Internal review tool

Sensitive information once completed

**Version 4, September 2022**

Entity name: Enter the name of the entity

Facility name: Enter the name of the facility

Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| Completed by: | Enter name  Enter position | Date: | Click or tap to enter a date. |
| Accepted by: | Enter name  Enter position | Date: | Click or tap to enter a date. |
| Accepted by: | Enter name  Enter position | Date: | Click or tap to enter a date. |

Review

| **Date** | **Name** | **Position title** | **Signature** |
| --- | --- | --- | --- |
| Click or tap to enter a date. | Enter the name of the person | Enter their position title |  |
| Click or tap to enter a date. | Enter the name of the person | Enter their position title |  |

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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*](https://www.health.gov.au/resources/publications/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 Standards[[1]](#footnote-2). 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.

## Terms and definitions

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

| Term | Definition |
| --- | --- |
| **Handling** | Includes   1. receiving, holding, using and storing biological agents; and 2. any operation incidental to, or arising out of, any of those operations. |
| **Health and Aged Care** | Australian Government Department of Health and Aged Care |
| **List of Security-sensitive Biological Agents** | The list established under the NHS Act. The list designates which biological agents are regulated. |
| **NHS Act** | The [*National Health Security Act 2007*](https://www.legislation.gov.au/Latest/C2021C00451)*.* |
| **NHS check** | A National Health Security check (background check). |
| **NHS Regulations** | The [National Health Security Regulations2018](https://www.legislation.gov.au/Latest/F2018L01247)*.* |
| **Record** | A document that states the results achieved or provides evidence of activities performed. |
| **Reportable event** | An event that must be reported to Health and Aged Care under section 48(1) of the NHS Act. Reportable events include:   * 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 SSBAs * Disposal * Suspected SSBAs * Temporary Handling |
| **Sensitive information** | Means any of the following:   1. an entity’s storage records for the security-sensitive biological agent handled at the facility; 2. an entity’s risk assessment plan for the security-sensitive biological agent handled at the facility; 3. an entity’s risk management plan for the security-sensitive biological agent handled at the facility; 4. 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. |
| **SSBA Standards** | The Security Sensitive Biological Agent (SSBA) Standards determined by the Minister for Health and Aged Care 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 SSBAs 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 SSBAs identified and documented? | | | Yes  No |
| Comments: | | | | |
| 2.2.2b | | Are the following risks/hazards identified and documented for inclusion in the risk assessment: |  | |
|  | | 1. Determination of the potential for/ possible causes of an incident? | Yes  No | |
|  | | 1. Human behavioural risk? | Yes  No | |
|  | | 1. Periods of reduced staff availability? | Yes  No | |
|  | | 1. Identification of potential emergency situations involving SSBAs? | Yes  No | |
| Comments: | | | | |

### 2.2.3 Risk assessment process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2.2.3a | | Has the entity undertaken a risk assessment for the SSBAs and the facilities in which they are handled? | Yes  No | |
| Comments: | | | | |
| 2.2.3b | | At a minimum, does the risk assessment include: | |  | |
|  | | 1. Communication and consultation plans with internal and external stakeholders? | | Yes  No | |
|  | | 1. Internal, external and security risk context? | | Yes  No | |
|  | | 1. The risks identified under the hazard/risk identification clause | | Yes  No | |
|  | | 1. Analysis of the risks and the effectiveness of existing controls, including: | | Yes  No | |
|  | | 1. If action is needed to prevent incidents? | | Yes  No | |
|  | | 1. Effectiveness of physical security controls? | | Yes  No | |
|  | | 1. Effectiveness of the procedures for decontamination/inactivation? | | Yes  No | |
|  | | 1. Identification of those responsible for devising, implementing and testing control measures? | | Yes  No | |
|  | | 1. If further controls are needed to reduce the risk | | Yes  No | |
| Comments: | | | | | |
| 2.2.3c | If the facility is handling Tier 1 SSBAs, 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: |  |
|  | 1. Treatment for the risks identified in the risk assessment? | Yes  No |
|  | 1. Plans for monitoring and review of the risk management process? | Yes  No |
| Comments: | | |
| 2.3c | Have the risk management plans been effectively communicated to |  |
|  | 1. All personnel handling SSBAs or sensitive information relating to SSBAs? | Yes  No |
|  | 1. Others as relevant (e.g. security personnel, maintenance contractors)? | Yes  No |
| Comments: | | |
| 2.3d | Have Standard Operating Procedures (SOPs) for the secure handling of SSBAs been: |  |
|  | 1. Developed? | Yes  No |
|  | 1. Documented? | Yes  No |
|  | 1. Implemented? | Yes  No |
| Comments: | | |

## 2.4 Incident management

|  |  |  |
| --- | --- | --- |
| 2.4a | Has the entity established, documented and maintained procedures to define, report, record and analyse incidents involving SSBAs?  *Note: Incidents can include any non-compliance with the NHS Act, NHS Regulations and the SSBA Standards.* | Yes  No |
| Comments: | | |
| 2.4b | Are records of the nature of the incident and any subsequent action taken maintained? | Yes  No |
| Comments: | | |
| 2.4c | Does analysis of the incidents include: |  |
|  | 1. Determining the cause/s of the incident? | Yes  No |
|  | 1. Evaluating the need for corrective action to ensure incidents do not re-occur? | Yes  No |
|  | 1. Determining and implementing any action needed? | Yes  No |
|  | 1. Recording the results of action taken? | Yes  No |
|  | 1. Review of the effectiveness of the action taken? | Yes  No |
| Comments: | | |
| 2.4d | Does the entity have in place processes to encourage learning from incidents involving SSBAs? | Yes  No |
| Comments: | | |

