

STANDARD OPERATING PROCEDURE (SOP) LABORATORY BIOHAZARD WASTE MANAGEMENT (UTM/OSHE/xxxxxxxxx)

	PREPARED BY	CHECKED BY	APPROVED BY
SIGNATURE			
NAME			
POSITION			
DATE			



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LABORATORY BIOHAZARD WASTE MANAGEMENT

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1.0 SCOPE

- 1.1 These procedures are intended for managing biological wastes at Universiti Teknologi Malaysia (UTM).
- 1.2 The purpose of these procedures is to ensure treatment and disposal of biological wastes are done in a manner that is safe and in compliance with:
 - a) Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline (2015).
 - b) Biosafety Guidelines: Contained Use Activity of Living Modified Organism (2010).
 - c) Manual Pengurusan Sisa Terkawal (Environmental Operations Control KTSP/SOP/446-09).
- 1.3 These procedures do not cover the disposal of:
 - a) Human cadavers or identifiable body parts.
 - b) Pharmacological wastes.
 - c) Biological waste mixed with radionuclides (for this type of wastes, please consult Unit OSHE UTM)

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2.0 DEFINITION

- 2.1 Biological wastes are materials containing biological agents that present potential risk to the health of humans, animals, plants, or the environment. This means biological wastes are biohazardous and the followings must be treated as scheduled wastes:
 - a) Any materials contaminated with microorganisms, including blood and body fluids, and culture of microorganisms.
 - b) Any materials contaminated with biological materials not approved for release outside of the Containment Facility including fetal bovine/calf serum and antibiotics.
 - c) Any materials contaminated with microorganism or biological materials that have not been approved for release outside of a Containment Facility, including any genetically modified organisms/microorganism, imported genetically modified organisms/microorganism, animal cell cultures, unwanted organisms/microorganism, carcasses of laboratory animals, carcasses of



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laboratory animals infected with genetically modified organisms/microorganism or which contains genetically modified cells or tissues (example: as a graft or implant), and any other 'risky goods'.

d) Items of disposable labware (example: disposable gloves, pipette tips, plastic tubes, Petri dish, foil, parafilm, plastic syringes) that are not subjected to specific hazard disposal requirements (example: requirements for disposing chemical or radiation hazard). Items subjected to specific hazard disposal procedures must be treated as in Section 9.

3.0 RESPONSIBILITY

- 3.1 Anyone working with biological materials (including students, technical staff, researcher, etc.) must receive training biowaste disposal procedures (Refer Appendix 1).
- 3.2 Anyone generating biohazard wastes is responsible for disposing of it in accordance with procedures described herein.
- 3.3 Responsibility for ensuring appropriate procedures are in place lies on the person in charge of each work site.

4.0 PERSONAL PROTECTIVE EQUIPMENT (PPE)

4.1 Person in charge of biowaste must wear personal protective equipment (PPE) such as gloves, goggles, fack mask, fully covered shoes and lab coat at all times while handling biowaste.

5.0 APPROVED EXTERNAL CONTRACTOR

- In general, most biological wastes must be disposed of as scheduled waste. Removal of scheduled waste from the site must be done by an approved external contractor for incineration at licensed facilities. Only few biological wastes can be disposed on site (Section 6).
- 5.2 UTM is currently engaging Cenviro Services Sdn. Bhd. as an approved contractor to dispose of biological wastes. Please contact the Institutional Biosafety Committee (IBC) at biosafety@utm.my for arrangement of biological waste disposal from your laboratory.



