

I-9/23/2024-W&M

Government of India

Ministry of Consumer Affairs, Food & Public Distribution

Department of Consumer Affairs

Legal Metrology Division

Krishi Bhawan, New Delhi-01

Dated: 29.11.2024

Subject- Draft Rules for Clinical Electrical Thermometer for comments from stakeholders – reg.

Undersigned is directed to refer to the above mentioned subject and to state that the Draft Rules for Clinical Electrical Thermometer are placed in the website of the Department www.consumeraffairs.nic.in for seeking comments from all stakeholders by 30.12.2024. The comments may be sent to email-ID: dirwm-ca@nic.in/ mk.naik72@gov.in.

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To:

All concerned (State Legal Metrology Departments, VCOs, Industries and Industry Associations)

[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRAORDINARY, PART II SECTION 3 SUB-SECTION (i)]
GOVERNMENT OF INDIA
MINISTRY OF CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION
(DEPARTMENT OF CONSUMER AFFAIRS)

Notification

New Delhi, the2024

GSR.....(E).- In exercise of the powers conferred by sub-section (1) read with clauses (c), (f), (h), (i) and (s) of sub-section (1) of section 52 of the Legal Metrology Act 2009, (1 of 2010), the Central Government hereby makes the following rules, namely:-

1. Short title and commencement.-

- (1) These rules shall be called the Legal Metrology (General) Amendment Rules, 2024.
- (2) They shall come into force on 1st July, 2025.

2. In the Legal Metrology (General) Rules, 2011, (herein after referred to as the said rules), under the Eight Schedule Part VI, Part C and the entries made thereunder, the following shall be substituted, namely.-

“PART VI

CLINICAL THERMOMETER

PART C

CLINICAL ELECTRICAL THERMOMETERS WITH MAXIMUM DEVICE

1. Scope.-

- (1) This Part specifies the metrological and technical requirements for clinical electrical thermometers with a maximum device. Such instruments are designed to measure human or animal body temperature. They indicate a maximum temperature measured after a steady state is reached or predicted after a time specific to the design of the instrument. Until the maximum temperature is indicated, the actual temperature may be indicated by the thermometer.
- (2) The measuring range of clinical thermometer shall be either of 35°C to 42°C or 35°C to 43°C. Two accuracy classes, class I and class II, are covered by this specification.
- (3) This specification applies to battery-powered instruments which provide a digital indication of temperature.
- (4) Clinical electrical thermometers designed to measure skin temperature are not covered by this specification.
- (5) This specification does not exclude the use of any contract device based on other measurement principles that meets equivalent performance standards in determining maximum body temperature at specified time intervals.

2. Terminology.-

- (1) A clinical electrical thermometer, as covered by this specification is a contact thermometer comprising a temperature probe and an indicating unit, and that is designed to measure human or animal body temperature.
- (2) A temperature probe is the component of a thermometer of which part is applied to a body cavity or tissue with which it establishes thermal equilibrium. It comprises a temperature sensor with associated parts including coverage, seals, inner leads, and connecting plug, where appropriate.

Notes:

1. A body or tissue may be the mouth (sublingual), rectum, or armpit.
2. The part of the probe in contact with a body cavity or tissue is called the ‘applied part’.
3. An indicating unit is the component of a thermometer that process the output signal of the temperature sensor and displays the measured temperature.

4. A maximum device is the component of a thermometer that monitors over a specified time the temperature measured by a probe in contact with a body cavity or tissue, at which it indicates the maximum temperature and maintains the indication until reset by the user.
5. Predicting clinical electrical thermometer calculates the maximum temperature of a probe in contact with a body cavity or tissue, without waiting for thermal equilibrium to occur, by using heat transfer data and a mathematical algorithm.

3. Description of the instrument.-

- (1) A complete thermometer consists of a temperature probe connected to any indicating unit.
 - (2) The instrument may be of one of the following types:
 - (i) an interchangeable temperature probe connected to an indicating unit that is compatible with the characteristic response of the probe, or
 - (ii) a temperature probe and an indicating unit permanently connected.

