

Complying with Defence Export Controls: a working perspective



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Abstract. The Royal College of Pathologists (RCPA) and then RCPA Quality Assurance Programs Pty Ltd (RCPAQAP), a company independent from but aligned with the RCPA, have been producing proficiency testing programs (PTP) for infectious diseases for 52 years. This involves sending infectious disease material in surveys to over 80 countries worldwide throughout any year. The PTP panels are developed depending on the prevalence of diseases, which requires flexible panel composition and dynamic enrolments. The Defence Trade Controls Act was introduced in 2012 as part of a wider international regulatory counter-proliferation framework. In 2017, the inclusion of inactivated infectious diseases as controlled microorganisms in the Defence Strategic Goods List (DSGL) had the potential to completely disrupt the RCPAQAP business model in the provision of infectious disease PTP. Some strategies for mitigating this risk are discussed in this paper.

The Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP)

RCPA and then RCPAQAP have been providing proficiency testing programs (PTP) for infectious diseases since 1968 when the RCPAQAP Microbiology program commenced. Since then, two other infectious disease programs have been introduced, Molecular Infectious Diseases (2005) and Biosecurity (2009). The latter is

funded by the Australian Government Department of Health to provide PTP for Security Sensitive Biological Agents (SSBA), other potential agents and disease threats to Australia following the introduction of the SSBA Regulatory Scheme in 2008. In recent years the Biosecurity program has produced PTP in response to the outbreaks of Ebola, Middle East Respiratory Syndrome (MERS CoV), and Zika virus and more recently, the SARS-CoV-2 (COVID-19) pandemic.

These programs are provided in accordance with ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing. RCPAQAP is also accredited as a Proficiency Testing Scheme Provider through the National Association of Testing Authorities (NATA).

Key requirements for RCPAQAP Infectious Diseases PTPs are that they should:

- include specimens containing microorganisms causing infectious diseases (includes inactivated materials) that are current and prevalent in Australia and/or worldwide. There is a need for flexible panel composition depending on the availability of material and relevancy in infectious disease diagnoses in a clinical setting;
- contain panels of specimens presented as unknowns with the requirement that there be no disclosure of the panel contents prior to the PTP closing for result submission;
- allow for dynamic enrolments, often programs are purchased just prior to PTP dispatch;
- maintain complete anonymity and confidentiality regarding participation and results submitted.

Export control policies

The Government's Export Control Policies are designed to encourage the export of defence and dual-use goods, which is consistent with Australia's broad national interests and biosecurity response^{1,2}. However, the introduction of the Defence Trade Controls Act in 2012 as part of a wider international regulatory counter-proliferation framework, had the potential to completely disrupt the RCPAQAP business model in the provision of infectious disease PTP.

Australia's export control system is part of an international effort to stem the proliferation of conventional, chemical, biological, and nuclear weapons and the systems that deliver them. Many goods designed for legitimate civil purposes can also contribute to the development of Weapons of Mass Destruction (WMD) or be used for a military end-use. Australia has a legislative framework that ensures that the Government can manage the Nation's exports of controlled goods, services and technology (Figure 1). The policies reflect the Government's commitment to ensure the export of defence and dual-use goods is consistent with Australia's national interests and international obligations^{1,2}. The policies and procedures are regularly reviewed to address any changes in strategic circumstances and priorities. In order to

strengthen Australia's export controls, and to stop technology that can be used in conventional and weapons of mass destruction programs, Defence worked with stakeholders to address concerns with the *Defence Trade Controls Act 2012*. As a result, amendments to the Act were adopted through the Defence Trade Controls Amendment Bill 2015 (DTC Amendment Bill).

The Defence and Strategic Goods List and Policy Criteria

Australia's defence export control list, the Defence and Strategic Goods List (DSGL)³, is drawn directly from, and agreed to, by the multilateral export control regimes of which Australia is a member. This list specifies the goods, software or technology subject to the export controls administered by Defence and is broken into two parts (Figure 2).

Applications to export defence and dual-use goods are considered on a case-by-case basis. All applications are assessed to determine whether the controlled activity would be prejudicial to the security, defence or international relations of Australia. In the Defence and Strategic Goods List³ RCPAQAP material comes under Part 2 Dual-use list, Category 1 – Materials, Chemicals, Microorganisms and Toxins.

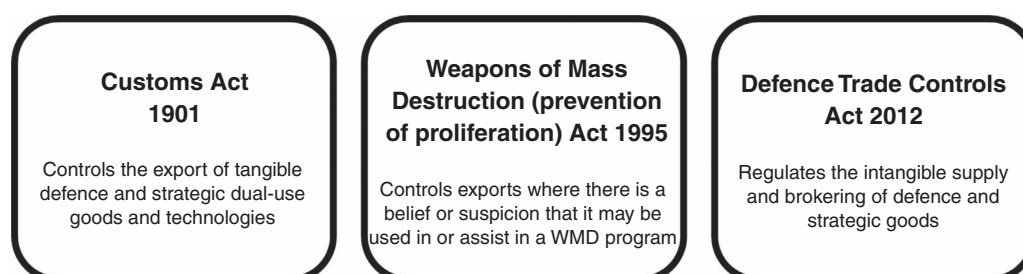


Figure 1. The legislative framework that governs Australia's export of controlled goods.

