DRAFT PROGRAMME – 22 May 2024

8.30 – 9.00	REGISTRATION	
9.00 – 9:15	OPENING REMARKS Welcome and introduction to the day with context setting. Speaker: **Cinzia Missiroli,** CEN and CENELEC Director of Standardization	
9:15 – 10:30	UNLOCKING EU STANDARDIZATION: LEGISLATIVE FRAMEWORK AND CITATION IMPLICATIONS This session will highlight the EU's relevant legislation and policies that frame the preparation, adoption, and execution of a Standardization Request from the European Commission to the European Standardization Organizations (ESOs). Roles and objectives, as well as specific aspects of Harmonized Standards will be discussed. Finally, the implication of the citation in the Official Journal of the EU will be covered (presumption of conformity). Speakers: EC representatives (DG GROW H2), CEN and CENELEC representatives	
10.30 – 11.00	*COFFEE BREAK*	
11.00 – 12.30	HARMONIZED STANDARDS: DEVELOPMENT, CHALLENGES AND DRAFTING GUIDANCE This session will provide a complete background on the development of harmonized standards, including highlight on critical elements from CEN and CENELEC's Internal Regulations Part 3. It will explain regional (Single Market) and international (ISO/IEC) interwork and challenges, deal with interactions with EY/HAS Consultants, and share drafting best practices. Speakers: CEN and CENELEC representatives, HAS contractor representatives	
12.30 – 13.30	*LUNCH BREAK*	
13.45 – 16.30 (coffee break in between)	HARMONIZED STANDARDS FOR MACHINERY, INCLUDING ALIGNMENT WITH THE MACHINERY REGULATION: GUIDANCE AND SOLUTIONS FOR TECHNICAL BODIES This break-out session will focus on the alignment of Harmonized Standards to the	HARMONIZED STANDARDS FOR HEALTHCARE: GUIDANCE AND SOLUTIONS FOR TECHNICAL BODIES This training will provide guidance and solutions for Technical Bodies in the preparation of harmonized standards in support of Medical Device Regulation (EU)

	Machinery Regulation and the most frequent issues in the HAS assessments for Machinery. Speakers: **Peter Broertjes,** DG GROW H2 **Frank Wohnsland,** CEN and CENELEC Sector Rapporteur for Machinery CEN and CENELEC representatives HAS Consultant for Noise EC desk officer for Machinery	2017/745 and In vitro Diagnostic Regulation (EU) 2017/746 to ensure a smooth citation of healthcare standards in the Official Journal of the European Union. It will also provide participants with the latest developments regarding the preparation of harmonized standards (hENs). Speakers: **Matthias Marzinko,** Vice-Chair of the CEN-CENELEC Sector Forum on Healthcare Standards **Thierry Wagner,** Global Director Regulatory & Standards, Dupont Tyvek **Mario Gabrielli Cossellu,** European Commission HAS consultant for Health **Jennifer Ogbonna,** Project Manager Healthcare Standards, CEN and CENELEC
16.30 – 17.00	CLOSING REMARKS	
	END OF TRAINING	

DRAFT PROGRAMME – 23 May 2024

8.30 – 9.00	REGISTRATION
9.00 – 9:15	OPENING REMARKS Welcome and introduction to the day with context setting. Speaker: **Frédéric Vaillant,** CENELEC Vice-President Technical
9:15 – 10:30	UNLOCKING EU STANDARDIZATION: LEGISLATIVE FRAMEWORK AND CITATION IMPLICATIONS This session will highlight the EU's relevant legislation and policies that frame the preparation, adoption, and execution of a Standardization Request from the European Commission to the European Standardization Organizations (ESOs). Roles and objectives, as well as specific aspects of Harmonized Standards will be discussed. Finally, the implication of the citation in the Official Journal of the EU will be covered (presumption of conformity). Speakers: EC representatives (DG GROW H2), CEN and CENELEC representatives
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12.30 – 13.30	*LUNCH BREAK*	
13.45 – 16.30 (coffee break in between)	ELECTROMAGNETIC COMPATIBILITY DIRECTIVE: TIPS FOR FACILITATING CITATION AND BEST PRACTICES This breakout session aims to introduce the Essential Requirements and key Articles of the Electromagnetic Compatibility Directive (EMCD). Tips for avoiding key traps related to the EMCD will be shared (e.g. emissions limit, generic standard, measurement uncertainty vs. measurement accuracy, justification for the needs of alternative test methods etc.). In addition, best practices related to the drafting of the Annex ZZ will be discussed. Speakers: HAS consultant for EMCD, CEN and CENELEC representatives, EC representative	THE LOW VOLTAGE DIRECTIVE (LVD) AND GUIDANCE FOR RISK ASSESSMENT This training will address the issue created by standards incorporating requirements on the use that creates a conflict with the LVD that covers the placement in the market. Information will be given related to issues arising with formal objections relating to blenders / cooking appliances and issues related to the interpretation of the standards. Moreover, guidance will be provided on the use of the CENELEC Guide 32 'Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment' as a path to a good Annex ZZ for LVD. Speakers: HAS consultant for LVD, CEN and CENELEC representatives, EC representative
16.30 – 17.00	CLOSING REMARKS	
	END OF TRAINING	