



Security Sensitive Biological Agents Regulatory Scheme

Internal Review Tool

Version 3 – January 2014

Aligned to SSBA Standards dated March 2013

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PART 1 – GENERAL INFORMATION

Introduction

The Internal Review Tool (IRT) is designed to assist entities and facilities when undertaking internal reviews for the purposes of the SSBA Standards. The IRT is not a mandatory document and other methods or documents may be used to undertake reviews.

The SSBA Standards require that entities conduct an internal review at planned intervals of no longer than 6 monthly for Tier 1 and 12 monthly for Tier 2 SSBAs, to determine that operations carried out by the entity comply with both the requirements of the SSBA Regulatory Scheme and the entity's SSBA policies. Records of internal review must be kept and these records should include the findings of the review, any non-compliance or improvement opportunities identified and any actions that result from the findings.

The IRT is designed to assist in determining if the entity and facility meets the requirements of the SSBA Standards, and can be used as a record that an internal review has taken place.

Corresponding SSBA Standards

This version of the IRT has been aligned with the requirements from the *SSBA Standards* – dated March 2013.

Using this Document

Requirements under the SSBA Standards:

Each Part of the IRT (except Part 1) covers the associated Part of the SSBA Standards¹. The IRT headings include the Standards clause number that is being covered by the questions. Please note that letters included after a question number (for example Q2.3a) are simply in place to designate that the clause is covered in several questions and do not relate to lettered sub clauses or paragraph numbering within the Standards.

Questions in each section cover the mandatory requirements of the SSBA Standards and the majority have a yes/no answer. A space for comments is included so that the entity can explain how these requirements are being met.

It should be noted that while the questions are based on the standards requirements they are not a word-for-word match. For the full details of the requirements, the latest version of the Standards should be consulted.

The IRT also includes sections on reporting to the SSBA Regulatory Scheme, compliance with internal policy and sections to record any non-compliances, corrective actions or improvement opportunities. A section on available resources is included at the end of the document.

Further consideration questions:

In addition to the questions that address the mandatory requirements under the SSBA Standards, the IRT includes a number of questions, found at the end of the section, that are based on the suggestions made under the commentary of the SSBA Standards or are recommendations about best practice. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

¹ Please note that *Part 1 – Scope and Definitions* of the SSBA Standards is not covered by this document.

Terms and Definitions

Below are a number of terms commonly used throughout this document.

Handling	Includes <ul style="list-style-type: none"> (a) receiving, holding, using and storing biological agents; and (b) any operation incidental to, or arising out of, any of those operations.
Health	Australian Government Department of Health
List of Security-sensitive Biological Agents	The list established under the NHS Act. The list designates which biological agents are regulated.
NHS Act	The <i>National Health Security Act 2007</i> .
NHS Check	A National Health Security check (background check).
NHS Regulations	The <i>National Health Security Regulations 2008</i> .
Record	A document that states the results achieved or provides evidence of activities performed.
Reportable event	An event that must be reported to Health under section 48(1) of the NHS Act. Reportable events include: <ul style="list-style-type: none"> • Initial Registration • Change of administrative details (including changes to Responsible Officer details) • Starting to handle a new SSBA • Changes to the purpose for handling an SSBA • Incident reports • Transfer In and Transfer Out of SSBA's • Disposal • Suspected SSBA's • Temporary Handling
Sensitive Information	Means any of the following: <ul style="list-style-type: none"> (a) an entity's storage records for the security-sensitive biological agent handled at the facility; (b) an entity's risk assessment plan for the security-sensitive biological agent handled at the facility; (c) an entity's risk management plan for the security-sensitive biological agent handled at the facility; (d) any other information that the entity identifies as being sensitive information under clause 5.3 of the SSBA Standards because it could compromise the security of the security-sensitive biological agent handled at the facility.
SSBA	A security sensitive biological agent.

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SSBA Standards	The Security Sensitive Biological Agent (SSBA) Standards determined by the Minister under the NHS Act.
Standard operating procedure (SOP)	A set of written instructions that documents a routine or repetitive activity to be followed by an entity or facility.
Suspected SSBA	A biological agent suspected, on the basis of testing in a laboratory, to be a security sensitive biological agent.
Temporary Handling	The handling of a known SSBA by an entity that is not registered to handle that particular SSBA. Handling may be for a period of up to seven working days after which an entity must either dispose of or register to handle the SSBA.
Tier 1 SSBAs	Means an agent that is referred to as a Tier 1 agent on the List of Security-sensitive Biological Agents. Tier 1 agents have the highest security concerns.
Tier 2 SSBAs	Means an agent that is referred to as a Tier 2 agent on the List of Security-sensitive Biological Agents. Tier 2 agents have a high security concern.

PART 2 – RISK AND INCIDENT MANAGEMENT

The objective of Part 2 of the SSBA Standards is to ensure that all known biosecurity risks in relation to the SSBA's handled by the entity are identified and managed through risk assessment and risk management plans prior to the commencement of SSBA related work.

2.2 Risk Assessment

2.2.1 Timing and Scope

2.2.1 Is the scope, nature and timing of the risk assessment proactive rather than reactive? Yes No

Comments:

2.2.2 Hazards / Risk Identification

2.2.2a Are the hazards/risks associated with the handling of the SSBA's identified and documented? Yes No

Comments:

2.2.2b Are the following risks/hazards identified and documented for inclusion in the risk assessment:

- | | | | |
|------|---|------------------------------|-----------------------------|
| i. | Determination of the potential for/ possible causes of an incident? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Human behavioural risk? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Periods of reduced staff availability? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. | Identification of potential emergency situations involving SSBA's? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

2.2.3 Risk Assessment Process

2.2.3a Has the entity undertaken a risk assessment for the SSBA's and the facilities in which they are handled? Yes No

Comments:

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2.2.3b At a minimum, does the risk assessment include:

- i. Communication and consultation plans with internal and external stakeholders? Yes No
- ii. Internal, external and security risk context? Yes No
- iii. The risks identified under the hazard/risk identification clause Yes No
- iv. Analysis of the risks and the effectiveness of existing controls, including:
 - a. If action is needed to prevent incidents? Yes No
 - b. Effectiveness of physical security controls? Yes No
 - c. Effectiveness of the procedures for decontamination/inactivation? Yes No
 - d. Identification of those responsible for devising, implementing and testing control measures? Yes No
 - e. If further controls are needed to reduce the risk Yes No

Comments:

2.2.3c If the facility is handling Tier 1 SSBA's, has a vulnerability analysis been undertaken? Yes No
N/A (No Tier 1)

Comments:

2.3 Risk Management Plan

2.3a Has a risk management plan been developed, documented and implemented following the risk assessment? Yes No

Comments:

2.3b At a minimum, does the risk management plan include:

- i. Treatment for the risks identified in the risk assessment? Yes No
- ii. Plans for monitoring and review of the risk management process? Yes No

Comments:

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2.3c	Have the risk management plans been effectively communicated to		
	i. All personnel handling SSBA's or sensitive information relating to SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Others as relevant (e.g. security personnel, maintenance contractors)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

2.3d	Have Standard Operating Procedures (SOPs) for the secure handling of SSBA's been:		
	i. Developed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Documented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Implemented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

2.4 Incident management

2.4a	Has the entity established, documented and maintained procedures to define, report, record and analyse incidents involving SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>Note: Incidents can include any non-compliance with the NHS Act, NHS Regulations and the SSBA Standards.</i>			
Comments:			

2.4b	Are records of the nature of the incident and any subsequent action taken maintained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

2.4c	Does analysis of the incidents include:		
	i. Determining the cause/s of the incident?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Evaluating the need for corrective action to ensure incidents do not re-occur?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Determining and implementing any action needed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iv. Recording the results of action taken?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	v. Review of the effectiveness of the action taken?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

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2.4d Does the entity have in place processes to encourage learning from incidents involving SSBA's? Yes No

Comments:

2.5 Review

2.5 Are all risk assessment and risk management plans reviewed at least:

- i. Every 12 months for risks involving Tier 1 SSBA's (or more frequently if required)? Yes No
N/A(No Tier 1)
- ii. Every 2 years for risks involving Tier 2 SSBA's (or more frequently if required)? Yes No
N/A(No Tier 2)
- iii. Or more frequently as required Yes No

Comments:

Part 2 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBA's in your facility.

P2a Have the roles and responsibilities of personnel who perform and verify work affecting risk management been defined and documented? Yes No

Comments:

P2b Does reactive risk assessment take place following an occurrence of an identified risk or following the occurrence of a new risk not previously considered? Yes No

Comments:

P2c Was professional advice sought when developing the risk assessment or risk management plan? Yes No

Comments:

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P2d Are there procedures to clearly communicate to all personnel what constitutes an incident? Yes No

Comments:

P2e Is the review plan included in the risk assessment and risk management document? Yes No

Comments:

P2f Does the review plan include space for documentation of outcomes and sign off once the review is completed? Yes No

Comments:

PART 3 - PERSONNEL

The objective of Part 3 of the SSBA Standards is to have personnel management systems in place to implement and manage the security of SSBAs and related sensitive information.

3.2 Responsible Officers

3.2a Has the entity documented top management's appointment of a Responsible Officer and a Deputy Responsible Officer? Yes No

Comments:

3.2b Do the duties of the Responsible Officer include:

- i. Overseeing the SSBA management system? Yes No
- ii. Reporting to top management on the performance of the entity's SSBA management system and any need for improvement? Yes No
- iii. Overseeing internal review, audit and reporting measures? Yes No
- iv. Verifying, in conjunction with other personnel, that all known SSBA risks have been addressed? Yes No
- v. Advising or participating in the reporting, investigation and follow-up of incidents? Yes No
- vi. Where appropriate, referring incidents to top management/ SSBA management committees? Yes No
- vii. Ensuring all work relating to SSBAs is conducted in accordance with established policies, SOPs, the NHS Act, NHS regulations and the SSBA Standards? Yes No
- viii. Advising top management as to whether staff levels, facilities and equipment are sufficient? Yes No
- ix. Maintaining lists of authorised and approved persons? Yes No

Comments:

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- 3.2c Do the lists of authorised and approved persons include:
- i. The period for which the person is authorised or approved? Yes No
- ii. The review date of the authorisation or approval? Yes No
- iii. What the person is authorised or approved for? Yes No

Note: A person may be authorised or approved to handle SSBA's, access a facility where SSBA's are handled or access sensitive information relating to SSBA's or any combination of the above.