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6.0 SEGREGATION AND DISPOSAL

The appropriate disposal procedure for all biological wastes depends on physical characters. Thus, all biological wastes must be segregated into one of the following types:

- a) Sharps
- b) Non-sharp solids
- c) Liquids
- d) Non-contaminated items
- e) Animal carcasses

6.1 Sharps

- 6.1.1 Sharp biological wastes include any items that could break or puncture the skin, e.g. needles, scalpel blades, glassware.
- 6.1.2 All sharps must be discarded directly into suitable containers that meet the definition of a sharp container (i.e., containers must be closable, puncture resistant, leak proof on sides and bottom, and labelled or color-coded) (Figure 1). The containers must not be filled more than 2/3 full. It must be closed immediately prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. CAUTION! Do not empty the contents of sharp container into another. Sharps biological waste must not be autoclaved and is only decontaminated off site.



Figure 1 (a) Closable, puncture resist and leak proof cardboard or plastic containers are suitable as sharp containers. (b) Containers must not be filled more than 2/3 full.



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6.1.3 Store sharp containers in a secure area (Section 12) until collection by approved external contractor.

6.2 Solids (non-sharp)

- 6.2.1 Non-sharp solid biological wastes typically consist of items such as gloves, paper towels, petri dishes, plastic culture vessels, solidified agar, and animal beddings. Rigid plasticware such as plastic serological pipette and plastic culture vessels could puncture autoclave bags. Thus, appropriate measure such as double bagging must be taken to prevent puncture.
- 6.2.2 Small volumes of liquid waste (no greater than 50 ml) may be placed in solid waste bags provided that the liquids are sealed in plastic tubes (e.g., microfuge tubes or centrifuge tubes). The total volume of liquid per waste bag must not exceed 500 ml.
- 6.2.3 All non-sharp solid biohazard waste must be decontaminated on site using autoclaves (Section 8). Store containers in a secure area (Section 12) until collection by approved external contractor.

6.3 Liquid waste

- 6.3.1 Liquid biological wastes are liquids containing organism/microorganism that are either:
 - a) High organic load contains >10⁵ cell/ml (e.g., microorganism/cell culture including bacteria, bacteriophages, fungi, spores).
 - b) Low organic load contains <10⁵ cells/ml (e.g., tap/distilled water, supernatant after centrifugation).
- 6.3.2 All high organic load waste must be decontaminated on site by autoclave (SECTION 8). Decontaminated waste is then disposed to laboratory sink. CAUTION! Liquid wastes containing spores, of any number, must be treated as a high organic load waste, thus must be autoclaved. Low organic load waste may be decontaminated either by autoclave as high organic load wastes or by chemical disinfection.
- 6.3.3 Chemical disinfection may be done using chlorine (e.g., sodium hypochlorite or other chlorine releasing compounds) (Table 1). The effectiveness of treatment is determined by available free chlorine, protein content of waste, and contact time between chlorine and waste. A general all-purpose



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laboratory disinfectant should have a concentration of 1 g/l (1,000 ppm) available chlorine. A stronger solution, containing 5 g/l (5,000 ppm) available chlorine, is recommended for dealing with biohazardous liquids in the presence of large amounts of proteins. **CAUTION!** Common household bleach usually contains not more than 5.25% sodium hypochlorite. Consult manufacturer. **CAUTION!** Chlorine is corrosive to metal piping. Treated waste must be diluted with copious amount of tap water when disposed through a laboratory sink. Other non-chlorine based chemical disinfectant may be used at its designated disinfecting-concentration as recommended by World Health Organization.

Table 1 Dilutions of chlorine-releasing compounds recommended by World Health Organization (WHO) in Laboratory Biosafety Manual, Third Edition (2004).

	"CLEAN" CONDITIONS ^a	"DIRTY" CONDITIONS
Available chlorine required	0.1% (1 g/l)	0.5% (5 g/l)
Sodium hypochlorite solution (5% available chlorine) 20 ml/l	100 ml/l
Calcium hypochlorite (70% available chlorine)	1.4 g/l	7.0 g/l
Sodium dichloroisocyanurate powder (60% available chlorine)	1.7 g/l	8.5 g/l
Sodium dichloroisocyanurate tablets (1.5 g available chlorine per tablet)	1 tablet per litre	4 tablets per litre
Chloramine (25% available chlorine) ^c	20 g/l	20 g/l

^a After removal of bulk material.

