Harmonized European Standards: A Journey from Legal Framework to Citation in the Official Journal of the European Union

22-23 May 2024
Brussels / Online

Welcome!

Harmonized European Standards: A Journey from Legal Framework to Citation in the Official Journal of the European Union

We start at 13:45

Harmonized European Standards: A Journey from Legal Framework to Citation in the Official Journal of the European Union

22-23 May 2024
Brussels / Online

BREAK-OUT SESSION 1.

Harmonized standards for Machinery, including alignment with the Machinery Regulation: guidance and solutions for Technical Bodies

Key changes brought by the Machinery Regulation

Policy Officer for Machinery at the European Commission (EC)

New Machinery Regulation – key dates

- **Entry into force** was on **19 July 2023**
- Some of the 2023 – 2026 listed **application dates** are relevant only for **Member States** and the **Commission**
- **Transitional period** provided in the new Regulation is **42 months / 3½ years**
- **Application date** for **manufacturers** will be from **20 January 2027**
- **No voluntary application** of Machinery Regulation by **manufacturers before 2027**

Aims of the revised Machinery Regulation

- Keep ensuring the well-functioning of the **single market**
- Create a **level playing field** for economic operators and preserve the competitiveness of the machinery sector in **global markets**
- Establish a **high level of trust** in **digital** innovative **technologies** for consumers and users
- Adapt to the **risks of emerging digital technologies**
- Boosting **innovation**
- **Reduce cost** for the industry, in particular SMEs, save natural resources, …
- **Digital instructions** and **EU Declaration of Conformity**
- Regulation through **Essential Health and Safety Requirements** supported by harmonised standards **cited in the EU Official Journal**

Key changes compared to Machinery Directive

- Increased **legal certainty**, uniform application (e.g. substantial modification)
- Integration of **Artificial Intelligence** related provisions for safety functions
- Integration of **Cyber Safety** related provisions for safety control systems and compliance related software and data
- **Autonomous** and **remote-controlled** machinery
- **Digitalisation** of instructions for use, assembly instructions and EU Declaration of Conformity and Incorporation
- **Mandatory Notified Body conformity assessment** for 6 product categories
- **Common specifications** as a fallback option when suitable harmonised standards are not available
- Streamlined **Safeguard Procedures**, aligned with other legislation

List of product categories with mandatory Notified Body conformity assessment

- Annex I Part A list of **machinery** with **mandatory** Notified Body assessment
  1) Removable mechanical transmission devices including their guards
  2) Guards for removable mechanical transmission devices
  3) Vehicle servicing lifts
  4) Portable cartridge-operated fixing and other impact machinery
  5) Safety components with fully or partially **self-evolving behaviour** using machine learning approaches ensuring safety functions
  6) Machinery that has embedded systems with fully or partially **self-evolving behaviour** using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems

List of product categories with optional* Notified Body conformity assessment

- Annex I Part B lists **machinery** with **optional** Notified Body assessment

  1) to 19) saws, presses, garbage trucks, lifts, …

  (Note: only if harmonised standards are fully applied, otherwise mandatory Notified Body assessment)

- Same list as current Machinery Directive Annex IV, except:

  14 (removable mechanical transmission devices including their guards),
  15 (guards for removable mechanical transmission devices),
  16 (vehicle servicing lifts), and
  18 (portable cartridge-operated fixing and other impact machinery),

  (Note: all moved to list with mandatory Notified Body conformity assessment)

- **Both Annex I Part A and B lists** will be **subject to updates** by the Commission, based on field accident data provided by EU Member States

Points of interest / main differences

Annex III Part B General Principles

- The risk assessment shall include **hazards that might arise during the lifecycle** of the machinery that are foreseeable at the time of placing the machinery on the market **as an intended evolution of its fully or partially self-evolving behaviour**

Points of interest / main differences

Annex III Part B Essential Health and Safety Requirements (1)

- User test of the safety functions **1.1.2. (e)**
- Avoiding demanding work postures or movements and manual force exertions that exceed the operator's capacity **1.1.6. (b)**
- AI use for adapting human-machine interface **1.1.6. (f)** and responses (e.g. verbally or non-verbally) **1.1.6. (g)**
- Protection against corruption (for software and connected machinery) **1.1.9.**
- Cyber resilience of control systems (including reasonably foreseeable malicious attacks) **1.2.1.**
- Traceability of interventions and software updates to control systems **1.2.1.**
- AI use in control systems, risk assessment, data recording, reliability and safety **1.2.1.**

Points of interest / main differences

Annex III Part B Essential Health and Safety Requirements (2)

- Avoidance of risk of contact in case of human-machine interaction or coexistence in a shared space (when AI-powered safety function) **1.3.7.**
- Adequate machine access dimensioning **1.6.2.**
- Portable hand-held or hand-guided machinery having fume exhausts **2.2.1.**
- Additional information on vibrations of portable hand-held or hand-guided machinery in the instructions for use **2.2.1.1. (a) and (b)**
- Seating as regards safety-belt reminder or inhibition of operating certain mobile machinery when the safety-belt is not used **3.2.2.**
- Supervisory function of autonomous mobile machinery **3.2.4.**
- Autonomous and remote-controlled mobile machinery **3.3.3.**

Points of interest / main differences

Annex III Part B Essential Health and Safety Requirements (3)

- Filtration of hazardous substances for operators of ride-on mobile machinery applying such substances **3.5.3.**
- Risk of contact with live overhead power lines on mobile machinery **3.5.4.**
- Alternative solutions to hold-to-run type control devices for lifting machinery (allowing technological neutrality) **6.2.**

Question for the audience [Menti]

Which of new or modified requirements of Machinery Regulation is the most relevant for you/your TC?

1. Ergonomics and human/machine interface **1.1.6**
2. Protection against corruption **1.1.9**
3. Additional information on vibrations of portable hand-held or hand-guided machinery in instructions for use **2.2.1.1**
4. Supervisory function of autonomous mobile machinery **3.2.4**
5. Risk of contact with live overhead power lines **3.5.4**
6. Other

Features of the draft Standardisation Request

- Integration of **Artificial Intelligence** related provisions for **safety functions**
- To ensure consistency and avoid an unnecessary administrative burden or unnecessary costs, we are requesting to develop specific standards covering such AI-powered machinery, **building on** the horizontal provisions and standards under the proposed **Artificial Intelligence Act**
- Coherent standards, potentially covering both Machinery and AI Regulations
- This helps providers of machinery or related products that contain high-risk AI systems, to which the requirements of both Artificial Intelligence Act and Machinery Regulation apply, to be flexible and efficient in their approach to ensure compliance

Features of the draft Standardisation Request

- Integration of **Cyber-safety** related provisions for **safety control systems** and compliance-related software and data
- Aiming to achieve a coherent cybersecurity framework across the European market, avoiding duplication of efforts for specific product categories and **facilitating compliance under both the Cyber Resilience Act and Machinery Regulation**
- Following the risk-based approach, machinery manufacturers should be able to carry out the risk assessment for cybersecurity risks, which in the case of the Machinery Regulation refer to risk to health and safety
- Such synergies should lead to future harmonised standards which are tailored to address the essential requirements of the Cyber Resilience Act and also to fit those of the Machinery Regulation

Features of the draft Standardisation Request

- **Autonomous** and **remote-controlled** machinery
- Specification of new or revised harmonised standards with specific provisions for autonomous mobile machinery and related products with, as pertinent, a supervisory function

Features of the draft Standardisation Request

- Harmonised standards must be **inclusive**, aiming to ensure equal or fairly distributed performance **regardless of gender, age, height and other** anthropometric and biomechanical **body characteristics**
- Preference is to be given to **ranges rather than averages** to describe product users or operators in terms of **body size**, structure and composition
- They must cover relevant **physical capabilities** in terms of **strength** limits, operating **postures** and movement ranges
- They should also, where appropriate and reasonably practicable, consider **persons with special needs**, persons relying on ease of access, persons depending on **ability aids** and persons relying on **assistance animals**

Features of the draft Standardisation Request

- **Additive manufacturing** and additive manufacturing relevant equipment
- Standardisation **area of particular interest** in the context of international standardisation activities
- To include a **classification scheme** for 3D-printing materials (e.g. aeronautic grade alloys, defense grade metals, ecological resins)

Thematic approach – standardisation domains

- The **machinery sector** and the new Machinery Regulation covers a very **large number of product categories** and technological fields
- Consequently, the related **number of existing harmonised standards is extraordinarily large** (currently over 800 harmonised standards)
- That list will **continue to be updated until end of 2026**
- Featuring a **static and exhaustive list** in Part 2 of the Standardisation Request **could lead to a disproportionate administrative burden** for Commission services and stakeholders
- For these reasons, we aim to present the standardisation deliverables in a **thematic list** covering the relevant product categories, technological fields and **74 standardisation domains** instead of 800+ individual standards

Next steps

- **Future updates of Annex I for machinery presenting a higher risk factor**
  - **Commission** to provide a reporting **template and guidance** to Member States on the collection and transmission of accident data by **July 2024**
- **Draft Standardisation Request**
  - **Consultation** with stakeholders is not yet finished, but envisioned to be finalised soon
  - **Notification on the Europa website** on possible future standardisation requests
  - Launch of the Commission's **inter-service consultation**
  - Final steps for **adoption** of the Implementing Decision

Thank you

For further information:

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Machinery and Equipment Unit

DG GROW – Unit H.2

grow-machinery@ec.europa.eu

Except where otherwise noted, this presentation is © European Union and is licensed under the CC BY 4.0 license.

European Commission

Alignment of hENs to the Machinery Regulation and gap-analysis

AFNOR/UNM representative
Secretary of the CEN-CENELEC Sector Forum on Machinery

Acronyms

BTs: Technical Boards of CEN and CENELEC
CCMC: CEN-CENELEC Management Centre
EC: European Commission
EHSR: Essential Health and Safety Requirements (of Machinery Directive and/or Machinery Regulation)
hEN: European harmonised standard
LoC: lack of compliance
MD: Machinery Directive
MR: Machinery Regulation
OJEU: Official Journal of European Union
SReq: Standardization Request
VA: Vienna Agreement
FA: Frankfurt Agreement

Development of hEN in support of MR
Carry over of “old” hEN

- Journey from Machinery Directive 2006/42/EC (MD) to Machinery Regulation (EU) 2023/1230 (MR):
  Ideally, as many harmonized MD-standards as possible should also be harmonized under new Machinery Regulation
- Challenge:
  - Most of today’s hENs do not necessarily cover new or strongly modified EHSRs of new MR
  - Revision or updating of all “old” hEN (taking account of all formal requirements etc.) to new MR-system is not feasible within < 3 years

Development of hEN in support of MR
Carry over of “old” hEN

Solution:

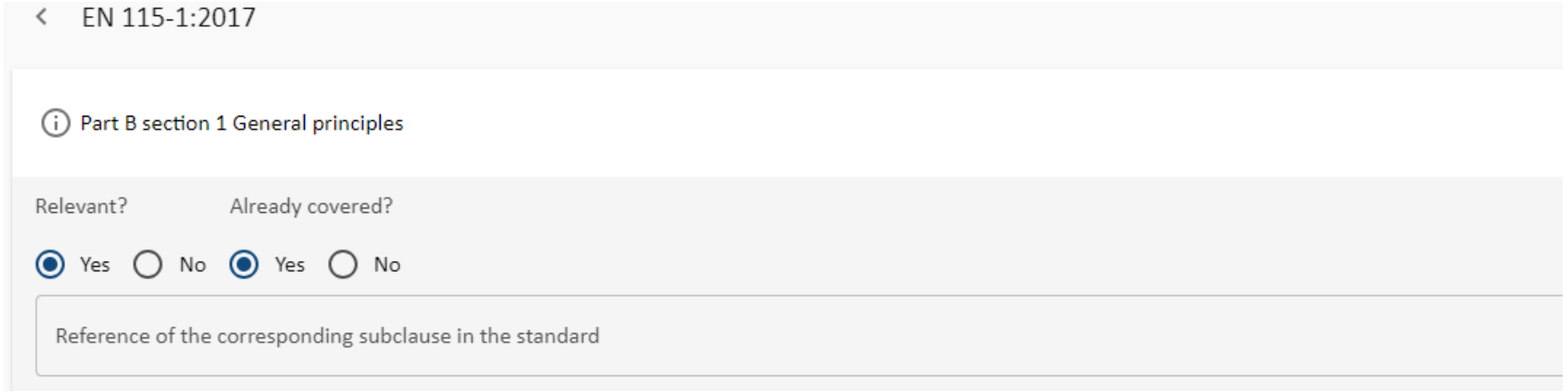
- Proposal to transfer – as far as feasible – “old” hENs under MD to OJEU for MR without regular revision or amendment (as a first step)
- Boundary conditions for such a procedure:
  - “Old” hEN under MD keep presumption of conformity only with respect to
    - those EHSRs that they used to address under the MD

    and
    - those new EHSRs from MR that they happen to already cover today
  - This needs to be indicated in the OJEU for MR

Gap-analysis (1/5)

Gap–analysis = **requested by EC** to assess impact of changes/new EHSRs of MR on existing hENs under MD

- whether the modification in EHSR is relevant for the hEN?
- whether it is already covered by hEN?
- if covered by hEN – by which clauses of hEN?



- 2024-02-02: TCs were requested this task (email sent to TC Secretaries)

Question for audience [Menti]

Have you / your TC started doing a gap-analysis?

