

Licence

Licence number	L8461/2010/2
	20+01/2010/2
Licence holder	Cleanaway Daniels Services Pty Ltd
ACN	093 315 014
Registered business address	Level 4, 441 St Kilda Road
	MELBOURNE VIC 3004
DWER file number	2010/004171-2
Duration	20/09/2010 to 19/09/2030
Date of amendment	12/06/2022
Date of amendment	13/06/2022
Premises details	Cleanaway Daniels Bibra Lake
	19 Coolibah Way
	BIBRA LAKE WA 6163
	Legal description -
	Lot 164 on Deposited Plan 17339

Prescribed premises category description (Schedule 1, <i>Environmental Protection Regulations 1987</i>)	Assessed production/ design capacity
Category 61A: Solid waste facility (other than premises within category 67A) on which solid waste produced on other premises is stored, reprocessed, treated or discharged onto land.	5,000 tonnes per annual period
Category 62: Solid waste depot: premises on which waste is stored, or sorted, pending final disposal or re-use.	1,000 tonnes per annual period

This licence is granted to the licence holder, subject to the attached conditions, on 13 June 2022, by:

MANAGER WASTE INDUSTRIES REGULATORY SERVICES an officer delegated under section 20 of the *Environmental Protection Act 1986* (WA)

Licence history

Date	Reference number	Summary of changes
10/09/2015	L8461/2010/2	Licence reissue
30/03/2016	L8461/2010/2	Licence amendment to updated occupier details (name change from SteriHealth to Daniels Health) and minor DWER initiated amendments.
02/11/2016	L8461/2010/2	Amendment Notice 1 (AN1) – Inclusion of GMO waste acceptance and increase in Premises capacity
08/02/2017	L8461/2010/2	Amendment Notice 2 (AN2) – Clarification to autoclaving activities
05/05/2020	L8461/2010/2	Licence amendment to include additional waste streams and administrative amendments including the amalgamation of AN1 and AN2
13/06/2022	L8461/2010/2	Licence amendment to change the clinical waste containment requirements for outside storage.

Interpretation

In this licence:

- (a) the words 'including', 'includes' and 'include' in conditions mean "including but not limited to", and similar, as appropriate;
- (b) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form of that word or phrase has a corresponding meaning;
- (c) where tables are used in a condition, each row in a table constitutes a separate condition;
- (d) any reference to an Australian or other standard, guideline, or code of practice in this licence:
 - (i) if dated, refers to that particular version; and
 - (ii) if not dated, refers to the latest version and therefore may be subject to change over time;
- (e) unless specified otherwise, any reference to a section of an Act refers to that section of the EP Act; and
- (f) unless specified otherwise, all definitions are in accordance with the EP Act.

NOTE: This licence requires specific conditions to be met but does not provide any implied authorisation for other emissions, discharges, or activities not specified in this licence.

Licence conditions

The licence holder must ensure that the following conditions are complied with:

Infrastructure and equipment

1. The licence holder must ensure that the site infrastructure and equipment listed in Table 1 and located at the corresponding infrastructure location is maintained and operated in accordance with the corresponding operational requirement set out in Table 1.

Infrastructure and equipment	Operational requirements	Infrastructure location
Autoclave	 (a) All waste treated in the autoclave is exposed to steam at a temperature of at least 145 degrees Celsius, for a continuous period of at least 15 minutes. 	Within warehouse (Schedule 1, Figure 2)
	(b) The autoclave treatment process achieves at all times a minimum sterility assurance level of 10 ⁻⁴ .	
	(c) Treatment of waste in the autoclave:	
	 i) ceases if any monitoring results obtained in accordance with condition 10 do not comply with the minimum sterility assurance level of 10⁻⁴; and 	
	 ii) only commences again when results obtained in accordance with condition 10 do comply with the minimum sterility assurance level of 10⁻⁴. 	
	(d) the blow down vessel, strainers and stack are regularly maintained to prevent accumulation of fats or other residues.	
Clinical waste containment	When outside of the warehouse, clinical waste accepted for sterilization must be contained:	Within the store areas
infrastructure	 (a) within locked primary containers that are airtight, leakproof and meet manufacturers specifications for drop, impact, leak and puncture resistance; 	(Schedule 1, Figure 2)
	 (b) within locked secondary cabinets that fully enclose the primary containers in a weather-proof and sealed container that ensures no liquid can leak from the cabinet; and 	
	(c) on a hardstand storage area.	

