



Security Sensitive Biological Agents Regulatory Scheme

SSBA – Fact sheet 17 – Changes to the National Health Security Legislation

June 2013

The changes to the *National Health Security Act 2007*, the National Health Security Regulations 2008 and the SSBA Standards have been made to reduce regulatory burden and increase the flexibility of the legislation when responding to certain events.

For an updated version of the NHS Act and Regulations, please refer to (www.legislation.gov.au). An updated version of the SSBA Standards is available from the SSBA website at (www.health.gov.au/ssba).

National Health Security Act (NHS Act)

The amendments to the NHS Act introduce greater flexibility to better manage the security risk associated with handling SSBAs.

Temporary handlings

New requirements have been added for facilities that may only handle known SSBAs on a temporary basis (less than seven working days). The new requirements of the Act include reporting to DoHA, disposal requirements and when to report to law enforcement. New SSBA Standards have also been drafted for these amendments.

Note: These new requirements do not affect the handling of suspected SSBAs, including when an entity receives a positive confirmatory test result from a previously suspected SSBA. These samples should continue to be handled under Division 4A of the NHS Act and Parts 9 and 9A of the SSBA Standards.

Facilities undergoing emergency maintenance or in the process of addressing corrective action requests

The secure handling of SSBAs may be vulnerable during times of emergency maintenance or when an inspection has revealed a non-compliance with the SSBA Standards. New measures ensure that DoHA has powers to impose conditions on entities proportionate to security risk, which ensures that the security of SSBA handlings are maintained until business as usual is re-established.

Suspected SSBAs

Other changes in the NHS Act relate to the regulation of agents suspected to be SSBAs and ensure that complete reporting information is included on the National Register of SSBAs. The changes include:

- ensuring that handling particulars are included on the National Register;
- requiring initial testers which are registered entities to report all (positive and negative) results of confirmatory testing; and
- ensuring that exempt entities are not subject to the requirements of handling suspected SSBAs. This will harmonise with the exemptions for reporting requirements for known SSBAs.

NHS Regulations

Following the amendments to the NHS Act, a number of changes were made to the NHS Regulations. These changes include:

- removal of regular reporting requirements (annual and biennial reports), including 'Nil' reporting. Any alterations to the entity contact details now must be reported at the time of occurrence and within two business days. A new administrative details form will be available on the SSBA website and through the DCS to report these changes.
- addition of requirements for reporting unauthorised access to an SSBA that is being handled temporarily under the new 'temporary handling' provisions.

SSBA Standards

Following the amendments to the NHS Act and the NHS Regulations, the SSBA Standards were updated to include standards relating to the changes and to address comments made by our stakeholders.

New Clauses under existing Parts

The SSBA Standards contain a number of new clauses (outlined below).

Stand alone facilities (Clause 4.2.1)

This new provision deals with a facility where all four walls of the secure perimeter are accessible from the outside (i.e. not surrounded by or connected to any other buildings). Additional perimeter security measures have been added to enhance security at these sites.

Providing sensitive information to other regulatory authorities (Clause 5.3.1)

New provisions are in place regarding the supply of sensitive information (for example as evidence of compliance with another regulatory scheme) to other regulatory authorities such as the Office of the Gene Technology Regulator or the Department of Agriculture, Fisheries and Forestry.

Transport of an SSBA from a receiving area to a registered facility (Clause 6.5)

These provisions relate to the movement of an SSBA from a receiving area, such as a reception desk, to a registered facility. This clause permits transport to the facility by non-authorized persons and imposes certain conditions on the transport, such as who can transport the material, what records must be kept and a requirement for the transport to be covered by the entity's risk assessment.

New standards for temporary handlings (less than 7 working days).

A non-registered entity handling an SSBA on a temporary basis (New Part 10)

These requirements apply when a non-registered entity receives a known SSBA (i.e. one that has **already** been confirmed as an SSBA).

These requirements cease to apply upon disposal of the SSBA. The NHS Act states that disposal under the temporary handling provisions must occur within seven business days of receipt of the agent.

It should be noted that these requirements do not apply to an entity, acting as an initial tester that has received a positive confirmatory testing result for a previously suspected SSBA. These SSBAs must be handled under Part 9A of the SSBA Standards.

A registered entity handling an SSBA on a temporary basis (New Part 11)

These requirements apply when a registered entity commences handling a known SSBA, that it is not registered for, on a temporary basis.

In situations where a registered entity is not registered to handle the SSBA (either the SSBA itself or the facility is not registered to handle any SSBAs, Part 11 of the SSBA Standards applies to the handling rather than Parts 2 – 8 of the Standards.

These requirements cease to apply upon disposal of the SSBA. Under the NHS Act, disposal under the temporary handling provisions must occur within seven business days of receipt of the agent. If the entity wishes to continue handling beyond 7 working days, it must register to handle the SSBA.

It should be noted that these requirements do not apply to an entity, acting as an initial tester that has received a positive confirmatory testing result for a previously suspected SSBA. These SSBAs must be handled under Part 9A of the SSBA Standards.

Significant changes to the SSBA Standards

In addition to the new clauses, a number of significant changes have been made to the SSBA Standards. These changes include:

- addition of paragraph numbers to the normative requirements. This will assist when undergoing inspections as it will be easier to pinpoint issues being discussed.
- new commentary under the SSBA Management Committee to reflect Terms of reference.
- breaking down a number of clauses into subclauses including:
 - NHS Checks – the transfer of NHS checks between entities is now a separate subclause.
 - Training and Competency - Training for authorised persons and competency levels are now new subclauses.
 - Storage – this has been broken down into new subclauses to improve clarity.
- changes to the Risk Assessment and Risk Management clauses. Material from clause 2.2.3 has now been moved into clause 2.2.2 to make it clearer what needs to be assessed as a hazard or risk.

Minor changes

A number of minor wording changes have been introduced to increase clarity on the requirements of the SSBA Standards. These include more information on what is required to be documented under the Standards.