Possible answers:

- Yes
- No
- I do not know what is a gap-analysis

Gap-analysis (2/5)

Outcome will be provided to EC→ impact on **OJEU list** for MR:

Three possible scenarios for each gap analysis:

1. hEN is NOT affected by the new/modified EHSRs:
   ⇒ likely to be cited in the OJEU under MR as it is
2. hEN is affected by some of the new/modified EHSRs, but already covers them:
   ⇒ likely to be cited in the OJEU under MR as it is
3. hEN is affected by some of the new/modified EHSRs, but is not (sufficiently) addressing them:
   ⇒ citation in the OJEU possible, but with restriction(s)

If a TC decides do not carry out the gap analysis for certain hENs, these are unlikely to be cited under this scheme ⚠

Gap-analysis (3/5)

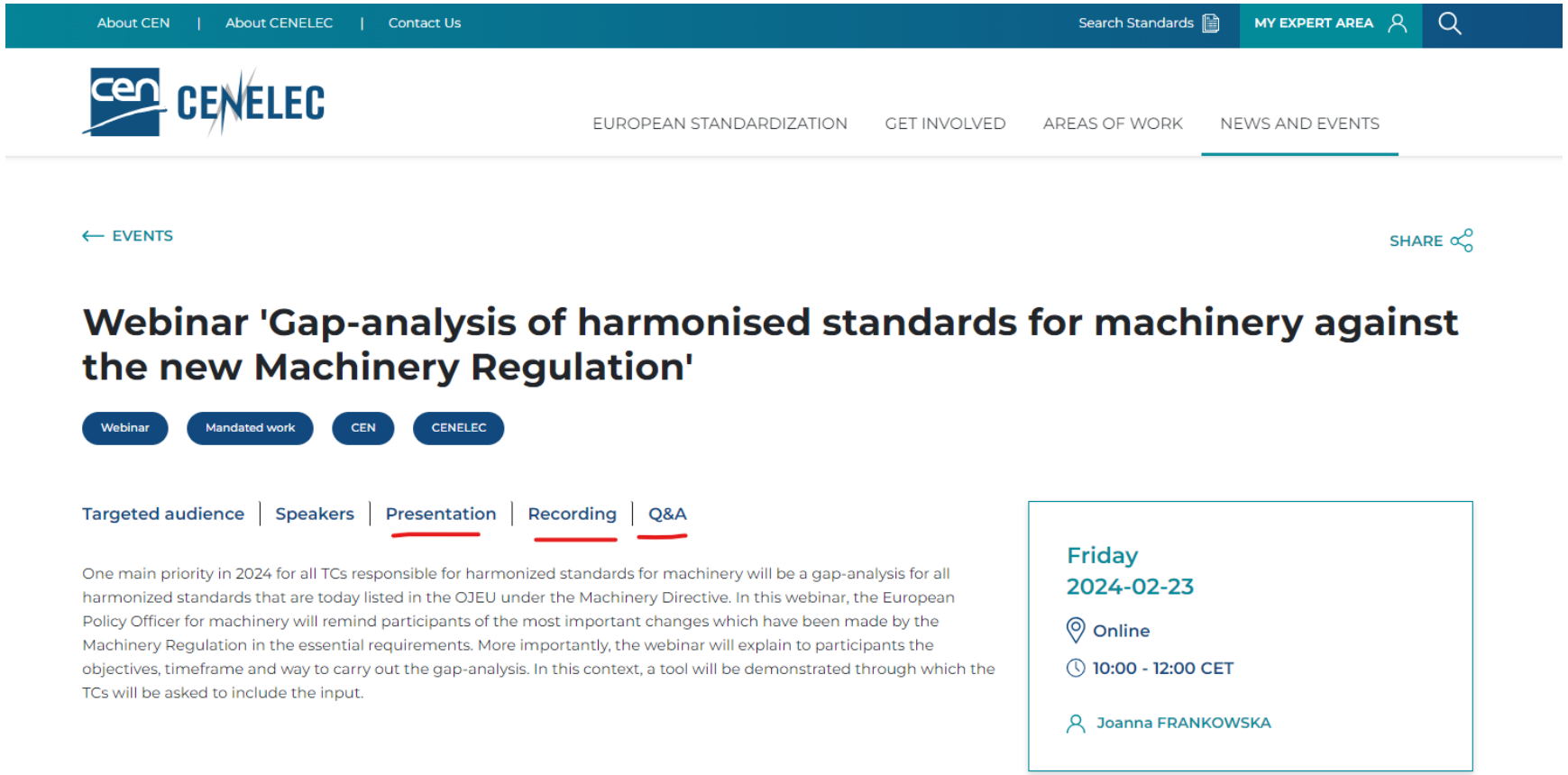
- Exercise on all active hENs **cited in OJEU** for Machinery Directive (including parallel work under VA and FA)
  - gap-analysis shall be made only for **the edition** of published and cited hEN as indicated in tool
- After each citation in OJEU for MD, newly referenced hENs will be added to tool
  - waiting for the citation, analysis can be made in PDF file
- Deadline: end October 2024 for hENs **already cited** and **to be cited in Spring 2024**
- Longer deadline expected for standards **to be cited in 2025**

Gap-analysis (4/5)

- Gap analysis does NOT depend on the status of the Standardization Request
- It is NOT a “regular” standardization process:
  - Hence gap analyses are not carried out under an own Work Item
  - They are NOT linked to the “typical” deadlines of CEN standard projects
- Each TC shall decide how to organise the work in this TC on gap-analysis

Gap-analysis (5/5)

Link to the Webinar for TCs with detailed information



Annexes Z in transition period

Decision BT D176/C008 (CENELEC) & Decision BT C153/2023 (CEN)

approved

- template of informative Annex Z for **draft** hENs for MR (see next slides);
- in transition period hENs will be sometimes developed with two Annexes Z: for MD & MR;

=> three possibilities:

1. hEN is published with Annex Z for MD
2. hEN is published with Annex Z for MR or
3. hEN is published with both Annexes Z: for MD and for MR

Alignment to MR - current situation

1. Standardization Request (SReq) for MR is planned to be adopted **in 2nd half of 2024**.
2. Priority: TCs shall make gap analysis →will help to draft Annex Z for MR
3. Template of Annex Z for MR is available (see next session)
4. HAS assessments of draft hENs for MR are already allowed
5. HENs with Annex Z for MR can be published (DAV) only **after adoption of SReq**;

Alignment to MR - current situation

6. Standards ready for submission to formal vote: at this moment shall have only Annex Z for MD
   - Harmonisation with MR can be achieved via amendment
   - TCs will be informed once it will be possible to submit to formal vote drafts with Annex Z for MR
7. For hENs whose publication is expected by Q1 2026:
   prepare two Annexes Z (one for MD and second for MR)
8. New projects shall be linked with MR because will be published after Q1 2026

Key take-aways

1. Exercise on all active **hENs cited in OJEU** for MD (including EN ISO and EN IEC standards)
2. Gap-analysis shall be made strictly for **the edition** of hEN as indicated in tool (only hENs cited in OJEU)→hENs cited in future will be gradually added to tool
3. PDF file is provided but result of gap-analysis shall be always inserted by TC **in tool**
4. Deadline: end October 2024 for hENs **already cited** and **hENs that will be cited in Spring 2024** (longer deadline for hENs which **will be cited in 2025)**
5. Each TC shall decide how to organise the work in this TC on gap-analysis
6. Projects can be **linked** with 1. MD, 2. MR or 3. both MD and MR
7. Now, only hENs in support of MD can be submitted to formal vote
8. Still prepare Annex Z for both MD and MR and see where you are when SReq is adopted

Addressing requirements on noise of MD/MR

HAS Consultant for noise (MD/MR)

Agenda

- Legal and technical background
- ESHR on noise and how to cover them in standards
- Typical mistakes
- Reasons
- Possible Improvements

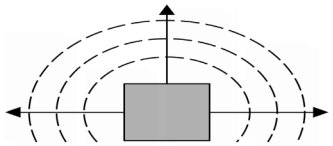
© CEN-CENELEC 2024

Responsible parties and duties

Article 114 of the TFEU

Manufacturer

Emission

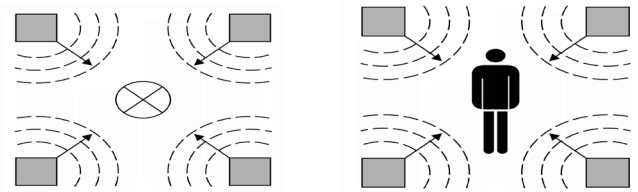


- **Design quiet machines**
- **Noise emission declaration**

Article 153 of the TFEU

Employer

Immission **Exposure**



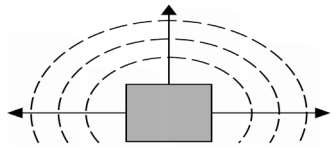
- **Risk assessment**
- **Buying quieter machines**

Sell and Buy Quiet

Reduced noise exposure for employees

Article 114 Free exchange of goods, ESHR on products

Emission



Essential Safety and Health requirements to be met

Machinery Directive (2006/42/EG)

Regulation on Machinery 2023/1230

“Outdoor”- Noise Directive (2000/14/EG)

Deligated Act 2024/1208

© CEN-CENELEC 2024

Acoustic **measures**, parameters, characteristics

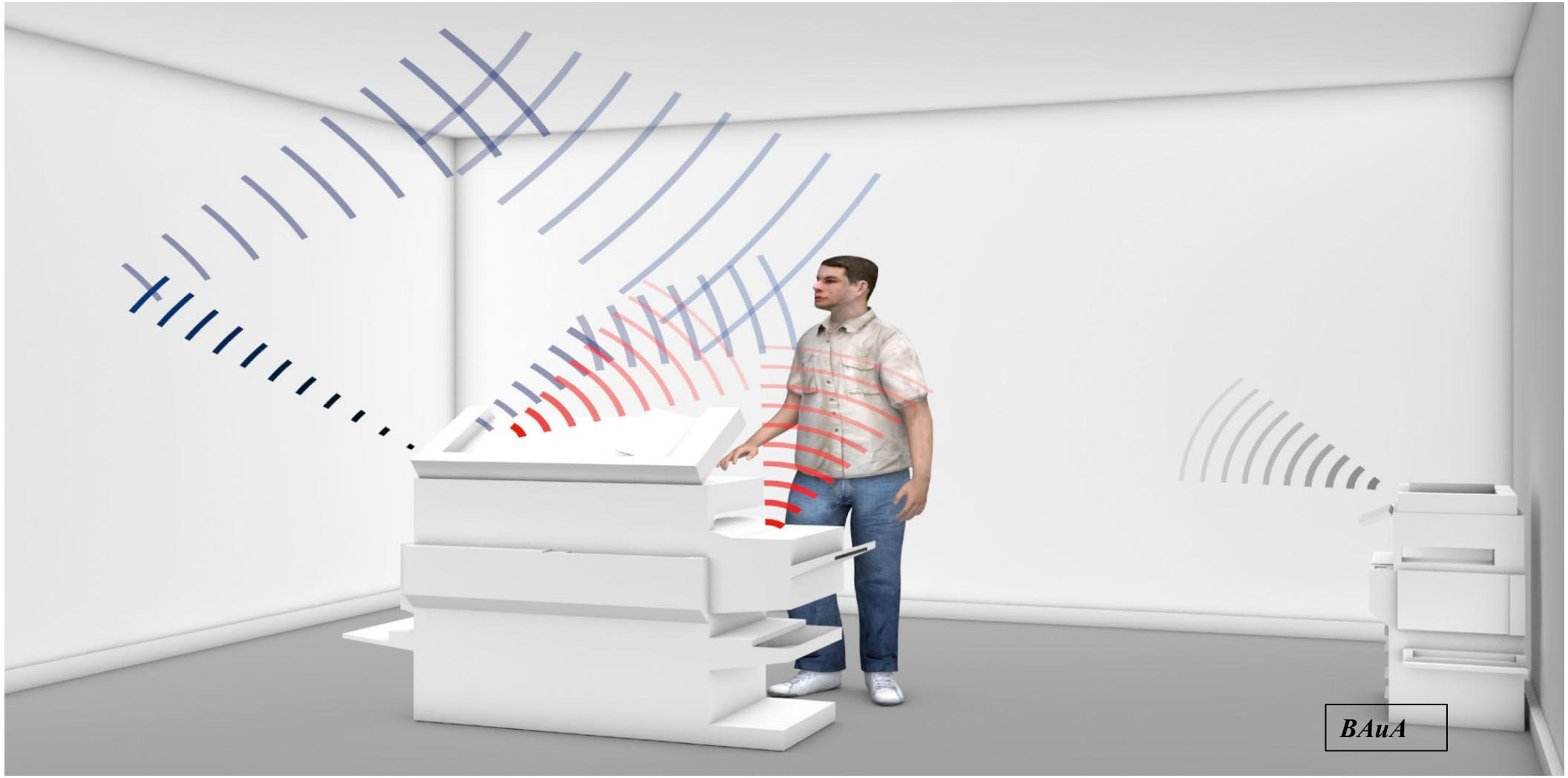
The machine manufacturer's responsibility

Emission	**Sound power level**	L_{WA}	**in dB**
	Emission sound pressure level at workstation	L_{pA}	**in dB**
	Peak emission sound pressure level	$L_{pC,peak}$	**in dB**