Comments:

- 3.2d Are the Responsible Officer and Deputy Responsible Officer authorised persons? Yes No

Comments:

3.3 Authorised Persons

- 3.3a Have all persons who: Yes No
- Handle SSBA's;
 - Access a facility where SSBA's are handled; or
 - Access sensitive information related to SSBA's
- been made authorised persons?

Note: an entity may choose to authorise a person to do all of the above or may limit the authorisation to any combination of the above.

A person may not need to be an authorised person if they are to be escorted or supervised in the facility or when handling SSBA's or sensitive information. These persons may instead be made approved persons if they meet the criteria for an approved person under the SSBA Standards. In addition to this, persons who meet certain criteria for handling sensitive information under Part 5 of the SSBA Standards may also not be required to be an authorised or approved person when handling that information.

Comments:

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3.3c	Are all authorised person statuses limited to the entity in which the status was conferred?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

3.3d	Are all students who handle SSBA's either authorised or approved persons?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

3.3f	Has the entity revoked (or have a process for revoking) the authorisation of any person who no longer has a need to handle SSBA's, access a facility that handles SSBA's or access sensitive information related to SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

3.3.1 Authorisation of a person

3.3.1	Have all authorised persons:		
	i. Been trained in the requirements of the NHS Act, NHS Regulations and SSBA Standards as relevant to their authorisation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Provided to the entity a signed and dated record of the training above?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Not been excluded from handling SSBA's by the entity nor have been directed not to handle SSBA's by the Secretary of Health?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iv. Undergone an identity check as outlined in the SSBA Standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	v. Been verified as 18 years old or over?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	vi. Undergone an NHS check if required to do so by the SSBA Standards and have a 'eligible' or 'qualified' status?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

3.3.2 Authorisation of a person with an NHS Check

3.3.2	If a person has undergone an NHS check and	N/A <input type="checkbox"/> (go to Q3.3f)
	i. Received a result of 'eligible' – is the person authorised for up to two years?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Received a result of 'qualified' – is the person authorised for a period of up to 12 months only?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. Received a result of 'non-eligible' – has the entity not authorised that person?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.4 Approved persons

3.4a	Does the entity have in place documented processes to ensure that contractors, visitors, suppliers, students and other such persons do not compromise the facility's SSBA security?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.4b	Do these processes include policies and procedures for the approval of persons who need to:	
	i. Handle SSBA's;	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Access a facility where SSBA's are handled; or	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. Access sensitive information related to SSBA's.	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Note: an entity may choose to approve a person to do all of the above or may limit the approval to any combination of the above.</i>		
Comments:		

3.4c	If the facility handles Tier 1 SSBA's, are all approved persons escorted by an authorised person at all times?	N/A <input type="checkbox"/> (no Tier 1 - go to Q3.4d) Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Note: Escorted is taken to mean that the approved person should remain within line of sight of the authorised person escorting them while the person is within the secure perimeter or handing sensitive information.</i>		
Comments:		

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3.4d	If the facility handles Tier 2 SSBA's, are all approved persons supervised by an authorised person at all times?	N/A <input type="checkbox"/> (no Tier 2) Yes <input type="checkbox"/> No <input type="checkbox"/>
	Is the degree of supervision of and the responsibility for an approved person by an authorised person determined by risk assessment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.4e	Has the entity revoked (or have a process for revoking) the approval of any person who no longer has a need to handle SSBA's, access a facility that handles SSBA's or access sensitive information related to SSBA's?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.5 Identity check

3.5a	Was an identity check conducted on all persons prior to the person being authorised?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.5b	If an NHS check was conducted, was the identity check completed on each person prior to the submission of the persons NHS check application to AusCheck?	N/A <input type="checkbox"/> (no NHS check) Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

3.5c	Did the documentation for all identity checks include:	
	i. Evidence of commencement of identity in Australia?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Linkage between the identity and the person?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. Evidence of operation in the community?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iv. Evidence of residential address?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Note: For more information about what can be used in each of these categories – see Table 1 under Clause 3.5 of the SSBA Standards.</i>		
Comments:		

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3.5d	Does the entity keep a record of which documents were provided? <i>Note: this may be a record of the type of document provided; it does not have to be a copy of the document itself.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

3.6 National Health Security (NHS) checks

3.6a	Does the facility undertake National Health Security checks (either mandatory checks for Tier 1 SSBA's or voluntary checks for Tier 2 SSBA's)? <i>Note: NHS checks are not required for persons who hold a national security clearance of Negative Vetting Level 1, Negative Vetting Level 2 or Positive Vetting.</i> <i>NHS checks are recommended for personnel handling Tier 2 SSBA's but are not mandatory. If they are undertaken, please answer the questions under 3.6.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(if No, go to Q3.7a)
Comments:				

3.6b	Has the entity applied to AusCheck for an NHS check of all persons who are authorised to handle Tier 1 SSBA's, access facilities where Tier 1 SSBA's are handled or access sensitive information relating to Tier 1 SSBA's? <i>Note: some persons may be able to access sensitive information for Tier 1 SSBA's without an NHS Check if they meet certain requirements under Part 5 of the SSBA Standards.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Comments:				

3.6c	At the time of application for an NHS check, was a recent photograph, taken by the entity, supplied to AusCheck?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Comments:				

3.6d	Did the entity take into account the results of the NHS check as part of the assessment for eligibility to become an authorised person?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Comments:				

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3.6e Has the entity ensured that NHS checks are conducted at intervals of no more than two years to maintain eligibility? Yes No

Note: NHS checks may be required more frequently (see clause 3.3 of the SSBA Standards)

Comments:

3.6f Does the entity have in place policies and procedures to ensure that a person who has undergone an NHS check and who changes their name:

i. Informs the entity of the change within 30 days? Yes No

ii. Provides appropriate documentation to support the change? Yes No

Comments:

3.6g Are any changes reported to the entity under 3.6f subsequently reported to AusCheck within two business days of the entity being notified of the change? Yes No

Comments:

3.6.1 Transfer of NHS checks between entities

3.6.1a Does the entity accept NHS check results obtained by another entity? Yes No
(if no – go to Q3.6.2a)

Comments:

3.6.1b If you answered yes to Q3.6.1a, does the entity:

i. Obtain the person's consent to request those results from AusCheck? Yes No

ii. Contact AusCheck to verify the result? Yes No

Comments:

3.6.2 Reporting new convictions

3.6.2a Does the entity have documented policies and procedures in place to require that:

i. A person who has undergone an NHS check must report any new convictions to the entity within two business days of being informed of the conviction? Yes No

ii. The entity reports this information to AusCheck within two business days from being informed of the conviction? Yes No

Note: New convictions that must be reported are only those against the disqualifying offences as listed in Appendix 1 of the SSBA Standards.

Comments:

3.6.2b If a new conviction is reported to the entity, does the entity suspend that person's authorised status pending a new NHS check? Yes No

Comments:

3.7 Provisional authorisation

3.7a Has the entity used the provisional authorisation clause at clause 3.7 of the SSBA Standards? Yes No
(if No, go to Q3.8a)

Comments:

3.7b Was the Provisional Authorisation clause used to authorise a person only if:

i. The person was to undergo an NHS check? Yes No

ii. The requirements of clause 3.3.1 (a) to (e) of the SSBA Standards were met? Yes No

iii. The relevant facility had no other authorised persons in place? Yes No

Comments:

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3.7c If the entity/facility was not previously registered with AusCheck, were the NHS checks commenced within four weeks of notification by AusCheck that submission of applications could begin? Yes No

Comments:

3.7d If a person had a provisional authorisation, did it cease upon receipt of their NHS check results? Yes No

Comments:

3.8 Recruitment

3.8a Is the identity, qualifications and experience of all persons recruited to handle SSBAs assessed as part of the recruitment process? Yes No

Comments:

3.9 Training and competency

3.9a Has the entity ensured that all personnel who have responsibilities or perform tasks that may have an impact on SSBAs:

- i. Have the appropriate education, training and experience? Yes No
- ii. Are provided with adequate and up-to-date information pertaining to the entity's identified SSBA risks? Yes No

Comments:

3.9b Has the entity ensured that requirements and procedures for SSBA-related training are established, documented, implemented and maintained? Yes No

Comments:

3.9c Do the minimum training requirements include:

i.	Defining SSBA related training needs?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Provision of required SSBA training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Determination of the effectiveness of SSBA training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Provision of SSBA refresher training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	Restriction on staff to ensure they do not perform tasks for which they are not trained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vi.	Records management including the maintenance of adequate records?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

3.9.1 Training for authorised persons

3.9.1a For all authorised persons, has the SSBA training at a minimum included:

i.	An overview of the NHS Act, NHS Regulations and why the SSBA Regulatory Scheme is in place?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Reporting requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Records management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

3.9.1b For all persons who handle SSBAs, does the SSBA training at a minimum include the requirements of the NHS Act, NHS Regulations and all parts of the SSBA Standards? Yes No

Comments:

3.9.1c For all persons who access the facility where SSBA are handled, does the SSBA training at a minimum include:

i.	Physical security?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Risk management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Information security?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Personnel security?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	Management system requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

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3.9.1d For all persons who access sensitive information relating to SSBAAs, does the SSBA training at a minimum include:

i. Risk management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Information security?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Personnel security?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Management system requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

3.9.1e Does all training include:

i. How the SSBA Standards are implemented at each facility?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Specific training in the requirements of the entity and facility in relation to SSBAAs?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Note: requirements of the facility may include the policies and procedures specific to the facility for handling SSBAAs and sensitive information, the requirements for escorting/supervising approved persons etc.

