STS002

Silverwater Facility Licensed Wastes

Introduction

The wastes which can be lawfully received at the SteriHealth Silverwater facility are governed by The Protection of the Environment Operations Act 1997 and associated Regulations and the Department of Environment and Climate Change license 3245 issued for 2-16 Wiblen Street, Silverwater. The wastes that the site is licensed to receive are detailed in the table below.

In evaluating waste for receipt at the site other considerations need to be considered such as the packaging of the waste and how it will handled, whether the treatment plant at the site can safely or satisfactorily treat the waste and the terms of the Development Consent for the site. Refer to SSS001 eneral Specification for Waste Services and STS001 General Specification for Incineration Services.

Wastes Covered by Silverwater Facility License

Waste Classification	Waste Code	Code Description	Further Definition/Description Or Qualifications
Special	R100	Clinical	***Clinical waste*** means any waste resulting from medical, nursing, dental, pharmaceutical, skin penetration or other related clinical activity, being waste that has the potential to cause injury, infection or offence, and includes waste containing any of the following: • human tissue (other than hair, teeth and nails) • bulk body fluids or blood • visibly blood-stained body fluids, materials or equipment • laboratory specimens or cultures • animal tissue, carcasses or other waste from animals used for medical research ***Sharps waste*** means any waste collected from designated sharps waste containers during business, commercial or community service activities, being waste resulting from the use of sharps for any of the following purposes: • human health care by health professionals and other health care providers • medical research or work on cadavers • veterinary care or veterinary research • skin penetration or the injection of drugs or other substances for medical or non-medical reasons but does not include waste that has been treated at premises at which a waste activity is carried on, or on the site where it was generated, and to a standard specified in an EPA gazettal notice. ***Sharps*** means anything: • that has sharp points or edges capable of cutting, piercing or penetrating the skin (such as needles, syringes with needles or surgical instruments) • that is designed for the purpose of cutting, piercing or penetrating the skin • that has the potential to cause injury or infection. Note: the license and Regulation definition does not cover Infectious Waste from research as opposed to clinical sources such as universities. Such waste might be covered under T100, but in the Dangerous Goods Code bioresearch waste goes with Clinical Waste. Clarification has been sought from the EPA. In the interim we will treat as R100.
	R130	Cytotoxic	***Cytotoxic waste*** means any substance contaminated with any residues or preparations that contain materials that are toxic to cells principally through their action on cell reproduction.
	R120	Waste pharmaceuticals, drugs and medicines	R120 taken to mean consumer packaged items. *As defined in Schedule 1 Part 3 of the Protection of the Environment Operations Act 1997* i.e.: ***Pharmaceutical, drug or medicine waste*** means waste generated by activities carried out for business or other commercial purposes and that consists of pharmaceutical or other chemical substances specified in the **Poisons List** made under section 8 of the *Poisons and Therapeutic Goods Act 1966*. It does not include pharmaceutical, drug, or medicine waste generated in the home. Refer to the latest edition of DEPARTMENT OF HEALTH, NEW SOUTH WALES POISONS LIST at http://www.comlaw.gov.au/comlaw/Legislation/LegislativeInstrument1.nsf/0/7805D97A4580CDAFCA2574A5001B7144?OpenDocument for a full listing. This list includes organic solvents, see summary for solvents in Appendix 1. *Other than as defined in Schedule 1 Part 3 of the Protection of the Environment Operations Act 1997* which is taken to mean: Over The Counter Medicines as defined in the TGA document “Australian regulatory guidelines for OTC medicines”, see Appendix 2 for excerpts.