Waste acceptance

2. The licence holder must only accept onto the premises waste of a waste type, which does not exceed the corresponding rate at which waste is received, and which meets the corresponding acceptance specification set out in Table 2.

Waste type	Rate at which waste is received	Acceptance specification
Category 61A: Solid waste facility		
Clinical waste (for sterilisation prior to removal offsite for landfilling)	5,000 tonnes per annual period	 Solid waste received from clinical and related waste generators. This includes: sharps and sharps containers; packaging and surgical instruments/equipment used during the collection/analysis/disposal of clinical waste; body piercing equipment/waste; and acupuncture waste.
Category 62: Solid wa	aste depot	
Cytotoxic, clinical & pharmaceutical waste (for storage prior to removal off- site for incineration)	500 tonnes per annual period	 Solid waste received from clinical and related waste generators. This includes: sharps and sharps containers, packaging and surgical instruments/equipment used during the collection/analysis/disposal of clinical waste and contaminated with cytotoxic waste; recognisable anatomical body parts; research animals; microbiological cultures from laboratory waste; human tissue and blood/body fluids; and by products of cytotoxic drug therapy. This does not include corpses.
GMO waste	500 tonnes per annual period	Solid waste that contains or is associated with GMO waste
Putrescible (paper) waste (for storage onsite prior to removal off-site for secure shredding)	100 tonnes per annual period	Must be paper in locked bins in the form of documents for secure shredding.
X-ray and photographic film	5 tonnes per annual period	Collected in labelled bins before being sent offsite for processing/recycling of silver.
Waste batteries, fluorescent tubes & dental amalgam	1 tonne combined total per annual period	Batteries are limited to nickel cadmium type only.
General waste (for storage prior to removal off-site for treatment/disposal)	60 tonnes per annual period	 General waste in the form of out of date stock only. This includes: baby powder; and effervescent multi-vitamin tablets

3. The licence holder must ensure that where waste does not meet the waste acceptance criteria set out in condition 2, it is removed from the premises by the delivery vehicle or, where that is not possible, stored in a quarantined storage area or container and removed to an appropriately authorised facility as soon as practicable.

- **4.** The licence holder must ensure:
 - (a) all untreated clinical waste is effectively segregated from treated clinical waste to ensure that cross-contamination does not occur;
 - (b) all clinical waste accepted for processing is effectively segregated from clinical waste accepted for storage only; and
 - (c) in the event that non-clinical waste is mixed with clinical waste, the licence holder must ensure the waste is managed as clinical waste; and
 - (d) all spills of waste are responded to, all waste is contained and contaminated stormwater is prevented from entering soak wells.

Waste processing

5. The licence holder must ensure that the waste types specified in Table 3 are only subjected to the corresponding process(es), subject to the corresponding process limits and/or specifications.

Waste type	Process(es)	Process limits and/or specifications
Category 61A: Solid waste facility		
Clinical waste (for sterilisation prior to removal offsite for landfilling)	Receipt, handling and storage. Autoclaving and shredding (if required) prior to disposal offsite.	 a) Prior to autoclaving clinical waste must be securely stored: i) within containers that are effectively labelled for that waste type; and ii) within the 'Autoclave waste storage' depicted in Schedule 1, Figure 2 or within the warehouse. b) Clinical waste must be autoclaved within seven (7) days of being accepted at the premises. c) Clinical waste shredding must only occur within the warehouse after autoclaving. d) In the event of a malfunction of the autoclave, the licence holder is permitted to store untreated clinical waste for a period of more than 7 days, as long as this waste is: i) stored in a fully enclosed, secure, refrigerated storage unit; and ii) stored at a temperature of 7 degrees Celsius or less; and iii) stored for no longer than 30 days.
Category 62: Solid	I waste depot	
All waste types accepted under Category 62: Solid waste depot	Receipt, handling and storage prior to transport off- premises for processing, recycling and/ or disposal	 a) Processing of all waste types with the autoclave is not permitted. b) All waste types must be stored within containers that are effectively labelled for that waste type. c) All waste types must be stored separately to any clinical waste accepted (for sterilisation prior to removal offsite for landfilling), including waste that has been processed via the autoclave or shredded.