6.4 Non-contaminated items

- 6.4.1 By default, disposable labware, must be treated as biological waste, even if it is not known to be contaminated.
- 6.4.2 Exception is permitted when clean items were clearly identified and segregated from potentially contaminated items present in the same laboratory. Permitted items include labware packaging (wrappers for pipette, wrappers for petri-dish, wrappers for culture flasks etc.) and clean plastic labware. Such items may be disposed as domestic waste to landfill.
- 6.4.3 However, this exception is not applicable for latex lab gloves. Because it is hard to ascertain the "cleanliness" of gloves, all gloves must be treated as biohazardous, thus disposed as biological wastes.

^b For flooding, e.g. on blood or before removal of bulk material.

c See text.



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6.5 Animal carcasses

- 6.5.1 All carcasses of laboratory animals must be treated as biohazardous. Carcasses may or may not contain the following:
 - a) Genetically modified cells or tissues (from graft, implant etc.).
 - b) Infected with genetically modified microorganisms or pathogenic microorganisms.
 - c) Implants / grafts including new materials.
- 6.5.2 All animal carcasses must be disposed as animal waste and must not be decontaminated on site. Animal carcasses must be sealed in leak proof plastic bags and transferred to either a biohazard bin or bag designated specifically for animal carcasses purpose. This bin or bag must be kept in a secure area (Section 12) at -20 °C (e.g. fridge, freezer, cold room) until pick up by approved external contractor.
- 6.5.3 All animal beddings, either from cages used to house animals, whether infected with pathogenic microorganisms or not infected must be treated as biohazardous. Thus, these must be decontaminated on site (by autoclave sterilization) and disposed through approved external contractor as solid biological waste (Section 6.2).

7.0 PACKAGING AND LABELLING

- 7.1 Segregated biological wastes must be packed into plastic bags approved for specific treatment (Figure 2). Plastic bags with standard color coding adopted by all healthcare establishments in Malaysia may be used as guideline below:
 - a) Autoclave bags steam and heat resist plastic bags with or without biohazard labelling.
 - b) Incineration bags durable tear resist plastic bags with biohazard labelling that melts at 98.9 °C (210 °F).



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Figure 2 (a) is an example of Autoclavable bag, (b) and (c) are examples of incineration bags not suitable for autoclave.

7.2 Non-sharp solid biological wastes that have been autoclaved must be secured in incineration bags using tape or cable tie and affixed with biohazard information card on the outside (Figure 3). The wastes must be kept in secure storage area (Section 11) while awaiting removal by approved external contractor



Figure 3 (a) Autoclaved waste is to be packed into incineration bags for pick-up by approved external contractor. (b) Biohazard information and contact information is to be fixed on the outside of the incineration bag.

7.3 Liquid biohazard wastes for autoclaving must be double contained. Liquid wastes are placed in primary container with loose lid or cover (e.g., Schott bottle, bijoux bottle, universal bottle, beaker covered with aluminum foil). This primary container is then placed in open autoclavable secondary container such as receptacles or deep pan. This second container is to catch any overflow from primary container caused by the pressure during autoclave.



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8.0 AUTOCLAVES

Saturated steam under pressure (autoclaving) is the most effective and reliable means of sterilizing laboratory materials and decontaminating biohazard wastes. On site decontamination by autoclave may be used for biohazard wastes, excluding biohazard sharps and animal carcasses.