Waste Classification	Waste Code	Code Description	Further Definition/Description Or Qualifications
			▪ Notwithstanding the forgoing: × *The only waste biocides and phytopharmaceuticals (botanical extracts/herbal medicines)which may be incinerated at the premises are organophosphate compounds which cannot viably be treated or disposed of by other techniques.* × *Any declared chemical waste that is the subject of a chemical control order under the Environmentally Hazardous Chemicals Act 1985 must not be incinerated at the premises.* See http://www.epa.nsw.gov.au/chemicals/ccos.htm for current listing (also Appendix 4). Includes: × Aluminum smelter wastes containing fluoride or cyanide × Dioxin-contaminated waste (specifically 2,3,7,8 tetrachlorobenzo-p-dioxin) × Polychlorinated biphenyl (PCB) as previously widely used in transformers and capacitors × Stockholm Convention POCs such as banned chemicals and industrial waste byproducts – see list in Appendix below. × Organotin which is found in marine antifouling paints
	R140	Waste from prod & prep of pharmaceutical products	Definition similar to R120 but not in retail packaging. Non Scheduled trial medicines and pharmaceutical manufacturing intermediates could also be included.
	H100	Waste biocides and phytopharmaceuticals	We are limited to Organophosphates which cannot viably be treated or disposed of by other techniques." Note: despite the use of the more general H100 in the license document Organophosphates are Waste Code H110.
Liquid	R150	Quarantine	Limited to biological, pharmaceutical and/or medicinal material **Biological Products** AQIS Biologicals Unit administers Australian quarantine conditions for the importation of biological products. These include animal or microbial derived products such as foods, therapeutics, laboratory materials, and vaccines. **Note**: The Biologicals Unit does not manage the following commodities which are administered by the sections below: × Plant produce - Grains, seeds, nursery stock, fruit & vegetables (AQIS Plant Programs) × Live animals - including viable reproductive material (AQIS Live Animal Imports) × Agricultural products - timber, dried fibre articles, herbs, used machinery (Treatments and Inspections - Import Clearance) × Inspection and certification of products exported from Australia (Export)
	T100	R&D Lab Chems	Laboratory chemicals from R&D and teaching – except declared wastes and biocides
Hazardous	R150	Quarantine	Limited to biological, pharmaceutical and/or medicinal material as per entry above
	T100	R&D Lab Chems	Laboratory chemicals from R&D and teaching – except declared waste
General Solid Waste (non-putrecible) General	N/A	N/A	General Solid Waste for incineration up to 200t p.a., but with the following not included in the 200t: × Security Related Office Waste originating from a Government Agency; and Contraband from Government Agencies meaning any goods or merchandise whose importation, exportation, or possession is forbidden by State or Commonwealth Legislation.

Waste Classification	Waste Code	Code Description	Further Definition/Description Or Qualifications
Solid Waste ((putrecible)			× Wastes containing radioactive substances which are not classified as hazardous waste according to their content of radioactive substances (as determined according to section 3.5 of the Waste Guidelines – see Appendix 3)
TBA	TBA		× Security Related Office Waste originating from a Government Agency; and Contraband from Government Agencies meaning any goods or merchandise whose importation, exportation, or possession is forbidden by State or Commonwealth Legislation. × Wastes containing radioactive substances which are not classified as hazardous waste according to their content of radioactive substances (as determined according to section 3.5 of the Waste Guidelines – see Appendix 3)
General Solid Waste (non-putrecible)			General Solid Waste not for incineration, recyclable solid materials up to 30,000T p.a. (if compatible with the DA issued by Council for the site - ?)

Appendix 1

Organic Solvents & Scheduled Poisons

The following substances appear in the 2007 edition of the Poisons List and are therefore R120 wastes compatible with SteriHealth's license for Silverwater:

Substance	Inclusions/Exclusions
Methanol	Preparations containing more than 2% methanol
Liquid Hydrocarbons other than aromatic hydrocarbons including: Xylene Toluene Kerosene Mineral turpentine White petroleum spirit Light mineral and paraffin oils (excluding their derivatives) *Presumably ethanol and Histolene*	Preparations containing more than 25% of designated solvents other than: × Pressurized spray packs × writing collection fluids of capacity < 20ml × food grade and pharmaceutical grade white mineral oils × semi solid preparations × adhesives in packs of 50g or less
Liquid aromatic hydrocarbons	Any fraction of than those solvents that boil above 350°C and have more than 1% of total aromatic compounds or do not have a Mutagenicity Index of zero. All other preparations containing more than 25% of designated solvents.
Formaldehyde	Preparations containing more than 5% (Formalin should be around 37%)
Sulfuric acid	Preparations containing more than 0.5% sulfuric acid (H_2SO_4)
Ethylene Glycol	

Please note that operational safety requirements and standards such as AS1940 place limits on the quantities of flammable liquids that can be stored at Silverwater. Generally speaking, Silverwater can only accept one pallet of flammable waste at a time.

Appendix 2

Medicines & Pharmaceuticals That are not on the Poisons List

Australian regulatory guidelines for OTC medicines

Overview

This Chapter gives an overview of the legislative and procedural framework within which OTC medicines are regulated. It also defines the terms used in these guidelines. Information on substances which are not, as yet, included in a product is contained in Chapter 6B, *New substances*.

Therapeutic Goods

The *Therapeutic Goods Act 1989* (the Act) came into operation in February 1991. Its object is:

to promote the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere.

'Therapeutic goods' are defined in the Act. All therapeutic goods (other than those which are exempt) must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported, manufactured or supplied in Australia.

