



AUSTRALIAN INSTITUTE OF MEDICAL SCIENTISTS

SUBMISSION IN RESPONSE TO THE CALL FOR PUBLIC CONSULTATION FROM TGA ON THE BIOLOGICALS FRAMEWORK: PROPOSED AMENDMENTS TO THERAPEUTIC GOODS REGULATIONS 1990

Background

The Australian Institute of Medical Scientists (AIMS) is the only professional association for medical scientists in Australia covering all disciplines of pathology.

AIMS has been specified by the Minister for Immigration and Citizenship in accordance with the *Migration Regulations 1994*, as the assessing authority for the occupations Medical Scientist ASCO 2115-11 (professional classification) or Medical Laboratory Technical Officer ASCO 3111-11 (technical classification) under the Australian Government's General Skilled Migration program.

AIMS accredits eight bachelor degree programs for medical laboratory science in universities in Australia and undertakes regular reviews to ensure that the courses meet the required standards. Graduates of the accredited courses are eligible for Graduate membership of AIMS on graduation and for full Professional Membership after two years' postgraduate work experience.

Our members are medical scientists who work in hospital laboratories, private pathology laboratories, state health laboratories, forensic laboratories, invitro fertilisation (IVF) centers, molecular genetics laboratories and universities.

Response to Draft NPAAC Documents

AIMS has asked members for their response to the draft NPAAC documents. Comments representing the consensus opinion to the three documents are attached.

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Organisation: Australian Institute of Medical Scientists (AIMS)_____

Thank you for providing your comments using the template below.

- Rows may be added or deleted as required. Tables may be left blank or deleted if no comments are to be made on other documents.
- 'Reference' indicates the specific section/ subsection/ paragraph where relevant, e.g. In the infectious disease Order, 8(1)(b) would be used to reference requirements for donor interview timeframe in Part 3, Section 8, Subsection (1), paragraph (b).
- 'Issue' invites a short statement to summarise the comment.
- 'Comments' may include a position including justification or an alternative position.
- Additional general comments are also invited on the impact of these standards, as indicated below each table.

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

SUBMITTING ORGANISATION: Australian Institute of Medical Scientists _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Thank you for giving AIMS the opportunity to comment on the Proposed Standards for human blood and blood components, human tissues and human cellular therapy products.

We have consulted with our members. We believe the submissions of The Australian group of the ISCT, the NSW Bone Marrow Transplant Network, and the Bone Marrow Transplant Scientists of Australasia (many of whose members are also AIMS members) best represent the views of medical scientists who are currently working in these fields. We endorse the views submitted by these groups.

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Standards for human cardiovascular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

See above

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

See above

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Standards for human ocular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

See above

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Standards for human skin

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

See above

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

See above