Australian Centre for Disease Control

Security Sensitive Biological Agents Regulatory Scheme

# SSBA – Guideline 10 – Monitoring inspections

January 2026

## Introduction

All facilities handling security sensitive biological agents (SSBAs) or biological agents suspected of being SSBAs are subject to inspections under the SSBA Regulatory Scheme. The main aim of inspections is to monitor an entity's or a facility's compliance with the *National Health Security Act 2007* (NHS Act), the *National Health Security Regulations 2018* (NHS Regulations) and the SSBA Standards. Inspections also provide opportunities to increase compliance with the NHS Act through communication, education, and the provision of advice.

This guideline provides information to assist entities and facilities in preparing for monitoring inspections under the SSBA Regulatory Scheme.

## Inspectors

The Office of the Gene Technology Regulator provides inspectors for the SSBA Regulatory Scheme. Each inspector has been provided with an SSBA Regulatory Scheme inspector identification card, and entities and facilities should ask to sight this card prior to the inspection.

The NHS Act provides the necessary monitoring powers for the SSBA Inspectors including, where necessary, powers to search premises and seize evidential material under offence based warrants. Inspections are generally undertaken with the consent of the entity and focus on achieving compliance with the requirements of the SSBA Regulatory Scheme through a co-operative approach.

## Type of inspections

All SSBA Inspection Program activities are conducted free of charge.

A guide to the type of inspection activities undertaken by the SSBA Regulatory Scheme is described below. Please note that this is indicative only, as each inspection plan is tailored to the specific requirements of the facility, staff availability and any pre-existing issues.

# Comprehensive inspections

Comprehensive inspections are an in-depth inspection covering all requirements of the SSBA Regulatory Scheme. The purpose of a comprehensive inspection is to determine a facility's compliance with the NHS Act, NHS Regulations and SSBA Standards. This inspection may take up to two days and consists of a pre-inspection analysis of documents, on-site activities (physical inspection of the facility, interviews with personnel and review of records) and post-inspection follow up review.

Comprehensive inspections comprise:

- Liaison with the Responsible Officer or Deputy Responsible Officer four to six weeks prior to the inspection.
- A pre-inspection analysis of documentation supplied by the facility. Documents supplied as part of this review must be sent by registered post to the Inspectors **at least** 14 days prior to the inspection date. The Inspectors will inform the facility exactly which documents will be required.
- A physical inspection of the facility which includes discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow-up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical comprehensive inspection plan

Day 1:

- Explanation of the inspection process.
- Discussion of any problems experienced with the scheme.
- Discussion of preliminary findings from the document review.
- Discussion of any previous corrective action requests.
- Discussion of each part of the SSBA Standards.
- Sampling of records and interviews with personnel.
- Inspection of facility, if time permits.

Day 2:

- Inspection of facility, if not done previous day.
- Review of findings (inspectors may hold private meeting).
- Exit meeting, includes presentation of preliminary findings of inspection.

# Mid-cycle inspections

Mid-cycle inspections are generally held over one to one and a half days and focus on new or changed entity/facility documentation, amendments to the SSBA legislation or changes to other SSBA Regulatory Scheme processes. This inspection consists of a pre-inspection analysis of documents, physical inspection and post-inspection follow up.

Mid-cycle inspections are conducted in between comprehensive inspections of registered facilities.

Mid-cycle inspections comprise:

- Liaison with the Responsible Officer or Deputy Responsible Officer four to six weeks prior to the inspection.
- A pre-inspection analysis of documentation supplied by the facility. Documents supplied as part of this review must be sent by registered post to the Inspectors **at least** 14 days prior to the inspection date. The Inspectors will inform the facility exactly which documents will be required.
- A physical inspection of the facility which includes discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow-up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical mid-cycle inspection plan

Day 1:

- Explanation of the inspection process.
- Discussion of preliminary findings from the document review and previously identified corrective actions.
- Discussion of relevant parts of the SSBA Standards.
- Sampling of records.
- Inspection of facility (if necessary).
- Review of findings (inspectors may hold a private meeting).
- Exit meeting with presentation of preliminary findings of inspection.

# Non-registered facility inspections

Non-Registered Facility inspections are held over half a day and focus on Parts 9, 9A and 10 of the SSBA Standards, facility documentation, and other SSBA Regulatory Scheme processes such as reporting. This inspection consists of a physical inspection and post-inspection follow up.

Non-registered facility inspections comprise:

- Liaison with the Contact Officer.
- A physical inspection of the facility which includes a review of paper-based records and discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow-up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical non-registered facility inspection plan

Half day:

- Explanation of the inspection process.
- Discussion of any problems experienced with the scheme.
- Discussion of the relevant parts of the SSBA Standards (Parts 9, 9A and 10).
- Sampling of records.
- Inspection of facility (if necessary).
- Review of findings (inspectors will privately discuss).
- Exit meeting with presentation of preliminary findings of inspection.

# Follow-up inspections

Follow-up inspections focus on specific issues or check on the implementation of remedial action as a result of a previous inspection. Follow-up inspections are primarily paper-based reviews that could span one or two days depending on the nature of the remedial action required.

Follow-up inspections comprise:

- Liaison with the Responsible or Deputy Responsible Officer or Contact Officer.
- A physical inspection of the facility which includes a review of paper-based records and discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical follow-up inspection plan

Day 1:

- Explanation of the inspection process.
- Discussion of relevant parts of the SSBA Standards.
- Sampling of records.
- Inspection of facility (if necessary).
- Review of findings (inspectors will privately discuss).
- Exit meeting with presentation of preliminary findings of inspection.