4. Metrological requirements.-

- (1) Unit of measurement-measuring range-scale interval,-

(i)The unit of temperature shall be the degree Celsius °C.

(ii)The measurement range shall be a minimum of 35°C to 43°C or 35°C to 42°C. Greater measuring ranges may be sub-divided into partial ranges; however, the range 35°C to 42°C shall be continuous.

(iii)The scale interval or digital increment shall not exceed—

- (a) 0.01°C for class I thermometers,
- (b) 0.1°C for class II thermometers.

- (2) Maximum permissible errors,-

(i)The maximum permissible error under reference conditions for the temperature range 32.0°C to 42.0°C for the two accuracy classes covered shall be as follows: —

Accuracy class	Maximum permissible errors (range 32.0°C to 42.0°C)		
	Complete thermometer	Indicating unit	Temperature probe
Class I	± 0.15°C	± 0.05°C	± 0.1°C
Class II	± 0.2°C	± 0.1°C	± 0.1°C

(ii)Outside the temperature range 32°C to 42°C, the maximum errors shall be at twice the values specified in clause (i) of sub-paragraph (2) of paragraph 4.

- (3) Reference conditions,-

The reference conditions for the requirements of sub-paragraph (2) of paragraph 4 shall be:

- (i) ambient temperature of 27°C ± 5°C
- (ii) relative humidity to 50% ± 20%
- (iii) the instrument operating within the specified range of battery voltage (specified power supply conditions).

- (4) Time response,-

The thermometer shall be submitted by the manufacturer to a testing laboratory to determine its time response. The test shall be based on any analysis of a significant sample of human subjects.

The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of calculating (predicting) thermometer shall not exceed 0.2°C.

5. Technical requirements.-

- (1) Temperature probe,-

- (i) For an interchangeable probe of the resistance type, the manufacturer shall specify the maximum power that may be supplied to the probe by an indicating unit; this power shall not cause energy dissipation (I²R) giving

rise to any increase in temperature by more than 0.02°C when immersed in a reference water bath maintained at a temperature range of 36.9°C to 37.1°C .

Note : (1) For a description of the reference water bath, see Annexure A.

(2) A test of this requirement is only applicable to inter-changeable probes submitted for pattern approval without a specific indicating unit. When a probe is submitted with an associated indicating unit, the requirement in clause (i) of sub-paragraph (2) of paragraph 5.

- (ii) The thermal stability of the probe, after exposure for 100 hours at $80^{\circ}\text{C} \pm 2^{\circ}\text{C}$ or 300 hours at $55^{\circ}\text{C} \pm 2^{\circ}\text{C}$, shall be such that the requirement for maximum permissible errors specified in paragraph 4(2) is met.
- (iii) The electrical insulation of the probe shall be sufficient to prevent a change in indicated temperatures greater than $\pm 0.02^{\circ}\text{C}$ when the probe is immersed in an electrically conducting liquid having an insulation resistance of 80 MW at 20°C . This insulation includes that between the inner lead wires, that between the wires and the surface of the probe, and that encasing and protecting connections and transitions.
- (iv) The locations of the sensors in the probe shall be such that, when the probe is immersed to depths greater than 50 mm from its tip in a reference water bath at a temperature does not vary by more than 0.05°C from that indicated at a depth of 50 mm.
- (v) The probe shall be strong enough to withstand mechanical stresses expected under normal conditions of the use.
- (vi) If the probe is inter-changeable, it shall be fitted with either a plug-in or quick dis-connectable electrical connector. The contact resistance of the connector or the insulation resistance between the circuits of the connector or to ground shall not cause a variation in the indicated temperature greater than 0.02°C .

Note : The connectors may not be required to be water resistant.

- (vii) The probe shall meet the requirements for maximum permissible errors specified in
- (viii) Sub-paragraph (2) of paragraph 4 when the applied part has been subjected to the cleaning in and disinfecting procedure specified by the manufacturer.

Notes : (1) For small compact thermometers this applies to the complete instrument.

(2) The materials of the probe that come into contact with the body should be selected for compatibility with body tissue.

- (viii) The output signal of the probe shall not vary by more than $\pm 0.05^{\circ}\text{C}$ when the temperature of the cable connecting it to an indicating unit varies by 20°C .

