



**CENELEC**

# Webinar

Informative Annex ZA/ZZ for the  
Machinery Directive



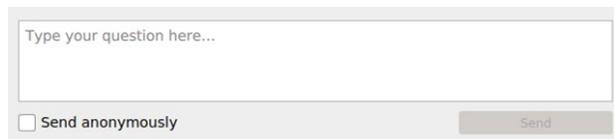
*We start at  
14:00 CET*



**Els SOMERS**  
**Project Manager**  
**Policy & Partnerships**  
**CEN-CENELEC**  
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# Get the most out of the webinar today

- ▶ You are muted
- ▶ Use the Q&A panel to submit your questions



Type your question here...

Send anonymously

Send

- ▶ Talk about us on Twitter [#training4standards](#) [@Standards4EU](#)

# Agenda

|    |             |  |   |
|----|-------------|--|---|
| 00 | 14:00-14:05 | Introduction & Practicalities  | Els Somers (CEN-CENELEC)  |
| 01 | 14:05-14:15 | Welcome remarks  | Frank Wohnsland, CEN-CENELEC Sector Rapporteur on Machinery<br>Peter Broertjes, EC Policy Officer for Machinery |
| 02 | 14:15-15:00 | Explanation of <a href="#">the CEN and CENELEC instructions on informative Annex Z for Machinery Directive</a> | Hugo DOURADO and Joanna FRANKOWSKA<br>Project Managers Manufacturing at CEN-CENELEC                             |
|    | 15:00-15:10 | BREAK  |   |
| 04 | 15:10-15:55 | Drafting a detailed informative Annex Z under the Machinery Directive in practice including the quiz           | Aline Vecchia and Catherine Lubineau of AFNOR/UNM   |
| 05 | 15:55-16:25 | Q&A  | all   |
| 06 | 16:25-16:30 | Closing  | Frank Wohnsland, CEN-CENELEC Sector Rapporteur on Machinery   |



# Welcome remarks

Frank Wohnsland - CEN-CENELEC Sector Rapporteur on Machinery

Peter Broertjes – EC Policy Officer for Machinery



# Why this seminar on informative Annex Z?

Question:

The rules for Annex Z are (or rather: should be) known to most standardizers.

⇒ So why this exercise?

Let's briefly recall the relevance of Annex Z:

- ▶ No harmonization without a legally sound Annex Z
  - ▶ It constitutes link between Directives and technical solutions in standards
  - ▶ Understanding of its role has changed over the years: Transition from a purely informative element into a legally relevant part
- ▶ Most rejections of harmonization in the recent past due to non-compliance with Annex Z (with quite a variety of “mistakes”)

# Good moment for the seminar!

- ▶ HAS-system had been suspended during 2022 due to change of contract (hardly any activities) – now the system is re-starting
- ▶ Machinery sector – new machinery regulation– huge task ahead:
  - ▶ An enormous number of standards will have to be brought in shape
  - ▶ Much of this work has to do with Annex Z
  - ▶ Success and speed of this action depends strongly on the (formal) quality of Annex Z
- ▶ This seminar will
  - ▶ contribute to a better understanding for those who are not really familiar with the system and/or
  - ▶ serve as a reminder or refresh the knowledge of those experts who knew about the details already



# Explanation of the CEN and CENELEC instructions on informative Annex Z for Machinery Directive

Joanna Frankowska, Hugo Dourado, CEN-CENELEC



# Instructions on informative Annex Z for machinery

## Decisions BT C036/2022 in CEN and D171/C076 in CENELEC

- having noted
  - ▶ that one of the common reasons for lack of compliance of harmonized standards under the Machinery Directive is related to issues in the informative Annex Z;
  - ▶ that the CEN-CENELEC Sector Forum on Machinery developed guidance containing instructions for TCs for preparing the informative Annex Z under Machinery Directive which were agreed with the European Commission;
  - ▶ the recommendation of the CEN-CENELEC Sector Forum on Machinery asking the BTs to approve the instructions for Technical Committees regarding the preparation of the Annex Z under the Machinery Directive and its availability on CEN and CENELEC BOSS;

