Guideline 3
HANDLING A PERSON OR ANIMAL, OR SAMPLES FROM A PERSON OR ANIMAL, AFFECTED BY AN SSBA

INTRODUCTION

This guideline provides information to entities, facilities and individuals to help interpret the NHS Regulations when handling samples from a person or animal affected by an SSBA. It is a guideline only and is provided to assist in understanding the SSBA Regulatory Scheme.

Inadvertent possession of a security sensitive biological agent (SSBA), for example, a person affected by an SSBA, is not intended to be covered by the SSBA Regulatory Scheme. The National Health Security Regulations 2008 (NHS Regulations) prescribe specific exemptions for people or animals affected by an SSBA, as well as prescribing certain circumstances where handling a person or animal or samples taken from a person or animal affected by an SSBA is exempt under the National Health Security Act 2007 (NHS Act).

LEGISLATION

The NHS Regulations prescribe that a person who is affected by an SSBA is an exempt entity.

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 here would 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, research.

Note also that the NHS Regulations prescribe as a reportable event, when ‘a person becomes affected by an SSBA as a result of the entity’s handling of an SSBA at the facility’, and must be reported to the Department of Health and Ageing (DoHA). 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, 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. 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 Parts 2–8 of the SSBA Standards.

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).

Special Note on Salmonella Typhi

Salmonella Typhi is an SSBA that is encountered in clinical diagnostic laboratories and this special note has been prepared to provide additional guidance on the handling of samples from patients infected with this bacterium.

The concentration of circulating S.Typhi bacteria in the blood of patients with typhoid fever, even those patients with a positive blood culture, is generally very low – typically less than 15 bacteria per mL. There is a low probability of significant quantities of viable S.Typhi in blood samples collected for diagnostic testing, other than those collected in enrichment media for blood cultures. Storage of blood samples at or below 4 °C when not in use will limit bacterial replication and the risk of S.Typhi being present in significant quantities.

Diagnostic samples, other than blood cultures and stool specimens, from patients with active typhoid fever do not need to be handled as SSBAs unless the entity is of the opinion that there is a strong probability of the sample containing the SSBA. Blood cultures and stool specimens from convalescing patients with a history of typhoid fever, even those patients with a positive blood culture, are also not generally considered to contain SSBAs, unless the entity is of the opinion that there is a strong probability of the sample containing the SSBA.

fever do not need to be handled as SSBAs until a laboratory test detects the presence of S.Typhi. This also applies to samples taken from chronic S.Typhi carriers.

**Reporting requirements**

**Non-registered** facilities should report handling of SSBAs on the Non-Registered Facility Report. 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 DoHA. The facility must still 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 DoHA to discuss the reporting requirements.

For more information, see the link to the NHS Act and the NHS Regulations on www.health.gov.au/ssba or contact DoHA on ssba@health.gov.au.