Table 3: Waste processing

Waste type	Process(es)	Process limits and/or specifications
Clinical waste (including anatomical waste) Wet Pharmaceutical waste Cytotoxic waste Dry pharmaceutical wastes	Receipt, handling and storage prior to removal transport off- premises for incineration	 a) All waste types must be removed from the premises within 60 days of being accepted. b) Clinical and wet pharmaceutical waste must be stored within: i) sealed bags or sealed containers; ii) the storage area depicted 'S1' in Figure 2, Schedule 1; and iii) a bunded concrete hardstand area. c) In addition, clinical anatomical waste must be stored at all times: i) a secure, refrigerated container; and ii) at a temperature of 4 degrees Celsius or less. d) Cytotoxic and dry pharmaceutical waste must be stored within: i) sealed bags or sealed containers; and ii) a secure, closable sea container that retains any liquids spilled within the sea container.
GMO waste (for storage prior to removal offsite for incineration)	Receipt, handling and storage prior to transport offsite for incineration	 a) GMO waste must be removed from the premises within 60 days of being accepted. b) GMO waste must be stored: i) within sealed bags or sealed containers; and ii) at a temperature of 4 degrees Celsius or less if the waste type contains organic material. c) In the event that the refrigeration unit ceases to function in working order, GMO waste must be removed from the premises within 24 hours, unless the refrigeration unit is repaired within that 24 hour period.
Putrescible (paper) waste	Receipt, handling and storage prior to transport off-	 a) Waste type must be stored temporarily at the premises in containers outside of the warehouse as shown in the Map of storage locations in Schedule 1.
X-ray and photographic film Fluorescent tubes	premises for processing, recycling and/ or disposal	 b) Waste type must be stored temporarily at the premises in labelled containers outside of the warehouse as shown in the Map of storage locations in Schedule 1.
Waste batteries, and dental amalgam		 c) All waste batteries, dental amalgam and general waste must be stored in a locked cage in the area marked "Incineration Waste Storage" in the map of storage locations in Schedule 1.
General waste		

Emissions

Point source emissions to air

6. The licence holder must ensure that the emissions specified in Table 4, are discharged only from the corresponding discharge point and only at the corresponding discharge point location.

Table 4: Authorised emission points

Emission	Emission point	Emission point location
Steam from the autoclave via the blow down vessel	Blow down vessel and stack	A1

7. The licence holder must only release steam through the stack of the blow down vessel, or from the pressure release stack, after the autoclave cycle has been completed.

Monitoring

- **8.** The licence holder must ensure all monitoring equipment used to comply with conditions 10, 11 and 12 is operated and calibrated in accordance with the manufacturers specifications.
- **9.** The licence holder must ensure that all non-continuous sampling and analysis undertaken pursuant to conditions 10 and 11 is undertaken by a holder of a current accreditation from the National Association of Testing Authorities (NATA) for the methods of sampling and analysis relevant to the corresponding relevant parameter.

Emission monitoring

10. The licence holder must monitor emissions in accordance with the requirements specified in Table 5 and record the results of all such monitoring.

Emission point Parameter Unit Frequency Averaging Method (monitoring period locations) Blow down vessel Coliforms cfu/100mL AS 4187: Spot • Once a year in the and stack (A1) month of September or Sample Section 7 October: and Enterococci · After each out of service period of the autoclave that exceeds 6 weeks; and E.coli • After any structural or operational change of the autoclaving process (time, temperature or pressure)

Table 5: Emission monitoring

Note 1: All units are referenced to STP dry

- Note 2: Monitoring shall be undertaken to reflect normal operating conditions and any limits or conditions on inputs or production.
- **11.** The licence holder must ensure that the commissioning, validation and monitoring of the autoclave process adheres to the requirements of Section 7 in AS 4187.
- **12.** The licence holder must ensure that the commissioning, validation and monitoring of the autoclave process outlined in Condition 11 is undertaken in accordance with the following:
 - (a) after each out of service period of the autoclave which is longer than 6 weeks; or
 - (b) after any structural or operational change of the autoclaving process (time, temperature or pressure).

