

Security Sensitive Biological Agents Regulatory Scheme

Non Registered Facility Report Temporary Handling or Disposal of an SSBA

Release Date: July 2019

Please complete this form if you are NOT REGISTERED to handle SSBAs and are undertaking a TEMPORARY HANDLING or DISPOSAL of a known SSBA.

A temporary handling must only be for seven (7) working days or less.

If you are reporting handling a **suspected SSBA** or the outcome of a confirmatory test, including reporting confirmation of the sample as an SSBA, please use the *Non Registered Report for Suspected SSBAs and Confirmatory Testing Results*.

Introduction

The *National Health Security Act 2007* allows entities to handle **known**¹ SSBAs on a temporary basis (seven working days or less). Following the handling, the entity <u>must</u> dispose of the SSBA, through complete transfer or destruction, and report the disposal to the Department of Health (Health). During this time, the SSBA must be handled according to Part 10 of the SSBA Standards.

If you are required to continue handling the SSBA for longer than the designated seven working days (for example, to complete testing on the SSBA), you must apply to Health for an extension prior to the end of the temporary handling period. You can apply for an extension by completing the *Application for Extension* section in this form. If this request is granted you must dispose of the SSBA at the end of the extended time period and report the disposal to Health within two business days after it has occurred.

If an extension is not requested or is not granted and you intend to continue to handle the SSBA, at the end of the temporary handling period you must apply to register to handle the SSBA using the *Initial Registration* form.

Note: These new requirements **do not affect the handling of suspected SSBAs**, **including an entity receiving a positive confirmatory test result** from a previously suspected SSBA. These agents must continue to be handled under Division 4A of the NHS Act and Parts 9 and 9A of the SSBA Standards. These handlings should be reported to Health on the Suspected SSBAs and Confirmatory Testing Results form.

¹ A known SSBA is one that has been confirmed by laboratory testing before being transferred into your facility.

Providing information to Health

The information you provide to Health is mandated by the *National Health Security Act 2007* and will be included on the National Register of Security Sensitive Biological Agents.

It is important to answer all questions and to provide accurate information. If the information you provide is incorrect or incomplete, Health may require you to provide additional information. This may cause delays.

Privacy

Personal information supplied to Health is handled according to the requirements of the *Privacy Act 1988*.

Application Authorisation

Please ensure that the person completing this form holds the appropriate authority to submit this application on the behalf of the entity or facility.

Instructions on completing this form

This document allows electronic entry of information into the required fields. It is recommended that, where possible, this form should be completed on a computer and a copy printed, signed and sent to Health.

All questions are mandatory unless otherwise stated and must be completed. If the space provided in each field is not sufficient to complete your answer, please include any additional information in an attachment with the information clearly marked as to which question it relates to.

Please ensure you retain a copy of this completed form as Health is unable to provide copies of submitted documents.

Lodgement

To lodge this form via post you will need to use an opaque envelope and post using Australia Post's Registered Mail service. You are considered to have submitted the report at the date and time shown on the registered post receipt.

Please do not email or fax forms to Health as these cannot be accepted.

Please submit all postal applications to:

The Director
Health Emergency Planning, Security and Laboratories Section
Department of Health
MDP 140, GPO Box 9848
Canberra ACT 2601

Once Health has received the form, you will be provided with a confirmation of receipt.

Further Information

Please use your facility registration number to refer to any matters relating to your facility.

If you have any queries about this form please contact the SSBA Regulatory Scheme:

Telephone: (02) 6289 7477 Email: <u>ssba@health.gov.au</u>

PART 1: ENTITY AND FACILITY DETAILS

If you have a facility reference number, please complete this section and move to Part 3.

Reference Number.	
Facility number (if known)	
Entity name	
Facility name	

PART 2: ENTITY AND FACILITY DETAILS

If you do not have a facility reference number please complete the details below.

•	•	Tiber please complete the details below.
Section 2.1:	Entity Details	
Full name of enti	ty (legal name)	
Entity trading na	me (if different)	
ABN		
ACN (if applicable)		
Australian Regis (if applicable)	tered Body Number	
Section 2.2:	Entity Physical	Address
Address 1		
Address 2		
Suburb/City		
State		
Postcode		
Section 2.3:	Entity Postal Ad	Idress (if different from above)
Address 1		
Address 2		
Suburb/City		
State		
Postcode		
Section 2.4:	Entity Contact D	Details
Telephone numb	er	
Email address		

