56th CIML Meeting - Working Document



56 CIML Addendum 9.1.2.7

2021-10-11

Agenda Item 9.1.2.7:

Project proposal: New Recommendation

Non-contact clinical thermometers

OIML		Proposal for a new project				
		Within:	TC	18	SC	2
		Date:	30.09.2021			
Proposer(s) (Add line if required):						
Name:	Country: Brazil		Organisation: INMETRO			
Proposed convener(s)*:						
Name: Rafael Farias	Country: Brazil		Organisation: INMETRO			
Type of proposed publication:	⊠ New					
\square Recommendation \square Document \square Basic			□ Vocabulary □ Guide			
Title of proposed publication:						
Non-contact clinical thermometers						
Terms of reference of the project, including detailed time frame in accordance with the provisions specified in B 6-1, 6.2:						
Scope: The COVID-19 pandemic has increased the use of infrared clinical thermometers. These are often poorly regulated and used, and there is a lack of guidance on their regulation at the international level. This project aims to address this need.						
Expected time frame: PG area set-up: 15.01.2022						
Members participation confirmation: 01.04.2022						
1WD: 01.07.2022 1CD: 01.02.2023						
Why should the OIML develop this publication?						
The OIML Task Group on medical devices in legal metrology requested that a Recommendation be developed						
to cover infrared clinical thermometers. In addition, the existing Recommendations on clinical thermometers are over five years old and therefore due for review. The view of the new TC 18/SC 2 secretariat is that the						
OIML Recommendations in the field of clinical thermometers should follow the proposals presented for the						
new edition of ISO/IEC 80601-2-56, which suggest the division of clinical thermometers based on "direct measurement" and "indirect measurement". Additionally, contact clinical thermometers use a standard						
(thermostatic bath) different from the standard (black body cavity) used by non-contact clinical thermometers.						
There are therefore two project proposals to cover this issue.						
Countries/Economies known to, or intending to apply this publication, if applicable:						
Relevant associated OIML publications:						
R 114:1995 Clinical electrical thermometers for continuous measurement R 115:1995 Clinical electrical thermometers with maximum device						
List of appropriate liaisons and their			(include s	upporting d	locument	tation

as necessary and reference it here):

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* As the CIML Member(s) of the Country(ies) holding the convenership of this project, I/we recognise the importance of TC/SC/PG secretariat/convenership work and will make available the resources to ensure the work on the publication is completed in a timely and professional manner in accordance with the provisions in OIML B 6-1 and the detailed time frame as part of this proposal.

Signature(s):