8.1 Sterilization cycle conditions

- 8.1.2 At a minimum, all parts of the load (i.e., waste) must reach either a temperature of 121 °C for 15 minutes or 134 °C for 4 minutes (to achieve complete sterilization). However, to allow time for the load to equilibrate to the same temperature as the autoclave, the minimum sterilization times that must be used are:
 - a) 121 °C for 20 minutes; or
 - b) 134 °C for 10 minutes
- 8.1.3 Autoclaves must be correctly loaded to allow steam penetration and air removal. This means autoclave bags must be loosely packed (i.e., content not compressed) and opened during autoclave. There should be no void spaces in the load. Void spaces trap airs that insulate against the steam this condition would prevent the transference of heat to the vessels resulting in no sterilization of the contents.
- 8.1.4 The success of the sterilization is very time-dependent in liquid, with large volumes requiring longer periods of time to reach the effective temperature within the liquid itself.
- 8.1.5 In dry loads, small amounts of water should be included inside the autoclave bag to ensure sufficient moisture content within the load to allow for heat transference and distribution.

8.2 Monitoring of sterilization cycle

8.2.1 Biological indicators (such as spore strips) must be used to validate the autoclave's performance. Monitoring of sterilization process should be done at a minimum of once per month (if autoclave is of high use) or whenever the autoclave is used (if autoclave is used less than once per month). **CAUTION!**Periodical autoclave validation is not the same as periodical certification.



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Where certification ensures the safe-to-use status of autoclave, validation confirms autoclave's performance.

8.2.2 A number of biological indicators are commercially available (e.g., Attest™ (3M™) biological indictor system) may be used, providing the 'kill time' of the indicator is equal to or greater than 15 minutes at 121 °C, or 4 minutes at 134 °C.

9.0 DISPOSAL AND REMOVAL AFTER DECONTAMINATION

- 9.1 Autoclaved non-sharp solid biohazard wastes must be placed in incineration bag, secure with tape/tie cable, labelled and kept in secure storage are until pick up by approved external contractor (Section 12).
- 9.2 Autoclaved liquid biohazard waste can be disposed to a laboratory sink. This is acceptable only when the autoclave received its regular scheduled certification and validation process (Section 8). Likewise, chemically inactivated liquid biohazard waste can be disposed to a laboratory sink.

10.0 MIXED WASTES

- 10.1 Mixed waste usually will contain both biohazard and hazardous chemical/toxic components.
- 10.2 Foremost, all practical steps should be taken to avoid mixing of biohazard with other hazardous wastes. Where the generation of such waste cannot be avoided, Safety and Health Officer (SHO) and Facility Manager must be consulted prior to any waste being generated in order that an appropriate means of disposal can be identified.
- 10.3 In general, the type of disposal method is decided based on component posing the greatest risk. If the risk from hazardous chemical/toxic component exceed the risk of biohazardous component, the mixed waste must be treated as hazardous chemical/toxic waste. In such cases, Guidelines for Packaging, Labelling and Storage of Scheduled Wastes in Malaysia (2014) must be followed.

11.0 TRANSPORT OF BIOHAZARD WASTES

Transport of biohazard waste may happen either in short distance such as within a premise but through non-laboratory areas (e.g., corridors, service elevator) or in long



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distance between premises/buildings. In both cases, transport of biohazard waste shall be carried out in a manner that minimizes the risk of any biohazard material being released. This shall be accomplished by following the following guidelines for each waste types.

11.1 Sharps

11.1.1 These must be transported in sealed biohazard sharps containers.

11.2 Non-sharp solid waste

11.2.1 Biohazard bags must be transported through non-laboratory areas within solid sided, covered receptacle on trolleys.

11.3 Liquid waste

- 11.3.1 Containers of liquid waste must be sealed and transported inside a closed secondary container (e.g., plastic box with click-on lids).
- 11.3.2 Where trolleys are used, these must have a lip to prevent containers from sliding off.

