



## Security Sensitive Biological Agents Regulatory Scheme

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# SSBA – Fact sheet 16 – Dealing with emergency situations

September 2013

In 2013 new provisions were added to the *National Health Security Act 2007* (NHS Act) relating to entities that may need to undertake emergency maintenance in one of their facilities. Emergency maintenance is defined as unscheduled or unplanned repairs or maintenance to the facility that significantly impacts the secure handling of the SSBA. An entity that needs to undertake emergency maintenance must report the arrangements, including timeframes and proposed security measures to the SSBA Regulatory Scheme.

Under these provisions the Secretary of the Department of Health has the capacity to suspend some or all regulatory requirements including application of the relevant areas of the SSBA Standards, if required during the maintenance period. The changes also allow for the Secretary to impose handling conditions to ensure the security of the SSBA during maintenance activities.

## Temporary arrangements

Under these new provisions it may be possible to make temporary arrangements for the secure storage of the SSBA until a permanent arrangement can be made. The entity must report the temporary storage and security arrangements by completing an Incident Report form as soon as possible and within two business days of the event occurring.

Following this report, the Secretary may impose conditions on the handling of the SSBA. These conditions may include:

- a direction to the entity not to handle the SSBA for any purpose other than to store the SSBA
- a condition that if the repairs are not completed within a certain timeframe, the SSBA must be moved to a registered facility
- restriction of access to the SSBA including a requirement to record access to the temporary storage area including the identity of the person and the date and time of access; and
- conditions to ensure that the SSBA is stored securely;
- conditions on the transfer the SSBA and transfer records;
- a requirement for the entity to consider the risk associated with the temporary storage arrangement; and

- requirements to maintain records relating to the temporary arrangements in accordance with Part 5 of the SSBA Standards.

If conditions are applied and these are breached, an offence may apply

## Long term arrangements

If the emergency maintenance is unable to be completed within a timeframe agreed to by the Department of Health (Health), other arrangements for the long term handling of the SSBA may need to be arranged. These arrangements include:

## Register a new facility

- Ensure that the proposed new facility complies with the requirements of the SSBA Standards; and
- Complete an *Initial Registration* application form within two business days of starting to handle (including storage) in the facility; and
- Transfer the SSBA following Part 6 of the SSBA Standards; and
- Report the *Transfer Out* of the SSBA from the current facility within two business days of the transfers occurring.

## Register a linked storage unit (Tier 2 SSBAs only)

- Ensure that the proposed storage unit complies with the linked storage requirements of the SSBA Standards (Part 4A); and
- Complete a *Registration of a Linked Storage Unit* form within two business days of starting to handle the SSBA; and
- Transfer the SSBA following Part 6 of the SSBA Standards; and
- Record the transfer of the SSBA from the current facility into the new linked storage unit. The transfer does not need to be reported to Health, but a record must be maintained by the facility.

## Transfer the SSBA to another facility

- Comply with the requirements of Part 6 of the SSBA Standards, including:
  - ensuring that the transport agent has policies and procedures in place to ensure compliance with Australian Government, State and Territory legislation governing the transport of biological agents;
  - ensuring that the receiving facility will accept the shipment.
- Notify the receiving facility of the shipment details.
- Report the transfer of the SSBA using the *Transfer Out* report within two business days.