(2) Indicating unit,-

(i) When connected to a resistance-type temperature probe, the indicating unit shall provide an energizing potential sufficiently low so that energy dissipation ($I^2 R$) in the probe shall not cause an increase in indicated temperature of over 0.01°C when the probe is immersed in a reference water bath at a temperature within the specified measuring range.

(ii) The indicating unit shall not indicate a temperature when connected to a battery charger.

(iii) The digital display of temperature shall be at least 4 mm in height or it shall be optically magnified so as to appear at least 4 mm in height.

(iv) The indicating unit shall provide a clear indicating or warning signal when the measured temperature is outside the specified measuring range.

(v) The indicating unit shall include a self-checking device that meets the requirements of the paragraph 4(2). This device, which may be manual or automatic, shall input a predetermined electrical signal. Failure shall be clearly indicated.

Note : This device checks only the operation of the indicating unit and does not ensure that a temperature measurement is correct. It provides a means of detecting a faulty operation caused by a defective component or other disturbance.

- (vi) In the case of a predicting thermometer, the indicating unit shall provide a means of displaying the measured temperature after reaching the thermal equilibrium.

(3) Complete thermometer,-

Note : The reference thermometer is that indicated (either before the test, or before and after the test, as appropriate) by the thermometer probe immersed in the reference water bath according to the paragraph 1 of Annexure A, the temperature being held constant within the working range of the thermometer.

- (i) The thermometer shall provide a clear indication or warning signals when the battery voltage is outside the specified limits and it shall meet the requirement specified in sub-paragraph (2) of paragraph 4 when the voltage is within these limits.
- (ii) The indicated temperature shall not vary by more than $\pm 0.1^{\circ}\text{C}$ from the reference temperature when the temperature of the thermometer casing varies from 10°C to 40°C .
- (iii) The indicated temperature shall not vary more than $\pm 0.1^{\circ}\text{C}$ from the reference temperature after a thermal shock resulting from an abrupt change in temperature from -5°C to $+50^{\circ}\text{C}$.
- (iv) The indicated temperature shall not vary by more than $\pm 0.1^{\circ}\text{C}$ from the reference temperature after storage for 24 hours at $-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and at $60^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- (v) The indicated temperature shall not vary by more than $\pm 0.1^{\circ}\text{C}$ from the reference temperature after storage at a relative humidity of 91% to 95% at a temperature constant within $\pm 2^{\circ}\text{C}$ in the range 20°C to 32°C .
- (vi) The indicated temperature shall not vary by more than $\pm 0.3^{\circ}\text{C}$ from the reference temperature during exposure to electromagnetic field having a frequency between 150 kHz and 500 MHz and a field strength of 10V/m.
- (vii) The indicated temperature shall not vary by more than $\pm 0.1^{\circ}\text{C}$ from the reference temperature after fall on to a hard surface from a height of 1m from three different orientations.
- (viii) Small and compact complete thermometers shall be water resistant.

6. Practical instructions.-

- (1) Manufacturers shall provide an operating manual, or instructions, including the following information:-
 - (i) description of appropriate uses and means of applications,
 - (ii) identification of the specified temperature measuring range of the complete thermometer taking into account, if applicable, the specified measuring ranges of both the interchangeable probes and the indicating unit,
 - (iii) instructions and precautions for cleaning and disinfecting the complete thermometer or the inter-changeable probes,
 - (iv) identification of components and suitable inter-changeable parts such as probes and batteries, including nominal voltage, if applicable,
 - (v) minimum time for achieving thermal equilibrium,
 - (vi) description of transition from the predicted temperature-measuring mode into the actual temperature-measuring mode,
 - (vii) instruction for the self-checking device,
 - (viii) information on the correct environmental conditions of use, storage, and transport of the thermometer.
- (2) Specific information should be provided by the manufacturer, on request, regarding possible sub-standard performance if used under the following conditions: —
 - (i) outside the prescribed environmental temperature and humidity range,
 - (ii) after an accidental mechanical shock.