## 2.5 Review

|  |  |  |
| --- | --- | --- |
| 2.5 | Are all risk assessment and risk management plans reviewed at least: |  |
|  | 1. Every 12 months for risks involving Tier 1 SSBAs (or more frequently if required)? | Yes  No N/A(No Tier 1) |
|  | 1. Every 2 years for risks involving Tier 2 SSBAs (or more frequently if required)? | Yes  No N/A(No Tier 2) |
|  | 1. 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 SSBAs 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: | | |
| 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: |  |
|  | 1. Overseeing the SSBA management system? | Yes  No |
|  | 1. Reporting to top management on the performance of the entity’s SSBA management system and any need for improvement? | Yes  No |
|  | 1. Overseeing internal review, audit and reporting measures? | Yes  No |
|  | 1. Verifying, in conjunction with other personnel, that all known SSBA risks have been addressed? | Yes  No |
|  | 1. Advising or participating in the reporting, investigation and follow-up of incidents? | Yes  No |
|  | 1. Where appropriate, referring incidents to top management/ SSBA management committees? | Yes  No |
|  | 1. 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 |
|  | 1. Advising top management as to whether staff levels, facilities and equipment are sufficient? | Yes  No |
|  | 1. Maintaining lists of authorised and approved persons? | Yes  No |
| Comments: | | |
| 3.2c | Do the lists of authorised and approved persons include: |  |
|  | 1. The period for which the person is authorised or approved? | Yes  No |
|  | 1. The review date of the authorisation or approval? | Yes  No |
|  | 1. What the person is authorised or approved for? | Yes  No |
|  | *Note: A person may be authorised or approved to handle SSBAs, access a facility where SSBAs are handled or access sensitive information relating to SSBAs 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 been made authorised persons if they:   * handle SSBAs; * access a facility where SSBAs are handled; or * access sensitive information related to SSBAs?   *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 SSBAs 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.* | Yes  No |
| Comments: | | |
| 3.3c | Are all authorised person statuses limited to the entity in which the status was conferred? | Yes  No |
| Comments: | | |
| 3.3d | Are all students who handle SSBAs either authorised or approved persons? | Yes  No |
| 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 SSBAs, access a facility that handles SSBAs or access sensitive information related to SSBAs? | Yes  No |
| Comments: | | |

### 3.3.1 Authorisation of a person

|  |  |  |
| --- | --- | --- |
| 3.3.1 | Have all authorised persons: |  |
|  | 1. Been trained in the requirements of the NHS Act, NHS Regulations and SSBA Standards as relevant to their authorisation? | Yes  No |
|  | 1. Provided to the entity a signed and dated record of the training above? | Yes  No |
|  | 1. Not been excluded from handling SSBAs by the entity nor have been directed not to handle SSBAs by the Secretary of Health and Aged Care? | Yes  No |
|  | 1. Undergone an identity check as outlined in the SSBA Standards? | Yes  No |
|  | 1. Been verified as 18 years old or over? | Yes  No |
|  | 1. Undergone an NHS check if required to do so by the SSBA Standards and have a ‘eligible’ or ‘qualified’ status? | Yes  No |
| 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  (go to Q3.3f) |
|  | 1. Received a result of ‘eligible’ – is the person authorised for up to two years? | Yes  No |
|  | 1. Received a result of ‘qualified’ – is the person authorised for a period of up to 12 months only? | Yes  No |
|  | 1. Received a result of ‘non-eligible’ – has the entity not authorised that person? | Yes  No |
| 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  No |
| Comments: | | |
| 3.4b | Do these processes include policies and procedures for the approval of persons who need to: |  |
|  | 1. Handle SSBAs; | Yes  No |
|  | 1. Access a facility where SSBAs are handled; or | Yes  No |
|  | 1. Access sensitive information related to SSBAs. | Yes  No |
|  | *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.* |  |
| Comments: | | |
| 3.4c | If the facility handles Tier 1 SSBAs, are all approved persons escorted by an authorised person at all times?  *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.* | N/A  (no Tier 1 – go to Q3.4d)  Yes  No |
| Comments: | | |
| 3.4d | If the facility handles Tier 2 SSBAs, are all approved persons supervised by an authorised person at all times? | N/A  (no Tier 2)  Yes  No |
|  | Is the degree of supervision of and the responsibility for an approved person by an authorised person determined by risk assessment? | Yes  No |
| 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 SSBAs, access a facility that handles SSBAs or access sensitive information related to SSBAs? | Yes  No |
| Comments: | | |

## 3.5 Identity check

|  |  |  |
| --- | --- | --- |
| 3.5a | Was an identity check conducted on all persons prior to the person being authorised? | Yes  No |
| 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  (no NHS check)  Yes  No |
| Comments: | | |
| 3.5c | Did the documentation for all identity checks include: |  |
|  | 1. Evidence of commencement of identity in Australia? | Yes  No |
|  | 1. Linkage between the identity and the person? | Yes  No |
|  | 1. Evidence of operation in the community? | Yes  No |
|  | 1. Evidence of residential address? | Yes  No |
|  | *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.* |  |
| Comments: | | |
| 3.5d | Does the entity keep a record of which documents were provided?  *Note: this may be a record of the type of document provided; it does not have to be a copy of the document itself.* | Yes  No |
| Comments: | | |

## 3.6 National Health Security (NHS) checks

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 3.6a | | Does the facility undertake National Health Security checks (either mandatory checks for Tier 1 SSBAs or voluntary checks for Tier 2 SSBAs)?  *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.*  *NHS checks are recommended for personnel handling Tier 2 SSBAs but are not mandatory. If they are undertaken, please answer the questions under 3.6.* | | Yes  No  (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 SSBAs, access facilities where Tier 1 SSBAs are handled or access sensitive information relating to Tier 1 SSBAs?  *Note: some persons may be able to access sensitive information for Tier 1 SSBAs without an NHS Check if they meet certain requirements under Part 5 of the SSBA Standards.* | | Yes  No |
| Comments: | | | | |
| 3.6c | | At the time of application for an NHS check, was a recent photograph, taken by the entity, supplied to AusCheck? | | Yes  No |
| 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  No |
| Comments: | | | | |
| 3.6e | | Has the entity ensured that NHS checks are conducted at intervals of no more than two years to maintain eligibility?  *Note: NHS checks may be required more frequently (see clause 3.3 of the SSBA Standards)* | | Yes  No |
| 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: | |  |
|  | | 1. Informs the entity of the change within 30 days? | | Yes  No |
|  | | 1. 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: |  |
|  | 1. Obtain the person’s consent to request those results from AusCheck? | Yes  No |
|  | 1. 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: |  |
|  | 1. 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 |
|  | 1. The entity reports this information to AusCheck within two business days from being informed of the conviction?   *Note: New convictions that must be reported are only those against the disqualifying offences as listed in Appendix 1 of the SSBA Standards.* | Yes  No |
| 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: |  |
|  | 1. The person was to undergo an NHS check? | Yes  No |
|  | 1. The requirements of clause 3.3.1 (a) to (e) of the SSBA Standards were met? | Yes  No |
|  | 1. The relevant facility had no other authorised persons in place? | Yes  No |
| Comments: | | |
| 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: |  |
|  | 1. Have the appropriate education, training and experience? | Yes  No |
|  | 1. 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: |  |
|  | 1. Defining SSBA related training needs? | Yes  No |
|  | 1. Provision of required SSBA training? | Yes  No |
|  | 1. Determination of the effectiveness of SSBA training? | Yes  No |
|  | 1. Provision of SSBA refresher training? | Yes  No |
|  | 1. Restriction on staff to ensure they do not perform tasks for which they are not trained? | Yes  No |
|  | 1. Records management including the maintenance of adequate records? | Yes  No |
| Comments: | | |