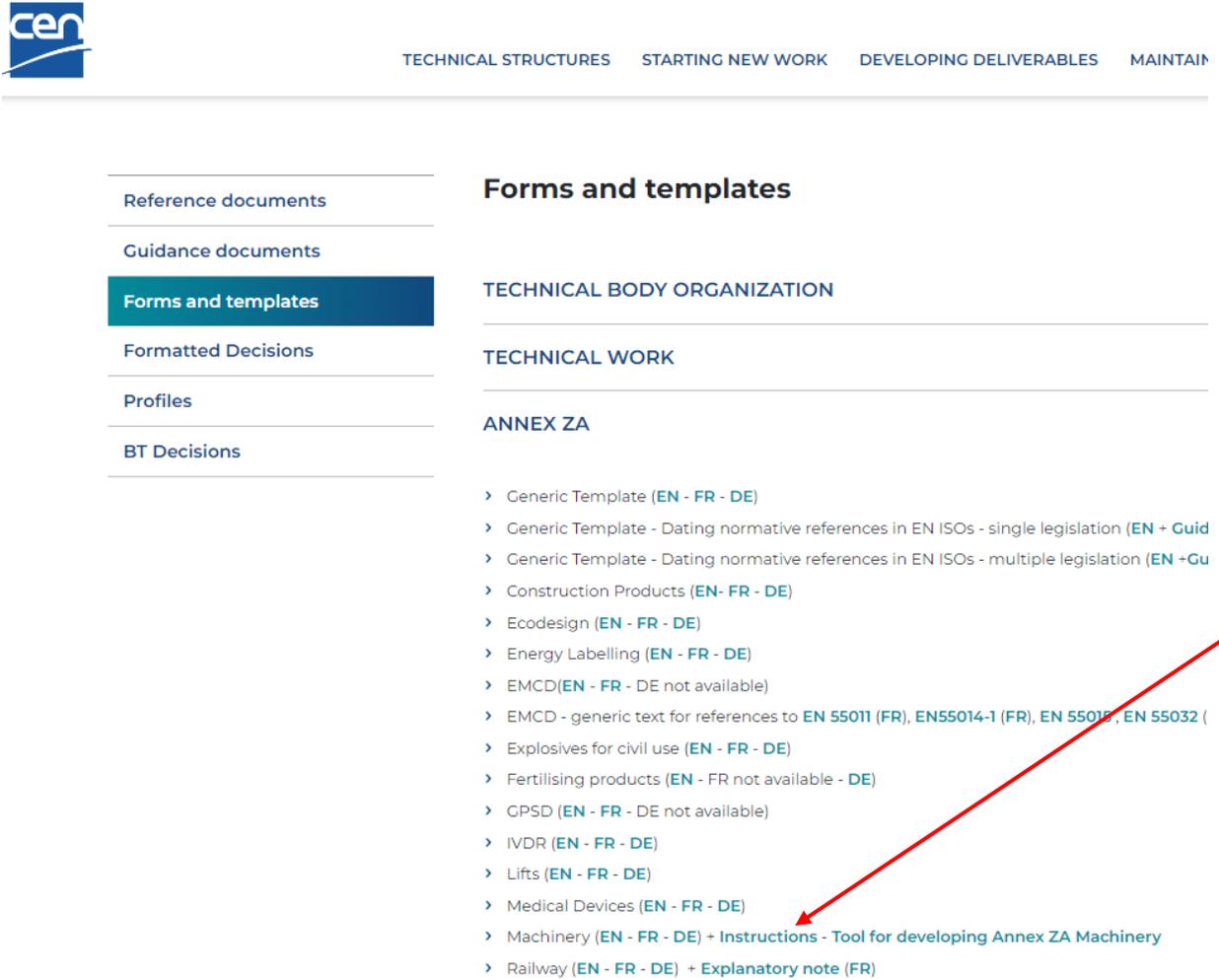
## Decisions BT C036/2022 in CEN and D171/C076 in CENELEC