Comments:

3.9.1f Does training for personnel handling Tier 1 SSBAAs include personal security awareness? Yes No
N/A (no Tier 1)

Comments:

3.9.1g Does the entity impose any other training requirements on each category of authorisation? Yes No

Comments:

3.9.2 Competency levels

3.9i Has the entity defined competency levels and maintain records verifying that personnel have attained and continue to demonstrate those levels of competency? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

3.9j Are competencies of personnel reviewed:

i. At least annually for facilities handling Tier 1 SSBA's? Yes No
N/A (no Tier 1)

ii. At least every two years for facilities handling Tier 2 SSBA's? Yes No
N/A (no Tier 2)

iii. In response to changes in risk assessment, risk management, SOPs or following an incident? Yes No

Comments:

3.10 Behavioural factors

3.10a Has the entity established and implemented measures to address risks associated with human behaviour, including reliability, of persons who handle SSBA's, access a facility where SSBA's are handled or access sensitive information relating to SSBA's? Yes No

Comments:
.....
.....

3.10b Are these measures documented as part of the risk assessment and risk management process and evidence of their application recorded? Yes No

Comments:

3.11 Exclusion

3.11a Has the entity established, documented and put into place measures for the removal and exclusion of personnel from the facility (on a temporary, or if appropriate, permanent basis) where deemed necessary or following a direction not to handle SSBA's from Health? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

3.11b	Do exclusion measures include:		
i.	Prompt removal of access to the facility?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Prompt removal of access to any SSBA's held in linked storage units?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Prompt removal of access to sensitive information?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Suspension or revocation of a person's authorised or approved status?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	Immediate physical removal if deemed necessary?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

Part 3 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBA's in your facility.

P3a	When deciding if a person is to be re-authorised following a new NHS check does the entity require the person to undergo refresher training before re-authorisation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/> (no NHS check)
Comments:				

P3b	If a person's authorised status is suspended due to a new conviction being reported, does the entity grant the person an approved status until the results of a new NHS check are received?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/> (no NHS check)
Comments:				

P3c	When determining the degree of supervision for an approved person, does the risk assessment take into account factors such as the set up of the facility, the SSBA involved, the role of the approved person and the results of an NHS check (if undertaken)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3d	Do supervision plans include how supervision is handled during an emergency situation (e.g. if security personnel require access to a facility after working hours and an authorised person is not available)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

SENSITIVE INFORMATION ONCE COMPLETED

P3e	Are identity checks undertaken for approved persons?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3f	Does training for SSBA's include raising awareness of general security issues associated with SSBA's, including the relevance of human behavioural factors?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3g	Does training for SSBA's include, if appropriate, hazard identification, risk assessment and management and vulnerability analysis?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3h	Does the entity have in place mechanisms to ensure that relevant and timely information is available regarding SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3i	Does the entity promote awareness of the potential risks (internal and external) associated with unauthorised access to SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3j	Does the entity have a program of briefing authorised persons on risks associated with their role and how to handle and report situations of concern?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P3k	Does the entity use the On-line Training Facility provided by Health as a training tool?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

PART 4 – PHYSICAL SECURITY

The objective of Part 4 is to have in place physical security measures, based on requirements identified in the risk assessment and risk management plan, to minimise the risk of unauthorised access to SSBA's.

4.2 Perimeter

4.2a Does the facility have a clearly defined perimeter that encloses the secure area where SSBA's are handled? Yes No

Comments:

4.2b Are the external walls that form part of the secure area of solid construction and physically sound? Yes No

Comments:

4.2c Are the external doors:

i. Self closing? Yes No

ii. Suitably protected against unauthorised access with control mechanisms? Yes No

Comments:

4.2d Are doors that form part of the secure perimeter locked when the facility is unattended? Yes No

Comments:

4.2e Are the windows of the secure perimeter non-opening and sealed at all times? Yes No

Comments:

4.2f Is unauthorised recording, photography or filming prohibited within the secure area? Yes No

Comments:

4.2.1 Stand-alone facilities

4.2.1a Does the facility have any stand-alone facilities? Yes No
 (if No, go to Q4.3a)

Note: Mobile laboratories, such as forensic laboratories are not subjected to the requirements for stand-alone facilities.

Comments:

4.2.1b Does the stand-alone facility meet the following requirements:

i. Has a back to base alarm system?	Yes <input type="checkbox"/> No <input type="checkbox"/>
ii. Is fixed in place and not easily transportable?	Yes <input type="checkbox"/> No <input type="checkbox"/>
iii. Have barriers to prevent vehicles from approaching the facility?	Yes <input type="checkbox"/> No <input type="checkbox"/>
iv. Have good external lighting?	Yes <input type="checkbox"/> No <input type="checkbox"/>
v. Regular inspections conducted of outer walls to detect tampering?	Yes <input type="checkbox"/> No <input type="checkbox"/>
vi. Outcomes of regular inspections are documented?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Comments:

4.3 Physical access controls

4.3a Is access to secure areas containing SSBAs restricted to authorised and approved persons? Yes No

Comments:

4.3b Is at least one form of access control on the secure perimeter? Yes No

Comments:

4.3c If the facility is handling Tier 1 SSBAs: N/A (go to Q4.3d)

- Is there an additional form of access control? Yes No

Comments:

4.3d Are there measures in place to prevent tail gaiting? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

4.3e Does the access control ensure that the details of all persons (including identification of the person and date and time of access) are recorded for all persons:

i. Entering the secure perimeter ? Yes No

ii. Accessing the secondary access control to the Tier 1 SSBA? Yes No

iii. For areas holding Tier 1 SSBAs – the time of exit of the person is also recorded? Yes No

Comments:

4.3f Are access records maintained for a minimum of:

i. 5 years for facilities holding Tier 1 SSBAs? Yes No
N/A (no Tier 1)

ii. 2 years for facilities holding Tier 2 SSBAs? Yes No
N/A (no Tier 2)

Comments:

4.3g Are access control systems tested at least every:

i. 6 months for facilities holding Tier 1 SSBAs? Yes No
N/A (no Tier 1)

ii. 12 months for facilities holding Tier 2 SSBAs? Yes No
N/A (no Tier 2)

Comments:

4.3h Are any losses of access cards, keys or other items used to access the secure areas reported immediately to the Responsible Officer once the loss is known? Yes No

Comments:

4.3i Are there measures in place to ensure that the lost items in 4.3h are not used? Yes No

Comments:

4.3j Are any reports of loss or theft and the actions taken documented? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

4.3k	If a person no longer requires access to the secure area, does the Responsible Officer ensure that access is removed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

Part 4 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P4a	Is there a marked floor plan of the secure area?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, is the floor plan kept securely?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4b	Is there a staffed reception area as part of the controls regarding access to the secure area?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4c	Are any intruder detection systems installed to Commonwealth, State or Territory standards and regularly tested to cover all external doors and accessible windows?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4d	Are unoccupied areas alarmed:		
	i. At all times?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. After hours only?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Other? (please note how in comments)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4e	Is there video monitoring?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

SENSITIVE INFORMATION ONCE COMPLETED

P4f	Are exit controls:		
	i. Able to be overridden in case of emergency?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. An alarm generated to indicate unauthorised exit?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4g	Is any alarm generation subject to an incident report and investigation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4h	Does risk assessment determine how access is handled in an emergency?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P4i	Are any policies or procedures regarding emergency access:		
	i. Documented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Communicated to relevant personnel, including contractors such as security guards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

PART 4A – STORAGE

The objective of Part 4A is to ensure that SSBA's are stored securely to reduce the risk of unauthorised access.

4A.2 Working Cultures

4A.2a Does the entity have in place documented policies and procedures to track the creation of working cultures from SSBA's held in long term storage? Yes No

Comments:

4A.2b Does the entity have in place documented policies and procedures to track and control the distribution of working cultures of SSBA's? Yes No

Comments:

4A.3 SSBA Inventory

4A.3a Has the entity established and maintained an accurate and up-to-date inventory of any SSBA held in storage? Yes No

Comments:

4A.3b Does the inventory identify and document which SSBA's are held and the location of each storage container? Yes No

Comments:

4A.3c Has the entity ensured that there are measures in place to minimise quantities of SSBA's stored? Yes No

Comments:

4A.3.1 Audit of Inventory

4A.3.1 Audits of the inventory:

i. Are conducted at predetermined intervals?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. The intervals determined through risk assessment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Audits are at a level and frequency that materials can be accounted for?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Results of the audit are documented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

4A.4 Storage of Tier 1 SSBAs

4A.4 Are Tier 1 SSBAs only stored within the secure perimeter of a registered facility? N/A (no Tier 1)
 Yes No

Comments:

4A.5 Storage of Tier 2 SSBAs

4A.5a Does the entity store Tier 2 SSBAs: N/A (no Tier 2)

i. Only within the secure perimeter of a registered facility?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Only in a linked storage unit?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. In both the facility and a linked storage unit?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

(if Yes, go to Q 4A.6)

Comments:

4A.5b Is the only handling of the SSBA within the linked storage unit either storage or preparation for storage? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

4A.5c	Is the linked storage unit:		
i.	Within the same building (preferably the same floor) as the registered facility?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Included as part of the facility registration?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Included in the risk assessment and risk management plans?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Fixed in place or non-transportable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

4A.5.1 Access to a linked storage unit

4A.5.1a	Is access to the SSBA within the linked storage unit:		
i.	Restricted to Authorised or Approved persons?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Recorded?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

4A.5.1b	Do access records include:		
i.	Identification of the person?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Date and time of access?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	A record if any of the SSBA was removed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

4A.5.1c	Are access records maintained for a minimum of 5 years for a Tier 1 SSBA or 2 years for a Tier 2 SSBA?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

4A.5.1d	Are any losses of access cards, keys or other items used to access the linked storage unit reported immediately to the Responsible Officer once the loss is known?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

4A.5.1e	Are there measures in place to ensure that the lost items in 4A.5.1d are not used?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

SENSITIVE INFORMATION ONCE COMPLETED

4A.5.1f Are reports of loss or theft of access cards, keys etc. and any actions taken documented? Yes No

Comments:

4A.5.1g If a person no longer requires access, does the Responsible Officer ensure that access to the area is removed? Yes No

Comments:

4A.5.2 Transport from and to a linked storage unit

4A.5.2a Is transport between the linked storage unit and the registered facility undertaken as required under clause 6.4 of the SSBA Standards? Yes No

Comments:

4A.5.2b Is transport between the linked storage unit and the registered facility recorded? Yes No

Note: this type of transport does not need to be reported to Health but a record of the transport must be made available on request.

