

AUSTRALIAN GUIDELINES 22 FOR WATER RECYCLING: MANAGING HEALTH AND ENVIRONMENTAL RISKS (PHASE 2)

AUGMENTATION OF DRINKING WATER SUPPLIES

2008



Natural Resource Management Ministerial Council
Environment Protection and Heritage Council
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Australian Guidelines for Water Recycling

Augmentation of Drinking Water Supplies

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Abbreviations and acronyms

General

ADI	acceptable daily intake
ADWG	<i>Australian Drinking Water Guidelines</i>
AGWR	<i>Australian Guidelines for Water Recycling</i>
AHMC	Australian Health Ministers' Conference
AICS	Australian Inventory of Chemical Substances
ANZECC	Australian and New Zealand Environment and Conservation Council
ARMCANZ	Agricultural and Resource Management Council of Australia and New Zealand (Note: in 2001, the functions of ARMCANZ and ANZECC were taken up by the Environment Protection and Heritage Council and the Natural Resource Management Ministerial Council)
BOD	biochemical oxygen demand
CCP	critical control point
CRCWQT	Co-operative Research Centre for Water Quality and Treatment
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Ct	the product of disinfectant concentration (C, in mg/L) and contact time (t, in minutes), used in disinfection
DALY	disability adjusted life year
DALYd	dose equivalent to 10^{-6} DALY
DCDD	dichlorodibenzo-p-dioxin
DNA	deoxyribonucleic acid
DOC	dissolved organic carbon
EC	European Commission
ECB	European Chemical Bureau
EC JRC	European Commission Joint Research Centre
EDC	endocrine disrupting chemical

EFSA	European Food Safety Authority (formerly the European Commission Scientific Committee on Food, SCF)
EPHC	Environment Protection and Heritage Council
EMA	European Medicines Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
GAC	granular activated carbon
HACCP	hazard analysis and critical control point
ILO	International Labour Organization
ILSI	International Life Sciences Institute
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JMPR	FAO/WHO Joint Meeting on Pesticide Residues
LDTD	lowest daily therapeutic dose
LOEL	lowest observed effect level
MRL	minimal risk level
NDEA	N-nitrosodiethylamine
NDMA	N-nitrosodimethylamine
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemical Notification and Assessment Scheme
NOEL	no observed effect level
NRMMC	Natural Resource Management Ministerial Council
NSAID	nonsteroidal anti-inflammatory
OCDD	octachlorodibenzodioxin
PAC	powdered activated carbon

PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PDTA	propylenedinitrilotetraacetic acid
RfD	reference dose
RO	reverse osmosis
S-ADI	surrogate acceptable daily intake
SAT	soil aquifer treatment
SCF	European Commission Scientific Committee on Food
TDI	tolerable daily intake
TEF	toxicity equivalency factor
TEQ	toxic equivalent
TGA	Therapeutic Goods Administration
TTC	thresholds of toxicological concern
US EPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
WSAA	Water Services Association of Australia

Units

Bq	Becquerel
g	gram
kg	kilogram
L	litre
m	metre
mg	milligram
mm	millimetre
ng	nanogram

pg	picogram
µg	microgram

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Joint Steering Committee

Chair

Mr Chris Bell Mr John Williamson	Environment Protection Authority, Victoria
-------------------------------------	--

Members

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Dr Helen Foard Ms Kerry Olssen Dr Paul Smith	National Water Commission
Dr Helen Cameron	Australian Government Department of Health and Ageing

Working Group

Chair

Dr David Cunliffe	Department of Health, South Australia
-------------------	---------------------------------------

Members

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Mr Peter Donlon	Water Services Association of Australia
Dr Martha Sinclair	Monash University, Victoria
Ms Suzie Sarkis	Department of Human Services, Victoria
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Prof Brian Priestley	Monash University, Victoria
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Dr Simon Toze	Commonwealth Scientific and Industrial Research Organisation (CSIRO), Land and Water
Mr Neil McGuinness	Department of Health, Western Australia
Dr Charles Lewis	Australian Government Department of the Environment, Water, Heritage and the Arts
Dr Robyn Maddalena/Dr Greg Jackson	Department of Health, Queensland
Mr Ian Marshall	Department of Health, Queensland/Golder Associates

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Public comments

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¹ <http://www.ephc.gov.au>

1 Introduction

This publication is one module in the second phase of the *Australian Guidelines for Water Recycling* (see Box 1.1, below). It deals with the use of recycled water to augment drinking water supplies — also referred to as ‘potable reuse’.²

The guidelines as a whole are designed to provide an authoritative reference that can be used to support beneficial and sustainable recycling of waters generated from sewage, grey water and stormwater, which represent an underused resource. The guidelines are intended to be used by anyone involved in the supply, use and regulation of recycled water schemes, including government and local government agencies, regulatory agencies, health and environment agencies, operators of water and wastewater schemes, water suppliers, consultants, industry, private developers, body corporates and property managers. The guidelines describe and support a broad range of recycling options, without advocating particular choices. It is up to communities as a whole to make decisions on uses of recycled water at individual locations. The intent of these guidelines is simply to provide the scientific basis for implementing those decisions in a safe and sustainable manner.

Box 1.1 Australian Guidelines for Water Recycling

National water recycling guidelines are being produced in two phases:

- Phase 1 — *Australian Guidelines for Water Recycling: Managing Health and Environmental Risks* (Natural Resource Ministerial Management Council (NRMMC), Environment Protection and Heritage Council (EPHC), Australian Health Ministers’ Conference (AHMC) 2006). Phase 1 of the guidelines provides a generic ‘framework for management of recycled water quality and use’ that applies to all combinations of recycled water and end uses. It also provides specific guidance on the use of treated sewage and greywater for purposes other than drinking and environmental flows.
- Phase 2 (module 1) — *Australian Guidelines for Water Recycling: Augmentation of Drinking Water Supplies* (NRMMC–EPHC–NHMRC)
This current document, the first module of Phase 2 of the guidelines, extends the guidance given in Phase 1 on the planned use of recycled water (treated sewage and stormwater) to augment drinking water supplies. The document focuses on the source of water, initial treatment processes and blending of recycled water with drinking water sources.
- Phase 2 (modules 2 and 3) — modules 2 and 3 cover use of stormwater for uses other than drinking water augmentation and managed aquifer recharge.

The *Australian Guidelines for Water Recycling* as a whole, including this module, is intended to provide principles and a framework for safe implementation of recycled water schemes. The module is not prescriptive and, within the bounds of ensuring safe drinking water, allows for flexibility in application. Decisions relating to application of the guidelines to specific schemes — including design, management, monitoring and regulation — will be a matter for individual jurisdictions or proponents.

² The term ‘drinking water augmentation’ is used here to refer to the use of recycled water to supplement drinking water supplies.

General principles described in Phase 1 of the *Australian Guidelines for Water Recycling* (NRMMC–EPHC–AHMC 2006) apply to this module. Key aspects are repeated or expanded in this module as appropriate, but further information on aspects such as managing environmental risks can be obtained by referring to the Phase 1 document. Box 1.2, below, shows how the water recycling guidelines, including this module, relate to state and territory guidelines.

Box 1.2 Relationship between the national guidelines and state and territory guidelines

A nationally consistent approach to the management of health and environmental risks from water recycling requires high-level national guidance on risk assessment and management. Such guidance is provided in the *Australian Guidelines for Water Recycling*. This document describes one particular end use, and forms part of the guidelines.

Although the guidelines are not mandatory and have no formal legal status, their adoption provides a shared national objective; at the same time, it allows flexibility of response to different circumstances at regional and local levels. All states and territories are encouraged to adopt the approach described in the guidelines. However, application may vary across jurisdictions, depending on the arrangements for water and wastewater management. This document describes a range of uses without advocating particular choices. Decisions on uses may also vary across jurisdictions.

Water recycling is regulated by states and territories. State or local jurisdictions may use their own legislative and regulatory tools to refine the information given here into their own guidelines. Where there are relevant state and territory regulations, standards or guidelines, these should be consulted to ensure that any local requirements are met. Where state and territory guidelines differ from this document, either those state and territory guidelines should be followed, or the local regulatory agency should be consulted to clarify requirements.

A key feature of drinking water augmentation is that the level of exposure of end users is much higher than for other uses of recycled water. The maximum exposure described in Phase 1 of the water recycling guidelines is less than one litre per person per year, and most of the uses covered by Phase 1 involve far lower exposure than this (NRMMC–EPHC–AHMC 2006). In comparison, guidelines for drinking water quality are based on consumption of two litres per person per day, equating to more than 700 litres per person per year. This high exposure is one of the main drivers for the guidance presented in this publication, and is emphasised throughout the document.

The relatively high exposure requires correspondingly high levels of control, and a commitment to ongoing management and continuous monitoring to ensure safety. As restrictions on end use are not applicable, the measures used to control risk start with reducing hazards in source waters (eg through mechanisms such as trade-waste controls), followed by application of multiple advanced treatment processes. Implementing the use of recycled water to augment drinking water supplies is a difficult, challenging and highly technical task. It requires high levels of skill, and there can be no short cuts. All parts of the guidance provided in this module need to be carefully considered, together with the Phase 1 document (NRMMC–EPHC–AHMC 2006).

1.1 Indirect and direct augmentation

1.1.1 Indirect augmentation

Indirect augmentation includes the discharge of highly treated recycled water into a receiving body such as a river, stream, reservoir or aquifer (through indirect injection or soil aquifer

percolation), before re-treatment and subsequent supply as drinking water. Receiving waters, which are also referred to as environmental buffers, can act as significant control measures. The advantages include:

- *additional time*, ranging from weeks to years
- *additional treatment*, through natural processes
- *dilution*, provided that contaminant levels in the receiving water are lower than those in the recycled water.

Of these advantages, additional time is the most important, and the time span is far longer than most treatment processes, which are usually completed within minutes to hours. Indirect augmentation schemes should be designed so that the time in receiving waters is sufficient to enable operators and regulators to assess recycled water treatment and recycled water quality and, where necessary, to intervene before water is supplied to consumers.

One important note of caution for indirect augmentation is that theoretical detention times and dilution can be greatly reduced by short-circuiting (ie using preferential flows in storages to reduce the transport time between inlets and outlets), particularly of surface reservoirs and lakes. It is therefore essential to determine the hydrological characteristics of the receiving water body used for each augmentation scheme.

It is difficult to prescribe a minimum dilution rate or detention time, because system-specific factors can have a significant influence. For example, where the receiving water is an aquifer, detention times are often couched in terms of many months or years, but dilution rates are less precise. In surface waters, dilution rates and detention times are influenced by factors such as the amount of natural inflow and reservoir levels. Both of these can be influenced by climate — including temperature, annual and seasonal rainfall — and by water demand. All of these factors need to be considered on a case-by-case basis.

There are no established standards for indirect augmentation, and detention times and dilution rates in existing schemes vary, for example:

- the Singapore NEWater Scheme³ currently contributes about 1% of reservoir supply, and there are plans to increase this to about 2.5% by 2011
- in the United Kingdom, the Langford Recycled Water Treatment Plant contributes about 10% of drinking water supplied through the Hanningfield Reservoir in Essex⁴
- in the United States:
 - discharges of recycled water from the Upper Occoquan Sewage Authority represent 7% of the average annual inflow into the water-supply reservoir, but this can increase to 80–90% in a drought year (US EPA 2004)
 - the San Diego Water Reuse Study⁵ indicates that recycled water should be detained for at least 12 months in receiving reservoirs
 - the draft *Californian Regulations for Groundwater Recharge* specify minimum detention times of 6 months for recycled water transported to aquifers by surface spreading and 12 months for subsurface injection (CDPH 2007); recycled water contributions can start at 20% and increase depending on results.

³ http://www.pub.gov.sg/NEWater_files/index.html

⁴ <http://www.eswater.co.uk/>

⁵ <http://www.sandiego.gov/water/waterreusestudy/involvement/fd2006.shtml>

The essential requirement is that the minimum detention times in receiving waters, taking account of worst-case circumstances, must always exceed the time required to:

- *detect faults* through operational monitoring of control measures and testing of treated recycled waters
- *complete corrective actions* (where required) before addition to drinking water supplies and subsequent supply to consumers.

The minimum detention times should include substantial safety margins, to take into account any and all possible delays in completing monitoring, communicating results and responding to results, where necessary.

Minimum dilution rates can include two components — public acceptability and hazard reduction. Public acceptability will need to be assessed on a case-by-case basis, with final decisions resting with local jurisdictions, in consultation with their communities.

Internationally, indirect use of recycled water to augment drinking water supplies is the favoured approach, far outweighing the direct use of recycled water. The importance of intervention time in assuring safety cannot be overstated.

1.1.2 Direct augmentation

Direct augmentation using recycled water derived from highly treated sewage or stormwater means that recycled water enters the recycling system without going through an intermediary receiving body of water. Unless large treated-water storages are included in systems, the time between the recycled water starting treatment and being distributed through drinking water systems could be hours. Thus, the scope for assessing water quality and intervening before substandard water is supplied to consumers is limited. Direct augmentation should not proceed unless sufficient mechanisms are established to prevent substandard water from being supplied. Implementation of direct augmentation presents substantial technical and management challenges. The need for reliability of processes, vigilance of monitoring and highly skilled operators — already high for indirect use — is magnified for direct augmentation. Knowledge and understanding of system reliability and control of variability is essential before direct augmentation can proceed. Further research is required in this area.

Replacing the benefits of receiving waters with additional engineered treatment barriers or large treated-water storages comes at a high cost. In addition, community acceptance of direct augmentation, particularly with treated sewage, will be difficult to achieve. Only one direct use scheme is currently in operation. That scheme was introduced at Windhoek, Namibia in the 1960s, and no others have been introduced since that time.

1.2 Australian Drinking Water Guidelines

The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) is Australia’s authoritative document on drinking water quality. Principles, systems and guideline values described in the *Australian Drinking Water Guidelines* have been adopted as the basis for this module, which is intended to complement the drinking water guidelines and not to supersede that document. At the core of the drinking water guidelines, and of both Phase 1 and Phase 2 of the water recycling guidelines, is the application of a preventive risk management approach. The framework for management of recycled water quality and use given in this publication is based on the framework used in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004).

Risk management systems are the most effective way to assure the appropriate quality of drinking water or recycled water. The framework incorporates hazard analysis and critical control point (HACCP) principles, and is consistent with other established systems such as ISO 9001 (Standards Australia/Standards New Zealand 2000) and AS/NZS 4360 (Standards Australia/Standards New Zealand 2004a). However, the framework applies these systems in a drinking and recycled water context, to support implementation of the guidelines by water utilities and suppliers.

1.2.1 Guideline values

The risk management approach described in both the drinking water and water recycling guidelines is designed to assure water quality at point of use by consumers. Guideline values for individual parameters and the principles for calculating guideline values from health and toxicological information described in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) are applied in this module.

As described in the drinking water guidelines, the guideline values represent minimum requirements and boundaries for defining safety. Water suppliers should always strive to maintain the highest practicable quality from treatment facilities that are fit for purpose, well designed and optimally maintained. Guideline values should never be seen or used as a licence to degrade water quality, to achieve marginal compliance.

1.2.2 Definition of drinking water

The definition of drinking water described in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) is applied in this publication. Drinking water is water intended primarily for human consumption, either directly, as supplied from the tap, or indirectly, in beverages, ice or foods prepared with water. Drinking water is also used for other domestic purposes such as bathing and showering. Drinking water quality may not be sufficient for particular purposes such as renal dialysis and other medical applications, and cleaning of contact lenses; water-quality requirements for such purposes are outside the scope of these guidelines.

Drinking water should be safe for consumption through a normal lifetime, taking into account all life stages, from infancy to older age. However, particularly sensitive subpopulations, including those who are severely immunocompromised, may need to take additional steps because of their greatly increased susceptibility to infection. This should be done under guidance from their medical practitioner.

1.2.3 Point of application

The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) defines how to provide water that is safe at the point of use (eg kitchen or bathroom tap). The same point of application applies in this module. In many cases, proponents will elect to produce recycled water that is safe to drink before being added to receiving waters and drinking water supplies (ie after recycled water treatment). The decision to produce water of this quality is one for individual proponents, jurisdictions and communities to make. In this case, verification of recycled water quality will be applied at point of entry into the receiving water. Potential impacts on receiving waters will need to be considered; for example, nutrients in the recycled water may promote the growth of cyanobacteria. The effectiveness of an overall risk management approach that incorporates

recycled water production, receiving water management, drinking water treatment and delivery to consumers will also need to be verified at point of use.

1.2.4 Points of difference between the *Australian Guidelines for Water Recycling* and the *Australian Drinking Water Guidelines*

There are some differences between the drinking water and water recycling guidelines. This is to be expected, given that the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) was issued as a draft in 2002 before being endorsed in 2004, whereas Phase 1 of the *Australian Guidelines for Water Recycling* (NRMMC–EPHC–AHMC 2006) was issued as a draft and endorsed in 2006. Aspects included in the water recycling guidelines but not in the drinking water guidelines are:

- a specific definition of safety, particularly for microbiological quality, based on the use of disability adjusted life years (DALYs)
- health-based performance targets, including required reductions of microbial and chemical hazards
- use of reference pathogens.

The use of DALYs, performance targets and reference pathogens is based on the approach described in the World Health Organization (WHO) *Guidelines for Drinking-Water Quality* (WHO 2006a).

This publication includes discussion of pharmaceuticals, personal-care products and compounds with potential endocrine disrupting activity to a greater extent than in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) or Phase 1 of the water recycling guidelines. The increased discussion of these potential contaminants reflects a heightened concern when recycled water is used to augment drinking water supplies.

1.3 Structure of the document

This document contains information on:

- the principles underlying safe and sustainable augmentation (Chapter 2)
- health-based targets (Chapter 3)
- the management of drinking water augmentation with recycled water (Chapter 4)
- monitoring (Chapter 5)
- the setting of guidelines for chemicals in drinking water augmented with recycled water (Appendix A).

The document also contains a glossary.

2 Principles

Augmenting drinking water supplies with recycled water is a complex task; therefore, this publication contains detailed advice on a range of scientific and technical issues. However, a number of key principles are fundamental to safe augmentation of drinking water supplies. It is important to keep these principles in mind and not lose them in the ‘forest’ of detail.

The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) also identified the importance of maintaining a focus on key principles. Given that the end product in a scheme involving augmentation is drinking water, the principles included in the drinking water guidelines remain important and have been included here.

2.1 Protection of public health

Protection of public health is of paramount importance and should never be compromised

Recycled water is a valuable resource. However, in using recycled water, protection of public health should never be compromised. Separation of humans and drinking water supplies from sewage is the measure that has had the greatest impact on improving public health through reducing infectious disease and extending life. Recycling water closes that physical gap; thus, the potential risks are higher than with other sources of drinking water. Using recycled water for augmentation of drinking water can and must be carried out with safety as the foremost requirement.

Ensuring recycled water safety and quality requires application of a considered risk management plan. A preventive risk management approach that covers all steps from collection of raw water sources to supply of water to consumers is the most effective way to assure drinking water quality (NHMRC–NRMMC 2004). Risk management involves taking a carefully considered and documented course of action. It is not about applying unnecessarily extreme measures; however, because protection of public health is paramount, the balance needs to be tipped in favour of being precautionary.

The system used to manage water quality should also ensure that all other beneficial values (either intended or inadvertent) are protected. Such values include those associated with recreational uses, agriculture and irrigation, aquaculture, fisheries and aquatic ecosystems. Phase 1 of these guidelines (NRMMC–EPHC–AHMC 2006) and the *Australian and New Zealand Guidelines for Fresh and Marine Water Quality* (ANZECC–ARMCANZ 2000a) provide information on protection of these values.

2.2 Community acceptance and support

Drinking water augmentation requires community acceptance and support

Community acceptance and support is vital for successful introduction of drinking water augmentation schemes, and effective community engagement is the best way to ensure such support. The community has to be a partner in the development of augmentation schemes. Provision and transfer of information must be transparent, and trust must be established and maintained. Presenting all options for provision of drinking water, including independently verified cost–benefit analyses, is an important part of consultation.

In gaining support for an augmentation scheme, all sectors of the community and stakeholders need to be considered, including industry, commercial interests, landowners and developers, special interest groups, existing users of the recycled water and users of waters downstream of existing discharges. For each scheme, there will be supporters, opponents and undecided individuals. Each of these groups needs to be considered and addressed. Uncertainty or lack of community support will generally represent an insurmountable barrier. Therefore, community consultation and communication needs to be maintained throughout the life of a recycling scheme.

2.3 Institutional capability

Institutional capacity is required

Providing safe drinking water using recycled water is a challenging task that involves complex technologies and exacting management requirements. Utilities and agencies that undertake the task need to have:

- sufficient resources
- appropriate levels of expertise and personnel
- a commitment to high levels of management and monitoring throughout the life of the scheme.

Designers and operators of schemes need to have high-level engineering skills, supported by scientific, public health and environmental expertise. Externally audited water quality management systems can help utilities and agencies to maintain and demonstrate such capacity.

Regulatory agencies must have the expertise to understand the complexities and challenges of managing and monitoring recycling schemes, and the ability to either audit schemes themselves or critically assess audits undertaken by third parties.

2.4 Multiple barriers

Recycled water systems need to include and continuously maintain robust and reliable multiple barriers

The multiple barrier approach is the foundation for ensuring safe drinking water. The approach applies no matter what the initial source of water. However, sewage may contain contaminants such as microbial pathogens and chemicals at levels greater than those commonly found in rivers or reservoirs, meaning that higher levels of treatment will be needed. The need for highly reliable barriers is essential for both microbial and chemical hazards. No single barrier is effective against all conceivable hazards or is completely effective all of the time. Multiple barriers protect against variations in performance of individual barriers. Variations in different barriers are unlikely to align to the extent that all perform poorly at the same time; nevertheless, every effort should be taken to ensure that barriers operate within acceptable ranges.

Processes, technologies and other preventive measures selected need to be robust, with reliable engineering techniques incorporated into design and operation. Preventive measures need to be maintained and monitored to minimise variability in performance and the potential for failure. Environmental buffers increase overall reliability by providing an independent barrier, including detention times that enable corrective action to be taken before recycled water is supplied to consumers. However, it is unrealistic to expect that failure will never occur. Where a system fails, corrective action must be taken immediately.

2.5 Skills and training

Designers, operators and managers of schemes must have appropriate skills and training

Everyone involved in the design, management, operation and audit of recycled water systems needs to have sufficient and appropriate knowledge and skills for their role. They also need to be aware of the consequences of failure or poor performance. Responsibilities and accountabilities need to be identified, communicated, understood and supervised.

Lack of knowledge is a significant cause of waterborne disease outbreaks involving serious illness and death. Organisations and contractors responsible for drinking water augmentation schemes must ensure that operators have sufficient and appropriate training and qualifications to undertake their tasks. Where available, accredited training and certification programs need to be used.

Overall operation of the treatment process needs to be supervised by managers with appropriate expertise in engineering and quality assurance.

System operators must be able to respond quickly and effectively to adverse monitoring signals

Sudden changes in process performance, even if seemingly minor, can signal problems in performance and water quality. No change should be overlooked. Small, short-term changes can lead to outbreaks of illness. Operators and managers must have the knowledge and appropriate responsibility to respond as necessary. Changes and responses need to be reported and documented.

System operators must maintain a personal sense of responsibility and be dedicated to providing consumers with safe water

Consumer service and safety has to be uppermost in the mind of operators. Consumers are the ultimate assessors of water quality, and their ability to recognise change should not be underestimated. Customer complaints need to be investigated to ensure that no problems that may compromise water quality have occurred. Addressing reasonable inquiries and questions, and maintaining public confidence is vital.

2.6 Management of industrial waste

Industrial waste management programs need to be established and maintained

Risk management plans are predicated on prevention and on dealing with contamination as close to the source as possible. Sewage will always contain pathogenic microorganisms. However, chemical quality depends on inputs and can therefore be influenced by trade-waste control programs. Questions about chemical quality have led to a great deal of public uncertainty in relation to drinking water augmentation. Trade-waste programs are essential for preventing or minimising contamination of source waters before treatment. This will have resource implications; hence, sufficient funding needs to be provided. Guidance on trade waste control should be considered (ANZECC–ARMCANZ 1994, WSA 2007).

Industrial waste discharges to sewers pose a particular risk to the integrity of the recycled water system. Agencies managing sewage systems need to characterise industries and chemical use within sewerage system catchments, and ensure that waste management systems are fully effective. The focus should be on prevention through on-site controls and pretreatment. Water utilities need to be able to deny acceptance of trade waste, impose restrictions and enforce

requirements on waste generators to install pretreatment facilities and technologies (ANZECC–ARMCANZ 1994). Trade-waste acceptance criteria need to be established and enforced; these criteria should be based on the national acceptance criteria (ANZECC–ARMCANZ 1994). Some contaminants should be precluded from discharge (eg contrast media; radionuclides; and medical, veterinary and laboratory wastes). Trade-waste programs need to include site monitoring and audit inspections of significant industrial dischargers.

All industrial and commercial dischargers need to be licensed, and proactive monitoring of sewer systems is required to detect spills or unusual changes to wastewater quality. Agencies also need to have an understanding of contaminants stored on sites and risks of accidental discharge to the sewer. Incident-reporting systems for industry need to be established and rigorously enforced.

Similar levels of protection from industrial discharges need to be applied to stormwater systems.

Households can also store (and potentially discharge) considerable quantities of toxic chemicals. Effective systems to collect household chemicals need to be in place to minimise risks of improper disposal to sewer systems. Education programs need to be implemented to reduce the risks from these discharges.

2.7 Regulatory surveillance

All schemes must be subject to regulatory surveillance

Lack of regulatory oversight has contributed to outbreaks of waterborne illness from drinking water supplies. A lack of oversight was identified as an important factor in the Walkerton outbreak in Canada, where seven people died from drinking contaminated water (Hrudey and Hrudey 2005).

Independent regulatory surveillance and auditing needs to be applied to drinking water augmentation, and needs to include involvement of public health agencies. The public has a reasonable expectation that such schemes will be subject to rigorous regulatory oversight. Surveillance and auditing verify that recycled water systems are being managed and operated correctly and at a high standard, and that public health is being protected. Outcomes should be published in publicly available reports.

2.8 Additional principles

Additional principles identified in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) are given below because they apply equally to augmentation of drinking water supplies.

The greatest risks to consumers of drinking water are pathogenic microorganisms; protection of water sources and treatment are of paramount importance and must never be compromised

Although a great deal of attention has been paid to chemical quality of recycled water used to augment drinking water supplies, the risks posed by pathogens remain significant. Impacts can be acute, severe and widespread.

Stormwater and receiving waters used in indirect augmentation should be protected from livestock and human waste. Although the levels of treatment used in drinking water augmentation schemes should reduce pathogenic microorganisms to safe levels, effective operation of these processes must be maintained and monitored.

Any sudden or extreme change in water quality, flow or environmental conditions (eg extreme rainfall or flooding) needs to arouse suspicion that drinking water might become contaminated

Water treatment processes generally function best under steady-state conditions, and performance can seriously deteriorate when there are major fluctuations in quality and flow. For drinking water augmentation schemes, fluctuations can be caused by events such as:

- influx of stormwater into sewerage systems following heavy rain or floods
- influx of sewage into stormwater systems
- influx of trade waste into sewerage systems or stormwater catchments
- influence of heavy rain, flooding or external contamination on receiving waters
- large variations in population densities in holiday destinations.

Processes need to be appropriately designed, with potential flow changes taken into consideration.

3 Health-based targets

Sewage and stormwater used as sources for the production of high-quality recycled water for drinking water augmentation can contain a wide range of agents that pose potential risks to human health, including chemicals and pathogenic (disease-causing) microorganisms.

Safe drinking water augmentation requires potential health risks to be reduced to acceptable levels. Hence, the first step is to define acceptable or tolerable risk and then to use this to set health-based targets for individual hazards. Health-based targets set the benchmarks for establishing the safety of water at point of use. Typically, they take the form of performance targets for microorganisms and guideline values for chemicals.

3.1 Tolerable risk

This document does not include a detailed discussion of health-based targets because these are covered in Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

3.1.1 Microbial risk

Disability adjusted life years (DALYs)

DALYs are the metric used in these guidelines to define tolerable microbial risk (Box 3.1). The advantage of DALYs is that they include a measurement of the severity of impacts on human health arising out of infection and illness. They differentiate between relatively mild impacts, such as diarrhoea, and severe impacts, such as haemolytic uremic syndrome and even death. In terms of waterborne disease, the most commonly recognised illness is gastroenteritis (involving symptoms such as diarrhoea and vomiting) caused by ingestion of enteric pathogens. However, a number of waterborne pathogens can cause more severe and long-lasting symptoms in a small percentage of infected people; possible effects include:

- diabetes, associated with Coxsackie B4 virus (Mena et al 2003)
- myocarditis, associated with echovirus and Coxsackievirus (Mena et al 2003)
- reactive arthritis and Guillain–Barré syndrome, associated with *Campylobacter jejuni* (Havelaar et al 2000, Nachamkin et al 2001)
- haemolytic uremic syndrome, associated with haemorrhagic *Escherichia coli* (Teunis et al 2004)
- reactive arthritis, associated with *Salmonella* (Rudwaleit et al 2001).

Determining DALYs for individual hazards includes considering acute impacts (eg diarrhoeal disease or even death) and chronic impacts (eg reactive arthritis and haemolytic syndrome). Calculation of DALYs includes consideration of each of the symptoms caused by a particular pathogen and the relative frequency of occurrence. Examples are provided in Box 3.1.

Box 3.1 Disability adjusted life years (DALYs)

The basic principle of the DALY is to weight each health impact in terms of severity within the range of 0 (for good health) to 1 (for death). Severities for outcomes of microbial infection include:

- 0.02–0.12 for mild diarrhoea
- 0.21 for reactive arthritis
- 0.23 for severe diarrhoea
- 1 for death

The severity is then multiplied by duration of the effect and the relative frequency of occurrence in those who become ill. In the case of death, duration is regarded as the years lost in relation to normal life expectancy. Hence DALYs can be calculated using the following equation:

$$\text{DALYs} = \text{YLL (years of life lost)} + \text{YLD (years lived with a disability or illness)}$$

In this context *disability* refers to conditions that detract from good health. In these guidelines, it generally relates to illness; however, in other areas it can also relate to physical or mental impairment.

Using an Australian example, infection with rotavirus causes:

- mild diarrhoea (severity rating of 0.1) lasting 3 days in 97.5% of cases
- severe diarrhoea (severity rating of 0.23) lasting 7 days in 2.5% of cases
- rare deaths of very young children in 0.015% of cases (a death at <1 years of age means a loss of up to 80 years of life)

Using the above equation, the DALY per case can be calculated as follows:

$$\begin{aligned} \text{DALY per case} &= (0.1 \times 3/365 \times 0.975) + (0.23 \times 7/365 \times 0.025) + (1 \times 80 \times 0.00015) \\ &= 0.0008 + 0.0001 + 0.012 \\ &= 0.013 \end{aligned}$$

Infection with *Cryptosporidium* can cause watery diarrhoea (severity weighting of 0.067) lasting for 7 days, with deaths in 0.0001 % of cases (ie extremely rare). This equates to a DALY per case of 0.0015.

Campylobacter can cause diarrhoea of varying severity, Guillain-Barré syndrome of varying severity, reactive arthritis and occasional deaths. This equates to a DALY per case of 0.046.

Based on DALYs per case, the impacts of the three pathogens is *Campylobacter* > rotavirus > *Cryptosporidium*.

DALYs per case is based on Havelaar and Melse (2003), with a modification using Australian data for rotavirus as described in WSAA (2004).

Tolerable risk

The tolerable risk adopted in these guidelines is 10^{-6} DALYs per person per year, which is consistent with the WHO *Guidelines for Drinking-Water Quality* (WHO 2006a). This is approximately equivalent to an annual diarrhoeal risk of illness of 10^{-3} (ie 1 illness per 1000 people). In comparison, the reported rate of diarrhoeal illness in Australia is 0.8–0.92 cases per person per year (Hellard et al 2001, OzFoodNet Working Group 2003).

Performance targets

Safety is defined as ‘ensuring that microbial health risk complies with the definition of tolerable risk’. This is achieved by meeting performance targets whereby concentrations of pathogens in sewage or stormwater are reduced to concentrations below those that would produce 10^{-6} DALYs per person per year.

3.1.2 Chemical risk

Ideally, DALYs would also be applied as a common metric to chemical parameters, but there is insufficient data to support such an approach at this stage. The approach adopted in these guidelines is based on that applied in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004). In the drinking water guidelines, tolerable risk is defined in terms of guideline values. For chemicals with threshold effects, guideline values are typically based on the highest dose that causes no adverse effects (no observed effect level, NOEL) multiplied by safety factors. For chemicals with no demonstrated threshold, such as carcinogens, the guideline values are based on concentrations that would give rise to one additional cancer per one million people following lifetime consumption. WHO bases its guideline values on concentrations giving rise to one additional cancer per 100 000 people following lifetime consumption. The WHO approach aligns more closely with the 10^{-6} DALYs per person per year used in these guidelines.

In these guidelines, the more conservative approach applied in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) has been adopted where applicable. Where chemicals are listed in the drinking water guidelines, it is appropriate to apply the same values to drinking water augmentation schemes. However, where chemicals are not dealt with in the drinking water guidelines, this publication provides an approach for determining guideline values (Appendix A).

Preventive measures, including trade waste controls and treatment processes, are applied to ensure compliance with guideline values and hence with tolerable risk.

4 Management of drinking water augmentation

This chapter describes how the generic ‘framework for management of recycled water quality and use’ described in Phase 1 of the water recycling guidelines can be applied to drinking water augmentation. Each of the 12 elements of the framework is described, including the components that make up the element and a summary of the actions to be taken under each component.

4.1 Commitment to responsible use and management of recycled water quality (Element 1)

Components:	Responsible use of recycled water (Section 4.1.1)
	Regulatory and formal requirements (Section 4.1.2)
	Partnerships and engagement of stakeholders (including the public) (Section 4.1.3)
	Recycled water quality policy (Section 4.1.4)

In developing schemes for drinking water augmentation, all relevant agencies and stakeholders must be identified and involved in the development process.

In most cases, responsibility for developing schemes should be coordinated and led by a single agency or entity. This approach will help to avoid duplication and working at cross purposes, both of which are counterproductive and tend to undermine confidence within the development team and, ultimately, among stakeholders.

4.1.1 Responsible use of recycled water

Summary of actions

- Involve agencies (ie stakeholders) with responsibilities and expertise in protection of public and environmental health.
- Ensure that design, management and regulation of recycled water schemes is undertaken by agencies and operators with sufficient expertise.
- Consider establishment of an independent advisory panel.

Involve relevant agencies

Drinking water augmentation requires involvement of agencies with expertise in water resources, water supply, public health and environmental protection. The agencies involved will need to address questions relating to:

- the need for augmentation schemes
- the possibility and viability of alternative solutions
- practical issues concerning recycled water and drinking water treatment
- protection of public and environmental health.

Ensure that agencies have sufficient expertise

Drinking water augmentation involves by far the highest potential exposure of consumers to recycled water. Such schemes will necessarily include multiple treatment barriers incorporating advanced processes. Ensuring safety requires that treatment processes are designed, managed, operated and maintained in a manner that continuously provides a high level of performance. Deviations in performance need to be detected rapidly and corrected immediately. Only agencies, utilities, contractors and personnel with sufficient qualifications, expertise, experience and resources should design, operate and monitor the treatment processes.

All aspects — from design through commissioning to operation — will need to be documented in a recycled water quality management plan. Also, they will need to be subject to external oversight and auditing by a regulatory agency. These processes require appropriate expertise and, in some cases, regulatory agencies may need to engage independent experts (Section 4.12). Governments have a responsibility to ensure that these requirements are in place before drinking water augmentation is undertaken.

Consider establishing an independent advisory panel

An independent advisory panel to provide oversight of individual drinking water augmentation schemes can be useful. Independent panels that include experts in the various facets of drinking water augmentation can provide assurance to proponents, regulators, government and communities that the design, implementation and ongoing management of a scheme is appropriate, responsible and protective of public and environmental health.

Independent panels can oversee the development and design of schemes, and to review performance for a period of time after schemes have been commissioned.

Existing projects — such as the Orange County Groundwater Replenishment Scheme⁶ and the Singapore NEWater Scheme⁷ — have used independent panels.

Any findings and reports prepared by independent panels need to be published.

4.1.2 Regulatory and formal requirements

Summary of actions

- Identify and document all relevant regulatory and formal requirements.
- Identify governance requirements.
- Ensure responsibilities are understood and communicated to all stakeholders.
- Review requirements periodically to reflect any change.

⁶ <http://www.gwrssystem.com>

⁷ http://www.pub.gov.sg/NEWater_files/index.html

The four actions described in this component are general requirements that apply to all recycled water systems. Further information is provided in Phase 1 of the water recycling guidelines. A clear and shared understanding of regulatory and governance requirements, and of responsibilities relating to operation, management and surveillance, are vital. These requirements and responsibilities need to be transparent and documented.

4.1.3 Partnerships and engagement of stakeholders (including the public)

Summary of actions

- Identify all agencies with responsibilities for water resources and use of recycled water; regularly update the list of relevant agencies.
- Establish partnerships with agencies or organisations as necessary or where this will support the effective management of recycled water schemes.
- Identify all stakeholders (including the public) affecting, or affected by, decisions or activities related to the use of recycled water.
- Develop appropriate mechanisms and documentation for stakeholder commitment and involvement.

Successful implementation of drinking water augmentation requires engagement and acceptance by stakeholders. The stakeholders for an augmentation scheme include:

- the general community (as consumers of the final product)
- industry
- commercial interests
- landowners and developers
- special interest groups
- existing users of the recycled water.

Consultation and communication needs to start as early as possible, and continue during planning, implementation and operation.

Engagement with communities requires effective partnerships to be established with all agencies responsible for water resources and use of recycled water. To achieve community engagement, agencies and utilities need to establish and demonstrate unity and certainty.

4.1.4 Recycled water quality policy

Summary of actions

- Develop a recycled water policy, endorsed by senior managers and implemented by an organisation or by participating agencies.
- Ensure that the policy is visible and is communicated, understood and implemented by employees and contractors.

A succinct, strong and transparent commitment by proponents to maintaining safety of drinking water augmentation schemes is required to underpin trust and confidence of stakeholders. It needs to be clear that the policy will translate to actions, and that these actions will be able to be measured by performance indicators. Actions should include auditing implementation of a recycled water quality management system.

4.2 Assessment of the recycled water system (Element 2)

Components:	Sources of recycled water and routes of exposure (Section 4.2.1)
	Recycled water system analysis (Section 4.2.2)
	Assessment of water-quality data (Section 4.2.3)
	Hazard identification and risk assessment (Section 4.2.4)

4.2.1 Sources of recycled water and routes of exposure

Summary of actions

- Identify source of water.
- Identify routes of exposure, receiving environments, end points and effects.

Sources of water

Highly treated sewage and stormwater can be used as sources for drinking water augmentation.

Sewage

Untreated sewage can sometimes contain industrial wastes, but will always contain:

- pathogenic bacteria, viruses, protozoa and helminths
- domestic chemicals, including household and garden chemicals, personal-care products, hormones and pharmaceuticals
- nutrients and salts.

In line with a preventive risk management approach, trade-waste programs need to be applied to control industrial discharges. The focus should be on diverting or preventing discharge of hazardous chemicals or on applying pre-treatment control. Water utilities need to work closely with all industries discharging to sewer, to ensure that pollution source control is effective. Programs, which will generally include licencing systems, need to incorporate monitoring and audit systems that can detect and minimise illegal discharges (see Section 4.4).