Therapeutic goods are divided into 'medicines' and 'medical devices'. Some 'medicines' are limited to prescription-only while others are available without a prescription. Non-prescription medicines may be 'complementary medicines' or 'OTC medicines' and may be 'listed' or 'registered' in the ARTG.

These guidelines are solely concerned with OTC medicines. Some OTC medicines (eg. sunscreens) are normally 'listable' but the majority are 'registrable'. Information on registration and listing is available on the TGA website[1].

Route of evaluation

Medicines are evaluated by one of three regulatory units. OTC Medicines are evaluated by the OTC Medicines Section (OTC), complementary medicines by the Office of Complementary Medicines (OCM) and prescription and other specified medicines by the Drug Safety and Evaluation Branch (DSEB). The criteria for deciding which of these units evaluates a particular medicine are set out in Schedule 10 to the *Therapeutic Goods Regulations*.

1 www.tga.gov.au/docs/html/infokit.htm

Regulation of cosmetics

The TGA assesses cosmetic products that make therapeutic claims. Many ingredients in cosmetic products are classed as industrial chemicals and the National Industrial Chemicals

Notification Assessment Scheme (NICNAS) must be notified of all cosmetics that contain industrial chemicals new to Australia.

Regulation

- In September 2007, a new framework for the regulation of cosmetic products was implemented following amendments to the Industrial Chemicals (Notification and Assessment) Act 1989. This Act is administered by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Act legally underpins the Cosmetics Standard 2007 and this Standard is supported by the NICNAS Cosmetic Guidelines 2007. Both documents are available from the NICNAS website <http://www.nicnas.gov.au/Current_Issues/Cosmetics.asp>.
- To assist with facilitating this new regulatory framework, on 11 June 2008 the TGA adopted a new Therapeutic Goods (Excluded Goods) Order No. 1 of 2008 <http://www.tga.gov.au/legis/tgeg0801.htm>.

Goods that are not therapeutic goods

4. For the purpose of the Therapeutic Goods Act 1989 and subject to section 5 of this Order, the following goods, being goods intended for use in humans, are declared not to be therapeutic goods:
    a. hair bleaches, hair dyes, hair-colorants or hair-perming preparations;
    b. household and personal aids, or furniture and utensils, for people with disabilities;
    c. menstrual pads other than tampons;
    d. incontinence pads, mattress overlays or mattress protectors;
    e. dental bleaches or dental whiteners;
    f. preparations that are applied topically to the nails to harden, or to deter biting of, the nails;
    g. compressed gases when supplied for use as a power source for medical devices;
    h. piped medical gas systems installed to comply with AS 2896-1998/Amdt No. 1-1999: Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems;
    i. disinfectant and sterilant gases;
    j. equipment for use in the purification or treatment of drinking water;
    k. sanitation, environmental control or environmental detoxification equipment;
    l. goods for the measurement of alcohol level either in body fluids or exhaled air;
    m. goods related to colostomy and ileostomy that are adhesive removers or non-medicated skin cleansers;
    n. goods for retail sale to the ultimate consumer for retention, cushioning or repairing of dentures;
    o. fresh viable:
        i. human tissue, other than blood; or

ii. human organs; or
iii. parts of human organs; or
iv. human bone marrow;

intended for direct donor-to-host transplantation and used in accordance with applicable laws and standards;

Goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way

5. For the purposes of the Therapeutic Goods Act 1989, the goods specified in column 2 in an item in the following Table, being goods that:
   a. are intended for use in humans, and
   b. are used, advertised, or presented for supply in the way specified in column 3;

   are declared not to be therapeutic goods.

TABLE		
Col 1 Item	**Column 2 Goods**	**Column 3 Specified use, advertisement, or presentation for supply**
1	Deodorant preparations	Use for dermal application or with therapeutic devices
2	Unmedicated dental chewing gums	If benefits claimed to result for the use of the goods are restricted to those consequential on improvements to oral hygiene
3	Soap and detergent, other than medicated soap and medicated detergent	Use for skin cleansing or hair cleansing
4	Non-sterile protective or safety apparel or equipment	Use in the home or for occupational or recreational use
5	Non-sterile apparel (including fitted support or insulating garments)	Use solely as an aid to physical comfort or relief of discomfort
6	Non-prescription spectacles	Use solely for magnification of image or sun protection
7	Preparations containing a sunscreening substance, if the primary purpose of the preparations is neither protection of the skin from injury from solar radiation nor another therapeutic purpose	If representations about the goods do not include: a. a statement of a claimed sun protection factor, or b. a description of a claimed sun protection category; or

		c. a reference to another therapeutic use in respect of the goods
8	Depilatory preparations	Use for dermal application
9	Spa waters or natural mineral waters	If no claims are made for therapeutic use
10	Substances for use in the purification or treatment of drinking water	If no claims are made for therapeutic use
11	Packs or kits containing medical devices for the prevention of blood borne and sexually transmissible diseases	Supply of the packs or kits: • is a part of a Government endorsed health promotion program; and • has been authorised by that Government as part of that program; and where each individual therapeutic good within the packs or kits is already included on the Australian Register of Therapeutic Goods

