

Updates to Technical and Quality Standards **Schedule 1 Annex 2**

For the Provision of **Mobile Preliminary Roads Drugs Testing Devices** **(MRDTD)**

1.0 Background

The updates to the Guide references reflect updates in national standards, specifications and technical regulations to support the type approval of mobile preliminary drug testing devices

2.0 Updates

The following national and international standards and specifications are referred to in this document:

- i. ISO 9001:2015 – Quality management systems – Requirements [1]
- ii. BS EN ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories [2]
- iii. BS EN 61000-6-3:2007+A1:2011 – Electromagnetic compatibility (EMC): Generic standards – Emission standard for residential, commercial and light-industrial environments [3]
- iv. BS EN IEC 61000-6-1:2019 – Electromagnetic Compatibility (EMC): Generic Standards – Immunity for Residential, Commercial and Light Industrial Environments [4]
- v. BS EN 55032:2015+A11:2020 – Electromagnetic compatibility of multimedia equipment – Emission Requirements [4]
- vi. BS EN 60068-1:2014 – Environmental testing. General and guidance [5]
- vii. BS EN 60068-2-30: 2005 – Environmental testing – Tests – Test Db and guidance: Damp Heat, Cyclic (12h + 12h cycle) [6]
- viii. BS EN 60068-2-27:2009 – Environmental Testing – Tests – Test Ea and guidance: Shock. [7]
- ix. BS EN 60068-2-6: 2008 – Environmental Testing – Tests – Test Fc: Vibration (sinusoidal). [8]
- x. BS EN 60068-2-68:1996 – Environmental Testing – Tests – Test L: Dust and sand [9]
- xi. BS EN 60068-2-18:2017 – Environmental Testing – Tests – Test R and guidance: Water [10]
- xii. DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) [11]
- xiii. OIML D 11 Edition 2013 (E) General requirements for measuring instruments - Environmental conditions [12]
- xiv. RF susceptibility test requirement – First edition – CAST Publication number: 010/18 [13]
- xv. BS EN IEC 61000-4-11:2020 – Electromagnetic compatibility (EMC). Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase [14]
- xvi. BS EN 61000-4-4:2012 – Electromagnetic compatibility (EMC): Testing and measurement techniques – Electrical fast transient/burst immunity test [15]
- xvii. BS EN 61000-4-2:2009 – Electromagnetic compatibility (EMC): Testing and measurement techniques – Electrostatic discharge immunity test [16]

Notes:

- The Directive 2014/30/EU replaces Directive 2004/108/EC
- Home Office RF susceptibility test requirement - 010/18 replaces the previous standard detailed in report FSS BAU 03-02 for Annex B5.7 testing
- ISO 9001:2015 - Quality management systems - Requirements replaces the previous version ISO 9001:2008.
- BS EN ISO/IEC 17025:2017 General requirements for competence of testing and calibration laboratories replaces the previous version BS EN ISO/IEC 17025:2005.
- BS EN IEC 61000-6-1:2019 - Electromagnetic Compatibility (EMC) - Part 6-1: Generic Standards - Immunity for Residential, Commercial and Light Industrial Environments replaces the previous version BS EN 61000-6-1.
- BS EN 55032:2015+A11:2020 - Electromagnetic compatibility of multimedia equipment – Emission Requirements replaces the previous standard BS EN 55022 as stated in Directive 2014/30/EU.
- BS EN 60068-1:2014 Environmental testing. General and guidance replaces the previous version of BS EN 60068-1.
- OIML Doc 11 Edition 2013 (E), General requirements for measuring instruments - Environmental conditions replaces previous version of OIML Doc 11.
- BS EN 61000-4-1:2007 - Electromagnetic compatibility (EMC). Testing and measurement techniques included as Overview of IEC 61000-4 series has been withdrawn.
- BS EN IEC 61000-4-11:2020 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase added as reference for Annex B5.2 testing
- BS EN 61000-4-4:2012 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test added as standard referenced for Annex B5.3 testing.
- BS EN 61000-4-2:2009 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test added as standard reference for Annex B5.6 testing.
- Annex B5.8 tests should be carried out with reference to BS EN 61000-4-8:2010, this is harmonised with OIML Doc 11 Edition 2013 (E)
- Annex C3 Data - Data Protection Act 2018 [17] replaces the Data Protection Act 1998