7. Metrological controls.-

(1) Pattern evaluation,-

- (i) Manufacturers shall provide the following information:
 - (a) location of sensor from tip of probe,
 - (b) description and principles of measurements of complete thermometer,
 - (c) description of electrical principles and of any necessary equipment's provided,
 - (d) description of test for self-checking device,
 - (e) specified working range for battery,
 - (f) nominal and specified temperature measuring ranges,
 - (g) nominal values of calibrations data for type of temperature probe, as applicable,
 - (h) precautions for cleaning and disinfecting complete thermometer or temperature probes, as appropriate, including test results as specified in paragraph 3 of Annexure B,
 - (i) indicating on instrument if a displayed value is calculated,
 - (j) test results,
 - (k) results of clinical test of time responses [sub-paragraph (4) of paragraph 4 and Annexure D],

(l) operating manual and/or instructions.

(ii) Thermometers shall be subjected to the following tests: —

Note: Requirements for the reference water bath and the test for maximum permissible errors are provided in Annexure A. The performance requirements for the instrument and its major components are provided in paragraphs 4 and 5. Where appropriate, an additional description of required tests is provided in Annexure B.

(a) Probe

(I) maximum permissible errors [sub-paragraph (2) of paragraph 4 and clause(i) of sub-paragraph (2) of paragraph 2 of Annexure A]

(II) long-term thermal stability [clause(ii) of sub-paragraph (1) of paragraph 5]

(III) electrical insulation and water resistance [clause(iii) of sub-paragraph (1) of paragraph 5 and paragraph 2 of Annexure B].

(IV) location of sensor [clause(iv) of sub-paragraph (1) of paragraph 5]

(V) mechanical strength [clause(v) of sub-paragraph (1) of paragraph 5]

(VI) electrical contact resistance of connector [clause(vi) of sub-paragraph (1) of paragraph 5]

(VII) cleaning and disinfecting [clause(vii) of sub-paragraph (1) of paragraph 5 and paragraph 3 of Annexure B]

(VIII) stability with changes in temperature of cables [clause(viii) of sub-paragraph (1) of paragraph 5]

(b) Indicating unit

(I) maximum permissible errors [sub-paragraph (2) of paragraph 4 and Annexure A]

(II) power provided to probe [clause(i) of sub-paragraph (1) of paragraph 5 and paragraph 1 of Annexure B]

(III) indication when connected to battery charger [clause(ii) of sub-paragraph (1) of paragraph 5]

(IV) indication if the thermometer is outside the specified measuring range [clause(iv) of sub-paragraph (1) of paragraph 5]

(V) self-checking device [clause(v) of sub-paragraph (1) of paragraph 5]

(VI) display of predicting thermometer [clause(vi) of sub-paragraph (1) of paragraph 5]

(c) Complete thermometer

(I) maximum permissible errors [sub-paragraph (2) of paragraph 4 and Annexure A]

(II) low battery indication [clause(i) of sub-paragraph (3) of paragraph 5 and paragraph 4 of Annexure B]

(III) ambient temperature [clause(ii) of sub-paragraph (3) of paragraph 5 and paragraph 6 of Annexure B]

(IV) thermal shock [clause(iii) of sub-paragraph (1) of paragraph 5 and paragraph 6 of Annexure B]

[paragraph 5 of Annexure B](#)

(V) storage temperatures [clause(iv) of sub-paragraph (3) of paragraph 5]

(VI) humidity [clause(v) of sub-paragraph (3) of paragraph 5 and paragraph 7 of Annexure B]

(VII) electromagnetic radiation interference [clause(vi) of sub-paragraph (3) of paragraph 5 and paragraph 8 of Annexure B]

(VIII) mechanical shock [clause(vii) of sub-paragraph (3) of paragraph 5 and paragraph 9 of Annexure B]

(IX) water resistance of small compact thermometers [clause(viii) of sub-paragraph (3) of paragraph 5 and Annexure C]

(X) instructions and precautions for cleaning and disinfecting the complete thermometer or the inter-changeable probes,

(XI) identification of components and suitable inter-changeable parts such as probes and batteries, including nominal voltage, if applicable,

(XII) minimum time for achieving thermal equilibrium by an indicating energy dissipation requirements [clause(i) of sub-paragraph (1) of paragraph 5 and paragraph 1 of Annexure B]

(iii) A report of the results of tests required in clause (ii) of sub-paragraph (1) of paragraph 7 and clause (iii) of sub-paragraph (1) of paragraph 7 shall be prepared.