Goods that are not therapeutic goods, with allowable limited therapeutic use when advertised, represented or presented for supply in a particular way

6. For the purposes of the Therapeutic Goods Act 1989, the goods specified in column 2 in an item in the following Table, being goods that:
   a. are cosmetics under the Industrial Chemicals Notification and Assessment Act 1989 (the ICNA Act) and comply with the Cosmetics Standards 2007 made under subsection 81(1) of the ICNA Act, and
   b.
      i. does not contain ingredients included in Schedules 2, 3, 4 or 8 to the Poisons Standard; or
      ii. are not promoted, represented, presented or labeled for therapeutic use, except for those therapeutic use specified in column 3 of Table 2

   are declared not to be therapeutic goods.

Table 2		
Col 1 Item	**Column 2 Goods**	**Column 3 Allowable therapeutic use**
1	Tinted bases or foundation	

	(liquids, pastes or powders) with sunscreen	
2	Products intended for application to the lips with sunscreen	
3	Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening	
4	Sunbathing products (eg oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15	Representations in connection with the product about pre-mature ageing linked to sun-exposure
5	Antibacterial skin products	If: a. presented as being active only against bacteria; and b. not presented as being: a. active against viruses, fungi or other microbial organisms (other than bacteria); or b. for use in connection with disease, disorders or medical conditions; or c. active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or d. for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or e. for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or f. for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or g. for use in connection with a procedure involving venipuncture or

		delivery of an injection
6	Anti-acne skin care products (including spot treatments, cleansers, face scrubs and masks	If presented as controlling or preventing acne only through cleansing, moisturizing, exfoliating or drying the skin
7	Oral hygiene products for care of the teeth and the mouth (e.g. dentrifices, mouth washes and breath fresheners)	If: a. any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and b. other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal conditions are not claimed to result from use
8	Anti-dandruff hair care products	If presented as controlling or preventing dandruff only through cleansing, moisturizing, exfoliating or drying the scalp

Sunscreens: Medicine or cosmetic?

Most sunscreens are regulated as medicines under the *Therapeutic Goods Act 1989*. Some products that contain an ingredient with sunscreening properties are regulated as cosmetics rather than as medicines where the primary purpose is not sunscreening. These cosmetic products are referred to as 'excluded' sunscreens and are not regulated under therapeutic goods legislation.

From the TGA Website:

Regulation of antibacterial hand washes

Question: I would like to import an antibacterial hand wash to sell in Australia. What regulations do I have to meet in order to do this?

Antibacterial hand washes are currently regulated as medicines by the TGA. However, one of the recommendations in the report Regulation of Cosmetic Chemicals: Final Report and Recommendations, published in November 2005 and available on the NICNAS website is that antibacterial skin washes be regulated as cosmetics.

Pending legislative underpinning of these recommendations, interim arrangements are in operation under NICNAS, the cosmetics regulator. This means that businesses introducing an antibacterial skin wash can choose to either remain regulated as a medicine by the TGA

or apply to NICNAS under interim arrangements to have the product regulated as a cosmetic. This provision is available for antibacterial skin products other than those used for:

a. Prevention of the transmission of disease; or
b. Specifically for use in clinical/surgical settings.

Forms and guidance on interim arrangements, including further explanation of these exclusion criteria, are available on the NICNAS website <http://www.nicnas.gov.au>.

Products that will now be regulated as medicines:

- Antiseptic wipes for use on human skin;
- Paper tissue with antiseptic and/or viricide for use on human skin.

Commonwealth Consolidated Acts

THERAPEUTIC GOODS ACT 1989 - SECT 3

"therapeutic use" means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or

(b) influencing, inhibiting or modifying a physiological process in persons or animals; or

(c) testing the susceptibility of persons or animals to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

Appendix 3

Radioactive Waste

3.5 Classification of wastes containing radioactive substances

Wastes containing any natural or artificial substance that emits ionising radiation spontaneously must be classified on the basis of both their radioactive and other characteristics, according to the stepwise procedure defined below:

1. The radioactivity of the waste must be assessed in accordance with the *Radiation Control Act 1990* and the Radiation Control Regulation 1993.

2. If the liquid or non-liquid waste has a specific activity greater than 100 becquerels per gram and consists of or contains more than the prescribed activity of any radioactive element listed in Schedule 1 of the Radiation Control Regulation 1993, whether natural or artificial, it must be classified as *hazardous waste*.

3. If the liquid or non-liquid waste has a specific activity of 100 becquerels per gram or less and/or consists of or contains equal to or less than the prescribed activity of any radioactive element listed in Schedule 1 of the Radiation Control Regulation 1993, whether natural or artificial, then the *total activity ratio* and the *specific activity ratio* must be calculated according to the mathematical expressions given below:

The **total activity ratio** is calculated using the expression:

Total activity ratio = $(A1 \times 10^{-3}) + (A2 \times 10^{-4}) + (A3 \times 10^{-5}) + (A4 \times 10^{-6})$

where A1 to A4 are the total activity of Group 1 to Group 4 radionuclides, as set out in Column 1 of Schedule 1 of the Radiation Control Regulation 1993.

The **specific activity ratio** is calculated using the expression:

Specific activity ratio = $SA1 + (SA2 \times 10^{-1}) + (SA3 \times 10^{-2}) + (SA4 \times 10^{-3})$

where SA1 to SA4 are the specific activity (of the material) of Group 1 to Group 4 radionuclides, as set out in Column 1 of Schedule 1 of the Radiation Control Regulation 1993.

Specific activity is defined in the *Code of Practice for the Safe Transport of Radioactive Materials, 1990*, which is referenced in clause 23 of the *Radiation Control Act 1990*. *Specific activity* of a radionuclide means the activity per unit mass of that nuclide. The specific activity of a material shall mean the activity per unit mass or volume of the material in which the radionuclides are essentially uniformly distributed.

The *total activity* of a material means the activity of the whole of the material in which the radionuclides are essentially uniformly distributed (determined using 1-kilogram representative samples of the whole material).

4. If the specific activity ratio, or total activity ratio, is greater than one, then the waste must be classified as follows:

Liquid wastes must be classified as *hazardous waste*.

Non-liquid wastes must be classified as *industrial waste* **unless** other characteristics of the waste mean that it must be classified as *hazardous waste* (for example, it may be classified as *hazardous waste* because it matches another one of the hazardous waste types or streams in Table 4, or it may contain chemical contaminants that will lead to its assessment as *hazardous waste* according to the chemical assessment procedure in Part 5 of Technical Appendix 1).

5. If the *specific activity ratio* and *total activity ratio* are equal to or less than one, then the waste must be classified as follows:

Liquid wastes must be classified according to their other characteristics (ignoring their low-level radioactivity), in accordance with the normal liquid-waste assessment and classification procedure specified in Section 3.

Non-liquid wastes must be classified according to their other characteristics (ignoring their low-level radioactivity), in accordance with the normal non-liquid-waste assessment and classification procedure specified in Section 3.
It is recommended that you read Section 4.6.4 *Managing and disposing of radioactive wastes*

Appendix 4

Controlled Wastes POCs

CONSTITUENT (common name)	**Chemical Abstract Registry Number**
Aldrin	309-00-2
Benzene Hexachloride-⟨-isomer (⟨-BHC)	319-84-6
Benzene Hexachloride-®-isomer (®-BHC)	319-85-7
Benzene Hexachloride-©-isomer (©-BHC, Lindane)	58-89-9
Benzene Hexachloride-⊗-isomer (⊗-BHC)	319-86-8
Chlordane	57-74-9
4,4'-DDD (p,p'-DDD, DDD)	72-54-8
4,4'-DDE (p,p'-DDE, DDE)	72-55-9
4,4'-DDT (p,p'-DDT, DDT)	50-29-3
Dieldrin	60-57-1
Endrin	72-20-8
Endrin aldehyde	7421-93-4
Heptachlor	76-44-8
Heptachlor epoxide	1024-57-3
Hexachlorobenzene	118-74-1
Hexachlorophene	70-30-4
Isodrin	465-73-6
Pentachlorobenzene	608-93-5
Pentachloronitrobenzene	82-68-8
Pentachlorophenol	87-86-5
1,2,4,5-Tetrachlorobenzene	95-94-3
2,3,4,6-Tetrachlorophenol	58-90-2
1,2,4-Trichlorobenzene	120-82-1
2,4,5-Trichlorophenoxy-acetic acid, salts and esters (2,4,5-T)	93-76-5