12.0 SECURE STORAGE AREAS

- 12.1 Non-sharp solid biohazard wastes that has been rendered innocuous by autoclave must be secured in incineration bags (Section 6). These biohazard wastes, including biohazard sharps, must be stored in a secure area at all times while awaiting pick up by approved external contractor. Storage area must comply with the followings:
 - a) Designated for biohazard waste storage.
 - b) Clearly labelled with the word biohazard or the universal biohazard symbol.
 - c) Temperature of the storage areas/units must be a minimum of 4 °C.
 - d) Properly ventilated, located to minimize exposure to the public.
 - e) Accessible only to authorized personnel.
 - f) Waste must be contained so that no discharge or release of any waste occurs, affords protection from the environment, and limits exposure to the public.
 - g) Maintained in a sanitary condition.
 - h) Free of rodents and insects.
 - i) Secure from vandalism.



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- 12.2 As an example, biosafety level (BSL) 1 and 2 laboratories are considered secure areas and may be used as temporary storage area as long as the above requirements are met. Outdoor biohazard wastes storage areas must be kept locked when unattended.
- 12.3 Biohazard wastes must not be stored with other solid wastes unless such waste is properly separated by barriers or unless all the waste is to be treated or disposed of as biohazard waste.
- 12.4 Temporary storage of waste awaiting pick up by approved external contractor is allowed for 30 days or total accumulated amount does not exceed 20 metric ton (Peraturan-peraturan Kualiti Alam Sekeliling (Buangan Terjadual) 2005). However, the general rule is stored waste does not become putrescent to ensure sanitation and prevent attraction of varmints. In this case, storage with temperature control able to prevent putrescent or decay may be used.

13.0 REFERENCES

- a) Malaysia Ministry of Health. Policy and Guideline 1st Edition. (2015).
- b) Department of Biosafety. Biosafety Guidelines for Contained Use Activity of Living Modified Organism (LMO). (2010).
- c) The University of Sydney. Guidelines for The Decontamination of Clinical/Biological Waste and Spill Management. (2016). Available at: http://sydney.edu.au/whs/guidelines/biosafety/decontamination_guidelines.shtml. (Accessed: 17th February 2017)
- d) Jabatan Alam Sekitar, Guidelines for Packaging, Labelling and Storage of Scheduled Waste in Malaysia. 1–33 (2014).
- e) Jabatan Alam Sekitar, Guidelines on the Handling and Management of Clinical Wastes in Malaysia. 1-29 (2009).
- f) Laboratory Biosafety Manual (Third Edition), World Health Organization (WHO). (2004).
- g) Peraturan-peraturan Kualiti Alam Sekeliling (Buangan Terjadual) 2005, Akta Kualiti Alam Sekeliling 1974 [Akta 217].



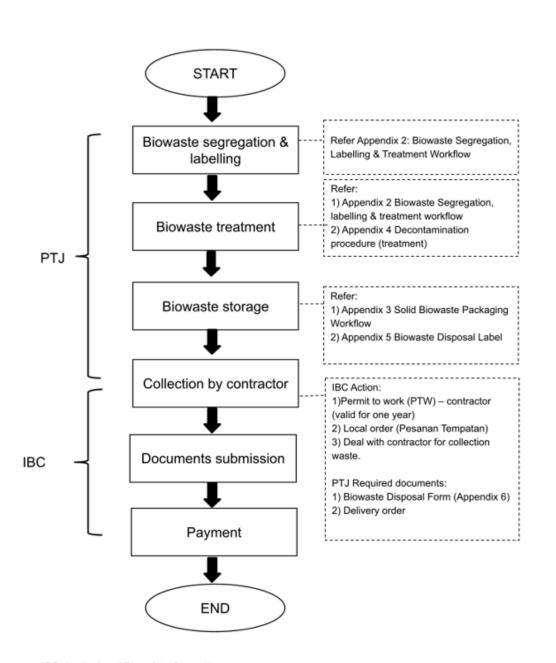
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APPENDIX 1: BIOWASTE MANAGEMENT WORKFLOW