An effective education program needs to be directed toward reducing discharge of hazardous chemicals from households. Such a program needs to be supported by a household chemical collection system, to provide an easily accessible alternative to inappropriate disposal. Considerable quantities of toxic chemicals are stored by urban householders. Collection programs can identify the types of risks to the system, based on the chemicals received.

Stormwater

Stormwater can also contain a wide variety of biological and chemical contaminants. Although concentrations for most contaminants will generally be lower than those found in sewage, there can be exceptions; for example, hydrocarbons from road networks and pesticides. Industrial discharges need to be managed to minimise impacts, and stormwater should be protected from human and livestock waste.

Routes of exposure

The routes of exposure associated with drinking water augmentation are ingestion or drinking, inhalation and contact with skin. Drinking generally represents the greatest risk. The following assumptions and approach described in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) apply equally to schemes incorporating recycled water:

- average drinking water consumption is assumed to be 2 L per day for adults and 1 L per day for children
- drinking water needs to be safe for use by the general population through all stages of life, including childhood and older age; life is assumed to last for an average of 70 years
- average adult weight is assumed to be 70 kg
- drinking water quality may not be sufficient for particular purposes such as renal dialysis and other medical applications, and cleaning of contact lenses; water-quality requirements for such purposes are outside the scope of these guidelines
- those who are severely immunocompromised may also need to take additional steps due to greatly increased susceptibility to infection, but should do so under guidance from their medical practitioner.

4.2.2 Recycled water system analysis

Summary of actions

- Assemble pertinent information and document key characteristics of the recycled water system to be considered.
- Assemble a team with appropriate knowledge and expertise.
- Construct a flow diagram of the recycled water system from the source to the application or receiving environments.
- Periodically review the recycled water system analysis.

Assemble pertinent information and document key characteristics of the recycled water system

Effective management requires an understanding of the recycled water system from the source to the end user. This means that information needs to be gathered on aspects such as:

- high-risk chemicals stored on industrial and other sites, which may gain access to sewerage systems or stormwater catchments
- the recycled water source and potential influences on water quality (including impacts of industrial wastes)
- volumes of domestic and industrial waste and discharge patterns into sewers (diurnal, seasonal, etc)

- existing and proposed treatment processes
- use of storages and receiving waters between recycled water treatment and abstraction for drinking water
- drinking water treatment processes
- distribution systems, numbers of consumers and volumes of use.

Assemble a team with appropriate knowledge and expertise

The analysis requires a team with appropriate knowledge and expertise. The team could include:

- water resource and environment agencies (eg for stormwater systems and receiving waters)
- management and operations staff from the suppliers of recycled water and drinking water
- health agencies
- microbiologists, chemists, toxicologists, industrial trade waste managers and treatment specialists
- local government and primary industry agencies (depending on the nature of the scheme)
- communications and public relations consultants
- representatives of stakeholders (including industry) and the general community.

Construct a flow diagram of the recycled water system

The next step is to construct a generalised flow diagram that describes the recycled water system from source to consumers. In most cases, systems will be developed and adapted from existing infrastructure including, for example, basic sewage treatment plants (eg those with only secondary treatment and disinfection), water supply reservoirs and storages, drinking water treatment plants and distribution networks.

The diagram needs to include existing and proposed components. Specifically, it needs to:

- outline all steps and processes
- summarise the basic characteristics of each component and level of variability
- make explicit any characteristics that are unique to the system
- identify physical, chemical and hydrological characteristics of receiving waters (ie waters that could receive discharges of recycled water in scheme involving indirect augmentation of drinking water).

Table 4.1 summarises the type of information that should be assembled. Much of the necessary information may be available in documentation held by the operators of the existing sewage and drinking water systems.

The flow diagram needs to be verified by field audits, and checked by those with specific knowledge of the system.

Table 4.1 Characteristics of recycled water systems

Recycled water sources (catchment and collection systems)	
<i>Sewage</i>	<i>Stormwater</i>
<ul style="list-style-type: none"> • Nature of inputs (types and range of industry, pharmaceutical and agricultural chemical manufacturers, paint manufacturers, hospitals and veterinary clinics, abattoirs, domestic wastes, etc) • Trade-waste programs and controls (including assessment of risks of accidental or illegal discharges) • Household chemical collection programs • Volumes of domestic and industrial waste and discharge patterns (eg contaminant loads, diurnal and seasonal variations) • Future developments • Stormwater discharges 	<ul style="list-style-type: none"> • Agricultural and mining activities • Residential and industrial developments • Septic waste or sewerage inputs • Input controls (on industrial and agricultural discharge and use) • Future planning activities • Weather patterns (climatic and seasonal variations)
Source water characteristics	
<ul style="list-style-type: none"> • Flow and reliability of source water (particularly for stormwater) • Physical characteristics • Bacteria, viruses, protozoa and helminths • Industrial chemicals 	<ul style="list-style-type: none"> • Metals and radionuclides • Organic chemicals • Biologically active compounds including endocrine disruptors, pharmaceuticals • Nutrients (nitrogen and phosphorus) • Salts
Storage lagoons and wetlands	
<ul style="list-style-type: none"> • Algae, macrophytes and zooplankton–plant dynamics • Storage design (construction type, depth, capacity, dimensions, intake location and operation) • Detention times and possibility of short circuiting • Protection (eg covers, enclosures, access controls, riparian zones) 	<ul style="list-style-type: none"> • Recreational use • Seasonal variations • Use of the site by birds, native and feral animals • Access and input from livestock
Recycled and drinking water treatment systems	
<ul style="list-style-type: none"> • Nature of existing and planned treatment processes • Equipment design (capacities, peak flow rates, process change control, backup systems, bypass provisions) • Treatment configuration and efficiencies 	<ul style="list-style-type: none"> • Stability and reliability of processes • Monitoring equipment and automation • Water treatment chemicals (coagulants, filtration aids, disinfectants, membrane de-scalants, etc) • Existing monitoring programs
Aquifer storage^a	
<ul style="list-style-type: none"> • Groundwater characteristics (nature of existing aquifers, current uses, depth and quality, etc) 	
Receiving waters (reservoirs, rivers and streams)	
<ul style="list-style-type: none"> • Reservoir design (construction type, depth, capacity, dimensions, intake location and operation) • Stream flows or volumes • Detention times and possibility of short circuiting • Dilution of recycled water (minimum and maximum, seasonal variation) 	<ul style="list-style-type: none"> • Access controls (eg fencing) • Recreational activity • Other inputs (eg agriculture, mining, industrial, residential, contaminated sites, etc) • Physical, chemical and microbial characteristics
Users of drinking water	
<ul style="list-style-type: none"> • Community (local and visitors) • Industry 	<ul style="list-style-type: none"> • Commerce • Special purpose users

Adapted from NRMCC–EPHC–AHMC 2006

^a See separate module of Phase 2 of the water recycling guidelines

Periodically review the recycled water scheme analysis

The analysis of the recycled water scheme should be reviewed periodically to incorporate any changes that occur; for example, in industrial activity, urban development, uses associated with accessible water storages and receiving waters, or the characteristics of the end-user populations. Any substantive changes need to be included in risk management plans.

4.2.3 Assessment of water-quality data

Summary of actions

- Assemble historical data about untreated and treated sewage or stormwater quality, identify gaps and assess reliability of data.
- Assess data (using tools such as control charts and trends analysis) to identify trends and potential problems.

Assemble historical data, identify gaps and assess reliability

Recycled water schemes — particularly those involving the use of highly treated sewage — are generally developed from existing sewerage networks, treatment plants and discharge facilities. Often, historical water-quality data is available. Such data can be useful in understanding source water characteristics and system performance; they can also help in identifying hazards and aspects of the system that require improvement. Historical data will include data from monitoring associated with:

- trade-waste programs
- household chemical collection programs
- treated water quality
- existing discharges to marine or freshwater resources.

Fewer data are usually available for stormwater systems, and stormwater quality is likely to vary much more than sewage quality.

Data need to be reviewed over time and after specific events, such as heavy rainfall, particularly for stormwater or for sewerage systems that receive stormwater discharges.

Although historical data can be useful, there are likely to be substantial gaps, particularly in relation to organic chemicals. These gaps need to be identified. In some cases, generic data (eg data from other sewage treatment plants) can be useful, but such data should be used with care. In many cases, it will be necessary to commission targeted sampling programs to underpin further assessment of source water quality. These programs need to consider catchment inputs and potential hazards and hazardous events, as described in Table 4.2. The particular types and nature of industries and trade-waste discharges need to be considered for sewage and stormwater systems. These programs will need to consider seasonal variations and impacts of specific events. For some characteristics (eg nutrients and industrial chemicals) total loadings will need to be assessed.

Knowledge of source water quality is essential for system assessment, identification of appropriate preventive measures (Section 4.3) and design of verification monitoring programs (Section 4.5).

The assessment needs to consider the reliability and accuracy of the available data.

Tools to analyse data

Tools that may be useful in assessing data include control charts and temporal analysis of water-quality records. Records should be analysed for short-term or seasonal spikes (eg caused by trade-waste discharges, seasonal occurrence of illnesses or storm events). Trends analysis can be a valuable tool for recognising cumulative effects and gradual changes.

4.2.4 Hazard identification and risk assessment

Summary of actions

- Define the approach to hazard identification and risk assessment.
- Identify and document hazards and hazardous events for each component of the recycled water system.
- Estimate the level of risk for each hazardous event and each hazard.
- Determine significant risks and document priorities for risk management.
- Evaluate the major sources of uncertainty associated with each hazard and hazardous event, and consider actions to reduce uncertainty.

Define approach to hazard identification and risk assessment

As defined in the *Australian Drinking Water Guidelines* (NHMRC–NMMRC 2004):

- a *hazard* is a biological, chemical, physical or radiological agent that has the potential to cause harm
- a *hazardous event* is an incident or situation that can lead to the presence of hazard (what can happen and how)
- *risk* is the likelihood that identified hazards will cause harm in exposed populations.

Effective risk management involves identifying all potential hazards and hazardous events, and assessing the level of risk that they present to public health. Parameters identified as potential risks by stakeholders, including community members, need to be carefully considered.

The method used needs to be fully understood by everyone involved in the process. Also, it needs to be transparent not only to those directly involved but also to scrutiny by stakeholders and external auditors. Confidence is needed that the process will identify all significant hazards and risks.

Identify and document hazards and hazardous events

Hazards and hazardous events need to be identified by systematically reviewing each component of the recycled and drinking water systems. The review needs to include point sources (eg industrial waste discharge) and diffuse sources (eg agricultural and animal husbandry activities in stormwater catchments). It should also consider continuous, intermittent or seasonal pollution patterns, and potential impacts associated with extreme events. Table 4.2 provides examples of potential hazardous events.

Table 4.2 Examples of potential hazardous events

Stormwater catchments	
<ul style="list-style-type: none">• Chemical use in catchment areas (eg use of fertilisers and agricultural pesticides)• Sewage overflows and septic system discharges• Entry of livestock waste• Climatic and seasonal variations (eg heavy rainfall, drought)• Industrial discharges	<ul style="list-style-type: none">• Major fires (firefighting chemicals), natural disasters, sabotage• Accidental spills or discharge• Leaching from existing or historical waste-disposal (eg landfill) or mining sites, and contaminated sites and hazardous wastes• Road washing
Sewerage systems	
<ul style="list-style-type: none">• Discharges of domestic and household chemicals• Discharges of toxic material• Infiltration of stormwater	<ul style="list-style-type: none">• Infiltration of saline groundwater to sewer• Trade-waste discharges, including accidental and illegal discharges• Infiltration of waste from contaminated sites or waste disposal sites (eg landfill)
Recycled water and drinking water treatment systems	
<ul style="list-style-type: none">• Chemical dosing failures• Disinfection malfunctions• Equipment malfunctions• Failure of alarms and monitoring equipment• Formation of disinfection byproducts• Inadequate:<ul style="list-style-type: none">– backup for key processes– equipment or unit processes– filter operation and backwash recycling– mixing of treatment chemicals and coagulants	<ul style="list-style-type: none">• Poor reliability of processes• Power failures• Sabotage and natural disasters• Significant flow variations through water treatment systems• Use of unapproved or contaminated water treatment chemicals and materials• Failure of staff to respond appropriately to alarms or fluctuations in treatment processes
Receiving waters (reservoirs, rivers and streams)	
<ul style="list-style-type: none">• Short circuiting• Bushfires and natural disasters• Climatic and seasonal variations (eg heavy rainfall, drought)• Cyanobacterial blooms• Livestock access• Inadequate buffer zones and vegetation	<ul style="list-style-type: none">• Inadequate storage (eg during winter or other times of low recycled water usage)• Leakage from storage to groundwater• Birds and vermin• Accidental spillage from public roads• Sabotage
Distribution systems	
<ul style="list-style-type: none">• Cross-connections with lower quality water or storages holding industrial chemicals• Inadequate repair and maintenance, inadequate system flushing and reservoir cleaning• Inappropriate materials and coatings or material failure	<ul style="list-style-type: none">• Biofilms, sloughing and resuspension or regrowth• Formation of disinfection byproducts• Pipe bursts or leaks• Sabotage and natural disasters
Users of drinking water	
<ul style="list-style-type: none">• Leaching of metals from piping and fittings• Unauthorised plumbing work leading to cross-connections to lower quality water	<ul style="list-style-type: none">• Inadequate auditing and inspection of internal plumbing systems• Use of inappropriate plumbing and construction materials

Microbial hazards

Microorganisms capable of causing enteric illness are the most significant human health hazards associated with recycled water and drinking water. Microbial contamination can cause widespread, acute and life-threatening disease outbreaks. Further discussion on enteric pathogens is provided in Chapter 3 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006). Table 4.3 summarises microbial hazards that can be found in sewage.

Table 4.3 Examples of microbial hazards in sewage

Pathogen type	Examples	Illness
Bacteria	<i>Salmonella</i>	Gastroenteritis, reactive arthritis
	<i>Campylobacter</i>	Gastroenteritis, Guillain–Barré syndrome
	Pathogenic <i>Escherichia coli</i>	Gastroenteritis, haemolytic uremic syndrome
	<i>Shigella</i>	Dysentery
	<i>Yersinia</i>	Gastroenteritis, septicaemia
	<i>Vibrio cholerae</i>	Cholera
	Atypical <i>Mycobacteria</i>	Respiratory illness (hypersensitivity pneumonitis)
	<i>Legionella</i> spp	Respiratory illness (pneumonia, Pontiac fever)
	<i>Staphylococcus aureus</i>	Skin, eye, ear infections, septicaemia
	<i>Pseudomonas aeruginosa</i>	Skin, eye, ear infections
Viruses	Enterovirus	Gastroenteritis, respiratory illness, nervous disorders, myocarditis
	Adenovirus	Gastroenteritis, respiratory illness, eye infections
	Rotavirus	Gastroenteritis
	Norovirus	Gastroenteritis
	Hepatitis A	Infectious hepatitis
	Calicivirus	Gastroenteritis
	Astrovirus	Gastroenteritis
	Coronavirus	Gastroenteritis
Protozoa	<i>Cryptosporidium</i>	Gastroenteritis
	<i>Giardia</i>	Gastroenteritis
	<i>Entamoeba histolytica</i>	Amoebic dysentery
Helminths	<i>Taenia</i> (<i>T. saginata</i> , <i>T. solium</i>)	Tapeworm (beef measles), neurocysticercosis
	<i>Ascaris</i>	Roundworm
	<i>Trichuris</i>	Whipworm
	<i>Ancylostoma</i>	Hookworm

Source: Adapted from Feacham et al (1983), Geldreich (1990), NRC (1996), Bitton (1999)

In sewage, enteric microorganisms are typically present in high concentrations. Numbers of individual pathogens will vary, depending on rates of illness in humans and animals contributing faecal waste. Seasonal variations can influence concentrations of pathogens (eg in some areas,

cryptosporidiosis is more common in spring and autumn), while outbreaks can markedly increase concentrations. Variability will generally be greater in smaller sewage systems, because the impact of outbreaks on major urban systems will be diluted by the total volumes of sewage from the large populations served by the plants. System-specific data are preferable for drinking water augmentation schemes. These data should be sufficient to enable determination of statistically valid 95th percentiles to account for variability. As discussed in Phase 1 of the recycled water guidelines (NRMMC–EPHC–AHMC 2006), analyses of Australian sewage have detected 2000 *Cryptosporidium*, 8000 rotavirus and 7000 *Campylobacter* per litre (as 95th percentiles).

In stormwater, concentrations of enteric microorganisms will be far more variable, influenced by levels of human and animal activity in catchments, and by seasonal and rainfall patterns. Rain events occurring after extended dry spells can lead to highly contaminated stormwater. Generally, system-specific testing will be required to determine concentrations of pathogens present in stormwater. Such testing will need to take into account potential seasonal influences, and impacts of rain or storm events.

Chemical hazards

Although microbiological quality remains paramount, much community concern has been expressed about chemical quality of recycled water used for drinking. This concern is increased by the level of uncertainty about the range of chemicals that may be present. Chemicals could include:

- inorganic chemicals
- nutrients (which could support or promote the development of cyanobacterial blooms in receiving waters)
- pesticides
- water treatment chemicals, disinfection byproducts and advanced oxidation byproducts
- industrial chemicals
- household and garden chemicals
- surfactants
- flame retardants
- human and veterinary pharmaceutical products
- radiological contrast media
- naturally occurring radionuclides
- radionuclides from medical, industrial and research wastes and discharges
- personal-care products (eg fragrances, cosmetics, antiperspirants, moisturizers, soaps, creams, whitening agents, dyes and shampoos)
- natural hormones
- general organic chemicals, such as aliphatics, chlorobenzenes, monocyclic hydrocarbons, nitrosamines, organotins, phenols, phthalates, plasticizers, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), sterols and stanols.

Table 4.4 lists maximum concentrations of chemicals that have been detected in secondary treated sewage. The table was compiled from a range of Australian and international data sets, but should not be regarded as exhaustive. Detailed assessment of individual systems — including surveys of industrial, agricultural, domestic and urban inputs — needs to be undertaken to identify potential

chemical hazards that could affect source water quality. In most cases, this assessment will need to be supported by extensive monitoring of source water quality.

The list of chemicals provided in Table 4.4 is reasonably extensive; however, more than two-thirds of the chemicals for which tests were performed were reported in the available data sets as being below limits of detection. These included a large range of pharmaceuticals, pesticides, fragrances, fire retardants, surfactants, dioxins, phthalates and organotins.

Table 4.4 includes health-related guideline values. As described in Appendix A, these values have been:

- derived from published guidelines and standards, giving preference to guideline values published in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004)
- developed from available health, toxicological and structural information.

Appendix A includes an approach for dealing with chemicals without existing guideline values or sufficient health and toxicological information for guideline derivation. This approach is based on the methodology for determining thresholds of toxicological concern (TTCs), which are then used to determine guideline values in a similar way to acceptable daily intakes (ADIs) or tolerable daily intakes (TDIs), using the formula described in the *Australian Drinking Water Guidelines* (NRMMC–NHMRC 2004). The use of TTCs is well established internationally and has been applied by the United States Food and Drug Administration (FDA) and the World Health Organization (WHO) for setting guidelines for minor chemical contaminants (FDA 2006, WHO 1987). The approach relies on a large toxicological database and advanced knowledge of structure–activity relationships that can be confidently applied to chemicals for which there is little toxicological data. The application of TTCs to recycled water has also been proposed by Rodriguez et al (2007).

For carcinogens, the TTC approach is based on a concentration that would give rise to less than one cancer per one million people following lifetime consumption.

Dioxins and PCBs

For dioxins, including dioxin-like PCBs, the TTC approach does not apply. Instead, guidelines for these compounds have been calculated using the recommended tolerable intakes developed by the NHMRC, taking into account toxicity equivalency factors (TEFs), which provide adjustments based on relative toxicity (NHMRC 2002). The guideline value for dioxin-like compounds applies to the sum of all dioxins, furans and PCBs calculated as toxicity equivalents (TEQs), using the TEFs reported in Van den Berg et al (2006). This translates to a total of 16 pg TEQ/L. The dioxin-like compounds included in Table 4.4 — PCBs 77, 105, 118, 156, 167; octachlorodibenzodioxins (OCDD); and dichlorodibenzo-p-dioxin (DCDD) — all have TEFs of 0.01 or lower, which signifies low toxicity relative to other compounds in this group. Applying these TEFs to the maximum concentrations of all dioxin-like compounds listed in Table 4.4 produces a combined TEQ below 1 pg TEQ/L.

At 0.1 ng/L, the combined concentration of PCBs presented in Table 4.4 is also below the calculated drinking water guideline of 0.14 µg/L for total PCBs.

Hormones and pharmaceuticals

Raw sewage will contain a variety of pharmaceuticals and natural hormones, such as estradiol, that are excreted by humans on a daily basis.

The TTC approach is not applicable to pharmaceuticals (Kroes et al 2004, Barlow 2005) and is not required, because health data are available. Pharmaceuticals have been divided into two groups: those used solely for humans and those used for agricultural and veterinary purposes (some of which may also be used for humans). ADIs have been established for pharmaceuticals used for agricultural and veterinary purposes by bodies such as the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Expert Committee on Food Additives (JECFA), the Australian Therapeutic Goods Administration (TGA) and the European Medicines Agency (EMA). These ADIs have been used to determine guideline values.

Derivation of guideline values for pharmaceuticals used solely in human medicine is based on therapeutic doses. The traditional approach applied by NHMRC and WHO to derive drinking water guidelines from toxicological data (NHMRC–NRMMC 2004, WHO 2006a) would not be practical. There are large numbers of pharmaceuticals, and new products appear on a regular basis. Pharmaceutical products are among the most extensively examined chemicals in terms of human health impacts. They are rigorously tested for safety before release, and systems are in place for reporting adverse side effects. However, the testing data are often confidential, and thus not available for the development of guideline values.

Guideline values for human use pharmaceuticals have been derived from lowest daily therapeutic doses. These doses are well established, and the general intent when pharmaceuticals are used medicinally is to have a large therapeutic index (ie the ratio of dose giving a beneficial effect to dose causing toxicity).⁸ The use of lowest daily therapeutic dose as a starting point for deriving guideline values or assessing risk has been adopted by others (Webb et al 2003, Schwab et al 2005, DEFRA 2007 and Versteegh et al 2007). The approach adopted in these guidelines to establish drinking water guidelines is to divide the lowest daily therapeutic dose by safety factors of 1000–10 000.

Pharmaceutical metabolites could also be present in source waters; however, the activity of these compounds is generally lower than the parent compound. Applying safety factors of 1000–10 000 should provide a safety buffer that is sufficiently conservative to deal with metabolites.

Antibiotic resistance

Antibiotic-resistant organisms have been detected in waters receiving sewage (Watkinson et al 2007). The presence of these organisms may be due to the release of antibiotic resistant strains in the treated sewage, or to the impact of residual concentrations of antibiotics from sewage. Recycled water used for drinking water augmentation will have lower concentrations of antibiotics and residual microorganisms than secondary or even tertiary treated sewage that has been treated using conventional processes. Treatment trains, including processes such as reverse osmosis and advanced oxidation, will reduce antibiotic concentrations by more than 95% compared to secondary treated sewage, and reduce levels of bacteria (including antibiotic resistant strains) by more than 10 logs. Guideline concentrations for human-use antibiotics are at least 1000-fold less than daily therapeutic doses. Thus, the risk of antibiotic resistance arising from the discharge of highly treated recycled water into receiving waters is relatively low. In addition, receiving waters augmented with recycled water will be subjected to further treatment (including disinfection) before supply to consumers.

Endocrine disrupting chemicals

An extensive range of chemicals have endocrine disrupting properties; these chemicals include natural hormones; pharmaceuticals; industrial, commercial and agricultural chemicals; and phytoestrogens. These compounds vary in their structure and potency. The concentrations and

⁸ Many of the pharmaceutical compounds in Table 4.4 are nonsteroidal anti-inflammatory agents, antibiotics or beta-blockers. These agents would be expected to have a therapeutic index far greater than 10.

potencies of exogenous compounds are typically lower than those of endogenous hormones and phytoestrogens (WHO 2005). Reviews published by WHO (2005) and the Cooperative Research Centre for Water Quality and Treatment (Falconer et al 2003) have indicated that — while evidence of impacts of endocrine-disrupting chemicals on wildlife has been confirmed in field and laboratory studies — the evidence of human health impacts from environmental exposure is not compelling. Impacts of endocrine disrupting chemicals on human health have been demonstrated, but these have largely been limited to high occupational and accidental exposures; investigations of human responses to low exposures have yielded inconsistent and inconclusive results. This does not dismiss concerns but means that far more research is needed to determine whether or not environmental exposures affect human health.

These current guidelines adopt the precautionary approach of applying large safety factors to all compounds, including those implicated as potential endocrine disrupting chemicals. As discussed below, the minimum safety factor applied in deriving guideline values is 1000, while the safety factor applied to endogenous and synthetic hormones is 10 000.

Chemical mixtures

There are no standardised procedures for incorporating potential effects of mixtures — additive, synergistic or suppressive — into the process of setting guideline values for regulatory purposes. Because of inherent uncertainties in the range and concentrations of possible components of complex mixtures in an environmental situation, it is generally not possible to use such information in setting standards.

There are established methods for aggregating estimates of risk when the composition of a chemical mixture is known or can be inferred using relevant data. Such methods usually aggregate risk by assuming that risks are additive, but this assumption implies that chemicals producing the same adverse health outcome act in the same way, which may not be the case. For example, endocrine disruption can operate through different receptors, pathways and signalling webs, and it is difficult to establish whether mixtures of endocrine disrupting chemicals will produce additive effects (with or without synergistic or antagonistic interactions), particularly at the low levels typically associated with environmental exposure. Therefore, when dealing with mixtures of chemicals in water or other media, quantitative health risk assessment tends to focus solely on the major individual contributors to risk.

Where chemicals in mixtures are at concentrations far below their individual toxicological thresholds (ie below individual guideline values), any additive or antagonistic effects are unlikely to contribute significantly or measurably to overall risk. Thus, the international regulatory approach to dealing with mixtures is to ensure that guideline values for individual chemicals are well below the concentrations required to produce an adverse health effect. This means that, even if mixtures contain multiple substances that cause the same effect by the same biological mechanism, the combined concentrations will still be well below toxicological thresholds. The process outlined in this document for determining guideline values for individual chemicals is sufficiently conservative (through the application of safety factors) to be consistent with the international regulatory approach. The process used means that compliance with individual guideline values will protect public health in schemes where recycled water is used to augment drinking water supplies.

In some cases, additive effects and toxicity equivalence have been applied in setting the guidelines given in this document. For example, a well-established process using toxic equivalence factors (TEFs) has been applied to setting guideline values for dioxins and related substances (NHMRC 2002), and a guideline value has been set for total PCBs. Also, the tetracyclines have been treated as a group, based on similar activity.

Allergens

The strongest allergens are proteins (eg in milk, eggs, fish crustaceans and peanuts) capable of inducing immunologically mediated allergic reactions. Some low molecular weight chemicals may also act as allergens, through binding to proteins, and some chemicals may cause non-immunologic hypersensitivity reactions and intolerances. However, doses required to elicit allergic responses vary widely, and there is a lack of data on this issue. Therefore, possible allergenicity is not included in the TTC approach (Kroes and Koziarowski 2002, Kroes et al 2004, Barlow 2005). Of the pharmaceuticals listed in Table 4.4, allergenicity is included in the derivation of the ADI for the penicillins (EMEA 2005); this has been extended to all β lactams. For the remaining chemicals, including safety factors for intraspecies variation and sensitive subgroups should protect against potential allergenicity.

Water treatment chemicals and byproducts

Detailed guidance on water treatment chemicals is provided in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004). Some processes and chemicals used in drinking water augmentation will be similar to those used in drinking water treatment. Where processes differ, the same principles apply. Any chemical used during the treatment of recycled water for augmentation of drinking water supplies should:

- be effective for the desired outcome
- not present a public health concern
- not result in the chemical, its byproducts or any contaminants exceeding drinking water guideline values.

A water quality management program needs to recognise any potential risks from use of drinking water treatment chemicals, and include strategies to manage them appropriately. Any risks need to be minimised by implementing quality assurance systems for the production, supply or delivery and use of water treatment chemicals.

Contamination of chemicals can be minimised by the use of good manufacturing practice, which involves using quality control and quality assurance programs to maximise product purity. Chemical suppliers should be selected on their ability to supply products in accordance with required specifications. Responsibilities for testing and quality assurance of chemicals (supplier, purchaser or both) should be clearly defined in purchase contracts.

In terms of byproducts, several of the processes used in treating recycled water are based on removal (eg membrane filtration, reverse osmosis and activated carbon) and will not produce byproducts. However, advanced oxidation and disinfection processes are likely to produce these compounds. The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) identifies byproducts associated with standard oxidation and disinfection processes, and includes guideline values for a range of these compounds. The relevant compounds should be considered. In addition, advanced oxidation is typically applied to remove compounds such as N-nitrosodimethylamine (NDMA) and 1,4-dioxin, which might not be completely removed by processes such as reverse osmosis. The possibility of byproducts caused by the interaction of advanced oxidation with target chemicals should be considered. If such compounds are identified, the approach described in Appendix A can be used to derive guideline values.

Safety factors

A conservative approach has been adopted in applying safety factors in deriving guideline values. As described in Appendix A, the TTC approach for compounds with structural alerts (eg for genotoxicity or carcinogenicity) usually incorporates a safety factor of 100. Rodriguez et al (2007) used this safety factor in applying the TTC approach to chemicals in recycled water.

In this document, the safety factor has been increased to 1500 for substances classified as ‘threshold compounds’ using the Cramer approach, based on ‘no observed effect levels’ (NOELs). This approach is consistent with the generally conservative approach adopted in drinking water guidelines. In the *Australian Drinking Water Guidelines* (NHMRC–NRMCC 2004), the safety factors applied in deriving guideline values from NOELs were 270 (median) and 1570 (95th percentile). These values are similar to those used in the *WHO Guidelines for Drinking-Water Quality* (WHO 2006a), which employed safety factors of 170 (median) and 1660 (95th percentile).

A similarly conservative approach has been applied to application of safety factors for pharmaceuticals used in human medicine (ie those without an ADI). Drinking water guidelines and standards established by WHO and in Australia, Canada and the United States incorporate safety factors ranging up to a maximum of 10 000, and it is generally agreed that safety factors should not exceed this upper limit (Ritter et al 2007).

In this publication, the following safety factors have been applied:

- *all pharmaceuticals* — a safety factor of 1000 is applied, comprising
 - 10 for differences in response between humans (intraspecies variation taking into account responses from sensitive individuals)
 - 10 for protection of sensitive subgroups including children and infants
 - 10 for the lowest daily therapeutic dose not being a NOEL
- *cytotoxic drugs* — an additional safety factor of 10 is applied due to the higher level of toxicity associated with these compounds
- *endogenous and synthetic hormones* — an additional safety factor of 10 is applied on the grounds that the potential effects of these chemicals on hormonal function and fertility are strong (eg contraception) and are unwanted in those not being treated.

The safety factors applied to pharmaceuticals thus range from 1000 to 10 000 (see Step 6c, Appendix A). Considering that a safety factor is not required for interspecies variation, this is considered to be conservative. The combined factor of 100 for intraspecies variation and protection of sensitive subgroups is considered to adequately address issues associated with potential exposure of infants, children and those with allergies or other contraindications.

The application of safety factors to pharmaceuticals in this document is more conservative than the application of safety factors by Schwab et al (2005), DEFRA (2007) and Versteegh et al (2007). Schwab et al (2005) applied safety factors of 22.5–500 (adjusted to adult bodyweights); DEFRA (2007) used a safety margin of 1000, and Versteegh et al (2007) applied a safety factor of 100 (together with an allocation of 10% to water).

Table 4.4 Chemicals detected in secondary treated sewage, maximum concentrations and guideline values

Chemical	Maximum concentration ^{ab}	Guideline value ^a	Chemical	Maximum concentration ^{ab}	Guideline value ^a
Inorganic chemicals					
Aluminium	2.2	0.2 ^c (aesth)	Iodide	0.048	0.1 ^c
Ammonia	39	0.5 ^c (aesth)	Iron	1.3	0.3 ^c (aesth)
Antimony	0.006	0.003 ^c	Lead	0.06	0.01 ^c
Arsenic	0.015	0.007 ^c	Manganese	0.47	0.5 ^c

Chemical	Maximum concentration^{ab}	Guideline value^a	Chemical	Maximum concentration^{ab}	Guideline value^a
Barium	0.1	0.7 ^c	Mercury	0.007	0.001 ^c
Boron	0.9	4 ^c	Molybdenum	0.03	0.05 ^c
Bromide	0.28	7 ^g	Nickel	0.6	0.02 ^c
Bromine	0.57	7 ^g	Nitrate (NO ₃)	19.7	50 ^c
Cadmium	0.004	0.002 ^c	Nitrite (NO ₂)	0.04	3 ^c
Chromium	0.11	0.05 ^c	Selenium	0.003	0.01 ^c
Copper	0.4	2 ^c	Silver	0.0028	0.1 ^c
Cyanide		0.08 ^c	Sulfate (SO ₄)	1870	500 ^c
Fluoride	1.4	1.5 ^c	Zinc	0.25	3 ^c
Disinfection byproducts					
2,4,6-Trichlorophenol (2,4,6-T)	0.00005	0.02 ^c	Chloroform	0.107	0.2 ^f
2,4-Dichlorophenol	0.0003	0.2 ^c	Dibromochloromethane	0.022	0.1 ^f
2,6-Dichlorophenol	0.000026	0.01 ^g	Dichloroacetic acid	0.0005	0.1 ^c
Bromoacetic acid	0.0004	0.00035 ^j	Dichloroacetonitrile	0.00072	0.002 ^f
Bromochloroacetonitrile	0.00025	0.0007 ^j	N-nitrosodiethylamine (NDEA)	3 ng/L	10 ng/L ^f
Bromodichloromethane	0.12	0.006 ^f	N-nitrosodimethylamine (NDMA)	550 ng/L	10 ng/L ^f
Bromoform	0.081	0.1 ^f	Trichloroacetic acid	0.004	0.1 ^c
Pesticides					
<i>Acetylcholinesterase inhibitors</i>					
Azinphos-methyl	0.0021	0.003 ^c	Dimethoate	0.0019	0.05 ^c
Bromophos-ethyl	0.0001	0.01 ^c	Ethion	0.0018	0.003 ^c
Carbendazim	0.0003	0.1 ^c	Ethoprophos (Mocap)	0.002	0.001 ^c
Chlorpyrifos	0.0007	0.01 ^c	Fenthion (fenthion-methyl)	0.0024	0.0005 ^d
Chlorpyrifos-methyl	0.0017	0.01 ^j	Malathion	0.0021	0.9 ^f
Demeton-S	0.003	0.00015 ^g	Parathion (ethyl parathion)	0.0022	0.01 ^c
Diazinon	0.0032	0.003 ^c	Parathion-methyl (methyl parathion)	0.0028	0.1 ^c
Dichlorvos	0.0024	0.001 ^c			
<i>Organochlorines</i>					
4,4'-DDT (44DDT; p,p'-DDT)	0.02	0.02 ^c	Endosulfan sulfate	0.00025	0.03 ^c
4,4'-DDE (44DDE; p,p'-DDE)	0.00015	0.02 ^c	Lindane	0.0001	0.02 ^c
Chlordane (gamma-Chlordane)	0.001	0.001 ^c	Pentachlorophenol (PCP)	0.0002	0.01 ^c
<i>General pesticides</i>					
2,4-D (2,4-Dichlorophenoxyacetic acid)	0.0046	0.03 ^c	4-Nitrophenol	0.0023	0.03 ^g
Alachlor (Lasso)	0.0002	0.002 ^f	2-Phenylphenol	0.0026	1 ^j
Atrazine	0.00088	0.04 ^c	Simazine	0.001	0.02 ^c

Chemical	Maximum concentration ^{ab}	Guideline value ^a	Chemical	Maximum concentration ^{ab}	Guideline value ^a
[(Carboxymethyl)imino bis(ethylenitrilo)] tetra acetic acid	0.0085	0.005 ^j	Thiophanate	0.012	0.005 ^c
Cypermethrin	0.00008	0.0005 ^d	Trifluralin	0.0006	0.05 ^c
N,N-diethyltoluamide (NN-diethyl-3-methylbenzamide (DEET))	0.00078	2.5 ^h	α-BHC (alpha-BHC)	0.00008	0.02 ^j
Diuron	0.00029	0.03 ^c	β-BHC (beta-BHC)	0.00033	0.02 ^j
Metolachlor	0.00037	0.3 ^c			
Fragrances					
2,4,6-Trinitro-1,3-dimethyl-5-tert-butylbenzene (musk xylene)	36 ng/L	350 µg/L ^h	Musk ketone	410 ng/L	350 µg/L ^h
4-Acetyl-6-t-butyl-1,1-dimethylindan	8 ng/L	7 µg/L ^j	Musk tibetene	0.04 ng/L	0.35 µg/L ^j
6-Acetyl-1,1,2,4,4,7-hexamethyltetraline	88 ng/L	4 µg/L ^j	Pentamethyl-4,6-dinitroindane	8.3 ng/L	0.35 µg/L ^j
Galaxolide	150 ng/L	1.8 ^h			
Pharmaceuticals and metabolites					
<i>Antibiotics</i>					
Amoxicillin	0.02 µg/L	1.5 µg/L ¹	Monensin	0.08 µg/L	35 µg/L ¹
Anhydroerythromycin A	0.92 µg/L	17.5 µg/L ¹	Naladixic acid	0.22 µg/L	1,000 µg/L ^k
Azithromycin	0.072 µg/L	3.9 µg/L ¹	Norflaxin	0.2 µg/L	400 µg/L ^k
Cefaclor	1.2 µg/L	250 µg/L ^k	Penicillin G	0.03 µg/L	1.5 µg/L ¹
Cephalexin	0.09 µg/L	35 µg/L ¹	Penicillin V	0.21 µg/L	1.5 µg/L ¹
Chloroamphenicol	0.56 µg/L	175 µg/L ^k	Roxithromycin	0.68 µg/L	150 µg/L ^k
Chlorotetracycline	0.28 µg/L	105 µg/L ¹	Sulfamethoxazole	1.9 µg/L	35 µg/L ¹
Ciproflaxin	0.4 µg/L	250 µg/L ^k	Sulfamethoxine	0.06 µg/L	35 µg/L ¹
Clarithromycin	0.24 µg/L	250 µg/L ^k	Sulfamethazine	0.68 µg/L	35 µg/L ¹
Clindamycin	0.120 µg/L	300 µg/L ^k	Sulfamethizole	0.13 µg/L	35 µg/L ¹
Demeclocycline	1.1 µg/L	300 µg/L ^k	Terramycin (oxytetracycline)	0.66 µg/L	105 µg/L ¹
Doxycycline	0.03 µg/L	10.5 µg/L ¹	Tetracycline (TCLN)	0.11 µg/L	105 µg/L ¹
Enrofloxacin	0.015 µg/L	22 µg/L ¹	Trimethoprim	0.35 µg/L	70 µg/L ¹
Erythromycin	1.7 µg/L	17.5 µg/L ¹	Tylosin	1.1 µg/L	1050 µg/L ¹
<i>Non-steroidal anti-inflammatory</i>					
Aspirin (Acetylsalicylic acid)	2.1 µg/L	29 µg/L ¹	Indomethacin	0.6 µg/L	25 µg/L ^k
Diclofenac	0.81 µg/L	1.8 µg/L ¹	Ketoprofen	0.38 µg/L	3.5 µg/L ¹
Dipyron (vet)	7.5 µg/L	525 µg/L ¹	Naproxen	0.57 µg/L	220 µg/L ^k
Fenoprofen	0.76 µg/L	450 µg/L ^k	Tolfenamic acid (vet)	1.6 µg/L	17.5 µg/L ¹
Ibuprofen	28 µg/L	400 µg/L ^k			
<i>β-adrenergic blockers</i>					
Betaxolol	0.19 µg/L	10 µg/L ^k	Nadolol	0.06 µg/L	20 µg/L ^k
Bisoprolol	0.37 µg/L	0.63 µg/L ^k	Propranolol	0.29 µg/L	40 µg/L ^k
Carazolol	0.12 µg/L	0.35 µg/L ¹	Timolol	0.07 µg/L	10 µg/L ^k

