to cremation (i.e., whether bodies with these devices can be cremated without risk). It was noted that the identification and removal of these type of devices is challenging and costly.
- Some stakeholders suggested that, to facilitate 'natural burials'[54], the Ministry could:
  - explore how the Regulation can facilitate the use of biodegradable linings or transporting bodies without the need for a coffin
  - review the Regulation in consideration of the negative environmental impacts of embalming and consider how new technologies in above ground burials can facilitate an exemption to the embalming requirements for vault burials in earth.
- Some stakeholders suggested that the Regulation should require that, if a body is infected with a prescribed infectious disease, cemetery/crematoria operators should be notified by funeral directors about the risk of infection. It was noted that this information is not only important for the handling of the body during burial/cremation, but also in the case of grave collapses or exhumations.
- It was noted by some stakeholders that notifications about registered medical practitioners temporarily or permanently prohibited from practicing should be kept up to date. This suggestion was made in relation to health practitioners prohibited from practicing providing documentation related to the disposal of bodies.
- Some stakeholders requested that the Ministry provides clarity about whether moving bodies between crypt spaces is considered an exhumation for the purposed of the Regulation and if so, to consider whether amendments to current exhumation requirements are required to facilitate this operational practice.
- Several stakeholders argued that infection control policies and guidance are lacking, this has been particularly evident through the COVID-19 pandemic. It was also noted that the Guidelines for the Funeral Industry have under review for many years now.
- Some industry stakeholders called for more regulation of funeral activities, particularly licensing of funeral providers, to improve the funeral industry's standards. In this respect it is useful to note that the recently released draft report of the review of competition, costs and pricing in the NSW funeral industry by the Independent Pricing and Regulatory Tribunal (IPART) found that:

> *there is no need for additional regulation or licensing of the funeral industry as an occupation, but compliance with existing regulation must be enforced…*
>
> *The competitive funeral market is already providing high industry standards. Licensing and additional regulation would add to the costs of the industry, impede innovation and not support competition, choice or affordability in the funeral market.*
>
> *IPART 2021, p. 14*

[54] A specific definition of 'natural burial' was not provided, but it was suggested these refer to burials where the interment of a boy is done in a simple, more environmentally sensitive manner (e.g. one where no chemical embalming fluids are used and/or the remains of the deceased are placed in a biodegradable coffin or shroud).

— A stakeholder suggested that the Ministry could consult with the Jewish Board of Deputies with regards to any appropriate regulatory change to accommodate the needs of the Jewish community around timely communication with the Sydney Chevra Kadisha when a Jewish person has died and the hospital cannot contact (or the deceased person does not have) a next of kin, so that the Chevra Kadisha can assist in organising the person's burial within their religion's preferred timeframe (24 hours).

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