(2) Marks and labels

(i) Manufacturers shall provide a space for marks and labels.

(ii)Manufacturers shall affix on the thermometer or indicating unit, if separate, the following marks or labels:

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- (a) name and address of manufacturer or supplier, and/or trademark,
- (b) model or type designation, and serial or lot number,
- (c) temperature values or indications given by the self-checking device,
- (d) indication of the orientation or position in use, where appropriate,
- (e) indication if a displayed value is calculated.

(iii)Inter-changeable temperature probes shall bear the following marks or labels: —

- (a) name and address of manufacture and/or trademark,
- (b) type designation,
- (c) serial or lot number, or relevant manufacturing production data.

(iv)A single-use temperature probe shall be sealed in a package on which the information specified in clause(iii) of sub-paragraph (1) of paragraph 7 and the measuring range shall be indicated. In addition, sufficient space on the package shall be provided for the application of official approval marks. It shall be clear if the package has been opened and the instructions shall stipulate that the user only opens the package immediately before use.

(v)The testing laboratory shall permit the application in a conspicuous place, of the following: —

- (a) pattern approval mark or label, on each complete thermometer or indicating unit and associated temperature probe(s).
- (b) indication of the specified temperature measuring range if the total range of the thermometer is greater.

(3) Model Approval

If the thermometer meets all the requirements and tests for model approval, the testing authority shall issue a certificate of approval.

(4) Verification

(i)The laboratory shall examine the information provided by manufacturers as specified in paragraph 6.

(ii)The laboratory shall examine the instrument's pattern approval certificate mark(s) or label(s).

(iii)The laboratory shall carry out any of the tests indicated in clause (ii) of sub-paragraph (1) of paragraph 7 that may be critical for the designated application of the instrument.

Note: The tests indicated in paragraph 2 of Annexure A may be sufficient for verification.

The laboratory shall provide a verified instrument with a mark or label.

- (iv) Single use temperature probes shall be examined following the sampling plan describe in annexure.

(iv)The water resistance of small and compact complete thermometers shall be examined by means of the procedure described in paragraph 2 of Annexure C.

(vi)The laboratory shall indicate the period of validity of the verification.

ANNEXURE A ESTABLISHING REFERENCE TEMPERATURES AND DETERMINING MAXIMUM PERMISSIBLE ERRORS

(Mandatory)

1. Reference temperatures.-

- (1) A well-regulated and stirred water bath containing at least one litre in volume shall be used to establish reference temperatures over the measuring range for conducting various performance tests on an instrument. The bath shall be controlled to a temperature stability of better than $\pm 0.02^{\circ}\text{C}$ over the specified temperature range and shall not have a temperature gradient greater than $\pm 0.01^{\circ}\text{C}$ within its working space at a specified temperature. This temperature gradient shall be assured under all conditions and methods of loading temperature probes.

Note: The water bath described above is referred to as a "reference water bath" in this specification.

- (2) A reference thermometer with an expanded uncertainty not greater than 0.03°C (calculated for a coverage factor $k = 3$) shall be used to determine the temperature of the water bath. The calibration shall be traceable to national measurement standards.

2. Determining maximum permissible errors.-

(1) Complete thermometer,-

(i)The temperature probe of a complete thermometer shall be immersed in a reference water bath at a constant temperature until temperature equilibrium is established. The temperature indicated by the thermometer shall be compared to that indicated by the reference thermometer. The bath temperature shall then be increased or decreased, the temperature equilibrium re-established, and the measurement process repeated. The difference between the measured and reference temperatures shall meet the requirements for maximum permissible errors as specified in sub-paragraph (2) of paragraph 4.