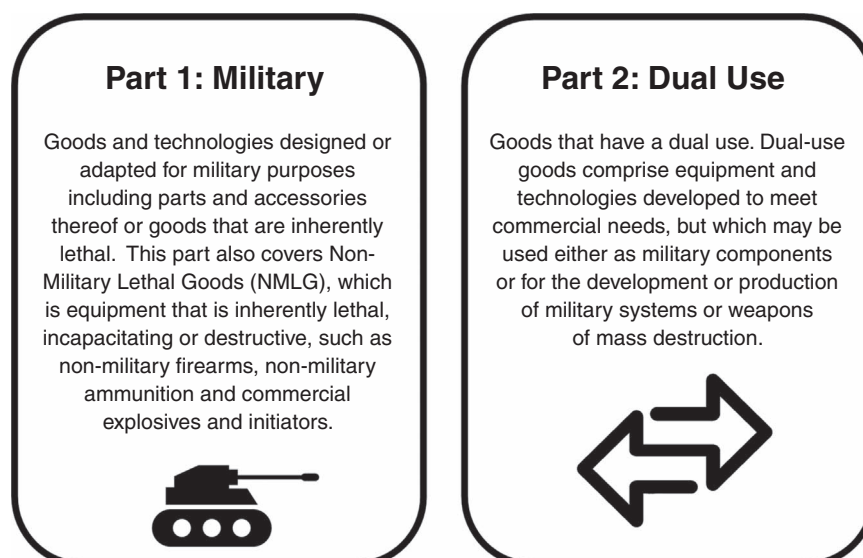


Figure 2. The categories included in the Defence and Strategic Goods List.

Table 1. RCPAQAP experience with DEC Regulations.

| RCPAQAP issues and concerns | Mitigation |
|--|---|
| Understanding Defence Export Controls and having them understand our business. | A face to face meeting was held with RCPAQAP staff and representatives from both the compliance and the technical teams from the DEC office to ensure that there was a complete understanding of what was required. |
| The way applications are assessed can change regularly: <ul style="list-style-type: none"> • DSSL List changes over time; • many overseas participants are required to complete the DEC03 – End Use and Non-Transfer Certificate forms; • permit expiry dates. | Ensure that there is a RCPAQAP resource dedicated to monitoring the DEC and particularly the DSSL and collating DEC communications and changes for timely and accurate application approvals. Additional resources were employed in the molecular infectious diseases team to manage this process and provide technical assistance to the Logistics Manager. |
| Leadtime required to build DEC applications into the scheduled PTP timelines with high potential for delays and confusion resulting in lost revenue due to requirement for the: <ul style="list-style-type: none"> • signed DEC03 – End Use and Non-Transfer Certificate forms required; • evidence of purchase of product required. | RCPAQAP close enrolments for affected infectious disease PTPs a month before the survey is open in order to apply and obtain DEC permits in time for the survey to open. |
| Requirement for DEC03 – End Use and Non-Transfer Certificate forms to be signed and proof of purchase documentation available for all relevant overseas participants. | This process requires careful management. Ensures resources are dedicated to keeping an eye on the DSSL for any changes and collating DEC communications and changes for timely and accurate application approvals. Additional resources were employed in the molecular area to manage this process and provide technical assistance to the Logistics Manager. |
| Participants often must sign multiple DEC03 – End Use and Non-Transfer Certificate forms depending on what programs are being offered and when. | Given the large number of PTPs offered at different times of the year by the different programs, it is very difficult to coordinate for a single DEC03 – End Use and Non-Transfer Certificate form to be signed by each participant. This continues to be an issue for some programs. |
| The DEC03 – End Use and Non-Transfer Certificate form must list what infectious disease material is being sent to participants, which is also a breach of the standard ISO/IEC 17043:2010. | This must be managed carefully as there is not a way of avoiding documenting information for regulatory purposes. The key here is to design the PTP carefully to avoid any obvious breaches of the standard. |
| DEC03 Forms are only available in English to date, which is a problem for some RCPAQAP agents and participants. | This has been discussed with the DEC and RCPAQAP understand that there are plans to offer the forms in different languages ongoing. |
| Some participants send the DEC03 to their lawyers before signing them resulting in long delays. | This cannot be avoided; some laboratory staff are not permitted to sign such documents. RCPAQAP hope that after the first few forms are signed that this process becomes more streamlined. |
| There is limited transparency regarding how and why applications are broken up into multiple applications, and when this happens there is often no reference to the original application and number provided. This can be confusing resulting in added complexity and permits needing to be carefully managed. | The Compliance Team assess applications and permits are split according to what material is being sent overseas and the countries they are being sent to. This information changes regularly and is often not transparent or disclosed for security of information purposes. It is noted that the DEC will now refer to an applicant's reference number if one is provided when applications are split. |
| To understand the likelihood of obtaining a permit for any activity such as when developing: <ul style="list-style-type: none"> • a new capability; • a new product that might be subject to export controls; • new marketing of existing controlled goods, services or technology overseas; • before signing contracts with collaborators or submitting applications for grants involving sending controlled material overseas to many indicated countries. | It is often difficult to obtain a list of the actual participants that the surveys should go to until after a contract is signed. RCPAQAP have navigated this by sending an 'In-principle Assessment' with a list of the probable countries included, so that the DEC can provide an indication of which countries could receive the materials. For an in-principle assessment, RCPAQAP provide as much detail as possible: <ul style="list-style-type: none"> • organisms to be used in proficiency testing (PTP) survey; • quantities of the above; • participant list, or at least a list of countries to be supplied; • enrolment certificates; • completed/signed DEC03 – End User and Non-Transfer Certificate Form for each participant. Note that RCPAQAP must apply for Department of Foreign Affairs and Trade (DFAT) approval to send material to sanctioned countries before applying to the DEC. Once the in-principle assessment is complete, then RCPAQAP apply for a DEC permit once the more detailed information is available. |