Chemical	Maximum concentration ^{ab}	Guideline value ^a	Chemical	Maximum concentration ^{ab}	Guideline value ^a
Metoprolol	2.2 µg/L	25 µg/L ^k			
<i>Estrogenic hormones</i>					
17α-estradiol	74 ng/L	175 ng/L ^l	Estriol	51 ng/L	50 ng/L ^k
17α-ethinyl estradiol	270 ng/L	1.5 ng/L ^k	Estrone	110 ng/L	30 ng/L ^k
17β-estradiol	93 ng/L	175 ng/L ^l	Mestranol	410 ng/L	2.5 ng/L ^k
Equilenin	280 ng/L	30 ng/L ^k	Norethindrone	870 ng/L	250 ng/L ^k
Equilin	150 ng/L	30 ng/L ^k	Progesterone	200 ng/L	105 µg/L ^l
<i>Androgens</i>					
Androsterone	0.21 µg/L	14 µg/L ^k	Testosterone	0.21 µg/L	7 µg/L ^l
<i>General pharmaceuticals</i>					
Alprazolam	0.62 µg/L	0.25 µg/L ^k	Fluoxetine (Prozac)	0.142 µg/L	10 µg/L ^k
Antipyrine (phenazone)	0.41 µg/L	1,000 µg/L ^k	Gemfibrozil	1.5 µg/L	600 µg/L ^k
Atorvastatin	0.04 µg/L	5 µg/L ^k	Iohexol	1.6 µg/L	720 µg/L ^k
Bezafibrate	4.6 µg/L	300 µg/L ^k	Iopamidol	15 µg/L	400 µg/L ^k
Carbamazepine	27 µg/L	100 µg/L ^k	Iopromide	11 µg/L	750 µg/L ^k
Cimetidine	0.58 µg/L	200 µg/L ^k	Isophosphamide	2.9 µg/L	3.5 µg/L ^{ko}
Clenbuterol	0.05 µg/L	15 µg/L ^l	Metformin (1,1-Dimethylbiguanide)	0.15 µg/L	250 µg/L ^k
Clofibric acid	1.6 µg/L	750 µg/L ^k	Paracetamol (acetaminophen)	4.3 µg/L	175 µg/L ^l
Codeine	9.1 µg/L	50 µg/L ^k	Salbutamol	0.035 µg/L	3 µg/L ^k
Cotinine	0.9 µg/L	10 µg/L ^k	Salicylic acid	60 µg/L	105 µg/L ^k
Cyclophosphamide	0.02 µg/L	3.5 µg/L ^{ko}	Sulfasalazine	0.12 µg/L	500 µg/L ^k
Dehydronifedipine	0.03 µg/L	20 µg/L ^k	Temazepam	1.6 µg/L	5 µg/L ^k
Diltiazem	0.049 µg/L	60 µg/L ^k	Terbutaline	0.12 µg/L	4.5 µg/L ^k
Enalaprilat	0.046 µg/L	1.3 µg/L ^k	Valium (Diazepam)	2.92 µg/L	2.5 µg/L ^k
Fire retardants					
Fyrol FR 2 (tri(dichlorisopropyl)phosphate) ^l	0.0002	0.001 ^j	Tris(2-chloroethyl)phosphate (TCEP)	540 ng/L	1,000 ng/L ^j
Dioxins and dioxin-like compounds					
2,3,3',4,4',5-Hexachlorobiphenyl (PCB156)	0.008 ng/L TEF 0.0005	0.016 ng/L ^{mm}	2,7-Dichlorodibenzo-p-dioxin (DCDD)	1200 ng/L No TEF	0.016 ng/L ^m
2,3,3',4,4'-pentachlorobiphenyl (PCB105)	0.027 ng/L TEF 0.0001	0.016 ng/L ^{mm}	3,4,5,3',4',5'-Hexachlorobiphenyl (PCB169)	0.002 ng/L TEF 0.01	0.016 ng/L ^{mm}
2,3',4,4',5-Pentachlorobiphenyl (PCB118)	0.064 ng/L TEF 0.0001	0.016 ng/L ^{mm}	Octachlorodibenzo-p-dioxin (OCDD)	0.1 ng/L TEF 0.0001	0.016 ng/L ^m
2,4,5,3',4',5'-Hexachlorobiphenyl (PCB167)	0.004 ng/L TEF 0.00001	0.016 ng/L ^{mm}	PCB77	0.006 ng/L TEF 0.0001	0.016 ng/L ^{mm}
Miscellaneous organic chemicals — polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), phthalates, organotins, etc					
1,1-Dichloroethene	0.03	0.03 ^c	Coprastanol	9.8 µg/L	0.7 µg/L ^j
1,7-Dimethylxanthine (Paraxanthine)	50 µg/L	0.7 µg/L ^j	Coumarin	1.3 µg/L	0.5 µg/L ^d

Chemical	Maximum concentration ^{ab}	Guideline value ^a	Chemical	Maximum concentration ^{ab}	Guideline value ^a
2,5-Dihydroxybenzoic acid	0.59 µg/L	7 µg/L ^j	Diatrizoate Sodium	230 ng/L	350 ng/L ^j
2,6-di-tert-butyl-1,4-benzoquinone (2,6-bis(1,1-dimethylethyl)-2,5-Cyclohexadiene-1,4-dione)	460 ng/L	14 ng/L ^o	Diatrizoic acid	1900 ng/L	350 ng/L ^j
2,6-di-tert-butylphenol (2,6-bis(1,1-dimethylethyl)phenol)	110 ng/L	2,000 ng/L ^j	Dibutyltin (DBT)	34 ng/L	2 µg/L ^g
4-Chlorophenol	16 ng/L	10 µg/L ^g	Di-n-butyl phthalate	891 ng/L	35 µg/L ^g
4-cumylphenol	0.98 µg/L	0.35 µg/L ^j	Methylene chloride (Dichloromethane)	0.011	0.004 ^c
4-Nonylphenol (4NP)	2.9 µg/L	500 µg/L ^h	4-Methylphenol (p-cresol)	0.54 µg/L	0.6 ^g
4-tert octylphenol	14 ng/L	50 µg/L ^h	Monobutyltin (MBT)	90 ng/L	700 ng/L ^j
5-methyl-1H-benzotriazole	2400 ng/L	7 ng/L ^o	Naphthalene	80 ng/L	70 µg/L ^g
Anthracene	110 ng/L	150 µg/L ^g	N-nitrosomorpholine (NMOR)	12 ng/L	1 ng/L ⁱ
Acetophenone	410 ng/L	400 µg/L ^g	Phenanthrene	0.53 µg/L	150 µg/L ^g
Benzo(a)pyrene	240 ng/L	10 ng/L ^c	Phenol	1.3 µg/L	150 µg/L ^g
Benzyl chloride	1.8 ng/L	200 ng/L ⁱ	Phthalic anhydride	1,000 ng/L	7 ^g
Bisphenol A	12 µg/L	200 µg/L ^g	Pyrene	840 ng/L	150 µg/L ^g
Bromochloromethane	66 µg/L	40 µg/L ^g	Stigmastanol	4 µg/L	1 ^k
Butylated hydroxytoluene (2,6-Di-tert-Butyl-p-Cresol)	100 ng/L	1 ^g	Tributyl phosphate	190 ng/L	500 ng/L ^j
Butylated hydroxyanisole (3-tert-butyl-4-hydroxy anisole)	200 ng/L	1.8 ^g	Tributyltin (TBT)	21 ng/L	1,000 ng/L ^c
Caffeine	44 µg/L	0.35 µg/L ^j	Tri(butyl cellosolve) phosphate (ethanol,2-butoxy-phosphate)	6700 ng/L	50 µg/L ^h
Chlorophene	710 ng/L	350 ng/L ^j	Triclosan	0.4 µg/L	0.35 µg/L ^j
Cholesterol	10 µg/L	7 µg/L ^j	Triphenyl phosphate	220 ng/L	1,000 ng/L ^j
Radiological					
Alpha particles	0.7 Bq/L	0.5 Bq/L ^c	Beta particles and photon emitters	1.2 Bq/L	0.5 Bq/L ^c
Gross gamma	0.1 Bq/L	0.5 Bq/L ^c			
Chelating agents					
Ethylenediaminetetraacetic acid (EDTA)	0.210	0.25 ^c	Propylenedinitrilotetraacetic acid (PDTA)	0.027	0.0007 ⁱ
Nitriolotriacetic acid (NTA)	0.012	0.2 ^c			

aesth = aesthetic guideline — no health guideline value

a Values expressed as mg/L unless otherwise indicated

b Maximum concentrations were obtained from unpublished Australian data and from Fent (1996), Castillo et al (1997), Daughton and Ternes (1999), Kolpin et al (2002), Costanzo and Watkinson (2007), Fatta et al (2007), Gomez et al (2007)

c NHMRC–NRMMC (2004)

d EC 98/83/EC

e US EPA (2007)

f WHO (2006a) (for non-threshold chemicals corrected to apply carcinogenicity risk of 10⁻⁶)

g Published tolerable daily intake or equivalent, Table A1

- h** Published NOEL or equivalent, Table A2
- i** Published guideline for a non-threshold chemical, Table A3
- j** Calculated value, Table A6
- k** Calculated from therapeutic doses, Table A8b
- l** Calculated from ADI, Table A8a
- m** Compounds with dioxin-like activity should provide a total of <16 pg toxic equivalent per litre taking into account toxicity equivalence factors (NHMRC 2002), Table A1
- n** Total PCBs should be below a guideline value of 0.14 µg/L derived from an ADI of 0.02 µg/kg/day (US EPA 1996) and an allocation to water of 20%
- o** Compounds with potentially genotoxic activity, calculated guideline value, Table A4.

Hazards to the environment

Indirect drinking water augmentation incorporates the discharge of treated recycled water into receiving waters such as rivers, reservoirs, streams and aquifers. The recycled water discharged to receiving waters will typically be subject to greater levels of treatment (Section 4.3) and hence will be of a much higher quality than the recycled water discussed in Phase 1 of the water recycling guidelines (NRMCC–EPHC–AHMC 2006).

The guideline values described for drinking water augmentation are more stringent than those for other uses of recycled water. However, chemical and physical parameters, including nutrients present in recycled water, may represent hazards to the environment when the water enters receiving waters. For example, drinking water augmentation could increase the salinity in environmental buffers, particularly in closed-loop recycling systems. Many aquatic organisms are significantly more sensitive to chemical contaminants than people, due to both level of exposure to the chemical and differences in internal systems. The drinking water guideline values proposed in this document are derived through assessment of potential impacts on human health; in some cases those values are higher than concentrations that could be harmful to aquatic ecosystems. Fully evaluating the potential effects on aquatic ecosystems in storages and waterways will be a critical component of any proposed project, and the approach described in Phase 1 of the guidelines should be applied.

The higher levels of treatment used in recycling water for use in drinking water augmentation will produce brine concentrates, membrane cleaning solutions and other residuals. The purpose of treatment processes such as reverse osmosis, ultrafiltration and microfiltration is to remove microbial and chemical hazards — including hormones, pharmaceuticals and personal-care products — from source waters. These hazards will be present in reject waters and brine concentrates, and will need to be dealt with in a way that causes no environmental harm. Discharge to sewer should be avoided, particularly where the sewer is part of the source water collection system. Treatment and processing options will need to be considered (Kepke et al 2007). Discharges from treatment plants will normally be subject to regulation by environment protection agencies.

Estimate level of risk

Once potential hazards and hazardous events have been identified, the level of risk associated with each needs to be estimated, so that priorities for risk management can be established and documented. Not all hazards will require the same degree of attention; risk estimation helps to direct attention and resources to those hazards that are most threatening.

Risk should be assessed at two levels:

- *Maximum risk* (also referred to as ‘unmitigated risk’) is risk in the absence of preventive measures. Assessment of maximum risk is used to identify high-priority risks, determine where attention needs to be focused and prepare for emergencies. Maximum risk can also be used to determine the targets that preventive measures need to achieve.

- *Residual risk* is risk after consideration of preventive measures. Assessment of residual risk provides an indication of the safety and sustainability of a recycled water scheme. Residual risk needs to be less than the upper limits of tolerable risk (ie a level of risk that is acceptable).

Determination of residual risk can be an iterative process. If initial assessments indicate that risk is unacceptable, then additional preventive measures will be required. Residual risk will need to be recalculated after inclusion of these additional measures.

Qualitative and quantitative risk

The level of risk can be described either qualitatively (by assessing risks as ‘high’, ‘moderate’ or ‘low’) or quantitatively (by determining a numerical estimate). Qualitative assessments for each hazard or hazardous event can be estimated by identifying the likelihood that the event will happen and the severity of the consequences if it does.

Tables 4.5–4.7 illustrate one approach to estimating the level of risk. These tables were derived from Australian and New Zealand Standard 4360:2004 (Standards Australia/Standards New Zealand 2004a). The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) contains a slightly different version of these tables, and Handbook 436 (Standards Australia/Standards New Zealand 2004a) discusses design, modification and use of these tables. The aim should be to separate risks classed as ‘high’ or ‘very high’ from those classed as ‘low’. This information can then be used to identify preventive measures that can reduce these higher risks to ‘low’ (Section 4.3).

For some hazards, it may be possible to carry out a quantitative or semiquantitative risk assessment. This assessment can provide a numerical estimate of risk, and an indication of whether the risk is tolerable or unacceptable. Quantitative risk assessment uses a four-step process that includes hazard identification, dose–response determination, exposure assessment and risk characterisation. This approach is described in Chapter 3 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006). It provides a quantitative assessment of the likelihood of identified pathogens causing illness. DALYs can then be used to determine the impact of the illness. In this way, concentrations of pathogens can be translated to a DALY score, which can in turn be compared to the defined tolerable level of risk (10^{-6} DALYs /person/year). This approach has been applied to chemicals such as arsenic and bromate, but is more generally used for microbial pathogens.

Although the application of DALYs to chemical parameters is likely to expand, there are insufficient data to develop DALYs for most chemical hazards. In these guidelines, quantitative risk for chemicals is based on comparison with guideline values. These values have been adopted from the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) or derived as described in Appendix A.

Exceedance of the limit of 10^{-6} DALYs per person per year, or of a guideline value, represents a potentially unacceptable risk. The extent of exceedance of DALYs or guideline values, and the frequency at which this is likely to occur, can be used to estimate risk by employing the approach outlined in Tables 4.5–4.7.

Table 4.5 Qualitative measures of likelihood

Level	Descriptor	Example description
A	Rare	May occur only in exceptional circumstances; may occur once in 100 years
B	Unlikely	Could occur within 20 years or in unusual circumstances
C	Possible	Might occur or should be expected to occur within a 5–10-year period
D	Likely	Will probably occur within a 1–5-year period
E	Almost certain	Is expected to occur, with a probability of multiple occurrences within a year

Table 4.6 Qualitative measures of consequence or impact

Level	Descriptor	Example description
1	Insignificant	Insignificant impact or not detectable
2	Minor	Health — minor impact for small population Environment — potentially harmful to local ecosystem with local impacts contained to site.
3	Moderate	Health — minor impact for large population. Environment — potentially harmful to regional ecosystem with local impacts primarily contained to on-site.
4	Major	Health — major impact for small population Environment — potentially lethal to local ecosystem. Predominantly local, but potential for off-site impacts.
5	Catastrophic	Health — major impact for large population. Environment — potentially lethal to regional ecosystem or threatened species. Widespread on-site and off-site impacts.

Table 4.7 Qualitative risk estimation

Likelihood	Consequences				
	1 — Insignificant	2 — Minor	3 — Moderate	4 — Major	5 — Catastrophic
A — Rare	Low	Low	Moderate	High	High
B — Unlikely	Low	Low	Moderate	High	Very high
C — Possible	Low	Moderate	High	Very high	Very high
D — Likely	Low	Moderate	High	Very high	Very high
E — Almost certain	Low	Moderate	High	Very high	Very high

Microbial health risk

A quantitative risk assessment can be applied to microbial hazards, based on the approach described in Chapter 3 and Appendix 2 of Phase 1 of the guidelines (NRMMC–EPHC–AHMC 2006). The approach uses the following reference pathogens:

- *Cryptosporidium* for protozoa and helminths
- a rotavirus and adenovirus combination for enteric viruses

- *Campylobacter* for bacteria.

The default 95th percentile values for these organisms, per litre of sewage are 2000 *Cryptosporidium*, 8000 rotavirus and 7000 *Campylobacter*.

The maximum risk associated with untreated or secondary treated sewage is clearly well above the tolerable level of 10^{-6} DALY per person per year. Using the default 95th percentile values given above, and an average daily consumption of two litres per person per year, the log reductions required to achieve compliance with 10^{-6} DALY per person per year can be calculated using the formula:

$$\text{Log reduction} = \log (\text{concentration in source water} \times 2 \text{ L} \times 365 \text{ days} \div \text{DALYd})$$

where DALYd (the dose equivalent to 10^{-6} DALY) is:

- 1.6×10^{-2} for *Cryptosporidium*
- 2.5×10^{-3} for enteric viruses
- 3.8×10^{-2} for *Campylobacter*.

Using this formula, the minimum log reductions required for production of drinking water from sewage are:

- 8 log *Cryptosporidium*
- 9.5 log enteric viruses
- 8.1 log *Campylobacter*.

Drinking water augmentation schemes will typically include high levels of treatment. A treatment train that incorporates membrane filtration, reverse osmosis and advanced oxidation will provide log reductions that exceed the minimum requirements. Residual risk will therefore be acceptable if the processes are well managed.

Log reductions for stormwater can be calculated in the same manner. The calculations will require input of system-specific data on reference pathogen concentrations. Default values are not available due to the variability of stormwater quality and the influence of catchment characteristics. This topic will be discussed further in Phase 2 of the water recycling guidelines, in the module on stormwater reuse.

Chemical health risk

Inorganic chemicals

Australian and international data show that, for about 20% of chemicals detected in secondary treated sewage or water receiving secondary treated sewage, maximum concentrations exceeded guideline values (Table 4.4).

Larger data sets are generally available for inorganic chemicals, and the 90th and 50th percentile concentrations typically comply, although the maximum concentrations occasionally exceed drinking water guidelines. Treatment processes, such as reverse osmosis and activated carbon, effectively reduce concentrations of inorganic chemicals to below guideline values.

Organic chemicals

Data for organic chemicals indicate exceedances for a number of disinfection byproducts, pesticides and trace organics. The largest exceedances were for:

- benzo(a)pyrene (PAH)
- bromodichloromethane, chloroform and NDMA (disinfection byproducts)
- demeton S (pesticide)
- diatrizoic acid (contrast medium)
- 2,6-di-tert-butyl-1,4-benzoquinone (antioxidant)
- 5-methyl-1H-benzotriazole (industrial anticorrosive)
- paraxanthine (caffeine metabolite)
- propylenedinitrilotetraacetic acid (PDTA, chelating agent).

Reverse osmosis systems will remove pesticides and compounds such as paraxanthine, diatrizoic acid, 2,6-di-tert-butyl-1,4-benzoquinone and PDTA. Combinations of reverse osmosis and advanced oxidation will remove 5-methyl-1H-benzotriazole, benzo(a)pyrene and disinfection byproducts (Ternes and Joss 2006, Snyder et al 2007).

As discussed in later sections, the capability of treatment processes to achieve compliance with drinking water guidelines will require verification (Section 4.5.1) and validation (Section 4.9.1).

Radionuclides

Maximum concentrations of alpha and beta particles detected in secondary treated sewage exceeded drinking water guidelines. The *Australian Drinking Water Guidelines* recommend that, if guideline values are exceeded, radium-226 and radium-228 should be determined; for example, by reverse osmosis (NHMRC–NRMCC 2004).

Dioxins and PCBs

The dioxin-like compounds included in Table 4.4 all have TEFs of 0.01 or lower, which signifies very low toxicity relative to other compounds in this group. Applying these TEFs to the maximum concentrations of all dioxin-like compounds listed in Table 4.4 produces a combined TEQ below 1 pg TEQ/L.

The combined concentration of PCBs presented in Table 4.4 at 0.1 ng/L is also below the calculated drinking water guideline of 0.14 µg/L for total PCBs.

Hormones and pharmaceuticals

Pharmaceuticals and natural hormones excreted by humans on a daily basis are generally present in low concentrations (compared with guideline values) in secondary treated sewage.

In most cases, hormone and pharmaceutical concentrations detected in secondary treated sewage are well below the calculated guideline values (Table 4.4 and Table A8), and would be decreased by treatment (Table 4.10). Concentrations detected in secondary treated sewage were generally more than 100-fold below the calculated guideline values. The concentrations of antibiotics detected in secondary treated sewage were typically low in comparison with the calculated guidelines (Table A8).

The exceptions are alprazolam, valium and the estrogenic hormones. The concentrations of each of these compounds would be reduced to below guideline values by advanced treatments,

including reverse osmosis (Table 4.10) (Ternes and Joss 2006, Costanzo and Watkinson 2007, Snyder et al 2007). Removal of estrogenic hormones has been demonstrated in a number of studies (Huang and Sedlak 2001, Khan and Roser 2007). Testing of recycled water produced at the Orange County Groundwater Replenishment Scheme⁹ (Daugherty et al 2005) and the Singapore NEWater Scheme¹⁰ has not detected 17 α -ethynylestradiol, estrone or 17 β -estradiol.

Risks to the environment

Although the recycled water will be highly treated, the potential for environmental impacts should be considered using the approach described in Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006). Waste products and residuals generated from treatment plants, such as membrane cleaning solutions and brine concentrates, will represent risks to the environment. Treating and processing these wastes will be required to prevent environmental harm. Discharge of wastes should not be considered unless the quality is consistent with the receiving environment.

Identify significant risks and document risk management priorities

Hazard identification and risk assessment provides a mechanism of identifying:

- significant risks
- preventive measures for ensuring control of these risks
- operational monitoring parameters that can be used to check that processes are maintaining control
- parameters to be included in verification monitoring.

Limitations

Realistic expectations for hazard identification and risk assessment are important. For example, for any recycled water scheme, a detailed quantitative risk assessment will be possible only for a limited range of contaminants. Hazard identification and risk assessment are predictive activities that will often include subjective judgment and that inevitably involve uncertainty. Factors that can contribute to uncertainty include:

- lack of high-quality data
- variability in parameter concentrations, and limited data on the extent of this variability
- lack of knowledge on significance of parameters (eg questions such as ‘Do chemicals that affect macroinvertebrates or fish affect humans?’ and ‘Are microorganisms detected in stormwater infectious for humans?’); variability and knowledge uncertainty are discussed in Chapter 2 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

These difficulties do not mean that risk assessment should not be performed or that it is not useful. Complete databases and knowledge are rarely available. One outcome of risk assessments is to identify the level of uncertainty and specific areas where further information and research is required to fill knowledge gaps. Proponents need to have a realistic understanding of the limitations of predictions, and convey this understanding to stakeholders.

⁹ <http://www.gwrsystem.com>

¹⁰ http://www.pub.gov.sg/NEWater_files/download/review.pdf

Periodically review and update hazard identification and risk assessment

The hazard identification and risk assessment needs to be reviewed and updated periodically because changing conditions may introduce important new hazards or modify risks associated with identified hazards.

4.3 Preventive measures for recycled water management (Element 3)

Components: Preventive measures and multiple barriers (Section 4.3.1) Critical control points (Section 4.3.2)

Preventive measures are the actions, activities and processes used to ensure that significant hazards are not present in recycled water or are reduced to acceptable levels. Critical control points are those preventive measures that are essential to prevent or reduce hazards representing high risks to acceptable levels. Compared to other forms of recycling, drinking water augmentation will generally rely more heavily on critical control points.

The multiple-barrier approach used in the management of drinking water quality is an essential requirement. Multiple barriers do not create redundancy — it is rare that a single barrier will remove all traces of individual hazards all of the time. However, having multiple preventive measures or barriers does mean that if one barrier is faulty:

- this does not lead to total loss of control (because other barriers will still be operating)
- it may be possible to temporarily increase the performance of the remaining barriers while remedial action is taken to restore function of the faulty barrier.

Combinations of barriers produce less variability in performance than single barriers (NRC 1998) — providing that barriers act independently, it is unlikely that highs and lows of performance in different barriers will coincide. Table 4.8 provides a simple example of the greater reliability provided by multiple barriers.

Table 4.8 Improved reliability provided by multiple independent barriers

System type	Reliability	Overall reliability
One treatment system able to reduce virus concentrations by 99%	One failure in 1,000 hours of operation	One failure in 1,000 hours of operation
Two independent treatment systems in series, each able to reduce virus concentrations by 90%	One failure in 100 hours of operation for each unit alone One failure in 10,000 hours of operation for common failure of both units	One failure in 10,000 hours of operation (plus 199 events with removal efficiency reduced to 90% instead of 99%)

The advantage of multiple barriers is diminished or even eliminated where one barrier depends on another. For example, the effectiveness of disinfection depends on previous filtration; in this case, poor performance of filtration can increase turbidity, which in turn reduces the effectiveness of disinfection. Similarly, where barriers share power supplies, failure of supply may lead to multiple inoperative systems.

Table 4.8 shows how reliability is increased by multiple barriers. The aim should be to maintain optimum performance of treatment processes at all times. However, this will not always occur. Performance could be reduced during expected events and unexpected incidents. For example, performance will be reduced during routine maintenance and procedures such as filter backwash. Reliability of performance is an important consideration in selecting treatment processes.

4.3.1 Preventive measures and multiple barriers

Summary of actions

- Identify existing preventive measures and estimate the residual risk.
- Identify alternative or additional preventive measures that are required to ensure risks are reduced to acceptable levels.
- Document the preventive measures and strategies addressing each significant risk.

Identify existing preventive measures

Where recycled water schemes are developed from existing infrastructure, established preventive measures need to be identified. These measures should be characterised in relation to performance and effectiveness. The characterisation needs to include consideration of existing quality management systems. For example, sewage treatment plants, drinking water treatment plants and trade-waste programs could have International Organization for Standardization (ISO) or HACCP accreditation.

Residual risk after application of these established preventive measures should be determined.

Identify alternative or additional preventive measures

Additional measures will be required to reduce risks to identified tolerable levels. For drinking water augmentation, this will involve tertiary processes such as membrane filtration, reverse osmosis and high-level disinfection.

Indirect augmentation involves the use of receiving waters between a recycled water treatment plant and a drinking water treatment plant. The receiving waters could be pre-existing infrastructure, such as a drinking water reservoir or aquifer, but could also be a river or stream upstream of the reservoir or aquifer.

Direct augmentation will require higher levels of treatment to provide sufficient assurance that water-quality targets can be met and maintained.

Box 4.1 lists examples of preventive measures for recycled water systems. Examples of treatment trains used in international drinking water augmentation schemes can be found in NRC (1998), US EPA (2004) and Khan and Roser (2007). These include:

- *Orange County Groundwater Replenishment System* — secondary treatment, membrane filtration, reverse osmosis and advanced oxidation
- *Singapore NEWater* — secondary treatment, membrane filtration, reverse osmosis, ultraviolet (UV) light disinfection
- *Upper Occoquan Sewage Authority* — secondary treatment, chemical lime treatment, multimedia filtration, granular activated carbon (GAC) adsorption, chlorination.

Preventive measures need to be applied as close as possible to the source of the hazard, and the focus needs to be on prevention wherever possible. This applies particularly to controlling industrial discharges into sewerage systems, and controlling industrial, agricultural and human discharges into stormwater systems. Effective household collection systems also minimise risks. Water-source protection and trade-waste control are essential elements of effective multiple barrier systems. High levels of treatment will also be required to assure quality of recycled water used to augment drinking water supplies. Tables 4.9 and 4.10 list typical removal efficiencies provided by treatment processes. These removal efficiencies need to be validated (Section 4.9.2); they may also need to be discounted, depending on the sensitivity of operational monitoring (Section 4.4.2).

Selection of preventive measures

A number of factors need to be considered in selecting preventive measures. These factors are based on the range and level of evidence required to validate measurable performance and assessment of the reliability and consistency of performance (Section 4.9).

Strong preference should be given to processes that have been validated using recognised procedures (eg US EPA 2005, 2006b) or by independent agencies (eg State of California 2007). Manufacturers of treatment processes should be able to provide evidence of validation or enough high-quality data to demonstrate that processes have been validated for targeted hazards under relevant conditions (ie for the type and nature of source water in question).

Measurable performance includes two components. The first is the demonstrated performance in terms of hazard reduction; the second is the sensitivity of operational monitoring (Section 4.4.2).

Treatment processes must have a measurable removal efficiency for target organisms or chemical compounds that can be verified through operational monitoring.

Removal efficiency needs to be consistent and reliable. Proponents of drinking water augmentation schemes need to provide evidence that reliability has been considered in selection of processes. When alternative processes or treatment trains are assessed and compared, the preferred choice needs to be the one that is most reliable, and produces the least variability in performance and maximum compliance (see Section 4.9).

Box 4.1 Examples of preventive measures for recycled water systems

Water-source protection and trade-waste control

Examples of water-source protection include preventing or minimising industrial discharges into sewerage networks or stormwater catchments, and protecting stormwater and storages from animal or human waste.

Water treatment

Treatment processes used to remove or reduce hazards include:

- *lagoons and wetlands* — these reduce microbial pathogens through settling and inactivation; the presence of vegetation in wetlands facilitates removal of suspended solids, biochemical oxygen demand (BOD), heavy metals and nutrients (particularly nitrogen)
- *primary and secondary sewage treatment* — these reduce microbial pathogens, biodegradable organics, volatile organic compounds and nutrients
- *tertiary treatment* (eg multimedia filtration with coagulation, sedimentation or flotation, membrane filtration, reverse osmosis, activated carbon, advanced oxidation and disinfection) — these reduce microbial pathogens and chemical hazards.

Detention — indirect augmentation

Microbial pathogens and chemical hazards are reduced by retention in aquifers, soil aquifer treatment, and dilution and detention in reservoirs or rivers and streams.

Management of distribution systems

Distribution systems and storages within distribution systems need to be designed in accordance with standard practices for drinking water systems. Prevention needs to be directed toward protecting the integrity of the system and preventing ingress of contamination through faults, cross-connections, etc.

Users of drinking water

Various education programs can act as preventive measures; for example, programs relating to:

- backflow prevention and cross-connection controls
- correct installation of plumbing and appliances.

Table 4.9 presents an indicative range of microbial log reductions reported in the literature for different treatment processes. This information is typically based on removal efficiency demonstrated by challenge testing; however, operational monitoring may not be sensitive enough to demonstrate these log removals. Further research in this area could provide greater confidence in the sensitivity of operational monitoring for these systems. Table 4.10 presents indicative reductions of organic chemical concentrations.

Tables 4.9 and 4.10 are intended to be informative and should not be used as the design basis for schemes. Scheme proponents must validate the treatment technology for the specific application and operational conditions (ie must demonstrate that they will work).

Table 4.9 Indicative log removals of enteric pathogens and indicator organisms

Treatment	Indicative log reductions ^a							
	<i>Escherichia coli</i>	Enteric bacteria (eg <i>Campylobacter</i>)	Enteric viruses	Phage	<i>Giardia</i>	<i>Cryptosporidium</i>	<i>Clostridium perfringens</i>	Helminths
Secondary treatment	1.0–3.0	1.0–3.0	0.5–2.0	0.5–2.5	0.5–1.5	0.5–1.0	0.5–1.0	0–2.0
Dual media filtration ^b	0–1.0	0–1.0	0.5–3.0	1.0–4.0	1.0–3.0	1.5–2.5	0–1.0	2.0–3.0
Membrane filtration	3.5–>6.0	3.5–>6.0	0.5–>6.0	3–>6.0	>6.0	>6.0	>6.0	>6.0
Ultrafiltration, nanofiltration, reverse osmosis	>6.0	>6.0	>6.0	>6.0	>6.0	>6.0	>6.0	>6.0
Reservoir storage	1.0–5.0	1.0–5.0	1.0–4.0	1.0–4.0	3.0–4.0	1.0–3.5	N/A	1.5–>3.0
Ozonation	2.0–6.0	2.0–6.0	3.0–6.0	2.0–6.0	2.0–4.0	1.0–2.0	0–0.5	N/A
Ultraviolet light	2.0–>4.0	2.0–>4.0	1.0 –>3.0	3.0–6.0	>3.0	>3.0	N/A	N/A
High-level ultraviolet	>6.0	>6.0	>6.0	>6.0	>6.0	>6.0	N/A	N/A
Advanced oxidation	>6.0	>6.0	>6.0	>6.0	>6.0	>6.0	N/A	N/A
Chlorination	2.0–6.0	2.0–6.0	1.0–3.0	0–2.5	0.5–1.5	0–0.5	1.0–2.0	0–1.0

N/A = not available

a Reductions depend on specific features of the process, including detention times, pore size, filter depths and disinfectant

b Including coagulation.

Sources: WHO (1989), Rose et al (1996, 2001), NRC (1998), Bitton (1999), US EPA (1999a, 2003, 2004), Mara and Horan (2003)

Table 4.10 Indicative removals of organic chemicals

Treatment	Percentage removal										
	Pharmaceuticals						Hormones				
	Anti-B(a)p	Antibiotics ^a	DZP	CBZ	DCF	IBP	PCT	Steroid ^b	Anabolic ^c	Fragrance	DBPs NDMA
Secondary (activated sludge)	nd	10–50	nd	–	10–50	>90	nd	>90	nd	50–90	–
Soil aquifer treatment	nd	nd	nd	25–50	>90	>90	>90	>90	nd	>90	>90
Aquifer storage	nd	50–90	10–50	–	50–90	50–90	Nd	>90	nd	–	–
Microfiltration	nd	<20	<20	<20	<20	<20	<20	<20	nd	<20	
Ultrafiltration/ powdered activated carbon (PAC)	nd	>90	>90	>90	>90	>90	nd	>90	nd	>90	>90
Nanofiltration	>80	50–80	50–80	50–80	50–80	50–80	50–80	50–80	50–80	50–80	
Reverse osmosis	>80	>95	>95	>95	>95	>95	>95	>95	>95	>95	25–50
PAC	>80	20–>80	50–80	50–80	20–50	<20	50–80	50–80	50–80	50–80	
Granular activated carbon		>90	>90	>90	>90	>90		>90		>90	>90
Ozonation	>80	>95	50–80	50–80	>95	50–80	>95	>95	>80	50–90	50–90
Advanced oxidation		50–80	50–80	>80	>80	>80	>80	>80	>80	50–80	>90
High-level ultraviolet		20–>80	<20	20–50	>80	20–50	>80	>80	20–50	nd	>90
Chlorination	>80	>80	20–50	<20	>80	<20	>80	>80	<20	20–>80	–
Chloramination	50–80	<20	<20	<20	50–80	<20	>80	>80	<20	<20	

B(a)p = benz(a)pyrene; CBZ = carbamazepine; DBP = disinfection byproduct; DCF = diclofenac; DZP = diazepam; IBP = ibuprofen; NDMA=N-nitrosodimethylamine; nd = no data; PAC = powdered activated carbon; PCT = paracetamol.

a erythromycin, sulfamethoxazole, triclosan, trimethoprim

b ethynylestradiol; estrone, estradiol and estriol

c progesterone, testosterone

Source: adapted from Ternes and Joss 2006, Snyder et al 2007

In selecting preventive measures, it is important to consider hazards within groups (eg antibiotics or viruses) that might be particularly resistant to inactivation or removal. For example, adenoviruses are more resistant than most viruses to UV-light disinfection.

When determining risk, the ability of preventive measures to reduce hazards cannot be based solely on reductions demonstrated in process validation. It is also important to consider the sensitivity of operational monitoring. Section 4.4.2 provides guidance on operational monitoring, and Section 4.9.1 on process validation.

Trade and domestic-waste control

A principle of risk management is that prevention should be applied as close as possible to sources of contamination. Trade and domestic-waste programs meet this requirement. Contamination that presents a challenge to the performance of recycled water treatment plants must be removed, to produce recycled water that is safe for use in drinking water augmentation. Water utilities need to work closely with all industries discharging to sewer to ensure that control of pollution sources is effective. Specific contaminants (eg contrast media, radioisotopes, and medical and laboratory wastes) should be stopped from discharging to sewer.

Education programs are also needed, to reduce inappropriate discharge of chemicals by households. These programs need to be supported by effective collection systems.

Secondary treatment

Secondary treatment reduces overall concentrations of organic chemicals including some human pharmaceuticals, hormones and fragrances. Removal is achieved primarily by the action of biomass, although some chemicals also adsorb to biomass (Ternes and Joss 2006). Removal tends to be variable and compound specific. Some chemicals, including the hormones estradiol and 17 α -ethynylestradiol, and the anti-inflammatory ibuprofen, can be removed to a large extent, whereas other chemicals, such as erythromycin, are difficult to remove.

Low reductions of microbial pathogens can be achieved by well-operated secondary treatment processes. Secondary treatment can include biological nutrient-reduction processes designed to reduce concentrations of nitrogen and phosphorus. The capability of a secondary treatment process to reduce hazards needs to be characterised over an extended period of time, taking into consideration seasonal variances and process upsets. Parameters and operational controls that influence performance need to be monitored at the same time as hazards.

Tertiary treatment

Membrane filtration

Microporous membranes (eg microfiltration and ultrafiltration membranes) are thin porous polymer films with nominal mean pore sizes ranging from less than 0.01 microns (for ultrafiltration membranes) to 1 micron (for the more porous microfiltration membranes). Wastewater containing suspended material comes into contact with the surface of the membrane under pressure. Materials larger than the pores in the membrane are removed on a size-exclusion basis (ie materials larger than the pores are excluded). However, many particles smaller than the nominal pore size of the membrane are also removed because material accumulates on the surface of the membrane (Gagliardo et al 1999). Removal of organic matter can be improved by flocculation (using a coagulant) before filtration (Schäfer 2001).

The primary function of microfiltration and ultrafiltration is to reduce fouling of downstream processes, including reverse osmosis or nanofiltration. Partial removal of organic compounds can be achieved, although generally this will be less than 50% for ultrafiltration (Snyder et al 2007) and less than 20% for microfiltration (Table 4.10). Ultrafiltration combined with PAC can provide higher removals.

Membrane filtration can provide high degrees of microbial removal, with effectiveness depending on absolute pore sizes. Removals can range from 0.5 logs for viruses using microfiltration to greater than 6-log reductions of all pathogens using ultrafiltration.

The performance of a membrane filtration system may be demonstrated in benchtop trials or in pilot plants using laboratory preparations of *Escherichia coli*, *Bacillus subtilis* and bacteriophage as surrogates for bacteria, viruses and protozoa (US EPA 2005). Performance in reducing concentrations of these surrogates needs to be demonstrated in conjunction with measurement of operational monitoring parameters that have been proven to reliably measure the efficacy of the treatment process, such as pressure-based tests, and particle and turbidity monitoring. In most cases the removal efficiency attributed to a membrane filtration process is limited by the sensitivity of the operational monitoring parameter.

Further discussion on operational monitoring is provided in Section 4.4.2.

Nanofiltration

Nanofiltration membranes have nominal pore sizes in the range 0.001–0.01 microns. The fundamental basis for removal of chemicals is size exclusion, although electrostatic repulsion and hydrophobic adsorption can also contribute to removal. Molecular weight cut-offs are of the order of 600 atomic mass units. As shown in Table 4.10, nanofiltration membranes can provide 50–80% removal of organic compounds.