Monitoring of inputs and outputs

13. The licence holder must record the total amount of waste accepted onto and transferred from the premises, for each waste type listed in Table 6, in the corresponding unit, and for each corresponding time period, as set out in Table 6.

Waste type	Waste type parameters	Unit	Frequency	
Waste inputs – accepted	All waste types, defined by the waste type in Condition 2, Table 2, accepted at the premises	tonnes	Each load arriving at the Premises	
Waste Outputs – to landfill	Waste type as defined in the Landfill Definitions		Each load leaving or	
Waste Outputs – to incineration facility	Cytotoxic, Clinical & Pharmaceutical waste		rejected from the Premises	

Table 6: Waste accepted onto and transferred from the premises

Records and reporting

- **14.** The licence holder must record the following information in relation to complaints received by the licence holder (whether received directly from a complainant or forwarded to them by the Department or another party) about any alleged emissions from the premises:
 - (a) the name and contact details of the complainant, (if provided);
 - (b) the time and date of the complaint;
 - (c) the complete details of the complaint and any other concerns or other issues raised; and
 - (d) the complete details and dates of any action taken by the licence holder to investigate or respond to any complaint.
- **15.** The licence holder must maintain accurate and auditable books including the following records, information, reports, and data required by this licence:
 - (a) the calculation of fees payable in respect of this licence;
 - (b) any maintenance of infrastructure that is performed in the course of complying with condition 1 of this licence;
 - (c) monitoring programmes undertaken in accordance with conditions 8 through 13 of this licence; and
 - (d) complaints received under condition 14 of this licence.
- **16.** The books specified under condition 15 must:
 - (a) be legible;
 - (b) if amended, be amended in such a way that the original version(s) and any subsequent amendments remain legible and are capable of retrieval;
 - (c) be retained by the licence holder for the duration of the licence; and
 - (d) be available to be produced to an inspector or the CEO as required.
- **17.** The licence holder must:
 - (a) undertake an audit of their compliance with the conditions of this licence during the preceding annual period; and
 - (b) prepare and submit to the CEO by no later than 28 days after the end of that annual period an Annual Audit Compliance Report in the approved form.

18. The licence holder must submit to the CEO by no later than 28 days after the end of each annual period, an Annual Environmental Report for that annual period for the conditions listed in Table 7, and which provides information in accordance with the corresponding requirement set out in Table 7.

Table 7: Annual Environmental Report

Condition	Requirement
3.2.1	Monitoring of point source emissions to air
3.3.1	Summary of inputs and outputs
4.1.3	Complaints summary

Definitions

In this licence, the terms in Table 8 have the meanings defined.

Table 8: Definitions

Term	Definition
ACN	Australian Company Number
Anatomical waste	means waste consisting of biological matter such as human and animal tissue (excluding human corpses or fetuses);
Annual Audit Compliance Report (AACR)	means a report submitted in a format approved by the CEO (relevant guidelines and templates may be available on the Department's website).
annual period	a 12 month period commencing from 1 November until 31 October of the immediately following year.
AS 4187	means the Australian Standard AS 4187:2014 <i>Cleaning, disinfecting</i> and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities which shall be read as with the following changes:
	(a) "sterilizer" is changed to "decontaminator";
	(b) "sterilization" is changed to "decontamination";
	(c) "sterilize" is changed to "decontaminate";
	(d) "sterilizing" is changed to "decontaminating"; and
	(e) "minimum sterility assurance level (SAL) of 10 ⁻⁶ " is changed to "minimum sterility assurance level (SAL) of 10 ⁻⁴ ".
autoclave	means a vessel designed to sterilise materials by exposing them to steam under pressure;
books	has the same meaning given to that term under the EP Act.
CEO	means Chief Executive Officer of the Department.
	"submit to / notify the CEO" (or similar), means either:
	Director General Department administering the <i>Environmental Protection Act 1986</i> Locked Bag 10 Joondalup DC WA 6919
	or:
	info@dwer.wa.gov.au
controlled waste	has the definition in <i>Environmental Protection (Controlled Waste)</i> Regulations 2004
clinical waste	has the definition in the Code of practice for clinical and related waste management