Comments:

4A.6 Record Keeping

4A.6a Has the entity ensured that records relating to the storage of SSBA's, including inventory records, are:

i. Current?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Complete?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Stored securely?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Adequately backed up?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

4A.6b Are the records kept in accordance with clause 5.2 of the SSBA Standards? Yes No

Comments:

Part 4A Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P4Aa Are any additional audits of inventory carried out outside of the predetermined intervals? Yes No

Note: additional audits might be undertaken when there are changes such as transfer of inventories to new areas, changes in personnel responsible for inventory or changes in the risk assessment or threat levels.

Comments:

PART 5 – INFORMATION MANAGEMENT

The objective of Part 5 is to ensure that information, including sensitive information, relating to the security of SSBAs is current, complete and stored securely.

5.2 Record Keeping

5.2a Does the entity maintain records of all activities related to the SSBA Standards including records of:

- | | | |
|--|------------------------------|-----------------------------|
| i. Receipt of SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. Holding of SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. Transport of SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. Disposal of SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. Decontamination and inactivation | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. Policies and procedures | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vii. Internal and external reviews? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| viii. Inspections? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ix. Incident investigations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| x. Risk assessment and risk management plans | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

5.2b Are records kept for a minimum of:

- | | | |
|-------------------------------|------------------------------|-----------------------------|
| i. 5 years for Tier 1 SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | N/A <input type="checkbox"/> | (no Tier 1) |
| ii. 2 years for Tier 2 SSBAs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | N/A <input type="checkbox"/> | (no Tier 2) |

(unless otherwise specified in the SSBA Standards)

Comments:

5.2c Has the entity developed and documented policies regarding records in accordance with the SSBA Standards relation to:

- | | | |
|--|------------------------------|-----------------------------|
| i. Access; | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. Retention; | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. Destruction (including timeframes)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

5.3 Information Security

5.3a Has the entity identified and documented sensitive information relating to SSBA's? Yes No

Note: Documentation may be part of a larger document such as the risk assessment and risk management plan.

Comments:

5.3b Is there a review and approval process to control access to sensitive information? Yes No

Comments:

5.3c Is access to sensitive information limited to those who have a need to know and who have been permitted access by the responsible officer? Yes No

Comments:

5.3d Is access to sensitive information controlled? Yes No

Note: Controls for sensitive information should cover all persons who can access the information (e.g. facility personnel, IT personnel, SSBA Committee members)

Comments:

5.3e Are access permissions reviewed at least:

- i. Every 6 months for facilities handling Tier 1 SSBA's? Yes No
N/A (no Tier 1)
- ii. Every 12 months for facilities handling only Tier 2 agents? Yes No
N/A (no Tier 2)

Are the outcomes of the review documented? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

5.3f	Is Tier 1 sensitive information:	N/A <input type="checkbox"/> (no Tier 1)
	i. Stored in a secure system?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Securely backed up at regular intervals?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

5.3.1 Provision of sensitive information to other regulatory agencies

5.3.1a	Does the entity/facility have a need to provide sensitive information to other regulatory authorities?	Yes <input type="checkbox"/> No <input type="checkbox"/> (if no, go to Q5.4a)
<i>Note: Documents may need to be provided to another regulatory authority as evidence of compliance with another regulatory scheme. A list of who this information may be provided to is available under clause 5.3.1 of the SSBA Standards.</i>		
Comments:		

5.3.1b	Is sensitive information only supplied under the following conditions?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	i. The regulatory authority has a need to know the information for their regulatory purposes.	
	ii. The regulatory authority is able to hold the information at the PROTECTED security level or higher.	
	iii. Measures are in place to limit the amount of sensitive information released	
Comments:		

5.3.1c	Does the entity document what is supplied to the regulatory authority?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

5.4 Disposal of Records

5.4a	Has the entity ensured that there are documented policies and procedures in place, consistent with the requirements of the SSBA Standards, for the disposal of records?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

Part 5 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P5a Has the entity considered information from research, diagnosis and other purposes (that is not identified as sensitive information) in regards to what is released, who may access such information and how it may impact on the security of SSBAs? Yes No

Note: Issues such as 'dual use' should be considered when releasing information. Dual use biological research is legitimate research which involves information or technology which can be used for both peaceful and malevolent purposes such as to threaten public health or other aspects of national security.

Comments:

P5b Before providing sensitive information to other regulatory authorities, does the entity determine if: Yes No

- The information can be deidentified instead?
- The sensitive information can be removed before provision of documentation?
- Can the regulatory officer simply sight the information rather than take copies for their records?

Comments:

P5c Does sensitive information supplied electronically have measures in place to prevent copying? Yes No

Do any hard copies supplied have clear markings to indicate the document is a copy and the documents security classification? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

- P5d At a minimum, do the procedures addressing information security consider:
- i. Secure storage of sensitive records including electronic records and electronic signatures? Yes No
 - ii. Computer security (e.g. firewalls)? Yes No
 - iii. Strict policies regarding the on-site security of equipment as well as equipment entering or leaving the facility? Yes No
 - iv. Destruction of unwanted paper files and complete erasure of electronic files? Yes No
 - v. Security measures and procedures? Yes No
 - vi. Adequate backup strategies for electronic data? Yes No

Comments:

PART 6 – TRANSPORT

The objective of Part 6 is to have policies and procedures in place for the secure movement of SSBA's.

6.2 Transport

6.2a	If the entity is sending SSBA's, does it ensure that the sending facility:	N/A <input type="checkbox"/> (entity does not send SSBA's)
	i. Has documented policies and procedures in place to ensure compliance with Commonwealth, State and Territory legislation governing the transport of biological agents?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Ensure that the receiving facility will accept the agent?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. Keep a record of that acceptance?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iv. Notifies the receiving facility of the shipment details at the time of shipment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	v. If the shipment is lost in transit—immediately informs Health and State/Territory police once aware of the loss?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	vi. If the shipment is reported unsuccessful by the receiving facility—immediately informs Health and State/Territory police once aware of the unsuccessful transfer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

6.2b	If the entity is receiving SSBA's, does it ensure the receiving facility:	N/A <input type="checkbox"/> (entity does not receive SSBA's)
	i. Verifies that the transfer was successful; including that:	
	a. the complete shipment was received	Yes <input type="checkbox"/> No <input type="checkbox"/>
	b. there was no tampering evident on the shipping container?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. If a shipment fails to arrive at the expected time—contacts the transport agent and sending facility to seek confirmation of the shipment's location and expected time of delivery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iv. If the shipment is lost in transit—immediately informs the sending facility, Health and State/Territory police once aware of the loss?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

6.3 Transport security

6.3a Is a transport agent contracted to transport SSBA's?

Yes No
(if No go to Q 6.4a)

Comments:

6.3b Has the entity ensured that the transport agent has a documented security plan and systems in place to track the shipment at all stages of transport?

Yes No

Comments:

6.3c At a minimum does the transport security plan comprise of:

- | | | | |
|-------|--|------------------------------|-----------------------------|
| i. | Specific allocation of security responsibilities to competent and qualified persons with the appropriate authorities? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Compliance with Commonwealth, State and Territory legislation governing the transport of biological agents? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Assessment and coverage of security risks, including inter-modal transport, temporary transit storage, handling and distribution? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. | Clear statements of measures and resources that are used to reduce security risks? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. | Up to date procedures for responding to and dealing with security threats, non-compliance with security protocols or security incidents? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. | Procedures for the evaluation and testing of security plans and procedures for periodic review and update of the plans? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vii. | Measures to ensure the security of information relating to transport of SSBA's? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| viii. | Measures to ensure that the distribution of transport information is as limited as possible? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Note: Due to security or confidentiality requirements, a transport company might not supply their transport security plan to an entity. The entity can supply the transport company with a copy of the requirements of clause 6.3 of the SSBA Standards and request that the company confirms, in writing, that the transport plan meets these requirements.

Comments:

6.4 Transport of SSBAs by Authorised Persons

6.4a Is transport that is not undertaken by a transport agent always undertaken by an authorised person? Yes No

Comments:

6.4b Are all transport movements by authorised persons:
 i. Reported to the Responsible Officer? Yes No
 ii. Recorded? Yes No

Comments:

6.4c If material is being transferred within a building, is the material triple packed unless documented in the risk assessment that double packaging can be used? Yes No

Comments:

6.4d If material is being transported outside of the building, is the movement consistent with the requirements of Commonwealth, State and Territory legislation governing the transport of biological agents? Yes No

Comments:

6.5 Transport of SSBAs from reception areas to a registered facility

6.5a Does the facility transport SSBAs from a designated reception area to a registered facility? Yes No
 (if No, go to Part 6 further considerations)

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

6.5b Is transport of the SSBA from the reception area to the registered facility undertaken under the following conditions:

- i. Transport occurs within a single building only? Yes No
- ii. Transport occurs only between the reception area and the registered facility? Yes No
- iii. The person handling the SSBA at the reception area does so only for the purposes of receiving the package and transporting to the registered facility? Yes No
- iv. The SSBA is delivered to an authorised person at the registered facility? Yes No
- v. The transport is covered by a documented policy and is included in the risk assessment? Yes No
- vi. All movements of the SSBA from the reception area to the registered facility are recorded? Yes No
- vii. An up to date list is kept of all persons who are permitted to undertake these transports? Yes No

Note: While a record of the movements must be kept, the entity is not required to report these movements to Health, but must make the records available on request.