Nanofiltration can provide greater than 6-log reductions of bacterial, viral and protozoan pathogens. However, as with membrane filtration, there are limitations on the log reductions that can be demonstrated by operational monitoring procedures.

Reverse osmosis

Reverse osmosis membranes remove dissolved organic compounds in a process driven by a pressure gradient that forces molecules across semipermeable membranes. The fundamental basis of removal is size exclusion, particularly for molecules such as surfactants, hormones and most pharmaceuticals with molecular weights greater than 100–200 atomic mass units. Electrostatic repulsion, hydrophobic adsorption and chemical shape also contribute to removal, particularly for low molecular weight compounds.

As shown in Table 4.10, reverse osmosis membranes can remove more than 95% of most organic compounds. NDMA, with a molecular weight of 74, is among the organic chemicals with a low level of removal (25–50%). Bellona et al (2004) have described a mechanism for predicting removal of organic compounds by nanofiltration and reverse osmosis.

Challenge studies have shown that reverse osmosis can provide greater than 6-log reductions of bacterial, viral and protozoan pathogens. Again, operational monitoring lacks sensitivity. Typically, the operation of reverse osmosis membranes is monitored using electrical conductivity or total carbon concentrations. These have a relative pathogen reduction sensitivity of <2 log and <3 log respectively.

Activated carbon

Adsorption to activated carbon is a well-established process for advanced removal of trace organic chemicals. Usually derived from charcoal, activated carbon is prepared in a manner that improves its ability to physically adsorb chemicals to its surface. Adsorption is the accumulation of a dissolved chemical (solute) onto a solid surface.

The most common types of activated carbon for water treatment are granular activated carbon (GAC) and powdered activated carbon (PAC). These terms refer to the physical form (particle size) in which the activated carbon is applied. PAC particles are smaller in size and thus have a high surface area; GAC particles are larger and tend to be more easily separated from the water subsequent to treatment. PAC is typically added directly to water, mixed and then separated by gravity or filtration. GAC is commonly used as a filtration medium, with the water being percolated through it.

The effectiveness of PAC and GAC to adsorb a particular chemical can generally be predicted based on how hydrophilic (water loving) or hydrophobic (water repelling) a chemical is. PAC and GAC are effective for the removal of a diverse range of hydrophobic organic compounds, as well as some relatively hydrophobic inorganic compounds such as nitrogen, sulphides and heavy metals. More hydrophilic compounds, such as small carboxylic acids and alcohols, are relatively poorly removed by activated carbon adsorption (Metcalf and Eddy Inc 2003)

GAC and PAC can be highly effective for removal of a wide range of pharmaceuticals, hormones and pesticides (Table 4.10) but do not greatly reduce concentrations of salts and nutrients. In combination with filtration processes, GAC and PAC can produce high-quality water.

Advanced oxidation

Advanced oxidation refers to the use of high-level oxidative processes to degrade organic constituents of wastewaters that are biologically persistent and poorly retained by membranes or activated carbon. Typically, advanced oxidation incorporates combinations of high doses of UV light or ozone with hydrogen peroxide to produce highly reactive hydroxyl radicals. Each of these processes independently degrades organic compounds, but the formation of hydroxyl radicals greatly improves degradation.

The effectiveness of advanced oxidation depends on the contact time and the concentration of scavengers in the water (ie non-target oxidisable species). Dissolved organic carbon (DOC) and carbonate or bicarbonate are generally the most important scavengers in drinking waters. Pretreatment processes such as GAC or reverse osmosis significantly increase oxidation efficiency.

Advanced oxidation has been shown to be highly effective in degrading organic chemicals, such as NDMA, that pass through reverse osmosis membranes.

Advanced oxidation incorporates levels of disinfectants that are much higher than those normally used to disinfect water. It is possible to achieve greater than 6-log reductions of bacterial, viral and protozoan pathogens.

Detention in storages, reservoirs, lakes and aquifers

The greatest advantage provided by detention in water storages and receiving waters is the addition of time. Constructed on-site storages at recycled water treatment plants tend to be relatively small and have limited detention (several hours to days) in comparison to receiving waters such as reservoirs. Sufficient time needs to be provided to allow operational monitoring of recycled water treatment processes to be completed and recycled water quality to be assessed before supply of water to downstream drinking water treatment plants and distribution systems. This allows corrective action to be taken or supply to be stopped before unsafe water is provided to consumers.

Detention in receiving waters can reduce concentrations of microbial pathogens, and provide attenuation or biodegradation of organic compounds. Reductions in concentrations of microbial pathogens will vary depending on conditions such as temperature and other physical characteristics and need to be validated for individual storages taking into account seasonal and water quality variability. Validation needs to be matched with operational monitoring parameters. Concentrations of biodegradable organics will reduce during storage. Dilution in receiving waters will also reduce concentrations of microbial pathogens and chemical hazards.

Reductions of microbial hazards and attenuation of organic contaminants has also been demonstrated in aquifer storage. This will be discussed in greater detail in a subsequent module focussing on managed aquifer recharge.

Soil aquifer treatment

In soil aquifer treatment (SAT), recycled water is applied to spreading basins and allowed to percolate through soil layers in the vadose zone (the zone between the land surface and the watertable — also referred to as the unsaturated zone). SAT with infiltration basins requires soils

that allow both rapid infiltration and filtration overlying unconfined aquifers (US EPA, 2004). Further discussion of SAT is provided in the publication on managed aquifer recharge.

Removal of microbial and chemical hazards is achieved by adsorption to soil particles or soil organic material. Biodegradation of chemicals also occurs. Attenuation then occurs through detention in receiving aquifers.

Further information on preventive measures is provided in Chapter 3 and Appendix 3 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

4.3.2 Critical control points

Summary of actions

- Assess preventive measures throughout the recycled water system to identify critical control points.
- Establish mechanisms for operational control.
- Document the critical control points, critical limits and target criteria.

Assess preventive measures and identify critical control points

‘Critical control points’ are defined as activities, procedures or processes where control can be applied, and that are essential for removing hazards that represent high risks or reducing them to acceptable levels. Although all preventive measures are important, not all of them can be critical control points. To be classed as ‘critical’, control points need to have associated target criteria and critical limits (see below), which can be used in operational monitoring to distinguish between acceptable and unacceptable performance. Operational monitoring needs to be undertaken in a timely fashion to allow corrective action to be taken to protect public health. Online and continuous monitoring is the norm for treatment processes used in drinking water augmentation schemes.

Although identification of critical control points is system specific, most advanced treatment processes are likely to be critical control points. Measures applied to protect source-water quality (eg trade-waste control), and reservoir and aquifer detention, can also be used as critical control points.

It is essential that the ability of critical control points to prevent or reduce target hazards is validated (Section 4.9).

Critical limits and target criteria

The performance of all critical control points has to be assessed by monitoring compliance with critical limits. Critical limits are criteria that separate acceptable from unacceptable performance in controlling the targeted hazard or hazards. The selection of criteria needs to be included in validation of each critical control point. For example, validation of disinfection could be based on demonstrating 2-log inactivation of enteric viruses, provided that a defined Ct — that is, the product of disinfectant concentration (C, in mg/L) and contact time (t, in minutes) — is achieved. In this case, the Ct becomes a validated critical limit.

Critical limits typically incorporate a numerical value and a consideration of time; for example, one critical limit might be ‘failure to provide a minimum disinfectant dose for a certain number of minutes’. Deviation from a critical limit represents loss of control of a process, and indicates that

there may be an unacceptable risk to public health or the environment. Such deviations need to lead to a particular response; that is, immediate corrective action to resume control of the process. Also, it may be necessary to notify the health or environmental regulator.

Target criteria (performance goals) are used to provide early warning that a critical limit is being approached. Target criteria are more stringent than critical limits, so that corrective actions can be instituted before an unacceptable risk to public health or the environment occurs. Where target criteria are exceeded, corrective actions need to be instituted immediately to maintain compliance with critical limits. If this is successful, it will generally not be necessary to notify the health or environmental regulator.

Table 4.11 lists examples of critical control points and parameters that could be used to monitor effectiveness.

Table 4.11 Examples of potential critical control points and monitoring parameters

Potential critical control point	Hazards	Potential critical limit parameters
Industrial discharges		
Telemetry in sewage system	Industrial chemicals	<ul style="list-style-type: none"> • System dependent — could include flow, pH, conductivity, temperature and ultraviolet (UV) scans
Treatment of sewage or stormwater		
Membrane filtration	Enteric bacteria, viruses, protozoa and helminths	<ul style="list-style-type: none"> • Transmembrane pressure • Pressure-based tests • Total organic carbon • Turbidity or particle counts • Flux
Reverse osmosis	Chemical hazards Enteric bacteria, viruses, protozoa and helminths	<ul style="list-style-type: none"> • Transmembrane pressure • Flow meters on permeate and brine • Conductivity in permeate and brine • Total organic carbon
Advanced oxidation	Organic chemicals Enteric bacteria, viruses, protozoa and helminths	<ul style="list-style-type: none"> • UV light dose and transmissivity • Hydrogen peroxide dose rates • Oxidation reduction potential • Turbidity • Flow rate
Reservoir or aquifer detention	Enteric bacteria, viruses, protozoa and helminths, and chemical contaminants	<ul style="list-style-type: none"> • Flow rates (in and out of the reservoir) • Injection rates
Final production of drinking water		
Dual-media filtration	Enteric bacteria, viruses, protozoa and helminths	<ul style="list-style-type: none"> • Filtered water turbidity (average and peak levels) • Particle counters • Flow rate • Head loss
Disinfection and storage	Enteric bacteria, viruses, protozoa and helminths	<ul style="list-style-type: none"> • Disinfectant residual or dose (concentration and time to set minimum Ct) • Temperature • pH

Ct = the product of disinfectant concentration (C, in mg/L) and contact time (t, in minutes); UV = ultraviolet

Document critical control points, critical limits and target criteria

Critical control points, critical limits and target criteria need to be documented.

4.4 Operational procedures and process control (Element 4)

Components: Operational procedures (Section 4.4.1)
Operational monitoring (Section 4.4.2)
Corrective action (Section 4.4.3)
Equipment capability and maintenance (Section 4.4.4)
Materials and chemicals (Section 4.4.5)

Continuous supply of high-quality recycled water is essential for schemes involving drinking water augmentation. Operational procedures, monitoring and process control are key components of ensuring that consistent and reliable performance is achieved and maintained. Monitoring plays a key role in risk management systems, but the focus is shifted from reliance on end-product compliance testing and verification (ie ‘too little too late’) to targeted operational monitoring of processes (ie ‘Is it working now?’). The different types of monitoring have different characteristics:

- *operational monitoring of processes* generally includes a high degree of immediate on-site and field testing and, in the case of drinking water augmentation, a high degree of online, continuous measurements, with 24-hour alarm systems
- *end product compliance testing and verification* tend to be based on laboratory analyses that entail significant time delays before sample results are obtained and any non-compliance is detected.

All types of monitoring are described in Chapter 5 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

4.4.1 Operational procedures

Summary of actions

- Identify procedures required for all processes and activities applied within the recycled water system (source to use).
- Document all procedures and compile into an operations manual.

Identify procedures for processes and activities

Even short periods of sudden change and suboptimal performance can represent a serious risk to public health or the environment. It is therefore vital to ensure that all operations are optimised and continuously controlled, and that preventive measures are functional at all times.

Detailed procedures (process-control programs) are required for the operation of all processes and activities (both ongoing and periodic), from the sewer or stormwater source through to the recycled water user. Examples of process-control programs are given in Box 4.2.

Box 4.2 Examples of process-control program

Examples of process-control programs, several of which are discussed below, include:

- descriptions of all preventive measures and their functions
- documentation of effective operational procedures, including identification of responsibilities and authorities
- procedures for performing operational monitoring
- procedures for implementing corrective actions
- equipment maintenance programs
- procedures for calibrating equipment including online monitoring equipment
- specifications and procedures for selecting materials and chemicals.

Effective implementation of process-control programs relies on the skills and training of operations staff. Operators need to be proficient, able to interpret the significance of changes in recycled water quality and treatment, and able to respond appropriately in accordance with established procedures (Section 4.7 Employee training and awareness).

Procedures are most effective when operations staff are involved in their development, documentation and verification. Participation helps to ensure that all relevant activities are included, improves operator and end-user training and awareness, and fosters commitment to operational and process control.

Procedures must include analysis of results, responses to alarms and implementation of corrective actions.

Document procedures

Process-control programs need to be documented in operations manuals, with controlled copies readily accessible to all appropriate personnel. Due to the complexity of drinking water augmentation schemes and the involvement of multiple treatment processes, one option is to organise manuals into sections dealing with individual components of the recycled water system. Manuals need to document all essential procedures including management and operation of treatment processes, monitoring, calibration of monitoring equipment and maintenance and replacement schedules.

4.4.2 Operational monitoring

Summary of actions

- Develop protocols for operational monitoring of the recycled water supply system, including the scientifically justified selection of operational parameters and criteria, and the routine analysis of results.
- Document monitoring protocols into an operational monitoring plan.

Develop protocols for operational monitoring

The aim of operational monitoring is different from that of recycled water quality monitoring (Section 4.5.1). Operational monitoring is used to assess and confirm the performance of

individual preventive measures through a planned sequence of observations and measurements. It is the means of providing proof and ongoing assurance that performance requirements and water-quality criteria are being met. In this context, operational monitoring includes observational monitoring and testing of parameters at critical control points. Observational monitoring is particularly important for assessing compliance with trade-waste programs. Data from operational monitoring can be used as triggers for immediate short-term corrective actions to protect recycled water quality and to prevent unacceptable risk to human or environmental health.

The main elements of operational monitoring are:

- identification of the preventive measures to be monitored (including industrial and domestic-waste programs)
- identification of the parameters and criteria to be used
- ongoing review and interpretation of results to confirm operational performance
- documentation of protocols and results.

Selection of operational parameters

Operational parameters need to reflect the effectiveness of each process or activity, and provide an immediate indication of performance. Typically, parameters need to be easy to measure and able to be responded to promptly. For example, in-sewer monitoring should be considered as a mechanism for detecting unusual flows or industrial discharges. Most preventive measures used in drinking water augmentation will be subject to online testing with 24-hour monitored alarm systems.

Operational monitoring can include testing of function or activity (eg disinfectant residual, flow rates and membrane integrity). Function is normally monitored using surrogates and indicators. It does not generally include direct measurement of most hazards because of practical difficulties, such as time factors associated with use of laboratory analyses rather than field measurement and cost.

Ideally, operational monitoring for drinking water augmentation will include parameters that:

- can be measured online
- correlate with the removal of targeted hazards or groups of hazards
- demonstrate that processes are operating as required or, alternatively, are operating poorly and require corrective action.

With the possible exception of operational monitoring of microbial inactivation by disinfection (disinfectant dose, Ct, pH, temperature, etc) there are no parameters that meet all of these requirements. However, monitoring of activity and function together provide surrogate and indicator parameters can be effective in gauging operational performance.

In this publication, definitions of surrogate and indicator parameters have been adapted from Drewes (2008) and WHO (2006a) whereby:

- a *surrogate* is a quantifiable parameter that can serve as a performance measure of treatment processes that relate to removal of specific hazards; for example:
 - turbidity for removal of pathogenic microorganisms by filtration
 - conductivity or total organic carbon for removal of chemical hazards by reverse osmosis

- an *indicator* is a chemical or microbial parameter that can be used to measure the effectiveness of a process; chemical indicators are selected to represent characteristics of a family or group of hazards that are relevant to fate, transport and removal; they need to provide conservative assessments for removal.

Surrogates

A range of surrogates have been identified that can be measured online and can be used to provide an indication of acceptable or unacceptable performance. Detection of unacceptable performance always requires an immediate response and, where necessary, implementation of corrective action. However, surrogates may not correlate well with hazards. It is unrealistic to expect that surrogates measured online can correlate with single pathogenic organisms or with microgram or nanogram per litre concentrations of chemicals. It is at best an approximate relationship that, although useful, lacks sensitivity in detecting small changes in hazard reduction of removal.

Perhaps the best known surrogate is turbidity in filtered water. Turbidity is widely used as an indicator of pathogen removal by a range of filtration processes, including membrane filtration. Turbidity can be measured online, and elevated turbidities can provide an indication of poor performance of filtration processes. However, lack of sensitivity has been noted as a particular problem for membrane filtration, with most online methods only capable of detecting gross breaches of integrity. This situation is compounded by the normally high performance levels of membranes. A small breach in a membrane that normally provides a 6-log removal of pathogens could impair performance without necessarily being detected by traditional online monitoring. The drinking water rules set by the United States Environmental Protection Agency (US EPA) specify that the maximum removal credit that a membrane filtration process may claim is the lower value of either the removal efficiency demonstrated during challenge testing (validation), or the maximum log removal value that can be verified by integrity tests (operational monitoring) (US EPA 2005). The latter value is normally substantially lower.

One solution can be to supplement testing for surrogates with functional tests. In the case of membrane filters this can include direct physical integrity tests, such as pressure decay and bubble point tests (US EPA 2005). These direct tests typically have a relative sensitivity of 4–5 log, compared to online tests such as turbidity monitoring and particle counting, which have a relative sensitivity of 1–3 log. Although these tests are more sensitive than online tests, they require the membrane unit to be taken offline. As a default, the US EPA's *Long Term 2 Enhanced Surface Water Treatment Rule* (US EPA 2006a) requires daily integrity testing of membrane units.

Physical integrity tests are more sensitive than surrogate monitoring, but have limitations in detecting minute breaches of membranes (eg, through deterioration of membrane surfaces over time). Such breaches may allow virus particles to pass through membranes. Annual challenge testing could be considered as an additional performance measure to confirm that virus reduction capabilities are maintained over time.

Indicators

Testing for indicator compounds correlates most closely with targeted hazards. However, such compounds are not measurable online; hence, the time for assessment and (where required) implementation of corrective action is longer. Indicators are individual parameters that can be used to measure the effectiveness of treatment processes in removing or inactivating broader groups of hazards that have similar properties. Indicator compounds may or may not be specific hazards (eg heterotrophic plate counts have limited significance for human health but can be useful indicators). Indicator compounds need to:

- have characteristics that can be linked to a predominant removal mechanism (eg filtration, adsorption or oxidation), because different treatment processes target different properties (eg

size in reverse osmosis, adsorption in activated carbon and chemical modification in advanced oxidation)

- be present in concentrations that are representative of the broader class of compounds and are sufficiently high to determine a meaningful degree of reduction through a unit process or a sequence of processes
- be quantifiable using an established, and preferably accredited, analytical method.

Heterotrophic plate count bacteria can be used as a microbial indicator to measure the effectiveness of disinfection against bacterial pathogens. Similarly, chemical compounds can be used to represent larger groups of compounds that share similar properties relating to removal by treatment processes (Chang et al 2002; Snyder et al 2003, Drewes et al 2003, Bellona et al 2004, Snyder et al 2007).

The most sensitive indicator chemicals for assessing the performance of a specific treatment process will be those that are partially removed under normal operating conditions. If the level of removal of the indicator compound is diminished, it will indicate system failure. An indicator compound that is easily removed by the treatment would be less sensitive to partial failure, and an indicator compound that is poorly removed under normal operating conditions would provide little insight into system performance under any conditions.

Monitoring frequency for indicators will vary depending on the treatment process and the characteristics of individual systems. Frequencies are likely to be higher during commissioning and initial phases of operation. The variability in concentrations detected during these stages will also influence frequency of testing. Weekly testing would be reasonable.

Table 4.12 provides examples of operational monitoring parameters including surrogates and indicators.

Table 4.12 Examples of operational monitoring parameters

Treatment process	Hazard	Activity and function	Surrogate parameter	Indicator parameter
Membrane filtration	Enteric bacteria, viruses, protozoa and helminths	Transmembrane pressure Pressure-based tests	Total organic carbon Turbidity or particle counts	
Reverse osmosis	Chemical hazards Enteric bacteria, viruses, protozoa and helminths	Transmembrane pressure Flow meters on permeate and brine Conductivity in permeate and brine	Conductivity Total organic carbon	Boron, N-nitrosodimethylamine, chloroform
Advanced oxidation	Organic chemicals Enteric bacteria, viruses, protozoa and helminths	Ultraviolet light dose and transmissivity Hydrogen peroxide dose rates Oxidation reduction potential		DEET, caffeine, meprobamate
Powdered activated carbon	Organic chemicals	Dose rate, contact time	Total organic carbon	Estrone, caffeine, DEET

Treatment process	Hazard	Activity and function	Surrogate parameter	Indicator parameter
Soil aquifer treatment	Organic chemicals		Total organic carbon	Meprobamate
Chlorination	Enteric bacteria, viruses	Ct, temperature, pH		Heterotrophic plate counts, bacteriophage

Ct = the product of disinfectant concentration (C, in mg/L) and contact time (t, in minutes), used in disinfection; DEET = N,N-diethyltoluamide (N,N-diethyl-3-methylbenzamide); NDMA = N-nitrosodimethylamine
Source: Adapted from Snyder et al 2007, Drewes 2008

As well as measuring parameters, operational monitoring may incorporate observations such as:

- sanitary surveys of:
 - stormwater catchments
 - sanitary surveys of reservoirs and rivers used to receive recycled water
- inspections of industrial waste facilities, sewer integrity and plant equipment.

Validation of operational parameters

The relationship between operational monitoring parameters, process performance and targeted hazard reduction needs to be validated. In the first instance, this can be done using published data combined with evidence provided by manufacturers of processes. Findings can be supported by data from pilot trials, precommissioning and commissioning of processes (Section 4.9.2).

Sampling locations

Sampling locations need to be chosen carefully to ensure that operational monitoring is both effective and reliable. Most treatment processes are monitored using some kind of averaging indicator of performance. This can impair accuracy and sensitivity, for example:

- *Accuracy* — Filtered water turbidity or disinfectant residual might be assessed at one point in space, albeit continually. Differential flow pathways may lead to certain streams of water receiving lower levels of treatment than those measured at the single point. This situation needs to be considered and avoided. Critical monitoring equipment needs to be correctly positioned.
- *Sensitivity* — If there are multiple filter units and turbidity is measured as an average of all units, it may be possible for some filtration units to experience significant breakthrough without raising the average turbidity above critical levels. As a result, breakthrough could be missed, making the monitoring unreliable. Therefore, the performance of individual units need to be monitored.

Systems need to be designed with as few opportunities for failure as possible. Operational monitoring is the cornerstone of quality assurance and should never be compromised. The cost of missing a failure due to inadequate monitoring will far outweigh the cost of appropriate and necessary monitoring equipment. Averaging is acceptable for analysing representative samples, but not where poor treatment or performance could be missed.

Automatic monitoring and alarms

Outputs from continuous online testing need to be monitored automatically, with excursions (ie deviations from set limits) activating alarms. Systems must be established to ensure that alarms

are received immediately, 24 hours a day. Every alarm must be investigated without fail. It is never acceptable to assume that an alarm might be false.

Online monitoring systems must be calibrated regularly. Calibration records will alert operators to instrument drift and to the fact that procedures may need to be altered accordingly.

Where critical limits are exceeded, automatic shut-off of supply or flow needs to be considered. Supply or flow should only resume after an operator has ensured that any faults have been corrected and acceptable performance has been restored.

Automatic monitoring equipment needs to include the capacity to record and store results. Excursions need to be logged and responses documented.

Analysis of results

Results must be reviewed frequently to confirm compliance with operational criteria and critical limits. Results should also be reviewed to assess reliability and consistency of performance of treatment trains. Variations in water quality should be within acceptable ranges established by assessments of system reliability. Reviews need to include an assessment of compliance with monitoring protocols, including frequency of testing. Those responsible for interpreting and recording operational results need to understand how the results should be assessed.

A system needs to be established for regular reporting of operational monitoring results to relevant staff, sections and organisations, using methods such as graphs or trend charts to facilitate interpretation.

Document monitoring protocols

Operational monitoring protocols need to be documented in a monitoring plan. The plan should include sampling and monitoring procedures, parameters, testing frequencies, limits and criteria and reporting requirements.

4.4.3 Corrective action

Summary of actions

- Establish and document procedures for corrective action to control excursions in operational parameters.
- Establish rapid communication systems to deal with unexpected events.

Establish and document procedures for corrective action

Procedures need to be developed to re-establish process control immediately in situations where target criteria or critical limits are not met. The procedures need to include instructions on required adjustments, process-control changes and additional monitoring. Where non-compliance leads to temporary cessation of supply of recycled water, procedures need to be established to deal with storage or discharge of the substandard water.

Box 4.3 lists possible corrective actions. Responsibilities and authorities, including communication and notification requirements, need to be clearly defined.

Further information on management of incidents and emergencies is provided in Section 4.6.

Box 4.3 Possible corrective actions

Examples of possible corrective actions include:

- identifying sources of chemical contaminants and reinforcing trade-waste controls
- replacing membranes
- increasing the frequency of backwashing
- optimising coagulant control
- changing treatment chemicals and using auxiliary chemicals such as coagulant aids, flocculant aids and filtration aids
- adjusting pH
- varying chemical feed rates and feed points
- adjusting filtration loading rate or operation
- increasing disinfectant dose
- flushing and cleaning of the supply system.

It is important to verify whether a corrective action has been effective, and this will usually require additional monitoring. Other factors that need to be considered are secondary impacts of the corrective action, and whether consequent adjustments or action may be needed in downstream processes.

Establish rapid communication systems to deal with unexpected events

Because it is not possible to predict all types of potential incidents, rapid communication systems need to be established to deal with any unanticipated types of event. Responses also need to be prepared for the worst-case scenario, in which corrective actions do not re-establish operational performance sufficiently quickly to prevent recycled water of unacceptable quality from reaching consumers. This should include ‘boil water’ and ‘avoid use’ notices (Section 4.6).

4.4.4 Equipment capability and maintenance

Summary of actions

- Ensure that equipment is adequately designed and provides sufficient flexibility and process control.
- Establish a program for regular inspection and maintenance of all equipment, including monitoring equipment.

Ensure that equipment is adequate

Equipment and infrastructure need to be adequately designed and of sufficient capacity (eg size, volume and detention times) to handle all flow rates (peak and otherwise) without limiting performance. Hydraulic overload of processes may compromise performance. Rapid changes in hydraulic loading (such as those expected in stormwater systems) must be considered in the design phase.

Design features that can improve performance and process control include:

- online measuring devices that monitor operational parameters continuously

- automated responses to changes in water quality
- backup equipment, including power generators
- variable control of pump rates and chemical dosing
- effective mixing facilities.

Design of equipment and processes needs to be validated (Section 4.9.2 Design of equipment). Equipment used to monitor process performance needs to be selected carefully and needs to be appropriate for the required tasks. Monitoring equipment needs to be sufficiently accurate and sensitive within required measurement ranges. Monitoring equipment failures should not compromise the system and, in some cases, particularly at critical control points, backup equipment should be available.

Establish a program for inspecting and maintaining equipment

Operators need to understand the operation of monitoring equipment so that causes of spurious results can be recognised and rectified. All equipment, from source to point of use, needs to be regularly inspected and maintained to ensure continuing process capability. A maintenance program needs to be established and documented. The program should detail:

- operational procedures and records for the maintenance of equipment, including the calibration of monitoring equipment
- schedules and timelines
- responsibilities
- resource requirements.

4.4.5 Materials and chemicals

Summary of actions

- Ensure that only approved materials and chemicals are used.
- Establish documented procedures for evaluating chemicals, materials and suppliers.

Ensure only approved chemicals and materials are used

Chemicals and materials used in recycled water systems have the potential to adversely affect water quality. Treatment chemicals added to recycled water include disinfectants, oxidants, coagulants, flocculants, antioxidants, softening agents, membrane cleaning agents, pH adjusters and antiscalants.

All chemicals need to be evaluated for potential contamination, chemical and physical properties, maximum dosages, behaviour in water, migration and concentration build-up. In addition, the potential impact of such chemicals on materials used in treatment plants or on the environment need to be considered. Chemicals used in treatment processes must be securely stored to avoid spills or leakage.

Chemical suppliers need to be evaluated and selected on their ability to supply product in accordance with required specifications. Documented procedures for the control of chemicals — including purchasing, verification, handling, storage and maintenance — need to be established, to assure their quality at the point of application. Responsibilities for testing and quality assurance of chemicals (supplier, purchaser or both) need to be clearly defined in purchase contracts.

Contaminants may also be introduced when recycled water comes into contact with materials such as filter media, protective coatings, linings and liners, jointing and sealing products, pipes and fittings, valves, meters and other components.

Products and materials used in recycled water infrastructure and plumbing systems need to be authorised or approved to ensure compliance with:

- AS/NZS 3500 (*Plumbing and Drainage Code*; Standards Australia/Standards New Zealand 1996–2003)
- AS/NZS 4020 (*Testing of Products for Use in Contact with Drinking Water*; Standards Australia/Standards New Zealand 1999)
- Water Services Association of Australia (WSAA) *Sewerage Code Version 2.1* (WSAA 2002a)
- WSAA Water Supply Code (*Dual Water Supply Supplement Version 1.1*) (WSAA 2002b).

4.5 Verification of recycled water quality and environmental performance (Element 5)

<p>Components: Recycled water quality monitoring, including monitoring of application site and receiving environment (Section 4.5.1)</p> <p>Documentation and reliability (Section 4.5.2)</p> <p>Satisfaction of users of recycled water (Section 4.5.3)</p> <p>Short-term evaluation of results (Section 4.5.4)</p> <p>Corrective action (Section 4.5.5)</p>
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Verification (ie ‘Did it work?’) assesses the effectiveness of the recycled water system in delivering safe drinking water to consumers. Verification includes compliance testing of the end-product, and testing of environmental buffers and receiving waters. Unlike operational monitoring, verification is not used as a continuous or day-to-day management tool. However, successful verification provides:

- confidence for all recycled water stakeholders, including consumers and regulators, in the quality of the water supplied and the functioning of the system as a whole
- confidence that environmental targets are being achieved
- an indication of problems and a trigger for corrective actions, or incident and emergency responses.

Verification may be conducted more frequently during the first weeks and months of operation, to demonstrate that water-quality targets are being achieved, and to provide confidence to operators and consumers that target criteria for water quality can be reliably achieved.

<p>All types of monitoring are described in Chapter 5 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).</p>
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4.5.1 Recycled water quality monitoring

Summary of actions

- Determine the characteristics to be monitored.
- Determine the points at which monitoring will be undertaken.
- Determine the frequency of monitoring.

Determine characteristics to be monitored

An extensive range of parameters can represent a risk or be perceived as representing a risk. It is not physically or economically feasible to test for all parameters, nor is it necessary. The list of chemicals provided in Table 4.4 should not be regarded as a mandatory set of parameters to be included in monitoring programs. Monitoring effort and resources need to be carefully planned.

Key characteristics that need to be considered for verification include:

- microbial indicator organisms
- health-related chemicals, including
 - those identified in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004)
 - key organic chemicals of concern (eg NDMA)
 - indicators or index chemicals for organic chemicals (eg contraceptive hormones)
- biological activity.

The choice of specific parameters needs to be informed by hazard identification and risk assessment (Section 4.2). Factors to be considered include source water quality; potential agricultural and industrial inputs; treatment processes, chemicals and byproducts; and receiving water quality. In designing verification programs, it is useful to consider the monitoring of input quality undertaken for system assessment (Section 4.2). For example, routine verification of recycled water quality may not require testing for pesticides and industrial chemicals that are not used or discharged in source water catchments and are not detected in monitoring of source water quality. Verification monitoring should include chemicals detected in high concentrations in source waters, particularly those that have either exceeded drinking water guideline values or have been detected in concentrations close to guideline values.

Snyder et al (2007) and Ternes and Joss (2006) selected suites of index parameters based on factors including:

- occurrence (based on published data), ensuring inclusion of a variety of physicochemical properties, to reflect variable responses to treatment (eg size; polarity; aromaticity; acidic, basic and neutral functional groups; and volatility)
- representatives from key groups of hormones, pharmaceuticals and personal-care products
- availability of analytical capability, including availability of analytical standards.

Availability of analytical capability is an important issue. Many of the compounds listed in Table 4.4 are not typically included in drinking water quality monitoring programs. It is important to establish whether there is access to laboratories accredited to perform the required tests and able to detect concentrations below guideline values. Where analytical procedures are not available to detect parameters below guideline values, it will instead be necessary to rely on validation to demonstrate that treatment processes are capable of removing the parameter of

concern. An example of such validation could be spike testing of pilot plants or inclusion of a surrogate parameter of similar physicochemical properties in verification monitoring programs (based on the approach of Snyder et al 2007).

Verification will typically include a broad range of parameters during commissioning and in the initial months of operation. Once sufficient data has been collected to confirm that water of the desired quality is being reliably produced, the list of parameters and monitoring frequencies can be reviewed and refined.

Biological screening assays

Traditional assays for chemicals do not deal with the issues of complex mixtures or biological activity. Both of these issues have been raised for drinking water in general, and for drinking water augmentation schemes in particular.

Biological activity is most commonly raised as an issue for chemicals, including natural human hormones that might cause endocrine disruption. Fish exposed to treated sewage have exhibited reproductive abnormalities (Jobling and Tyler 2003). As discussed above (Section 4.2.2), it is difficult to extrapolate from these observations to possible effects on human health from much lower levels of such chemicals in highly treated recycled water. Nevertheless, it may be useful to include biological screening assays in verification monitoring programs. Biological assays can also provide an indication of potential impacts of complex mixtures contained in recycled water.

International experience has shown that biological monitoring of recycled water after complete treatment does not detect any biological activity (NRC 1998, NEWater¹¹, Khan and Roser 2007). Product water should be tested, but it is also informative to test source water and water after initial treatment steps (eg after secondary treatment), to verify the effectiveness of treatment processes.

In vitro tests have been used to measure chemical quality of Australian sewage (Leusch et al 2005 and 2006, Muller et al 2007), and a similar approach could be used to monitor the quality of source waters, and of partially and completely treated recycled water. Detection of biological activity should lead to further investigations into the cause of that activity. Biological tests can be used as a screening and prioritisation tool for subsequent chemical analysis.

A range of bioassays can be applied to test for end points such as genotoxicity, mutagenicity, tumour induction, whole-animal toxicity, estrogenicity and androgenicity (Leusch et al 2006, Chapman 2007, Khan and Roser 2007, WERF 2007). Biological screening can include both in vivo and in vitro assays.

Selection of tests will be influenced by a range of factors, including the end point of interest and availability and accessibility to laboratories able to undertake testing. Due to ethical considerations and speed of completion, in vitro tests should take priority. Researchers are evaluating and comparing the efficacy and sensitivity of in vitro tests, and the findings will influence test selection (CRCWQT 2007).

In vivo assays

In vivo tests can include assessments for a range of end points, including whole-animal toxicity, carcinogenicity, androgenicity or estrogenicity. Whole-animal tests often use mice and rats, and guideline values for many chemicals have been generated from this type of testing. However, there are ethical issues that have to be addressed before this type of testing can be applied, and applicability of the finding to humans can vary. Testing using mice and rats can take anything from several months to years. In Singapore, for example, a mice-feeding study over two years was

¹¹ http://www.pub.gov.sg/NEWater_files/index.html

undertaken in association with the NEWater scheme¹². One alternative is to use fish, which can be exposed to recycled water continuously, and are relative inexpensive to maintain. Disadvantages of fish are that (NRC 1998):

- fish and humans differ significantly in biological terms
- being completely immersed in water, the sensitivity of fish gills, in particular, may result in overestimation of acute toxicity
- pharmacokinetics and metabolism of chemicals in fish may differ significantly from mammals.

In vitro assays

In comparison to whole-animal assays, in vitro testing — performed at the molecular or cellular level — can provide results within hours or days. Examples of molecular end points include binding to specific biological receptors or induction of particular biomolecular pathways, whereas cellular events could be cell death, maturation or growth. In vitro assays can be based on human cells, thus eliminating the interspecies predicament of in vivo testing (Barratt et al 1995). In vitro tests can also detect biological effects at much lower, environmentally relevant concentrations, which are often below detection limits of chemical analysis and in vivo testing (Asano and Cotruvo 2004).

Limitations to in vitro bioassays include a lack of metabolism and transport mechanisms — factors that may modulate toxicity in whole organisms (NRC 1998). Nevertheless, in vitro bioassays can be useful adjuncts to traditional analyses for individual parameters, and there has been progress in standardising in vitro tests; for example, through programs such as those operated by the European Centre for the Validation of Alternative Methods¹³ and the US National Toxicology Program Interagency Centre for the Evaluation of Alternative Toxicological Methods.¹⁴

Determine points at which monitoring will be undertaken

Verification includes regular sampling and testing to assess whether recycled water quality is meeting guideline values, regulatory requirements and agreed levels of service.

The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) provides guidance on how to provide water that is safe at the point of use (eg kitchen or bathroom tap), and the same approach needs to be adopted for drinking water augmentation schemes. Verification will need to include monitoring at point of use.

Proponents may also elect to produce recycled water that is safe to drink before it is added to receiving waters and drinking water supplies (ie after recycled water treatment). In this case, verification of recycled water quality will also be applied at the point of entry into the receiving water. This could reduce the range of parameters included in point-of-use monitoring. However, potential impacts of the recycled water on receiving waters (eg growth of cyanobacteria promoted by nutrients in recycled water) will need to be considered.

In addition to assessing drinking water quality, verification monitoring may also need to consider compliance with other environmental values. These could include recreational use of receiving waters, agricultural use and protection of ecosystems.

¹² http://www.pub.gov.sg/NEWater_files/index.html

¹³ <http://ecvam.jrc.cec.eu.int/index.htm>

¹⁴ <http://iccvam.niehs.nih.gov/>

Determine frequency of monitoring

Frequency of testing for individual characteristics will depend on variability. Sampling needs to be sufficiently frequent to obtain meaningful information. Guidance on frequency of monitoring is provided in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004).

From a public health perspective, microbiological quality is generally subject to more frequent testing than chemical quality. Exposure to microbial pathogens can lead to immediate illness, whereas, in the absence of a specific event (eg chemical overdosing at a treatment plant), episodes of chemical contamination leading to acute health concerns are rare. Health-based guideline values for most chemical parameters are based on effects of chronic exposure. However, public concern associated with drinking water augmentation is likely to focus on chemical quality. This will increase requirements associated with chemical testing. Monitoring frequencies are likely to exceed those specified in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004). Indicative frequencies are presented in Table 5.2. The high level of removal or inactivation of microbial hazards by typical treatment trains also decreases the relative requirement for testing of microbial parameters.

From an environmental perspective, chemical testing in receiving waters will be required. Environmental impacts of some parameters can be acute and, in these cases, more frequent sampling is required. However, most environmental impacts follow chronic exposure, and sample frequency can often be monthly or yearly, rather than continuously or daily. Sampling frequency will also depend on the level of risk and confidence in preventive measures in place. Monitoring of receiving waters will generally incorporate testing of aquatic biota, including macroinvertebrates and growth of cyanobacteria. Greater detail is provided in Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

4.5.2 Reliability and documentation

Summary of actions

- Establish and document a sampling plan for each characteristic, including the location and frequency of sampling, ensuring that monitoring data is representative and reliable.

Establish a sampling plan and ensure monitoring is reliable

Once parameters and sampling locations have been identified, these need to be documented in a consolidated monitoring plan. Monitoring programs need to provide data that is representative, reliable and fully validated. This means that:

- approved sampling methods and techniques need to be applied
- analyses need to be performed by laboratories accredited for the purpose (where accredited methods have been established)
- field and laboratory equipment need to be maintained and calibrated
- limits of detection and characteristics measured need to be appropriate (limits of detection need to be below concentrations representing potential health risks)
- all procedures need to be performed by qualified personnel and be subject to quality-assurance and quality-control procedures.