BT

- ▶ **decided to approve the guidance** for Technical Committees containing [instructions for preparing Annex Z under Machinery Directive](#);
- **asked**
- ▶ **CEN and CENELEC Technical Committees** of the machinery sector to comply with the [instructions for preparing the informative Annex Z](#) under the Machinery Directive;
- ▶ CCMC to make the instructions on Annex Z available on CEN and CENELEC BOSS - DONE



# 1. Apply correct template and instructions



The screenshot shows the CEN website navigation menu. The left sidebar contains a list of menu items: Reference documents, Guidance documents, Forms and templates (highlighted in blue), Formatted Decisions, Profiles, and BT Decisions. The main content area is titled 'Forms and templates' and lists various technical documents under the heading 'ANNEX ZA'. A red arrow points from the text on the right to the 'Machinery (EN - FR - DE) + Instructions - Tool for developing Annex ZA Machinery' item in the list.

- Reference documents
- Guidance documents
- Forms and templates**
- Formatted Decisions
- Profiles
- BT Decisions

**Forms and templates**

TECHNICAL BODY ORGANIZATION

TECHNICAL WORK

ANNEX ZA

- > Generic Template (EN - FR - DE)
- > Generic Template - Dating normative references in EN ISOs - single legislation (EN + Guid
- > Generic Template - Dating normative references in EN ISOs - multiple legislation (EN +Gu
- > Construction Products (EN - FR - DE)
- > Ecodesign (EN - FR - DE)
- > Energy Labelling (EN - FR - DE)
- > EMCD(EN - FR - DE not available)
- > EMCD - generic text for references to EN 55011 (FR), EN55014-1 (FR), EN 55015, EN 55032 (
- > Explosives for civil use (EN - FR - DE)
- > Fertilising products (EN - FR not available - DE)
- > GPSD (EN - FR - DE not available)
- > IVDR (EN - FR - DE)
- > Lifts (EN - FR - DE)
- > Medical Devices (EN - FR - DE)
- > Machinery (EN - FR - DE) + Instructions - Tool for developing Annex ZA Machinery
- > Railway (EN - FR - DE) + Explanatory note (FR)

## Where to find?

Annex ZA (CEN): **CEN BOSS** website: Reference Material/Forms and templates/Technical Work (link: <https://boss.cen.eu/reference-material/formstemplates/pages/>)

# 1. Apply correct template and instructions

Reference documents

Guidance documents

Forms and templates

## Forms and templates

### TECHNICAL BODY ORGANIZATION

### TECHNICAL WORK

### ANNEX ZZ

- › Generic template (EN - FR - DE)
- › Ecodesign (EN - FR - DE)
- › EMCD (EN - FR - DE)
- › EMCD - generic text for references to EN 5
- › GPSD (EN - FR and DE not available)
- › IVDR (EN - FR - DE)
- › LVD (EN - FR - DE)
- › Medical Devices (EN - FR - DE)
- › Machinery (EN - FR - DE) + Instructions
- › RED - EMC (EN - FR (not available) - DE)

## Where to find?

Annex ZZ (CENELEC): [CENELEC BOSS](https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/) → Reference Material → Forms and Templates → Annex ZZ (link: <https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/>)

# 1. Apply correct template

“The relevant” shall be indicated in the heading of the 1<sup>st</sup> column of an informative Annex Z of type-B and type-C standards

Table Z....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 |
|---|--|---------------|
| <i>[Per row: an essential requirement]</i>                  | <i>[The relevant normative clauses linked to the individual essential requirement]</i> |               |
| <i>[Per row: an essential requirement]</i>                  | -  | not covered   |
| <i>[Example] / 1.7.4.2 u)</i>                               |  | not covered   |

Non-covered elements shall only be indicated in an informative Annex Z of type-C standards

Template **agreed with European Commission and approved by CEN and CENELEC Technical Boards** (decisions C147/2019 in CEN and D163/C089 in CENELEC)

1. Apply correct template - indicate relevant EHSRs
6. Do not refer to 'not relevant' EHSRs

What is wrong in this table?