The employer's responsibility

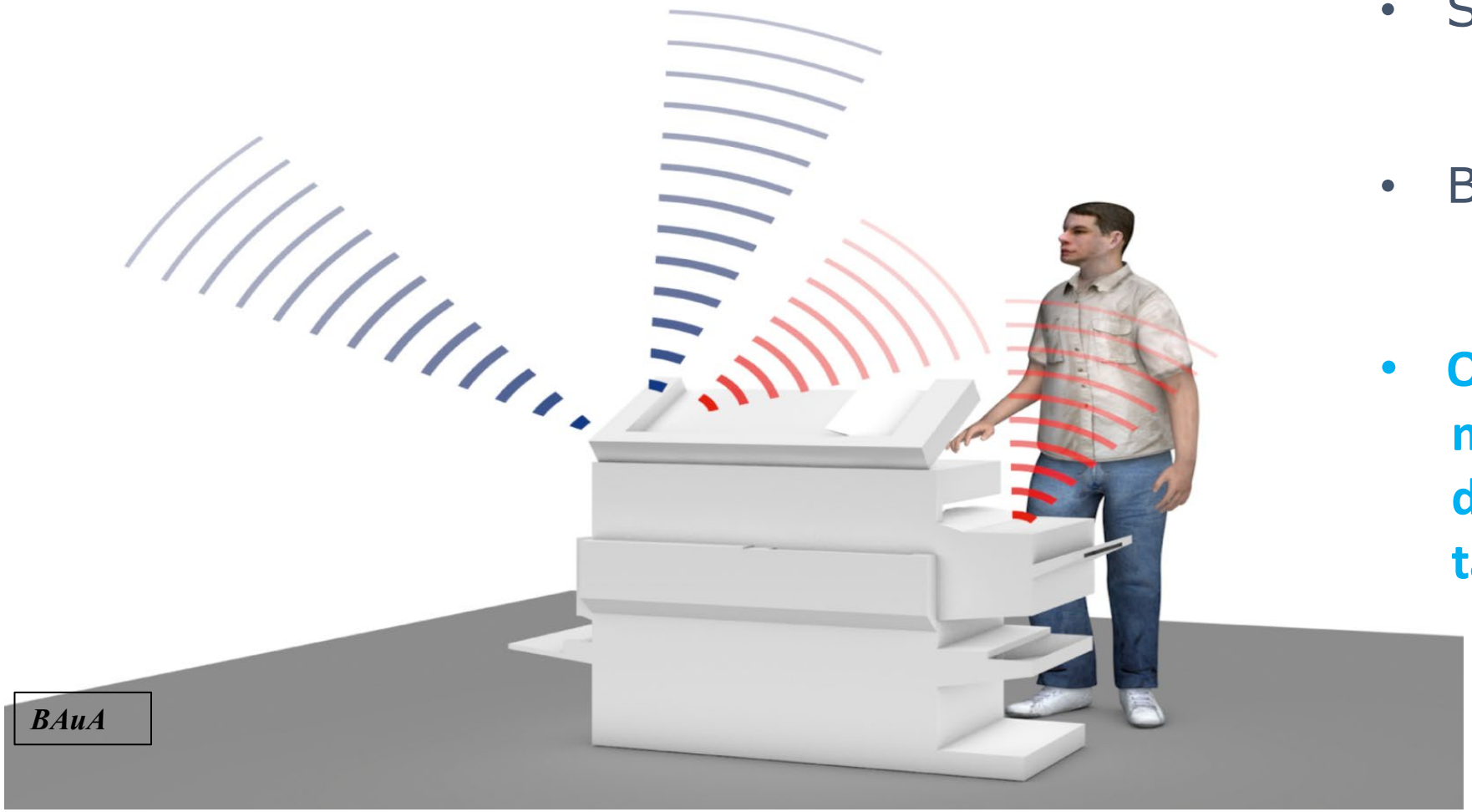
Immission	**Sound pressure level**	L_{pA}	**in dB**
Exposure	**Daily noise exposure level**	$L_{EX,8h}$	**in dB**
	Peak sound pressure level	$L_{pC,peak}$	**in dB**

Sound pressure level at the workstation



© CEN-CENELEC 2024

Emission sound pressure level



- Sound reflections are not taken into account
- Background noise is not taken into account
- **Only the sound from the machine that radiates directly to the workplace is taken into account!**

Emission sound pressure level L_{pA}

- The LpA is a sound pressure level measured in an acoustic free field (no contribution from sound reflections, no consideration of back ground noise) measured at the operator position designated by the manufacturer and assigned to the machine (operator station, control station etc.).

- If no operator station is provided, measurements should be taken at a distance of about 1 m at various positions around the machine and indicate the highest value and its position.

- The emission sound pressure level is always A-weighted and must be measured with a class 1 sound pressure level meter

- The emission sound pressure level at workstations shall be measured in accordance with the relevant B standards.

© CEN-CENELEC 2024

Sound power level I

In an empty room, a carpet is cleaned using a vacuum cleaner.

It is loud! (High sound pressure level)

Sound power level II

Now the room is furnished and the same vacuum cleaner is used again to clean the carpet.
But it's quieter now (lower sound pressure level)!
Has the vacuum cleaner's ability to generate noise changed? NO!

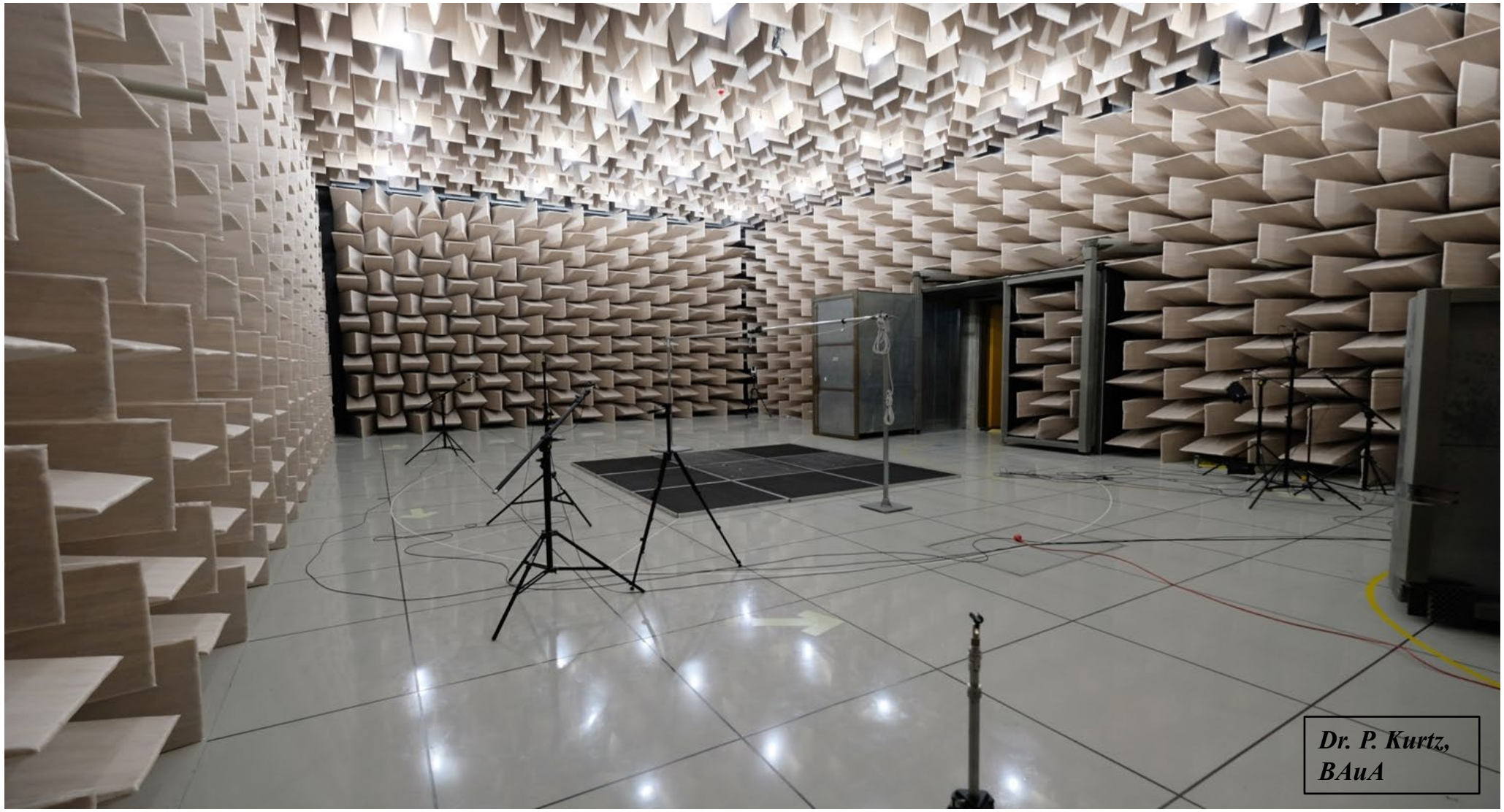
© CEN-CENELEC 2024

Sound power level III

- The sound power level LWA describes the mean sound energy emitted into the environment by a machine per second
- The L_{WA} is **independent of the environment** in which the machine is operated
- The L_{WA} is given in dB and should absolutely **not be confused with a sound pressure level**
- The L_{WA} **cannot be measured directly**, but is calculated from measured sound field quantities (sound pressure level, sound intensity level, etc.) using standardized methods.
- The L_{WA} is **used to compare the noise emission of machines** of the same type and is the key parameter for the noise respectively **noise exposure prediction**.

© CEN-CENELEC 2024

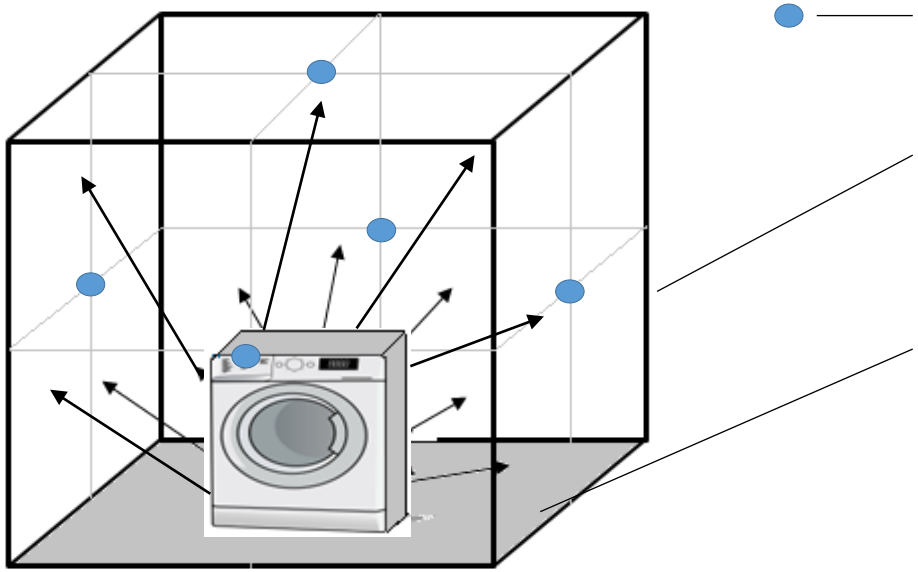
The ideal measurement environment for determining noise emission measures!



© CEN-CENELEC 2024

The cheapest free-field measurement environment!

Sound power - Enveloping surface method – Physics simplified



Microphones measure the sound energy flow (intensity I_i) from the machine approximated by the squared sound pressure p_i of i-th partial area of the enveloping surface!

$$\text{Intensity } I = \frac{\text{Power } W}{\text{Area } S_{ESA}}$$

$$\text{Power } W = \text{Intensity } I \cdot \text{ Area } S_{ESA}$$

A-weighted sound power level L_{WA}

$$L_{WA} = \overline{L_{pA}} + 10 \cdot \log \frac{S_{ESA}}{1\text{m}^2} \quad \text{dB}$$

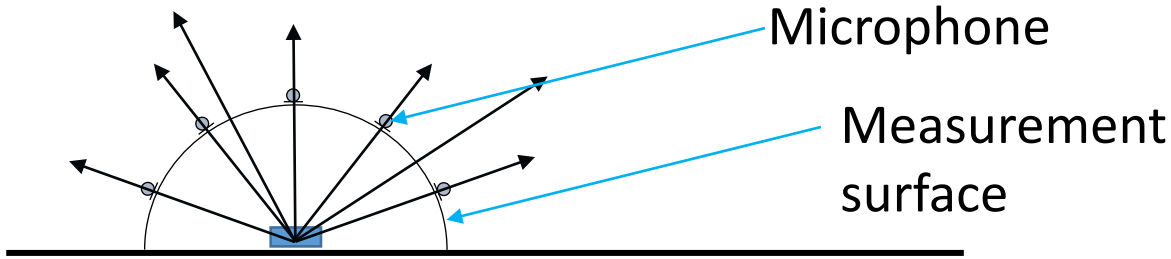
S_{ESA} = Total area of the enveloping surface

$\overline{L_{pA}}$ = energetic average of the sound pressure levels at all measurement positions

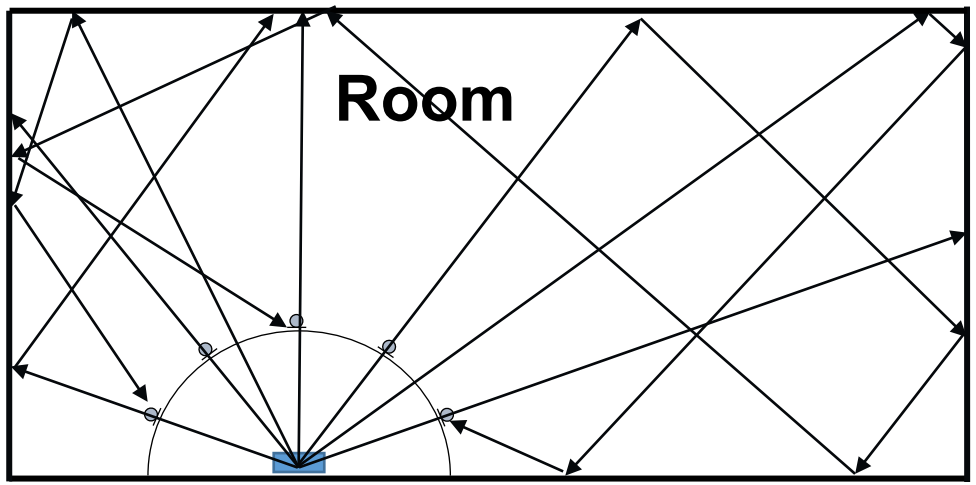
© CEN-CENELEC 2024

Sound power determination in practice I

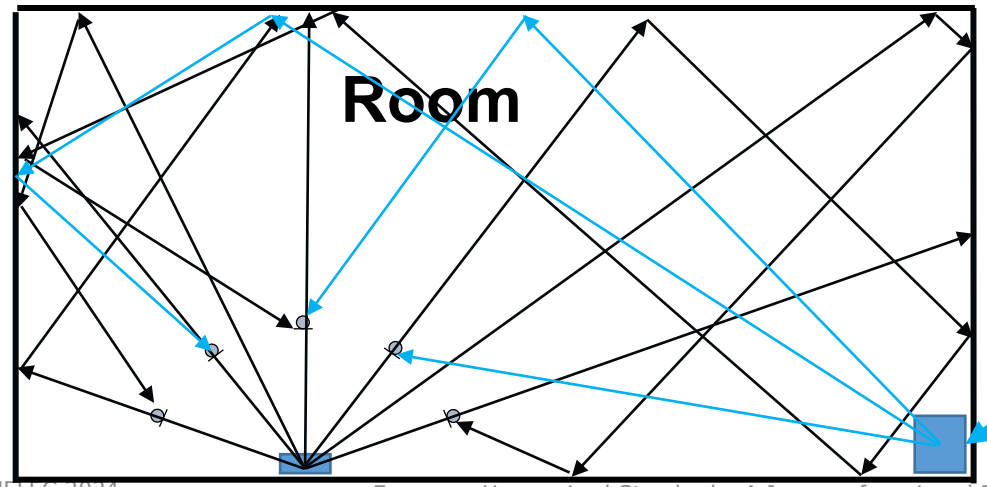
Free field



Direct sound incidence on the microphone positions



Direct sound incidence on the microphone positions **plus reflected sound**, which leads to higher sound pressure levels at the microphone positions!