Section 2.5:	Facility Details	
Facility name		
Room number/s (i	if applicable)	
Level/floor (if applica	able)	
Building name (if a	pplicable)	
Section 2.6:	Facility Physical	Address
Address 1		
Address 2		
Suburb/City		
State		
Postcode		
Section 2.7:	Facility Postal A	ddress (if different from above)
Address 1		
Address 2		
Suburb/City		
State		
Postcode		
Section 2.8:	Contact Details	of person responsible for the facility
Title (e.g. Dr, Mr, Ms	s etc)	
First name		
Middle name		
Last name		
Telephone number	er	
Facsimile number	r	
Email address		

PART 3: SSBA HANDLING DETAILS

Please complete the details for the SSBA

Section 3.1: SSBA Details	
SSBA details	
Specific strain, serotype or toxin subunit (if applicable)	
Section 3.2: Origin of the SS	BA
Received from	
Received date	
Reason for receipt E.g.: diagnostics, antibiotic sensitivity testing etc.	
Section 3.3: Handling of the	SSBA
What have you done/intend to do with the SSBA?	Handle If you intend to continue to handle this SSBA you must complete an Initial Registration application within two business days of the end of the temporary handling period. To apply for an extension of the temporary handling period, complete the question below and Part 3.4. If you intend to register, please move to Part 4.
	Transfer Please note: you may both transfer a sample of the SSBA and destroy the remaining SSBA as part of the disposal process
	Destroy
Do you need to retain the SSBA for longer than seven business days prior to disposal (transfer or destruction)?	Yes Please move to section 3.4 No Please move to next applicable section 3.5 or 3.6
Section 3.4: Application for than Seven Bus	Extension - Retain the SSBA for Longer iness Days
Why do you need to retain the SSBA for longer than seven business days?	
What date do you intend to dispose of (transfer or destroy) the SSBA?	
How do you intend to dispose of the SSBA?	Transfer Destroy
The SSBA must be disposed of by complete transfer or destruction of the agent at the end of the handling period. SSBAs may be disposed of by both transfer (eg to a reference laboratory) and destruction (of any remaining samples).	Please note that if an extension is granted you will need to report the complete transfer or destruction of the SSBA within two business days after the action has occurred or the end of the extended handling period, whichever comes first.
Comments (if applicable)	

Section 3.5: Transfer of the SSBA		
Have you transferred your entire holding of this SSBA?	Yes Please complete remaining questions in this section	
	No Please complete the remaining questions in this section AND section 3.6 explaining what you have done with the remainder of this SSBA	
Date of transfer		
Receiving organisation name		
Receiving organisation address		
Receiving organisation contact name		
Receiving organisation contact telephone number		
Arrival date at receiving facility (if known)		
Was the transfer successful ² according to the SSBA standards?	Yes Move to Section 3.6 or Part 4 No Please provide description in field below	
Lost in Transit or Unsuccessf	ul Transfer	
Please provide a brief description of what happened		
Mandatory reporting to law enforcement is required under the NHS Act. For further information please see Guideline 05 - Reporting to Law Enforcement or the National Security Hotline, available through our website – www.health.gov.au/ssba		
Section 3.6: Destruction of the SSBA		
Have you destroyed your entire holding of this SSBA?	Yes Please complete remaining questions in this section	
	No Please complete the remaining questions in this section AND section 3.5 explaining what you have done with the remainder of this SSBA	
Date of destruction		
Method of destruction		
Comments (if applicable)		

² A successful transfer is defined under the SSBA Standards as verification that the complete shipment of the SSBA (quantity and type), as covered by the shipment documents, has been received and that there is no evidence of tampering to the shipping container.

PART 4: SIGNATURES

The information collected on this form may be used by the Department of Health to decide whether to vary the National Register of Security Sensitive Biological Agents (National Register). If a decision is made to vary the National Register, the information contained on this form, including personal information, will be recorded on the National Register by the Department.

The information collected on this form is authorised under the *National Health Security Act* 2007 and *National Health Security Regulations* 2018. Information collected on this form may be disclosed by the Department to the Australian Security Intelligence Organisation, law enforcement agencies such as the Australian Chemical Biological Radiological and Nuclear Data Centre, the Australian Federal Police and State and Territory police forces, other agencies responsible for responding to emergencies and other specified persons. The Department is unlikely to disclose personal information to overseas recipients.

The Department has an Australian Privacy Principles (APP) privacy policy which you can read at www.health.gov.au/internet/main/publishing.nsf/content/privacy-policy. You can obtain a copy of the APP privacy policy by contacting the Department by telephone on (02) 6289 1555, freecall 1800 020 103 or by using the online enquiries form at www.health.gov.au.

The National Register is hosted and maintained by the Department of Home Affairs.

I declare that:

- I am duly authorised to sign this declaration on behalf of the entity associated with this facility:
- The information supplied on this form and any attachment is true and correct; and
- This entity is compliant with the SSBA Standards currently in force.

Signature	
Date	
Full name (Please print)	
Position title	
Contact telephone number	
Contact e-mail address	