Monitoring programs need to also consider requirements associated with assessment of data (Chapter 5 in Phase 1 of the water recycling guidelines, NRMMC–EPHC–AHMC 2006).

4.5.3 Satisfaction of recycled water users

Summary of actions

- Establish a feedback program for users of recycled water.
- Establish programs for receiving and dealing with complaints including appropriate training of people responsible for the program.

Establish a user complaint and response program

User satisfaction is vital in ensuring the ongoing success of drinking water augmentation. A program for assessing satisfaction should be established.

Although comments and complaints from users of recycled water are often based on perceptions of water quality and aesthetic issues, they should not be dismissed because they can provide valuable information on problems that may not have been identified by traditional monitoring programs.

User comments and complaints should always be considered and documented. Contact details of complainants should always be recorded (with permission), so that they can be followed up, and further details obtained if necessary. A complaint and response program needs to be established and operated by appropriately trained personnel. Dissatisfaction with recycled water schemes, if not dealt with appropriately, may lead to negative perceptions that have a potential to escalate. Complaints and responses need to be evaluated according to type, pattern and frequency.

The accuracy and value of user feedback will be influenced by levels of knowledge. Thus, complaints and responses will reflect the effectiveness of ongoing consultation and education programs, and should be used to evaluate these initiatives.

4.5.4 Short-term evaluation of results

Summary of actions

- Establish procedures for the short-term review of monitoring data and satisfaction among users of recycled water.
- Develop reporting mechanisms internally and externally, where required.

Establish procedures for short-term review

Short-term performance evaluation involves review of monitoring data and satisfaction of users of recycled water to verify that:

- the quality of water supplied to consumers conforms to established targets, guideline values and regulatory requirements, and meets user expectations
- the quality of receiving environments complies with approval conditions.

In cases of non-conformance, corrective actions need to be taken immediately, or incident and emergency responses implemented.

Timeframes for reviewing results need to be established and adhered to. Those responsible for interpreting and recording results need to understand clearly how results should be assessed and

communicated. Procedures for performance evaluation and recording of results need to be established and documented.

Develop reporting mechanisms

Mechanisms and responsibilities need to be identified for the reporting of results, both internally (to operators and managers) and externally where necessary (to stakeholders such as regulators and recycled water consumers). More detail on reporting is given in Section 4.10.

4.5.5 Responses to non-conformance

Summary of actions

- Establish and document procedures for corrective action in response to non-conformance or feedback from users of recycled water.
- Establish rapid communication systems to deal with unexpected events.

Establish procedures for corrective action

Where evaluation of results indicates non-conformance, an investigation needs to be initiated immediately. Individual results need to be assessed in the context of system performance and supporting data. Effectiveness of preventive measures and associated operational monitoring needs to be reviewed. If necessary, corrective action needs to be implemented. Failure to take immediate or effective action may lead to situations requiring activation of incident and emergency response protocols (Section 4.6). Corrective action may also be required in response to information or reports from users of recycled water. Corrective actions need to be developed in consultation with relevant regulatory authorities and other stakeholders.

Establish rapid communication systems to deal with unexpected events

It is important to respond immediately to system failures that could pose a risk to public health or the environment, or adversely affect water quality. Such failures need to be immediately reported to the relevant health or environment authority (Section 4.6). Corrective actions need to be documented, responsibilities and authorities need to be clearly defined both internal and external to the organisation, and staff need to be trained in appropriate procedures.

4.6 Management of incidents and emergencies (Element 6)

Components: Communication (Section 4.6.1)

Incident and emergency response protocols (Section 4.6.2)

Continuous performance and compliance with targets should always be the goal of any water recycling scheme, but it is unrealistic and potentially dangerous to expect that faults and incidents will not occur. In most cases, considered, controlled and timely responses will prevent such events from posing a risk to public health or requiring public notification.

Protocols need to be established for dealing with identifiable events such as power outage, equipment breakdown, exceedance of monitoring criteria and consumer dissatisfaction. Such responses protect public and environmental health, and help to maintain the supplier's reputation

and confidence among users of recycled water. Some events cannot be anticipated. Therefore, utilities must 'expect the unexpected'. Where such incidents occur, the organisation must be able to adapt to the circumstances, and respond constructively and efficiently.

Some of the potential hazards and events that can lead to emergency situations or incident investigations are listed in Box 4.4.

Box 4.4 Hazards and events that may lead to emergency situations or incident investigations

Potential hazards and events that can lead to emergency situations include:

- non-conformance with critical limits, guideline values and other requirements
- accidents that increase levels of contaminants or cause failure of treatment systems (eg spills in catchments, illegal discharges into collection systems and incorrect dosing of chemicals)
- equipment breakdown and mechanical failure
- prolonged power outages
- extreme weather events (eg flash flooding and cyclones)
- natural disasters (eg fire, earthquakes and lightning damage to electrical equipment)
- human actions (eg serious error, sabotage and strikes)
- cyanobacterial blooms in storages or waterways
- illegal or accidental cross connections
- kills of fish or other aquatic life in receiving waters

4.6.1 Communication

Summary of actions

- Define communication protocols with the involvement of relevant agencies and prepare a contact list of key people, agencies and stakeholders.
- Develop a communications strategy for the public and media.

The immediate questions asked when an incident is communicated to the public are:

- What happened?
- Why did it happen?
- What are the impacts?
- When was it detected?

These questions need to be dealt with openly and with as much clarity as possible. Gathering information to include in answers is important, but cannot be allowed to delay communication. Telling stakeholders that they have been exposed to a risk that was detected days or even many hours ago is unacceptable and will immediately undermine confidence.

Define communication protocols with the involvement of relevant agencies

Effective communication is vital in managing incidents and emergencies. Clearly defined protocols for both internal and external communications need to be established, with the involvement of relevant agencies, including health, environment and other regulatory agencies. The protocols need to define time requirements and mechanisms for reporting. Potentially serious incidents need to be notified immediately and verbally; they should also be provided in written form to ensure that they are received.

Protocols need to include a contact list of key people, agencies and businesses; detailed notification forms; procedures for internal and external notification; and definitions of responsibilities and authorities. Contact lists need to be updated regularly (eg six-monthly) to ensure they are accurate. Systems need to be established to ensure that changes in contact details are notified.

Develop a public and media communications strategy

User confidence and trust during and after an incident or emergency is essential and will be influenced by how incidents and emergencies are handled. A public and media communication strategy needs to be developed before any incident or emergency situation occurs. Draft public and media notifications should be prepared in advance of any incident, and need to be appropriately designed for the target audience. An appropriately trained and authoritative contact person needs to be designated to handle all communications in the event of an incident or emergency. Lead agencies need to be identified for delivery of public and media notifications. Generally, lead agencies will be health agencies where the incident represents a potential risk to public health, environment agencies where the incident could impact receiving waters, and suppliers where incidents involve interruptions or restrictions to supply. Issuing of notifications from multiple sources should be avoided because this increases the potential for conflicting and confusing messages. Where incidents involve different aspects (eg health impacts and interruptions to supply) joint advice and joint media conferences should be considered.

All employees need to be kept informed during any incident for their own needs, and because they provide informal points of contact for the community.

Consumers need to be told when an incident has ended; they also need to be provided with information on the cause and actions taken to minimise future occurrences. This type of communication helps to allay community concerns and restore confidence in the water supply. Surveys of the community after an incident are valuable for establishing how users of recycled water perceived the events and how they were managed.

Further information on communication and consultation is given in Chapter 6 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006).

4.6.2 Incident and emergency response protocols

Summary of actions

- Define potential incidents and emergencies, and document procedures and response plans with the involvement of relevant agencies.
- Train employees and regularly test emergency response plans.
- Investigate any incidents or emergencies and revise protocols as necessary.

Define potential incidents and emergencies, and document procedures and response plans

Incident and emergency response protocols are essential. Plans and procedures must be established during normal operation; trying to establish protocols in the middle of an incident is a recipe for disaster. Potential incidents and emergencies need to be defined, criteria need to be identified and response plans developed and documented in advance of any incident. Plans and procedures need to be developed in consultation with relevant regulatory authorities and other key agencies, and should be consistent with existing government arrangements for emergency responses.

Key areas to be addressed in incident and emergency response plans include clearly specified:

- response actions, including increased monitoring
- responsibilities and authorities, both internal and external to the organisation
- predetermined agreements on which agency will take the lead for decisions on potential health or environmental impacts
- plans for alternative water supplies
- communication protocols and strategies, including notification procedures (internal, regulatory body, media and public)
- mechanisms for increased health or environmental surveillance.

Train employees

Employees need to be trained in emergency response and incident protocols. Emergency response plans need to be regularly reviewed and practised. Such activities improve preparedness and provide opportunities to increase the effectiveness of plans before an emergency occurs.

Investigate incidents and emergencies, and revise protocols

Following any incident or emergency situation, an investigation needs to be undertaken and all involved staff need to be debriefed, to discuss performance and address any issues or concerns. The investigation needs to consider questions such as:

- What was the initiating cause of the problem?
- How was the problem first identified or recognised?
- What can be done to prevent the problem from occurring again?
- What were the most critical actions required?
- How effective were the corrective actions?
- What communication problems arose and how were they addressed?
- What were the immediate and longer term consequences?
- How well did the emergency response and communication protocol function? Are any changes required?

Appropriate documentation and reporting of the incident or emergency also needs to be established. The organisation needs to learn as much as possible from the incident, to improve preparedness and planning for future incidents. Review of the incident may mean that emergency response and communication protocols need to be amended. It may also necessitate changes in other aspects of system management including operational procedures, process controls and corrective actions.

Input needs to be sought from stakeholders affected by incidents and emergencies and from regulators. Outcomes of investigations need to be communicated to regulators. Changes to existing protocols should be approved by regulators.

4.7 Operator and contractor awareness and training (Element 7)

Components: Operator and contractor awareness and involvement (Section 4.7.1)

Operator and contractor training (Section 4.7.2)

The importance of operator capability is often underestimated. Establishment of a drinking water augmentation scheme requires construction of recycled water systems and design of comprehensive risk management systems. However, effective ongoing implementation over the lifetime of schemes relies on the skills, awareness and commitment of operators and contractors, who need to be trained to maintain a precautionary approach. This training needs to include the need to react to any faults or changes in performance, and to report these events and any doubts about performance of any action or process that might affect recycled water quality.

New employees need to receive sufficient training before being given responsibility for key processes.

Organisations that operate drinking water augmentation schemes are responsible for ensuring that all personnel with responsibilities related to the scheme have sufficient training, qualifications and expertise to undertake their tasks. Overall operation of treatment trains — including the performance of operators and contractors — needs to be supervised by managers with appropriate engineering and quality assurance expertise.

4.7.1 Operator and contractor awareness and involvement

Summary of actions

- Develop mechanisms and communication procedures to increase operator and contractor awareness of, and participation in, recycled water quality management and environmental protection.

Develop mechanisms and procedures to increase awareness and participation

Operators and contractors need to be aware of the potential consequences of system failure, and of how decisions can affect public and environmental health. There are notable examples of serious incidents occurring or being exacerbated by the operator failing to appreciate the consequences of their actions. The outbreak linked to drinking water in Walkerton, Canada provides a clear example of poor operator skills and understanding — 7 people died and more than 2000 became ill in an incident that could easily have been avoided (Hrudey and Hrudey 2005).

Operators and contractors

In addition to understanding their individual responsibilities, operators and contractors need to understand the principles of recycled water quality management. All operators and contractors need to be aware of:

- how their actions can affect water quality and public and environmental health
- roles and responsibilities of employees and departments
- the organisation's recycled water quality policy
- the principles of risk management
- characteristics of the recycled water supply system and of preventive strategies in place throughout the system
- regulatory and legislative requirements.

Methods to increase employee awareness can include employee education and induction programs, newsletters, guidelines, manuals, notice boards, seminars, briefings and meetings.

Operator and contractor participation and involvement in decision making is an important part of establishing the commitment needed to continually improve recycled water quality management. Operators need to be encouraged to participate in decisions that affect their areas of responsibility. This provides a sense of ownership for decisions made and their implications. Open and positive communication is the foundation for a participatory culture, and operators need to be encouraged to discuss issues and actions with management. This includes the need for additional training.

Operators need to acknowledge their responsibilities.

4.7.2 Operator and contractor training

Summary of actions

- Ensure operators and contractors maintain appropriate experience and qualifications.
- Identify training needs and ensure resources are available to support training programs.
- Document training and maintain records of all training sessions.

Ensure operators and contractors maintain appropriate experience and qualifications

All personnel involved in the operation of a recycled water system need to have the appropriate skills and training to undertake their responsibilities. Operators and contractors must be appropriately skilled and trained in the management and operation of recycled water supply systems because their actions can have a major impact on water quality, and on public and environmental health.

Operators and contractors need to have a sound knowledge base from which to make effective operational decisions. This requires training in the methods and skills required to perform their tasks efficiently and competently, as well as knowledge and understanding of the effect their activities can have on water quality. For example, treatment plant operators should understand water treatment concepts, and be able to apply these concepts and adjust processes appropriately to respond to variations in water quality.

Identify training needs and resources

Training needs should be identified and adequate resources made available to support appropriate programs. Where available, accredited training and certification programs should be used. The programs need to be relevant to the responsibilities of the operator. Production of recycled water for addition to drinking water supplies will involve advanced and highly technical processes. Operators need to have the necessary skills to run the specific processes included in drinking water augmentation schemes. Training and skills in operating secondary treatment plants, for example, are not sufficient.

Operators and contractors need to be trained in specific aspects and programs associated with individual schemes, including incident and emergency response, documentation, record keeping and reporting.

Minimum training and qualification needs need to be established for new employees.

In addition to formal training courses, other mechanisms include in-house training, on-the-job experience, mentor programs, workshops, demonstrations, seminars, courses and conferences. Training programs need to encourage operators and contractors to communicate and think critically about the operational aspects of their work.

Documentation

Training needs to be documented, and records of all operators and contractors who have participated in training need to be maintained. Mechanisms for evaluating the effectiveness of training also need to be established and documented. Training is an ongoing process, and requirements need to be reviewed regularly to ensure that operators and contractors maintain appropriate experience and qualifications. Where activities have a significant impact on recycled water quality, periodic verification of the capability of operations staff is necessary.

Box 4.5 Contractors

Contractors are increasingly used to undertake work associated with recycled and drinking water schemes. In some cases, more than one contractor might be involved. For example, separate contractors might be involved in construction, operation of treatment processes, operation of distribution systems, and sampling and analytical work.

Requirements for contractor acceptability need to be established, and contractors need to be evaluated and selected on the basis of their ability to meet the specified requirements.

Agencies that award contracts need to ensure that contractors are qualified and have undergone appropriate training related directly to their task or role. When contracting labour, the organisation needs to educate and train contractors on the requirements for adherence to the organisation's policy and protocols.

Contractors who undertake analytical work need to be accredited for the tests to be performed.

Conditions of the contract under which a contractor operates need to be clear, accurate and achievable, with scope for ongoing review and improvement. Partnerships will be more successful where the recycled water supplier retains sufficient knowledge and technical expertise to manage the contract efficiently.

4.8 Community involvement and awareness (Element 8)

Components: Community consultation (Section 4.8.1)
Communication and education (Section 4.8.2)

As discussed in Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006), consultation with the community is a vital element in developing recycled water schemes, particularly those involving drinking water augmentation. Surveys have indicated that community concerns increase as the degree and likelihood of personal contact with recycled water rises. For example, use of recycled water for urban or agricultural irrigation has high levels of acceptance (Po et al 2004), whereas closer contact, including consumption of recycled water, has lower levels of support. Proposals to augment drinking water supplies with recycled water also tend to polarise views, with some people strongly supportive and others strongly opposed. Communication needs to involve information provision and education. Consultation will be more effective if participants are well informed.

Public and stakeholder concerns can be very powerful, and can mean the difference between acceptance and rejection of recycled water schemes. In some cases, public support has helped schemes to proceed; in other cases, public opposition has stopped schemes from being developed.

The aim of consultation needs to be to arrive at a sustainable outcome rather than to seek acceptance of a system preferred by its proponents. Informed deliberations needs to include complete information on the status quo, the full range of alternatives available, and the costs and risks associated with each of these alternatives. Any issues raised during the consultation process need to be recorded and addressed. Feedback needs to be provided on responses to issues raised during consultation. Communication will necessarily be an iterative process.

Community consultation and education is a specialist area and expert advice should be sought or engaged to assist in designing and implementing processes. A brief overview of issues is provided here. Further guidance is provided in Chapter 6 of Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006). In addition, a number of frameworks have been developed for communicating the issues involved with recycled water; for example, the publication *Refilling the Glass* (WSAA 2006) summarises information from the WateReuse Foundation.

4.8.1 Community consultation

Summary of actions

- Assess requirements for effective involvement of the community.
- Develop a comprehensive strategy for stakeholder engagement and consultation.

Assess requirements for effective involvement of the community

The decision to introduce drinking water augmentation must be aligned with the needs and expectations of stakeholders and the community as a whole. Therefore, to maximise community acceptance, all stakeholders need to be consulted and involved in decision-making processes.

Pre-existing community attitudes will influence the degree of acceptance of proposed schemes. As attitudes are likely to vary from one area to another, acceptance of a scheme in one area will not guarantee acceptance of a similar scheme in another area.

Develop a comprehensive strategy for stakeholder engagement and consultation

Involving stakeholders in an effective way can be complex. A range of methods need to be adopted to engage the community, including:

- stakeholder forums and workshops
- focus groups
- individual discussion
- community workshops
- briefing of the media and individual journalists
- presentations at schools and other educational institutions.

4.8.2 Communication and education of the community

Summary of actions

- Develop an active two-way communication program to promote awareness of recycled water quality issues.
- Provide information on the benefits of recycled water use, including cost comparisons with alternative solutions.

Develop a two-way communication program

Effective communication is essential to increase community awareness and knowledge of recycled water quality issues and the various areas of responsibility. The communication needs to be based on a thorough understanding of the diversity of views held by individuals in the community. A community is not a single, uniform entity, but contains groups with different levels of understanding and concerns. Communication programs have to be tailored to deal with this diversity.

Methods for communicating include:

- face-to-face presentations
- newsletters
- fact sheets
- freecall information services
- public displays
- the media
- internet, compact discs (CDs) and digital versatile discs (DVDs).

Education has been identified as a key component to any successful community consultation and communication program involving recycled water. Both the Orange County Groundwater

Replenishment Scheme¹⁵ and the Singapore NEWater Project¹⁶ have invested heavily in education programs. The Orange County Scheme has involved broadscale consultation, an effective internet site, distribution of press kits and educational tours of the scheme.

The Singapore NEWater Project was introduced as part of a ‘Four Tap Strategy’ that involved imported water, seawater desalination, collection and treatment of local surface run-off, and water reuse (Seah et al 2003). Currently, 1% of the daily water consumption in Singapore is augmented with recycled water, and this figure is expected to increase to 2.5% (~45 million L/day) by 2011 (Po et al 2004).

To raise people’s awareness of NEWater, Singapore’s Public Utilities Board used intensive education campaigns including:

- a documentary feature film
- media briefings and reports
- information briefings at community centres and schools
- establishment and promotion of a NEWater visitor centre.

The government also distributed 1.5 million bottles of NEWater for the public to see and sample.

Provide information on the need to use recycled water

Providing information on the need for, and benefits of, using recycled water is important in gaining community acceptance of a project. Potential alternatives need to be explored and discussed, and these should include an independently verified cost–benefit analysis.

4.9 Validation, research and development (Element 9)

Components: Validation of processes (Section 4.9.1)
Design of equipment (Section 4.9.2)
Investigative studies and research monitoring (Section 4.9.3)

Validation of preventive measures (ie ‘Will they work?’) is crucial. Schemes cannot be developed and introduced without conclusive evidence that they will provide safe drinking water. Validation involves evaluating available scientific and technical information (including historical data and operational experience) and, where necessary, undertaking investigations, including performance monitoring and water quality testing.

Drinking water augmentation is at the leading edge of recycled water use, and there is much debate about a broad range of issues associated with augmentation, such as water quality, potential impacts on public health, reliability and regulation. Understanding and knowledge will never be complete and new issues requiring investigation will regularly emerge. Improved understanding has the potential to improve effectiveness of treatment processes and may make it possible to apply a less conservative risk assessment. Proponents and agencies associated with schemes need to be committed to expanding their understanding of drinking water augmentation.

¹⁵ <http://www.gwrsystem.com>

¹⁶ http://www.pub.gov.sg/NEWater_files/index.html

This will require research and development. Possible areas for applied research and development are listed in Box 4.6.

Box 4.6 Possible areas for applied research and development

Augmentation provides opportunities for applied research and development in a number of areas, some of which are listed below:

- *Greater understanding of sources and potential hazards*
Monitoring of source waters will provide increased evidence about the range and concentrations of potential hazards in Australian sewage and stormwater. Of particular interest are hormones, pharmaceuticals and personal-care products not normally included in monitoring programs.
- *Validation of the operational effectiveness of treatment processes, including new products*
Further research is required to develop validation methods for advanced processes used in drinking water augmentation. Research into validation needs to be combined with research into more sensitive operational monitoring, particularly for physical processes such as membrane filtration (including reverse osmosis). Currently, operational monitoring of physical removal of microbial pathogens, using parameters such as turbidity, lacks sensitivity and greatly reduces the log credits that can be attributed to these processes. Further research is required into the identification, application and sensitivity of surrogate and indicator parameters for both chemical and microbial hazards.
- *Review of the operation of environmental barriers*
Further research is required into the effectiveness of barriers, appropriate dilution rates and detention times, and the relationship between detention times, recycled water monitoring and the application (where necessary) of corrective actions
- *Investigation of production of chemical byproducts*
Research is required into the production of byproducts during treatment of recycled water, particularly by processes such as advanced oxidation and disinfection.
- *Development of analytical procedures*
Further research is required into analytical procedures for organic chemicals including hormones, pharmaceuticals and personal-care products. This research should consider sensitivity and reliability of procedures. Further research is also required into biological monitoring, including selection and application of different methods.
- *Development of new processes and improvement of efficiency in existing processes*
New processes need to be developed, and existing ones refined. These processes and refinements will require validation, and assessment of reliability and of sensitivity to operational monitoring.
- *Emerging water-quality issues*
Water-quality issues (eg nanomaterials) will continue to emerge and require investigation.
- *Synergistic, additive and antagonistic effects of chemicals*
Research is needed to better understand the potential for synergistic and additive effects of chemicals, which has been raised as a possible concern for many years; similarly, a better understanding of potential antagonistic effects of chemicals is needed.
- *Interactions of recycled water with receiving waters*
Investigation of interactions with receiving waters is required; this should include research into the potential for nutrients and salts to cause environmental impacts. Improved understanding of attenuation of microbial and chemical parameters in surface and groundwater storages would be valuable, as would calibration of detention times in relation to completion of quality assurance procedures.

- *Assessment of epidemiological effects of recycled water schemes*
Moderate to long-term epidemiological studies of drinking water augmentation schemes would be valuable, to support investigations conducted internationally. These studies will require sufficient funding if they are to be sufficiently sensitive.
- *Composition of treatment-waste streams and prevention of environmental impacts*
Removal processes generate waste streams; the composition and processing of these streams needs further investigation, particularly in relation to prevention of potential environmental impacts

Collaborations for a broader understanding of recycled water issues

Partnerships and industry-wide cooperation in research and development can be a cost-effective way to address issues associated with drinking water augmentation. Opportunities for such collaboration should be identified with partnership organisations, including health, environment and natural resource management agencies; industry associations; other recycled water suppliers; university departments; and other research organisations and community groups.

4.9.1 Validation of processes

Summary of actions

- Validate processes and procedures to ensure they control hazards effectively.
- Validate reliability and consistency.
- Revalidate processes when variations in conditions occur.

Validate processes and procedures to ensure they control hazards effectively

Validation involves the assessment of processes as a whole, as well as the assessment of individual components, such as process-specific operational procedures, operational parameters, critical limits, target criteria and corrective actions.

Validation needs to be open and transparent, and needs to include community consultation and communication. This will reinforce public confidence in the findings of such investigations and the efficacy of schemes.

Validation of processes may take a number of forms, including:

- *evaluation of existing data for the treatment process in question* — for example from the scientific literature, manufacturer challenge studies, peer-reviewed experimental trials and historical data (eg from other schemes); factors to be considered are that:
 - existing data need to be critically reviewed to ensure they are directly applicable to the treatment process and operating conditions under investigation
 - data collected needs to be statistically valid and correlated to the specific operational conditions that will apply
 - the evaluation needs to include an assessment of whether treatment processes have been assessed in accord with existing protocols (eg US EPA 2005, 2006b) or by independent agencies (eg State of California 2007)
- *On-site testing of full-scale or pilot systems* — with appropriate challenge parameters, including indicator surrogates; where pilot systems are used, the relative size of these systems will influence how well performance will translate to full-scale plants; Snyder et al (2007)

reported good agreement between bench and pilot-scale treatment studies, and performance of full-scale treatment plants

- *On-site tracer studies* —for demonstrating detention time in disinfection systems, lagoon treatment systems, reservoirs and aquifers.

Validation needs to deal with selection of operational parameters, critical limits and target criteria, to ensure that the parameters are appropriate for the hazards in question and that the limits define acceptable performance in terms of inactivation or reduction of hazards. This is particularly important where surrogates are used. For example, if total organic carbon is used as a surrogate for a membrane performance, validation is required to show that compliance with the critical limit means that the required level of hazard reduction is achieved.

Variation in performance of control measures, and of uncertainties and variations in validation testing, need to be considered. Safety margins need to be applied to account for these potential uncertainties.

Factors that need to be considered in validation monitoring include:

- reliability and robustness of control measures
- process variability, including variability in equipment and monitoring performance, and susceptibility to environmental stressors and factors
- availability of:
 - validated analytical and sampling methodologies
 - statistically valid data
 - established and credible guidelines on validation protocols for specific treatment processes (eg US EPA 2005, 2006b)
 - appropriate and sensitive direct and indirect integrity test methods (eg US EPA 2005)
 - credible experimental data on the inactivation and removal of parameters and appropriate surrogates (eg US EPA 1999ab)
- that published data and performance of processes at other locations cannot be assumed to translate without variation, and that processes and equipment used in traditional drinking water treatment plants may not perform as expected or required with recycled water
- that performance in a pilot plant may not reflect performance in full-scale systems.

Validate reliability and consistency

Validation of short-term performance is not sufficient. Drinking water augmentation schemes need to maintain high levels of performance over many years. Validation needs to consider reliability and consistency of performance.

One way to assess reliability is to extend validation from examination of published data through to pilot-plant testing, precommissioning testing, postcommissioning testing (this testing should be heightened) and, if necessary, periodic revalidation. A number of factors need to be considered, including:

- the fact that seasonal variations can influence performance, as can substantial changes in conditions from year to year (eg drought or very high rainfall)

- variability of treatment effectiveness under normal operating conditions; this includes:
 - predictable variations such as diminishing output from UV lights in proportion to age and reduced performance during processes such as filter backwashing or direct integrity testing
 - observed variations in performance reflected by water-quality data
- the probability of mechanical failures
- impacts of mechanical failures on recycled water quality.

These factors are adapted from the methods described by Eisenberg et al (1998) for evaluation of treatment plant variability. Proponents need to assess the reliability of treatment processes and treatment trains, and provide evidence that selected processes are the most reliable, and produce least variability and maximum compliance with water-quality targets. Initially, this will involve assessment of published data together with pilot-plant performance. Reliability and consistency of performance will need to be confirmed by analysis of results obtained in precommissioning and postcommissioning testing. Expected and acceptable variations in performance should be identified. These variations should be within a range that ensures compliance with recycled water quality.

Evidence of reliability provides assurance that water quality will be maintained in the periods between operational monitoring events where continuous measurements are not possible (eg testing for indicator chemicals or direct integrity of membranes).

Revalidation of processes

Processes need to be revalidated when variations occur that may affect performance of processes; for example, if:

- hazard concentrations increase
- an emerging hazard is identified
- systematic failures are detected
- catchment inputs change (eg increased flows)
- process configuration, operational parameters and mode of operation is varied
- upstream treatment processes are changed (eg primary or secondary treatment)
- dilution rates or detention times in receiving water and storages change (eg increased demand, drought and changes to peak flows).

Any new processes need to be tested using bench-top, pilot-scale or full-scale experimental studies, to confirm that the required results are produced under conditions specific to the individual water-supply system.

4.9.2 Design of equipment

Summary of actions

- Validate the selection and design of new equipment and infrastructure to ensure continuing reliability.

Validate the selection and design of new equipment and infrastructure

New equipment and infrastructure or changes designed to improve system performance should never be introduced without performance being validated. New technologies require pilot-scale research and evaluation before full-scale implementation. Design specifications need to be established to ensure that new equipment is able to meet the intended requirements and provide the necessary process flexibility and controllability. Specifications need to include consideration of reliability and incorporation of backup systems for emergency conditions (eg alternative power generation).

4.9.3 Investigative studies and research monitoring

Summary of actions

- Establish programs to increase understanding of the recycled water supply system and improve management.

Programs to increase understanding and improve management

Investigative studies and research monitoring include strategic programs designed to:

- increase understanding of a water-supply system
- identify and better characterise potential hazards
- fill gaps in knowledge.

For example, the quality of stormwater can vary over a wide range; therefore, improved understanding of factors that affect source water quality can lead to a better understanding of control measures required to improve management of recycled water systems.

In the case of stormwater, improved understanding could enable operators and suppliers to anticipate periods of poor source-water quality and develop responses. Other examples include:

- assessing trade-waste agreements to identify chemical contaminants that may be discharged into source waters
- examining chemical quality of sewage to identify potential sources of industrial discharges and to assess effectiveness of trade-waste programs
- monitoring source water quality to understand the temporal and spatial variability of water-quality parameters
- developing early warning systems to improve the management of poor water quality
- using event-based monitoring to determine the magnitude of impacts (duration and maximum concentrations)
- studying the movement of water within storages, including lagoons and wetlands, to determine real detention times and to identify short-circuiting effects.

Careful consideration needs to be given to selection of water-quality characteristics to be analysed, use of statistical techniques, collection of samples (frequency and location), use of appropriate sampling and testing procedures, and evaluation and management of results.

4.10 Documentation and reporting (Element 10)

Components: Management of documentation and records (Section 4.10.1)
Reporting (Section 4.10.2)

Appropriate documentation provides a foundation for establishing and maintaining effective recycled water quality management systems. Documentation needs to:

- demonstrate that a systematic approach is established and is implemented effectively
- develop and protect the organisation's knowledge base
- provide an accountability mechanism and tool
- satisfy regulatory requirements
- facilitate reviews and audits by providing written evidence of the system
- establish due diligence and credibility.

Documentation is increasingly available in electronic format. Where documentation is electronic, formal systems must be in place to ensure ready access to relevant information. As is the case for hardcopy information, a document control system is necessary for electronic information, to ensure that the most up-to-date information is available to all staff.

Documentation provides a basis for effective communication within the organisation, as well as with the community and various stakeholders. A system of regular reporting, both internal and external, is important to ensure that the relevant people receive the information needed to make informed decisions about the management or regulation of recycled water quality and the system (from source to consumer).

4.10.1 Management of documentation and records

Summary of actions

- Document information pertinent to all aspects of recycled water quality management, and develop a document control system to ensure that current versions are in use.
- Establish a records management system and ensure that employees complete records.
- Periodically review documentation and revise as necessary.

Document information on water quality management and develop a document control system

Documentation pertinent to all aspects of managing recycled water quality needs to describe activities and explain procedures, including detailed information on:

- water sources, collection systems and catchments
- responsibilities and authorities

- trade and industrial-waste management systems
- preventive measures, including target criteria and related critical limits
- critical control points, including specific operational procedures and criteria, monitoring and corrective actions
- operational procedures for relevant activities
- operational monitoring protocols, including parameters and criteria
- corrective actions to be implemented when required
- maintenance procedures
- incident and emergency protocols
- validation
- data and records management requirements
- procedures for evaluating results and reporting
- internal and external communication and reporting requirements
- communication protocols
- training programs.

A document control system needs to be developed to ensure that only the most recent version of a particular appropriately approved document is in use.

Establish a records management system and ensure that employees complete records

Documentation needs to be visible, and readily available to operators and contractors, as required. Mechanisms need to be established to ensure that operators read, understand and adhere to the appropriate documents.

Operation of systems and processes generates large amounts of data that need to be recorded. Efficient record keeping can indicate and forewarn of potential problems; it can also provide evidence that the system is operating effectively. Activities that generate records include:

- operational monitoring and monitoring of recycled water quality
- monitoring of receiving waters and storages
- corrective actions
- incident and emergency responses
- training
- research and development, validation and verification
- assessment of the water supply system (flow diagrams, potential hazards, etc)
- community consultation
- performance evaluations, audits and reviews.

Documentation and records systems need to be kept as simple and focused as possible. There should be sufficient detail to provide assurance of operational control when coupled with a suitably qualified and competent operator. Records of all activities need to be easily accessible, but need to be stored in a way that protects them against damage, deterioration or loss. A system

should be in place to ensure that operators are properly trained to fill out records. Records need to be regularly reviewed, quality controlled, signed and dated.

Documents and records can be stored as written documents, electronic files and databases, video and audiotapes, and visual specifications (flow charts, posters, etc). Computer-based documentation is preferable because it provides faster and easier access, distribution and updating. Electronic documentation needs to be regularly backed up.

Retention of ‘corporate memory’ should also be considered in documentation of procedures.

Periodically review documentation and revise as necessary

Documents need to be reviewed and revised periodically to reflect changing circumstances, and need to be assembled in a manner that will allow them to be easily modified, where necessary.

4.10.2 Reporting

Summary of actions

- Establish procedures for effective internal and external reporting.
- Produce an annual report aimed at users of recycled water, regulatory authorities and stakeholders.

Establish procedures for effective reporting

Internal and external reports will be required for activities relating to recycled water quality management.

Internal reporting supports effective decision making at the various levels of the organisation, including operations staff and management, senior executive and boards of directors. It also provides a way to communicate decisions to employees throughout the organisation. Reporting requirements need to be defined and a system developed for communication between the various levels of the organisation. Documented procedures (including definition of responsibilities and authorities) need to be established for regular reporting (daily, weekly, monthly, etc). Results from audit and management reviews need to be communicated to those within the organisation responsible for performance.

External reporting ensures that recycled water quality management is open and transparent. External reporting requirements need to be established in consultation with users of recycled water and the relevant regulatory authorities. External reports need to include:

- performance and monitoring data
- event and incident reports in accord with agreed protocols (Section 4.6.2)
- internal and external (independent) audits.

Produce an annual report

An annual report needs to be produced and made available to users of recycled water, regulatory authorities and stakeholders. The annual report needs to:

- summarise:
 - performance of management systems

- quality of recycled water and monitoring of receiving waters and storages against numerical guideline values, regulatory requirements or agreed levels of service
- water-quality trends and problems
- any system or performance failures, and the action taken to resolve them
- discuss compliance with statutory or legislative requirements, and minimum reporting requirements
- indicate whether monitoring was carried out in accordance with the principles of risk management set out in these guidelines, standards set by regulators and any requirements contained in agreed levels of service
- provide outcomes of external audits.

Annual reports need to contain sufficient information to enable individuals or groups to make informed judgments about the quality of recycled water; they also need to provide a basis for discussions about the priorities that will be given to improving recycled water quality. The annual report represents an opportunity to canvass feedback and it should, therefore, encourage consumers and stakeholders to provide comment. This should include comment on the nature of the report, the amount and presentation of data, and the level of detail provided.

4.11 Evaluation and audit (Element 11)

Components: Long-term evaluation of results (Section 4.11.1)
 Audit of recycled water quality management (Section 4.11.2)
 Regulatory oversight and surveillance (Section 4.11.3)

Long-term evaluation of recycled water quality results and audit of recycled water quality management are essential to determine whether preventive strategies are effective and whether they are being implemented appropriately. This long-term evaluation allows performance to be measured against objectives and helps to identify opportunities for improvement.

Evaluation and audit programs need to incorporate requirements of regulatory agencies.

4.11.1 Long-term evaluation of results

Summary of actions

- Collect and evaluate long-term data to assess performance and identify problems.
- Document and report results.

Collect and evaluate long-term data to assess performance and identify problems

A systematic review of monitoring results over an extended period (typically the preceding 12 months or longer) is required to:

- assess overall performance against numerical guideline values, regulatory requirements or agreed levels of service

- identify emerging problems and trends
- help to determine priorities for improving recycled water quality management.

There will inevitably be instances when the system does not comply with operational criteria or numerical guideline values. Each event, including responses, need to be assessed.

Document and report results

Mechanisms for evaluation of results need to be documented, with responsibilities, accountabilities and reporting requirements defined. Useful tools to interpret data sets include statistical evaluation of results, and graphs or trend charts.

Evaluations need to be reported internally, to senior managers, and externally, to consumers, stakeholders and regulatory authorities, in accordance with established requirements (Section 4.10). Consumers will have greater confidence in the scheme if they know that data are reviewed regularly and that improvements are made in response to identified problems.

4.11.2 Audit of recycled water quality management

Summary of actions

- Establish processes for internal and external audits.
- Document and communicate audit results.

Establish processes for internal and external audits

Auditing is the systematic evaluation of activities and processes to confirm that objectives are being met. It includes assessment of the implementation and capability of management systems. Periodic auditing of all aspects of the management system for recycled water quality is needed to confirm that activities are being carried out according to defined requirements and are producing the required outcomes. The frequency and schedule of audits, as well as the responsibilities, requirements, procedures and reporting mechanisms, need to be defined.

Internal audits will involve trained staff and need to include review of the management system and associated operational procedures, monitoring programs, and the records generated to ensure that the system is being implemented correctly and is effective.

External auditing provides independent assessment; it also establishes credibility and maintains confidence among users of recycled water. Affiliation and qualifications of external auditors need to be recorded. External audits need to assess:

- results of internal audits
- the management system including design and implementation of each of the 12 elements
- operational activities
- monitoring programs and results
- compliance with regulatory requirements
- routine and incident reporting
- the effectiveness of incident and emergency responses.

Audit systems and tools have been developed to assess implementation of the ‘framework for management of drinking water quality’ — the framework on which the *Australian Drinking Water Guidelines* (NHMRC–NRMCC 2004) is based. Similar audit systems and tools will be developed for external and internal assessment of implementation of the ‘framework for management of recycled water quality and use’ — the framework on which the Australian guidelines for water recycling is based.

Document and communicate audit results

Audit results need to be

- appropriately documented and communicated to management and operational personnel
- considered as part of the review by senior executive
- reported to consumers, stakeholders and regulatory authorities.

4.11.3 Regulatory oversight and surveillance

Summary of actions

- Establish mechanisms for regulatory oversight and surveillance.
- Communicate and report outcomes.
- Establish mechanisms for reporting evidence of increased illness

Regulatory oversight and surveillance of drinking water augmentation by recycled water are essential components of effective risk management and protection of public and environmental health. Communities provided with augmented drinking water have the right to expect that regulatory oversight will be rigorous and exacting. For this to occur, regulatory agencies must be committed to providing surveillance, and must have the resources and expertise to do so.

Regulatory oversight and surveillance should be similar in scope to existing regulations, codes of practice and memorandums of understanding applied by health agencies to drinking water supplies, and should deal with:

- requirements for documented risk management plans
- auditing of risk management plans
- operator competency
- water quality requirements
- monitoring programs
- routine reporting and incident reporting.

The emphasis should always be on working cooperatively — imposing penalties should be a last resort. However, regulatory agencies need to have legislative powers to enforce actions required to protect public and environmental health. These powers need to include penalties that act as effective deterrents to non-compliance.