Comments:

6.5c The person undertaking the transport:

- i. Is 18 years or older? Yes No
- ii. Has undergone an identity check? Yes No
- iii. Has not been excluded from handling SSBA's by the entity? Yes No
- iv. Has not been directed not to handle SSBA's by Health? Yes No
- v. Has basic training in the requirements of the SSBA Standards and the internal requirements for this type of transport? Yes No

Are records of the training listed above kept? Yes No

Comments:

Part 6 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P6a Are the Responsible Officers from both the sending and receiving facilities involved when transport agreements are made? Yes No

Comments:

P6b Does the entity have in place guidance about what it considers to be tampering? Yes No

For example – does the entity require the use of tamper proof packaging to indicate tampering during transport?

Comments:

P6c Does the entity use Security Construction and Equipment Committee (SCEC) approved couriers where possible? Yes No

Comments:

PART 7 – INACTIVATION AND DECONTAMINATION

The objective of Part 7 is to ensure that all types of contaminated and potentially contaminated materials, including those that may result from an emergency, are identified and documented, and that effective procedures are in place to ensure decontamination of materials or inactivation of the SSBA prior to destruction or further use.

7.2 Procedures

7.2a Is risk assessment an integral part of the process to identify and develop effective decontamination and inactivation regimes? Yes No

Comments:

7.2b Are effective procedures and detailed protocols documented and in place to decontaminate or inactivate the SSBA or waste products potentially contaminated with the SSBA, prior to destruction or further use? Yes No

Comments:

7.2c Do the protocols include:

i. Validation data on inactivation procedures? Yes No

ii. Quality assurance to ensure inactivation has been correctly performed? Yes No

Comments:

7.3 Waste management

7.3a Has the entity ensured that its waste management procedures are such that no SSBA leaves the control of the entity without being inactivated or destroyed, unless it is being transported to another entity or facility for further handling or destruction? Yes No

Comments:

7.3b Has a risk assessment been undertaken to determine the procedures that are required to ensure that safe destruction of the waste is carried out? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

7.3c Is a contracted waste disposal company used for waste disposal? Yes No
if No, go to Q7.4a)

Comments:

7.3d Does the entity have in place mechanisms to ensure that waste taken by an external contractor is:

- i. Kept secure until it is picked up? Yes No
- ii. The entity is notified when the waste is destroyed? Yes No

Comments:

7.4 Record Keeping

7.4a Was risk assessment an integral part of the process to identify records of decontamination/deactivation and validation data that must be kept? Yes No

Comments:

7.4b Are records of decontamination/deactivation kept for at least 5 years for Tier 1 SSBA's or 2 years for Tier 2 SSBA's? Yes No

Comments:

Part 7 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBA's in your facility.

P7a Do the validation procedures take into account issues such as:

i. Nature of the material being treated? Yes No

ii. Contact times and material compatibility issues? Yes No

iii. Potential health hazards? Yes No

iv. Need to maintain the required level of active compound including deterioration over time? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

P7b When planning and conducting decontamination activities did the entity consider:

i. Ensuring all disinfectants contain sufficient compound to address the working conditions under which they will be applied and that such concentrations are maintained throughout the process?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Implementing monitoring measures to ensure the methods have been effective?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. Ensuring adequate methods and resources are available to deal with routine work, spills or other incidents during handling and transport inside and outside the facility?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Implementing programs to ensure the amount of contaminated waste is minimised?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

P7c When using a waste contractor to dispose of materials, is waste moved from secure areas to collection points as close as possible to the time for pick up?

Yes No
 NA (No waste contractor used)

Comments:

P7d Does the entity have an arrangement with the waste contractor that waste is destroyed as soon as possible after arrival at the treatment facility?

Yes No
 NA (No waste contractor used)

Comments:

P7e If waste is destroyed by the entity, is:

NA (Not destroyed by entity)

i. Transport carried out by authorised persons?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii. Validated destruction processes carried out by authorised persons?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii. The waste destroyed as soon as possible after arrival in the waste destruction area?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

- P7f Were the following elements considered for the waste management policy:
- i. Ensuring a program is in place to minimise waste production? Yes No
 - ii. Ensuring effective waste audit trails are in place and documented? Yes No
 - iii. Provision of adequate facilities and procedures for storage of waste? Yes No
 - iv. Ensuring appropriate packaging material is used to contain waste and maintain its integrity during storage and transport? Yes No

Comments:

PART 8 – SSBA MANAGEMENT SYSTEM REQUIREMENTS

The objective of Part 8 is to establish a systematic approach to the management of the biosecurity of SSBA that takes into account risk and incident management, personnel management, physical security, information management, transport and inactivation and decontamination in accordance with the requirements of the SSBA Standards, NHS Act and NHS Regulations.

8.2 Policy

8.2a Has the entity developed, documented, authorised and implemented policies concerning the management of SSBA? Yes No

Comments:

8.2b Does the policy clearly state the overall SSBA management objectives and commitment to improving biosecurity management? Yes No

Comments:

8.2c Was the policy in place prior to the handling of SSBA? Yes No

Comments:

8.2d Does the entity continually assess and improve the effectiveness of the SSBA management system through use of:

- | | | |
|---|------------------------------|-----------------------------|
| i. Policies? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. Objectives? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. Procedures? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. Self review programs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. Analysis of data? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. Risk assessment and management? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vii. Corrective and preventative actions? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| viii. Management review? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

8.2e Has the entity ensured that relevant information relating to the SSBA Management system and activities is communicated to personnel and other relevant parties? Yes No

Note: Other relevant parties may include persons such as cleaners, security staff and maintenance staff. Entities should consider what information is required as part of their duties.

Comments:

8.3 Roles, Responsibilities and Authorities

8.3.1 Top Management

8.3.1a Does top management:

- | | | | |
|-------|--|------------------------------|-----------------------------|
| i. | Take ultimate responsibility for the development and implementation of the entity's SSBA management system and policy? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Ensure the availability of resources to establish, implement, maintain and improve the SSBA management system? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Appoint and empower a Responsible Officer and Deputy Responsible Officer for the SSBA Regulatory Scheme and puts in place processes to ensure the continuity of the staffing and effectiveness of the positions? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. | Ensure that all SSBA related activities conducted in the facility are authorised, defined and reviewed at least annually? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. | Ensure that criteria and processes are established for work that requires prior approval? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. | Ensure that actions are taken promptly in regards to any non-compliance of the management system with the SSBA Standards, NHS Act or NHS Regulations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vii. | Deal with any identified instances of the entity's non compliance with the SSBA Standards, NHS Act or NHS Regulations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| viii. | Ensure verification of any actions taken to deal with instances of non-compliance and documents such actions? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ix. | Establish controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in risk assessment processes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| x. | Ensure that staff levels, facilities and equipment are sufficient to effectively carry out work involving SSBA in accordance with technical protocols, approved policies and SOPs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| xi. | Ensure all requirements for reporting to Health are met? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

8.3.2 SSBA Management Committee

8.3.2a Has the entity:

i. Established an SSBA Management Committee? Yes No

or

ii. Assigned the tasks required of such a committee to an existing committee? Yes No

Comments:

8.3.2b Does this committee act as a review group for SSBA risks and issues? Yes No

Comments:

8.3.2c Does the committee report to top management? Yes No

Comments:

8.3.2d Does the committee:

i. Have documented terms of reference? Yes No

ii. Include a representative cross section of expertise, appropriate to the nature and scale of activities undertaken? Yes No

iii. Include the Responsible Officer and Deputy Responsible Officer? Yes No

iv. Meet at defined and appropriate frequency and when otherwise required? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

- 8.3.2e Do the functions of the committee include:
- i. Contributing to the development to the entity's SSBA policies and procedures? Yes No
 - ii. Reviewing and approving protocols and risk assessments for work involving SSBAs? Yes No
 - iii. Reviewing information relating to significant incidents, non-compliance, data trends, associated local/entity action and associated communication needs? Yes No
 - iv. Ensuring biosecurity issues are formally recorded; actions allocated, tracked and closed out effectively? Yes No
 - v. Reviewing internal inspection reports? Yes No

Comments:

8.4 Checking and Corrective Action

8.4.1 Performance management and analysis of data

- 8.4.1a Has the entity ensured that data is identified, collected, stored and analysed to:
- i. Assess the suitability and effectiveness of the SSBA management system? Yes No
 - ii. Evaluate where continual improvement of the system can be made? Yes No

Comments:

- 8.4.1b Are all outcomes of the performance management process documented? Yes No

Comments:

8.4.2 Records, documentation and data control

- 8.4.2a Has the entity ensured that records, documents and data to provide evidence of compliance with the SSBA Standards are:
- i. Established? Yes No
 - ii. Controlled? Yes No
 - iii. Maintained? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

8.4.2b	Have such records, documents and data remained, in alignment with the information management requirements of Part 5 of the SSBA Standards,:		
	i. Legible?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Readily identifiable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Retrievable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.2c	Has the entity documented its record retention policies and ensured that they are implemented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.3 Internal review

8.4.3a	Has the entity ensured that a program of internal review is conducted?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.3b	Are the internal reviews conducted at planned intervals of no longer than:		
	i. 6 monthly for Tier 1 SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
		N/A <input type="checkbox"/>	(no Tier 1)
	ii. Annually for Tier 2 SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
		N/A <input type="checkbox"/>	(no Tier 2)
<i>Note: Reviews should determine that operations carried out by the entity comply with the requirements of the SSBA Standards, NHS Act, NHS Regulations and the entity's policies.</i>			
Comments:			

8.4.3c	Are records maintained:		
	i. Of the findings of the review?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Of the actions taken to close out any non-compliances?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Of the actions taken for any improvement opportunities?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iv. In accordance with Part 5 of the SSBA Standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.4 Control of non-compliance and corrective action

8.4.4a	Has the entity ensured that any areas of non-compliance with the SSBA Standards, NHS Act, NHS Regulations or SSBA management system are identified and managed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.4b	Has the entity ensured that action is taken to eliminate the causes of non-compliance to prevent recurrence?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>Note: Non-compliances may be identified during regular reviews by the entity, during day to day operations of the entity or through the SSBA Inspection Program.</i>			
Comments:			

8.4.4c	Are records of the nature of the non-compliance and any subsequent action taken maintained in accordance with Part 5 of the SSBA Standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.5 Preventive action

8.4.5a	Has the entity ensured that action is taken to identify, through risk management or other sources, potential non-compliance to eliminate its causes and to prevent occurrence or recurrence?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

8.4.5b	Is preventive action appropriate to the effects of the potential non-compliance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

Part 8 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P8a Has the management system approach been built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and action that the entity undertakes to meet goals? Yes No

Comments:

P8b Does the SSBA management system policy specifically include provisions covering:

- | | | | |
|------|--|------------------------------|-----------------------------|
| i. | Meeting the reporting requirements under the NHS Act and NHS Regulations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Justification of all legitimate uses of the SSBA? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Documentation and communication of roles, responsibilities and authorities for SSBA management within the facility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. | Effectively informing personnel and other relevant parties of individual obligations? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. | Requirements for all projects/work involving SSBAs to be assessed for risks and mitigation strategies before work is approved to commence? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. | Reviews of the management system following an incident? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

P8c Does the review of the management system include assessment and evaluation of opportunities for improvement and the need for changes to the system, procedures, policies and objectives? Yes No

Comments:

P8d Is the policy appropriate to the nature and scale of risks associated with the facility and associated activities? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

P8e	Does the policy commit to:		
	i. Complying with legal requirements for handling SSBA's?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Reducing the level of biosecurity risk to an acceptable level?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Ensuring that the need for effective SSBA management takes precedence over non 'health and safety' operational requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv. Continually improving SSBA management performance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Comments:			

P8f	When communicating information regarding SSBA policies to relevant parties, does the entity consider if the person has a need-to-know the information as part of their activities?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P8g	When assigning roles and responsibilities under the SSBA management system, are potential conflicts of interest taken into account?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P8h	Is determination of staffing levels, equipment and facilities done in consultation with the Responsible Officer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P8g	Does documentation of SSBA related activities include the nature of the activities authorised to be conducted and their definitions?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P8h	Are all activities routinely associated with the work program specified and supported by formal SOPs?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

SENSITIVE INFORMATION ONCE COMPLETED

P8i	Are any changes to these activities subjected to a formal change management process, including approval by management and communication to and training of staff?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

P8j	Are controls monitored by:		
	i. Regular reviews?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	ii. Using corrective action reporting processes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iii. Investigation of accidents and incidents?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	iv. Improving controls and their implementation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	v. Ensuring adequate resources are provided?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

SENSITIVE INFORMATION ONCE COMPLETED

P8k Do the terms of reference include:

i.	A short statement of the purpose of the committee?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Defined roles and functions of the committee and how objectives are achieved?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Who is part of the committee as a member, observer or other?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Details regarding quorums – is there one, what is the number and what happens if this is not reached?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	Defined deliverables?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vi.	Defined timeframes such as meeting frequency, reporting, review and set task timeframes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vii.	Details on what is to be reported and to whom?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
viii.	Details on the evaluations undertaken by the committee on the role and function or other terms of reference	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ix.	Details on how the effectiveness of the committee will be evaluated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

P8l For the performance management analysis are:

i.	Data sets generated as a consequence of monitoring, measuring, reviews and other sources considered?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Analyses conducted every 2 years or more often if justified by the risks and scope of operations?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Results of the analysis considered as part of the management review?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

P8m Are documents identified and controlled on the basis of the nature of the work and the need for record keeping?

Yes No

Comments:

P8n Do controlled documents include:

i.	Risk assessments, SOPs and safety manuals?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Job hazard analyses and charts of authority?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Audit and inspection checklists	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Laboratory SSBA manuals, authorisations and other security documents?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	Training records?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

P8o Are records kept of internal reviews and actions taken? Yes No
Comments:

P8p Are reviews undertaken by a team? Yes No
Comments:

P8q Has a procedure been established to define requirements for:

- i. Reviewing all non-compliances? Yes No
- ii. Determining the causes of non-compliances? Yes No
- iii. Evaluating the need for action to ensure that non-compliances do not occur or recur? Yes No
- iv. Determining and implementing the actions needed? Yes No
- v. Recording results of actions taken? Yes No
- vi. Reviewing corrective actions taken? Yes No

Comments:

PART 9 – HANDLING BIOLOGICAL AGENTS SUSPECTED OF BEING SSBAS

The objective of Part 9 is to ensure that biological agents suspected, on the basis of laboratory testing, of being an SSBA are handled securely prior to receiving the outcomes of confirmatory testing or destruction.

Does the facility handle biological agents suspected of being SSBAs? Yes No
(if No, go to Internal Policies)

9.2 Access and Storage

9.2a Once a reasonable suspicion is formed that the biological agent is an SSBA, is access restricted to persons that have a need to handle? Yes No

Comments:

9.2b Does the entity store suspected SSBAs securely to ensure that access is restricted to those who have a need to handle the SSBA? Yes No

Comments:

9.2c Does the entity maintain a record of who accessed the suspected SSBA, including the identity of the person and time and date of access? Yes No

Comments:

9.3 Transport

9.3.1 Transport requirements for a sending facility

9.3.1 If the entity is sending suspected SSBA, does it ensure that the sending facility:

i.	Has documented policies and procedures in place to ensure compliance with Commonwealth, State and Territory legislation governing the transport of biological agents?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Ensures that the confirmatory testing facility will accept the agent	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Keeps a record of that acceptance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Notifies the receiving facility of the shipment details at the time of shipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	If the shipment is lost in transit—immediately informs Health once aware of the loss?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vi.	If the shipment is reported unsuccessful by the receiving facility—immediately informs Health once aware of the unsuccessful transfer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

9.3.2 Transport requirements for a receiving facility

9.3.2 If the entity is receiving suspected SSBA, does it ensure the receiving facility:

i.	Verifies that the transfer was successful; including that:		
	a. the complete shipment was received?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	b. there was no tampering evident on the shipping container?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Notifies the sending facility of the receipt of the shipment and if the transfer has been successful?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	If a shipment fails to arrive at the expected time—contacts the transport agent and sending facility to seek confirmation of the shipment's location and expected time of delivery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Comments:

9.4 Destruction

- 9.4a If destruction has taken place prior to confirmatory testing, has the entity ensured that the processes for destruction are such that no suspected SSBA leaves the entity without being destroyed or inactivated, unless it is being transported for confirmatory testing or destruction? Yes No
N/A (no destruction prior to confirmatory testing)

Comments:

- 9.4b If destruction has taken place following receipt of confirmatory testing results, has the entity ensured that the processes for destruction are such that no confirmed SSBA leaves the entity without being destroyed or inactivated, unless it is being transported in its entirety for the purposes of disposal under Division 4A of the NHS Act? Yes No
N/A (no destruction after to confirmatory testing)

Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.

Comments:

9.5 Waste Disposal

- 9.5 Does the entity have validated procedures for the decontamination of waste materials potentially contaminated with suspected SSBA? Yes No

Comments:

9.6 Record Keeping

- 9.6a Once a reasonable suspicion is formed that the biological agent is an SSBA, are records maintained of all activities relating to the requirements of Part 9 of the SSBA Standards? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

9.6b	Unless otherwise specified in the SSBA Standards, are records relating to suspected SSBAs maintained for a minimum of	
	i. 12 months for agents suspected to be Tier 1 SSBAs?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> (no Tier 1)
	ii. 6 months for agents suspected to be Tier 2 SSBAs?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> (no Tier 2)
	<i>Note: records do not need to be kept if confirmatory testing shows that the agent is not an SSBA.</i>	
Comments:		

Part 9 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P9a	Does the entity have policies in place to contact a receiving facility within two business days of the expected date of arrival of a sample if receipt has not been confirmed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

P9b	Does the entity have data available to demonstrate that the methodology used for destruction is capable of inactivating the agent under the specific conditions encountered in the facility?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

P9c	Does decontamination take place as soon as possible after the waste is generated?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

P9d	If waste is disposed of outside the facility through a waste disposal company, does the entity:	
	i. Move waste to the disposal point as close as practical to the time of pickup?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Have arrangements to ensure destruction will take place as soon as possible after the waste arrives at the treatment facility?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

PART 9A – HANDLING FOLLOWING A POSITIVE CONFIRMATORY TEST RESULT

The objective of Part 9A is to ensure that biological agents previously suspected and subsequently confirmed as an SSBA are handled securely prior to disposal.

9A.2 Access and Storage

9A.2a Does the entity ensure that access to the SSBA is restricted to persons that have a need to handle? Yes No

Comments:

9A.2b Does the entity store SSBA's securely to ensure physical access is restricted to those who have a need to handle? Yes No

Comments:

9A.2c Does the entity maintain a record of who accesses the SSBA, including the identity of the person and time and date of access? Yes No

Comments:

9A.3 Transport

9A.3.1 Transport requirements for a sending facility

9A.3.1	If the entity is sending confirmed SSBA's, does it ensure that the sending facility:	
	i. Has documented policies and procedures in place to ensure compliance with Commonwealth, State and Territory legislation governing the transport of biological agents?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Ensures that the receiving facility will accept the agent	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. Keeps a record of that acceptance?	
	iv. Notifies the receiving facility of the shipment details at the time of shipment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
	v. If the shipment is lost in transit—immediately informs Health and State/Territory police once aware of the loss?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	vi. If the shipment is reported unsuccessful by the receiving facility—immediately informs Health and State/Territory police once aware of the unsuccessful transfer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

9A.3.2 Transport for a receiving facility

9A.3.2	If the entity is receiving confirmed SSBA's, does it ensure the receiving facility:	
	i. Verifies that the transfer was successful; including that:	
	a. the complete shipment was received?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	b. there was no tampering evident on the shipping container?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ii. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	iii. If a shipment fails to arrive at the expected time—contacts the transport agent and sending facility to seek confirmation of the shipments location and expected time of delivery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Comments:		

9A.4 Destruction

9A.4a Has the entity ensured that the processes for destruction are such that no SSBA leaves the entity without being destroyed or inactivated, unless it is being transported in its entirety for the purposes of disposal?

Yes No
 N/A (SSBA not destroyed)

Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.

Comments:

9A.5 Waste Disposal

9A.5a Does the entity have validated procedures for the decontamination of waste materials potentially contaminated with the SSBA?

Yes No

Comments:

9A.6 Record Keeping

9A.6a Does the entity maintain a record of all activities relating to the requirements of the SSBA Standards that relate to Part 9A of the SSBA Standards?

Yes No

Comments:

9A.6b Are records relating to SSBA's maintained for a minimum of

i. 12 months for Tier 1 SSBA's?

Yes No

N/A (no Tier 1)

ii. 6 months for Tier 2 SSBA's?

Yes No

N/A (no Tier 2)

Comments:

Part 9A Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P9Aa Does the entity send confirmed SSBAs to a reference laboratory for further genetic typing? Yes No

Comments:

PART 10 – NON REGISTERED ENTITY HANDLING AN SSBA ON A TEMPORARY BASIS

The objective of Part 10 is to ensure that SSBAs are handled temporarily are handled securely prior to disposal.

10.2 Access and Storage

10.2a Does the entity ensure that access to the SSBA is restricted to persons that have a need to handle? Yes No

Comments:

10.2b Does the entity store SSBAs securely to ensure physical access is restricted to those who have a need to handle? Yes No

Comments:

10.2c Does the entity maintain a record of who accesses the SSBA, including the identity of the person and time and date of access? Yes No

Comments:

10.3 Transport

10.3.1 Transport requirements for a sending facility

10.3.1 If the entity is sending confirmed SSBAs, does it ensure that the sending facility:

- | | | | |
|------|---|------------------------------|-----------------------------|
| i. | Has documented policies and procedures in place to ensure compliance with Commonwealth, State and Territory legislation governing the transport of biological agents? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Ensures that the receiving facility will accept the SSBA | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Keeps a record of that acceptance? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iv. | Notifies the receiving facility of the shipment details at the time of shipment? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| v. | If the shipment is lost in transit–immediately informs Health and State/Territory police once aware of the loss? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| vi. | If the shipment is reported unsuccessful by the receiving facility–immediately informs Health and State/Territory police once aware of the unsuccessful transfer? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Comments:

10.3.2 Transport for a receiving facility

SENSITIVE INFORMATION ONCE COMPLETED

10.3.2 If the entity is receiving confirmed SSBA's, does it ensure the receiving facility:

- i. Verifies that the transfer was successful; including that:
 - a. the complete shipment was received? Yes No
 - b. there was no tampering evident on the shipping container? Yes No
- ii. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? Yes No
- iii. If a shipment fails to arrive at the expected time—contacts the transport agent and sending facility to seek confirmation of the shipments location and expected time of delivery? Yes No

Comments:

10.4 Destruction

10.4 Has the entity ensured that the processes for destruction are such that no SSBA leaves the entity without being destroyed or inactivated, unless it is being transported in its entirety for the purposes of disposal? Yes No
N/A (SSBA not destroyed)

Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.

Comments:

10.5 Waste Disposal

10.5 Does the entity have validated procedures for the decontamination of waste materials potentially contaminated with the SSBA? Yes No

Comments:

10.6 Record Keeping

10.6a Does the entity maintain a record of all activities relating to the requirements of the SSBA Standards that relate to Part 10 of the SSBA Standards? Yes No

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

10.6b Are records relating to SSBA's handled under Part 10 of the SSBA Standards maintained for a minimum of

i. 12 months for Tier 1 SSBA's?

Yes No

N/A (no Tier 1)

ii. 6 months for Tier 2 SSBA's?

Yes No

N/A (no Tier 2)

Comments:

Part 10 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBA's in your facility.

P10a Does the entity send confirmed SSBA's to a reference laboratory for further genetic typing? Yes No

Comments:

PART 11 –REGISTERED ENTITY HANDLING AN SSBA ON A TEMPORARY BASIS

The objective of Part 11 is to ensure that SSBAs are handled temporarily by a facility of a registered entity are handled securely prior to disposal.

11.2 Access and Storage

11.2a Does the registered entity ensure that access to the SSBA is restricted to persons that have a need to handle? Yes No

Comments:

11.2b Does the registered entity store SSBAs securely to ensure physical access is restricted to those who have a need to handle? Yes No

Comments:

11.2c Does the registered entity maintain a record of who accesses the SSBA, including the identity of the person and time and date of access? Yes No

Comments:

11.3 Transport

11.3.1 Transport requirements for a sending facility

11.3.1	If the registered entity is sending confirmed SSBA's, does it ensure that the sending facility:		
i.	Has documented policies and procedures in place to ensure compliance with Commonwealth, State and Territory legislation governing the transport of biological agents?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Ensures that the receiving facility will accept the SSBA	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	Keeps a record of that acceptance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iv.	Notifies the receiving facility of the shipment details at the time of shipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
v.	If the shipment is lost in transit—immediately informs Health and State/Territory police once aware of the loss?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
vi.	If the shipment is reported unsuccessful by the receiving facility—immediately informs Health and State/Territory police once aware of the unsuccessful transfer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

11.3.2 Transport for a receiving facility

11.3.2	If the registered entity is receiving confirmed SSBA's, does it ensure the receiving facility:		
i.	Verifies that the transfer was successful; including that:		
a.	the complete shipment was received?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
b.	there was no tampering evident on the shipping container?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ii.	Notifies the sending facility of the receipt of the shipment and if the transfer has been successful?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
iii.	If a shipment fails to arrive at the expected time—contacts the transport agent and sending facility to seek confirmation of the shipments location and expected time of delivery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments:			

11.4 Destruction

11.4 Has the registered entity ensured that the processes for destruction are such that no SSBA leaves the entity without being destroyed or inactivated, unless it is being transported in its entirety for the purposes of disposal?

Yes No
 N/A (SSBA not destroyed)

Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.

Comments:

11.5 Waste Disposal

11.5 Does the registered entity have validated procedures for the decontamination of waste materials potentially contaminated with the SSBA?

Yes No

Comments:

11.6 Record Keeping

11.6a Does the registered entity maintain a record of all activities relating to the requirements of the SSBA Standards that relate to Part 10 of the SSBA Standards?

Yes No

Comments:

11.6b Are records relating to SSBA's handled under Part 11 of the SSBA Standards maintained for a minimum of

i. 12 months for Tier 1 SSBA's?

Yes No

N/A (no Tier 1)

ii. 6 months for Tier 2 SSBA's?

Yes No

N/A (no Tier 2)

Comments:

Part 11 Further considerations

The questions below are based on the suggestions made under the commentary of the SSBA Standards or are best practice recommendations. These are not mandatory requirements but may be used to enhance the security of the SSBAs in your facility.

P11a Does the entity send confirmed SSBAs to a reference laboratory for further genetic typing? Yes No

Comments:

REPORTING

The following questions are not based on the requirements of the SSBA Standards but are best practice recommendations. They are not mandatory but are recommended to ensure that all requirements for reporting to Health are met

Ra Does the entity have documented policies and procedures to ensure that the mandatory time frames for reporting to Health are met? Yes No

Note: The timeframes for reporting to health are set out in the NHS Act, NHS Regulations and Standards. For all reportable events, this timeframe is 2 business days.

Comments:

Rb How does the entity submit reports to Health?

- Hard copy submission via Registered Post? Yes No
- Electronic submission via the online Data Collection System (DCS)? Yes No

Comments:

Rc If the entity uses the DCS to submit reports who administers the passwords for this system?

Comments:

Rd Does the entity have documented policies about who can sign and submit mandatory reports to Health? Yes No

Comments:

Re What policies and procedures are in place regarding storage of reportable event reports?

- i. Where are they stored?
- ii. Hard copy or electronic storage?
- iii. Who can access?

Comments:

SENSITIVE INFORMATION ONCE COMPLETED

Rf Is there training available for completion and submission of reports? Yes No

Comments:

INTERNAL POLICIES

IPa Does the facility conform to the internal policies regarding SSBA's set by the entity? Yes No

Note: Non-compliances should be recorded in Table 2 below

Comments:

IPb Where are these policies kept and how can they be accessed by personnel?

Comments:

OUTCOMES FROM REVIEW

Areas of non-compliance

ORa Are there any areas of non-compliance with the SSBA Regulatory Scheme? Yes No

Record details in Table 1 below.

Comments:

ORb Are there any areas of non-compliance with the internal policies set by the entity in regards to SSBA's? Yes No

Record details in Table 2 below.

Comments:

Further improvements

Are there any areas of potential improvement?

Yes No

What are they?

Comments:

Recommended Policies, Procedures and Processes

Personnel policies, procedures or processes for:

- authorising people to handle and access SSBAs and sensitive information relating to SSBAs;
- recruitment, including establishing identity, history, qualifications, experience and character references of job applicants;
- approving persons who are not authorised persons;
- escorting/supervising approved persons;
- ensuring personnel have an appropriate level of education, training and experience;
- ensuring staff are provided with up-to-date information pertaining to the entity's SSBA risks;
- establishing minimum training requirements for personnel including competency levels for this training;
- ensuring staff meet the competency levels for training;
- providing security awareness training to staff with access to SSBA or sensitive information relating to SSBAs;
- ensuring staff have the required technical competency to handle SSBAs;
- addressing risks associated with human behaviour; and
- excluding personnel, either temporarily or permanently, from the facility.