4.0 References

[1]: ISO 9001:2015 – Quality management systems – Requirements

<https://www.iso.org/standard/62085.html>

[2]: BS EN ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories

<https://www.iso.org/standard/66912.html>

[3]: BS EN 61000-6-3:2007+A1:2011 – Electromagnetic compatibility (EMC): Generic standards – Emission standard for residential, commercial and light-industrial environments

<https://shop.bsigroup.com/products/electromagnetic-compatibility-emc-generic-standards-emission-standard-for-residential-commercial-and-light-industrial-environments-1>

[4]: BS EN IEC 61000-6-1:2019 – Electromagnetic Compatibility (EMC): Generic Standards – Immunity for Residential, Commercial and Light Industrial Environments

<https://shop.bsigroup.com/products/electromagnetic-compatibility-emc-generic-standards-immunity-standard-for-residential-commercial-and-light-industrial-environments>

[5]: BS EN 60068-1:2014 – Environmental testing. General and guidance

<https://shop.bsigroup.com/products/environmental-testing-general-and-guidance-1>

[6]: BS EN 60068-2-30: 2005 – Environmental testing – Tests – Test Db and guidance: Damp Heat, Cyclic (12h + 12h cycle)

<https://shop.bsigroup.com/products/environmental-testing-tests-test-db-and-guidance-damp-heat-cyclic-12-h-12-h-cycle>

[7]: BS EN 60068-2-27:2009 – Environmental Testing – Tests – Test Ea and guidance: Shock

<https://shop.bsigroup.com/products/environmental-testing-tests-test-ea-and-guidance-shock>

[8]: BS EN 60068-2-6: 2008 – Environmental Testing – Tests – Test Fc: Vibration (sinusoidal).

<https://shop.bsigroup.com/products/environmental-testing-tests-test-fc-vibration-sinusoidal>

[9]: BS EN 60068-2-68:1996 – Environmental Testing – Tests – Test L: Dust and sand

<https://shop.bsigroup.com/products/environmental-testing-test-methods-test-l-dust-and-sand>

[10]: BS EN 60068-2-18:2017 – Environmental Testing – Tests – Test R and guidance: Water

<https://shop.bsigroup.com/products/environmental-testing-tests-test-r-and-guidance-water>

[11]: DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0030>

[12]: OIML D 11 Edition 2013 (E) General requirements for measuring instruments - Environmental conditions

https://www.oiml.org/en/files/pdf_d/d011-e13.pdf

[13]: RF susceptibility test requirement – First edition – CAST Publication number: 010/18

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/696819/rf-susceptibility-test-requirement-cast1018.pdf

[14]: BS EN IEC 61000-4-11:2020 – Electromagnetic compatibility (EMC). Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase

<https://shop.bsigroup.com/products/electromagnetic-compatibility-emc-testing-and-measurement-techniques-voltage-dips-short-interruptions-and-voltage-variations-immunity-tests-for-equipment-with-input-current-up-to-16-a-per-phase>

[15]: BS EN 61000-4-4:2012 – Electromagnetic compatibility (EMC): Testing and measurement techniques – Electrical fast transient/burst immunity test

<https://shop.bsigroup.com/products/electromagnetic-compatibility-emc-testing-and-measurement-techniques-electrical-fast-transient-burst-immunity-test-1>

[16]: BS EN 61000-4-2:2009 – Electromagnetic compatibility (EMC): Testing and measurement techniques – Electrostatic discharge immunity test

<https://shop.bsigroup.com/products/electromagnetic-compatibility-emc-testing-and-measurement-techniques-electrostatic-discharge-immunity-test>

[17]: Data Protection Act 2018

<https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>