Regulation needs to be transparent, proportionate and targeted. Regulators need to communicate their requirements to operators of drinking water augmentation schemes. These requirements need to include mechanisms and procedures that will be applied in conducting surveillance and audits, and decision-making processes related to enforcement.

Outcomes of surveillance and assessment of audits need to be communicated by regulators to operators, together with recommendations for any corrective actions or improvements in management. Assessments need to be published in publicly available reports.

Surveillance undertaken by public health agencies routinely includes monitoring of infectious diseases. Mechanisms should be established to ensure that unusual patterns of illness are assessed for possible involvement of water supplies. Public health agencies should communicate the occurrence of such events to water suppliers.

4.12 Review and continual improvement (Element 12)

Components: Review by senior managers (Section 4.12.1)
Recycled water quality management improvement plan (Section 4.12.2)

Senior management's support, commitment and ongoing involvement are essential to continual improvement of the organisation's activities. Senior managers need to regularly review their approach to recycled water quality management, develop action plans and commit the resources necessary to improve operation and management.

Drinking water augmentation schemes require a high level of performance and management from the time of introduction. It is important not to become complacent — continual improvement always needs to be the goal.

4.12.1 Review by senior managers

Summary of actions

- Senior managers review the effectiveness of the management system and evaluate the need for change.

Review the effectiveness of the management system and evaluate the need for change

To ensure continual improvement, the highest levels of the organisation need to review the effectiveness of the management system for recycled water quality, and evaluate opportunities for change, by considering:

- reports from audits, recycled water quality performance and previous management reviews
- concerns of regulators, consumers and other stakeholders
- the suitability of the recycled water quality policy, objectives and preventive strategies in relation to changing internal and external conditions, such as
 - changes to legislation, expectations and requirements
 - changes in the activities of the organisation
 - advances in science and technology
 - new and emerging issues
- outcomes of recycled water quality incidents and emergencies

- reporting and communication.

The review by senior managers needs to be documented. Reviews of specific concerns, detection of significant failures and identification of emerging hazards and risks need to be communicated to regulators, consumers and stakeholders.

4.12.2 Recycled water quality management improvement plan

Summary of actions

- Develop an improvement plan for management of recycled water quality.
- Ensure that the plan is communicated, implemented and monitored for effectiveness.

Develop an improvement plan for management of recycled water quality

An improvement plan should be developed to address needs identified by the senior management review. The plan should be endorsed by senior executive. Improvement plans may encompass:

- capital works
- training
- improved operational procedures
- improved reliability and reduced variation in performance of treatment processes
- consultation programs
- research and development
- incident protocols
- communication and reporting.

Improvement plans can be short term (eg one year) or long term. Short-term improvements might include actions such as improving on-site audit programs, increasing staffing levels and developing community awareness programs. Long-term capital works projects might include increasing storage capacity, extending distribution systems or expanding treatment processes.

Ensure that improvement plans are implemented and monitored for effectiveness

Improvement plans need to include objectives, actions to be taken, accountability, timelines and reporting. They need to be communicated throughout the organisation, and to the community, regulators and other agencies.

Implementation of plans needs to be monitored to confirm that improvements have been made and are effective. Design and implementation of improvement plans need to be reviewed as part of external audits.

5 Monitoring

Monitoring is discussed in detail in Chapter 5 of the Phase 1 of the water recycling guidelines (NRMMC–EPHC–AHMC 2006) and in Sections 4.4, 4.5 and 4.9 of this document. This chapter provides an overview of monitoring.

5.1 General principles

Monitoring can be undertaken for a range of purposes; for example, monitoring may be used to:

- obtain baseline information (to underpin the risk assessment process)
- determine whether recycled water systems will be safe and not represent a risk to human health or have detrimental effects on the environment (*validation*, ie ‘Will it work?’)
- ensure that preventive measures are working (*operational monitoring*, ie ‘Is it working now?’)
- determine whether the recycled water system has operated effectively, achieved compliance with management requirements and has not represented a risk to public health or had detrimental effects on the environment (*verification*, ie ‘Did it work?’)
- provide information needed for investigation, follow-up and research.

Monitoring may also form part of the surveillance undertaken as a statutory requirement under licence or approval from a regulatory authority.

The main functions of each of these types of monitoring are given in Table 5.1 below.

Table 5.1 Purpose of main types of monitoring

Type of monitoring	Main functions
Baseline	Gather information that will underpin the risk assessment process, and provide a basis for assessing potential impacts of the use of recycled water on the environment
Validation	Obtain evidence that the elements of the recycled water quality management plan will achieve performance requirements
Operational	Conduct a planned sequence of observations or measurements of control parameters to assess whether a preventive measure is operating within design specifications and is under control
Verification	Apply methods, procedures, tests and other evaluations (in addition to those used in operational monitoring), to determine compliance with the management plan for recycled water quality, and to determine whether the plan needs to be modified

Baseline monitoring is undertaken before establishing a recycled water system, whereas validation, operational and verification monitoring are undertaken in establishing and running such a system. These latter forms of monitoring are common to risk management systems such as the hazard analysis critical control point (HACCP) approach.

Detailed guidance on the design and development of monitoring programs is provided in the *Australian Guidelines for Water Quality Monitoring and Reporting* (ANZECC–ARMCANZ 2000b). In the context of recycled water quality management, an effective monitoring program needs to:

- include clearly defined objectives that are set within the context of the recycled water management plan
- be carefully designed to ensure that the stated monitoring objectives will be met
- clearly specify what data will be gathered, how the data will be obtained and how results will be used
- involve sampling and analytical techniques that are reliable and sufficiently sensitive
- outline how data will be analysed and reported so that valuable information is provided, which can then inform the operation of the recycled water system
- be developed in conjunction with stakeholders who need to have confidence in the system; for example, water users, and regulators or authorities responsible for auditing the performance of the recycled water system.

5.2 Validation monitoring

Validation monitoring is an intensive activity used to prove that preventive measures are capable of adequately controlling recycled water quality within the bounds required to achieve health and environmental target criteria. As far as practicable, validation monitoring should be completed before recycled water is supplied for use, although it may continue into a pilot-testing period.

Once the setup of the whole system has been validated, it is generally sufficient to monitor and audit samples of the system, as part of operational and verification monitoring. However, further validation is needed for variations such as seasonal changes, and all new processes and configurations should be validated to confirm that a modified recycled water system achieves the required results.

Validation needs to be performed, or at least overseen in detail, by an independent and appropriately qualified professional or group of professionals. For example, validation of a disinfection system would require expertise in microbiology. The work would need to be overseen by someone independent of any organisation with a stake in the system, and independent of the laboratory that undertakes the microbial validation testing. Validation of reverse osmosis and advanced oxidation processes would require expertise in chemical testing. Such oversight provides independent assurance that the system being validated, and the sampling strategies and laboratory techniques being applied, are sound.

One of the objectives of validation monitoring is to prove that the system delivers the expected water quality when operational monitoring results are specified. Therefore, operational monitoring, discussed below, is generally performed at the same time as validation monitoring, to provide a point of comparison.

5.3 Operational monitoring

Operational monitoring is the routine monitoring of preventive measures such as trade-waste control programs and treatment processes. It provides generally rapid assessment of performance of individual preventive measures. A properly designed operational monitoring program should

provide a timely warning to the manager of a recycled water scheme, allowing corrective action to be taken before unsafe recycled water is supplied.

Operational monitoring is required for all preventive measures, but is particularly important for critical control points. The intensity of operational monitoring needs to be commensurate with the variability and criticality of the specific preventive measure. Drinking water augmentation will typically incorporate online monitoring for a number of critical processes.

Operational monitoring can also include discreet events; for example, direct integrity testing of membrane filters and testing for operational indicators (Section 4.4.2). In some cases, operational monitoring can also include an observational component (eg inspection of on-site trade-waste controls).

Online monitoring devices must be reliable; they must also be properly and regularly calibrated, and compared with laboratory determinations of reference meters. Online systems can produce false alarms caused by factors such as instrument errors, blockages and air bubbles. However, all alarms must be treated as real unless or until it becomes clear that a false alarm has occurred. If excessive false alarms are happening, then improved instrumentation and control algorithms are needed, rather than less urgent responses.

5.4 Verification monitoring

The purpose of verification monitoring is to confirm compliance with the recycled water quality management plan. Verification of recycled water quality assesses the overall performance of the recycled water system, the ultimate quality of recycled water being supplied or discharged, and the quality of the receiving environment. Verification includes monitoring for compliance with criteria associated with:

- drinking water quality
- environmental values, including recreational use of receiving waters and ecological values.

Verification monitoring is independent of operational monitoring and is not intended to be applied as a day-to-day management tool. It is less intensive than operational monitoring, and generally takes the form of laboratory-based testing. For long-term environmental target criteria, verification of sustainability may require years of annual monitoring data.

Verification monitoring is often conducted more frequently during the first weeks and months of operation, to demonstrate that water quality and receiving environment targets are being achieved, and to provide confidence that the target criteria for water quality will be reliably achieved in the future.

Verification provides:

- confidence for users of recycled water and regulators in the quality of the water supplied and the functionality of the system as a whole
- confidence that environmental targets are being achieved
- an indication of problems, and a trigger for corrective actions, or for incident and emergency responses.

Verification testing should only be undertaken by laboratories accredited for the specific tests. Laboratories need to provide evidence that test results have been conducted in accordance with

accredited techniques, and that appropriate quality control procedures have been applied, including the use of analytical standards.

5.5 Summary of monitoring requirements

Table 5.2 provides an overview of indicative monitoring requirements for public health aspects of drinking water augmentation. The table is not intended to be prescriptive. Environmental monitoring should be performed as described in Phase 1 of the Australian guidelines for water recycling.

Table 5.2 Indicative monitoring requirements — public health aspects

Type of monitoring	Where	Parameters	Frequency
Baseline	Source and receiving water	<p>Pathogens or indicators: <i>Cryptosporidium</i>, <i>Campylobacter</i>, <i>Escherichia coli</i>, <i>Clostridium perfringens</i>, enteric viruses, coliphage, etc</p> <p>Inorganic chemicals: As specified in the <i>Australian Drinking Water Guidelines</i> (see ADWG)</p> <p>Organic chemicals: Health-related chemicals (see ADWG), pesticides, hormones, pharmaceuticals, personal-care products, fire retardants, dioxins, etc^a</p>	Source waters and receiving waters to be monitored on a weekly basis for pathogens or indicators and on a monthly basis for chemicals, for at least 12 months, to establish the range of hazards and seasonal variations
Validation	Pilot plants (laboratory and on-site, after process being validated), pre-commissioning and commissioning trials (on-site, after process being validated)	<p>Target parameters that are meant to be removed or inactivated by the process (eg pathogens for disinfection, chemicals and pathogens for reverse osmosis, NDMA for advance oxidation).</p> <p>Operational monitoring indicators and surrogates (see below).</p>	Sufficient frequency to prove effectiveness of the process against target compounds, in a statistically valid manner
Operational	On-site	<p>Process specific monitoring of activity, surrogates and indicators.</p> <p>Activity: Transmembrane pressure, flow rates, dose rates, ultraviolet light transmission, chlorine residual</p> <p>Surrogates: Turbidity, total organic carbon, conductivity</p> <p>Indicators: Boron, NDMA, chloroform, DEET, caffeine, estrone, meprobromate, heterotrophic plate count, coliphage, <i>Clostridium perfringens</i></p>	<p>Activity and surrogates Most monitoring will be continuous but pressure-based testing of membranes daily</p> <p>Indicators Tested weekly</p>

Type of monitoring	Where	Parameters	Frequency
Verification	At entry into receiving waters and at point of supply ^b Biological monitoring from locations within treatment train	Microbial indicators: (<i>E. coli</i> , <i>Clostridium perfringens</i> , coliphage) Inorganic chemicals: (see ADWG) Organic chemicals: Health related chemicals (see ADWG), pesticides, hormones, pharmaceuticals, personal-care products, fire retardants, dioxins etc Disinfection byproducts Biological monitoring	Microbial indicators Tested 3 times/week Inorganic chemicals Monthly Organic chemicals. Key parameters monitored monthly, other compounds monitored quarterly or annually based on likelihood of occurrence (from baseline monitoring and catchment surveys) Disinfection byproducts Monthly Biological monitoring Monthly

ADWG = *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004); DEET = N,N-diethyltoluamide (N,N-diethyl-3-methylbenzamide); NDMA = N-nitrosodimethylamine

- a** Range of parameters based on existing system specific data, catchment surveys, published data, consumers perceptions.
b Design of point of supply monitoring program should consider program and results from receiving water input.

Appendix A Setting guidelines for chemicals in drinking water augmented with recycled water

A1 Overview

Whatever the source of water — treated sewage, stormwater or traditional sources such as rivers, reservoirs or groundwater — it will contain a variety of chemicals. This appendix explains the process for setting guidelines to protect human health from chemicals in drinking water when recycled water is used as the source. The process described in this appendix was used to set the drinking water guidelines given in Table 4.4 (Chapter 4); Box A1 explains what is meant by the term ‘drinking water guideline’.

Box A1 Drinking water guideline

Throughout this appendix, the term ‘drinking water guideline’ refers to a concentration of chemical in drinking water delivered to the consumer that may, either in whole or in part, include recycled water. The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) explains the rationale behind a guideline value for a particular chemical as follows:

‘... the concentration that, based on present knowledge, does not result in any significant risk to the health of the consumer over a lifetime of consumption and is consistent with water of good quality.

The health related guideline values are very conservative, and are calculated using a range of safety factors. They always err on the side of safety, particularly where scientific data are inconclusive or where the only data available are from animal studies.’

In other words, if the water complies with the drinking water guidelines, then drinking water containing recycled water is safe to drink. Short periods of consuming water containing chemicals at concentrations higher than the guideline values do not necessarily equate with a high likelihood of adverse health effects. The probability of an adverse health effect depends mainly on the actual concentration of chemical in the water and the length of time it was consumed.

The primary focus of the approach described here is augmentation of drinking water with recycled water derived from highly treated sewage. However, the approach could be applied to drinking water produced from any raw water supply, such as stormwater, reservoirs, rivers, groundwater, rain water, industrial waste water and mine waters.

Unlike the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004), aesthetic considerations of taste are not considered in this publication.

The drinking water guidelines recommended here for chemicals have the ‘end-of-pipe’ consumer as the target receptor. The overriding philosophy applied in this document is that drinking water produced from source water that may contain recycled water needs to be at least as safe as that from traditional water sources. Consequently, the guidelines have been established in a way that is consistent with the approach currently used in Australia and internationally for setting health-protective guidelines for chemicals potentially found in food, water or air. The main focus of this appendix is the process for setting guidelines for chemicals for which no drinking water guideline is available.

A2 Process for setting guidelines

Figure A1 summarises the process for setting drinking water guidelines as a hierarchical decision tree. This section of the appendix discusses each of the steps outlined in the diagram.

A2.1 Step 1 — List chemicals of interest

The first step in the decision tree for setting drinking water guidelines is to list chemicals of interest. These could include:

- chemicals that have been found in the effluent of secondary sewage treatment, either in Australia or overseas (assuming that sewage used as source of recycled water to augment drinking water supplies will be subject to secondary treatment)
- chemicals of general interest to the community.

For individual schemes, this listing needs to be augmented by analyses of proposed water sources.

Table 4.4 in Chapter 4 provides data from secondary treated effluent from a range of Australian treatment plants and published international reports. The data are not exhaustive but are representative of the range of chemical types and classes that could be present in treated sewage. The data in Table 4.4 are used here to develop and illustrate the approach taken for determining guideline values. The approach can be applied to any chemical of interest.

A2.2 Step 2 — Is there an existing drinking water guideline?

Having identified chemicals of interest, the next step is to determine whether a drinking water guideline has already been set for that chemical. Box A2 lists established drinking water guidelines produced by authorities around the world, as examples of the type of document that can be searched to match against the chemicals of interest. The sources are listed in order of preference of acceptance, based on recommendations from the National Health and Medical Research Council (NHMRC) and the enHealth Council of Australia in relation to risk assessment of environmental hazards (enHealth 2004).

In developing the guideline values given in this document (Table 4.4), the guidelines listed in Box A2 were searched. In line with the recommendations of the NHMRC and enHealth Council, drinking water guidelines from Australia and the World Health Organization (WHO) were given preference over those of other authorities.

The guidelines for chemicals given in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) are largely based on the methods and outcomes of the relevant WHO publications. However, there are some distinctions between the WHO guidelines and Australian drinking water guidelines; for example:

- the WHO guidelines assume a bodyweight of 60 kg, to cater for the lighter bodyweights of developing countries; however, Australian guidelines assume a bodyweight of 70 kg
- for carcinogenic compounds, the WHO guidelines use a risk assessment calculation, with the guideline value set at the concentration that would give rise to a risk of one additional cancer per 100 000 people, whereas the Australian guideline values for these types of compounds are based on a risk of one in a million.

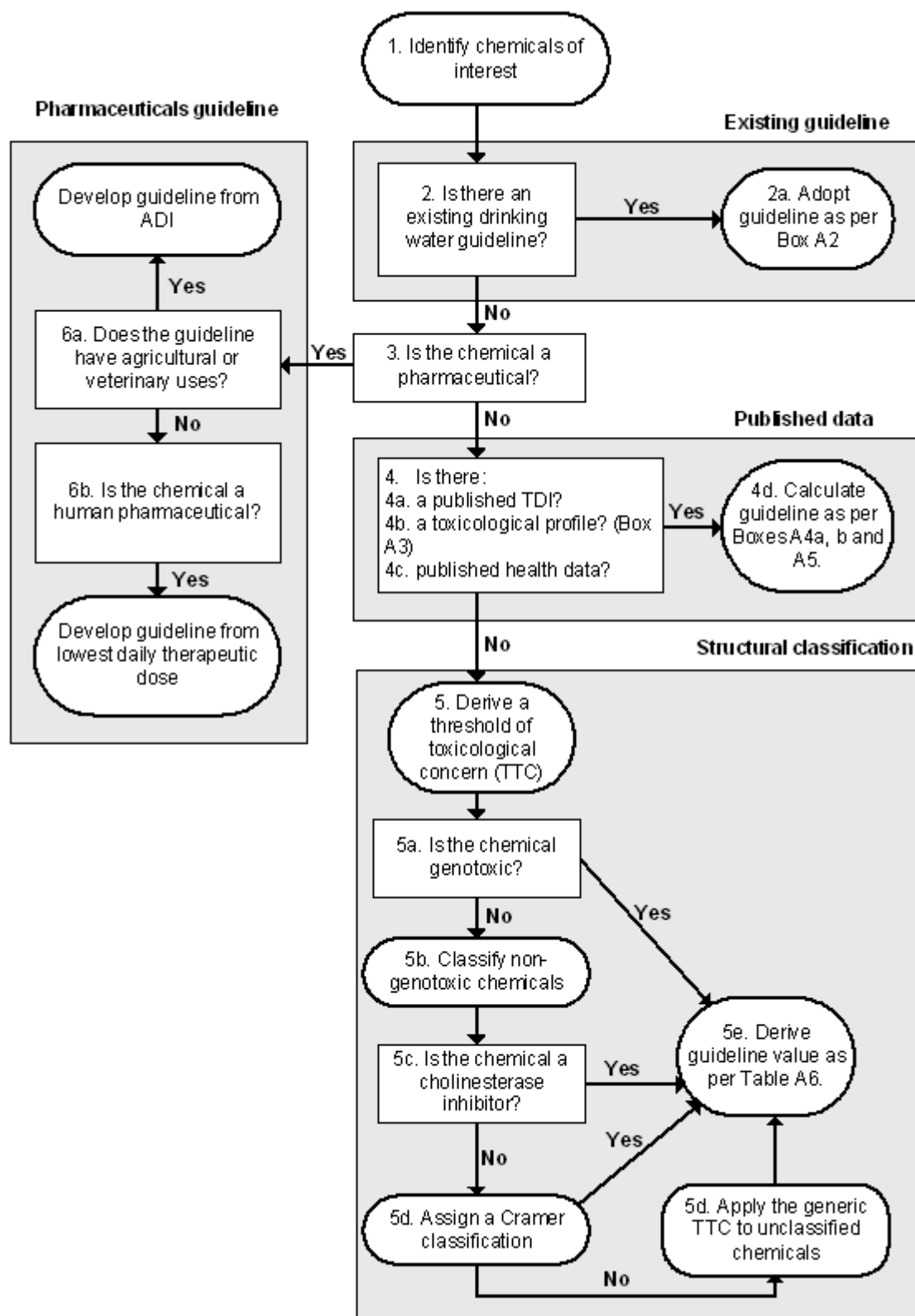
Where WHO guidelines for non-threshold chemicals have been used in this appendix, the values have been adjusted to take into account the lower level of risk used in the Australian guidelines.

Box A2 Hierarchy of drinking water guidelines

The following list details documents in which drinking water guidelines can be found. As described in Section A2.3, it follows a hierarchy, with the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) taking precedence over other publications.

- NHMRC–NRMMC (National Health and Medical Research Council — Natural Resource Management Ministerial Council) (2004). *Australian Drinking Water Guidelines*. http://www.nhmrc.gov.au/publications/files/adwg_11_06.pdf
- WHO (World Health Organization) (2006). *Guidelines for Drinking-Water Quality*, third edition, incorporating first addendum. http://www.who.int/water_sanitation_health/dwg/gdwq3rev/en/index.html
- EU (European Union) (1998). *Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption*, Official Journal L 330, 05/12/1998 p 0032–0054. http://ec.europa.eu/environment/water/water-drink/index_en.html
- NZ MoH (New Zealand Ministry of Health) (2005). *Drinking Water Standards for New Zealand*, NZ MoH, Wellington, New Zealand. [http://www.moh.govt.nz/moh.nsf/0/12F2D7FFADC900A4CC256FAF0007E8A0/\\$File/drinkingwaterstandardsnz-2005.pdf](http://www.moh.govt.nz/moh.nsf/0/12F2D7FFADC900A4CC256FAF0007E8A0/$File/drinkingwaterstandardsnz-2005.pdf)
- Health Canada (2006). *Guidelines for Canadian Drinking Water Quality*. http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/doc_sup-appui/index_e.html
- US EPA (United States Environmental Protection Agency) (2007). *Drinking Water Contaminants Lists*. Office of Water, US EPA. <http://www.epa.gov/safewater/hfacts.html>
- OEHHA (Office of Environmental Health Hazard Assessment) (Various dates). *Public Health Goal for Chemical Substances in Drinking Water*. California Environmental Protection Agency. <http://www.oehha.ca.gov/water/phg/allphgs.html>
- US EPA (United States Environmental Protection Agency) (Various dates). *Health Advisories for Drinking Water Contaminants*. Office of Water, US EPA.

Figure A1 Decision tree for setting guidelines for chemicals in recycled water that will be used as a source of drinking water



ADI = acceptable daily intake; TDI = tolerable daily intake; TTC = threshold of toxicological concern.

When setting drinking water guidelines, WHO uses the best scientific and human health advice available. For example, preparation of the 2004 WHO *Guidelines for Drinking-water Quality* involved the participation of 490 leading scientists from nearly 90 developing and developed countries (WHO 2006a). If properly implemented, the WHO guidelines ensure the safety of drinking water supplies by reducing to safe levels the concentration of contaminants that are known to be potentially hazardous to health. Therefore, it is advisable to use drinking water guidelines from the WHO guidelines or the *Australian Drinking Water Guidelines* where available. Drinking water guidelines from the other authorities listed in Box A2 should be used only where there is appropriate documentation to allow the basis of the guideline to be summarised.

Step 2a — Adopt drinking water guideline

In this document, existing drinking water guidelines have been adopted and included in Table 4.4 (Chapter 4), as appropriate. As explained above for Step 2, values published in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) or the WHO guidelines (WHO 2006a) were given priority in adopting guidelines for Table 4.4.

Where no drinking water guideline has been published for a chemical, it is necessary to set a guideline, using the process outlined in Figure A1.

A2.3 Step 3 — Is the chemical a pharmaceutical?

The method used to set a drinking water guideline will depend on the nature of the chemical involved. Where the chemical is not a pharmaceutical, a guideline is set using one of the following:

- toxicological information, such as acceptable daily intake (ADI), tolerable daily intake (TDI), a review of toxicological or health effects, or suitable data from the literature (*Step 4*)
- an appropriate threshold of toxicological concern (TTC) (*Step 5*).

In the case of pharmaceuticals, a guideline is set using lowest daily therapeutic doses or ADIs (for veterinary pharmaceuticals) where available (*Step 6*).

A2.4 Step 4 — Is there health and toxicological information?

This section describes the method used to set guidelines for non-pharmaceutical chemicals for which toxicological information is available. Steps 5a–5c cover the process of determining whether the appropriate information exists, and Step 4d explains how to set the guideline using that information.

Steps 4a–4c

The method used in this document for setting drinking water guidelines from health or toxicological data is the same as used by the NHMRC for establishing the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004). It is also the same as that used by the WHO for its drinking water guidelines (WHO 2006a).

The health effects of concern for chemical contaminants of water relate primarily to lifetime (ie chronic) exposure. Epidemiological surveillance methods or case–control studies are not particularly useful, or appropriate, for determining dose–response health effects from chemical

exposure via drinking water. The most common approach is to gather information on toxicological or health effects chemical by chemical. The whole database is then evaluated to find one or more pivotal studies identifying the critical adverse effects and the exposure (dose) to be used in the calculation of a drinking water guideline.

It was not viable (or indeed necessary) for data evaluations to be undertaken in developing this document. Therefore, in setting guidelines for nonpharmaceuticals for these guidelines, the following information was sought:

- *Step 4a* — ADIs or TDIs established by Australian, WHO and other agencies listed in Box A3 (note: reference doses (RfD) are the equivalent safe ingestions of chemicals established by United States health agencies)
- *Step 4b* — appropriate toxicological information sourced from a toxicological profile written by one of the authorities listed in Box A3 (where no ADI (or equivalent) for a chemical of interest has been established by a credible authority)
- *Step 4c* — appropriate information sourced through a search of the scientific literature (where no suitable toxicological information can be obtained from Steps 4a or 4b).

In gathering toxicological information for use in calculating the drinking water guidelines given in this document, the information was appraised according to the principles for hazard evaluation described by the enHealth Council (enHealth 2004) and WHO (WHO 1987, 1990, 1994, 1999).

Box A3 Sources of health and toxicological information

Listed below are examples of the type of document that can be used as sources of health and toxicological information for setting drinking water guidelines, as covered in Steps 4a and 4b of the process outlined in Figure A1, which relate to pharmaceutical guidelines.

- TGA (Therapeutic Goods Administration, Australia) (2006). Acceptable daily intakes for agricultural chemicals. TGA
<http://www.tga.gov.au/docs/html/adi.htm> Last updated 31st December 2006.
- IPCS (International Programme on Chemical Safety) (various dates). Monograph series from the IPCS on environmental health criteria; the IPCS is a cooperative program of the World Health Organization (WHO), the International Labour Organization (ILO), and the United Nations Environment Programme (UNEP). <http://www.inchem.org>
- IPCS (various dates). Concise international chemical assessment documents from the IPCS. <http://www.inchem.org>
- FAO/WHO JECFA (Joint FAO/WHO Expert Committee on Food Additives) (Various dates). *Safety Evaluation of Certain Food Additives and Contaminants*. WHO Food Additives Series: Prepared by JECFA, Geneva. <http://www.inchem.org>
- FAO/WHO JMPR (Joint FAO/WHO Meeting on Pesticide Residues) (Various dates). Safety Evaluation of Pesticide Residues. WHO Pesticide Residue Series: Prepared by the WHO JMPR, Geneva <http://www.inchem.org>
- US EPA (United States Environmental Protection Agency) (various dates). Integrated Risk Information System. Full summary — various chemical substances. <http://www.epa.gov/iris>
- ATSDR (Agency for Toxic substances and Disease Registry) (various dates). Toxicological profiles for chemical substances, ATSDR, US Department of Health and Human Services.
- RIVM (2001). Re-evaluation of human toxicological maximum permissible risk levels, Dutch National Institute of Public Health and the Environment.

- EU (European Union) (various dates). EU existing chemical risk assessment reports, European Commission, Joint Research Centre European Chemical Bureau, European Union. <http://ecb.jrc.it/esis/index.php?PGM=ora>
- Health Canada (2004). Health-based guidance values for substances on the second priority substances list. Minister of Supply and Services Canada. http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/psl2-lsp2/guidance_values.pdf

Step 4d

Step 4d is to use the information obtained at Steps 4a–4c to set guidelines. The method used depends on whether the chemicals are threshold or non-threshold chemicals. This classification can be explained as follows:

- *Threshold chemicals* — These are chemicals for which effects are only observed above a threshold dose; no effects are observed at doses below this threshold.
- *Non-threshold chemicals* — These are chemicals, typically those that cause cancer by inducing mutations in deoxyribonucleic acid (DNA), that are considered to have no safe level of exposure. Calculation of drinking water guidelines for non-threshold chemicals are developed from dose–response relationships, and are often extrapolated from responses elicited by relatively high doses.

Threshold chemicals

Wherever possible, data from human studies are used for calculating guideline values based on toxicological information. However, little such information is available, and extrapolations are therefore made from toxicological information obtained from animal studies. Because there is uncertainty associated with the extrapolation from effects seen in animals, a number of uncertainty factors — referred to as ‘safety factors’ in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) — are applied to ensure that human health is protected. Also, because it is possible that exposure of an individual to a particular chemical may occur through media other than water, only a portion of the chemical dose considered safe is allocated to come from water when setting the guideline.

Boxes A4a and A4b summarise the mathematical mechanics for setting drinking water guidelines using toxicological information.

Box A4a Calculation of drinking water guidelines using toxicological data — threshold chemicals

The equation used by the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) for establishing a health protective drinking water guideline is:

$$\text{Drinking water guideline} = \frac{\text{animal dose} \times \text{human weight} \times \text{proportion of intake from water}}{\text{safety factor} \times \text{volume of water consumed (L/day)}}$$

This can be expressed as:

$$\text{Drinking water guideline (mg/L)} = \frac{\text{NOEL (mg/kg bw/day)} \times \text{bw (kg)} \times \text{P}}{\text{SF} \times \text{V (L/day)}} \quad (\text{Equation 1})$$

Where:

- NOEL (no observed effect level) = the NOEL from a chronic animal study expressed as mg compound/kg bw/day. When the animal dose is different from this, appropriate safety factors are used
- bw (bodyweight) = assumed average bodyweight of an Australian adult (70 kg) or a 2-year-old child (13 kg)
- V (volume of water consumed) = 2 L/day for an adult and 1 L/day for a 2-year-old child; this amount is considered by the *Australian Drinking Water Guidelines* to be appropriate for Australian conditions
- SF (safety factor) = a factor of up to 10 000, allocated according to advice in the *Australian Drinking Water Guidelines*
- P (proportion from water) = P is variable, but the default value is 10% (ie P = 0.1).

The general form of Equation 1 is used by most countries to set drinking water guideline values; the assumptions used in the equation are conservative and err on the side of safety. Box A4b, below, provides further information on V, SF and P.

The acceptable daily intake (ADI), or tolerable daily intake (TDI) is an estimate of the daily amount of a substance that can be ingested over a life time that is considered safe. It is calculated by dividing the NOEL by the SF. Thus, in Equation 1, the term NOEL/SF can be replaced by the ADI or TDI. That is:

$$\text{Drinking water guideline (mg/L)} = \frac{\text{ADI (mg/kg bw/day)} \times \text{bw (kg)} \times \text{P}}{\text{V (L/day)}} \quad (\text{Equation 2})$$

Equation 2 is that used by WHO (2006a) and invoked at Step 4a in the process shown in Figure A1.

Box A4b Notes on values given in equations in Box A4a

Volume of water consumed

The assumed amount of water consumed is the same as that used by the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) to be appropriate for Australian conditions. However, in some circumstances (eg in the tropical north of Australia), water intake may be more than the assumed 2 L/day. Although amounts of 5 L/day may sometimes be ingested, this intake is unlikely to be sustained over a long period.

As discussed in Section A2.2, the *Australian Drinking Water Guidelines* assumes a human bodyweight of 70 kg, the same as that used by other developed countries, whereas the WHO guidelines assume a human bodyweight of 60 kg.

Proportion of safe intake allocated to water

The assumed amount of chemical ingested per day that is regarded as safe (ie the ADI or its equivalent) may come from sources other than drinking water. To ensure that the ADI is not exceeded, the amount that can come from drinking water must be a fraction of the total allowed. Ideally, background intakes (ie intakes other than from drinking water) need to be determined for each chemical of interest. However, it is not feasible to do this for all the chemicals considered in this document. According to the *Australian Drinking Water Guidelines*:

- for chemicals used commercially or industrially, a default apportionment of 10% of total intake is allocated to water
- for chemicals that are not used commercially or industrially, a higher proportion of intake (usually 20% but sometimes 80% or even 100%) is assumed to come from drinking water.

In deriving drinking water guidelines, Health Canada has a default assumption that 20% of the ADI may be associated with the water (Health Canada 2006). In this document, the default assumptions of the *Australian Drinking Water Guidelines* have been adopted unless particular circumstances mean that they are inappropriate. Hence, it has been assumed that, for industrial chemicals, 10% of the ADI is from water, and for all other substances, 20% of the ADI is from water. For individual chemicals, these apportionments may be adjusted as information on background intakes from sources other than drinking water becomes available.

The Australian Inventory of Chemical Substances (AICS) was used to judge whether a chemical is in commercial use in Australia. The AICS lists chemicals approved for industrial use in Australia under the National Industrial Chemical Notification and Assessment Scheme (NICNAS). It does not include active chemicals of pharmaceutical, or agricultural or veterinary preparations, but does include cosmetic ingredients.

Safety factors

Safety factors can be thought of as translating the dose causing no adverse effects in experimental animals (ie the NOEL) into an equivalent no effect dose for humans, taking into account the uncertainties involved with such extrapolation. In many other countries, and in other applications in Australia, safety factors are referred to as uncertainty factors. The advice given by the NHMRC (1999) on the size and technical application of uncertainty factors was used in this document in Step 4d of the process shown in Figure A1.

Non-threshold chemicals

Chemicals that cause cancer by directly altering either the structure or function of DNA are not considered to exhibit absolute safety; that is, there is no unconditional threshold below which effects do not occur. Instead, some risk is deemed to be associated with any level of exposure.

In this document, for a non-threshold chemical whose carcinogenicity has been characterised by experimental determination of potency (ie by derivation of a ‘slope factor’), the calculation of a drinking water guideline is undertaken with a target risk of one in a million (1×10^{-6}). The resulting guideline is taken to mean that, if a population of one million people were to consume water at the guideline concentration for a lifetime, then one additional cancer might plausibly be expected to occur. In reality, since cancer potency factors are usually calculated as an upper estimate (ie at the upper 95% confidence limit) the drinking water guidelines are set for risks much lower than 10^{-6} .

The calculation for setting a drinking water guideline for non-threshold chemicals is shown in Box A5.

Box A5 Calculation of drinking water guidelines using toxicological data — non-threshold chemicals

The equation used to set drinking water guidelines for non-threshold chemicals is:

$$\text{Drinking water guideline (mg/L)} = \frac{R \times P \times \text{bw (kg)}}{\text{SF (mg/kg/day)}^{-1} \times V \text{ (L/day)}} \quad (\text{Equation 3})$$

Where:

R = risk (1×10^{-6})

P = proportion of risk from water; variable, but default is 10% (ie P = 0.1).

bw = bodyweight (70 kg for an adult)

SF= slope factor (mg/kg/day^{-1}); cancer potency factor derived from literature

V = volume of water consumed (2 L/day).

The tables below show the recommended drinking water guidelines for chemicals established for this publication based on:

- toxicological information; that is, using an agency-derived ADI or cancer risk (Table A1)
- an agency-derived NOEL (Table A2)
- an agency-derived cancer slope factor for non-threshold chemicals (Table A3).

Table A1 Recommended drinking water guidelines established from toxicological information (ie with an agency-derived TDI, ADI or RfD)

Chemical name	Tolerable intake (mg/kg bw/day)	Reference	Recommended drinking water guideline ($\mu\text{g/L}$) ^a
<i>Pesticides</i>			
4-Nitrophenol	0.008 ^d	US EPA (2006c) ^o	30 ^b
Demeton-S	0.00004 ^{d,i}	US EPA (1988b)	0.15 ^b
<i>Other compounds</i>			
<i>Inorganic</i>			
Bromide/bromine	1 ^f	TGA (2006) FAO/WHO (1988a)	7,000 ^c
Iodine	0.017 ^e	FAO/WHO (1988b)	60 ^b

Chemical name	Tolerable intake (mg/kg bw/day)	Reference	Recommended drinking water guideline (µg/L) ^a
<i>Organic</i>			
2,6-dichlorophenol	0.003 ^e (total dichlorophenols)	RIVM (2001)	10 ^b
4-Chlorophenol	0.003 ^e (total monochlorophenols)	RIVM (2001)	10 ^b
4-methylphenol (p-Cresol)	0.17 ^f (total cresols) ⁱ	WHO (1995)	600 ^b
Acetophenone	0.1 ^d	US EPA (1989)	400 ^b
Bisphenol A	0.05 ^{d,e}	US EPA (1993a) EFSA (2006)	200 ^b
Bromochloromethane	0.01 ^d	US EPA (2006c) ^o	40 ^b
Butylated hydroxyanisole	0.5 ^f	FAO/WHO (1988c)	1750 ^b
Butylated hydroxytoluene	0.3 ^f	FAO/WHO (1995)	1,000 ^b
Dibutyltin (DBT)	0.00025 ^{e,j}	EFSA (2004)	2 ^c
Di-n-butyl phthalate	0.01 ^{e,k}	EFSA (2005)	35 ^b
Phenol	0.04 ^{e,m}	RIVM (2001)	150 ^b
Phthalic anhydride	2 ^d	US EPA (1988a)	7,000 ^b
<i>Polyaromatic hydrocarbons (PAHs)</i>			
Anthracene	0.04 ^{e,g}	RIVM (2001)	150 ^b
Naphthalene	0.02 ^{d,l}	US EPA (1998)	70 ^b
Phenanthrene	0.04 ^e	RIVM (2001)	150 ^b
Pyrene	0.03 ^{d,n}	US EPA (1993b)	150 ^b
<i>Dioxin-like compounds</i>			
2,3,3',4,4',5-Hexachlorobiphenyl (PCB156)	Tolerable monthly intake for dioxin like substances is 70 pg TEQ/kg/month; this is equivalent to 2.3 pg TEQ/kg bw/day.	NHMRC (2002)	16 pg TEQ/L ^{c,p}
2,3,3',4,4'-pentachlorobiphenyl (PCB105)			This recommended drinking water guideline is for the total of all dioxin-like substances in drinking water and needs to consider toxicity equivalent factors (TEFs) for individual compounds. The recommended guideline value for PCBs (dioxin like and non-dioxin like compounds) is 0.14 µg/L ^q
2,3',4,4',5-Pentachlorobiphenyl (PCB118)			
2,4,5,3',4',5'-Hexachlorobiphenyl (PCB167)			
2,7-Dichlorodibenzo-p-dioxin (DCDD)			
3,4,5,3',4',5'-Hexachlorobiphenyl (PCB169)			
Octachlorodibenzo-p-dioxin (OCDD)			

ADI = acceptable daily intake; RfD = reference dose; TDI = tolerable daily intake; TEF = toxicity equivalent factor; TEQ = toxic equivalent

a Drinking water guideline calculated using Equation 2 in Box A4a.

b Chemical may be in commercial use; proportion from water (P) = 10%.