Other sound sources in the room also increase the sound pressure level at the microphone positions!

© CEN-CENELEC 2024

Sound power level determination in practice II

The sound pressure level at a measurement point in the room is the sum of direct sound from the machine, reflected sound and background noise.

Outside of acoustic free fields, the sound pressure levels measured on the enveloping surface are therefore too high, resulting in determined sound power levels being too high !

In practice, the application of corrections is necessary!

$$L_{WA} = \overline{L_{pA}}' + 10 \log \frac{S_{ESA}}{1m^2} - K_{1A} - K_{2A} \text{ dB}$$

Environmental correction

Background noise correction

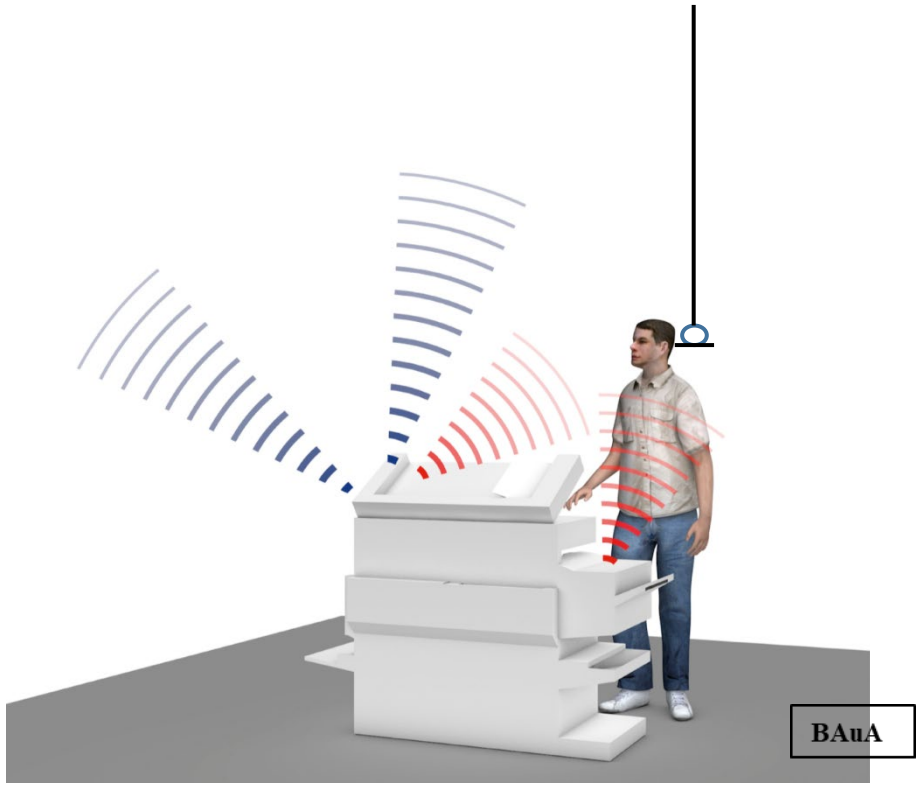
$K_{2A} \approx$ 2- 4 dB in a typical large industrial environments;

$K_{1A} \approx$ 0 dB if background noise is low

Determination of the emission sound pressure level L_{pA} in practice

Free field

Emission sound pressure level L_{pA}

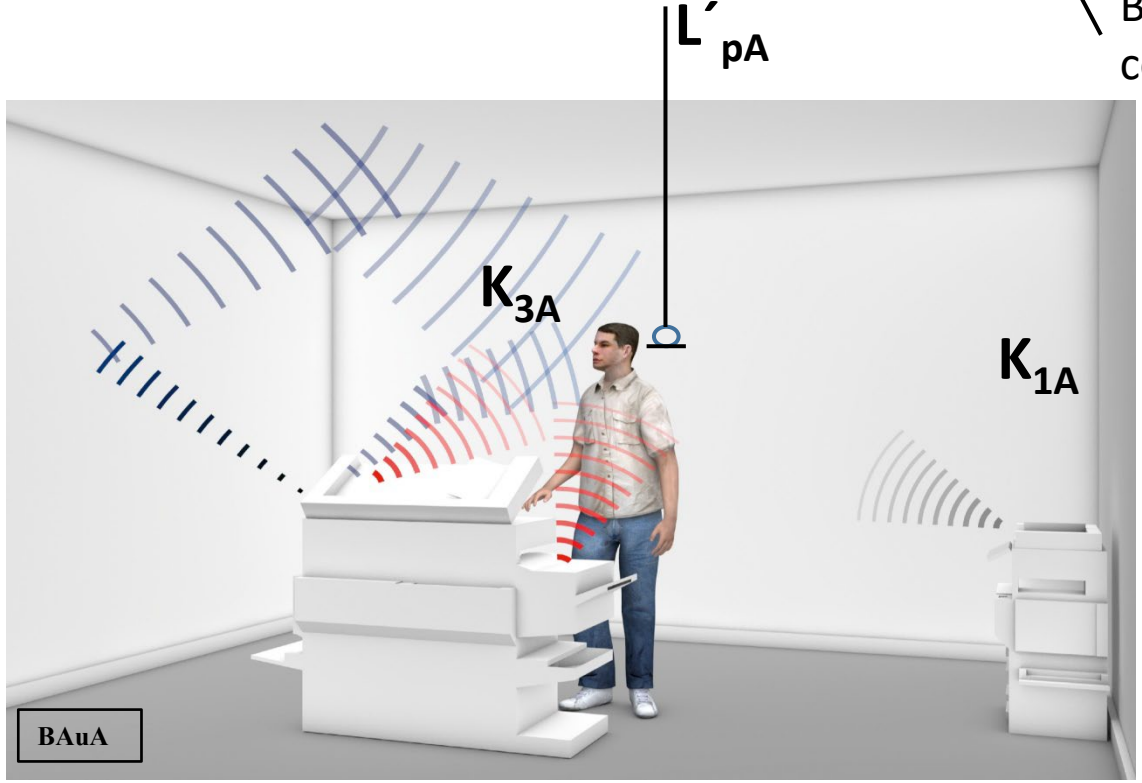


in situ

Emission sound pressure level $L_{pA} = L'_{pA} - K_{1A} - K_{3A}$

Local environmental correction

Background noise correction



© CEN-CENELEC 2024

B-standards on the determination of the A-weighted emission sound pressure level at workstation

EN ISO 11201: 2010	Method for an essentially free field, grade 1 and 2
EN ISO 11202: 2010 + A1: 2021	Method applying approximate environmental corrections, grade 2 and 3
EN ISO 11203: 2009 + A1: 2020	Calculation method using the sound power level
EN ISO 11204: 2010	Method applying accurate environmental corrections, grade 2 and 3
EN ISO 11205:2009	**Method applying sound intensity**

© CEN-CENELEC 2024

B-standards on the determination of the sound power level

Preferred measurement method!

Grade 1 methods

EN ISO 3741: 2010 **EN ISO 3743 - 1: 2010** EN ISO 3743 - 2: 2019	Sound pressure level measurement methods in diffuse or approximately diffuse sound fields
EN ISO 3744: 2010 EN ISO 3745: 2011 EN ISO 3746: 2010	Methods based on sound pressure level measurements in acoustic free fields or essentially free fields
EN ISO 3747: 2010	Comparison method for measurements in situ
EN ISO 9614 - 1: 2009 **EN ISO 9614 - 2: 1996** EN ISO 9614 - 3: 2009	Methods based on sound intensity measurements

Starting with drafting noise clauses in European standards supporting the MD

The 1st most important step when drafting a machinery safety standard observing the ESHR of the MD on noise is to come to a conclusion concerning the significance of noise as a hazard for the specific kind of machine.

- if L_{pA} is likely to never exceed 70 dB(A), **then noise is irrelevant** and the safety standard doesn't have to deal with noise at all, except stating in the scope that noise emission from that machine is considered not to cause any hazards and state in the instructions that the LpA is ≤ 70 dB.

- if LpA is likely to exceed 70 dB(A) but never 80 dB(A), **then noise is a relevant** but not a significant hazard.
  EN 1746 and ISO 12001 have to be observed but the noise test code provides only a method to determine LpA.

- if LpA is likely to exceed 80 dB(A) for at least some items in the family, **then noise is a significant hazard** and
  there is a need for noise clauses (drafted according to EN 1746) and a noise test code providing a method to determine both LpA and LWA (drafted according to EN ISO 12001).

Clause on noise as a hazard

"XY machines generate noise which can result in:

- *hearing damage,*
- *tinnitus,*
- *physiological and psychological disorders (stress),*
- *in accidents due to interference with speech communication and interference with the perception of acoustic signals."*

EHSR on Noise reduction

1.5.8. Noise

Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

Clause on noise reduction

"Noise reduction shall be an integral part of the design process thus specifically taking into account measures at source as given in EN ISO 11688-1:1998. The success of the applied noise reduction measures is assessed on the basis of the actual noise emission values determined in accordance with the noise test code (e.g. Annex A) in relation to other machines of the same family with comparable performance.

NOTE ISO/TR 11688-2: 1998 provides useful information on noise generation mechanisms in machinery and ISO 14163: 1998 gives guidelines for noise control by mufflers.

Major sound sources are……..

Typical noise reduction measures, for the respective machine, are ….”

Clause on verification of safety requirements/measures in respect to noise

Verification of noise reduction (already included in the noise reduction clause)

"*The success of the applied noise reduction measures is assessed on the basis of the actual noise emission values determined in accordance with the noise test code (e.g. Annex A) in relation to other machines of the same family with comparable performance.*"

Verification on noise emission values

"*Measurement of noise emission values shall be made in accordance with Annex X (noise test code), including declaration of dual-number noise emission values and verification in accordance with EN ISO 4871:2009*."

ESHR of the MD 2006/42/EC – Noise emission declaration in the instructions

ESHR 1.7.4.2 u)

The following information on airborne noise emissions shall be given in the instructions:

- **the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,**
- **the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),**
- **the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).**

Noise emission declaration in the instructions

The instructions shall include:

" information about airborne noise emissions of the machine according to Annex xx (noise test code). This includes:

- ***A-weighted emission sound pressure level L_{pA} and its uncertainty K_{pA}, where L_{pA} exceeds 70 dB(A). Where L_{pA} does not exceed 70 dB(A), this fact shall be indicated.***
- ***A-weighted sound power level L_{WA} and its uncertainty K_{WA}, where the A-weighted emission sound pressure level L_{pA} exceeds 80 dB(A)***
- ***C-weighted peak emission sound pressure level $L_{pC,peak}$, where this exceeds 130 dB."***

© CEN-CENELEC 2024

Noise emission declaration in the instructions II

- **for large machines the sound power level can be substituted by emission sound pressure levels at specified positions around the machine**

  - **What is a large machine? „large“ has nothing to do with a specific length, width, height e.g. > 7m. What is if the machine has a dimension of 7,01m respectively 6,99m? It´s the amount of effort required for the measurement and thus it depends on the generated sound field of the machine.**

- **for machines with undefined workstations the max. emission sound pressure level and it´s position around the machine shall be declared**

Further information in the instructions related to noise emission

(j) instructions relating to installations and assembly for reducing noise

(m) instructions on the protective measures to be taken by the user, personal protective equipment

- ***If the A-weighted emission sound pressure level is exceeding 80 dB the use of adequate hearing protection should be recommended. In cases where the A-weighted emission sound pressure level is exceeding 85 dB the use of adequate hearing protection should be required.***

- ***information on available noise reduction options and operating conditions which lead to lower noise emission values***

Further information in the instructions related to noise emission

- **that the declared noise emission value(s) have been measured in accordance with a standard test method and may be used for comparing one tool with another;**

- **that the declared noise emission value(s) may also be used in a preliminary assessment of exposure.**

- **A warning:**
  that the noise emissions during actual use of the power tool can differ from the declared values depending on the ways in which the tool is used especially what kind of workpiece is processed;
  And of the need to identify safety measures to protect the operator that are based on an estimation of exposure in the actual conditions of use (taking account of all parts of the operating cycle such as the times when the tool is switched off and when it is running idle in addition to the trigger time).

© CEN-CENELEC 2024

„Outdoor"- Directive 2000/14/EG plus new Annex III: 2024/1208

- Labelling with the **guaranteed A-weighted sound power level**,
- Limits for 22 kinds of machines,
- Use of the basic noise emission standard **EN ISO 3744**,
- Definition of mounting and operating conditions partly in the directive (deligated act) or references to existing noise test codes
- Applies for **57 kinds of machines**, e.g. for: earth moving machinery, excavater loaders, tower cranes dumpers, compressors, chain saws, lawn mowers, grass trimmers, leaf blowers, leaf collectors etc.

Noise test code – Structure according to EN ISO 12001:2009

1. Scope
2. References
3. Definitions
4. **Description of machine family**
5. **Emission sound pressure level determination**
6. **Sound power level determination**
7. **Installation and mounting conditions**
8. **Operating conditions**
9. **Measurement uncertainties**
10. **Information to be recorded**
11. **Information to be reported**
12. **Declaration and verification of noise emission values**

© CEN-CENELEC 2024

Most difficult questions to be answered when drafting a noise test code

- Which basic measurement standards shall be used for determining the A-weighted emission sound pressure level or the A-weighted sound power level
- Which measurement positions, which kind of measurement surface (parallelepiped, sphere etc.), how many measurement points for determining the sound power level
- Defining a representative and reliable operating condition
  - No load condition
  - Load condition but observing that
    - it is cheap and representing the highest noise emission under typical use and resulting in a high repeatability
    - the work piece, used accessory if required, operation (work cycle, speed, depth of cut, torque etc.) is clearly defined
    - the machine is not additionally covered by the OND
- Measurement uncertainty, a complicated story; GUM approach
    - B-standards for the noise emission are complying with the GUM, however, the terminology differs from the standard on the noise emission declaration and verfication EN ISO 4871!
    - A new guide on how to determine the expanded uncertainty in measurement is close to finalisation. Its the ISO 5114-1:FDIS 2024
- Noise emission declaration according to EN ISO 4871:2009

Noise Consultants **proposal** for a clause on the measurement uncertainty I

"The total measurement uncertainties of the noise emission values determined according to this standard are depending on the standard deviation σ_{R0} given by the applied basic noise emission measurement method and the uncertainty associated with the instability of the operating and mounting conditions σ_{omc} . The resulting total uncertainty is then calculated from:

$$\sigma_{tot} = \sqrt{\sigma_{R0}^2 + \sigma_{omc}^2}$$

NOTE 1 *The standard deviation σ_{tot} is referred to in EN ISO 4871: 2009 as the standard deviation of reproducibility σ_R !*

The upper bound value of σ_{R0} is 1,5 dB for grade-2-measurement methods, and 3 dB for grade-3-methods, assuming noise sources which emit sound without significant tones. These values apply for both the determined A-weighted emission sound pressure level and the A-weighted sound power level.

Noise Consultants **proposal** for a clause on the measurement uncertainty II

NOTE 2 *For machines with a rather constant noise emission σ_{omc} is typically 0,5 dB. In other cases, e.g. a large influence of the material flow into and out of the machine or material flow that varies in an unpredictable manner, it is possible that a value of 2 dB may be more appropriate. Methods to determine σ_{omc} are described in the basic noise emission measurement standards.*

The expanded measurement uncertainty U, in decibels, shall be calculated from:

$U = k \cdot \sigma_{tot}$, where k is the coverage factor.

NOTE 3 *The expanded measurement uncertainty U depends on the degree of confidence that is desired. For the purpose of comparing the result with a limit value, it is appropriate to apply the coverage factor for a one-sided normal distribution. In that case, the usually applied coverage factor of k = 1,6 corresponds to a 95 % confidence level. Further information is given in EN ISO 4871:2009, where the expanded measurement uncertainty U is denoted as K!*

© CEN-CENELEC 2024

Noise Consultants **proposal** for a clause on the measurement uncertainty III

The expanded measurement uncertainty U as described in the basic noise emission standards does not include the standard deviation of production σ_P which is used in EN ISO 4871:2009 for the purpose of making a noise emission declaration for batches of machines.

In the case of preparing a noise emission declaration for batches of machines σ_{tot} is replaced by σ_t, the total standard deviation defined in EN ISO 4871:2009. σ_t can be calculated by using the equation

$$\sigma_t = \sqrt{\sigma_{R0}^2 + \sigma_{omc}^2 + \sigma_P^2} = \sqrt{\sigma_{tot}^2 + \sigma_P^2}$$

with σ_P the standard deviation of production.”

Example of a clause on noise emission declaration and verification I

EN ISO 4871:2009 descibes how to declare and verify noise emission values! It also provides examples!

"***Declaration and verification of noise emission values***
The declaration of the noise emission values shall be made as a dual number noise emission declaration according to EN ISO 4871: 2009.
It shall declare the emission sound pressure level L_{pA} and the respective uncertainty K_{pA} and if required additionally the sound power level L_{WA} and the uncertainty K_{WA}.

NOTE *The uncertainties K_{pA} and K_{WA} are expected to have values of about 3 dB when applying a grade 2 measurement method respectively 5dB for a grade 3 measurement method.*

The noise emission values shall be rounded to the next higher decibel.

Example of a clause on noise emission declaration and verification II

The noise emission declaration shall state that the noise emission values for the A-weighted emission sound pressure level have been obtained according to this noise test code and to the basic standards EN ISO 11201:2010 grade 2 or EN ISO 11202:2010+A1:2021 grade 2 respectively grade 3.

Accordingly, if additionally required for the noise emission declaration, reference shall be made to the use of EN ISO 3744:2010 or if only grade 3 is possible EN ISO 3746:2010 for the A-weighted sound power level.

If this statement is not true, the noise emission declaration shall indicate clearly what the deviations are from this noise test code and/or from the basic noise emission measurement standards applied.

If undertaken, verification shall be done according to EN ISO 4871:2009 by using the same mounting, installation and operating conditions as those used for the initial determination of the noise emission values."

© CEN-CENELEC 2024

Guideline standards supporting the drafting of standards with noise clauses

- **EN 1746:1998 Safety of machinery – Guidance for the drafting of the noise clauses of safety standards**
- **EN ISO 12001: 2009 Acoustics – Noise emitted by machinery and equipment – Rules for the drafting and presentation of a noise test code**
- **EN ISO 11200:2014 +A1:2020 Acoustics – Noise emitted by machinery and equipment – Guidelines for the use of basic standards for the determination of emission sound pressure levels at a work station and at other specified positions**
- **EN ISO 3740:2019 Acoustics - Determination of sound power levels of noise sources Guidelines for the use of basic standards**
- **EN ISO 11688-1:2009 Acoustics – Recommended practice for the design of low-noise machinery and equipment – Part 1: Planning**
- EN ISO 11688-2:2000 Acoustics – Recommended practice for the design of low-noise machinery and equipment – Part 2: Introduction to the physics of low-noise design
- EN ISO 14163:1998 Acoustics – Guidelines for noise control by silencers
- EN ISO 15667:2000 Acoustics – Guidelines for noise control by enclosures and cabins

© CEN-CENELEC 2024

Typical mistakes when dealing with noise emission in standards

- Inadequate selection and designation of basic measurement standards (missing date or amendment; wrong or missing grade of accuracy; inadequate method in respect to the machine)

- Wrong terminology (A-weighting if missing, noise instead of noise emission, noise level instead of emission sound pressure level etc.)

- Inadequate or missing information on the measurement positions, distances, heights, tolerances, measurement surfaces (L_{WA}), number of measurement positions for determining the L_{WA} etc.

- Inadequate operating conditions
  - no load instead of load conditions in cases where the no load condition is not sufficient or inadequate
  - missing detailed description of the work piece and its support, test table, whole test set up
  - Unsuitable workpiece (radiates itself too much noise)
  - missing information of the set operating conditions of the machine (nominal power, full power, number of revolutions, speed, type of operation if there are several etc.)
  - missing definition of the installed tool e.g. saw blade, drill, grinding wheel etc.
  - missing statement that the operating conditions must be the same when determining the sound power level and the emission sound pressure level
  - unclear defined measurement cycles, number of repetitions, chosen value for declaration (max., average), use of operators or not

© CEN-CENELEC 2024

Annex ZA (CEN) and Annex ZZ (CENELEC)

Typical mistakes

- **reference(s) to clauses that have no direct relation to emission of noise, such as clauses on operator locations**
- **Forgotten references e.g. to the noise reduction clause (ESHR 1.5.8)**
- **In multipart standards references to clauses of part 1 although part 2 does not address the ESHR.**
- **Annex ZA for type B and type C standards**
- **…**

© CEN-CENELEC 2024

Reasons for the many negative assessments of standards with the noise clauses

- **Lack of manpower**
- **Lack of technical competence**
- **Underestimation of the work to be done in drafting e.g. an accurate noise test code**
- **Constant postponement of drafting the noise clauses with the result of considerable time pressure in the end**
- **Using the simplest approach by copy and pasting clauses from other standards without observing technical differences**
- **Total negligence when drafting the different clauses: “ The consultant will tell me what is wrong or needs to be improved.“**
- **Guidance documents are not used at all!**

Some arguments in favor of communication between the noise consultants and the TCs

Helping

- the TCs to decide whether the machine´s noise emission is a irrelevant, relevant or significant hazard
- to choose an adequate basic noise emission measurement standard
- in delimiting possible sub-families of machines requiring the application of other basic measurement methods
- in selecting an operating condition which sufficiently describes the noise emission of the machine
- in selecting an adequate material to be processed respectively an accessory (kind of saw blade, grinding wheel etc.) to be used; how to define the accessory if providing a specific brand, type is forbidden.
- in choosing the measurement positions for machines without typical operator´s positions
- in deciding whether the machine is a large machine
- in finding a compromise between economical and technical aspects of noise emission measurement
- in dealing with measurement uncertainties
- etc.

© CEN-CENELEC 2024

How to improve the current unsatisfactory situation of too many negative assessments

- **Training of the TCs in drafting the noise clauses in machinery safety standards**
- **Absolutely essential is to allow communication between the Noise Consultants and the respective WGs on specific technical issues. The Commission should allow the technical expertise in noise emissions to be combined with the expertise of the members of the WG in relation to the specific machine. Not in the sense of drafting the noise clauses but in the sense of avoiding mistakes.**
- **Requesting feedback from the notified bodies or other users of these standards e.g. by setting up a web site to easily collect comments**
- **…**

© CEN-CENELEC 2024

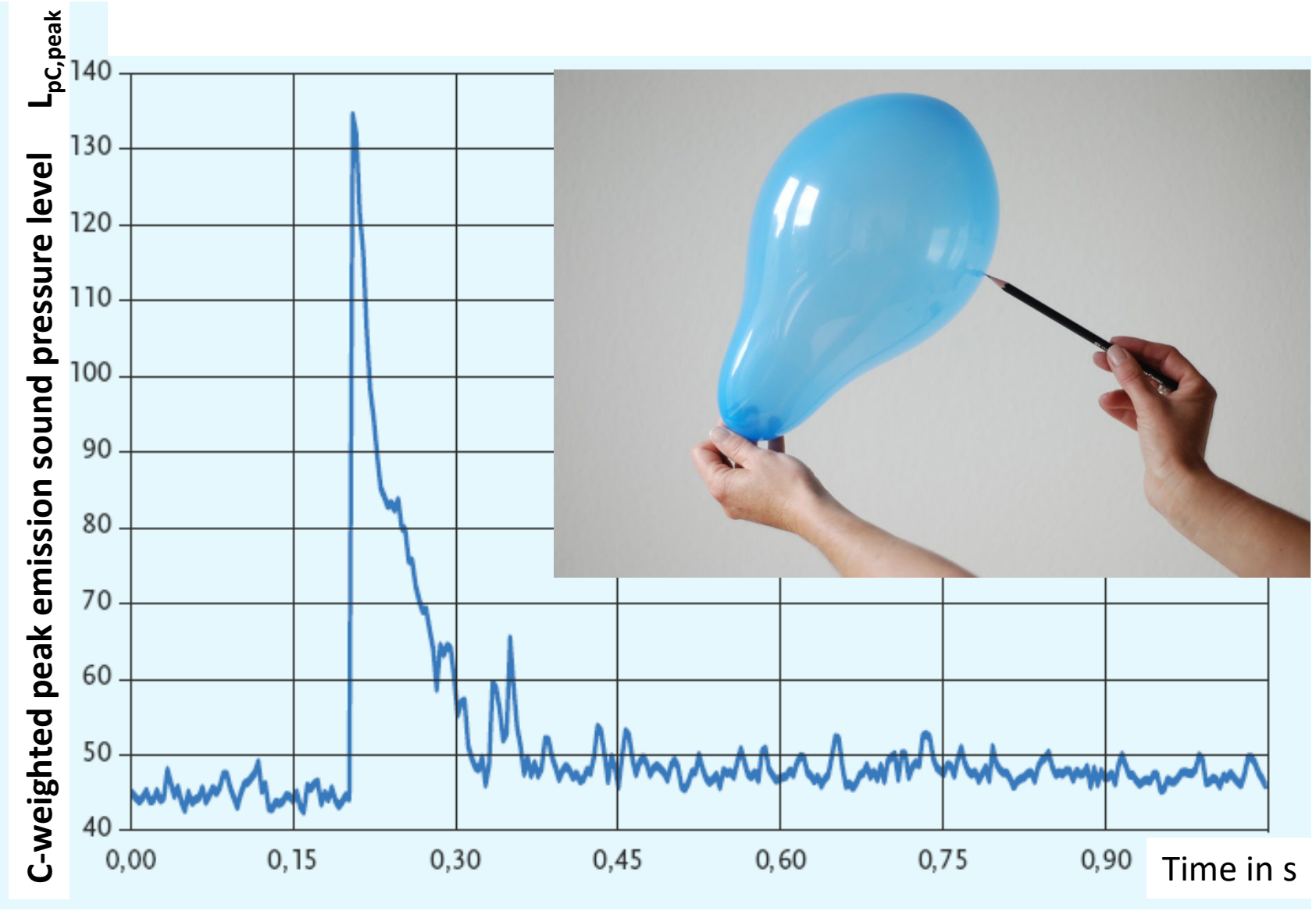
Questions to be discussed

- **Choice of operating condition (e.g. the angle grinder case)**
- **Machine specificities e.g. machinery that never operate at the manufacturer's place or machinery with operating cycles based on data from sensors**
- **Measurement uncertainties e.g. RFU 07-003 R2 (Work Group of Notified Body´s 2000/14/EC) standard deviations of reproducibility ?!**
- **ESHR 1.7.4.3 is a major requirement in the context of SBQ but it is most cases not covered by noise test codes. How to give value to this EHSR?**
- **…**

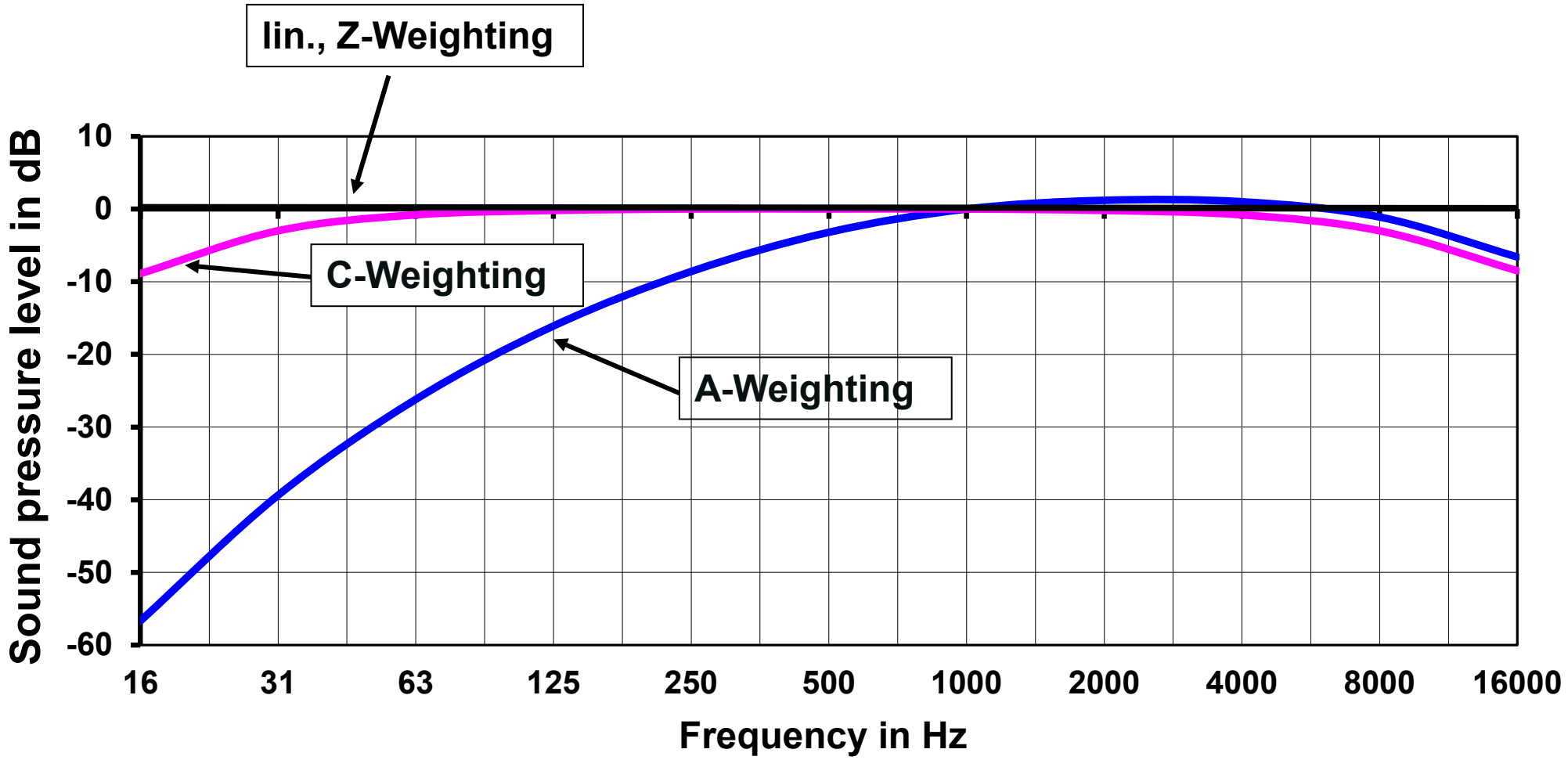
© CEN-CENELEC 2024

Table 1 Suggested values for σ_R for use within assessment following 2000/14/EC

No	Type of Equipment	Article 12	Article 13	σ_R
1	Arial access platforms with combustion engine		x	0.70
2	Brush cutters		x	0.50
3	Builders hoist for the transport of goods	x		0.60
4	Building site band saw machines		x	0.50
5	Building site circular saw bench		x	0.50
6	Chain saw, portable		x	1.00
7	Combined high pressure flusher and suction vehicle		x	0.50
8.1	Compaction machine, non vibration rollers	x		0.50
8.2	Compaction machine, vibrating rollers for ride on operation	x		0.50
8.3	Compaction machine, vibratory plates, vibratory rammers and walk behind vibrating rollers	x		0.80
8.4	Compaction machine, explosive rammers	x		1.00
9.1	Compressor; P ≤ 15 kW	x		0.50
9.2	Compressor; P > 15 kW	x		0.50
10	Concrete-breakers and picks, hand held	x		1.00
11	Concrete or mortar mixer		x	0.50
12	Construction winch	x		0.60
13	Conveying and spraying machine for concrete and mortar		x	0.50
14	Conveyor belt		x	0.50
15	Cooling equipment on vehicles		x	0.50
16	Dozer	x		0.50
17.1	Drill rig, drilling only		x	0.50
17.2	Drill rig, roto hammers		x	1.00

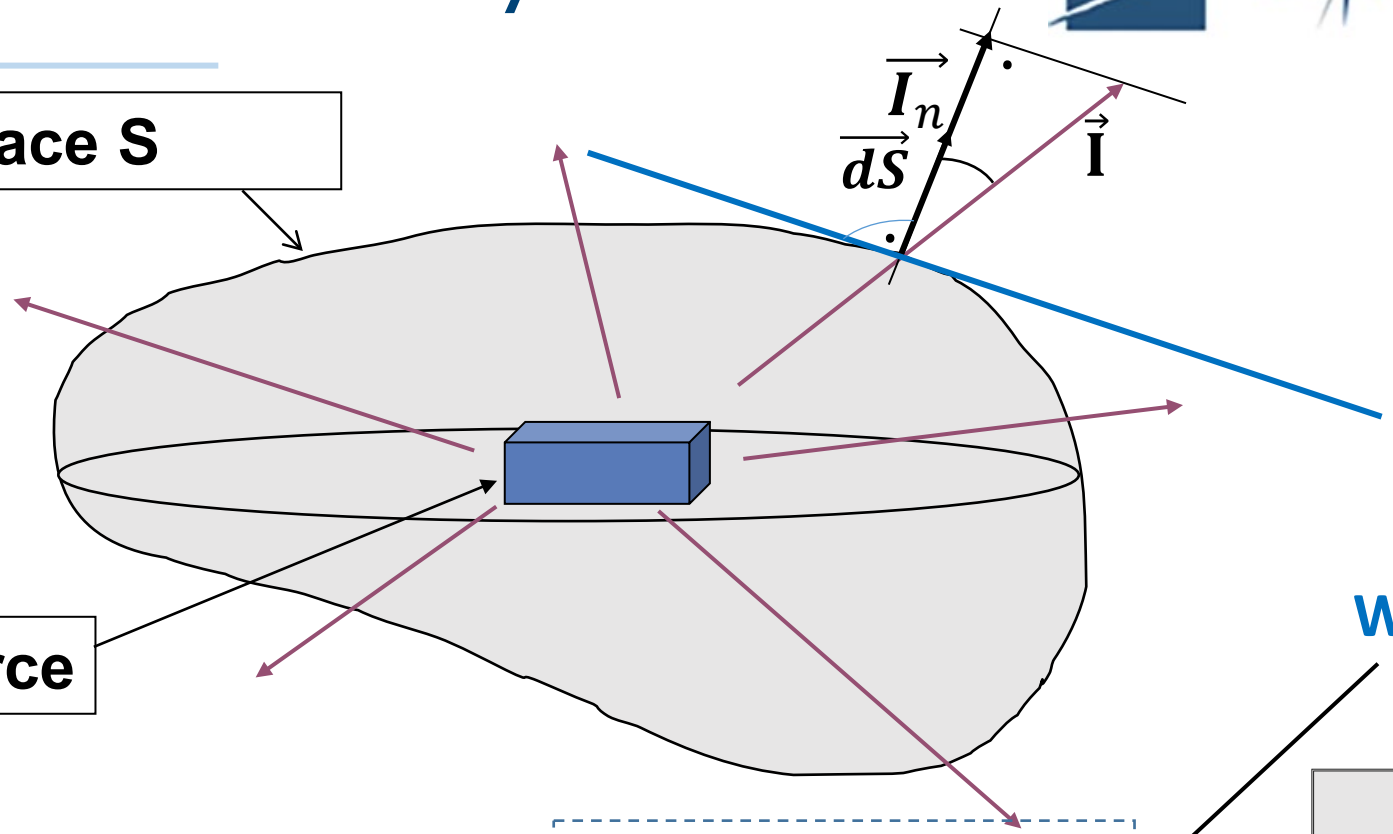

C-weighted peak emission sound pressure level $L_{pC,peak}$ in dB
140
130
120
110
100
90
80
70
60
50
40
0,00
0,15
0,30
0,45
0,60
0,75
0,90
Time in s

Frequency weighting of sound levels



© CEN-CENELEC 2024

Sound power – Physics



W stands for the power P !

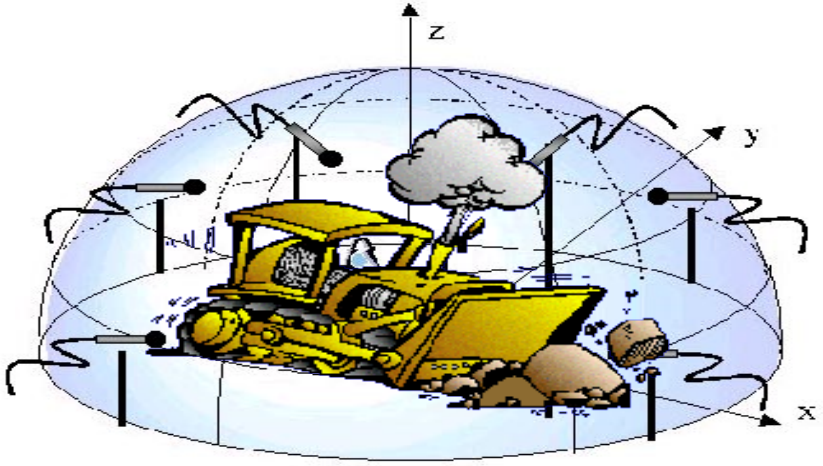
$$\iiint_V \operatorname{div}\vec{I}\,dV = \oiint_S \vec{I}\cdot\overrightarrow{dS} = \oiint_S I_n \cdot dS = W$$

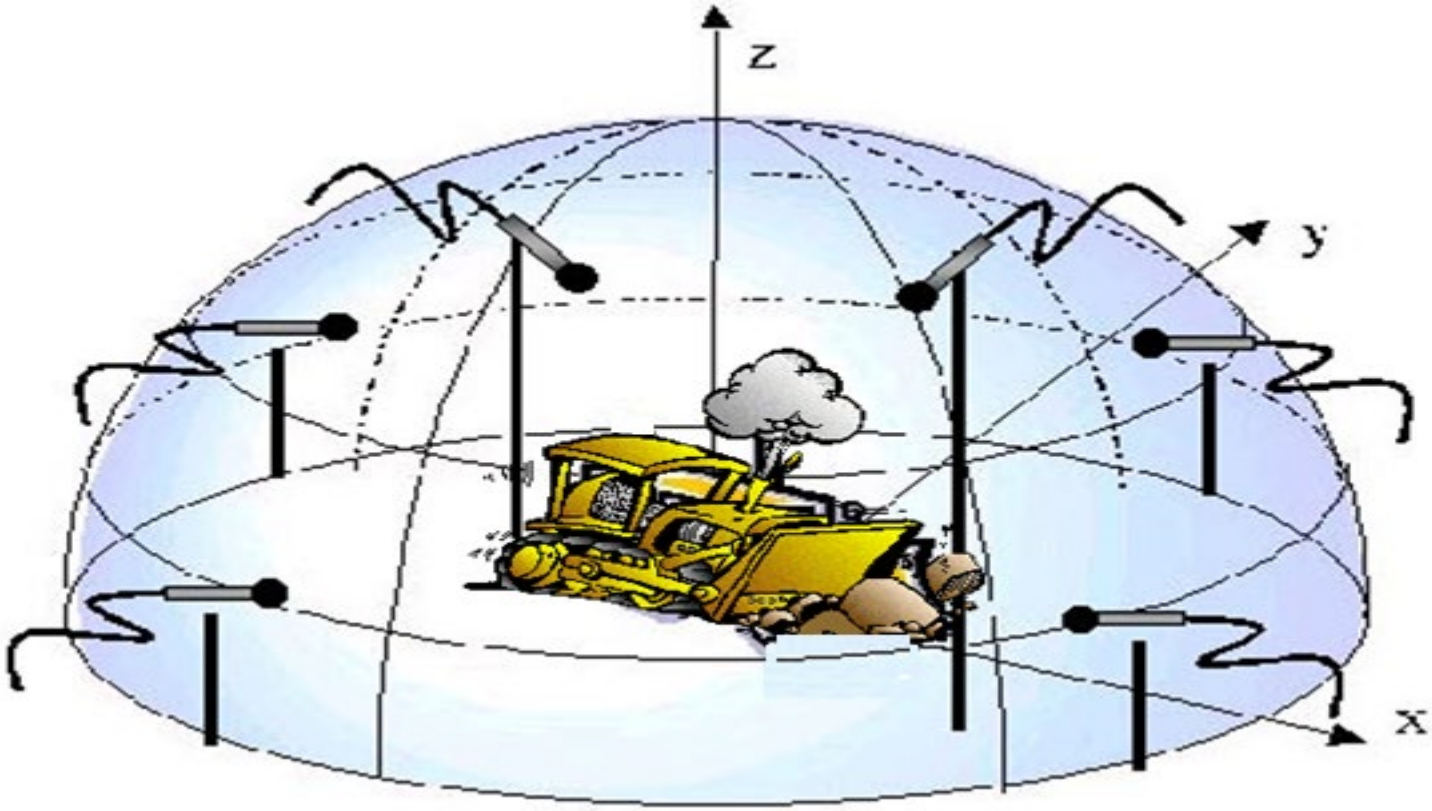
$$I_n \approx \frac{\tilde{p}^2}{\rho c} = \left|\vec{I}\right| = I$$

I_n measurement

© CEN-CENELEC 2024

The sound power level is independent from the size of the measurement surface





$$L_{WA} = \overline{L_{pA}} + 10 \cdot \log \frac{S_{ESA}}{1m^2} = L_{WA} = \overline{L_{pA}} + 10 \cdot \log \frac{S_{ESA}}{1m^2}$$

© CEN-CENELEC 2024

Communication with WGs

Attitudes noise HAS are often facing in WGs:

- **Our company has no competence on noise**
- **We really don’t know what to write about noise**
- **We have a person in charge of noise in the company but he/she is not a member of the WG**
- **We have some competence on noise but we don’t want to share it with competitors (refusal to share noise emission data)**
- **Noise is a negative feature of a machine. The less we talk /write about it, the better it is.**
- **Sell and Buy Quiet ? What is that ?**
- **Our clients are not asking for info on noise. Why should we invest in getting knowledgeable?**
- **There is no market surveillance!**

© CEN-CENELEC 2024

Harmonized European Standards: A Journey from Legal Framework to Citation in the Official Journal of the European Union

22-23 May 2024
Brussels / Online

Thank you!

Any questions?

Informative Annex Z: most frequent issues and guidance

Joanna FRANKOWSKA, Sectoral Project Manager for Machinery at CEN-CENELEC.

Key documents to write Annex Z for Machinery

- Template Annex Z for Machinery (CEN) (CENELEC)
- Instructions on Annex Z for Machinery (CEN) (CENELEC)
- Possible European Annex ZA.2 table on normative references in EN ISO (Generic Template + Guidance)
- Checklist for hENs (CEN) (CENELEC)
- Machinery Directive, Annex I (to become Machinery Regulation, Annex III)
- **Guide to application of the Machinery Directive** (European Commission website)

What is the role of informative Annex Z? [Menti]

- Highly important: it is the link between Machinery Directive/Regulation and technical solutions in standards
- Highly important: it is a legally relevant part
- Highly important: no citation possible without a very good Annex Z
- Not important so can be drafted at the late stage of standard development

Annex Z...
(informative)

Relationship between this European Standard and the essential requirements of Regulation (EU) 2023/1230 aimed to be covered

This European Standard has been prepared under a Commission's standardization request C(202X)XXXX final[1] Commission Implementing Decision of DD Month YYYY[2] to the European Committee for Standardization and to the European Committee for Electrotechnical Standardization as regards machinery in support of Regulation (EU) 2023/1230 of the European Parliament and of the Council (M/XXX)[3] to provide one voluntary means of conforming to essential requirements of Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery (OJ L 165, 29.6.2023).

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table Z....1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Regulation, and associated EFTA regulations.

Table Z....1 — Correspondence between this European Standard and Annex III of Regulation (EU) 2023/1230

The relevant Essential Requirements of Regulation (EU) 2023/1230	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
[Per row: an essential requirement]	[The relevant normative clauses linked to the individual essential requirement]	
[Per row: an essential requirement]	-	not covered

Template is on CEN Boss website and on CENELEC Boss website

Template shall be used in **draft** standards only!

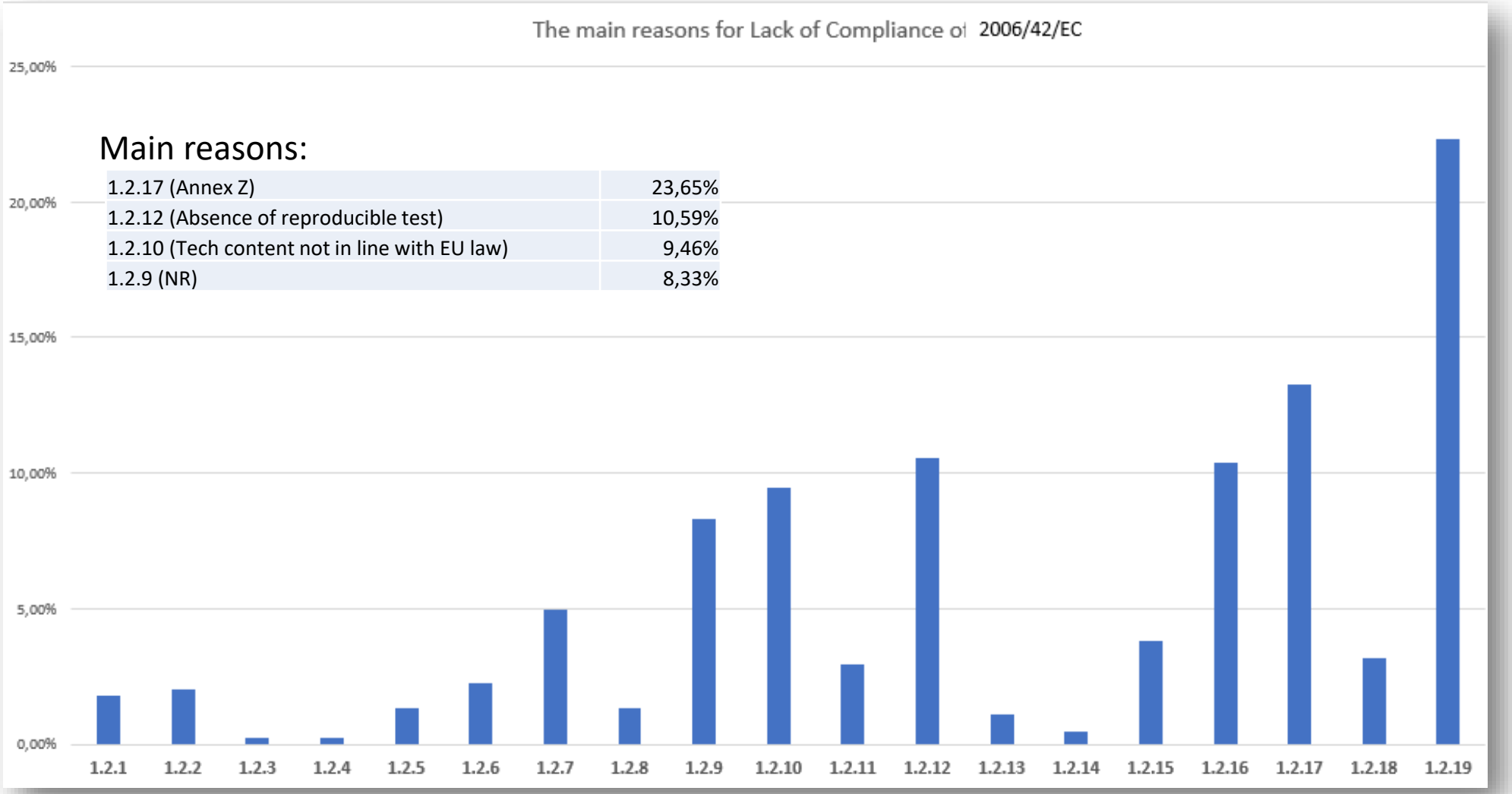
After Standardization Request is adopted, template will be reviewed→ for use in **final** standards

template is to be used in draft harmonised standards in support of the Machinery Regulation.

Since the Standardization Request in support of Machinery Regulation is not yet adopted (expected to take place in 2024 and then accepted by CEN and CENELEC BTs) the reference and the date of the Standardization Request are not known and therefore the references shall be kept as 'C(202X)XXXX', 'DD Month YYYY' and 'M/XXX'.

When the Standardization Request is adopted, this template will be revised to include the number references and the date of the adopted Standardization Request.

Main reasons for LoC: Machinery



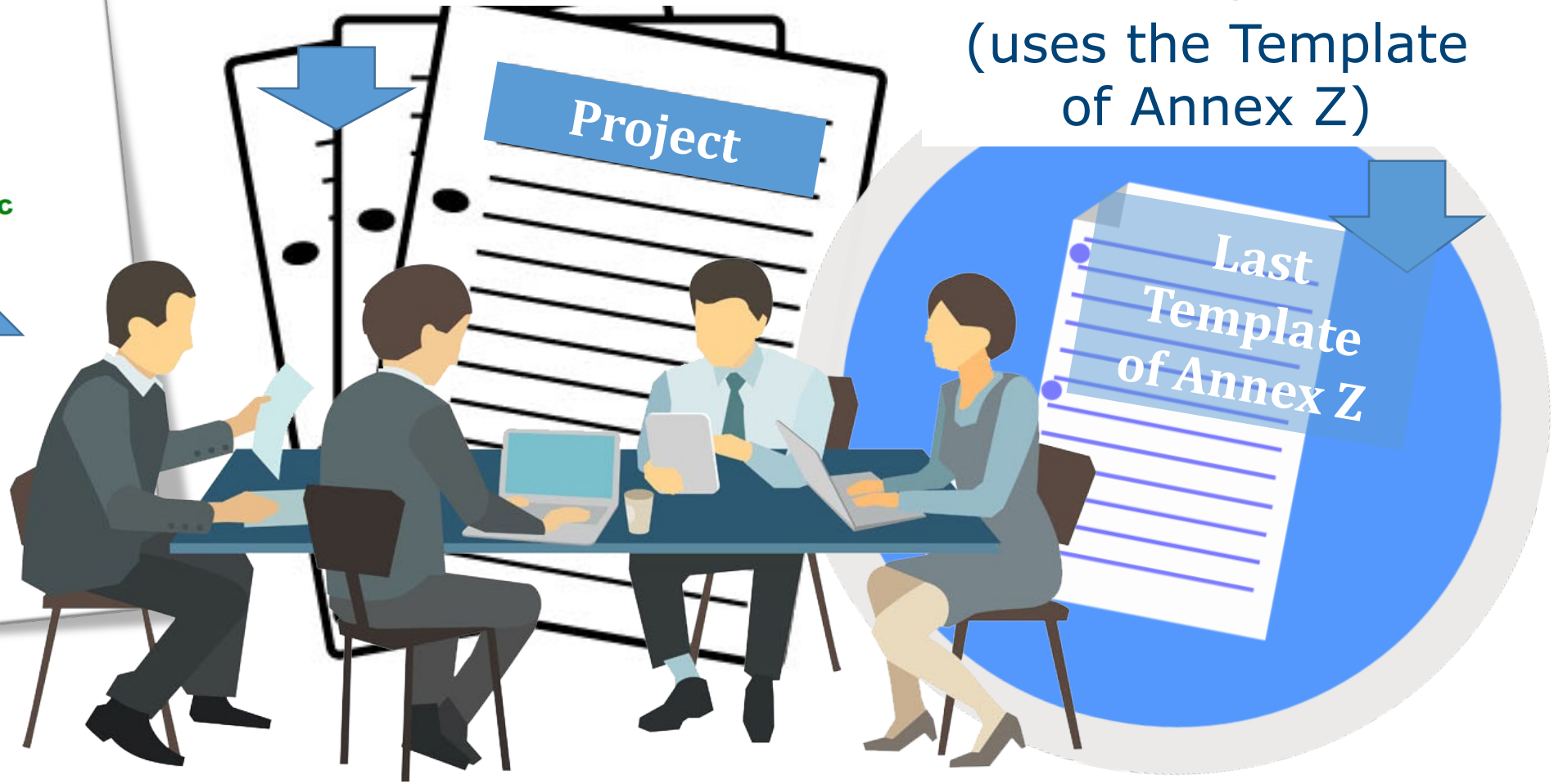
Main reasons:

1.2.17 (Annex Z)	23,65%
1.2.12 (Absence of reproducible test)	10,59%
1.2.10 (Tech content not in line with EU law)	9,46%
1.2.9 (NR)	8,33%

Useful documents and organisation e.g.

European expert(s) to read the Guide and/or the draft

Convenor / experts (who know well the draft)



The WG Secretary in TC (uses the Template of Annex Z)

2. Do only refer to the parts of standard which are normative, deal with significant hazards contain verifiable requirements and are specific

Extract from HAS assessment of draft hEN in support of MD

[redacted]		Annex ZA	1.3.2	Ge	The listed clauses do not provide specific technical requirements able to cover this EHSR.	Please, provide specific and measurable technical requirements or state this EHSR as not covered	PL agree: It is too late to introduce measurable technical requirements. Keep this for the upcoming revision and change ESHR to not covered in this edition→ Modify ZA, 1.3.2: not covered Add to Scope: This document does not deal with hazard due to the risk of break-up during operation.

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.3.2. Risk of break-up during operation	4.8.4, 4.11, 5.1, 6.2.3	

1.3.2. Risk of break-up during operation	~~4.8.4, 4.11, 5.1, 6.2.3~~	not covered

2. Do only refer to the parts of standard which are normative, deal with significant hazards, contain verifiable requirements and are specific

What is wrong in this table?

1.1.3	1, 5.1	

1 Scope

This European Standard applies to tyre curing machines having the following configuration:

— crossing flow tyre curing machines, with one cavity with manual or automatic feeding and discharge;

5 Safety requirements and/or protective measures

5.1 General safety requirements and/or protective measures

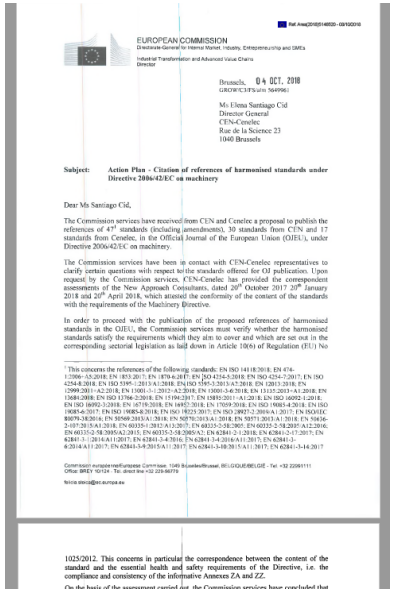
Machinery shall comply with the safety requirements and/or protective measures of this clause. In addition, the machines shall be designed according to the principles of EN ISO 12100:2010 for relevant but not significant hazards, which are not dealt with by this document.

1.1.3	4.2	

3. Don’t indicate other standards or legislation

Extract from the European Commission letter to CEN and CENELEC:

(see Annex). In addition, I would like to underline that, as of this date, any reference in Annex ZA/ZZ to other standards or documents (which are not standards) including to other legal acts than the one which should be supported are not acceptable. Annex ZA/ZZ cannot be used to establish relationship between the 'legal requirements' and other standards or documents. In consequence, all harmonised standards proposed as of 1 April 2019 failing to comply with this, will not be published in the OJEU.


EUROPEAN COMMISSION

Brussels, 04 OCT. 2018

Ms Elena Santiago Cid
Director General
CEN-Cenelec
Rue de la Science 23
1040 Brussels

Subject: Action Plan - Citation of references of harmonised standards under Directive 2006/42/EC on machinery

Dear Ms Santiago Cid,

The Commission services have received from CEN and Cenelec a proposal to publish the references of 47[1] standards (including amendments), 30 standards from CEN and 17 standards from Cenelec, in the Official Journal of the European Union (OJEU), under Directive 2006/42/EC on machinery.

The Commission services have been in contact with CEN-Cenelec representatives to clarify certain questions with respect to the standards offered for OJ publication. Upon request by the Commission services, CEN-Cenelec has provided the correspondent assessments of the New Approach Consultants, dated 26th October 2017, 20th January 2018 and 20th April 2018, which attested the conformity of the content of the standards with the requirements of the Machinery Directive.

In order to proceed with the publication of the proposed references of harmonised standards in the OJEU, the Commission services must verify whether the harmonised standards satisfy the requirements which they aim to cover and which are set out in the corresponding sectorial legislation as laid down in Article 10(6) of Regulation (EU) No

1025/2012. This concerns in particular the correspondence between the content of the standard and the essential health and safety requirements of the Directive, i.e. the compliance and consistency of the informative Annexes ZA and ZZ.

3. Don’t indicate other standards or legislation

What is wrong in this table?

3.6.2·Marking¤	9.2.1¤	°¤
3.6.3·Instructions¤	9.1¤	°¤

[1)]°Compliance· with· EN· ISO· 1234-17· and· the· relevant· requirements· of· EN· ISO· 1234-1:2015· is· necessary· to· achieve· presumption·of·conformity·with·the·essential·requirements·of·EU·Directive·2006/42/EC·aimed·to·be·covered.·For·relevant· requirements·of·EN·ISO·1234-1·see·Table°1,·List·of·significant·hazards,·of·this·standard.¤

WARNING°1·—·Presumption·of·conformity·stays·valid·only·as·long·as·a·reference·to·this·European· Standard·is·maintained·in·the·list·published·in·the·Official·Journal·of·the·European·Union.·Users·of· this· standard· should· consult· frequently· the· latest· list· published· in· the· Official· Journal· of· the· European·Union.¶

WARNING°2·—·Other·Union·legislation·may·be·applicable·to·the·product(s)·falling·within·the·scope· of·this·standard.¶

3.6.2·Marking¤	9.2.1¤	°¤
3.6.3·Instructions¤	9.1¤	°¤

WARNING°1·—·Presumption·of·conformity·stays·valid·only·as·long·as·a·reference·to·this·European· Standard·is·maintained·in·the·list·published·in·the·Official·Journal·of·the·European·Union.·Users·of· this· standard· should· consult· frequently· the· latest· list· published· in· the· Official· Journal· of· the· European·Union.¶

WARNING°2·—·Other·Union·legislation·may·be·applicable·to·the·product(s)·falling·within·the·scope· of·this·standard.¶

The links with other standards, if necessary, in line with CEN-CENELEC Internal Regulations Part 3 (IR3), shall be made:

- In Foreword -> see IR3, Clause 12
- via the normative references

4. Apply agreed solution for EHRS 1.1.2 - Principles of safety integration

- As EHRS 1.1.2 of Machinery Directive **indent (b)** is covering "procedural aspects" it should not be covered at all in Annex ZA/ZZ.
- EHRS 1.1.2 indents (a); (c); (d) and (e) should be covered as follows:

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2 (a)	4, 5, 6 [1)]	
1.1.2 (c)	4, 5, 6 [1)]	
1.1.2 (d) [2)]	4, 5, 6 [1)]	
1.1.2 (e) [2)]	4, 5, 6 [1)]	

1) Clauses according to CEN Guide 414:

4 Safety requirements and/or protective/risk reduction measures

5 Verification of safety requirements and/or protective/risk reduction measures

6 Information for use

2) To be integrated only in case aspect stated in indent is relevant for machinery covered by hEN and to the extent these product requirements are dealt with in the concerned standard

4. Apply agreed solution for EHRS 1.1.2 - Principles of safety integration

Correct example of addressing EHSR 1.1.2

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2 a)	4,5,6	
1.1.2 c)	4,5,6	
1.1.2 d)	4,5,6	
1.1.2 e)	4,5,6	

Contents of this hEN

Contents Page

European foreword ... 3
Introduction ... 5
1 Scope ... 6
2 Normative references ... 6
3 Terms and definitions ... 7
4 Safety requirements and/or protective/risk reduction measures ... 9
4.1 General ... 9
4.2 Operator's station ... 9
4.3 Seat ... 10
4.4 Steering system ... 11
4.5 Brake systems ... 11
4.6 Operator's field of view ... 11
4.7 Stability ... 12
4.8 Lifting operation ... 13
4.9 Quick coupler ... 14
4.10 Specific requirements for walking excavators ... 14
5 Verification of the safety requirements and/or protective/risk reduction measures ... 16
6 Information for use ... 18
6.1 General ... 18
6.2 Machine safety labels ... 18
6.3 Operator's manual ... 19
Annex A (informative) List of significant hazards ... 21

The numbers of clauses to indicate in 2nd column depend on Contents of a hEN ->
These can be different numbers than 4,5 and 6.

4. Apply agreed solution for EHRS 1.1.2 - Principles of safety integration

Correct example of addressing EHSR 1.1.2

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2006/42/EC

The relevant Essential Requirements of EU Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2.a) Principles of safety integration	4; 5; 6; 7; 8; 9	
1.1.2.c) Principles of safety integration	4; 5; 6; 7; 8; 9	

Contents of this hEN

4 Safety requirements and/or protective/risk reduction measures for all machines 4
4.1 General 4
4.2 Controls 4
4.3 Visibility 4
4.4 Haulm/leaf topping device 5
4.4.1 Protection against unintentional contact with the rotating tools 5
4.4.2 Haulm/leaf conveying device of a haulm/leaf topping device 7
4.4.3 Haulm/leaf loading device of a haulm/leaf topping device 8
4.4.4 Protection against thrown objects 8
4.5 Bunker 9
4.6 Unloading 9
4.7 Prevention of hazards related to blockages 9
4.8 Prevention of risks of unintentional contact with power-driven functional elements 9
4.9 Platforms used as workplace on the machine 10
4.9.1 General 10
4.9.2 Sorting platform 10
4.9.3 Packing platform 11
4.10 Other places than the operator's stations 12
4.11 Leaf spreading device 13
4.11.1 General 13
4.11.2 Protection against unintentional contact 13
4.12 Haulm spreading devices 17
4.12.1 Protection on the top and at the front 17
4.12.2 Protection at the sides 19
4.13 Noise reduction as safety requirement 19
5 Additional requirements for sieving harvesters 19
5.1 Digging devices 19
5.2 Cleaning and conveying devices 19
5.2.1 General 19
5.2.2 Cleaning belts 19
5.2.3 Other cleaning devices 19
5.2.4 Conveying devices 20
6 Additional requirements for root lifting harvesters 20
6.1 Root lifting devices 20
6.2 Cleaning devices 20
6.2.1 General 20
6.2.2 Cleaning turbines 20
6.2.3 Cleaning belts 22
6.2.4 Cleaning rollers 23
6.3 Conveying devices 24
7 Additional requirements for top lifting harvesters 24
7.1 Top lifting devices 24
7.2 Cleaning devices 26
7.3 Cleaning belts 26
7.4 Conveying devices 26
7.5 Devices in front of the top lifting devices 26
7.6 Haulm/leaf removing device 27
8 Verification of the safety requirements and/or protective/risk reduction measures 27
9 Information for use 28
9.1 Operator's manual 28
9.1.1 General 28
9.1.2 All machines 28
9.1.3 Sieving harvesters 29
9.1.4 Root lifting harvesters 29
9.1.5 Top lifting harvesters 30
9.2 Marking 30
9.2.1 General 30
9.2.2 Warnings 30
Annex A (informative) List of significant hazards 32
Annex B (informative) Examples of machines and components 39
Annex C (informative) Prevention of hazards related to blockages and removal of blockages on root crop harvester 51
Bibliography 54

4. Apply agreed solution for EHRS 1.1.2 - Principles of safety integration

▶Example of **incorrect** Annex Z

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2. Principles of safety integration	-----	
1.1.2(a)	4.1, 4.2, 4.4	
1.1.2(c)	4.4	
1.1.2(d)		NOT COVERED
1.1.2(e)		NOT COVERED

Clause 4.1, which often contains sentence on the not significant hazards, shall not be indicated in the Annex Z table. See item 10 of Instruction and previous slides

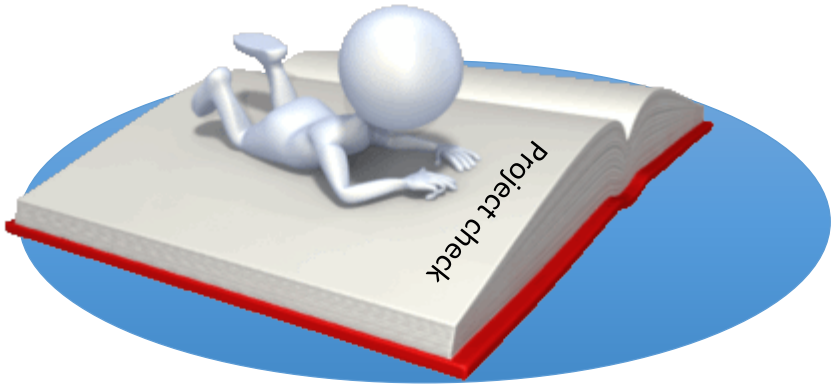
5. Check each of the EHSR up to 6.5

List of clauses of the MD (extracts)

The relevant Essential Requirements of Directive 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.2 (a)		
1.1.2 (c)		
1.1.2 (d)	5.6·Exhaust·emissions¤	
1.1.2 (e)	6·ADDITIONAL·ESSENTIAL·HEALTH·AND·SAFETY·REQUIREMENTS·FOR·MACHINERY·PRESENTING·PARTICULAR·HAZARDS·DUE·TO·THE·LIFTING·OF·PERSONS¤	
1.1.3 Materials and products	6.1·GENERAL·INFORMATION¤	
1.1.4 Lighting	6.1.1·Mechanical·strength¤	
1.1.5 Design of machinery to facilitate its handling	6.1.2·Control·of·stresses·for·machinery·powered·by·energy·other·than·human·strength¤	
1.1.6 Ergonomics	6.2·OPERATING·ELEMENTS¤	
1.1.7 Operating positions	6.3·RISKS·TO·PERSONS·IN·THE·PASSENGER·COMPARTMENT¤	
1.1.8 Seating	6.3.1·Risks·due·to·movement·of·the·carrier¤	
	6.3.2·Risks·of·persons·falling·from·the·carrier¤	
	6.3.3·Risks·due·to·objects·falling·on·the·carrier¤	
	6.4·MACHINERY·SERVING·FIXED·LANDINGS¤	
	6.4.1·Risks·to·persons·inside·the·carrier¤	
	6.4.2·Controls·located·at·landings¤	
	6.4.3·Access·to·the·carrier¤	
	6.5·Markings¤	

© CEN-CENELEC 2024

5. Check each of the EHSR up to 6.5



When Annex Z is completed, for each stage, **double check** :
each clause/subclause of the project in relation with machinery legislation must be cited in Annex Z.

If one clause/subclause is not cited, add it to the relevant row of Annex Z

Modifications introduced in the project at later stage shall be reflected in Annex Z

Harmonized European Standards: A Journey from Legal Framework to Citation in the Official Journal of the European Union

22-23 May 2024
Brussels / Online

Thank you!

Any questions?