Term	Definition
Code of practice for clinical and related waste management	means the document titled Code of practice for clinical and related waste management Public Health Act 2016 published by the Department of Health as amended from time to time
cytotoxic waste	has the definition in the Code of practice for clinical and related waste management
Department	means the department established under section 35 of the <i>Public</i> Sector Management Act 1994 (WA) and designated as responsible for the administration of the EP Act, which includes Part V Division 3.
discharge	has the same meaning given to that term under the EP Act.
emission	has the same meaning given to that term under the EP Act.
EP Act	Environmental Protection Act 1986 (WA)
EP Regulations	Environmental Protection Regulations 1987 (WA)
GMO	means Genetically Modified Organisms
hardstand	means a surface with a permeability of 10 ⁻⁹ metres/second or less
Landfill definitions	Landfill Waste Classification and Waste Definitions 1996 (as amended from time to time)
licence	refers to this document, which evidences the grant of a licence by the CEO under section 57 of the EP Act, subject to the specified conditions contained within.
licence holder	refers to the occupier of the premises, being the person specified on the front of the licence as the person to whom this licence has been granted.
normal operating conditions	means any operation of a particular process (including abatement equipment) excluding start-up, shut-down and upset conditions, in relation to stack sampling or monitoring;
pharmaceutical waste	has the definition in the Code of practice for clinical and related waste management
premises	refers to the premises to which this licence applies, as specified at the front of this licence and as shown on the premises maps (Figure 1and Figure 2) in Schedule 1 to this licence.
prescribed premises	has the same meaning given to that term under the EP Act.

Term	Definition
quarantined storage area or container	means a hardstand storage area or sealed-bottom container that is separate and isolated from authorised waste disposal areas and is capable of containing all non-conforming waste and its constituents, these areas must be clearly marked and their access restricted to authorised personnel;
spot sample	means a discrete sample representative at the time and place at which the sample is taken;
sterility assurance level	means the probability of single viable (micro) organism (non sterile) being present on an item after autoclaving;
waste	has the same meaning given to that term under the EP Act.

END OF CONDITIONS

L8461/2010/2 (13 June 2022)

Schedule 1: Maps

Premises map

The boundary of the prescribed premises is shown in the map below (Figure 1).



Figure 1: Map of the boundary of the prescribed premises

L8461/2010/2 (13 June 2022)