IBC: Institutional Biosafety Committee

PTJ: Pusat Tanggungjawab



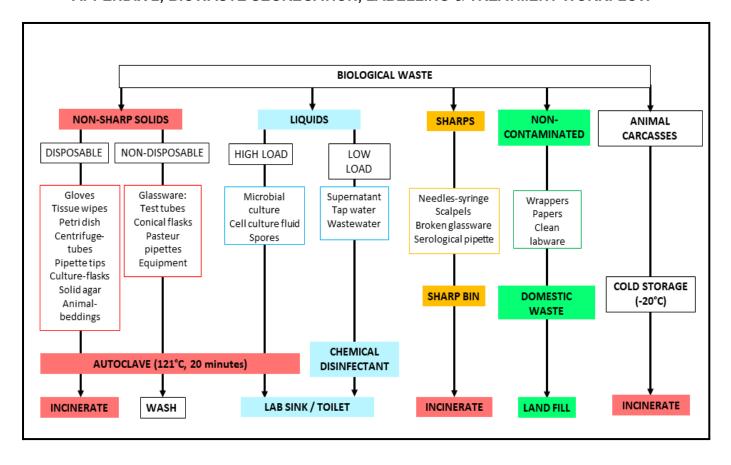
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APPENDIX 2; BIOWASTE SEGREGATION, LABELLING & TREATMENT WORKFLOW





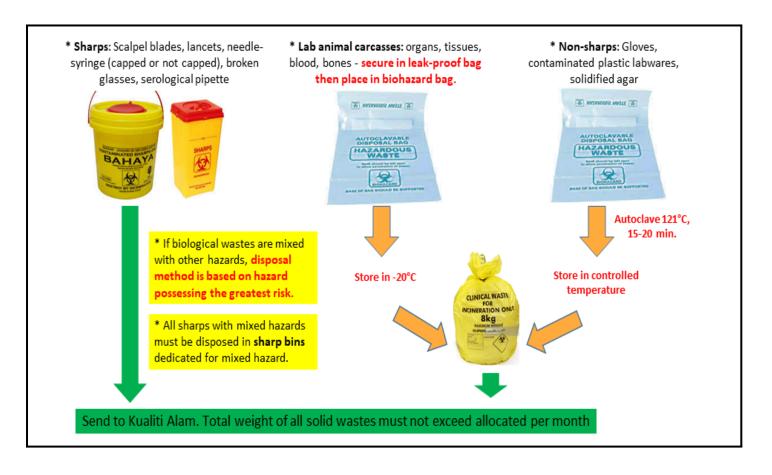
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APPENDIX 3: SOLID BIOWASTE PACKAGING WORKFLOW





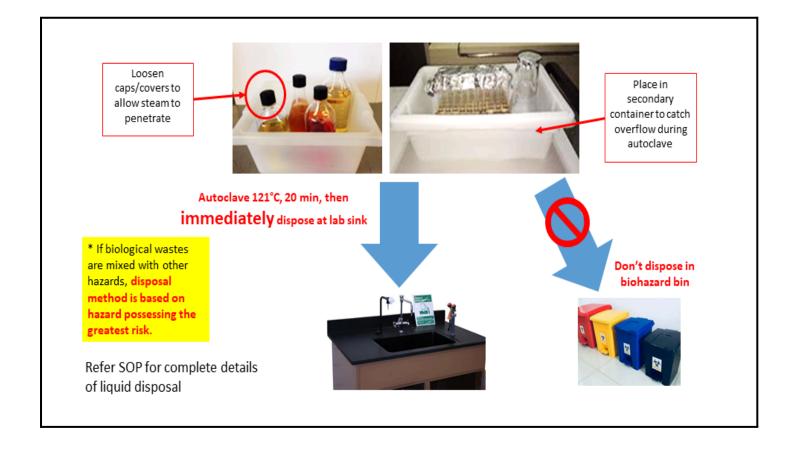
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APPENDIX 4: DECONTAMINATION TREATMENT PROCEDURE





