

Non-Registered Facility Report for Suspected SSBA's and Confirmatory Testing Results

Release Date: July 2019

Please complete this form if you are NOT REGISTERED to handle SSBA's and:

- you transfer a suspected SSBA for confirmatory testing; or
- you destroy a suspected SSBA prior to confirmatory testing; or
- you performed your own confirmatory testing on a suspected SSBA and are reporting the results of the test; or
- you sent a suspected SSBA to another facility for confirmatory testing and you are reporting the results of the test.

Please note: If your facility has received a known¹ SSBA please complete a *Non Registered Facility Report - Temporary Handling or Disposal of an SSBA*.

Introduction

If, on the basis of your facility's normal testing procedures, you form a **reasonable suspicion**² that you are handling an SSBA, you must arrange for confirmatory testing or destroy the suspected SSBA as soon as possible and within two business days after forming your suspicion. If the confirmatory testing is to take place at another facility, you must also report the transfer of the suspected SSBA to the confirmatory testing facility.

If you arranged for confirmatory testing of the SSBA, either by your facility or by another facility, you must report the results of the confirmatory test as soon as possible and within two business days after receiving the results.

If the suspected SSBA is confirmed you must decide to either register to handle the SSBA or transfer or destroy the entire holdings of the SSBA. Registration or transfer/destruction must take place within two business days of receipt of the positive confirmatory test result unless an extension of time is permitted – see Retention Requirements below.

Suspected SSBA's and SSBA's confirmed by confirmatory testing must be handled according to the requirements of Parts 9 and 9A of the SSBA Standards.

You must complete a separate form each time the facility handles a suspected SSBA.

¹ A known SSBA for the purposes of temporary handling requirements is one that was **confirmed** by laboratory testing **before** being transferred into your facility.

² Reasonable suspicion does not apply just because an SSBA is not yet ruled out but rather, on the balance of probabilities, the agent is likely to be an SSBA.

Retention Requirements

If you intend to dispose³ of the SSBA once confirmatory testing is completed and there are requirements for you to retain the confirmed SSBA for longer than two business days (for example due to requirements under the National Pathology Accreditation Advisory Council (NPAAC) guideline on *Requirements for the Retention of Laboratory Records and Diagnostic Materials*), you must:

- report the positive confirmatory result to Health within two business days of receipt of the results; **and**
- request a extension to the prescribed handling period prior to disposal.

To apply for an extension, please complete the *Application for Extension* section of this form. If this request is granted your time period for handling will be extended and following the end of this period you will be required to dispose of the SSBA and must report the disposal to Health within two business days of the disposal occurring.

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 SSBA's.

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 provided 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 behalf of the entity or facility. For non-registered facilities the person authorised to make this report may be a person who senior management determines has responsibility for overseeing work related to SSBA material, eg Laboratory Managers.

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 marked with an * are mandatory and must be completed. Other fields are to be completed only if the information has changed. 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.

³ Disposal is the complete transfer or destruction of the SSBA.

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 by email to the contact officer listed for the facility.

Further Information

Please use your facility reference 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: ssba@health.gov.au

PART 1: ENTITY AND FACILITY DETAILS

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

Reference Number.	
Facility reference number <i>(if known)</i>	
Entity name	
Facility name	

PART 2: ENTITY AND FACILITY DETAILS

If you do not have a facility reference number please complete the details for the entity and facility.

Section 2.1: Entity Details	
Full name of entity <i>(legal name)</i>	
Entity trading name <i>(if different)</i>	
ABN	
ACN <i>(if applicable)</i>	
Australian Registered Body Number <i>(if applicable)</i>	
Section 2.2: Entity Physical Address	
Address 1	
Address 2	
Suburb/City	
State	
Postcode	
Section 2.3: Entity Postal Address (if different from above)	
Address 1	
Address 2	
Suburb/City	
State	
Postcode	
Section 2.4: Entity Contact Details	
Telephone number	
Facsimile number	
Email address	

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

PART 3: REPORTING DETAILS

Please provide the details of the report type.

Reporting Details	
What are you reporting ⁴ ? (Select as many as required)	A Suspected SSBA <input type="checkbox"/>
	Outcome of Confirmatory Testing <input type="checkbox"/> <i>Please note: if you have previously reported the transfer of a suspected SSBA for confirmatory testing and are now reporting the results of this test, please complete Section 4.1, then move to Section 7.2 and follow the prompts as appropriate.</i>

PART 4: SUSPECTED SSBA DETAILS

Section 4.1: Suspected SSBA Details	
Suspected SSBA	
Specific strain, serotype or toxin subunit (if applicable)	
Section 4.2: Origin of the Suspected SSBA	
Sample identification number	
Received from <i>Please do not enter patient names</i>	
Received date	
Reason for receipt <i>E.g.: diagnostics, antibiotic sensitivity testing etc.</i>	
Section 4.3: Initial Handling Details of the Suspected SSBA	
What have you done with the suspected SSBA?	<input type="checkbox"/> Destroyed prior to arrangement of confirmatory testing – please move to Part 5. <i>This box should only be checked if no confirmatory testing has been arranged. If you have arranged for confirmatory testing AND destroyed any remaining samples please fill in Part 6 or Part 7 as appropriate.</i> <input type="checkbox"/> Undertaken in-house confirmatory testing – please move to Part 6 <input type="checkbox"/> Transferred for confirmatory testing – please move to Part 7

⁴ If you have received a known SSBA (i.e. one that has been previously confirmed through testing at another facility) please fill in a Temporary Handling or Disposal form.