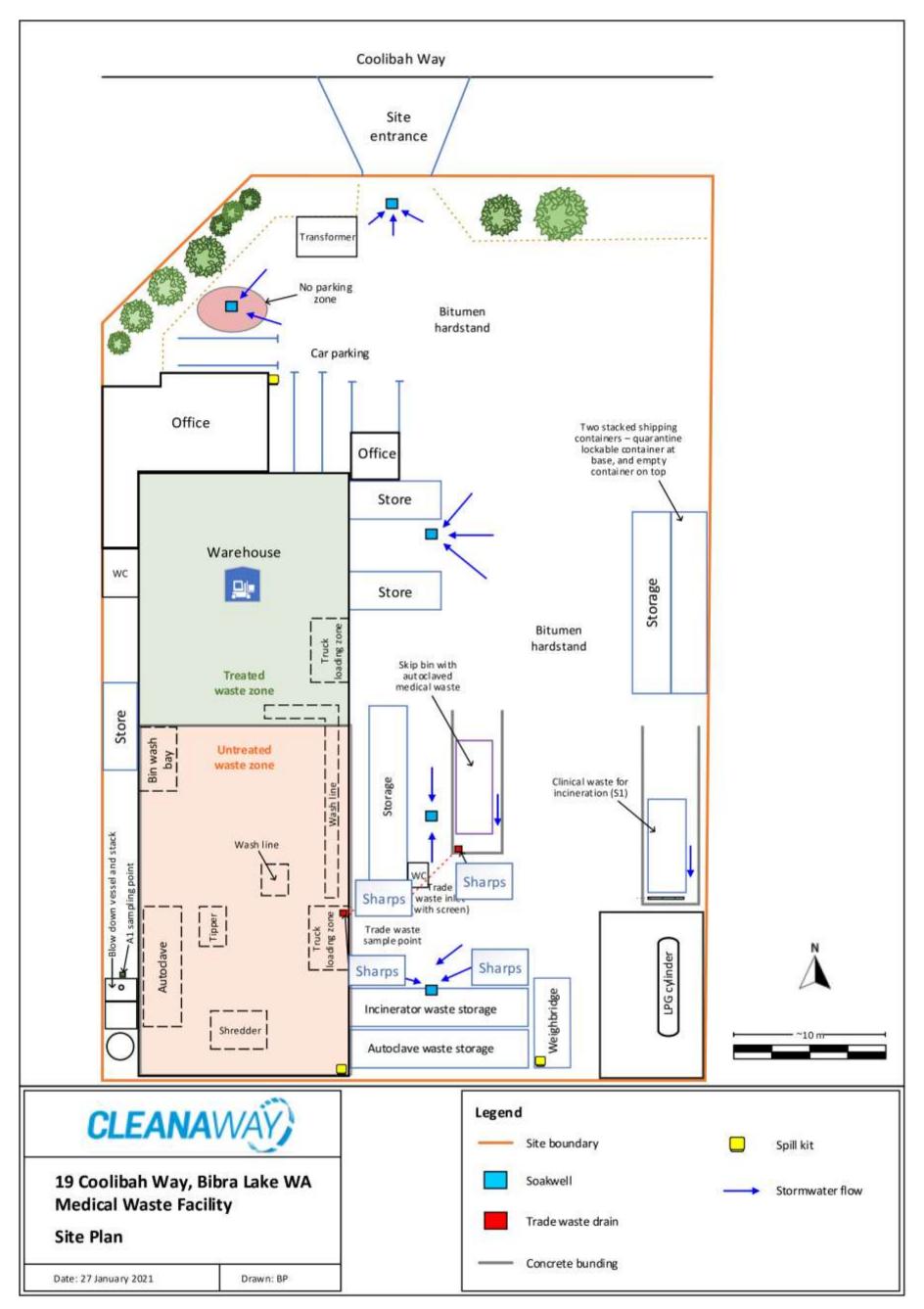


Figure 2: Plan of the prescribed premises operations

L8461/2010/2 (13 June 2022)

IR-T06 Licence template (v7.0) (February 2020)

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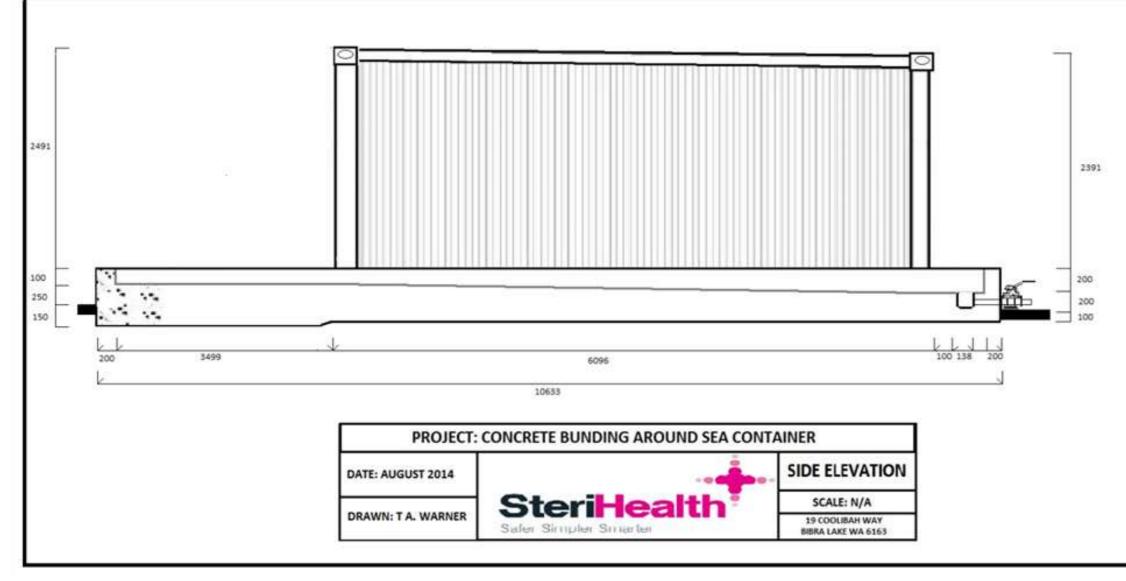


Figure 3: Plan of the specifications for the bunded concrete hardstand area

