




**Agenda Item 9.1.2.8:**

**Project proposal: New Recommendation**

*Contact clinical thermometers*

## Annex C.2 to OIML B 6-1: Proposal for a new project

	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:	<input checked="" type="checkbox"/> New	<input checked="" type="checkbox"/> Revised			
<input checked="" type="checkbox"/> Recommendation	<input type="checkbox"/> Document	<input type="checkbox"/> Basic	<input type="checkbox"/> Vocabulary	<input type="checkbox"/> Guide	
Title of proposed publication:					
The revision and combination of three existing Recommendations:					
R 7:1979	<i>Clinical thermometers, mercury-in-glass with maximum device</i>				
R 114:1995	<i>Clinical electrical thermometers for continuous measurement</i>				
R 115:1995	<i>Clinical electrical thermometers with maximum device</i>				
Into one new Recommendation: <i>Contact clinical thermometers</i>					
Terms of reference of the project, including detailed time frame in accordance with the provisions specified in B 6-1, 6.2:					
<b>Scope:</b> The revision and technical updating of three existing Recommendations into one new Recommendation, reflecting the IEC proposed classification of clinical thermometers as described below.					
<b>Expected time frame:</b>					
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?					
<p>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.</p> <p>There are therefore two project proposals to cover this issue.</p>					
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 work related to this proposed project (include supporting documentation 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):