PART 5: DESTRUCTION PRIOR TO ARRANGEMENT OF CONFIRMATORY TESTING

Section 5.1: Destruction of the suspected SSBA prior to confirmatory testing	
Have you destroyed your <u>entire</u> holding of this suspected SSBA prior to arrangement of confirmatory testing?	Yes <input type="checkbox"/> Complete the remaining questions in this section and then move to Part 9 No <input type="checkbox"/> Contact Health
Date of destruction	
Method of destruction	
Comments (if applicable)	

PART 6: IN-HOUSE CONFIRMATORY TESTING RESULTS

Section 6.1: In-house confirmatory testing results	
Was confirmatory testing undertaken by this facility?	Yes <input type="checkbox"/> Please answer the next question No <input type="checkbox"/> Please move to Part 7
Date results received	
Was the SSBA confirmed?	Yes <input type="checkbox"/> Please move to Part 8 No <input type="checkbox"/> Please move to Part 9

PART 7: TRANSFER OF THE SUSPECTED SSBA FOR CONFIRMATORY TESTING

Section 7.1: Transfer of the Suspected SSBA for Confirmatory Testing	
Date of transfer	
Receiving organisation name	
Receiving organisation address	
Receiving organisation contact name	
Receiving organisation contact telephone number	
Did the suspected SSBA arrive?	Yes <input type="checkbox"/> Please move to next question No <input type="checkbox"/> Please complete lost in transit or unsuccessful transfer section Other <input type="checkbox"/> Please provide comments
Arrival date at receiving facility (if known)	

Was the transfer successful ⁵ according to the SSBA standards?	Yes <input type="checkbox"/> Please move to section 7.2 No <input type="checkbox"/> Please complete lost in transit or unsuccessful transfer section
Lost in Transit or Unsuccessful transfer	
Please provide a brief description of what happened	

Section 7.2: External Confirmatory Testing Results	
Are you reporting the results of external confirmatory testing?	Yes <input type="checkbox"/> Please answer next question No <input type="checkbox"/> Please move to Part 9
Sample identification number	
Date results received	
Was the SSBA confirmed	Yes <input type="checkbox"/> Please move to Part 8 No <input type="checkbox"/> Please move to Part 9

PART 8: SSBA HANDLING DETAILS FOLLOWING A POSITIVE CONFIRMATORY TEST

Please complete the details for confirmed SSBAs

Section 8.1: SSBA Details	
SSBA details	
Specific strain, serotype or toxin subunit <i>(if applicable)</i>	
Section 8.2: Handling of the Confirmed SSBA	
What have you done with the SSBA?	<p>Handle <input type="checkbox"/> <i>If you intend to continue to handle this SSBA you must complete an Initial Registration application within two business days of confirmation of the SSBA, unless you are applying for an extension. To apply for an extension complete the question below and Part 8.3. If you intend to register, please move to Part 9.</i></p> <p>Transfer <input type="checkbox"/> <i>You may both transfer a sample of the SSBA and destroy the remaining SSBA as part of the disposal process.</i></p> <p>Destroy <input type="checkbox"/></p>
Do you need to retain the SSBA for longer than two business days prior to disposal (transfer or destruction)?	Yes <input type="checkbox"/> Please move to section 8.3 No <input type="checkbox"/> Please move to next applicable section 8.4 or 8.5

⁵ 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.

Section 8.3: Application to Retain the SSBA for Longer than Two Business Days	
Reason for retaining the SSBA for longer than two business days?	
What date do you intend to dispose of (transfer or destroy) the SSBA?	
What do you intend to do with the SSBA after this period? <i>The SSBA must be disposed of by complete transfer or destruction of the agent. SSBA's may be disposed of by both transfer and destruction.</i>	Transfer <input type="checkbox"/> <i>Please note that if an extension is granted you must report the transfer or destruction of the SSBA</i> Destroy <input type="checkbox"/> <i>within two business days after the action has occurred</i>
Comments (if applicable)	
Section 8.4: Transfer of the SSBA	
Have you transferred your <u>entire</u> holding of this SSBA? <i>Please note you are not required to report in this section the transfer of any samples previously reported as transferred for confirmatory testing.</i>	Yes <input type="checkbox"/> Please complete remaining questions in this section No <input type="checkbox"/> Please complete the remaining questions in this section AND section 8.5 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 ⁶ according to the SSBA standards?	Yes <input type="checkbox"/> Move to Section 8.5 or Part 9 No <input type="checkbox"/> Please complete remaining question
Lost in Transit or Unsuccessful Transfer	
Please provide a brief description of what happened <i>Reporting to law enforcement is required. Please see the guideline "Reporting to Law Enforcement or the National Security Hotline" for further information.</i>	

⁶ 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.

Section 8.5: Destruction of the SSBA after confirmatory testing	
Have you destroyed your <u>entire</u> holding of this SSBA? <i>Please note that destruction of any remaining samples may take place at the same time a sample is sent for a confirmatory test.</i>	Yes <input type="checkbox"/> Please complete remaining questions in this section No <input type="checkbox"/> Please complete the remaining questions in this section AND section 8.4 explaining what you have done with the remainder of this SSBA
Date of destruction	
Method of destruction	
Comments <i>(if applicable)</i>	

PART 9: 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 Health to the Australian Security Intelligence Organisation, law enforcement agencies such as 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	

All fields are mandatory unless otherwise stated.

Contact telephone number	
Contact e-mail address	