Australian Centre for Disease Control

Security Sensitive Biological Agents Regulatory Scheme

SSBA – Guideline 3 – Handling a person or animal, or samples from a person or animal, affected by an SSBA

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Introduction

This guideline provides information to help interpret the *National Health Security Regulations 2018* (NHS Regulations) when handling a person or animal or samples from a person or animal, affected by a security sensitive biological agent (SSBA). It is a guideline only and is provided to assist in understanding the SSBA Regulatory Scheme.

Legislation

Inadvertent possession of a SSBA, for example a person affected by an SSBA, is not intended to be covered by the SSBA Regulatory Scheme. The NHS Regulations prescribe the exemptions for people or animals affected by an SSBA, and outline when handling them or their samples is exempt under the *National Health Security Act 2007* (NHS Act). Details of the exemptions are provided below.

1. The NHS Regulations prescribe that a person who is affected by an SSBA is an exempt entity.
2. The NHS Regulations also exempt an entity if:
    a. the entity destroys an animal that is affected by an SSBA;
    b. the entity's destruction of the animal is carried out because the animal is affected by an SSBA;
    c. the entity provides treatment to a person or animal that is affected by an SSBA; and
    d. the entity handles an SSBA:
        i. while the SSBA is in the body of the person or animal; or
        ii. while taking a sample from the person or animal for the purposes of the treatment.

The following scenarios illustrate the application of the NHS Regulations:

Treatment of a person who is affected by an SSBA

The NHS Regulations exempt both a person who is affected by an SSBA and any other person or entity treating the person affected by an SSBA, such as a doctor, nurse, hospital or clinic, from the requirements of the SSBA Regulatory Scheme. These entities and persons are exempt **only** if they handle the SSBA while it is in the body of the person (or normal human and clinical waste for disposal) or during the taking of samples from the body of the person for the purposes of treatment. Samples may include tissue, bodily wastes or fluids such as faeces, vomitus, blood, etc.

This exemption **does not** apply to:

- handling samples once they are sent to a pathology laboratory for diagnostic testing; or
- taking samples from an affected person where the purpose is other than treatment, for example taking samples for research.

Note: the NHS Regulations prescribe that if '*a person becomes affected by an SSBA as a result of the entity's handling of an SSBA at the facility*', it is a reportable event and must be reported to the Australian Centre for Disease Control (CDC) For more information about reporting see *Guideline 2 – Registered Facility Reporting Requirements*.

Handling Animals affected by an SSBA

The NHS Regulations exempt an entity or person, such as a veterinarian or wildlife officer, who provides treatment to an animal affected by an SSBA. Again, this is **only** while the SSBA is in the body of the animal (or normal animal or clinical waste for disposal) or during the taking of samples from the body of the animal for the purposes of treatment.

This exemption **does not** apply to:

- the deliberate inoculation of animals with an SSBA (however, an entity is exempt when it conducts a test on mice for the presence of botulinum toxin);
- handling samples once they are sent to a diagnostic laboratory for testing; or
- taking samples from an affected animal where the purpose is other than treatment, for example taking samples for research.

Handling Samples from Persons or Animals affected by an SSBA

After a sample has been taken from the body of a person or animal affected by an SSBA it is no longer covered by the exemptions under the NHS Regulations. The handling of diagnostic samples containing an SSBA is subject to the requirements of the NHS Act, the NHS Regulations and the SSBA Standards.

When is a diagnostic sample considered to contain an SSBA and how should the sample be handled?

If a sample is tested in a laboratory and the initial tester forms a reasonable suspicion that the sample contains an SSBA, the sample is considered a suspected SSBA, therefore, Part 9 of the SSBA Standards apply. The NHS Act and Regulations require the initial tester to arrange for confirmatory testing or to destroy a suspected SSBA within two business days of forming the initial suspicion. Where further testing **confirms** the presence of an SSBA, the sample must be handled according to the requirements of the NHS Act, the NHS Regulations and Part 9A of the SSBA Standards. If the entity intends to retain the confirmed SSBA beyond the prescribed handling period, then the entity must register to handle the SSBA and comply with the appropriate parts of the legislation.

Without appropriate diagnostic testing for the presence of the SSBA it is not certain that any sample taken from a person or animal affected by an SSBA will contain that SSBA. However, entities handling samples where there is **a strong probability that they contain an SSBA** should handle the samples according to the requirements of the NHS Act, the NHS Regulations and the SSBA Standards.

For example:

- where a sample that is tested and shown to contain an SSBA is an aliquot or part of a larger sample, then all aliquots or parts of that larger sample could reasonably be considered to contain the SSBA; or
- where a sample of blood from the person or animal is shown to contain an SSBA, then all other samples of blood drawn at the same time could reasonably be considered to contain the SSBA.

In the course of diagnostic testing if an SSBA is rendered inactive, non-viable or non-pathogenic, then it no longer meets the definition of an SSBA as per note 1 to the List of SSBAs (please refer to *Fact Sheet 5 - List of SSBAs*).

Reporting requirements

Non-registered facilities should report handling of SSBAs on the *Non-Registered Facility Report for Suspected SSBAs or the Outcome of Confirmatory Testing* or the *Temporary Handling Report* (if the SSBA has been confirmed previously). The facility must report the initial isolation of each SSBA. Subsequent isolations of the same SSBA from the same patient during the same occurrence do not need to be reported to the Australian CDC. The facility must comply with the requirements of the SSBA Standards for all handlings of SSBAs.

Note: For this purpose “occurrence” is taken to mean each occasion a patient or animal affected by an SSBA presents to a medical or veterinary facility.

Facilities that are **registered** to handle the SSBA do not need to report when any additional samples of the SSBA are handled. Registered facilities that start to handle an SSBA for which they are not registered should refer to *Guideline 2 – Registered Facility Reporting Requirements* for further information on handling and reporting requirements.

NOTE: if there is an outbreak of an SSBA in animals, please contact the SSBA Regulatory Scheme to discuss the reporting requirements.