### 3.9.1 Training for authorised persons

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 3.9.1a | | | For all **authorised** persons, has the SSBA training at a minimum included: | | |  | | |
|  | | | 1. An overview of the NHS Act, NHS Regulations and why the SSBA Regulatory Scheme is in place? | | | Yes  No | | |
|  | | | 1. Reporting requirements? | | | Yes  No | | |
|  | | | 1. Records management? | | | Yes  No | | |
| 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 SSBAs are handled, does the SSBA training at a minimum include: | | |  | | |
|  | | 1. Physical security? | | | Yes  No | | |
|  | | 1. Risk management? | | | Yes  No | | |
|  | | 1. Information security? | | | Yes  No | | |
|  | | 1. Personnel security? | | | Yes  No | | |
|  | | 1. Management system requirements? | | | Yes  No | | |
| Comments: | | | | | | | |
| 3.9.1d | | | For all persons who **access sensitive information** relating to SSBAs, does the SSBA training at a minimum include: | | |  | | |
|  | | | 1. Risk management? | | | Yes  No | | |
|  | | | 1. Information security? | | | Yes  No | | |
|  | | | 1. Personnel security? | | | Yes  No | | |
|  | | | 1. Management system requirements? | | | Yes  No | | |
| Comments: | | | | | | | | |
| 3.9.1e | | | Does all training include: | | |  | | |
|  | | | 1. How the SSBA Standards are implemented at each facility? | | | Yes  No | | |
|  | | | 1. Specific training in the requirements of the entity and facility in relation to SSBAs?   *Note: requirements of the facility may include the policies and procedures specific to the facility for handling SSBAs and sensitive information, the requirements for escorting/supervising approved persons etc* | | | Yes  No | | |
| Comments: | | | | | | | | |
| 3.9.1f | Does training for personnel handling Tier 1 SSBAs 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: | | |
| 3.9j | Are competencies of personnel reviewed: |  |
|  | 1. At least annually for facilities handling Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. At least every two years for facilities handling Tier 2 SSBAs? | Yes  No N/A  (no Tier 2) |
|  | 1. 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 SSBAs, access a facility where SSBAs are handled or access sensitive information relating to SSBAs? | 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 SSBAs from Health and Aged Care? | Yes  No |
| Comments: | | |
| 3.11b | Do exclusion measures include: |  |
|  | 1. Prompt removal of access to the facility? | Yes  No |
|  | 1. Prompt removal of access to any SSBAs held in linked storage units? | Yes  No |
|  | 1. Prompt removal of access to sensitive information? | Yes  No |
|  | 1. Suspension or revocation of a person’s authorised or approved status? | Yes  No |
|  | 1. Immediate physical removal if deemed necessary? | Yes  No |
| 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 SSBAs 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  No  N/A  (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  No  N/A  (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  No |
| 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  No |
| Comments: | | |
| P3e | Are identity checks undertaken for approved persons? | Yes  No |
| Comments: | | |
| P3f | Does training for SSBAs include raising awareness of general security issues associated with SSBAs, including the relevance of human behavioural factors? | Yes  No |
| Comments: | | |
| P3g | Does training for SSBAs include, if appropriate, hazard identification, risk assessment and management and vulnerability analysis? | Yes  No |
| Comments: | | |
| P3h | Does the entity have in place mechanisms to ensure that relevant and timely information is available regarding SSBAs? | Yes  No |
| Comments: | | |
| P3i | Does the entity promote awareness of the potential risks (internal and external) associated with unauthorised access to SSBAs? | Yes  No |
| 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  No |
| Comments: | | |
| P3k | Does the entity use the On-line Training Facility provided by Health and Aged Care as a training tool? | Yes  No |
| 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 SSBAs.

## 4.2 Perimeter

|  |  |  |
| --- | --- | --- |
| 4.2a | Does the facility have a clearly defined perimeter that encloses the secure area where SSBAs 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: |  |
|  | 1. Self closing? | Yes  No |
|  | 1. 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?  *Note: Mobile laboratories, such as forensic laboratories are not subjected to the requirements for stand-alone facilities.* | Yes  No  (if No, go to Q4.3a) | |
| Comments: | | | |
| 4.2.1b | Does the stand-alone facility meet the following requirements: | |  |
|  | 1. Has a back to base alarm system? | | Yes  No |
|  | 1. Is fixed in place an not easily transportable? | | Yes  No |
|  | 1. Have barriers to prevent vehicles from approaching the facility? | | Yes  No |
|  | 1. Have good external lighting? | | Yes  No |
|  | 1. Regular inspections conducted of outer walls to detect tampering? | | Yes  No |
|  | 1. Outcomes of regular inspections are documented? | | Yes  No |
| 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:   * Is there an additional form of access control? | N/A  (go to Q4.3d)  Yes  No |
| Comments: | | |
| 4.3d | Are there measures in place to prevent tail gaiting? | Yes  No |
| Comments: | | |
| 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: |  |
|  | 1. Entering the secure perimeter? | Yes  No |
|  | 1. Accessing the secondary access control to the Tier 1 SSBA? | Yes  No |
|  | 1. 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: |  |
|  | 1. 5 years for facilities holding Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 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: |  |
|  | 1. 6 months for facilities holding Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 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: | | |
| 4.3k | If a person no longer requires access to the secure area, does the Responsible Officer ensure that access is removed? | Yes  No |
| 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  No |
|  | If yes, is the floor plan kept securely? | Yes  No |
| Comments: | | |
| P4b | Is there a staffed reception area as part of the controls regarding access to the secure area? | Yes  No |
| 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  No |
| Comments: | | |
| P4d | Are unoccupied areas alarmed: |  |
|  | 1. At all times? | Yes  No |
|  | 1. After hours only? | Yes  No |
|  | 1. Other? (please note how in comments) | Yes  No |
| Comments: | | |
| P4e | Is there video monitoring? | Yes  No |
| Comments: | | |
| P4f | Are exit controls: |  |
|  | 1. Able to be overridden in case of emergency? | Yes  No |
|  | 1. An alarm generated to indicate unauthorised exit? | Yes  No |
| Comments: | | |
| P4g | Is any alarm generation subject to an incident report and investigation? | Yes  No |
| Comments: | | |
| P4h | Does risk assessment determine how access is handled in an emergency? | Yes  No |
| Comments: | | |
| P4i | Are any policies or procedures regarding emergency access: |  |
|  | 1. Documented? | Yes  No |
|  | 1. Communicated to relevant personnel, including contractors such as security guards? | Yes  No |
| Comments: | | |