# Desktop inspections

Desktop Inspections are a paper-based assessment of a facility's compliance with the SSBA Standards and require no on-site assessment of activities.

A Desktop Inspection could be conducted on registered or non-registered facilities and may include an assessment against:

- the entire SSBA Standards; or
- a specific Part of the SSBA Standards; or

- a specific Clause of the SSBA Standards; or
- a specific area of regulatory compliance such as reporting.

Desktop inspections comprise:

- Liaison with the Responsible Officer, Deputy Responsible Officer or Contact Officer.
- A review of paper-based records supplied by the facility.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests.
- If required, a follow-up inspection that reviews paper-based evidence supplied by the facility (refer to *Post Inspection* for further information).

## Typical desktop inspection plan

No onsite visit:

- Facility provides paper-based records to inspectors based on the focus of the desktop inspection.
- Inspectors review paper-based records.
- Letter provided to facility of desktop inspection findings.
- Follow up on Corrective Action Request, if required.

# Spot checks

Spot checks are a subset of routine monitoring and may also be conducted as part of follow-up reviews and focus on the outcome of previous inspections. This type of inspection can be conducted on registered or non-registered facilities.

Spot checks comprise:

- Liaison with the Responsible Officer, Deputy Responsible Officer or Contact Officer. 24 hours notice will generally be provided to the facility to ensure security arrangements associated with inspectors being on site are met.
- A physical inspection of the facility which includes a review of paper-based records and discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical spot check plan

Day 1 (if required, a second day would include any items not covered on Day 1):

- Explanation of the inspection process.
- Discussion of relevant parts of the SSBA Standards.
- Sampling of records.
- Inspection of facility (if necessary).
- Review of findings (inspectors will privately discuss).
- Exit meeting with presentation of preliminary findings of inspection.

# Audits

Audits are a comprehensive examination of an entity to:

- Verify that an entity has relevant and effective management procedures and practices to meet requirements under the NHS Act;
- Assess whether or not procedures and practices provide mechanisms to identify and resolve emerging risks; and
- Where appropriate suggest improvements to procedures and practices.

Audits comprise:

- Liaison with the Responsible Officer or Deputy Responsible Officer four to six weeks prior to the inspection.
- A pre-inspection analysis of documentation supplied by the facility. Documents supplied as part of the audit must be sent by registered post to the Inspectors **at least** 14 days prior to the inspection date. The Inspectors will inform the facility exactly which documents will be required.
- A physical inspection of the facility which includes discussions with relevant staff.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical audit plan

Pre inspection:

- Facility provides paper-based records to inspectors based on the focus of the desktop inspection.
- Inspectors review paper-based records.

Day 1:

- Explanation of the inspection process.
- Discussion of any problems experienced with the scheme.
- Discussion of preliminary findings from the document review.
- Discussion of each part of the SSBA Standards.

Day 2:

- Inspection of facility, if not done previous day.
- Review of findings (inspectors will privately discuss).
- Exit meeting with presentation of preliminary findings of inspection.

# Formal investigations

Formal investigations are an inquiry into allegations of a breach of the NHS Act, NHS Regulations or SSBA Standards and comprise:

- Liaison with the Responsible Officer or Deputy Responsible Officer.

- A physical on site visit which includes interviews with relevant staff and a review of paper-based records.
- A letter provided to the facility outlining the outcome of the inspection including any Corrective Action Requests and/or Best Practice Recommendations.
- If required, a follow up review will be undertaken post-inspection on any paper-based evidence supplied by the facility in relation to the inspection findings (refer to *Post-Inspection* for further information).

## Typical formal investigation plan

Day 1:

- Explanation of the process.
- Discussion of relevant parts of the SSBA Standards.
- Interviews with relevant staff.
- Reviewing records.
- Inspection of facility (if necessary).
- Review of findings (conducted by the inspectors alone).
- Exit meeting covering preliminary findings.

# Post-inspection

Depending upon availability of documentation at the time of inspection, the entity may be required to provide further information to the Inspectors post-inspection.

Once the inspection, audit or investigation process is complete, the findings will be collated and provided to the relevant Australian Centre for Disease Control (CDC) delegate for review. Following this, a letter of response will be sent to the Responsible Officer for the facility detailing the outcomes of the inspection and may also outline any Corrective Action Requests (CARs) or best practice recommendations that were identified during the inspection. The entity will be given details of the non-compliance, including which clause of the NHS Act, NHS Regulations or SSBA Standards the CAR is against and a timeframe in which the CAR must be met.

The NHS Act specifies what action(s) can be taken in the event of non-compliance including:

- The Australian CDC providing advice on rectifying the non-compliance;
- The Australian CDC directing the entity to dispose of the SSBA/s;
- The Australian CDC directing a particular individual not to handle SSBAs, or to handle the SSBA only after fulfilling specified conditions; and
- an entity being prosecuted for an offence under the NHS Act.

Should the entity wish to discuss the outcome of the inspection, seek further information or does not agree with the findings, the entity may respond with ten days from the receipt of the inspection, audit or investigation letter. Should the entity not respond before the end of this period, the outcome will be considered finalised and any identified CARs must be remediated before the facility can be considered to be compliant with the SSBA Regulatory Scheme requirements.

## Follow-up review

In the letter of response the entity will be given a specified time period in which to remediate the identified CARs and provide written evidence of compliance. Once this evidence is received, a follow up review will be conducted to determine if the CARs have been met. A site visit is not required for the review process.

Once a determination of compliance has been made, a second letter will be sent to the Responsible Officer either stating that the CARs have been met and the inspection is finalised or outlining any outstanding CARs and any further actions that must be taken.