- c** Chemical unlikely to be in commercial use; P = 20%.
- d** Reported as RfD.
- e** Reported as TDI.
- f** Reported as ADI.
- g** An RfD of 0.3 mg/kg/day was reported for anthracene by US EPA (1993c).
- h** A TDI of 0.05 mg/kg bw/day has been reported for total cresols (RIVM 2001); however, the TDI was derived in 1991 and the documentation for its derivation is not available; therefore, the TDI from a more recent evaluation (WHO 1995) was used. An intermediate duration oral minimal risk level (MRL) of 0.1 mg/kg/day (ATSDR 2006a) was also reported.
- i** The tolerable intake reported is for demeton; that is, a mixture of demeton-O and -S. An ADI value for demeton-S was not found; hence, the guideline calculation is based on the RfD for demeton.
- j** A group TDI of 0.00025 mg/kg bw/day is established for tributyltin, dibutyltin, triphenyltin and di-n-octyltin.
- k** Tolerable intake values for di-n-butyl phthalate were also reported as a TDI of 0.066 mg/kg bw/day (WHO 1997), an RfD of 0.1 mg/kg bw/day (US EPA 1990) and a TDI of 0.052 mg/kg bw/day (RIVM 2001). Recent scientific studies have focused on the developmental and reproductive effects of di-n-butyl phthalate. Because the EFSA (2004) evaluation considered the recent studies on developmental and reproductive toxicity of di-n-butyl phthalate in the context of modern risk assessment methods for assessing endocrine disruptors, the EFSA (2004) TDI was used instead of the WHO (1997) value.
- l** A TDI of 0.04 mg/kg bw/day was reported for naphthalene by RIVM (2001).
- m** Tolerable intake values for phenol were also reported as a TDI of 0.06–0.2 mg/kg bw/day (WHO 1994), an RfD of 0.3 mg/kg/day (US EPA 2002), an acute oral minimal risk level (MRL) of 0.6 mg/kg/day (ATSDR 2006b) and a TDI of 0.12 mg/kg bw/day (Health Canada 2004). The WHO (1994) review was prepared by RIVM; thus, the RIVM (2001) value was considered an update of the risk assessment conducted in 1994 on behalf of the WHO.
- n** A 1×10^5 lifetime excess oral cancer risk was reported for pyrene as 0.5 mg/kg bw/day (RIVM 2001).
- o** No primary documentation could be located at the time of writing to support the reported value.
- p** The drinking water guideline for dioxin like compounds is for the sum of all dioxins, furans and PCBs calculated as TEQs using the TEFs reported in Van den Berg et al (2006). The following dioxin like substances have been reported in Australian sewage effluent: octachlorodibenzo-p-dioxin (OCDD); 2,3,3',4,4',5-hexachlorobiphenyl (PCB156); 2,3,3',4,4',5-pentachlorobiphenyl (PCB105); 2,3',4,4',5-pentachlorobiphenyl (PCB118); 2,4,5,3',4',5'-hexachlorobiphenyl (PCB167); 3,4,5,3',4',5'-hexachlorobiphenyl (PCB169); PCB77.
- q** Total PCBs should be below a guideline value of 0.14 µg/L derived from an ADI of 0.02 ug/kg/day (US EPA, 1996) and an allocation to water of 20%.

Table A2 Recommended drinking water guidelines for non-pharmaceuticals established from an agency derived no observed effect level

Chemical name	Reported NOEL (mg/kgbw/day)	Reference	UF	Derived ADI (mg/kgbw/day)	Recommended guideline value (µg/L) ^a
<i>Pesticides</i>					
N,N-diethyltoluamide (N,N-diethyl-3-methylbenzamide) (DEET)	75	COT/COM/COC (2002)	100	0.75	2,500 ^b
<i>Other compounds</i>					
Musks					
2,4,6-Trinitro-1,3-dimethyl-5-tert-butylbenzene (musk xylene)	10	SCCNFP (2004)	100	0.1	350 ^b
Galaxolide	50	HERA (2004)	100	0.5	1,750 ^b
Musk ketone	10	SCCNFP (2004)	100	0.1	350 ^b
<i>Other organic compounds</i>					
4-Nonylphenol (4NP)	15	EC(2002)	100	0.15	500 ^b
4-tert-octylphenol	15	OECD(1995)	1,000	0.015	50 ^b

Chemical name	Reported NOEL (mg/kgbw/day)	Reference	UF	Derived ADI (mg/kgbw/day)	Recommended guideline value (µg/L) ^a
Nonylphenol	15	EC(2002)	100	0.15	500 ^b
Tri(butyl cellosolve) phosphate (ethanol,2-butoxy-phosphate)	15	WHO(2000)	1,000	0.015	50 ^b

NOEL = no observed effect level; UF = uncertainty factor

a Drinking water guideline calculated using Equation 1 in Box A4a, values have been rounded.

b Potentially in commercial use; hence P = 10%.

Table A3 Recommended drinking water guidelines for non-threshold chemicals

Non-threshold chemicals	Cancer slope factor (mg/kg/day)	Reference	Recommended drinking water guideline (µg/L)
Benzyl chloride		US EPA (1994)	0.2 ^a
N-nitrosomorpholine	6.7 (mg/kg/day) ⁻¹	CAL EPA (1999)	0.001 ^{bc}

a Reported drinking water concentration at a risk of 1 in 1 000 000.

b Drinking water guideline calculated using Equation 3.

c Chemical unlikely to be in commercial use; P = 20%.

A2.5 Thresholds of toxicological concern — chemicals with no guideline values or sufficient toxicological information

Guideline values for chemicals for which there are no established guidelines and for which relevant health or toxicological information does not exist at this time (identified at Step 4c in Figure A1) are derived from TTCs, as described in Steps 5a–5d. This approach is not applied to pharmaceutical compounds (see Section 6), to metals or to dioxins.

Step 5a — Is the chemical genotoxic?

Step 5a is to assess whether chemicals are genotoxic; that is, whether they have the ability to cause direct damage to DNA. Genotoxicity is a well-recognised toxicological mode of action through which chemicals may induce a cancer; thus, the supposition associated with genotoxicity is that the chemical may be a carcinogen of high potency. This is a precautionary assumption. Genotoxicity does not automatically equate with the substance causing cancer in experimental animals, nor does it imply that substances carcinogenic to experimental animals are necessarily carcinogenic to humans. In addition, not all types of genotoxicity are associated with non-threshold carcinogenic responses¹⁷ (CHMP 2006). However, since many more chemicals have been tested either in vitro or in vivo for broad genotoxic activity than have been tested for carcinogenicity, a protective approach is taken in setting drinking water guidelines for chemicals that do not have an existing guideline, and for which no health or toxicological data have been located.

¹⁷ Examples of mechanisms of genotoxicity that may lead to dose–response relationships with a threshold include interaction with the spindle apparatus of cell division leading to aneuploidy, topoisomerase inhibition, inhibition of DNA synthesis, overloading of defence mechanisms, metabolic overload and physiological perturbations (eg induction of erythropoiesis, hyper or hypothermia) (CHMP 2006).

Threshold of toxicological concern for genotoxic compounds

The starting point for developing a TTC for genotoxic compounds is a threshold of regulation derived from a carcinogenic potency database of more than 500 chemicals examined in more than 3500 experiments (FDA 1995, CFR 2001). The database includes genotoxic carcinogens. The United States Food and Drug Authority (FDA) (1995) and other leading researchers (Munro et al 1996, 1999) concluded that if no toxicological data are available to derive a health-based guideline for a chemical, intakes of 1.5 µg/person/day (0.02 µg/kg bw/day for a bw of 70 kg) are unlikely to result in appreciable health risk, even if the substance was later found to be a carcinogen.¹⁸ According to Munro (1990), a daily intake of 1.5 µg/person corresponds to a 96% probability that the lifetime risk of cancer would be less than one in a million (1×10^{-6}).

The FDA threshold of regulation has been adopted by WHO and the European Community (EC HCPD 2003) as a threshold intake of minor substances in food; this level of intake will trigger detailed risk assessments or experimental programs to investigate the toxicity of chemicals. These authorities consider that, at intakes below 1.5 µg/person/day, specific toxicity testing of the chemical is unwarranted, and only an abbreviated safety assessment, mainly focused on intake estimations, is needed (FDA 2006, EC 2003).

The FDA threshold of regulation is lower than the TTCs developed for structurally defined chemicals (Cramer Classifications I–III and cholinesterase inhibitors; see Table A6), because carcinogenicity can be triggered at lower exposures than those associated with other toxic effects. The TTC estimate of 0.02 µg/kg bw/day is conservative, erring on the side of safety, because of the numerous compounding conservative assumptions used to derive the low-dose cancer risk estimates (Barlow et al 2001, Kroes et al 2004). In this publication, the FDA threshold of regulation is referred to as the ‘generic’ TTC.¹⁹

The Expert Group of the Threshold for Toxicological Concern Task Force of the European branch of the International Life Sciences Institute (ILSI) further examined the issue of carcinogenicity, with particular reference to the potential for very high potency chemicals (Kroes et al 2004, Barlow 2005). The group examined an expanded carcinogenic potency database of 730 compounds, and divided the compounds into carcinogenicity structural alerts defined by Ashby and Tennant (1991). The expert group found that some genotoxic carcinogens with potential potency could represent a risk of greater than one in a million, if ingestion occurred at the generic TTC intake level over a lifetime. These substances were aflatoxin-like compounds, or were chemicals incorporating N-nitroso or azoxy functional groups. The expert group suggested that a TTC should not be derived for these compounds and that, if detected, the compounds should be subject to individual risk assessments (Kroes et al 2004). This deliberation has been adopted in this document as a precautionary measure because it provides increased safety assurance. Aflatoxin-like compounds and azoxy compounds have not been identified as issues in treated sewage (see Table 4.4) or drinking water. N-nitroso compounds— such as NDMA and N-nitrosodiethylamine (NDEA) — have been detected, but these compounds have established guideline values. If compounds without established guideline values are identified, they should be

¹⁸ The TTCs recommended here may be slightly lower than those reported in the scientific literature because of the assumed bodyweight of 70 kg, which, as discussed in Section A2.2, contrasts with the assumed bodyweight of 60 kg used by the WHO and European Community.

¹⁹ The generic TTC of 0.02 µg/kg bw/day was determined by the US EPA from the experimental carcinogenic database as the 5th percentile intake associated with an upper bound lifetime cancer risk of one in a million (1×10^{-6}). The distribution of upper bound cancer potencies (ie intake at the 1×10^{-6} risk level) was constructed from linearised low-dose extrapolation calculated using the TD₅₀ as the departure point for the extrapolation. The TD₅₀ is the lifetime dose of carcinogen that causes cancer in 50% of the test animals. Kroes et al (2004) followed a similar methodology and noted that a simple linear extrapolation from the TD₅₀ to a one in a million incidence was extremely conservative.

subject to individual risk assessments that include consideration of toxicological data and effectiveness of treatment processes.

The ILSI assessment also noted that 2–3% of chemicals in the extended database, other than the ones named above, presented a greater risk than one in a million at the TTC promulgated by the FDA (1995). As a conservative measure, they recommended a TTC of 0.15 µg/person/day (ie 0.002 µg/kg/day) for compounds recognised as genotoxic carcinogens of high potency. This is 10 times lower than the generic TTC adopted by the FDA. According to ILSI, this threshold gives a probability of 86–97% that any risk would be less than 1×10^{-6} if the intake were at or below the TTC, and the compound was a genotoxic carcinogen (Kroes et al 2004).

A precautionary approach has been adopted in these guidelines. Any genotoxic compound could be a carcinogen of high potency. For compounds with genotoxic alerts, the TTC of 0.15 µg/person/day recommended by ILSI (Kroes et al 2004, Barlow 2005) was used to derive a drinking water guideline. The generic TTC was used for deriving a drinking water guideline for organic compounds for which genotoxicity is unknown and classification by ToxTree into a Cramer class is not possible.²⁰ This highly conservative approach provides a high degree of confidence in the safety of the derived drinking water guideline.

For this publication, genotoxicity was assessed for listed chemicals for which no ADI or NOEL was identified. The results are shown in Table A4.

Table A4 Genotoxicity evaluation of substances without a tolerable daily intake or with no observed effect level

Chemical name	Genotoxic	Reference
<i>Acetylcholinesterase inhibitors</i>		
Triphenyl phosphate ^a	Unknown	WHO (2002a)
<i>Fire retardants</i>		
Fyrol FR 2 (tri(dichlorisopropyl) phosphate) ^a	Unknown	WHO (1998a)
Tris(2-chloroethyl)phosphate ^a	Unknown	WHO (1998a)
<i>Fragrances</i>		
Musk tibetene	No ^b	SCCNFP (2004)
Pentamethyl-4,6-dinitroindane (Musk moskene)	No ^b	SCCNFP (2004)
<i>Miscellaneous organic compounds</i>		
(Propylenedinitrilo)tetraacetic acid (PDTA)	No	
1,7-Dimethylxanthine (Paraxanthine)	No ^b	WHO (2002b)
2,5-Dihydroxybenzoic acid	No	FAO/WHO (2002)
2,6-di-tert-butyl-1,4-benzoquinone (2,6-bis(1,1-dimethylethyl)-2,5-cyclohexadiene-1,4-dione)	Yes ^d (DWG = 0.014 µg/L) ^h	NICNAS (2001)
2,6-di-tert-butylphenol (2,6-bis(1,1-dimethylethyl)phenol)	No ^b	SCCNFP (2004)
4-Acetyl-6-t-butyl-1,1-dimethylindan	No ^b	
4-cumylphenol	No ^e	EC (2002)

²⁰ ToxTree is a software program released by the European Chemical Bureau (ECB) for use in Cramer classification. The program is currently being validated, in conjunction with the ECB.

Chemical name	Genotoxic	Reference
5-methyl-1H-benzotriazole	Yes ^f (DWG = 0.007 µg/L) ^h	HCN (2000)
6-Acetyl-1,1,2,4,4,7-hexamethyltetraline	No	Api & San (1999)
Bromoacetic acid	No	WHO (2004a)
Bromochloroacetonitrile	No	WHO (2004b)
Caffeine	No	WHO (2002b)
Chlorophene	No	WHO (1998)
Cholesterol	No	IARC (1987)
Coprostanol (5beta-Cholestan-3beta-ol)	No ^g	IARC (1987)
Diatrizoate Sodium	Unknown	
Diatrizoic acid	Unknown	
Monobutyltin (MBT)	No	WHO (1990a)
Triclosan	No	NSCF (2004)

DWG = drinking water guideline

- a** Insufficient information available to assess whether these compounds are genotoxic.
- b** Considered non-genotoxic on the basis of structural similarity to musk ketone and musk xylene.
- c** Information could not be located on the genotoxicity of paraxanthine, but the chemical is not expected to be genotoxic because it is a metabolite of caffeine, and caffeine has been assessed by WHO (2002b) to be non-genotoxic.
- d** Considered genotoxic on the basis that quinones are chemically reactive and capable of forming adducts with DNA (NICNAS 2001).
- e** Alkylphenols were considered non-genotoxic based on structural analogy to nonylphenol.
- f** HCN (2000) considered the weight of evidence to indicate a potential for 1,2,3-benzotriazole to be a possible genotoxic carcinogen. Based on structural analogy, 5-methyl-1H-benzotriazole is considered genotoxic.
- g** Sterols as a chemical class are not regarded as genotoxic.
- h** The drinking water guideline is determined by use of the TTC for genotoxic compounds (0.002 µg/kg/day) (see Table A6) and assignment of either 10% or 20% of the TTC to water, depending on whether the compound is likely to be in commercial use.

Step 5b — Apply ‘structural’ thresholds to non-genotoxic compounds

For chemicals that were not identified as being genotoxic in Step 5a, guideline values were derived from TTCs using structural information. The thresholds determined using this concept are intakes of chemicals below which a given compound of known structure is not expected to present a toxicological concern. On the basis of classical pharmacological and toxicological concepts of dose response, exposure to trace levels of chemicals represents very low risks. TTCs have been developed for classes of substances with a systemic mode of toxicological action and with exposure by ingestion.

For many years, the TTC approach was seen as a pragmatic solution for addressing low concentrations of additives in food (Frawley 1967, Munro 1990, Munro et al 1996). It was first applied in a regulatory sense by the FDA (1995) and was later used by the EC (2003) to address chemicals migrating from plastic packaging into food. Today, the TTC approach is applied by the FDA, the EC and the WHO (Joint FAO/WHO Expert Committee on Food Additives, JECFA) in their deliberations on direct and indirect (ie contaminants) food additives, including flavouring substances (FDA 1995; FAO/WHO 1995, 1999; Munro et al 1999; EC 2003; Renwick 2004, 2005; EC JRC 2005). The TTC concept has also been adapted by Wilson et al (2000) for deriving criteria for soil risk management, for chemicals of unknown toxicological hazard or potency at contaminated sites.

Recently, the TTC has been suggested as a means of judging whether ingredients at low concentration in personal and household-care products require toxicological testing (Blackburn et al 2005). Also, Dolan et al (2005) have proposed a scientific rationale based on the TTC for estimating TDIs for compounds with limited or no toxicity data, to support pharmaceutical manufacturing operations.

TTCs are similar in concept to traditional use of TDIs or ADIs, and represent a level of exposure that is not of toxicological concern. Table A5 summarises some current regulatory uses of TTCs.

Table A5 Current uses of the threshold of toxicological concern

Organisation	Use	References
United States Food and Drug Administration (FDA)	De minimus level (ie level of minimum importance) for regulation of minor contaminants (ie chemicals in food packaging materials that can migrate). Threshold of toxicological concern (TTC) is applied as a threshold of regulation for indirect food additives. The FDA has dealt with 183 applications under this regulation and issued 78 exemptions using the TTC concept (Barlow 2005).	FDA (1993ab, 2006)
Joint FAO/WHO Expert Committee on Food Additives (JECFA)	Evaluation of flavouring substances. TTCs for different structural classes have been used for the safety evaluation of more than 1200 flavouring substances.	FAO/WHO (1993,1995, 1999), Munro et al (1999), Renwick (2004, 2005)
European Commission Scientific Committee on Food (SCF) ^a	Evaluation of flavouring substances.	EFSA (2004)
European Medicines Agency (EMA)	Assessment of genotoxic impurities in pharmaceutical preparations. See also Dolan et al (2005).	CHMP (2006)
European Commission, Joint Research Centre (EC JRC)	The TTC principle has been endorsed as a mechanism for the regulation of chemicals under draft chemical legislation reforms being considered by the European Union.	EC JRC (2005)

a The SCF is now known as the European Food Safety Authority (EFSA).

In establishing TTCs for chemicals that are not carcinogens, an evaluation of toxicological databases undertaken for non-carcinogenic end points is used (Munro et al 1996, 1999; Kroes et al 2000, 2004). In these evaluations, some 900 non-carcinogenic organic chemicals were assigned to three 'classes' based on their chemical structure, presence of structural alerts for toxicity and known metabolic pathways, according to the classification scheme of Cramer et al (1978), in which:

- *class I* are substances of simple chemical structure with known metabolic pathways and innocuous end products that suggest a low order of toxicity
- *class II* are substances with intermediate chemical structures that are less innocuous; that is, they may contain reactive functional groups but do not contain the structural features suggestive of toxicity
- *class III* are chemicals for which structural features or likely metabolic pathways either permit no strong presumption of safety, or actually suggest significant toxicity.

The 5th percentile NOEL of each of the three Cramer classes was divided by an uncertainty (safety) factor of 100 to yield TTC values that are somewhat higher than those determined by the FDA for carcinogens. No formal stratification of toxicological end points was used in establishing NOELs for the three Cramer chemical classes. The NOELs are:

- *class I* — 3 mg/kg/day (equates to a TTC of 30 µg/kg bw/day)
- *class II* — 0.9 mg/kg/day (equates to a TTC of 9 µg/kg bw/day)
- *class III* — 0.15 mg/kg/day (equates to a TTC of 1.5 µg/kg bw/day).

Renwick (2004, 2005) describes how JECFA applies the TTCs of the Cramer structural classes to the safety evaluation of flavouring agents. Since 1996, some 1200 compounds have been assessed using the TTC concept.

The Expert Group of the Threshold for Toxicological Concern Task Force of the European branch of ILSI has examined the TTC principle. The experts were asked to address the question of whether neurotoxic, developmental, immunotoxic, allergenic or endocrine activities could occur at low-dose levels, and to explore whether they warranted separate structural ‘classes’, with TTCs different from those of the Cramer classes.

Within the limitation of the databases, developmental neurotoxicity and developmental toxicity were no more sensitive than other non-specific end points. The cumulative distribution NOELs for these end points were similar to those for the chronic toxicity of the class III compounds of Munro et al (1996, 1999). Although data were relatively limited, it was also concluded that immunotoxicity was no more sensitive than other end points (Kroes et al 2000, 2004). The cumulative distribution of NOELs for neurotoxic compounds was lower than for other non-cancer end points, suggesting this to be a more sensitive effect. The distribution for neurotoxic compounds was driven primarily by the organic phosphate esters and a biochemical response (inhibition of cholinesterase) rather than a toxicological response (Step 5c, below).

With the exception of a subclass of neurotoxicants, all these potential health effects are thus accommodated by the TTCs developed for the Cramer classes and the generic TTC established for genotoxic carcinogens. With regards to endocrine toxicity, the panel noted that miscellaneous estrogenic compounds of anthropogenic origin (excluding those specifically designed for endocrine activity) possess only low hormonal activity, and animal studies do not indicate that hormonal effects are expected from low concentrations in food. This is also likely to be the case for low concentrations of these chemicals in water. Because there were conservative assumptions at each step of data compilation and analysis, and ‘worst case’ perspectives were taken, the expert group concluded that intake at or below the TTCs provides an adequate safety assurance.

Step 5c— Is the chemical a cholinesterase inhibitor?

The cumulative distribution of NOELs for neurotoxic compounds differs from the distribution of the NOELs for chronic toxicity for structural class III (Kroes et al 2000). Therefore, the expert group (Kroes et al 2004) examining the acceptability of the TTC values assigned to Cramer structural classes I, II, and III by Munro et al (1996) looked at whether neurotoxicants need to be considered as a separate class for TTC application. The database used by Kroes et al (2000) and by Kroes and Kozianowski (2002) was biased towards high potency because most compounds considered were organophosphates, and the ‘toxicological’ end point was based on inhibition of cholinesterase. The latter, especially inhibition of plasma cholinesterase, is arguably a biochemical marker rather than a functional alteration of physiology falling within the usual definition of an adverse effect used to establish an ADI.

Kroes et al (2004) investigated the effect of replacing the plasma cholinesterase inhibition with end points of neurotoxicological relevance. Their review found no clear relationship between brain, red blood cell and plasma cholinesterase inhibition,²¹ and concluded that organophosphates need to be considered as a separate class of substances within the TTC framework. Furthermore:

- the cumulative distribution of organophosphates differed by one order of magnitude from the distribution of NOELs of neurotoxicants that are not organophosphates
- the 5th percentile NOEL of 31 organophosphates was lower than the 5th percentile NOEL of Cramer structural class III compounds in the Munro et al (1996) database.

The 5th percentile NOEL for the organophosphates, divided by an uncertainty (safety) factor of 100, yields a TTC for organophosphates of 18 µg/person/day (0.3 µg/kg bw/day); non-organophosphate neurotoxicity is adequately allowed for by the class III TTC (Munro et al 1996, 1999, Kroes et al 2000, 2004).

For this publication, the recommended TTC for organophosphates was extended to cover all substances whose primary mode of toxicological action is inhibition of cholinesterase. Thus, for cholinesterase inhibiting substances in Table 4.4 for which no drinking water guideline existed, a TTC of 0.3 µg/kg/day was applied in Equation 2 of Box A4a to set a guideline.

Only three compounds in Table 4.4 were acetylcholine esterase inhibitors and did not have an assigned drinking water guideline. These were tri(dichlorisopropyl)phosphate, triphenyl phosphate and tris(2-chlorethyl)phosphate. Since all these substances are on AICS, they were presumed to be in commercial use; hence, 10% of the TTC for anticholinesterase compounds (0.3 µg/kg/day) was assigned to drinking water. The recommended drinking water guideline was therefore set at 1 µg/L (Table A6).

Step 5d — Assign Cramer classifications for non-cholinesterase chemicals

In this document, the Cramer classification has been performed using ToxTree. All the compounds classified by Cramer et al (1978), Munro et al (1996) and Blackburn et al (2005) were classified using ToxTree, to assess the suitability of the software for classifying organic chemicals found in recycled water into the Cramer classes. Concordance was found between the software classifications and the manual classifications undertaken by experts and reported in the above publications. However, in some instances, ToxTree did not produce clear classifications; these primarily relate to stereochemistry issues and are easily recognised in the output of ToxTree. Consequently, in Figure A1, at Step 5d, if there is a question regarding the possible reliability of the ToxTree classification, the default is to apply the generic TTC of 0.02 µg/kg/day for potential genotoxic compounds.

Step 5e — Setting guideline values

Based on the approach described in Steps 6a–6d non-pharmaceutical chemicals without guideline values or suitable toxicological information can be classified as shown in Table A6 for chemicals listed in Table 4.4. These classifications can then be used to determine drinking water guidelines using the approach summarised in Table A7.

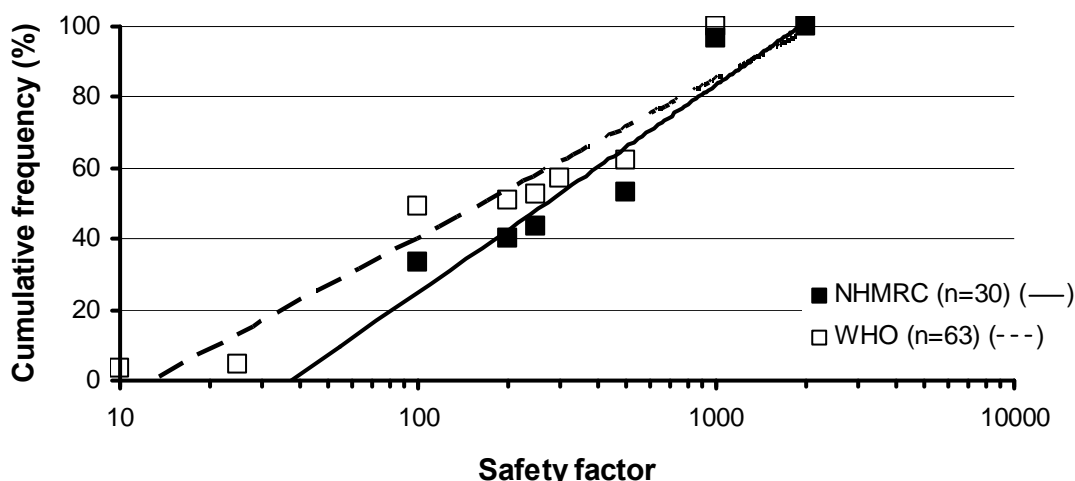
As discussed above, the derivation of TTCs includes the application of a safety factor of 100. In this document, a more conservative approach has been applied to the derivation of drinking water guidelines, using safety factors.

²¹ 20% inhibition was taken as the level of toxicological significance for cholinesterase inhibition end points.

In terms of safety factors applied to NOELs, the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) uses a 95th percentile of 1570 and the *Guidelines for Drinking-Water Quality* (WHO, 2006a) use a 95th percentile of 1660 (Figure A2). Accordingly, a total safety factor of 1500 has been applied in this document, in deriving drinking water guidelines from the 5% NOELs. The exception is cholinesterase inhibitors; for these chemicals, the TTC is based on the toxicological end point ‘inhibition of blood cholinesterase’. The effect on human health of inhibition of blood cholinesterase is well defined; consequently, there is much less uncertainty associated with this group of compounds and a lower safety factor is appropriate.

As shown in Table A7, the standard safety factor of 100 is applied in deriving TTCs from the 5% NOELs. A further factor of 15 is then applied in converting the TTCs into guideline values.

Figure A2 Cumulative distributions of safety factors applied by NHMRC (2004) and WHO (2006a) to NOEL of organic compounds when setting drinking water guideline



NHMRC: Regression equation: $Y = 25.414 \ln(x) - 92.001$
Coefficient of determination (R^2) = 0.9009

WHO: Regression equation: $Y = 19.492 \ln(x) - 49.485$
Coefficient of determination (R^2) = 0.9143

Descriptive statistics of safety factor distributions:

	Geometric mean	50th percentile	95th percentile
NHMRC	380	270	1,570
WHO	260	170	1,660

NHMRC = National Health and Medical Research Council; NOEL = no observed effect level; WHO = World Health Organization

Table A6 Cramer classification of compounds without toxicological information that are not genotoxics, pharmaceuticals or cholinesterase inhibitors

Chemical name	ToxTree classification class	TTC ($\mu\text{g}/\text{kg}$ bw/day) ^a	Recommended drinking water guideline ($\mu\text{g}/\text{L}$) ^b
<i>Organic compounds</i>			
Musks			
Musk tibetene	III	1.5	0.35 ^b
Pentamethyl-4,6-dinitroindane (musk moskene)	III	1.5	0.35 ^b
<i>Other compounds</i>			
(Propylenedinitrilo)tetraacetic acid (PDTA)	III	1.5	0.7 ^c
1,7-Dimethylxanthine (Paraxanthine)	III	1.5	0.7 ^c
2,5-Dihydroxybenzoic acid	I	30	7 ^b
2,6-di-tert-butylphenol (2,6-bis(1,1-dimethylethyl)phenol)	II	9	2 ^b
4-Acetyl-6-t-butyl-1,1-dimethylindan	I	30	7 ^b
4-cumylphenol	III	1.5	0.35 ^b
6-Acetyl-1,1,2,4,4,7-hexamethyltetraline	II	9	4 ^c
Bromoacetic acid	III	1.5	0.35 ^b
Bromochloroacetonitrile	III	1.5	0.7 ^c
Caffeine	III	1.5	0.35 ^b
Chlorophene	III	1.5	0.35 ^b
Cholesterol	I	30	7 ^b
Coprostanol (5beta-Cholestan-3beta-ol)	III	1.5	0.7 ^c
Diatrizoate sodium	III	1.5	0.35 ^b
Diatrizoic acid	III	1.5	0.35 ^b
Monobutyltin	III	1.5	0.7 ^c
Triclosan	III	1.5	0.35 ^b
<i>Genotoxic compounds</i>			
2,6-di-tert-butyl-1,4-benzoquinone (2,6-bis(1,1-dimethylethyl)-2,5-Cyclohexadiene-1,4-dione)		0.02	0.14 ^c
<i>Cholinesterase inhibitors</i>			
Fyrol FR 2 (tri(dichlorisopropyl)phosphate)		0.3	1 ^b
Triphenyl phosphate		0.3	1 ^b
Tris(2-chloroethyl)phosphate		0.3	1 ^b

TTC = threshold of toxicological concern

a Drinking water guidelines taken from Table A6.

b Likely to be in commercial use, P = 10%.

c Presumed not to be in commercial use, P = 20%.

Table A7 Thresholds of toxicological concern for Cramer structural chemical classes and certain toxicological end points, with corresponding drinking water guideline recommendations

Chemical class/ toxicological end point	5th percentile NOEL (mg/kg/day)	TTC (µg/kg/day)	Reference	Recommended drinking water guideline (µg/L) ^c
Structural class I	3	30 ^a	Munro et al 1996, 1999	7 or 14
Structural class II	0.91	9 ^a	Munro et al 1996, 1999	2 or 4
Structural class III ^b	0.15	1.5 ^a	Munro et al 1996, 1999	0.35 or 0.7
Neurotoxicity (cholinesterase inhibitors)	0.03 ^c	0.3 ^a	Kroes et al 2000, Kroes and Kozianowski 2002	1 or 2
Generic TTC	5th percentile associated with 10 ⁻⁶ carcinogenic risk	0.02 ^d	FDA 1995, CFR 2001	0.07 or 0.14
Genotoxic carcinogenicity	5th percentile associated with 10 ⁻⁶ carcinogenic risk	0.002 ^f	Kroes et al (2004) Barlow (2005)	0.007 or 0.014
Potentially high potency carcinogens	Aflatoxin-like compounds, N-nitroso compounds and azoxy compounds			Individual risk assessments required

NOEL = no observed effect level; TTC = threshold of toxicological concern

a Calculated by dividing the 5th percentile no observed effect level (NOEL) by a safety factor of 100. This is the TTC used by various authorities in assessing risks associated with minor contaminants in food.

b Substances whose structure or presumed metabolism permit no strong presumption of safety, or even suggest significant toxicity.

c This NOEL is driven by inhibition of cholinesterase by phosphate esters.

d This TTC is applied to compounds without genotoxic alerts but which are not cholinesterase inhibitors or cannot be assigned a Cramer structural classification. The TTC is inserted into Equation 2 of Box A3 in lieu of the acceptable daily intake (ADI).

e The recommended drinking water guideline is calculated by inserting the 5th percentile NOEL into Equation 1 (Box A4) and assuming P = 10% or 20%, depending on whether the chemical is likely to be in commercial use (10%) or not (20%), according to the Australian Inventory of Chemical Substances (AICS). The safety factor used is 1500 (this is the 95th percentile value of safety factors used by the NHMRC [NHMRC–NRMCM 2004] or WHO [2006a] on experimental NOELs, see text). The exception is for cholinesterase inhibitors where the toxicological end point upon which the TTC is based is inhibition of blood cholinesterase which is well defined; consequently, there is much less uncertainty associated with this group of compounds and a lower safety factor is appropriate. The safety factor applied is the standard TTC factor of 100. Values in table have been rounded.

f Genotoxic compounds are assumed to potentially be carcinogens of high potency, consequently the TTC recommended by Kroes et al (2004) and Barlow (2005) is the value used to set a drinking water guideline, rather than the FDA value (FDA 1995) as it embodies a later assessment of an expanded database than was undertaken by the FDA. The recommended TTC is 0.15 µg/person/day (ie 0.002 µg/kg/day). The appropriate TTC, as mg/kg/day, is inserted into Equation 2 of Box A3 in lieu of the ADI.

A2.6 Step 6 — Pharmaceuticals

The chemicals listed in Table 4.4 (Chapter 4) include many that are active ingredients of pharmaceutical compounds. In the human body, pharmaceuticals are generally metabolised and cleared as the parent compound and metabolites. Excretion from the body is the primary source of pharmaceuticals in wastewater. Less commonly, pharmaceuticals may be introduced through industrial accidents and releases from hospitals.

A regulatory framework for establishing guidelines for pharmaceutical substances in drinking water was not identified in developing these guidelines. The TTC approach is not required for pharmaceuticals as health data is available. Pharmaceuticals have been divided into two groups — those used solely for humans and those used for agricultural and veterinary purposes (some of which may also be used for humans).

Step 6a — Pharmaceuticals used for agricultural and veterinary purposes

ADIs for agricultural and veterinary chemicals including pharmaceuticals have been established by bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Australian Therapeutics Goods Administration (TGA) and the European Medicines Agency (EMA). These ADIs have been used to determine guideline values.

Step 6b — Pharmaceuticals used for humans

Derivation of guideline values for pharmaceuticals used solely in human medicine was based on therapeutic doses. The traditional approach applied by NHMRC and WHO to derive drinking water guidelines (NHMRC–NRMCC 2004, WHO 2006a) from toxicological data would not be practical. There are large numbers of pharmaceuticals with new products appearing on a regular basis. Pharmaceutical products are among the most extensively examined of chemicals in terms of human health impacts. They are rigorously tested for safety prior to release and systems are in place for reporting adverse side effects. However, much of the testing data is confidential and not available for development of guideline values.

The biological or pharmacological activity at therapeutic doses for pharmaceuticals used in human medicine can be found in the manufacturer's literature and in various pharmacopoeias. The recommended therapeutic doses of pharmaceuticals are intended to elicit a biological outcome (albeit beneficial) in patients. For most pharmaceuticals, the ratio of doses causing toxicity to the doses giving a beneficial effect (the therapeutic index) is large.²² Hence, to establish a drinking water guideline for a pharmaceutical chemical, guideline values could be derived by dividing the lowest daily therapeutic dose by a factor that would provide reasonable assurance that effects, either pharmacological or toxic, would be unlikely. This approach has been applied by Schwab et al (2005) in a human health risk assessment of pharmaceuticals in United States surface waters and by Versteegh et al (2007). DEFRA (2007) also used the lowest therapeutic dose as the basis for assessing the risk from pharmaceuticals in drinking water.

Dolan et al (2005) took a different approach to assessing the risk of pharmaceuticals in environmental media. The authors reviewed ADI values derived since 1981 for active pharmaceutical ingredients of the Merck pharmaceutical company. The analysis excluded genotoxic compounds. The database consisted of 120 compounds, with a broad range of potencies that are administered orally or parenterally. The study found that 94% of the compounds with

²² Many of the pharmaceutical compounds in Table 4.4 are nonsteroidal anti-inflammatory agents, antibiotics or beta-blockers. These agents would be expected to have a therapeutic index of much more than 10-fold.

known pharmacological activity had ADIs²³ greater than 10 µg/day (ie 0.15 µg/kg/day); this ADI applied to Equation 2 of Box A.4a and attributing 100% of non-prescribed exposure to water would result in a drinking water guideline of 5 µg/L.

The approach adopted here is to calculate surrogate ADIs for human pharmaceutical agents by dividing the lowest recommended therapeutic dose (as mg/kg/day) by safety factors. The approach is illustrated using pharmaceuticals detected in secondary treated sewage, as shown in Table A8. However, the process can be equally applied to any pharmaceutical no matter what the source (eg appropriate therapeutic use, hospital discharges or inadvertent releases into water bodies).

Step 6c — Setting safety factors

It is standard practice to apply safety (or uncertainty) factors to derive guideline values from base data for threshold chemicals (in this case lowest recommended therapeutic doses) that are designed to be protective of human health. The *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) uses the term safety factor while WHO (2006a) uses the term uncertainty factor. Ritter et al (2007) have reviewed these factors and their application by WHO and by Australia, Canada and the United States. Safety factors described in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) are as follows:

- *Interspecies variation* — a factor of 10 is applied to account for uncertainty when extrapolating from studies on experimental animals to humans.
- *Intraspecies variation* — a factor of 10 is applied to take account of variations within humans.
- *Subchronic to chronic* — a factor of 10 is applied if data from a subchronic study is used in the absence of reliable data from chronic studies (this factor can be less if chronic studies are available and indicate that no other effects occur, or that other effects are mild).
- *Lowest observed effect level (LOEL) versus NOEL* — a factor of up to 10 is applied if effects have been observed at the lowest doses (guidelines are preferably derived from the highest dose at which no adverse effects are seen).

Other safety factors have been described for data base uncertainty (1–10), protection of infants and children (1–10) and nature or severity of effect. Individual safety factors lower than 10 can be applied where there is sufficient information to justify a reduction. This can include information on mechanisms of action, human epidemiological data and evidence that adverse effects are relatively minor. The rationale for using safety factors between 1 and 10 are discussed in Ritter et al (2007). In deriving guideline values for pharmaceuticals, Schwab et al (2005) applied safety factors for LOEL to NOEL, subchronic to chronic, interspecies variation, intraspecies variation and database uncertainty. In a number of cases, safety factors of 2–5 were used rather than 10.

While application of safety factors are entrenched in international guideline setting practices, application is influenced by subjective judgments. Nonetheless, there is a degree of consistency in the magnitude of total or composite safety. There is general agreement that the total safety factor should not exceed 10 000 and this convention is applied by Health Canada, WHO, US EPA and NHMRC. The US EPA uses an upper limit of 10 000 to avoid overlap and overprotection associated with higher safety factors (Dourson et al 1996, Ritter et al 2007).

As shown in Figure A2, the 50th and 95th percentiles of safety factors used in deriving guideline values from NOELs in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) are

²³ Dolan et al (2005) do not provide the basis of the ADIs (ie whether set on pharmacological or toxic NOEL) or the magnitude of the uncertainty factor applied to the NOEL.

