Table 3. Reportable events.

Reportable events
• The entity or facility starts to handle a SSBA that they have not registered on the national register.
• The entity or facility completely destroys its stock of SSBAs.
• The entity or facility falls below the toxin threshold stated in the regulation.
• The entity or facility starts, or ceases to handle, a SSBA that is included on the national register, for a purpose other than that stated on the national register.
• The entity or facility transfers a SSBA that is included on the national register to another entity or facility.
• There is a change in personnel access to the SSBAs.
• A SSBA is lost or stolen
• An authorised person accesses a SSBA.

inspected, reporting, and actions following detection of breaches has not yet been developed. This will be finalised prior to the scheme's implementation to ensure the regulated community understands the inspection regime.

The national authority will be holding an educational roadshow in July 2008, and training for the regulated community in late 2008. The SSBA website will provide up to date information on the development of the SSBA regulatory scheme, including roadshows being held in each jurisdiction.

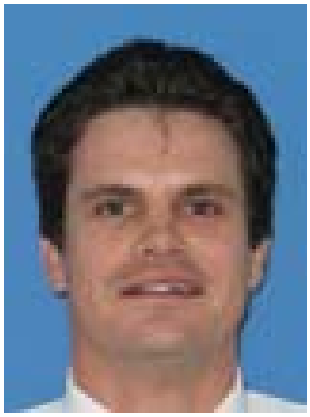
References

1. Available at: www.health.gov.au/ssba

Letitia Toms is a graduate of the University of Canberra having studied medical laboratory science. She has a graduate diploma in public health from the University of Queensland, and has been employed by the Department of Health and Ageing for 9 years. She currently heads the Laboratory Capacity and Regulation Section in the Office of Health Protection.

Dr Gary Lum AM trained in medicine and specialised as a pathologist (microbiologist). He spent 12 years in charge of pathology in the Northern Territory. From 2005 to 2007 he was chair of the Public Health Laboratory Network. Gary is now an Assistant Secretary in the Department of Health and Ageing.

New quarantine criteria for microbiological laboratories



Jeff Cates

Email: Jeff.Cates@aqis.gov.au

The Australian Quarantine Inspection Service (AQIS) has developed new systems to enhance quarantine controls and procedures for containment facilities. AQIS engaged stakeholders throughout the development process to ensure the strengthened requirements would impose a minimal burden on industry while maintaining quarantine integrity.

Laboratories and other facilities registered with AQIS as Class 5 Quarantine Containment (QC) Quarantine Approved Premises (QAPs) will soon need to comply with new criteria to enhance quarantine integrity at Class 5 facilities. More than 750 QC facilities across Australia handle a wide range of materials such as biological products, soil, animal, plant and human products. Most of these facilities are analytical and research laboratories, but there are also a number of premises such as insectaries and facilities that handle live laboratory animals that will also be affected by the changes.

The new system for Class 5 QAPs represents a shift from classification on the basis of type of facility to a classification based on risk level, using joint Australia / New Zealand (AS/NZS) Standards for physical containment. The two Standards being used are the AS/NZS Standard 2982.1.1997 (*Laboratory design and construction*) and AS/NZS Standard 2243.3.2002 (*Safety in laboratories, microbiological aspects and containment facilities*). Where a laboratory meets all the design and construction requirements for physical containment described in these Standards, AQIS will recognise this in the approval process.

Premises approval is also based on general QAP requirements such as isolation and hygiene requirements, waste disposal and operating procedures. These requirements take into account factors such as location, the facilities provided and the level of quarantine risk associated with the activities being undertaken. Standards Australia specifies four levels of containment for facilities in ascending order of stringency of containment QC1 (PC1), QC2 (PC2), QC3 (PC3) and QC4 (PC4). In implementing these new requirements, AQIS is reflecting the graduated levels of quarantine risk posed by the products and activities being undertaken at these facilities. Containment and risk management requirements under these criteria become increasingly stringent as the level of quarantine risk being managed increases.

Facilities that wish to handle higher risk quarantine material, such as QC2, QC3 or QC4 premises, will need to undergo assessment by an AQIS approved third party assessor to certify that the facility meets the relevant components of the required Standards. Assessors will complete an assurance certificate that must be provided by the operator to the nearest AQIS regional approved premises officer. A list of approved third party assessors is available on the AQIS website [1].

To facilitate the introduction of the new system, AQIS has asked Class 5 operators to submit a list of all quarantine material held at their containment facility, using a laboratory QC template available from the AQIS website [2] or from their nearest AQIS approved premises officer. The points below may assist QAP operators in meeting the new requirements.

If you currently hold quarantine material at your Class 5 premises, you'll need to complete the laboratory QC template and email it to the AQIS industry partnerships unit at aqisqap@aqis.gov.au. AQIS will then notify you of the applicable QC level.

Once you've been notified of the applicable QC level, you will be able to identify what actions you need to take. If any material subject to quarantine requires containment at the QC2 to QC4 level, you'll need to arrange for an approved third party assessor to assess your facility at a time that is mutually convenient. Your chosen assessor should be able to provide you with a quotation or an approximate cost for the visit, report and submission of the assessment.

When the assessment is complete, your assessor will discuss it with you and, where applicable, assist you to identify any defects. If there are high level defects, your assessor may be able to indicate how to rectify them; operators will need to complete the appropriate checklist [3] and contact AQIS to discuss a suitable implementation program. Once defects are corrected, you'll need to request a further assessment by your assessor before submitting your third party assessment which will form part of your QAP approval.

AQIS has developed a website that provides an overview of facility and quarantine material assessment procedures to help operators with managing the transition to the new criteria [3].

For more information on the revised criteria and the implementation process, phone:

ACT	(02) 8334 7511
NSW	(02) 8334 7511
NT	(08) 8920 7000
QLD Sth	(07) 3246 8685
QLD Cairns	(07) 4030 7852
QLD Townsville	(07) 4789 7821
SA	(08) 8201 6138
TAS	(03) 6233 2635
VIC	(03) 8318 6945
WA	(08) 9334 1504

References

1. Available at: www.aqis.gov.au/qap
2. Available at: www.aqis.gov.au/qapclass5
3. Available at: www.aqis.gov.au/qapco-location

Jeff Cates has been the project manager for the development of the new criteria for microbiological laboratories.