# Part 4A – Storage

The objective of Part 4A is to ensure that SSBAs 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 SSBAs 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 SSBAs? | 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 SSBAs 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 SSBAs stored? | | Yes  No | |
| Comments: | | | | |

### 4A.3.1 Audit of Inventory

|  |  |  |
| --- | --- | --- |
| 4A.3.1 | Audits of the inventory: |  |
|  | 1. Are conducted at predetermined intervals? | Yes  No |
|  | 1. The intervals determined through risk assessment? | Yes  No |
|  | 1. Audits are at a level and frequency that materials can be accounted for? | Yes  No |
|  | 1. Results of the audit are documented? | Yes  No |
| Comments: | | |

## 4A.4 Storage of Tier 1 SSBAs

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

## 4A.5 Storage of Tier 2 SSBAs

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 4A.5a | | Does the entity store Tier 2 SSBAs: | | N/A  (no Tier 2) | |
|  | | 1. Only within the secure perimeter of a registered facility? | | Yes  No  (if Yes, go to Q 4A.6) | |
|  | | 1. Only in a linked storage unit? | | Yes  No | |
|  | | 1. In both the facility and a linked storage unit? | | Yes  No | |
| Comments: | | | | | |
| 4A.5b | | Is the only handling of the SSBA within the linked storage unit either storage or preparation for storage? | | Yes  No | |
| Comments: | | | | | |
| 4A.5c | Is the linked storage unit: | |  | |
|  | 1. Within the same building (preferably the same floor) as the registered facility? | | Yes  No | |
|  | 1. Included as part of the facility registration? | | Yes  No | |
|  | 1. Included in the risk assessment and risk management plans? | | Yes  No | |
|  | 1. Fixed in place or non-transportable? | | Yes  No | |
| Comments: | | | | |

### 4A.5.1 Access to a linked storage unit

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4A.5.1a | | | Is access to the SSBA within the linked storage unit: | | |  | | |
|  | | | 1. Restricted to Authorised or Approved persons? | | | Yes  No | | |
|  | | | 1. Recorded? | | | Yes  No | | |
| Comments: | | | | | | | | |
| 4A.5.1b | | | Do access records include: | | |  | | |
|  | | | 1. Identification of the person? | | | Yes  No | | |
|  | | | 1. Date and time of access? | | | Yes  No | | |
|  | | | 1. A record if any of the SSBA was removed? | | | Yes  No | | |
| 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  No | | |
| 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  No | | |
| Comments: | | | | | | | | |
| 4A.5.1e | | | Are there measures in place to ensure that the lost items in 4A.5.1d are not used? | | | Yes  No | | |
| Comments: | | | | | | | | |
| 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?  *Note: this type of transport does not need to be reported to Health and Aged Care but a record of the transport must be made available on request.* | Yes  No |
| Comments: | | |

## 4A.6 Record keeping

|  |  |  |
| --- | --- | --- |
| 4A.6a | Has the entity ensured that records relating to the storage of SSBAs, including inventory records, are: |  |
|  | 1. Current? | Yes  No |
|  | 1. Complete? | Yes  No |
|  | 1. Stored securely? | Yes  No |
|  | 1. Adequately backed up? | Yes  No |
| 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?  *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.* | Yes  No |
| 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: |  |
|  | 1. Receipt of SSBAs? | Yes  No |
|  | 1. Holding of SSBAs? | Yes  No |
|  | 1. Transport of SSBAs? | Yes  No |
|  | 1. Disposal of SSBAs? | Yes  No |
|  | 1. Decontamination and inactivation | Yes  No |
|  | 1. Policies and procedures | Yes  No |
|  | 1. Internal and external reviews? | Yes  No |
|  | 1. Inspections? | Yes  No |
|  | 1. Incident investigations? | Yes  No |
|  | 1. Risk assessment and risk management plans | Yes  No |
| Comments: | | |
| 5.2b | Are records kept for a minimum of: |  |
|  | 1. 5 years for Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 2 years for Tier 2 SSBAs?   (unless otherwise specified in the SSBA Standards) | Yes  No N/A  (no Tier 2) |
| Comments: | | |
| 5.2c | Has the entity developed and documented policies regarding records in accordance with the SSBA Standards relation to: |  |
|  | 1. Access | Yes  No |
|  | 1. Retention | Yes  No |
|  | 1. Destruction (including timeframes)? | Yes  No |
| Comments: | | |

## 5.3 Information security

|  |  |  |
| --- | --- | --- |
| 5.3a | Has the entity identified and documented sensitive information relating to SSBAs?  *Note: Documentation may be part of a larger document such as the risk assessment and risk management plan.* | Yes  No |
| 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?  *Note: Controls for sensitive information should cover all persons who can access the information (e.g. facility personnel, IT personnel, SSBA Committee members)* | Yes  No |
| Comments: | | |
| 5.3e | Are access permissions reviewed at least: |  |
|  | 1. Every 6 months for facilities handling Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 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: | | |
| 5.3f | Is Tier 1 sensitive information: |  |
|  | 1. Stored in a secure system? | Yes  No N/A  (no Tier 1) |
|  | 1. Securely backed up at regular intervals? | Yes  No |
| 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?  *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.* | Yes  No  (if no, go to Q5.4a) |
| Comments: | | | |
| 5.3.1b | | Is sensitive information only supplied under the following conditions?   1. The regulatory authority has a need to know the information for their regulatory purposes. 2. The regulatory authority is able to hold the information at the PROTECTED security level or higher. 3. Measures are in place to limit the amount of sensitive information released. | Yes  No |
| Comments: | | | |
| 5.3.1c | Does the entity document what is supplied to the regulatory authority? | | Yes  No |
| Comments: | | | |