(ii)The number of measurements at different temperatures depends on the measuring range of the instrument; however, measurements shall be carried out for at least the following number of temperatures within the measuring range:

Measuring range	Number of temperatures
$\leq 10^{\circ}\text{C}$	3
$\geq 10^{\circ}\text{C}$	5

(2) Inter-changeable and single-use probe

(i)An inter-changeable or single-use probe shall be immersed in a reference water bath as specified in clause(i) of sub-paragraph (1) of paragraph 2 of Annexure A measured physical property of the probe shall be converted to a temperature value by using an appropriate instrument to measure a change in that property as a function of temperature. For a resistance-type probe, an appropriate instrument for measuring its output signal may be an ohm meter that can apply power to the probe at a level below the limit specified in clause (i) of sub-paragraph (2) of paragraph 5 and the temperature value is obtained from the manufacturer's data of resistance versus temperature. The expanded measurement uncertainty of the appropriate instrument shall not be greater than a value equivalent to 0.01°C (calculated for a coverage factor $k = 3$), referring to the manufacturer's data at a temperature of 37°C . The calibration shall be traceable to national measurement standards. Each temperature value obtained for the probe in this way shall be compared to that indicated by the reference thermometer in the bath. The difference between these temperature values shall meet the requirements for maximum permissible errors as specified in sub-paragraph (2) of paragraph 4.

(ii)The number of measurements required shall be the same as specified in paragraph clause (ii) of sub-paragraph (1) of paragraph 2 of Annexure A.

(3) Indicating unit

(i)The performance of an indicating unit shall be tested using a device that simulates the relevant physical properties of the appropriate probe type. The expanded measurement uncertainty of the simulating device shall not be greater than a value equivalent to 0.01°C (calculated for a coverage factor $k = 3$), referring to the manufacturer's data at a temperature of 37°C . The calibration shall be traceable to national measurement standards.

Note: For example, a calibrated decade resistance box may be used to provide a variable resistance to simulate a resistance-type probe. Values of resistance for input to the indicating unit over its specified measuring range shall be selected from the manufacturer's data of resistance versus temperature. Similarly, variable voltage sources may be used to simulate a thermocouple.

(ii)The difference between the temperatures displayed by the indicating unit and the corresponding simulated values of temperature shall meet the requirements for maximum permissible errors specified in sub-paragraph (2) of paragraph 4.

(iii)The number of measurements shall be the same as specified in clause (ii) of sub-paragraph (1) of paragraph 2 of Annexure A.

ANNEXURE B

BRIEF DESCRIPTION OF INSTRUMENT PERFORMANCE TESTS

(Mandatory)

1. Energy dissipation of a resistance-type interchangeable probe.-

- (1) The probe shall be placed in a reference water bath as specified in paragraph 1(1) of Annexure A at a temperature of $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$. Measurements shall be carried out at three or more DC currents with the highest power being 2mW. For each applied current, the voltage and current shall be measured.
- (2) The equivalent resistance values shall be calculated and then converted to temperature values using the manufacturer's characteristic (resistance versus temperature) table for the probe type. A linear (least-squares fit) curve of temperature as a function of applied power shall be drawn. From this curve, power corresponding to the maximum energy dissipation that will cause a change in indicated temperature by 0.01°C for reusable, interchangeable, or single-use probes shall be determined. This value is the maximum power that may be provided by an indicating unit for the type of probe tested and the manufacturer's specified value shall be equal to or less than the value determined.

2. Electrical insulation resistance of the probe.-

- (1) The resistance of the temperature probe shall be determined at one or more temperatures using the procedure specified in paragraphs clause (i) of sub-paragraph (1) of paragraph 2 or clause (ii) of sub-paragraph (1) of paragraph 2 of Annexure A. The probe shall then be immersed to a length equal to that intended to be in contact with the body, or 50 mm, whichever is greater, in a physiological saline solution (9.5g of NaCl per litre of distilled water).
- (2) After at least one minute, the resistance between the electrical connections of the probe taken together and an electrode immersed in the physiological saline solution shall be measured using an instrument that applies a voltage of $10\text{ V} \pm 1\text{ V}$ between the probe connections and the electrode. The resistance measured shall be greater than the shunt resistance that would correspond to a change in indicated temperature of 0.02°C .
- (3) The probe shall be left in the physiological saline solution for 24 hours, after which its resistance shall be re-measured as specified in paragraph 2(1) of Annexure B. The difference in indicated temperature between measurements shall not be greater than 0.02°C .

