

SSBA NEWSLETTER

Issue 22 - May 2014

Changes to SSBA Reporting

In 2013, the SSBA Regulatory Scheme made changes to the National Health Security Act removing the need for annual and biannual reporting and introducing Temporary Handling provisions for entities that have a requirement to handle known SSBAs for less than 7 working days.

To reflect these changes, new reporting forms are now available in the Data Collection System and in hard copy form on our website:

- **Change of Entity and Facility Details.** This form replaces the Annual and Biannual reports for Registered facilities. Any changes to the entity and facility administrative details must now be reported to the SSBA Regulatory Scheme within two business days of the change.
- **Temporary Handling or Disposal of a known SSBA.** These new forms are for reporting the receipt and temporary handling of a known SSBA that you are not registered for and that was previously confirmed by another facility and transferred to your laboratory. The form can also be used to report the disposal of the SSBA at the end of the temporary handling period. There are separate forms available for registered and non-registered facilities.
- **Suspected SSBAs and Confirmatory Testing Results.** These forms have been modified to remove the reporting of handling a known SSBA received from another facility and will now be used to only report the **receipt of a suspected SSBA** and the **outcome of any confirmatory testing**. There are separate forms available for registered and non-registered facilities.

If you are experiencing any issues with reporting please contact us by e-mail at ssba@health.gov.au or by phone on 02 6289 7477
The helpdesk is available Monday to Friday, 9 am to 5pm.

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Reporting timeframes

New Reports	1	The introduction of the Temporary Handling provisions of the NHS Act have introduced a new timeframe for reporting.
Reporting Timeframes	1	Entities handling a known SSBA (i.e. one that was previously confirmed in another facility prior to transfer to your laboratory) can handle this SSBA for up to 7 working days. After this period, you must either dispose of the SSBA, or, if you intend to continue to handle it, register the SSBA with the SSBA Regulatory Scheme.
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New Publications	2	It should be noted that this 7 day working period does not apply to an SSBA that was initially transferred to your facility as a suspected SSBA and has subsequently been confirmed by confirmatory testing. In this case, you must continue to report the suspected SSBA within two days of receipt and arrange for confirmatory testing. You must then report the outcome of the confirmatory test and dispose of the SSBA, or register to handle the SSBA, within two business days of receipt of the confirmatory testing results.
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For more information check out our web site: www.health.gov.au/SSBA

Non-Registered Facilities and the Storage of SSBA's

The SSBA Standards require that suspected or confirmed SSBA's are stored securely. This includes a requirement to restrict and record access to the SSBA. For non-registered facilities these requirements are set out in Parts 9, 9A and 10 of the SSBA Standards.

The access controls and the recording of access should be at the last barrier to the SSBA. For example, if the SSBA is kept in an unlocked box in a freezer,

then the access control should be at the freezer door. If the box is able to be locked and secured to the freezer, the access controls / recording of access can then be at the box itself.

If the agent is to be stored in the open in the general laboratory, then any access controls must be on the laboratory entry points. It is not sufficient to 'hide in plain sight' for the purposes of the SSBA Standards.

Secure storage is required for all suspected and confirmed SSBA's

Updated Publications

The following publications have been updated to reflect the legislative changes made in 2013.

Fact Sheets

- Fact Sheet 03 - Legislative Framework
- Fact Sheet 04 - Exemptions
- Fact Sheet 06 - Management Committees
- Fact Sheet 10 - Information Security
- Fact Sheet 11 - Upgrading from Tier 2 to Tier 1
- Fact Sheet 16 - Emergency Maintenance

Guidelines

- Guideline 01 - Entities and Facilities
- Guideline 02 - Registered Facility Reporting Requirements
- Guideline 09 - Non-Registered Facility Reporting Requirements
- Guideline 10 - SSBA Monitoring Inspections

Did you know? Spot checks

Spot checks are a subset of routine monitoring and can be conducted at any time on registered or non-registered facilities.

A spot check may be conducted as part of a follow-up review or it may be conducted in response to information received by the SSBA Regulatory Scheme about potential SSBA handlings.

Spot checks comprise:

- Liaison with the Responsible Officer, Deputy Responsible Officer or Contact Officer. At least

- Guideline 11 - SSBA's and Other Regulatory Schemes

Guidelines 2 and 9 also have updated flow charts on the reporting process, including the addition of the reporting processes for the new Temporary Handlings and Administrative Changes reports.

Internal Review Tool

The IRT has been updated to reflect the changes made to the SSBA Standards, and includes two new sections relating to the new temporary handling provisions.

A new section on reporting has also been added to assist entities in determining if they are meeting the reporting requirements of the SSBA Regulatory Scheme.

24 hours notice will be provided to assist with provision of any security arrangements associated with inspectors being on site.

- A physical inspection of the facility and discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests.
- A follow up inspection may be undertaken depending on the actions required.

More information about spot checks can be found in Guideline 10 - SSBA Monitoring Inspections.