## 5.4 Disposal of records

|  |  |  |
| --- | --- | --- |
| 5.4a | Has the entity ensured that there are documented polices and procedures in place, consistent with the requirements of the SSBA Standards, for the disposal of records? | Yes  No |
| 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?  *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.* | Yes  No |
| Comments: | | |
| P5b | Before providing sensitive information to other regulatory authorities, does the entity determine if:   * 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? | Yes  No | |
| 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: | | | |
| P5d | At a minimum, do the procedures addressing information security consider: |  |
|  | 1. Secure storage of sensitive records including electronic records and electronic signatures? | Yes  No |
|  | 1. Computer security (e.g. firewalls)? | Yes  No |
|  | 1. Strict policies regarding the on-site security of equipment as well as equipment entering or leaving the facility? | Yes  No |
|  | 1. Destruction of unwanted paper files and complete erasure of electronic files? | Yes  No |
|  | 1. Security measures and procedures? | Yes  No |
|  | 1. Adequate backup strategies for electronic data? | Yes  No |
| Comments: | | |

# Part 6 – Transport

The objective of Part 6 is the have policies and procedures in place for the secure movement of SSBAs.

## 6.2 Transport

|  |  |  |
| --- | --- | --- |
| 6.2a | If the entity is sending SSBAs, does it ensure that the sending facility: | N/A  (entity does not send SSBAs) |
|  | 1. Has documented policies and procedures in place to ensure compliance with Commonwealth, state and territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Ensure that the receiving facility will accept the agent? | Yes  No |
|  | 1. Keep a record of that acceptance? | Yes  No |
|  | 1. Notifies the receiving facility of the shipment details at the time of shipment? | Yes  No |
|  | 1. If the shipment is lost in transit–immediately informs Health and Aged Care and state/territory police once aware of the loss? | Yes  No |
|  | 1. If the shipment is reported unsuccessful by the receiving facility–immediately informs Health and Aged Care and state/territory police once aware of the unsuccessful transfer? | Yes  No |
| Comments: | | |
| 6.2b | If the entity is receiving SSBAs, does it ensure the receiving facility: | N/A  (entity does not receive SSBAs) |
|  | 1. Verifies that the transfer was successful; including that:    1. the complete shipment was received    2. there was no tampering evident on the shipping container? | Yes  No |
|  | 1. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? | Yes  No |
|  | 1. 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 |
|  | 1. If the shipment is lost in transit–immediately informs the sending facility, Health and State/Territory police once aware of the loss? | Yes  No |
| Comments: | | |

## 6.3 Transport security

|  |  |  |
| --- | --- | --- |
| 6.3a | Is a transport agent contracted to transport SSBAs? | 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: |  |
|  | 1. Specific allocation of security responsibilities to competent and qualified persons with the appropriate authorities? | Yes  No |
|  | 1. Compliance with Commonwealth, State and Territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Assessment and coverage of security risks, including inter-modal transport, temporary transit storage, handling and distribution? | Yes  No |
|  | 1. Clear statements of measures and resources that are used to reduce security risks? | Yes  No |
|  | 1. Up to date procedures for responding to and dealing with security threats, non-compliance with security protocols or security incidents? | Yes  No |
|  | 1. Procedures for the evaluation and testing of security plans and procedures for periodic review and update of the plans? | Yes  No |
|  | 1. Measures to ensure the security of information relating to transport of SSBAs? | Yes  No |
|  | 1. Measures to ensure that the distribution of transport information is as limited as possible? | Yes  No |
|  | *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: |  |
|  | 1. Reported to the Responsible Officer? | Yes  No |
|  | 1. 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: | | |
| 6.5b | Is transport of the SSBA from the reception area to the registered facility undertaken under the following conditions: |  |
|  | 1. *Transport* occurs within a single building only? | Yes  No |
|  | 1. Transport occurs only between the reception area and the registered *facility*? | Yes  No |
|  | 1. 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 |
|  | 1. *The* SSBA is delivered to an authorised person at the registered facility? | Yes  No |
|  | 1. The *transport* is covered by a documented policy and is included in the risk assessment? | Yes  No |
|  | 1. All *movements* of the SSBA from the reception area to the registered facility are recorded? | Yes  No |
|  | 1. 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 and Aged Care, but must make the records available on request.* |  |
| Comments: | | |
| 6.5c | The person undertaking the transport: |  |
|  | 1. Is 18 years or older? | Yes  No |
|  | 1. Has undergone an identity check? | Yes  No |
|  | 1. Has not been excluded from handling SSBAs by the entity? | Yes  No |
|  | 1. Has not been directed not to handle SSBAS by Health and Aged Care? | Yes  No |
|  | 1. 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?  *For example – does the entity require the use of tamper proof packaging to indicate tampering during transport?* | Yes  No |
| 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: |  |
|  | 1. Validation data on inactivation procedures? | Yes  No |
|  | 1. 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: | | |
| 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: |  |
|  | 1. Kept secure until it is picked up? | Yes  No |
|  | 1. 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 SSBAs or 2 years for Tier 2 SSBAs? | 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 SSBAs in your facility.

|  |  |  |
| --- | --- | --- |
| P7a | Do the validation procedures take into account issues such as: |  |
|  | 1. Nature of the material being treated? | Yes  No |
|  | 1. Contact times and material compatibility issues? | Yes  No |
|  | 1. Potential health hazards? | Yes  No |
|  | 1. Need to maintain the required level of active compound including deterioration over time? | Yes  No |
| Comments: | | |
| P7b | When planning and conducting decontamination activities did the entity consider: |  |
|  | 1. 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  No |
|  | 1. Implementing monitoring measures to ensure the methods have been effective? | Yes  No |
|  | 1. 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  No |
|  | 1. Implementing programs to ensure the amount of contaminated waste is minimised? | Yes  No |
| 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) |
|  | 1. Transport carried out by authorised persons? | Yes  No |
|  | 1. Validated destruction processes carried out by authorised persons? | Yes  No |
|  | 1. The waste destroyed as soon as possible after arrival in the waste destruction area? | Yes  No |
| Comments: | | |
| P7f | Were the following elements considered for the waste management policy: |  |
|  | 1. Ensuring a program is in place to minimise waste production? | Yes  No |
|  | 1. Ensuring effective waste audit trails are in place and documented? | Yes  No |
|  | 1. Provision of adequate facilities and procedures for storage of waste? | Yes  No |
|  | 1. 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 SSBAs 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 SSBAs? | 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 SSBAs? | Yes  No |
| Comments: | | |
| 8.2d | Does the entity continually assess and improve the effectiveness of the SSBA management system through use of: |  |
|  | 1. Policies? | Yes  No |
|  | 1. Objectives? | Yes  No |
|  | 1. Procedures? | Yes  No |
|  | 1. Self review programs? | Yes  No |
|  | 1. Analysis of data? | Yes  No |
|  | 1. Risk assessment and management? | Yes  No |
|  | 1. Corrective and preventative actions? | Yes  No |
|  | 1. Management review? | Yes  No |
| 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?  *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.* | Yes  No |
| Comments: | | |