- **Table°ZZB.1--Correspondence-between-this-European-standard-and-Annex°I-of-Directive-2006/42/EC· [OJ·No·L·157]¶**

|  |                    |               |
|--|--------------------|---------------|
| Essential Requirements of Directive 2006/42/EC | Clauses of this EN | Remarks/Notes |
|--|--------------------|---------------|



1.

- **Table°ZZB.1--Correspondence-between-this-European-standard-and-Annex°I-of-Directive-2006/42/EC· [OJ·No·L·157]¶**

|  |                    |               |
|--|--------------------|---------------|
| <u>The relevant</u> Essential Requirements of Directive 2006/42/EC | Clauses of this EN | Remarks/Notes |
|--|--------------------|---------------|



6.

Do not refer to "not relevant" EHSRs as an informative Annex Z under the Machinery Directive shall list only the relevant EHSRs as indicated in the heading of the first column of the table.

# 1. Apply correct template – mention 'not covered'

What is wrong in this table?

|   |                         |                   |  |
|---|-------------------------|-------------------|--|
| between self-propelled machinery (or tractor) and recipient machinery |                         |                   |  |
| 3.5.1. Batteries  | 4.7                     |                   |  |
| 3.5.2. Fire   | 4.16                    |                   |  |
| 3.6.1. Signs, signals and warnings                                    | 4.11.2; 4.11.3; 4.13; 6 | Partially covered |  |



|                                    |                                    |   |  |
|------------------------------------|------------------------------------|---|--|
| 3.6.1. Signs, signals and warnings | <del>4.11.2; 4.11.3; 4.13; 6</del> | <del>Partially</del> <u>Not</u> covered |  |
|------------------------------------|------------------------------------|---|--|



|                                    |                         |  |  |
|------------------------------------|-------------------------|--|--|
| 3.6.1. Signs, signals and warnings | 4.11.2; 4.11.3; 4.13; 6 |  |  |
|------------------------------------|-------------------------|--|--|

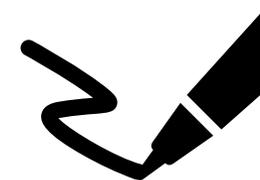


## 2. Don't indicate other standards or legislation



### 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.



## 2. Don't indicate other standards or legislation

### What is wrong in this table?

|  |                    |                |
|--|--------------------|----------------|
| 3.6.2-Marking <sup>□</sup>   | 9.2.1 <sup>□</sup> | ° <sup>□</sup> |
| 3.6.3-Instructions <sup>□</sup>  | 9.1 <sup>□</sup>   | ° <sup>□</sup> |
| <del>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. <sup>□</sup></del> |                    |                |

~~WARNING<sup>□</sup>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. <sup>□</sup>~~

~~WARNING<sup>□</sup>2—Other Union legislation may be applicable to the product(s) falling within the scope of this standard. <sup>□</sup>~~

|                                 |                    |                |
|---------------------------------|--------------------|----------------|
| 3.6.2-Marking <sup>□</sup>      | 9.2.1 <sup>□</sup> | ° <sup>□</sup> |
| 3.6.3-Instructions <sup>□</sup> | 9.1 <sup>□</sup>   | ° <sup>□</sup> |

WARNING<sup>□</sup>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. <sup>□</sup>

WARNING<sup>□</sup>2—Other Union legislation may be applicable to the product(s) falling within the scope of this standard. <sup>□</sup>



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

# 3. Apply instructions on the level of detail

## Warning 1:

Do not list paragraphs of the EHSRs if there is only a title without requirement.