Physical access policies, procedures or processes for:

- ensuring all recording, photography and filming is authorised;
- access during an emergency;
- managing, reviewing and testing access to secure areas containing SSBA;
- recording, storing and reviewing details of all approved and authorised persons entering areas where SSBAs are handled;
- recording, storing and reviewing exit details from Tier 1 area;
- monitoring, managing and investigating access alarms;
- issuing and managing keys/proximity cards/PINS for access to secure areas; and
- testing access control systems.

Storage of SSBAs policies, procedures or processes for:

- location, security and use of linked storage units for Tier 2 SSBAs;
- minimising the quantities of SSBA held by the facility
- recording transport between the linked storage unit and registered facility; and
- establishing, maintaining and auditing an SSBA inventory

Information management policies, procedures or processes for:

- access, retention and destruction of records relating to all activities relating to the SSBA Standards;
- identifying which material relating to the security of SSBAs is deemed sensitive;
- approving and reviewing access to sensitive information relating to SSBAs;
- storing sensitive information appropriately;
- ensuring computer security;
- on-site security of IT equipment, including IT equipment entering and leaving the building; and
- investigating, managing and reporting breaches of information security.

SSBA Regulatory Scheme

Transport policies, procedures or processes for:

- ensuring the transport agent has a documented transport security plan and complies with the requirement set out in the section 6.3 of the SSBA Standards;
- verifying that the receiving facility will accept the SSBA;
- supplying the shipping details to the receiving facility;
- notifying the receiving facility at the time of shipment;
- involving the Responsible Officer in the transport process;
- recording incoming shipments of SSBAs;
- notifying the sending facility of the receipt of the shipment;
- liaising with the transport agent to ensure that if there are delays they are informed of these;
- notification when a shipment fails to arrive at the expected time;
- verifying the complete shipment of the SSBA;
- verifying there is no evidence of tampering;
- transporting SSBAs using authorised persons between entities and between facilities in one entity; and
- recording the transport of SSBA by authorised persons.

Inactivation and decontamination policies, procedures or processes for:

- ensuring decontamination and/or inactivation of SSBAs and all contaminated items before their destruction or use as an inactive SSBA;
- ensuring appropriate methodologies are selected;
- ensuring appropriate validation data and verification procedures used to guarantee inactivation has occurred correctly; and
- ensuring no SSBA leaves the facility without being inactivated or destroyed unless for the purpose of transport to another facility or entity.

SSBA management system policies, procedures or processes for:

- the development, authorisation and implementation of the SSBA management system;
- continually assessing and improving the effectiveness of the SSBA management system;
- ensuring that relevant information relating to the SSBA management system is communicated to and from the employees and other relevant parties;
- reviewing the SSBA management system for improvement opportunities;
- meeting the reporting requirements under the NHS Act and the NHS Regulations in respect of any SSBA held;
- justification for all legitimate uses of SSBA held;
- documentation and communication of roles, responsibilities and authorities for SSBA management;
- requirements for all work involving SSBA to be assessed for risks and for mitigation strategies to be prepared before any work is approved to commence;
- complying with legal requirements in relation to handling SSBAs and their transport;
- reducing the level of biosecurity risk;
- continually improving SSBA management performance;
- identifying, collecting, storing and analysing data to assess the suitability and effectiveness of the SSBA management system;
- ensuring that records, documents and data are established, controlled and maintained to provide evidence of compliance with the requirement of the SSBA Standards;

SENSITIVE INFORMATION ONCE COMPLETED

- ensuring SSBA record retention;
- establishment and management of an internal audit program;
- identifying and managing areas of non-compliance with the SSBA Standards, the NHS Act, the NHS Regulations or the SSBA management system;
- acting upon, recording and eliminating the causes of non-compliance;
- reviewing non-compliance records;
- defining, reporting, recording and analysing incidents involving SSBAs; and
- maintaining records of the nature of the incident and any subsequent action taken.

Suspected SSBAs policies, procedures or processes for:

- what constitutes a reasonable suspicion based on laboratory testing;
- restriction of access to those who have a need to handle;
- recording access, transport and destruction;
- verifying that the receiving facility will accept the SSBA;
- supplying the shipping details to the receiving facility;
- notifying the receiving facility at the time of shipment;
- recording incoming shipments of suspected SSBAs;
- notifying the sending facility of the receipt of the shipment;
- liaising with the sending facility in regards to any delays;
- notification when a shipment fails to arrive at the expected time;
- verifying the complete shipment;
- verifying there is no evidence of tampering; and
- reporting to Health receipt, transport and disposal of suspected SSBAs.

RESOURCES

The SSBA Regulatory Scheme has produced a series of documents to assist in compliance with the scheme. This list is current at the time of publication. Please check the SSBA website – www.health.gov.au/ssba - for the latest version of these documents.

Fact Sheets

Fact Sheet 1 Overview

This fact sheet provides an overview of the background of the SSBA Regulatory Scheme.

Fact Sheet 2 About Us

This fact sheet provides information about the SSBA Regulatory Scheme's administering body along with relevant contact details.

Fact Sheet 3 Legislative Framework

This fact sheet provides an overview of the legislation that governs the regulation of controls for handling SSBA in Australia.

Fact Sheet 4 Exemptions

This fact sheet provides an overview of the exemptions under the SSBA Regulatory Scheme.

Fact Sheet 5 List of Security Sensitive Biological Agents

This fact sheet provides information about the List of SSBA.

Fact Sheet 6 Top Management

This fact sheet provides information about the roles and responsibilities of Top Management.

Fact sheet 7 – please note that this fact sheet has now been superseded by Guideline 10

Fact Sheet 8 Emergency Disease Situations

This fact sheet provides information about the emergency disease situation provisions that enable the Minister to suspend some or all regulatory obligations for handling SSBA should there be an SSBA-related disease outbreak.

Fact Sheet 9 Disposal

This fact sheet provides information about disposal under the NHS Act and provides an overview of common means of destruction.

Fact Sheet 10 Information Security

This fact sheet provides an overview of the information security requirements of the SSBA Regulatory Scheme, and is designed to assist entities and facilities in meeting the information security requirements under the SSBA Standards.

Fact Sheet 11 Upgrading a Facility from Tier 2 to Tier 1 SSBA

This fact sheet provides an overview of the additional requirements for handling Tier 1 SSBA if you are already registered for handling Tier 2 SSBA.

Fact Sheet 12 Domestic Legislation

This fact sheet provides an overview of domestic legislation that may have implications for entities handling biological agents.

Fact Sheet 13 International Conventions and Agreements

This fact sheets provide an overview of international conventions that may have implications for entities handling SSBA.

Fact Sheet 14 Dual-Use

This fact sheet provides an overview about the dual-use issues.

Fact Sheet 15 National Health Security Checks

This fact sheet provides an overview of the National Health Security (NHS) checks conducted under the SSBA Standards.

Fact Sheet 16 Emergency Situations

This fact sheet provides information about how to handle the security considerations when an emergency situation, such as a freezer malfunction, or if emergency maintenance is required, that may require the SSBA to be moved outside of the secure perimeter.

Fact Sheet 17 – Changes to the NHS Legislation

This fact sheet provides information about the 2013 changes in March 2013 to the legislation governing the handling of SSBA.

Guidelines

Guideline 1 Entities and Facilities

This guideline assists entities to determine what is an entity or facility for the purposes of the SSBA Regulatory Scheme.

Guideline 2 Registered Facility Reporting Requirements

This guideline provides information to registered entities and facilities about their reporting requirements.

Guideline 3 Handling a Person or Animal, or Samples from a Person or Animal, Affected By an SSBA

This guideline provides information to help interpret the NHS Regulations when handling samples from a person or animal affected by an SSBA.

Guideline 4 Defining Loss, Theft and Accidental Release of SSBA

This guideline outlines the circumstances that may distinguish between the loss, theft or accidental release of an SSBA.

Guideline 5 Reporting to Law Enforcement or the National Security Hotline

This guideline provides an overview of the process that should be undertaken if an entity or facility has an incident that must be reported to law enforcement or should be reported to the National Security Hotline.

Guideline 6 SSBA Toxins

This guideline provides information about handling toxins on the List of SSBA.

Guideline 7 SSBA in the Natural Environment

SENSITIVE INFORMATION ONCE COMPLETED

This guideline provides general information to entities, facilities and individuals who have concerns regarding their obligations for SSBAs occurring in the natural environment.

Guideline 8 Transporting SSBAs and Suspected SSBAs

This guideline provides information to facilities transporting confirmed or suspected SSBAs. The transport guideline contains a practical checklist covering the requirements for transferring both confirmed and suspected SSBAs.

Guideline 9 Non-Registered Facility Reporting and Requirements

This guideline provides information about the reporting and other general requirements for a non-registered facility that receives an SSBA or biological agent suspected of being an SSBA.

Guideline 10 SSBA Regulatory Scheme Monitoring Inspections

This guideline provides information to facilities about what to expect when scheduled to undergo a monitoring inspection.

Guideline 11 SSBAs and Other Regulatory Schemes

This guideline provides information on providing access to secure SSBA areas or to information that is considered sensitive under the SSBA Regulatory Scheme to other regulatory schemes.

The fact sheets and guidelines listed above are available for download on our website at www.health.gov.au/ssba.

Other Guidelines

The Australian Federal Police have prepared the following two guidelines to assist entities handling SSBAs:

- *Toxin levels in environmental and clinical samples*
- *Indicators of Suspicious Behaviour in Laboratories Handling SSBA*

A copy of these guidelines is available by request – please email ssba@health.gov.au.

Newsletter

The SSBA Regulatory Scheme produces a biannual newsletter containing information about the scheme and any upcoming changes. If you would like to be included on the mailing list for the newsletter and other updates, please email ssba@health.gov.au.

Security Risk Template

The Security Risk Template (SRT) was developed as a tool to assist the regulated community to ensure that all risks associated with handing SSBA's have been identified and treated.

The use of the revised SRT is not mandatory and entities and facilities may choose to use other means to assist with risk assessment and risk management.

Contact Us

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Postal Address:

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