3. Cleaning and disinfecting the probe.-

- (1) The applied part of the temperature probe or of the complete compact thermometer shall be cleaned and disinfected twenty times according to the manufacturer's instructions.
- (2) After cleaning and disinfecting as specified in sub-paragraph (1) of paragraph 3 of Annexure B, the requirements of sub-paragraph (2) of paragraph 4 shall be met.

4. Low battery indication.-

Note : paragraphs 4 to 9 of Annexure B it is to be understood that the temperature indication of a complete thermometer shall be generated within the measuring range by inserting the probe in a reference water bath or in another bath with similar qualities. The temperature indication of an indicating unit designed for use with interchangeable probes shall be generated by replacing the probe by an auxiliary device, such as an appropriate precision resistor simulating the temperature of a resistance probe. The reference temperature indication is that obtained under the reference conditions described in sub-paragraph (3) of paragraph 4

(1) The battery shall be replaced by a variable DC voltage source.

(2) The voltage of the source shall be reduced until a low battery indication or warning signal is activated at the level specified by the manufacturer. The test shall be carried out at three different temperatures; $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$, and the lower and upper limits of the measuring range.

5. Ambient temperature.-

- (1) The complete thermometer or indicating unit shall be placed in a test chamber, and the temperature of the chamber varied from 10°C to 40°C with each temperature setting constant within $\pm 2^{\circ}\text{C}$. Sufficient time shall be allowed at each temperature setting to permit the complete thermometer or indicating unit to reach thermal equilibrium with the chamber.
- (2) At each temperature tested, the requirements specified in sub-paragraph (2) of paragraph 4 shall be met.

6. Thermal shock.-

- (1) The indicating unit shall be placed in a test chamber at $-5^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- (2) After thermal equilibrium has been established, the complete thermometer or indicating unit shall be placed in a test chamber at $50^{\circ}\text{C} \pm 2^{\circ}\text{C}$ until thermal equilibrium has been established and all traces of condensed moisture have evaporated.

- (3) The process described in sub-paragraph (1) of paragraph 6 and sub-paragraph (2) of paragraph 6 of Annexure B shall be performed five times.
- (4) The indicating unit shall be allowed to achieve thermal equilibrium at room temperature after which the indicated temperature shall not change by more than $\pm 0.1^{\circ}\text{C}$ as a result of exposure to the thermal shocks described in sub-paragraph (1) of paragraph 6 and sub-paragraph(2) of paragraph 6 of Annexure B.

Note : Thermal equilibrium may be achieved more quickly and completely by opening the casing of the thermometer, if possible.

7. Humidity.-

- (1) The complete thermometer or indicating unit shall be stabilized at a temperature t within the range 20°C to 32°C for 4 hours or more. During this time, t shall remain constant within $\pm 2^{\circ}\text{C}$.
- (2) After achieving a stable temperature as specified in sub-paragraph (1) of paragraph 7 of Annexure B, the complete thermometer or indicating unit shall be placed in a humidity test chamber containing air at a temperature between t and $t + 4^{\circ}\text{C}$ and a relative humidity between 91% and 95% for a period of 48 hours.
- (3) After exposure as specified in sub-paragraph (2) of paragraph 7 of Annexure B, the complete thermometer or indicating unit shall be removed from the test chamber and allowed to stabilize at room temperature for 48 hours. The indicated temperature shall not vary by more than $\pm 0.1^{\circ}\text{C}$ as a result of this test.

8. Electro-magnetic radiation interference.-

- (1) The complete thermometer or indicating unit shall be exposed to an electromagnetic field with a field strength of 10 V/m at frequencies between 150 kHz and 500 MHz modulated by a 1 kHz sine wave and 80% amplitude modulation.
- (2) The specific field strength shall be established prior to testing and without the instrument being placed in the electro-magnetic field. The field strength may be generated as follows:
 - (i) a strip line for low frequencies (below 3 MHz) or in some cases 150 MHz) for small instruments,
 - (ii) dipole antennas, or antennas with circular polarization, placed 1 m from the instrument at higher frequencies.
- (3) The field shall be generated with two orthogonal polarizations and then slowly scanned through the frequency range. Antennas with circular polarization may be used to generate the electro-magnetic field without a change in their positions. The test shall be carried out in a shielded enclosure to comply with international laws prohibiting interference with radio communications, but care shall be taken to minimize reflections.
- (4) During the test, the requirements specified in clause (vi) of sub-paragraph (3) of paragraph 5 shall be met.

9. Mechanical shock.-

- (1) The complete thermometer or indicating unit shall be allowed to fall from a height of 1 m on to a hard surface (for example, a block of hard wood of density greater than 700 kg/m^3 and of suitable size lying flat on a rigid base). The drop shall be performed once for three different orientations of the complete thermometer or indicating unit.
- (2) After the test, the requirements specified in clause (vii) of sub-paragraph (3) of paragraph 5 shall be met.

ANNEXURE C

TEST OF WATER RESISTANCE OF COMPLETE THERMOMETERS

(Mandatory)

1. Pattern approval

- (1) A total of 10 samples shall be tested.
- (2) The battery casing shall be opened and closed several times before the tests if the thermometer is equipped with replaceable batteries.
- (3) The thermometer shall be totally immersed in an equivalent physiological solution (9.5 g NaCl per litre of distilled water) to a depth of 15 cm and at temperatures of 50°C and 20°C for the following periods of time and in the sequence indicated: —
 - (i) 1 hour at $50^{\circ}\text{C} \pm 2^{\circ}\text{C}$
 - (ii) 1 hour at $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$

- (iii) 24 hours at $50^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- (iv) 24 hours at $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- (4) The indicated values shall be measured at two or more temperatures near the lower and upper limit of the measuring range before the first immersion and after the second and last immersion. The thermometers shall have reached equilibrium with room temperature before recording the indicated values. After the last immersion, the thermometers shall be stored for 14 days in air at room temperature before taking the last measurement.
- (5) The test may be discontinued if it is obvious that water has penetrated into the casing of a thermometer.
- (6) The thermometer pattern shall be declared to be water resistant if, for nine out of ten thermometers, the difference in indicated temperatures for any individual thermometer is less than—
 - (i) 0.04°C for thermometers with a minimum digital increment of 0.01°C (class I),
 - (ii) 0.1°C for thermometers with a minimum digital increment of 0.1°C (class II).

2. Verification.-

- (1) The thermometers shall be totally immersed in an equivalent physiological solution at a temperature of $50^{\circ}\text{C} \pm 2^{\circ}\text{C}$ to a depth of 15 cm for one hour, after which they shall be immersed for another hour under same conditions but at a temperature of $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Before the first immersion and after the second immersion, the indicated values shall be measured at two temperatures.
- (2) A thermometer shall be accepted if the performance requirements specified in sub-paragraph (6) of paragraph 1 are met.

ANNEXURE D
CLINICAL TEST OF RESPONSE TIME
(Mandatory)

1. Non-predicting clinical electrical thermometers

The minimum time for achieving thermal equilibrium at each appropriate body site shall be determined on the basis of testing at least ten persons.

2. Predicting (calculating) clinical electrical thermometers

- (1) The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of a calculating (predicting) thermometer shall be determined on the basis of testing at least 100 persons. The predicted temperature of each person at an appropriate body site shall be determined by the method specified by the manufacturer. After the predicted indication, the thermometer shall remain at the site for measuring and indicating the actual temperature of its sensor. The total time allowed shall be sufficient to attain thermal equilibrium. The difference in the first and second indicated temperatures for 95% of the persons tested shall not be more than 0.2°C.
- (2) If an oral (sublingual) test has been carried out, the minimum number of persons required for rectal measurement shall be twenty.”

[File No. WM-9(23)/2024]

(Anupam Mishra)

Joint Secretary to the Government of India

Note:- The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), vide notification number G.S.R.71(E), dated the 7th February, 2011 and was last amended, vide notification G.S.R 763(E), dated the 4th October, 2022.