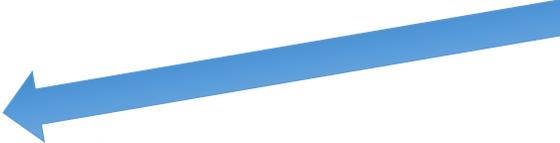
EXAMPLE:



**1.2 CONTROL SYSTEMS**

**1.2.1 Safety and reliability of control systems**

*Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:*



Title, no requirement, but subclauses

According to the rules agreed with EC in CEN-CENELEC Sector Forum on Machinery, when you refer to the main clause (e.g. 1.3) of a EHSRs structured in multi-clauses (e.g. 1.3.1; 1.3.2; etc.), ALL the subclauses shall be covered.

# 3. Apply instructions on the level of detail

## Warning 2:

If one EHSR is dealt with in ALL subclauses of one Clause of the project, it is allowed to refer only to the Clause.



**1.2.2 Control devices**  
...

|              |  |           |
|--------------|--|-----------|
| <b>4.2</b>   | <b>Location of the manual controls .....</b>             | <b>11</b> |
| <b>4.2.1</b> | <b>General.....</b>                                      | <b>11</b> |
| <b>4.2.2</b> | <b>Requirements for hold-to-run controls .....</b>       | <b>11</b> |
| <b>4.2.3</b> | <b>Additional requirements for manual controls .....</b> | <b>12</b> |

|                        |                                       |  |
|------------------------|---------------------------------------|--|
| 1.2.2 .Control devices | 4.2, 4.8, 6.1 d), e), h), j), p), 6.2 |  |
|------------------------|---------------------------------------|--|

# 4. Do not modify or add any text

# 5. Apply correct order of columns

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

~~This standard has been finalised by CEN/TC 123 in the framework of the MECH-1 project. Amendment is planned to be developed soon on visibility.¶~~

4.

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

| The relevant Essential Requirement of Directive 2006/42/EC¶ | Clause(s)/subclause(s) of this EN¶ | Remarks/Notes¶ |
|---|------------------------------------|----------------|
| 1.1.2.(a)¶  | 5,6,7¶                             | °¶             |

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

| Clause(s)/subclause(s) of this EN¶ | The relevant Essential Requirement of Directive 2006/42/EC¶ | Remarks/Notes¶ |
|------------------------------------|---|----------------|
| 5,6,7¶                             | 1.1.2.(a)¶  | °¶             |
| 5,6,7¶                             | 1.1.2.(c)¶  | ¶              |
| 5,6,7¶                             | 1.1.2.(d)¶  | ¶              |
| 4.2¶                               | 1.1.3.¶   | °¶             |
| 4.3¶                               | 1.1.6¶  | ¶              |



5.



# 7. Always provide numbers of EHSRs and of clauses

What is wrong in this table?

|  |                       |   |
|--|-----------------------|---|
| All relevant Essential Health and Safety Requirements except 1.2.4.1 and 1.2.5 | All normative clauses | 0 |
|--|-----------------------|---|



|         |             |             |
|---------|-------------|-------------|
| 1.2.4.1 |             | Not covered |
| 1.2.4.3 | 5.3, 7.2.12 |             |
| 1.2.5   |             | Not covered |



# 8. Do not refer to definitions

Do not refer to 1.1.1, 3.1.1 and 4.1.1. from Machinery Directive because they deal with definitions

**1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS**

**1.1. GENERAL REMARKS**

**1.1.1. Definitions**

For the purpose of this Annex A

**3.1.1. Definitions**

- (a) 'hazard' means a situation which is likely to cause death or serious injury or damage to health;
- (b) 'danger zone' means a zone in which the presence of a person is likely to cause death or serious injury or damage to health;
- (c) 'exposed person' means a person who is in a danger zone;
- (d) 'operator' means the person who is responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control;
- (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation:

(a) 'Machinery presenting hazards due to its mobility' means — machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or

— machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control;

(c) 'Machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another' means — machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

# 9. 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 <sup>1)</sup>              |               |
| 1.1.2 (c)   | 4, 5, 6 <sup>1)</sup>              |               |
| 1.1.2 (d) <sup>2)</sup>                                     | 4, 5, 6 <sup>1)</sup>              |               |
| 1.1.2 (e) <sup>2)</sup>                                     | 4, 5, 6 <sup>1)</sup>              |               |

## 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

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

## The correct example of addressing EHRS 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                              |               |

The numbers of clauses to indicate in 2nd column depend on the structure of a given standard -> check it! These can be different numbers than 4,5 and 6.



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

What is wrong in this table?

|         |   |         |    |
|---------|---|---------|----|
| 1.1.3.α | . | 1, 5.1α | °α |
|---------|---|---------|----|



4.1 → 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¶

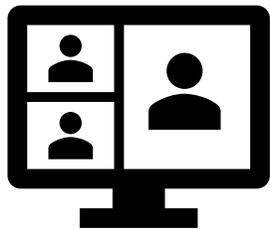
5.1 **General safety requirements and/or protective measures**¶

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.α |  | 4.2α | °α |
|---------|--|------|----|



- ▶ Compliance with European legislation is CEN/TC and CLC/TC **responsibility** (even if ISO or IEC lead) especially for Annex Z
- ▶ Very good **cooperation** between European and International Technical Body is **important**