## 8.3 Roles, responsibilities and authorities

### 8.3.1 Top management

|  |  |  |
| --- | --- | --- |
| 8.3.1a | Does top management: |  |
|  | 1. Take ultimate responsibility for the development and implementation of the entity’s SSBA management system and policy? | Yes  No |
|  | 1. Ensure the availability of resources to establish, implement, maintain and improve the SSBA management system? | Yes  No |
|  | 1. 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  No |
|  | 1. Ensure that all SSBA related activities conducted in the facility are authorised, defined and reviewed at least annually? | Yes  No |
|  | 1. Ensure that criteria and processes are established for work that requires prior approval? | Yes  No |
|  | 1. 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  No |
|  | 1. Deal with any identified instances of the entity’s non compliance with the SSBA Standards, NHS Act or NHS Regulations? | Yes  No |
|  | 1. Ensure verification of any actions taken to deal with instances of non-compliance and documents such actions? | Yes  No |
|  | 1. 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  No |
|  | 1. Ensure that staff levels, facilities and equipment are sufficient to effectively carry out work involving SSBAs in accordance with technical protocols, approved policies and SOPs? | Yes  No |
|  | 1. Ensure all requirements for reporting to Health and Aged Care are met? | Yes  No |
| Comments: | | |

### 8.3.2 SSBA Management Committee

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 8.3.2a | | Has the entity either: |  | | |
|  | | 1. Established an SSBA Management Committee?   or | Yes  No | | |
|  | | 1. 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: |  | | |
|  | | 1. Have documented terms of reference? | Yes  No | | |
|  | | 1. Include a representative cross section of expertise, appropriate to the nature and scale of activities undertaken? | Yes  No | | |
|  | | 1. Include the Responsible Officer and Deputy Responsible Officer? | Yes  No | | |
|  | | 1. Meet at defined and appropriate frequency and when otherwise required? | Yes  No | | |
| Comments: | | | | | |
| 8.3.2e | | Do the functions of the committee include: |  | | |
|  | | 1. Contributing to the development to the entity’s SSBA policies and procedures? | Yes  No | | |
|  | | 1. Reviewing and approving protocols and risk assessments for work involving SSBAs? | Yes  No | | |
|  | | 1. Reviewing information relating to significant incidents, non-compliance, data trends, associated local/entity action and associated communication needs? | Yes  No | | |
|  | | 1. Ensuring biosecurity issues are formally recorded; actions allocated, tracked and closed out effectively? | Yes  No | | |
|  | | 1. 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: |  | |
|  | 1. Assess the suitability and effectiveness of the SSBA management system? | Yes  No | |
|  | 1. 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: |  | | |
|  | | 1. Established? | Yes  No | | |
|  | | 1. Controlled? | Yes  No | | |
|  | | 1. Maintained? | Yes  No | | |
| Comments: | | | | | |
| 8.4.2b | | Have such records, documents and data remained, in alignment with the information management requirements of Part 5 of the SSBA Standards:? |  | | |
|  | | 1. Legible? | Yes  No | | |
|  | | 1. Readily identifiable? | Yes  No | | |
|  | | 1. Retrievable | Yes  No | | |
| Comments: | | | | | |
| 8.4.2c | Has the entity documented its record retention policies and ensured that they are implemented? | | | Yes  No |
| Comments: | | | | |