Since 2012, when the DEC was first introduced, RCPAQAP was able to obtain permits for the DSGL listed live organisms that were included in the surveys with relative ease. However, processing the applications took several weeks as the controls and application processes were new.

In 2017, there was a significant revision to the regulations introduced for genetic elements control, which included inactivated pathogens. Prior to this, genetic elements were controlled if they contained nucleic acid sequences associated with pathogenicity of organisms listed under 1C351 and 1C352. The nucleic acid sequence in itself or through its transcribed or translated products had to represent a significant hazard to human, animal or plant health; or had to be known to enhance the ability of a specified micro-organism, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to humans, animals or plant health.

After discussions with international export control regimes, and notably the Australia Group⁴, the DEC regulations were amended to include the control of inactivated organisms. This also has a revised definition of what is now considered to be 'recoverable'.

This change to Entry 1C353 for genetically modified organisms and genetic elements had the potential to cause the most disruption to the RCPAQAP business model since many PTP were prepared from inactivated material. From the RCPAQAP perspective, Table 1 lists what is currently being done to mitigate the issues and concerns that the organisation had with complying with the DEC regulations.

Conclusion

Defence Export Controls are an essential regulatory component involving the exportation of organisms of security and biothreat relevance in compliance with Australian legislation. This paper discusses strategies that RCPAQAP have developed to detail a user-end experience with Defence Export Controls in the hope of highlighting the important considerations, to which those involved in the exportation of controlled goods must adhere.

Conflicts of interest

The authors declare no conflicts of interest.

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Biographies

Joanna Gray is currently RCPAQAP Head of Molecular Infectious Diseases, Genetics and Biosecurity. She also oversees the WHO infectious diseases contract work. The Biosecurity program provides proficiency testing surveys and educational modules for Security Sensitive Biological Agents, other potential agents and emerging communicable diseases threats to Australia. The Biosecurity program is funded by the Australian Government's Department of Health. She has a Bachelor of Applied Science majoring in Microbiology from the University of Technology, Sydney with 40 years' experience in microbiology, quality management and training. Joanna also has a black belt in Six Sigma and Lean with a broad range of experience in business improvement roles in the pharmaceutical and medical industries.

Dr Torsten Theis is a Senior Scientist at the Biosecurity Department of the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP). He received his PhD in Molecular Microbiology from the Berlin University of Technology (Germany). A post-doctorate fellow at University Colleges London (UK), University of Sydney and University of Technology Sydney, he investigated different aspects of the multidrug resistant phenotype of *Staphylococcus aureus*. Dr Theis joined RCPAQAP in 2010, and is currently responsible for all program aspects that require PC3/PC4 laboratory work, including researching, evaluation, and preparation of specimens to be used in the proficiency testing programs (PTP) offered by the Biosecurity Department of the RCPAQAP. He liaises with leading specialists in the fields of public health, forensics and counter-bioterrorism, researching current issues and authoring educational material and reports. In collaboration with the Laboratory Strengthening and Biorisk Management department at the World Health Organization, Dr Theis is the RCPAQAP project lead for the development of PTPs for the detection of arboviruses, coronaviruses, and agents responsible for viral haemorrhagic fevers.

Dr Alexa Kaufer graduated with a Bachelor (Honours) of Forensic Biology in Biomedical Science in 2015. She received her PhD in parasitology from the University of Technology Sydney in 2020, investigating the use of kinetoplast DNA molecular systematics, species identification and diagnostics of trypanosomatid parasites. She began her role as a scientist at the Biosecurity Department of the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) in 2019.