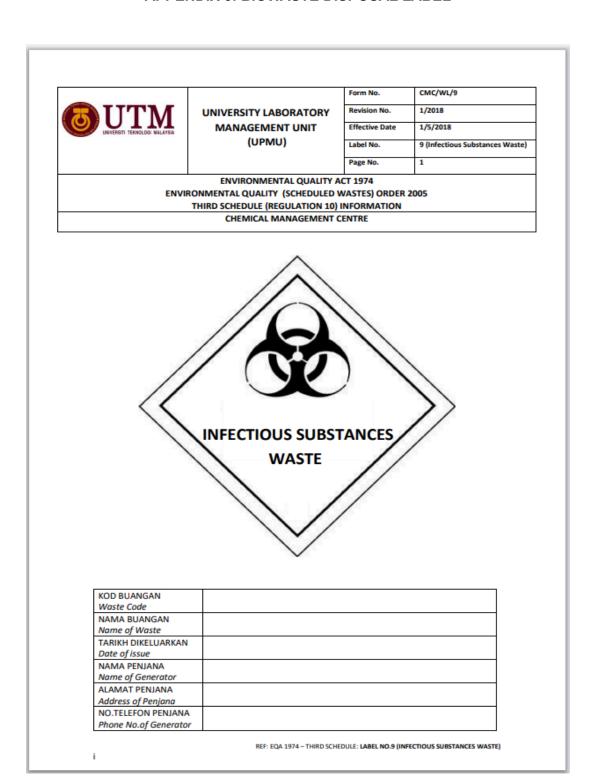
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APPENDIX 5: BIOWASTE DISPOSAL LABEL





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APPENDIX 6: BIOWASTE DISPOSAL FORM

To the state of th	UNIVERSITI TEKNOLOGI MALAYSIA	JAWATANKUASA KEIN Blok T02, Fakulti Sains 81310, UTM Johor Bal Tel: 019-7340629 / 0	(Jabatan Biosains) nru, Johor					
Nota	BORANG PERMOHONAN UNTUK MELUPUS SISA PEPEJAL BIOLOGI (SW404) Nota : Pemohon dikehendaki melengkapkan semua butiran di bahagian yang disediakan dan serahkan kepada Unit OSHE selepas proses pengutipan selesai. Sila buat satu salinan untuk simpanan dan rujukuan Jabatan/Bahagian.							
ВАНА	GIAN A: MAKLUMAT PEMOHON							
Nama	Pemohon :		Tel. No. / Sam	b :				
Tanda	atangan :		Tarikh	:				
ВАНА	GIAN B : LOKASI							
Fakult	i / Bahagian :		No. Bilik & B	ok :				
Makm	al / Bengkel :							
ВАНА	GIAN C: BUTIRAN SISA PEPEJAL BI	OLOGI		(* Sila lihat p	anduan)			
		•						
Bil.	* Jenis	* Pembungkusan	Kuantiti					



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Panduan : *Pembungkusan T - Bekas sisa tajam (Sharp bin)

P - Beg plastik autoklaf

* No. Kod SW SW 404 (bahan biologi, tercemar biologi dan termasuk bahan terkuarantin)

* Jenis1) Benda tajam (Sharps)2) Pepejal bukan tajam

3) Bangkai / organ / tisu haiwan makmal/penyelidikan

ARAHAN:

Label hendaklah dilekatkan dengan sempurna dan mestilah tidak mudah tanggal.

 Unit OSHE berhak tidak melupus bahan buangan jika terdapat kriteria yang dinyatakan di atas tidak dipatuhi.