270 and 1570 respectively, and in the WHO Guidelines (WHO 2006a) are similar at 170 and 1660 respectively. About 90% of safety factors applied in drinking water guidelines are 1000 or less.

Schwab et al (2005) applied safety factors ranging from 9 to 200 to the lowest daily therapeutic dose for 26 pharmaceuticals (50th percentile 90). An additional safety margin was applied by using child body weights of 14 kg and consumption of 1 L per day (compared to adult body weights of 70 kg and consumption of 2 L per day). In effect this adds a further margin of 2.5, meaning that total safety factors of 22.5 to 500 were applied (50th percentile 225).

Versteegh et al (2007) derived guideline values for pharmaceuticals using the lowest pharmacologically effective dose, a safety factor of 100, a body weight of 60 kg and consumption of 2L per day.

DEFRA (2007) applied a safety margin of 1000.

In this publication, the following safety factors have been applied:

- *all pharmaceuticals* — a safety factor of 1000 is applied, comprising
 - 10 for differences in response between humans including sensitive individuals (intraspecies variation)
 - 10 for protection of sensitive subgroups including children and infants
 - 10 for the lowest daily therapeutic dose not being a no-effect level
- *cytotoxic drugs* — an additional safety factor of 10 is applied due to the higher level of toxicity associated with these compounds
- *hormonally active steroids* — an additional safety factor of 10 is applied, on the grounds that potential effects on hormonal function and fertility is unwanted in those not being treated.

This means that the safety factors applied to pharmaceuticals range from 1000 to the maximum applied in all drinking water guidelines of 10 000. Considering that a safety factor is not required for interspecies variation, this is considered to be a conservative approach. The combined factor of 100 for intraspecies variability and protection of sensitive subgroups is considered to be adequately address issues associated with potential exposure of infants, children and those with allergies or other contraindications. Specific health risks for children and infants has been the subject of some discussion (WHO 2006b, US EPA 2006d) but there is no consistent approach for applying safety factors to infants or other sensitive subgroups. Application of an additional safety factor of 10 is considered a conservative approach. The United States Food Quality Protection Act (US 1996) applies a default safety factor of 10 in dealing with pesticides in food products.

There is limited information on allergic reactions that can be used in modifying guideline values. The guideline value for the penicillins is based on preventing allergic reactions (EMEA 2005). This value has been applied to all β -lactams.

Step 6d — Proportion allocated to water

Based on the rationale that pharmaceutical chemicals used in human medicine are not widespread in the environment or likely to be present in food, the proportion of the surrogate ADI (S-ADI) allocated to water for pharmaceuticals is 100%. For persons taking medication, intake of a pharmaceutical chemical at the recommended drinking water guideline determined using this methodology (shown in Box A6) will be an additional 0.1% of their daily dose or 0.01% for cytotoxic drugs or steroidal hormones.

For pharmaceuticals with agricultural or veterinary use the proportion allocated to water is 10%.

Box A6 Calculation of drinking water guidelines using therapeutic doses

$$\text{Drinking water guideline } (\mu\text{g/L}) = \frac{\text{S-ADI (ug/kg/day)} \times \text{bw (kg)} \times \text{P}}{\text{V (L/day)}} \quad \text{Equation 4}$$

Where:

S-ADI = surrogate-ADI (ug/kg/day) = lowest daily oral therapeutic dose for an adult (LDTD) (mg/day) \div [safety factor (SF) (1000 or 10 000) \times bw (kg)] $\times 10^3$

P = proportion of S-ADI from water = 100%

bw = bodyweight (70 kg)

V = volume of water drunk (2 L/day)

10^3 = unit conversion mg/L to $\mu\text{g/L}$.

If using the lowest daily therapeutic dose directly instead of the S-ADI, Equation 4 becomes:

$$\text{Drinking water guideline } (\mu\text{g/L}) = \frac{\text{LDTD (mg/day)} \times \text{P} \times 10^3}{\text{SF} \times \text{V (L/day)}} \quad \text{Equation 4a}$$

Where:

The LDTD is taken from (in order of priority) MIMS, Martindale, or another pharmacopeia for preparations that have the chemical as a sole ingredient. If dose information is not available for the single agent, then doses from combination preparations are used. If an LDTD cannot be located, then either the LDTD for a similar active ingredient can be used with an extra safety factor of 10, or a TTC can be derived using a Cramer classification.

SF is 1000 for most pharmaceuticals, 10 000 for cytotoxic compounds and for synthetic or natural hormones.

Example — norflaxin

An example of this approach can be demonstrated using the antibiotic norfloxacin, which has been found at concentrations of up to 7 $\mu\text{g/L}$ in wastewater. The lowest recommended daily dose in two parts is 800 mg (ie 400 mg every 12 hours). Applying a safety factor of 1000 this represents a daily dose of 800 μg per day. Attributing 100% of the non-prescribed dose to the average 2 L of water consumed per day means that the drinking water guideline value is 400 $\mu\text{g/L}$, which is substantially above the measured concentration of 7 $\mu\text{g/L}$ identified in secondary treated sewage.

Table A8 presents calculated drinking water guidelines for the pharmaceutical chemicals identified in Table 4.4 and compares them with the highest concentrations measured in secondary treated effluent. With limited exceptions, the margins of exposure resulting from this comparison are greater than 1 with many being 1000 or more. Given that this does not take into account reductions achieved by advanced treatment processes, it is unlikely that pharmaceutical chemicals will be present at levels approaching the recommended drinking water guideline, or cause untoward effects in people drinking water produced from recycled water.

The exceptions are alprazolam, valium and the estrogenic hormones. The concentrations of each of these compounds would be reduced to below guideline values by advanced treatments, including reverse osmosis (Table 4.10) (Ternes and Joss 2006, Costanzo and Watkinson 2007, Snyder et al 2007). Removal of estrogenic hormones has been demonstrated in a number of studies (Huang and Sedlak 2001, Khan and Roser 2007). Testing of recycled water produced at

the Orange County Groundwater Replenishment Scheme (Daugherty et al 2005) and the Singapore NEWater Scheme²⁴ has not detected 17 α -ethynylestradiol, estrone or 17 β -estradiol.

Table A8a Recommended drinking water guideline for pharmaceuticals with agricultural and veterinary applications

Pharmaceutical	Maximum concentrations detected ($\mu\text{g/L}$) ^a	ADI ($\mu\text{g/kg/day}$) ^b	DWG ($\mu\text{g/L}$)	Margin of exposure (DWG \div highest concentration)
Antibiotics				
Amoxicillin	0.02	0.43 ^c	1.5	75
Anhydro-erythromycin A	0.92	5 ^d	17.5	10
Azithromycin	0.072	11 ^d	3.9	54
Cephalexin	0.09	10 ^g	35	390
Chlorotetracycline	0.28	30 ^e	105 ^e	375
Doxycycline	0.03	3 ^f	10.5	350
Enrofloxacin	0.015	6.2 ^f	22	1500
Erythromycin	1.7	5 ^f	17.5	10
Lincomycin	0.015	1,000 ^g	3500	230,000
Monensin	0.08	10 ^g	35	440
Penicillin G	0.03	0.43 ^c	1.5	50
Penicillin V	0.21	0.43 ^c	1.5	7.1
Sulfadimethoxine	0.06	10 ^h	35	580
Sulfamethazine	0.68	10 ^h	35	52
Sulfamethiazole	0.13	10 ^h	35	269
Sulfamethoxazole	1.9	10 ^h	35	18
Terramycin (oxytetracycline)	0.66	30 ^e	105 ^e	160
Tetracycline	0.11	30 ^e	105 ^e	950
Trimethoprim	0.35	20 ^g	70	200
Tylosin	1.1	300 ^g	1050	950
Nonsteroidal anti-inflammatory drugs (NSAIDs)				
Aspirin	2.1	8.3 ^f	29	14
Diclofenac	0.81	0.5 ^f	1.8	2.2
Dipyron	7.5	150 ^f	525	70
Ketoprofen	0.38	1 ^g	3.5	9.2
Tolfenamic acid	1.6	5 ^g	17.5	11
β-adrenergic blockers				
Carazolol	0.12	0.1 ⁱ	0.35	2.9

²⁴ http://www.pub.gov.sg/NEWater_files/download/review.pdf

Pharmaceutical	Maximum concentrations detected ($\mu\text{g/L}$) ^a	ADI ($\mu\text{g/kg/day}$) ^b	DWG ($\mu\text{g/L}$)	Margin of exposure (DWG \div highest concentration)
Estrogenic compounds				
17 α -estradiol	0.074		0.175 ^j	2.4
17 β -estradiol	0.027	0.05 ^k	0.175	6.5
Progesterone	0.199	30 ^k	105	530
Androgenic compounds				
Testosterone	0.214	2 ^k	7.0	33
Other pharmaceuticals				
Clenbuterol	0.05	4.2 ⁱ	15	300
Paracetamol (acetaminophen)	4.3	50 ^f	175	41

ADI = acceptable daily intake; DWG = drinking water guideline

a See Table 4.4

b ADI's used for veterinary drugs and where published by EMEA, WHO or TGA.

c The maximum permitted daily intake of 30 μg parent compound per person (0.43 $\mu\text{g/kg}$ bw/day), is agreed for penicillins in relation to the prevention of allergic reactions (EMEA 2005). This approach also applied to amoxicillin.

d Azithromycin is considered the parent compound of tulathromycin. An ADI of 11 $\mu\text{g/kg}$ bw/day has been developed for tulathromycin (EMEA 2004). An additional safety factor of 10 has been used in the calculation of a drinking water guideline for azithromycin, on the basis that the ADI from tulathromycin was used. Anhydro-erythromycin A is a derivative of erythromycin, and the ADI of 5 $\mu\text{g/kg}$ bw/day adopted for erythromycin has been applied (EMEA 2000).

e An ADI of 30 $\mu\text{g/kg}$ bw/day was established for the tetracyclines (oxytetracycline, chlorotetracycline and tetracycline) alone or in combination (FAO/WHO 1998b). Applied as a total for all tetracyclines.

f EMEA (various dates). The European Agency for the Evaluation of Medicinal Products, Veterinary Medicines Evaluation Unit.

g TGA (2006)

h A guideline for sulphonamides in drinking water made from recycled water has been established by applying the lowest ADI for sulphonamides established by the NRA (ie 0.01 mg/kg bw/day [NRA 2000]). It is recommended that this be applied to all individual sulphonamides.

i Although an ADI for this compound has been published by the WHO, the EMEA published ADI value has been sourced on the basis that the EMEA report is a more recent evaluation.

j Assumed same potency as 17 β -oestradiol.

k FAO/WHO 2000

Table A8b Recommended drinking water guideline for human pharmaceuticals

Human pharmaceuticals	Maximum conc detected ($\mu\text{g/L}$) ^a	LDTD (mg/day)	S-ADI ^b ($\mu\text{g/kg/day}$)	DWG ($\mu\text{g/L}$)	Margin of exposure (DWG \div highest conc)
Antibiotics					
Cefaclor	1.21	500	7.1	250	200
Chloramphenicol	0.56	3,500	5 ^c	175	310
Ciprofloxacin	0.4	500	7.1	250	630
Clarithromycin	0.24	500	7.1	250	1,040
Clindamycin	0.120	600	8.6	300	2,500
Demeclocycline	1.12	600	8.6	300	270
Naladixic acid	0.22	2,000	28.4	1,000	4,550

Human pharmaceuticals	Maximum conc detected (µg/L)^a	LDTD (mg/day)	S-ADI^b (µg/kg/day)	DWG (µg/L)	Margin of exposure (DWG ÷ highest conc)
Norfloxacin	0.2	800	11.4	400	2000
Roxithromycin	0.68	300	4.3	150	220
Nonsteroidal anti-inflammatory drugs (NSAIDs)					
Fenoprofen	0.759	900	12.9	450	590
Ibuprofen	28	800	11.4	400	14
Indomethacin	0.6	50	0.71	25	14
Naproxen	0.57	440	6.3	220	380
β-andrenergic blockers					
Betaxolol	0.19	20	0.28	10	53
Bisoprolol	0.37	1.25	0.018	0.63	1.7
Metoprolol	2.2	50	0.71	25	11
Nadolol	0.06	40	0.57	20	330
Propranolol	0.29	80	1.14	40	140
Timolol	0.07	20	0.28	10	140
Estrogenic compounds					
17α-ethinyl estradiol	0.270	0.03	4.3 x10 ^{-5 d}	0.0015	0.006
Equilenin	0.278	0.6	8.6 x10 ^{-4 d}	0.03	0.11
Equilin	0.15	0.6	8.6 x10 ^{-4 d}	0.03	0.2
Estriol	0.051	1	1.4 x10 ^{-3 d}	0.05	1
Estrone	0.11	0.6	8.6 x10 ^{-4 d}	0.03	0.27
Mestranol	0.407	0.05	7.1 x10 ^{-5 d}	0.0025	0.006
Norethindrone	0.872	5	7.1 x10 ^{-3 d}	0.25	0.29
Androgenic compounds					
Androsterone	0.214	-		14.0 ^e	65
Other pharmaceuticals					
Alprazolam	0.62	0.5	0.0071	0.25	0.4
Antipyrine	0.41	2,000	28.4	1,000	2400
Atorvastatin	0.044	10	0.14	5	110
Bezafibrate (benzafibrate)	4.6	600	8.6	300	65
Carbamazepine	27.3	200	2.8	100	3.7
Cimetidine	0.58	400	5.7	200	340
Clofibric acid (clofibrate)	1.6	1,500	21.4	750	470
Codeine	9.1	100	1.4	50	5.5

Human pharmaceuticals	Maximum conc detected (µg/L) ^a	LDTD (mg/day)	S-ADI ^b (µg/kg/day)	DWG (µg/L)	Margin of exposure (DWG ÷ highest conc)
Cotinine ((S)-1-methyl-5-(3-pyridinyl)-2-Pyrrolidinone) ^f	0.9	20	0.28	10	11
Cyclophosphamide	0.02	70	0.1 ^g	3.5	175
Dehydronifedipine ^h	0.03	40	0.57	20	670
Diazepam	2.92	5	0.071	2.5	0.9
Diltiazem	0.049	120	1.7	60	1220
Enalaprilat	0.046	2.5	0.036	1.25	27
Fluoxetine	0.142	20	0.28	10	70
Gemfibrozil	1.5	1,200	17	600	400
Iohexol	1.6	1,440	20.6	720	450
Iopamidol	1.6	800	11.4	400	250
Iopromide	1.8	1,500	21.4	750	420
Isophosphamide ⁱ	2.9	70	0.1 ^g	3.5	1.2
Metformin	0.15	500	7.1	250	1670
Salbutamol	0.035	6	0.086	3	86
Salicylic acid	60	Topical preparations only		105	1.8
		Cramer class I			
Stigmastanol	4	2,000	28.4	1,000	250
Sulfasalazine	0.12	1,000	14.2	500	4,170
Temazepam	1.64	10	0.14	5	3
Terbutaline	0.12	9	0.13	4.5	38

DWG = drinking water guideline; LDTD = lowest daily therapeutic dose; S-ADI = surrogate acceptable daily intake

a See Table 4.4

b S-ADI calculated as described in Box A6 using a safety factor of 1000 unless otherwise indicated.

c Safety factor of 10 000 applied due to concerns of potential carcinogenicity.

d Steroid hormone — safety factor of 10 000.

e Androsterone is a weak androgen; here it is assumed to be 50% of testosterone potency.

f Cotinine is major metabolite of nicotine, rapidly cleared by the kidneys. Less active than nicotine which is given in antismoking regimes from about 10 mg/person (transdermal). Assume 50% activity of nicotine gives 20 mg/person for cotinine.

g Cytotoxic, or genotoxic agent — safety factor of 10 000.

h Dihydronifedipine is the predominant metabolite of nifedipine. Minimal dose of nifedipine is 20 mg/day; assume 50% activity for the metabolite yields 40 mg/person.

i Isomer of cyclophosphamide.

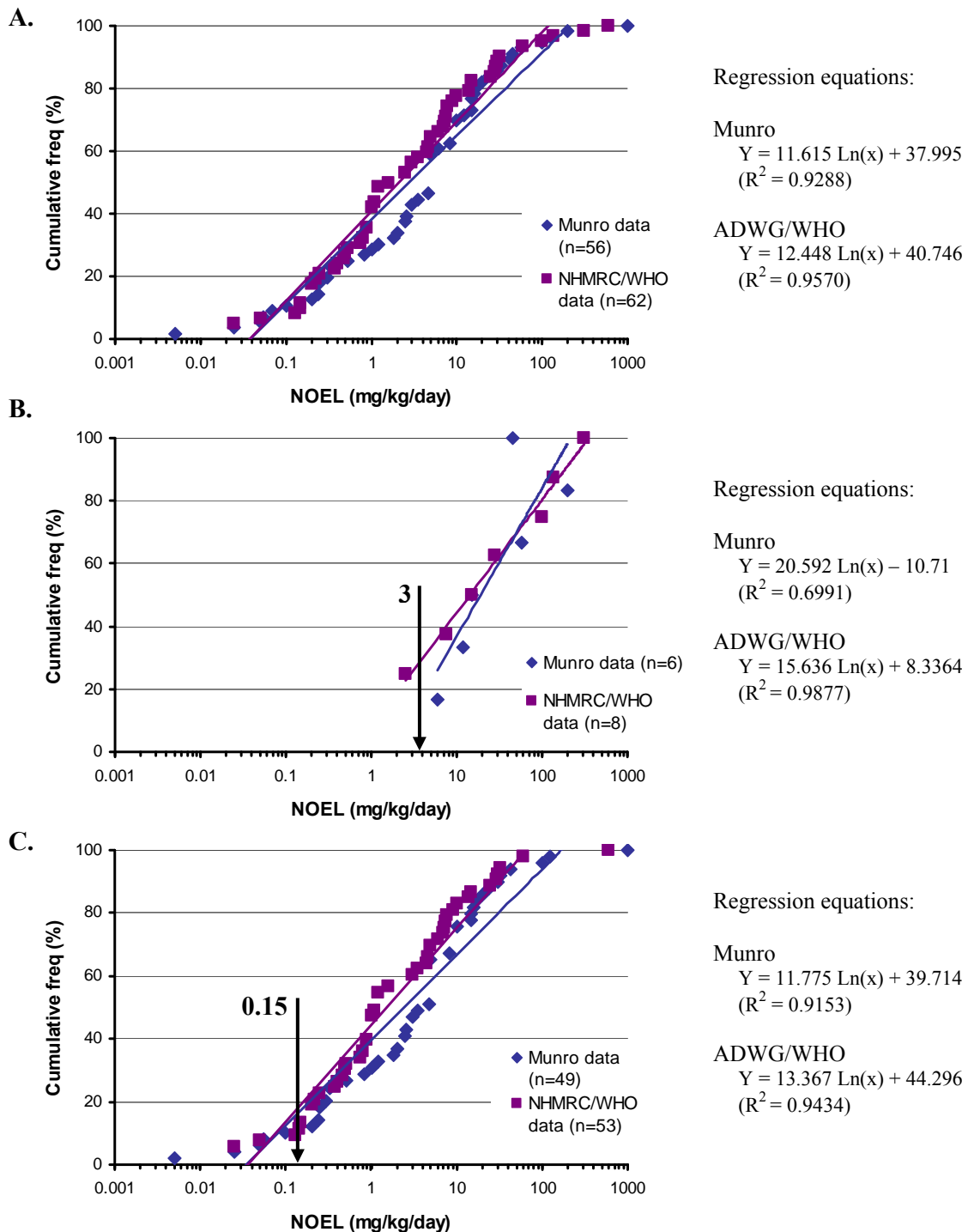
A3 Validation of the threshold of toxicological concern for drinking water standards

The validity of the TTC approach for setting drinking water guideline values was assessed by applying it to organic chemicals with existing guidelines described in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) or *Guidelines for Drinking-Water Quality* (WHO 2006a). The classification was undertaken using ToxTree. The classification of the drinking water organic chemicals from the two publications fell mainly into either class I or III, with only one chemical falling into class II.

Figure A3 compares the NOELs from the database of Munro et al (1996), which is used as a basis for determining TTCs, with NOELs from the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) and *Guidelines for Drinking-Water Quality* (WHO 2006a). The figure shows the NOELs for compounds listed in Table 4.4 both as a group and after classification into Cramer classes I or III. The figures demonstrate a high level of agreement between the Munro database NOELs and those from the Australian and WHO guidelines.

Figure A4 shows the cumulative frequency of guideline values for the chemicals listed in the *Australian Drinking Water Guidelines* (NHMRC–NRMMC 2004) and *Guidelines for Drinking-Water Quality* (WHO 2006a) classified as Cramer class I or III. The arrows indicate guideline values derived from 5% NOELs for genotoxic compounds and Cramer classes I and III, as described in Table A6. The cumulative frequencies of the chemicals listed in the two publications converge on the 5% NOELs. This is not surprising, given the harmonisation of safety factors in deriving guideline values using the TTC approach.

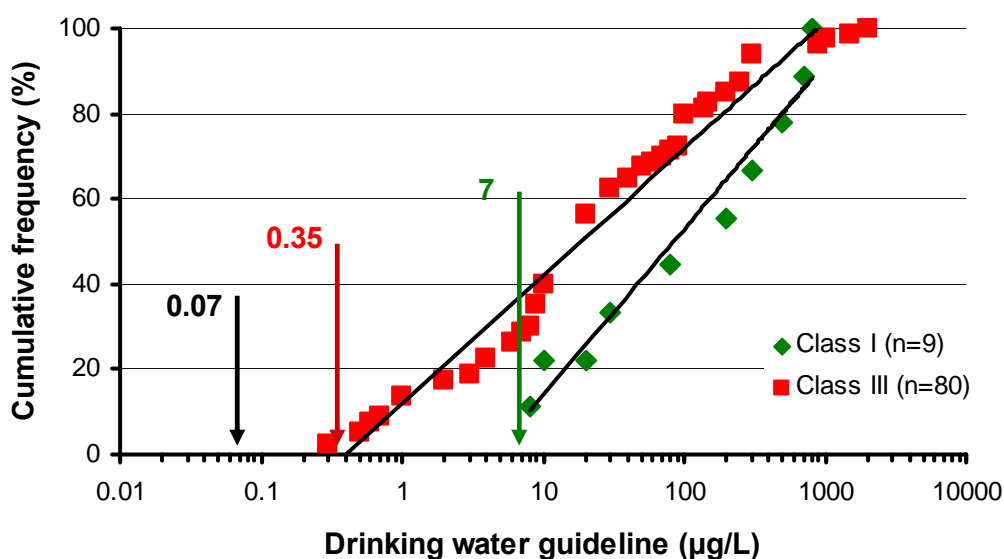
Figure A3 Cumulative frequency distribution of Munro no observed effect levels (NOELs) and corresponding NHMRC and WHO NOELs for compounds with Australian and WHO drinking water guidelines



ADWG = Australian Drinking Water Guidelines; NHMRC = National Health and Medical Research Council; NOEL = no observed effect level; WHO = World Health Organization

- a All compounds in Table 4.4 in common with Munro database.
- b Class I compounds (corresponding Munro database derived TTC value indicated by arrow).
- c Class III compounds (corresponding Munro database derived TTC value indicated by arrow).

Figure A4 Cumulative percentage frequency distributions of drinking water guideline values for compounds classified into Cramer classes I and III using ToxTree



(For compounds of interest in recycled water, ToxTree gave the same Cramer classification as Munro et al 1996).

A logarithmic regression analysis of the cumulative per cent frequency data gives the following equations and coefficients of determination:

- regression equation for class I: $Y = 16.904 \ln(x) + 91.887$; $R^2 = 0.9564$
- regression equation for class III: $Y = 12.981 \ln(x) + 101.7$; $R^2 = 0.9682$.

The black arrow represents the drinking water guideline set using the generic FDA TTC of 0.02 µg/kg bw/day.

The red arrow shows the drinking water guideline set using the 5th percentile NOEL for Cramer class III; that is, 0.15 mg/kg/day.

The green arrow shows the drinking water guideline set using the 5th percentile NOEL Cramer class I; that is, 3 µg/kg bw/day.

The drinking water guideline for class I and III substances were derived according to NHMRC procedure (Equation 1 of Box A3) with 10% as the proportion of intake allocated to drinking water and a safety factor of 1500. The later was derived from analysis of the distribution of safety factors applied by NHMRC–NRMMC (2004) and WHO (2006a) in setting drinking water guidelines from an experimental NOEL (Figure A2). The 95th percentile safety factor value by these organisations as 1570 ($n = 30$ compounds) for the Australian guidelines and 1660 ($n = 63$) for the WHO guidelines. A value of 1500 was chosen here.

Glossary

aquatic ecosystem	Any water environment from small to large, from pond to ocean, in which plants and animals interact with the chemical and physical features of the environment.
aquifer	A geological formation or group of formations capable of receiving, storing and transmitting significant quantities of water. Aquifers include confined, unconfined and artesian types.
benchmark	A standard or point of reference.
biochemical oxygen demand	The decrease in oxygen content in a sample of water that is brought about by the bacterial breakdown of organic matter in the water. the biochemical oxygen demand (BOD) measured over 5 days is referred to as BOD ₅ .
blackwater	Water containing human excrement.
bloom	An unusually large number of organisms of one or a few species, usually algae, per unit of water.
<i>Campylobacter</i>	A gram negative bacterium that is a major cause of diarrhoeal illness in developed countries. Symptoms include abdominal pain and fever. Has been associated with Guillain-Barre syndrome.
catchment	Area of land that collects rainfall and contributes to surface water (streams, rivers, wetlands) or to groundwater.
chronic toxicity	Toxicity that acts over a long period of time and that typically affects a life stage (eg reproductive capacity); it can also refer to toxicity resulting from a long-term exposure.
coliform bacteria	Group of bacteria whose presence in drinking water can be used as an indicator for operational monitoring.
consumer	An individual or organisation that uses drinking water.
contaminant	Biological or chemical substance or entity, not normally present in a system.
conventional filtration	The process of passing wastewater through a bed of granular media (eg sand and anthracite to remove particulate matter).
corrective action	Procedures to be followed when monitoring results indicate a deviation occurs from acceptable criteria (adapted from Codex Alimentarius).
critical control point	A point, step or procedure at which control can be applied and that is essential for preventing or eliminating a hazard, or reducing it to an acceptable level (adapted from Codex Alimentarius).

critical limit	A prescribed tolerance that must be met to ensure that a critical control point effectively controls a potential health hazard; a criterion that separates acceptability from unacceptability (adapted from Codex Alimentarius).
crop plants	Plants grown for harvest as food, feed or forage.
<i>Cryptosporidium</i>	Microorganism commonly found in lakes and rivers that is highly resistant to disinfection. <i>Cryptosporidium</i> has caused several large outbreaks of gastrointestinal illness (cryptosporidiosis); symptoms include diarrhoea, nausea and stomach cramps. Outbreaks typically associated with contamination by human and livestock waste. People with severely weakened immune systems (ie severely immunocompromised people) are likely to have more severe and more persistent symptoms than healthy individuals (adapted from United States Environmental Protection Agency).
Ct	The product of residual disinfectant concentration (C) in milligrams per litre determined before or at taps providing water for human consumption, and the corresponding disinfectant contact time (t) in minutes.
cyanobacteria	Bacteria containing chlorophyll and phycobilins, commonly known as 'blue-green algae'.
direct drinking water (potable) reuse	The discharge of recycled water directly into a drinking water treatment facility or into a drinking water distribution system.
disinfectant	A chemical, typically an oxidising agent (eg chlorine, chlorine dioxide, chloramines and ozone), that is added to water and is intended to kill or inactivate pathogenic (disease-causing) microorganisms.
disinfection	The process designed to kill most microorganisms in water, including essentially all pathogenic (disease-causing) bacteria. There are several ways to disinfect, with chlorine being most frequently used in water treatment.
disinfection byproduct	Products of reactions between disinfectants, particularly chlorine, and naturally occurring organic material.
distribution system	A network of pipes leading from a treatment plant to customers' plumbing systems.
dose-response	The quantitative relationship between the dose of an agent and an effect caused by the agent.
drinking water	Water intended primarily for human consumption (but excluding bottled water, for the purposes of these guidelines).
drinking water quality management audit	The systematic and documented evaluation of activities and processes to confirm that objectives are being met, and which includes an assessment of management system implementation and capability.

drinking water quality monitoring	The wide-ranging assessment of the quality of water in the distribution system and as supplied to the consumer, which includes the regular sampling and testing performed for assessing conformance with guideline values and compliance with regulatory requirements and agreed levels of service.
drinking water supplier	An organisation, agency or company that has responsibility and authority for treating or supplying drinking water.
drinking water supply system (water supply system)	All aspects from the point of collection of water to the consumer (can include catchments, groundwater systems, source waters, storage reservoirs and intakes, treatment systems, service reservoirs and distribution systems, and consumers).
effluent	The out-flow water or wastewater from any water processing system or device.
endocrine disrupting chemical	Substance that can stop the production or block the transmission of hormones in the body.
enteric pathogen	Pathogen that infects the gut of humans and other animals.
environmental flows	Environmental allocation for surface water rivers, streams or creeks.
epidemiology	The study of the distribution and determinants of health and disease states in human populations.
<i>Escherichia coli</i>	A member of the coliform group of bacteria that is found in the gut of humans and other animals and is used as an indicator of faecal contamination of water.
exposure	Contact of a chemical, physical or biological agent with the outer boundary of an organism (eg through inhalation, ingestion or dermal contact).
exposure assessment	The estimation (qualitative or quantitative) of the magnitude, frequency, duration, route and extent of exposure to one or more contaminated media.
filtration	Process in which particulate matter in water is removed by passage through porous media.
flocculation	Process in which small particles are agglomerated into larger particles (which can settle more easily) through gentle stirring by hydraulic or mechanical means.
<i>Giardia lamblia</i>	A protozoan frequently found in rivers and lakes. <i>Giardia</i> can cause a gastrointestinal disease called giardiasis. More common cause of disease than <i>Cryptosporidium</i> , but more sensitive to disinfection.

greywater	Wastewater from the hand basin, shower, bath, spa bath, washing machine, laundry tub, kitchen sink and dishwasher. Water from the kitchen is generally too high in grease and oil to be reused successfully without significant treatment.
groundwater	Water contained in rocks or subsoil.
groundwater recharge	Replenishing of groundwater naturally by precipitation or runoff, or artificially by spreading or injection.
guideline	Numerical concentration limit or narrative statement recommended to support and maintain a designated water use.
guideline value	The concentration or measure of a water quality characteristic that, based on present knowledge, either does not result in any significant risk to the health of the consumer (health-related guideline value), or is associated with high-quality water (aesthetic guideline value).
hazard	A biological, chemical, physical or radiological agent that has the potential to cause harm.
hazard analysis critical control point (HACCP) system	A systematic method to control safety hazards in a process by applying a two-part technique: <ul style="list-style-type: none"> • an analysis that identifies hazards and their severity and likelihood of occurrence • an identification of critical control points and their monitoring criteria to establish controls that will reduce, prevent, or eliminate the identified hazards.
hazard control	The application or implementation of preventive measures that can be used to control identified hazards.
hazard identification	The process of recognising that a hazard exists and defining its characteristics (Standards Australia/Standards New Zealand 1998).
hazardous event	An incident or situation that can lead to the presence of a hazard (ie ‘What can happen and how’).
helminth	A worm-like invertebrate of the order Helminthes that is a parasite of humans and other animals.
impact	An effect on end points, such as people, plants, soil, biota, water or a part of the environment.
indicator	Measurement parameter or combination of parameters that can be used to assess the quality of water; a specific contaminant, group of contaminants or constituent that signals the presence of something else (eg the presence of <i>Escherichia coli</i> indicates the presence of pathogenic bacteria).
indicator organisms	Microorganisms whose presence is indicative of pollution or of more harmful microorganisms.

indirect drinking (potable) reuse	The discharge of recycled water directly into groundwater or surface water with the intent of augmenting drinking water supplies.
industrial wastewater	Wastewater derived from industrial sources or processes.
insignificant	Not valuable or large enough to be considered important.
integrated catchment management	The coordinated planning, use and management of water, land, vegetation and other natural resources on a river or groundwater catchment, based on cooperation between community groups and government agencies in considering all aspects of catchment management.
intentional discharge	Release of water directly into water bodies (eg during system maintenance, pressure release, flushing and cleaning of systems, fire drills and equipment maintenance) or for environmental allocation.
irrigation	Provision of sufficient water for the growth of crops, lawns, parks and gardens by flood, furrow, drip, sprinkler or subsurface water application to soil.
ISO 9001:2000 (Quality Management)	An international accredited standard that provides a generic framework for quality management systems. Designed to assure conformance to specified requirements by a supplier at all stages during the design, development, production, installation, and servicing of a product, it sets out the requirements needed to achieve an organisation's aims with respect to guaranteeing a consistent end product.
log removal	Physical–chemical treatment of water to remove, kill, or inactivate microorganisms such as bacteria, protozoa and viruses (1-log removal = 90% reduction in density of the target organism, 2-log removal = 99% reduction, 3-log removal = 99.9% reduction, etc).
macrophyte	A member of the macroscopic plant life of an area, especially of a body of water; large aquatic plant.
major impact	Event that is potentially lethal to the local ecosystem.
maximum risk	Risk in the absence of preventive measures.
mean	The arithmetic average obtained by adding quantities and dividing the sum by the number of quantities.
microfiltration	The process of passing wastewater through porous membranes in the form of sheets or tubes to remove suspended and particulate material. Pore sizes can be very small and particles down to 0.2 microns can be retained.
microorganism	Organism too small to be visible to the naked eye. Bacteria, viruses, protozoa, and some fungi and algae are microorganisms.
minor impact	Event that is potentially harmful to the local ecosystem.

moderate impact	Event that is potentially harmful to the regional ecosystem.
monitoring	Systematically keeping track of something, including sampling or collecting information and documenting it.
multiple barriers	Use of more than one preventive measure as a barrier against hazards.
operational monitoring	The planned sequence of measurements and observations used to assess and confirm that individual barriers and preventive strategies for controlling hazards are functioning properly and effectively.
osmosis	The flow of water from an area with a low concentration of dissolved material to an area with a high concentration of dissolved material, moving through a membrane. This process occurs by itself, with no need for outside energy (unlike reverse osmosis, in which the water is moved the other way).
pathogen	A disease-causing organism (eg bacteria, viruses and protozoa).
pH	An expression of the intensity of the basic or acid condition of a liquid. Natural waters usually have a pH between 6.5 and 8.5.
point-of-use treatment device	A treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that tap.
pollutant	Substance that damages the quality of the environment.
potable water	Alternative term for drinking water
preventive measure	Any planned action, activity or process that is used to prevent hazards from occurring or reduce them to acceptable levels.
primary sedimentation	Initial treatment of wastewater involving screening and sedimentation to remove solids.
protozoa	A phylum of single-celled animals.
quality	The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs; in this context, the term 'quality' should not be used to express a degree of excellence (Standards Australia/Standards New Zealand 1994).
quality assurance	All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality (Standards Australia/Standards New Zealand 1994).
quality control	Operational techniques and activities that are used to fulfil requirements for quality (Standards Australia/Standards New Zealand 1994).

quality management	Includes both quality control and quality assurance, as well as additional concepts of quality policy, quality planning and quality improvement. Quality management operates throughout the quality system (Standards Australia/Standards New Zealand 1994).
quality system	Organisational structure, procedures, processes and resources needed to implement quality management (Standards Australia/Standards New Zealand 1994).
raw water	Water in its natural state, before any treatment; or the water entering the first treatment process of a water treatment plant.
reclaimed water	Alternative but less accurate term for treated sewage.
recycled water	Water generated from sewage, greywater or stormwater systems and treated to a standard that is appropriate for its intended use.
refractory	A stable material difficult to convert or remove entirely from wastewater.
representative sample	A portion of material or water that is as nearly identical in content and consistency as possible to that in the larger body of material or water being sampled.
reservoir	Any natural or artificial holding area used to store, regulate or control water.
residual risk	The risk remaining after consideration of existing preventive measures.
reverse osmosis	An advanced method of wastewater treatment that relies on a semipermeable membrane to separate water from its impurities.
risk	The likelihood of a hazard causing harm in exposed populations in a specified time frame, including the magnitude of that harm.
risk assessment	The overall process of using information to predict how often hazards or specified events may occur (likelihood) and the magnitude of their consequences (adapted from Standards Australia/Standards New Zealand 1999).
risk management	The systematic evaluation of a system (in this document, the water supply system), the identification of hazards and hazardous events, the assessment of risks, and the development and implementation of preventive strategies to manage the risks.
runoff	Surface overland flow of water resulting from rainfall or irrigation exceeding the infiltration capacity of the soil.
salinity	The presence of soluble salts in soils or waters; electrical conductivity and total dissolved salts are measures of salinity.

secondary treatment	Generally, a level of treatment that removes 85% of biochemical oxygen demand (BOD) and suspended solids, usually by biological or chemical treatment processes. Secondary effluent generally has BOD <30 mg/L, and suspended solids (SS) <30 mg/L, but SS may rise to >100 mg/L due to algal solids in lagoon or pond systems.
sewage	Material collected from internal household and other building drains (includes faecal waste and urine from toilets, shower and bath water, laundry water and kitchen water).
sewer mining	Process of extracting wastewater directly from a sewer (either before or after a sewage treatment plant) for reuse as recycled water.
short circuiting	Preferential flows in storages that reduce the transport time between inlets and outlets.
source water	Water in its natural state, before any treatment to make it suitable for drinking.
species	Generally regarded as a group of organisms that resemble each other to a greater degree than members of other groups, and that form a reproductively isolated group that will not normally breed with members of another group. (Chemical species are differing compounds of an element.)
stakeholder	A person or group (eg an industry, a government jurisdiction, a community group, the public, etc) that has an interest or concern in something.
standard (eg water quality standard)	An objective that is recognised in environmental control laws enforceable by a level of government.
storage reservoir	A natural or artificial impoundment used to hold water before its treatment or distribution.
surface water	All water naturally open to the atmosphere (eg rivers, streams, lakes and reservoirs).
surrogate	<i>See</i> indicator.
target criteria	Quantitative or qualitative parameters established for preventive measures to indicate performance; performance goals.
TD ₅₀	The lifetime dose of carcinogen that causes cancer in 50% of the test animals.
tertiary treatment	Includes treatment processes beyond secondary or biological processes, which further improve effluent quality. Tertiary treatment processes include detention in lagoons, conventional filtration via sand, dual media or membrane filters, which may include coagulant dosing and land-based or wetland processes.

thermotolerant coliforms	<i>See</i> coliform bacteria.
total coliforms	<i>See</i> coliform bacteria.
total quality management	A long-term global management strategy and the participation of all members of the organisation for the benefit of the organisation itself, its members, its customers and society as a whole (Standards Australia/Standards New Zealand 1994).
toxicity	The extent to which a compound is capable of causing injury or death, especially by chemical means.
toxicology	Study of poisons, their effects, antidotes and detection.
turbidity	The cloudiness of water caused by the presence of fine suspended matter.
validation of processes	The substantiation by scientific evidence (investigative or experimental studies) of existing or new processes, and of the operational criteria needed to ensure that the system can effectively control hazards.
verification of drinking water quality	An assessment of the overall performance of the water supply system and the ultimate quality of drinking water being supplied to consumers; incorporates both drinking water quality monitoring and monitoring of consumer satisfaction.
virus	Molecules of nucleic acid (RNA or DNA) that can enter cells and replicate in them.
waterlogging	Saturation of soil with water.
water recycling	A generic term for water reclamation and reuse. It can also be used to describe a specific type of 'reuse' where water is recycled and used again for the same purpose (eg recirculating systems for washing and cooling), with or without treatment in between.
watertable	Groundwater in proximity of the soil surface with no confining layers between the groundwater and soil surface.
zooplankton	The animal portion of plankton.

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