Australian Government
Department of Industry, Innovation and Science

National Measurement Institute

NMI submission

National Measurement Institute submission to the TGA consultation on:

"Changes to a number of definitions and the scope of the medical device regulatory framework in Australia"[1]

This submission from the National Measurement Institute (NMI) addresses the TGA's proposal to include in the Australian regulatory framework the groups of products that are not intended for a specific medical purpose listed in Annex XVI of the EU MD Regulations; specifically group 5 – high intensity electromagnetic radiation emitting equipment.

NMI is a division within the Department of Industry, Innovation and Science, and is Australia's peak measurement body responsible for biological, chemical, legal, physical and trade measurement. NMI delivers world-class measurement capabilities to the Australian government, industry and the community, and supports increased industrial efficiency, enhances export trade, and supports effective regulatory frameworks, including for health, safety and the environment. Given the potential requirement to provide measurement services to industry participants that would be affected by the regulatory changes, NMI and the Australian accredited laboratory system could also be considered to be stakeholders directly affected by the proposed changes. One of NMI's key roles is to ensure that the Australian measurement infrastructure is able to support the requirements of regulatory systems.

NMI has the internationally recognised measurement capabilities[2] necessary to support regulation of both medical lasers and intense pulse light sources and is currently regularly delivering calibration, testing and assessment services on a cost-recovery basis for Australian users, importers and manufacturers. The same or similar capabilities would support the proposed regulatory changes for non-medical equipment. Although these non-medical uses are largely unregulated domestically, an important objective for NMI's work is to support Australian manufacturers to meet requirements specified in documentary standards when seeking to export their products to overseas markets.

Currently, commercial realities mean that although accredited Australian laboratories possess the core competencies to perform the necessary measurements and calibrations, they have not developed routine capabilities supported by accredited quality systems that could meet broad industry requirements with commercial, cost-effective services. While NMI can cover gaps in private sector capabilities over the short term, it is likely that increased test demand flowing from the proposed regulatory framework would stimulate other Australian accredited laboratories to develop capabilities necessary to support new regulatory requirements. These local accredited commercial services would reduce the cost burden to Australian firms seeking to satisfy the regulations in place both in Australia and in importing countries.

[1] https://www.tga.gov.au/consultation/consultation-changes-number-definitions-and-scope-medical-device-regulatory-framework-australia

[2] https://measurement.gov.au/Publications/FactSheets/Documents/TF18.pdf

NMI notes that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) investigated the benefits of regulating lasers, intense pulsed light sources and LED phototherapy in the cosmetic and beauty therapy industry, leading to a consultation RIS in 2015. ARPANSA's associated documentation[3] includes information about the potential hazards of such devices, the state of the industry and public perception of the procedures.

In summary, NMI believes that the Australian measurement framework is suitably equipped to support the proposed expansion of regulatory scope. NMI considers that the proposal would foster expansion of Australia's advanced technical and quality infrastructure, increasing both consumer confidence and the competitiveness of local manufacturers

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[3] https://www.arpansa.gov.au/advice-cosmetic-treatments-and-beauty-therapy-using-lasers-intense-pulsed-light-ipl-devices-and-high