### 8.4.3 Internal review

|  |  |  |  |
| --- | --- | --- | --- |
| 8.4.3a | Has the entity ensured that a program of internal review is conducted? | | Yes  No |
| Comments: | | | |
| 8.4.3b | Are the internal reviews conducted at planned intervals of no longer than: |  | |
|  | 1. 6 monthly for Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) | |
|  | 1. Annually for Tier 2 SSBAs? | Yes  No N/A  (no Tier 2) | |
|  | *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.* |  | |
| Comments: | | | |
| 8.4.3c | Are records maintained: | |  |
|  | 1. Of the findings of the review? | | Yes  No |
|  | 1. Of the actions taken to close out any non-compliances? | | Yes  No |
|  | 1. Of the actions taken for any improvement opportunities? | | Yes  No |
|  | 1. In accordance with Part 5 of the SSBA Standards? | | Yes  No |
| 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  No | | | |
| Comments: | | | | | | |
| 8.4.4b | | Has the entity ensured that action is taken to eliminate the causes of non-compliance to prevent recurrence?  *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.* | | | Yes  No | |
| 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  No | |
| 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  No |
| Comments: | | |
| 8.4.5b | Is preventive action appropriate to the effects of the potential non-compliance? | Yes  No |
| 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: |  |
|  | 1. Meeting the reporting requirements under the NHS Act and NHS Regulations? | Yes  No |
|  | 1. Justification of all legitimate uses of the SSBA? | Yes  No |
|  | 1. Documentation and communication of roles, responsibilities and authorities for SSBA management within the facility? | Yes  No |
|  | 1. Effectively informing personnel and other relevant parties of individual obligations? | Yes  No |
|  | 1. Requirements for all projects/work involving SSBAs to be assessed for risks and mitigation strategies before work is approved to commence? | Yes  No |
|  | 1. Reviews of the management system following an incident? | Yes  No |
| 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: | | |
| P8e | Does the policy commit to: |  |
|  | 1. Complying with legal requirements for handling SSBAs? | Yes  No |
|  | 1. Reducing the level of biosecurity risk to an acceptable level? | Yes  No |
|  | 1. Ensuring that the need for effective SSBA management takes precedence over non ‘health and safety’ operational requirements? | Yes  No |
|  | 1. Continually improving SSBA management performance? | Yes  No |
| 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  No |
| Comments: | | |
| P8g | When assigning roles and responsibilities under the SSBA management system, are potential conflicts of interest taken into account? | Yes  No |
| Comments: | | |
| P8h | Is determination of staffing levels, equipment and facilities done in consultation with the Responsible Officer? | Yes  No |
| Comments: | | |
| P8g | Does documentation of SSBA related activities include the nature of the activities authorised to be conducted and their definitions? | Yes  No |
| Comments: | | |
| P8h | Are all activities routinely associated with the work program specified and supported by formal SOPs? | Yes  No |
| Comments: | | |
| 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  No |
| Comments: | | |
| P8j | Are controls monitored by: |  |
|  | 1. Regular reviews? | Yes  No |
|  | 1. Using corrective action reporting processes? | Yes  No |
|  | 1. Investigation of accidents and incidents? | Yes  No |
|  | 1. Improving controls and their implementation? | Yes  No |
|  | 1. Ensuring adequate resources are provided? | Yes  No |
| Comments: | | |
| P8k | Do the terms of reference include: |  |
|  | 1. A short statement of the purpose of the committee? | Yes  No |
|  | 1. Defined roles and functions of the committee and how objectives are achieved? | Yes  No |
|  | 1. Who is part of the committee as a member, observer or other? | Yes  No |
|  | 1. Details regarding quorums – is there one, what is the number and what happens if this is not reached? | Yes  No |
|  | 1. Defined deliverables? | Yes  No |
|  | 1. Defined timeframes such as meeting frequency, reporting, review and set task timeframes? | Yes  No |
|  | 1. Details on what is to be reported and to whom? | Yes  No |
|  | 1. Details on the evaluations undertaken by the committee on the role and function or other terms of reference | Yes  No |
|  | 1. Details on how the effectiveness of the committee will be evaluated? | Yes  No |
| Comments: | | |
| P8l | For the performance management analysis are: |  |
|  | 1. Data sets generated as a consequence of monitoring, measuring, reviews and other sources considered? | Yes  No |
|  | 1. Analyses conducted every 2 years or more often if justified by the risks and scope of operations? | Yes  No |
|  | 1. Results of the analysis considered as part of the management review? | Yes  No |
| 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: |  |
|  | 1. Risk assessments, SOPs and safety manuals? | Yes  No |
|  | 1. Job hazard analyses and charts of authority? | Yes  No |
|  | 1. Audit and inspection checklists | Yes  No |
|  | 1. Laboratory SSBA manuals, authorisations and other security documents? | Yes  No |
|  | 1. Training records? | Yes  No |
| Comments: | | |
| 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: |  |
|  | 1. Reviewing all non-compliances? | Yes  No |
|  | 1. Determining the causes of non-compliances? | Yes  No |
|  | 1. Evaluating the need for action to ensure that non-compliances do not occur or recur? | Yes  No |
|  | 1. Determining and implementing the actions needed? | Yes  No |
|  | 1. Recording results of actions taken? | Yes  No |
|  | 1. 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 SSBAs, does it ensure that the sending facility: |  |
|  | 1. Has documented policies and procedures in place to ensure compliance with Commonwealth, state and territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Ensures that the confirmatory testing facility will accept the agent | Yes  No |
|  | 1. Keeps a record of that acceptance? | Yes  No |
|  | 1. Notifies the receiving facility of the shipment details at the time of shipment? | Yes  No |
|  | 1. If the shipment is lost in transit – immediately informs Health and Aged Care once aware of the loss? | Yes  No |
|  | 1. If the shipment is reported unsuccessful by the receiving facility – immediately informs Health and Aged Care once aware of the unsuccessful transfer? | Yes  No |
| Comments: | | |

### 9.3.2 Transport requirements for a receiving facility

|  |  |  |
| --- | --- | --- |
| 9.3.2 | If the entity is receiving suspected SSBAs, does it ensure the receiving facility: |  |
|  | 1. Verifies that the transfer was successful; including that:    1. the complete shipment was received? | Yes  No |
|  | * 1. there was no tampering evident on the shipping container? | Yes  No |
|  | 1. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? | Yes  No |
|  | 1. 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  No |
| 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?  *Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.* | Yes  No N/A  (no destruction after to confirmatory testing) |
| 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: | | |
| 9.6b | Unless otherwise specified in the SSBA Standards, are records relating to suspected SSBAs maintained for a minimum of |  |
|  | 1. 12 months for agents suspected to be Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 6 months for agents suspected to be Tier 2 SSBAs? | Yes  No N/A  (no Tier 2) |
|  | *Note: records do not need to be kept if confirmatory testing shows that the agent is not an SSBA.* |  |
| 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  No |
| 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  No |
| Comments: | | |
| P9c | Does decontamination take place as soon as possible after the waste is generated? | Yes  No |
| Comments: | | |
| P9d | If waste is disposed of outside the facility through a waste disposal company, does the entity: |  |
|  | 1. Move waste to the disposal point as close as practical to the time of pickup? | Yes  No |
|  | 1. Have arrangements to ensure destruction will take place as soon as possible after the waste arrives at the treatment facility? | Yes  No |
| 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 SSBAs 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

### 9A3.1 Transport requirements for a sending facility

|  |  |  |
| --- | --- | --- |
| 9A.3.1 | If the entity is sending confirmed SSBAs, does it ensure that the sending facility: |  |
|  | 1. Has documented policies and procedures in place to ensure compliance with Commonwealth, state and territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Ensures that the receiving facility will accept the agent | Yes  No |
|  | 1. Keeps a record of that acceptance? | Yes  No |
|  | 1. Notifies the receiving facility of the shipment details at the time of shipment? | Yes  No |
|  | 1. If the shipment is lost in transit – immediately informs Health and Aged Care and state/territory police once aware of the loss? | Yes  No |
|  | 1. If the shipment is reported unsuccessful by the receiving facility–immediately informs Health and Aged Care and state/territory police once aware of the unsuccessful transfer? | Yes  No |
| Comments: | | |

### 9A.3.2 Transport for a receiving facility

|  |  |  |
| --- | --- | --- |
| 9A.3.2 | If the entity is receiving confirmed SSBAs, does it ensure the receiving facility: |  |
|  | 1. Verifies that the transfer was successful; including that:    1. the complete shipment was received? | Yes  No |
|  | * 1. there was no tampering evident on the shipping container? | Yes  No |
|  | 1. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? | Yes  No |
|  | 1. 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  No |
| 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?  *Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.* | Yes  No N/A  (SSBA not destroyed) |
| 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 SSBAs maintained for a minimum of |  |
|  | 1. 12 months for Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 6 months for Tier 2 SSBAs? | 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: |  |
|  | 1. Has documented policies and procedures in place to ensure compliance with Commonwealth, state and territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Ensures that the receiving facility will accept the agent | Yes  No |
|  | 1. Keeps a record of that acceptance? | Yes  No |
|  | 1. Notifies the receiving facility of the shipment details at the time of shipment? | Yes  No |
|  | 1. If the shipment is lost in transit – immediately informs Health and Aged Care and state/territory police once aware of the loss? | Yes  No |
|  | 1. If the shipment is reported unsuccessful by the receiving facility–immediately informs Health and Aged Care and state/territory police once aware of the unsuccessful transfer? | Yes  No |
| Comments: | | |

### 10.3.2 Transport for a receiving facility

|  |  |  |
| --- | --- | --- |
| 10.3.2 | If the entity is receiving confirmed SSBAs, does it ensure the receiving facility: |  |
|  | 1. Verifies that the transfer was successful; including that:    1. the complete shipment was received? | Yes  No |
|  | * 1. there was no tampering evident on the shipping container? | Yes  No |
|  | 1. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? | Yes  No |
|  | 1. 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  No |
| Comments: | | |

## 10.4 Destruction

|  |  |  |
| --- | --- | --- |
| 10.4a | 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?  *Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.* | Yes  No N/A  (SSBA not destroyed) |
| Comments: | | |

## 10.5 Waste disposal

|  |  |  |
| --- | --- | --- |
| 10.5a | 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: | | |
| 10.6b | Are records relating to SSBAs handled under Part 10 of the SSBA Standards maintained for a minimum of |  |
|  | 1. 12 months for Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 6 months for Tier 2 SSBAs? | 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 SSBAs in your facility.

|  |  |  |
| --- | --- | --- |
| P10a | Does the entity send confirmed SSBAs 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 SSBAs, does it ensure that the sending facility: |  |
|  | 1. Has documented policies and procedures in place to ensure compliance with Commonwealth, state and territory legislation governing the transport of biological agents? | Yes  No |
|  | 1. Ensures that the receiving facility will accept the agent | Yes  No |
|  | 1. Keeps a record of that acceptance? | Yes  No |
|  | 1. Notifies the receiving facility of the shipment details at the time of shipment? | Yes  No |
|  | 1. If the shipment is lost in transit – immediately informs Health and Aged Care and state/territory police once aware of the loss? | Yes  No |
|  | 1. If the shipment is reported unsuccessful by the receiving facility–immediately informs Health and Aged Care and state/territory police once aware of the unsuccessful transfer? | Yes  No |
| Comments: | | |

### 11.3.2 Transport for a receiving facility

|  |  |  |
| --- | --- | --- |
| 11.3.2 | If the registered entity is receiving confirmed SSBAs, does it ensure the receiving facility: |  |
|  | 1. Verifies that the transfer was successful; including that:    1. the complete shipment was received? | Yes  No |
|  | * 1. there was no tampering evident on the shipping container? | Yes  No |
|  | 1. Notifies the sending facility of the receipt of the shipment and if the transfer has been successful? | Yes  No |
|  | 1. 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  No |
| Comments: | | |

## 11.4 Destruction

|  |  |  |
| --- | --- | --- |
| 11.4a | 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?  *Note: disposal means either complete destruction/deactivation or transfer of all of the SSBA.* | Yes  No N/A  (SSBA not destroyed) |
| Comments: | | |

## 11.5 Waste disposal

|  |  |  |
| --- | --- | --- |
| 11.5a | 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 SSBAs handled under Part 11 of the SSBA Standards maintained for a minimum of |  |
|  | 1. 12 months for Tier 1 SSBAs? | Yes  No N/A  (no Tier 1) |
|  | 1. 6 months for Tier 2 SSBAs? | 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 and Aged Care are met.

|  |  |  |
| --- | --- | --- |
| **Ra** | Does the entity have documented policies and procedures to ensure that the mandatory time frames for reporting to Health are met?  *Note: The timeframes for reporting to Health and Aged Care are set out in the NHS Act, NHS Regulations and Standards. For all reportable events, this timeframe is 2 business days.* | Yes  No |
| 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 and Aged Care? | Yes  No |
| Comments: | | |
| **Re** | What policies and procedures are in place regarding storage of reportable event reports? |  |
|  | 1. Where are they stored? |  |
|  | 1. Hard copy or *electronic* storage? |  |
|  | 1. Who can *access*? |  |
| Comments: | | |
| **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 SSBAs set by the entity?  *Note: Non- compliances should be recorded in* [*Table 2*](#_Table_2_–) *below* | Yes  No |
| 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?  *Record details in* [*Table 1*](#_Table_1_–) *below.* | Yes  No |
| Comments: | | |
| **ORb** | Are there any areas of non-compliance with the internal policies set by the entity in regards to SSBAs?  *Record details in* [*Table 2*](#_Table_2_–) *below.* | Yes  No |
| Comments: | | |

## Actions to address non-compliance

### Table 1 – Non-compliance with the SSBA Standards

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SSBA Standards clause number** | **Information about the non-compliance** | **Actions to rectify** | **Timeframe for action** | **Responsibility for action** |
|  |  |  |  |  |
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|  |  |  |  |  |

Comments:

### Table 2 – Non-compliance with internal policies

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Policy** | **Information about the non-compliance** | **Actions to rectify** | **Timeframe for action** | **Responsibility for action** |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |

Comments:

## Further improvements

|  |  |  |
| --- | --- | --- |
|  | Are there any areas of potential improvement?  What are they? | Yes  No |
| 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.

### 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;
* 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 and Aged Care 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. Please check our website for the [latest version of these documents](https://www.health.gov.au/initiatives-and-programs/ssba-regulatory-scheme/resources#resource-collections).

## 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](mailto:ssba@health.gov.au_).

1. Please note that *Part 1 – Scope and Definitions* of the SSBA Standards is not covered by this document. [↑](#footnote-ref-2)