Response ID ANON-CBS3-RZTD-F

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-03 14:00:43

Introduction

What is your name?

Name:
Wayne Dimech

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
National Serology Reference Laboratory, Australia

Responding to this Consultation

Question 1(a): Do you agree with the proposals to change the Australian classification rules and principles that have an impact on approved products (as specified in the first Section of the paper), noting the changes are reflective of the regulatory scrutiny based on the associated health risks?

Respond to the question 1a:

No

Question 1(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 1b:

Proposed changes E. Quality control.

The purpose of a third-party quality control (QC) ie a control provided by a manufacturer other than the assay manufacturer is not used or designed to validate the assay performance, but to monitor the assays performance. In infectious disease testing in particular, the manufacturer's kit controls are designed and used to validate the assay. The assay manufacturer has provided the regulator evidence that, when the kit controls are within the manufacturer's specifications in the IFU, the results can be released. Third party QCs are designed to be stable over time and therefore provide the user an indication as to whether the assay is in control. But they are not designed to be part of the validation of the assay and therefore should not be assumed to be of the same Class as the assay.

There is an implication in the Proposed Changes that third party controls that are nominated to be positive or negative for an analyte has an "assigned value". This is not common usage of the term. In other jurisdictions "assigned values" refers to a quantitative assignment, implying that the third party QC is somewhat traceable to a standard. It is imperative that the manufacture of a third party QC for use on a qualitative test provide a status of negative or positive. Therefore, by definition all qualitative third party QCs will be captured by this change.

We would support a change that requires third party QCs with an "assigned" qualitative value be assumed to be in the same Class as the assay on which is it used; however strongly disagree with the concept that a qualitative third party QC has an "assigned value" and therefore is in the same Class as the assay it monitors.

Question 1(c): Are there any other classification rules and principles, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 1c:

no

Question 2(a): Do you agree with the proposals to adopt certain terminology in the Australian classification rules that have no impact on approved products (as specified in Appendix A of the paper), noting the changes are to improve clarity?

Respond to the question 2a:

1

Question 2(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 2b:

Question 2(c): Do you agree the proposed changes in Appendix A of the paper, would not result in any impact on existing ARTG entries of IVD medical devices?

Respond to the question 2c:

1

Question 2(d): Are there any other classification rules, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 2d:

1

Question 3(a): Do you agree with the proposal to amend the Australian definitions as specified in Appendix B of the paper?

Respond to the question 3a:

1

Question 3(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 3b:

Question 3(c): Are there any other definitions, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 3c:

1

Question 4(a): Do you agree with the proposal to apply a 6-month transition period after the EU IVDR transition timelines for the proposed Australian amendments to take effect?

Respond to the question 4a:

Question 4(b): Provide reasons for your position.

Respond to the question 4b:

Question 5: Do you consent to your response being made publicly available on the TGA's Consultation Hub website? Please indicate your publishing preferences.

I consent to my submission being published, including both my name and my organisation's name

Question 6: If you consent to your submission being published, are there parts that you do not want published? Please specify which part(s). Please note – your contact email address and/or phone number will not be published with your submission.

Respond to the question 6: