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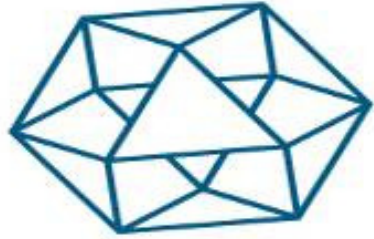
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HOW HOT IS YOUR FRIDGE?

GUIDE TO TEMPERATURE MAPPING

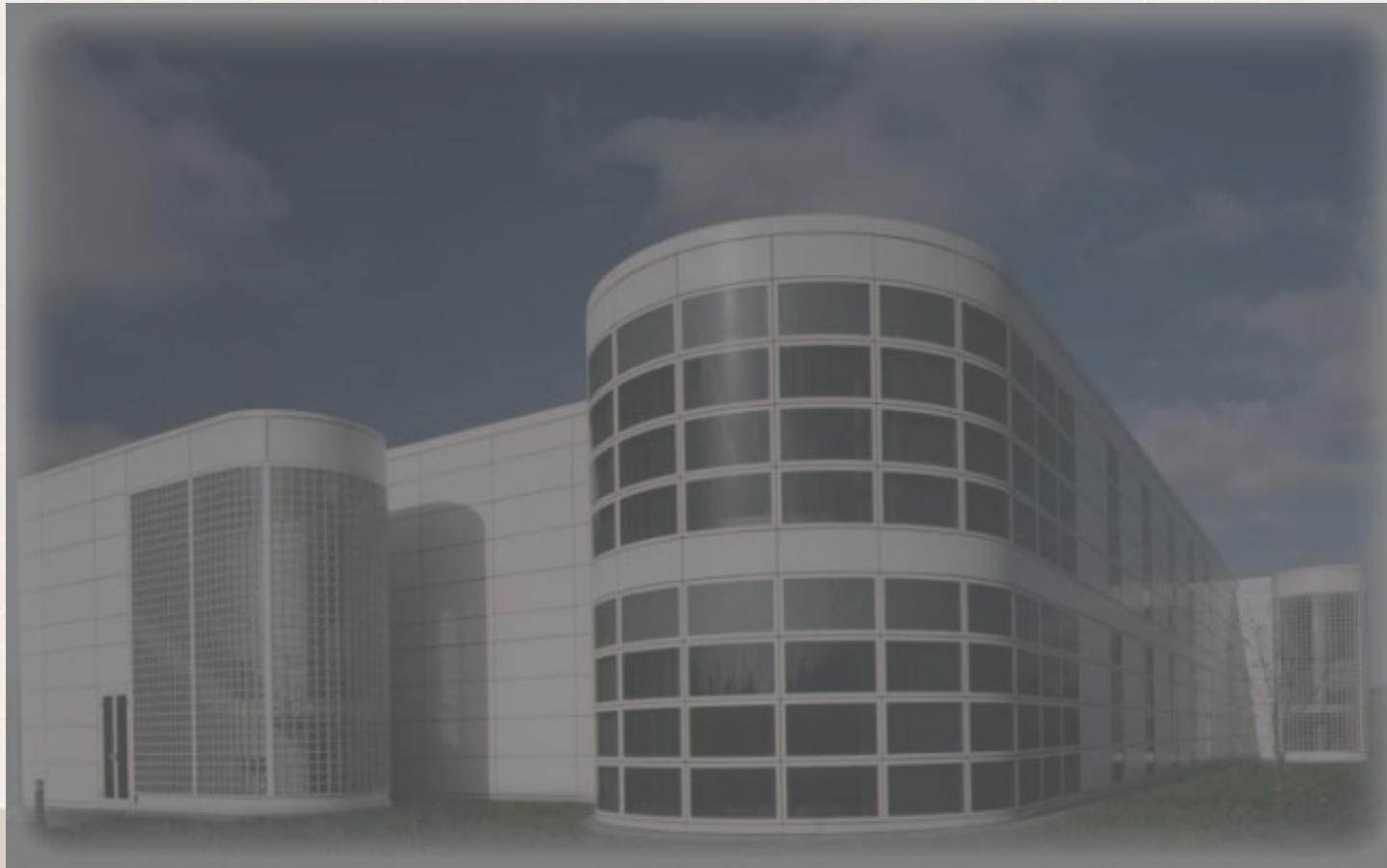
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Temperature/Humidity Laboratory
National Metrology Laboratory
NSAI
Email: mary.white@nsai.ie

7th October 2010



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Division of
NSAI

Staff: 25

Laboratories:

Mass
Dimensional
Pressure
Force
Acoustics
Electrical
Humidity
Temperature



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Glasnevin Dublin 9

Functions of Temperature/Humidity Laboratory

- Maintain National Standards for Temperature, and disseminate **Traceability** to the latest Temperature Scale: ITS-90
- Participate in International Comparisons
- Calibrate Temperature Measuring Instruments and standards, in the temperature range from -100°C to $+700^{\circ}\text{C}$.
 - Digital Thermometers
 - Liquid In Glass
 - Block Calibrators
 - Data Loggers
 - Fixed Point Cells
 - Relative Humidity Instruments
- **Provide Temperature and Humidity Training Workshops**
- **Conduct Technical audits for clients seeking INAB accreditation**
- **New Service for 2011: Measurement at -196°C**

European Association of National Metrology Institutes

Calibration of Climatic Chambers Requirements for the Accreditation of Calibration Laboratories

EURAMET/cg/20/v.01

June 2010

Calibration Guide

Download from Website at: www.euramet.org

IMB GUIDE TO CONTROL AND MONITORING OF STORAGE AND TRANSPORTATION:

TEMPERATURE CONDITIONS FOR MEDICINAL PRODUCTS AND ACTIVE SUBSTANCES.
MARCH 2006

BLOOD STORAGE

IMB Compliance for Storage

$4^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Temperature Monitoring for 24 Hours with Calibrated Thermometer

Stability Testing: Ensures Product is acceptable during Storage.
Temperature Mapping

Examples of Product Requirements

Process	Temperature (°C)	Tolerance Of Process (°C)	Required Accuracy of Monitoring Thermometer	Required Accuracy of Reference Thermometer
Blood Storage	4°C	±2°C	±0.5°C	±0.13°C
Platelet Agitator Storage	22°C	±2°C	±0.5°C	±0.13°C
Freezer	≤18°C -20 °C Or below	TBA		

What is Required to do

Continuous Monitoring in a Fridge at 4°C

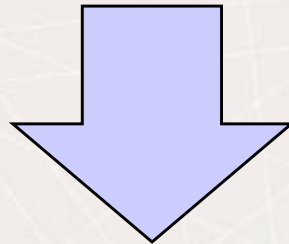
- **Initial Temperature Mapping** should be performed to identify the location of the monitoring probe
- **Monitoring Thermometer** should be placed in a location which has been assessed to be the worst case. It should not be mounted on wall of fridge.
- Temperature monitoring device should be accurate to $\pm 0.5^{\circ}\text{C}$.
- Temperature monitoring device should be **calibrated** annually against certified traceable national standards.
- **Product temperature monitoring** involves temperature probe located within a buffer.
- **Note:** If the buffer method is used for continuous monitoring it must also be used as part of initial temperature mapping

Measurement defined :

“The set of operations with the object of determining the value of a quantity.”

All measurements are IMPERFECT

Measured Value



**An ESTIMATE of the value
of the measured quantity.**




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CALIBRATION

The **DETERMINATION** and **DOCUMENTATION**
of the **ERRORS OF INDICATION**
of a measuring instrument.

Typical Calibration Results for a Thermometer



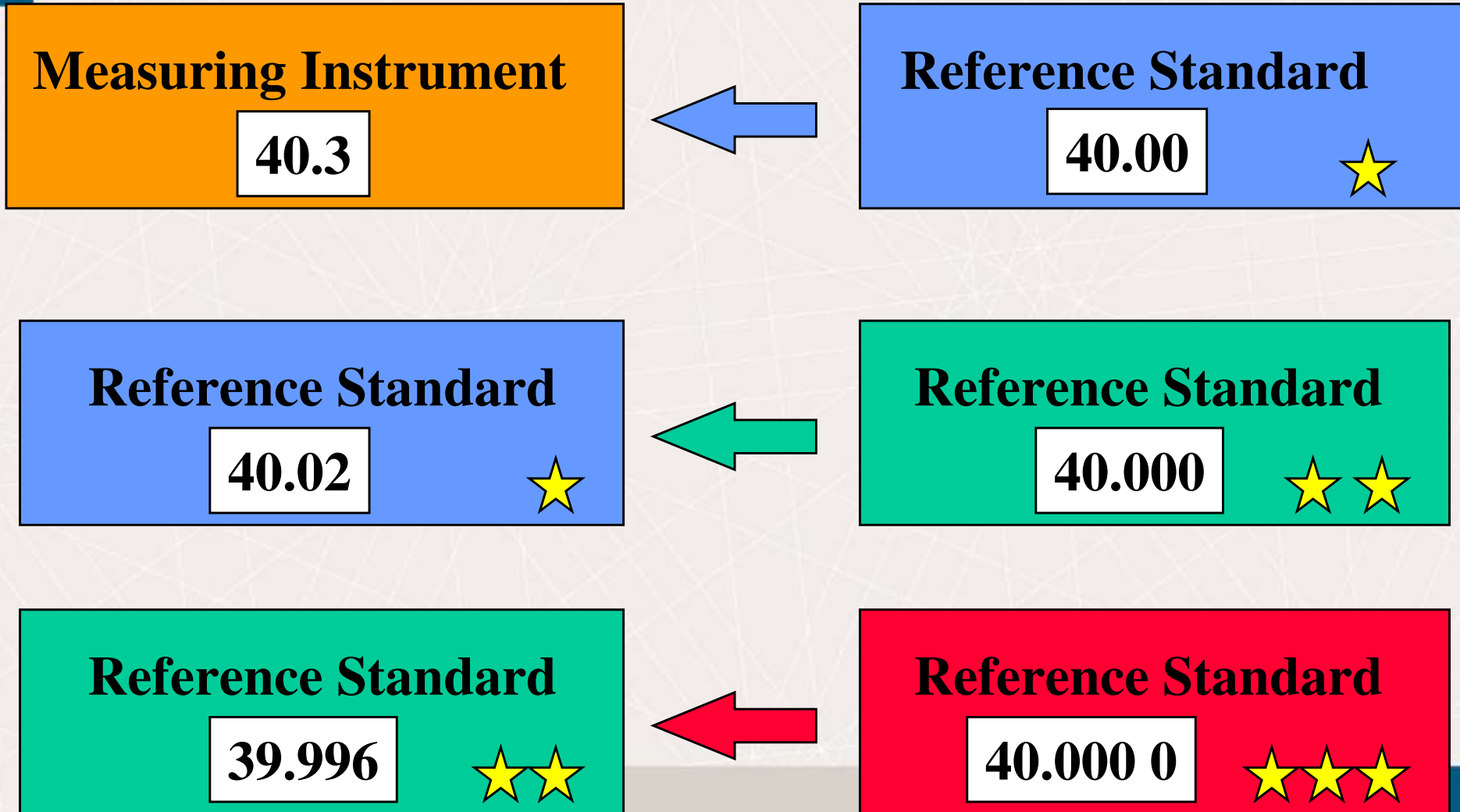
Reference Temperature	Thermometer Reading	Error of Indication
0.00°C	0.1°C	-0.10°C
4.00	4.3	-0.30
22.00	21.9	+0.10



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The Calibration Process



and so on.....

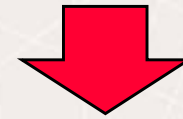
Measurement Result



Measured Value

4°C

consists of

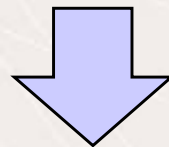


Measurement Uncertainty

2°C

±

±



means

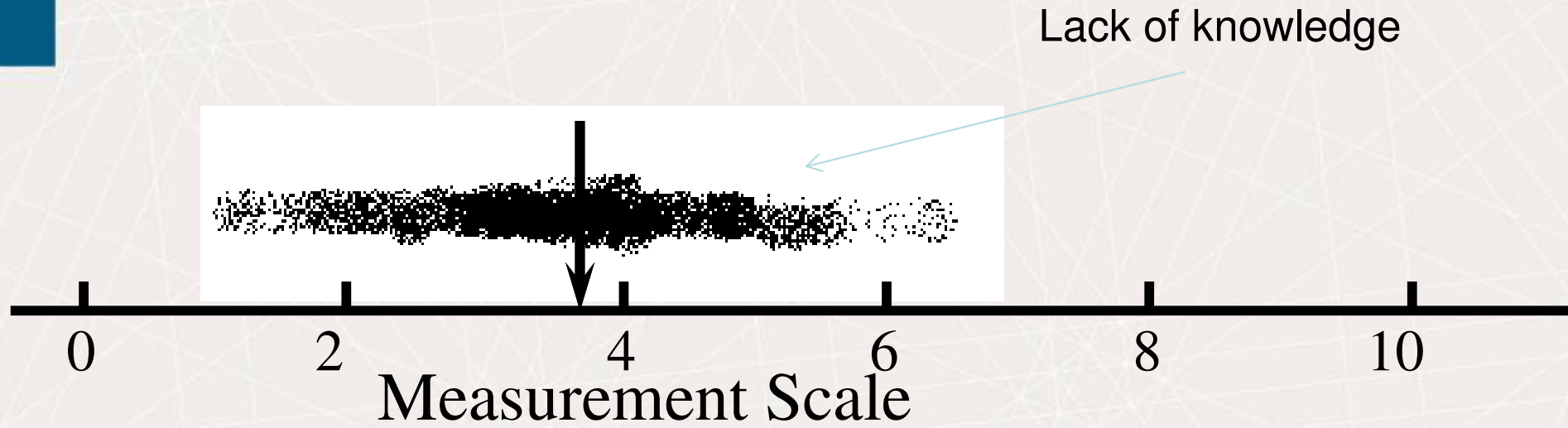
The temperature of the object lies in the range
2°C to 6°C.



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MEASUREMENT RESULT



Uncertainty of Measurement :

A PARAMETER, associated with the result of a measurement, that characterizes the DISPERSION of the values that could reasonably be attributed to the measured quantity.

ISO 15189 Section 3.19 IEC-60068-3-11 Section 3.27

MEASUREMENT TRACEABILITY

This is the property of a measurement result whereby it can be related to national or International standards through an **unbroken** chain of comparisons (calibrations), all having known uncertainties.

All measurements must be **TRACEABLE** in order to be valid

TRACEABILITY

- **ISO-15189:2007**

Medical Laboratories
Particular Requirements
for Quality and
Competence

Refers to Traceability of
Blood Products through
un-broken traceable
chains

- **ISO/IEC 17025 :2005**

General Requirements For
Competence of Testing
and Calibration
Laboratories

Refers to Traceability of
measurement through an
un-broken chain of
measurements

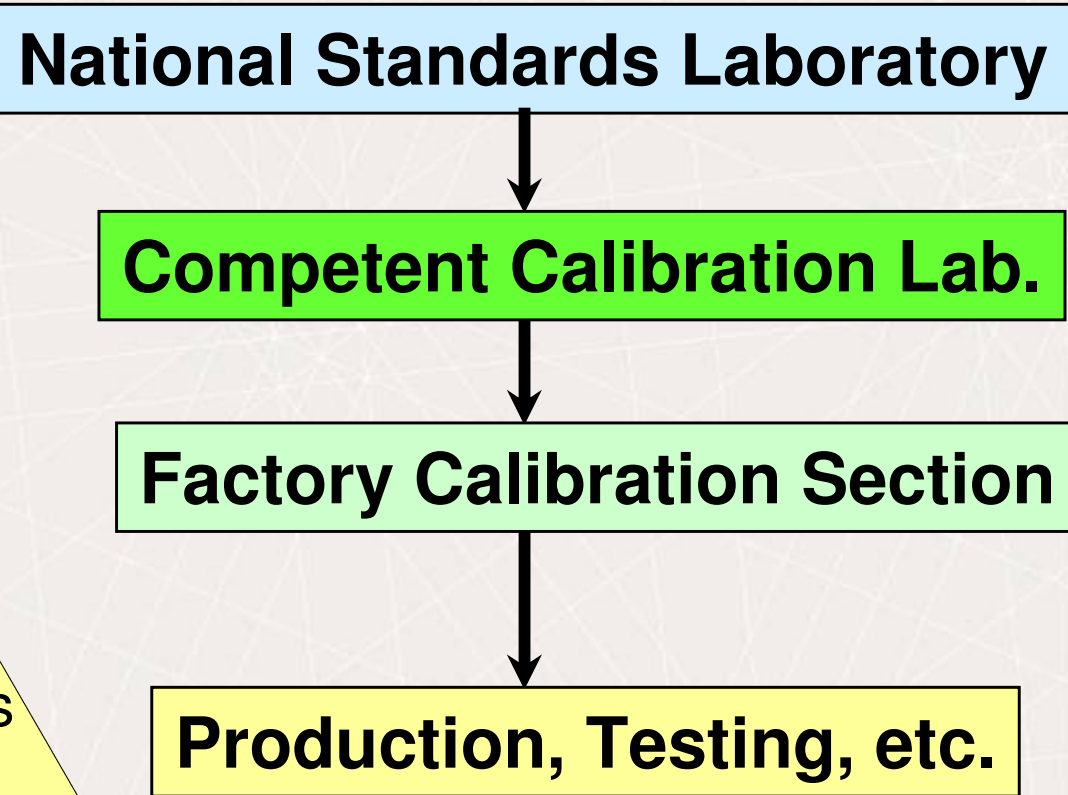
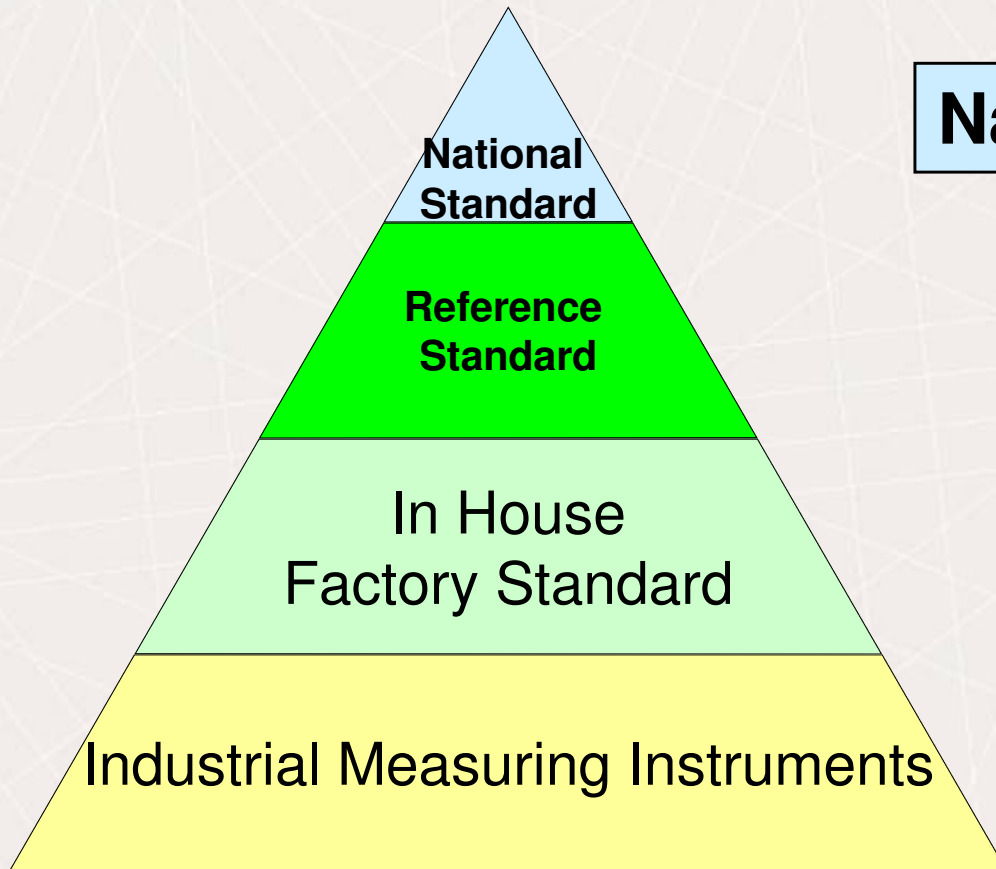


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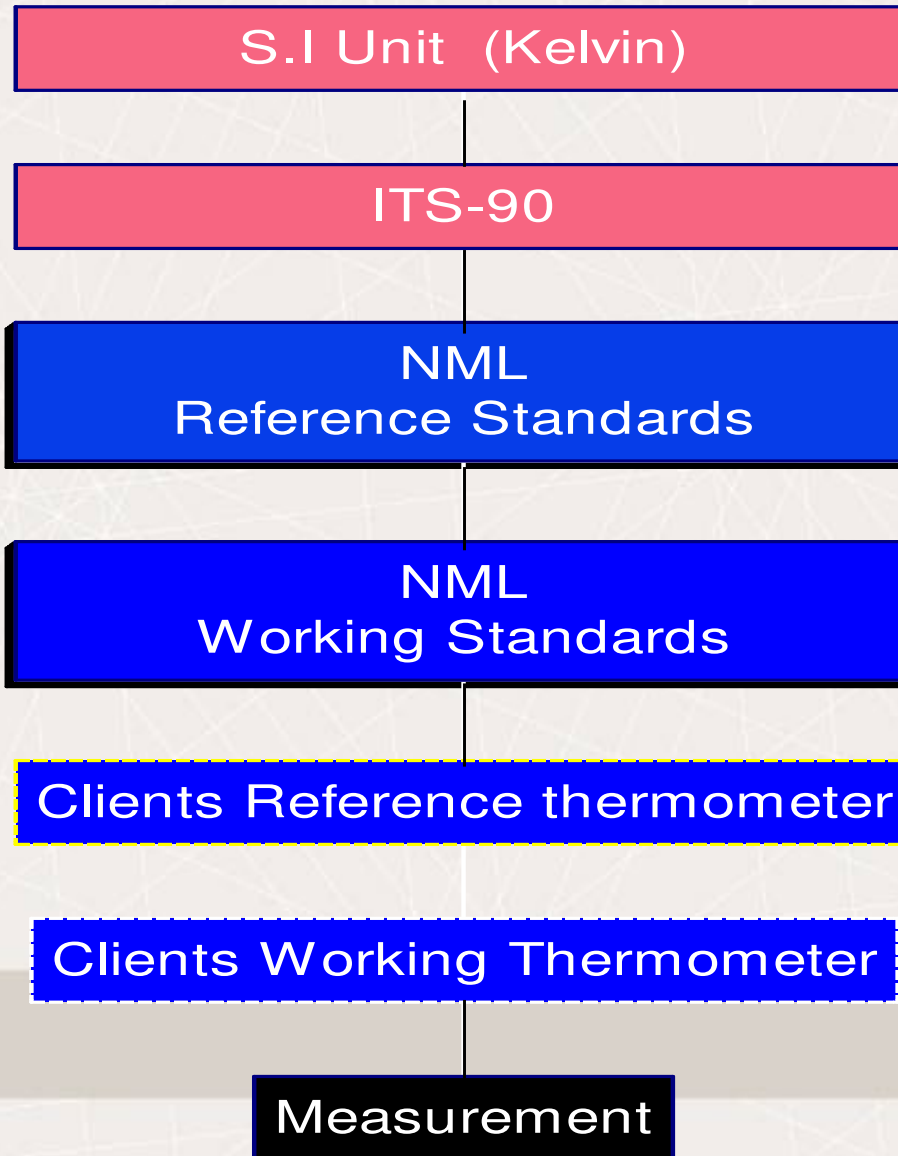
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Calibration Hierarchy

Traceability Chain



Traceability Path



Traceable
Accurate
Temperature
Equipment

Probes in
Air
or
Buffer
Block/Liquid

Compliance
With
Regulations

**TEMPERATURE
MAPPING**
at a
Measuring Location

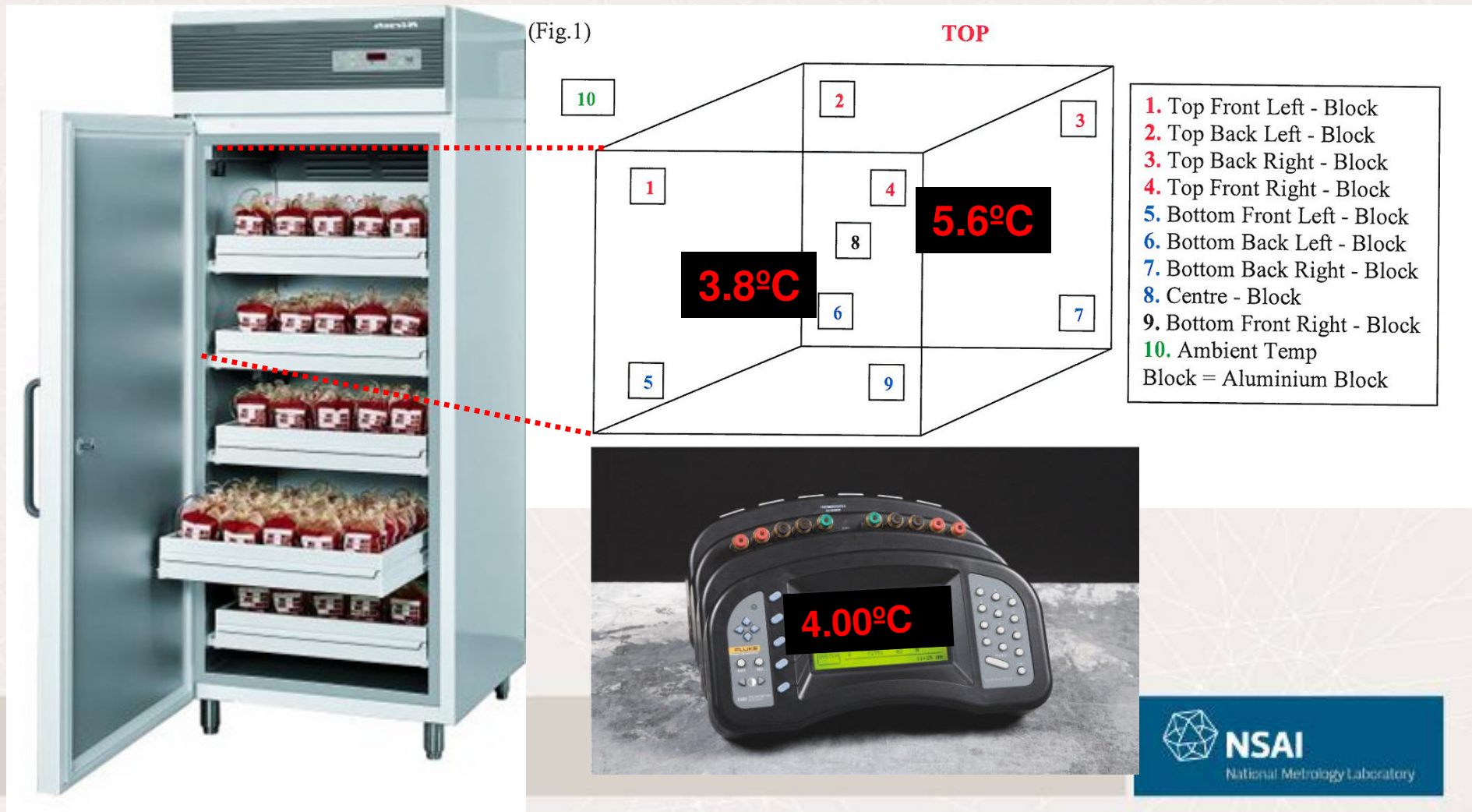
Empty
And
Full Loads

Decides
Best
Location of
Monitoring
Probe

Profile
Gradients
in Fridge

Duration of
Mapping

What is the Temperature at the back and front of the fridge?



TEMPERATURE MAPPING

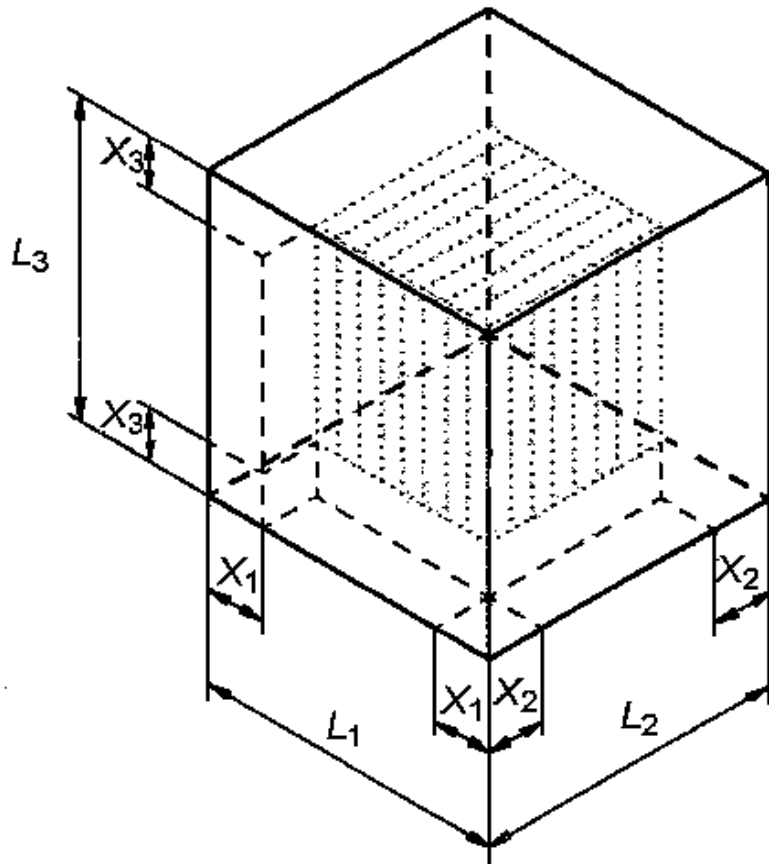
- ❑ IMB say:
 - “Onus on user/owner of storage unit to ensure that Temperature Mapping (T.M.) studies have been appropriately conducted.”
- ❑ Define **Useful/Working Volume** of Chamber/Fridge...
 - Remember product **not permitted** on floor of fridge
- ❑ The working volume is designed to guarantee temperature uniformity



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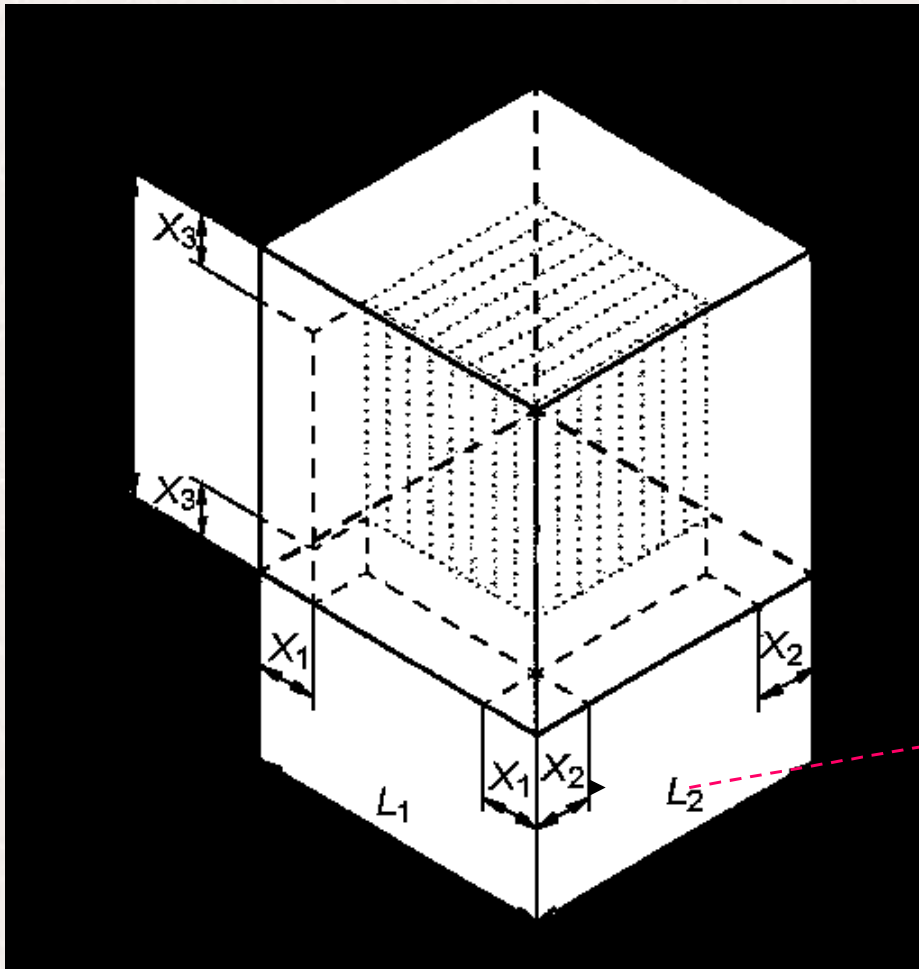
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WORKING VOLUME-Temperature Mapping



Size	Volume (Litres)	Distance X (mm)	X(Min) (mm)
Small	Up to 1000	L/10	50
Medium	1000 to 2000	L/10	100
Large	More than 2000	L/10	150

Working Volume Sample



	W mm	D mm	H mm	V litres
Ext. Dim.	770	970	196	1464
Int. Dim.	600 L/10	780 L/10	1400 L/10	655
Working Volume	480	624	1120	430



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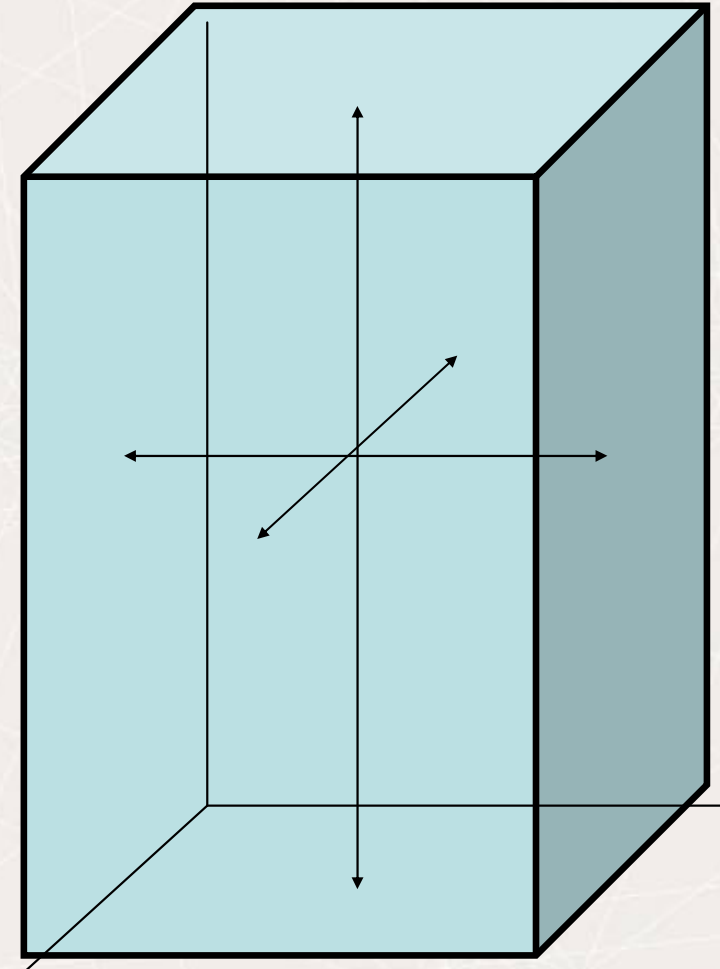
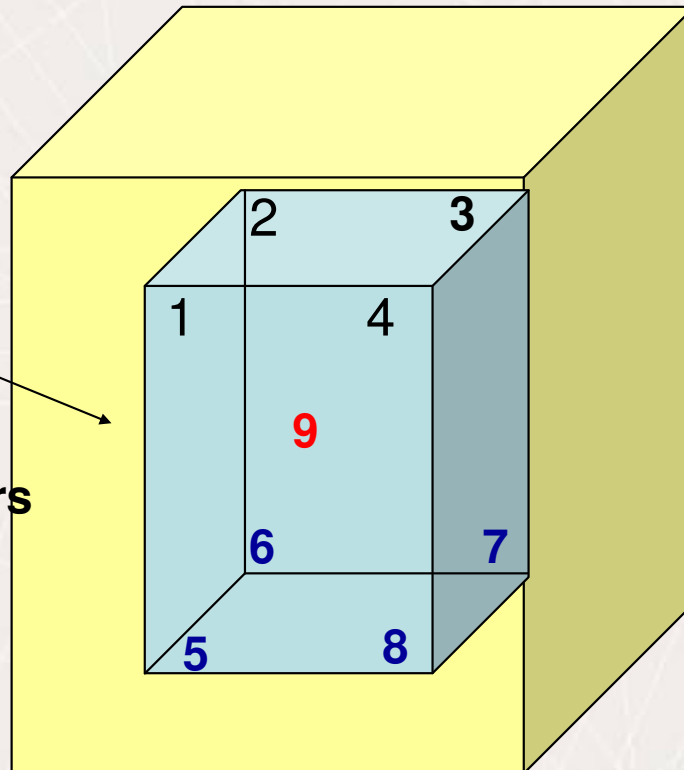
Location of Sensors

Required number of Sensors

Working Volume

Location of 9 Sensors

4 on top
4 on bottom
1 in middle



Very Small areas
4 sensors

No of Sensors
 $\leq 2000L = 9$ Sensors

6 Additional Sensors
 $\geq 2000L = 15$ Sensors



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Monitoring and Temperature Mapping Devices and Sensors

- Device and Sensor calibrated annually and traceable to National Standards. Calibration over a range of 3 temperature points
- Sensor mounted in steel sheath and water impermeable
- Accuracy of Device and Sensor or Wireless Device: $\pm 0.5^{\circ}\text{C}$
- Sensor: PT 100 Class A (IEC 60751-2008)
 - Thermocouple Type T Class 1 IEC 60584 Part 2
 - Thermistor (No recognised International Standards)
- Size of Sensor: Diameter $\leq 5\text{mm}$
- Calibrated Sensor performs differently in fridge
- Choice of placing probes in air or buffer should be scientifically justified. *Is there a difference?*

Temperature of Thermometers in Fridge depend on following parameters (Contents of an Uncertainty Budget)

- Dimensions of Thermometer
- Thermal Stability of Medium Air Vs Buffer
(after 30 mins of stabilisation)
- Response Time of Sensor
- Radiation from inner walls of climatic chamber at the
position of thermometer
- Emissivity of Surface of Probe, **Error= 0.3°C**
- Velocity of Air
- Loading Effect
- Ambient Conditions

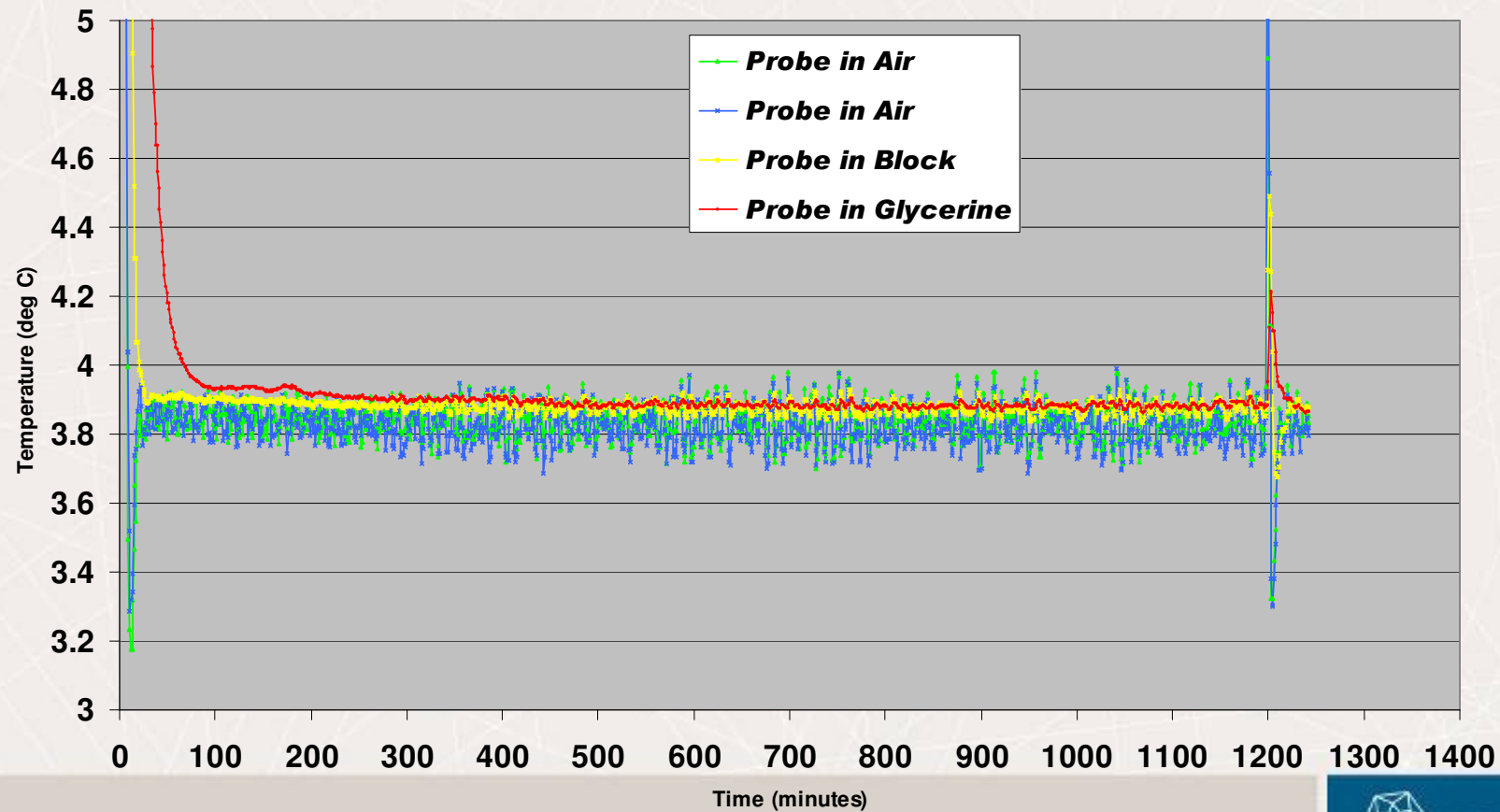


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Use of Stabilisation Media in Temperature Mapping. (24 HOURS)

Stability of measurements, with and without buffers

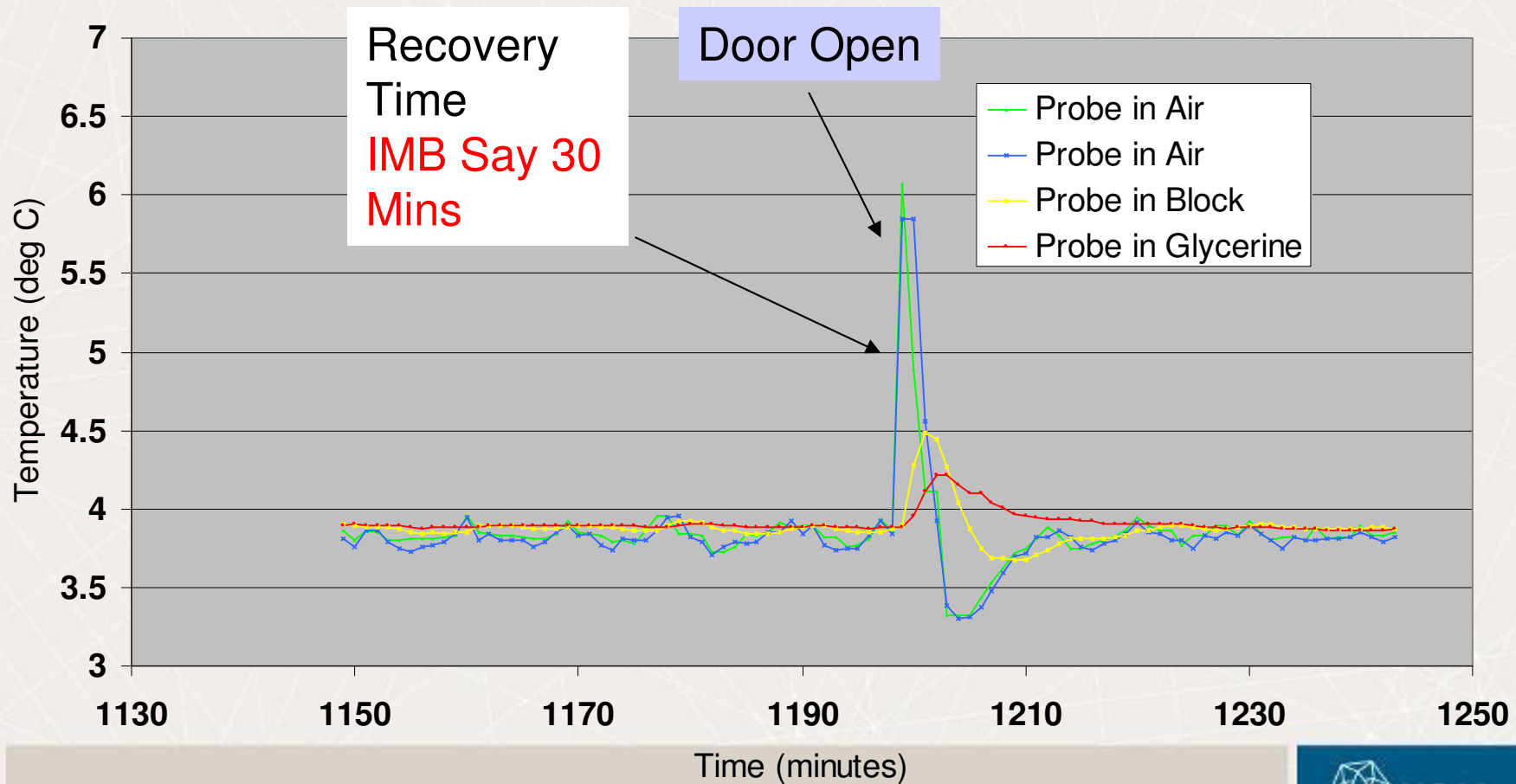


Average Thermal Stability over 10 minutes, for each Probe

Probe	Average over 10 minutes (° C)	Stability over 10 minutes (° C)
Probe 1 in Air	3.83	0.17
Probe 2 in Air	3.82	0.17
Probe 3 in Al Block	3.88	0.05
Probe 4 in Glycerine	3.88	0.02

Recovery time of probes, using different stabilisation media, after opening chamber door for 20 seconds

Recovery time of probes in different media



REQUIRED DURATION OF MAPPING WITH AN EMPTY AND FULL LOAD

- 24 Hour Monitoring requires initial 24 hour mapping with both empty and full loads
 - Measuring test Empty Load : En 60068-3-6
 - Measuring test with Full Load : EN60068-3-7
 - A test load must be 40% of working Volume
 - Recording commences after 30 minutes of steady state conditions
 - Record once a minute
 - Repeat empty and full load mapping whenever fridge undergoes repair/maintenance to heating cooling system

Contents of Temperature Mapping Report

IEC 60068-3-5

- Administrative details including Identification of Chamber
- Details of calibration standards
- Atmospheric conditions
- Size and Volume of Fridge including Working Space
- Sketch/Map of Temperature Points
- Calibration Results
- Supplementary Information for Calibration of Climatic Chambers (See EURAMET GUIDE ANNEX A)



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CALIBRATION RESULTS

Consists of

- ◆ Measurement Results
- ◆ Measurement Uncertainties
- ◆ Traceability Statement

◆ Measurement Results include:

- Temperature Fluctuations
- Temperature Extremes (Max,Min)
- Specify Test Load Empty or Full

◆ Measurement Uncertainties

The uncertainty statement should specify that:

- The radiation effect was/was not included in uncertainty budget
- Loading Effect is /is not part of uncertainty budget
- Uncertainty is for individual locations



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Sample Uncertainty Budget

Calibration Uncertainty of Ref. PRT	0.003°C
Ref. PRT Stability/ year	0.008°C
Ref. Bridge/ indicator unc.	0.010°C
Settability of Climatic chamber	0.010°C
Axial inhomogeneity between 2 probes	0.015°C
Radiation Effect	0.170°C
Loading Effect	0.030°C
Temp. stability	0.050°C
Combined Uncertainty	0.296°C
Expanded Uncertainty	0.59°C



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SOME RELEVANT STANDARDS AND GUIDELINES

- Guide to Control and Monitoring of Storage and transportation Temperature Conditions for Medicinal Products and Active Substances. March 2006
- EURAMET/cg/20/v.01 Calibration of Climatic Chambers Requirements for the Accreditation of Calibration Laboratories June 2010 ([Full list of Standards included in Appendix A](#))
- DKD-R 5-7: Calibration of Climatic Chambers.(2004) English Translation (2007)
- IEC CEI 60068-3-11 – Environmental Testing – Part 3-11: (2007)
- Calculation of Uncertainty of conditions in Climatic Test Chambers
- IEC 60584-1 Thermocouples – (1995) Part 1 Reference Tables
- IEC 60751. (2008) Industrial Platinum Resistance Thermometers Class A



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