Untuk Kegunaan Jabatan Sahaja (Unit OSHE) :

(Form 2/2)



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APPENDIX 7: LABORATORY BIOHAZARD WASTE MANAGEMENT CHECKLIST

4	AFFENDIX 1. LABORATORT DIOTIAZARD WASTE MANAGEMEN	i i Oili	LOILLI	, ,
Υ	: Yes			
N	: No			
NA	: Not available			
		Y	N	NA
1.0	Personal Protective Equipment (PPE)		1	
1.1	PPE is worn by Person in Charge (PIC) during biowaste handling			
	(Section 4.0).			
	0-11-1-11-1-1			
2.0	Solid Waste	1	1	
2.1	All sharps (SECTION 5.1.1) are placed in sharp bin, labelled with			
	the word "Biohazard" and "Sharps".			
2.2	All solid biological wastes (non-sharp) are placed in dedicated bin lined with Autoclavable waste-bag.			
	Autoclavable waste-bag. Autoclavable waste-bag have the word "Autoclave" and labelled			
2.3	with universal biohazard symbol.			
	Only non-sharp solid biological wastes (SECTION 5.2.1) are			
2.4	placed in Autoclavable waste-bag (i.e. content of bag is not			
	mixed with domestic solid wastes).			
	Only domestic solid wastes (SECTION 5.4.1) are placed in bin			
2.5	for land-fill disposal (i.e. content is not mixed with solid biological			
	waste).			
3.0	Liquid Waste			
	All liquid biological wastes (SECTION 5.3.1) for autoclave are in			
3.1	primary container with loose cover (e.g. Schott bottle, universal			
	bottle, beaker covered with aluminum foil).			
4.0	Audinostanos			
4.0	Animal waste		1	
4.1	Laboratory animal carcasses are separated from other animal			
	solid wastes (i.e. bedding).			
4.2	Laboratory animal carcasses are securely packed in			
4.2	puncture-proof and leak-proof plastic bag and kept frozen until collection for disposal by incineration.			
	Animal solid wastes other than carcasses are placed in			

Autoclavable waste-bag and treated as solid biological waste.



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5.0	Autoclave		
5.1	Autoclave is in clean condition.		
5.2	Autoclave operation is periodically validated using appropriate		
0.2	spore-inactivation methods. (Proof of valid operation is provided)		
5.3	Autoclave is correctly loaded to allow through steam penetration		
	of wastes (SECTION 7.0).		
	Autoclave of liquid wastes is done at temperature and length of		
5.4	time intended for the volume of liquid waste (SECTION 7.1.2).		
	(This can be shown using operation log of treatment and load size).		
	Primary containers of liquid waste are placed in secondary		
5.5	container (e.g. open and deep Autoclavable receptacle) to collect		
	overflow during autoclave.		
	The cover of primary containers for liquid waste (bottle		
5.6	caps/aluminum foils) are loosely attached during autoclave to		
	allow penetration of steam.		
	All Autoclavable waste-bag is correctly packed and opened		
5.7	during autoclave to allow penetration of steam (SECTION		
	7.1.3).		
5.8	Autoclavable waste-bag is closed and secured with tape/cable		
	tie after autoclave.		
6.0	Temporary Storage		
	Sharp bins are placed in secured BSL1 or BSL2 lab until		
6.1	scheduled pick-up for incineration by approved contractor.		
	Autoclaved solid biological wastes are placed in secured		
6.2	designated storage (SECTION 11.1) until scheduled pick-up for		
	incineration by approved contractor.		
7.0	Transport		
	All wastes are double contained in non-porous, solid sided and		
7.1	covered receptacle.		
7.2	When trolley is used, trolley has lip to prevent containers from		
1.2	sliding off.		
9.0	Disposal		
8.0	1 (15.1) (5.4)		
g 1	Autoclaved liquid biological wastes are disposed to laboratory		
8.1			



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LABORATORY BIOHAZARD WASTE MANAGEMENT

8.2	Autoclaved solid biological wastes are packed in yellow bag with the word "Incineration" and standard biohazard symbol after autoclave.		
8.3	Yellow bag for incineration is secured with tape/cable tie and tag with biohazard information card.		

9.0 Mixed Waste

9.1		Appropriate waste management procedure was approved by		
		Health and Safety Officer and Facility Manager.		
9.2	0.2	Disposal method is determined based on hazardous component		
	posing the highest risk.			