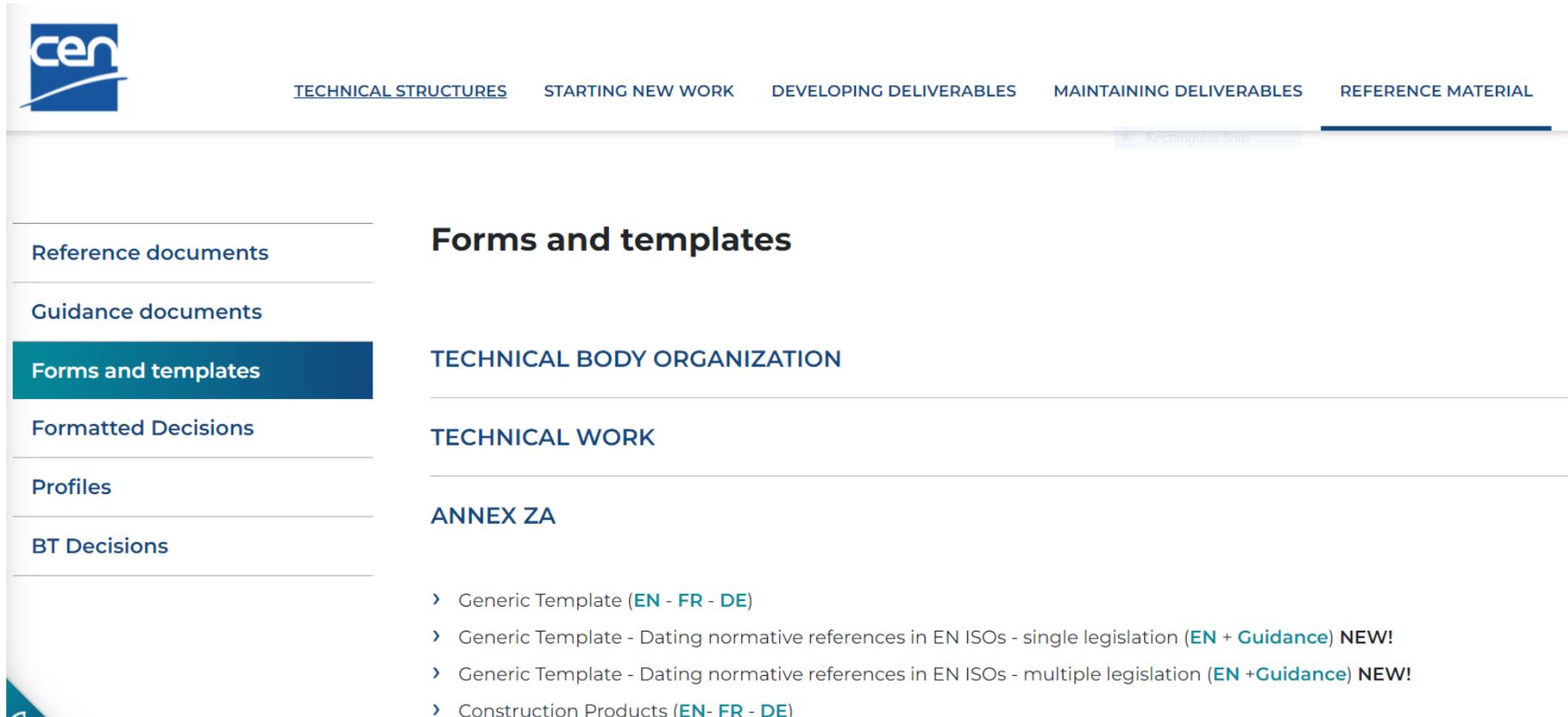
## DECISION BT 027/2021

- ▶ confirms that **dating normative references in main body** of the ISO standard **remains the preferred option**
- ▶ approves a generic approach for a **dedicated template for Annex ZA** which shall be used in harmonized EN ISO standards containing undated normative references
- ▶ **new template** and **the guidance document** available on [CEN BOSS](#)
- ▶ **LINK HERE** to the [dedicated webinar](#)

# Dating of Normative references in EN ISOs harmonized standards (2/3)

## New templates and guidance - Where to find them?

<https://boss.cen.eu/reference-material/formstemplates/pages/>





[TECHNICAL STRUCTURES](#) [STARTING NEW WORK](#) [DEVELOPING DELIVERABLES](#) [MAINTAINING DELIVERABLES](#) **[REFERENCE MATERIAL](#)**

Rectangular Slip

Reference documents

Guidance documents

**Forms and templates**

Formatted Decisions

Profiles

BT Decisions

### Forms and templates

TECHNICAL BODY ORGANIZATION

TECHNICAL WORK

ANNEX ZA

- › Generic Template ([EN](#) - [FR](#) - [DE](#))
- › Generic Template - Dating normative references in EN ISOs - single legislation ([EN](#) + [Guidance](#)) **NEW!**
- › Generic Template - Dating normative references in EN ISOs - multiple legislation ([EN](#) + [Guidance](#)) **NEW!**
- › Construction Products ([EN](#) - [FR](#) - [DE](#))

# Dating of Normative references in EN ISOs harmonized standards (3/3)

The example of Annex ZA.2 table:

**Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA**

| <b>Column 1<br/>Reference in<br/>Clause 2</b> | <b>Column 2<br/>International<br/>Standard Edition</b> | <b>Column 3<br/>Title</b>  | <b>Column 4<br/>Corresponding European<br/>Standard Edition</b> |
|---|--|--|---|
| IEC 60068-2-1                                 | IEC 60068-2-1:2007                                     | Environmental testing —<br>Part 2-1: Tests — Test A:<br>Cold   | EN 60068-2-1:2007   |
| IEC 60068-2-2                                 | IEC 60068-2-2:2007                                     | Environmental testing —<br>Part 2-2: Tests — Test B:<br>Dry heat   | EN 60068-2-2:2007   |
| IEC 60068-2-30                                | IEC 60068-2-<br>30:2005                                | Environmental testing —<br>Part 2-30: Tests — Test Db:<br>Damp heat, cyclic (12 h + 12<br>h cycle)                             | EN 60068-2-30:2005  |
| IEC 60068-2-31                                | IEC 60068-2-<br>31:2008                                | Environmental testing —<br>Part 2-31: Tests — Test Ec:<br>Rough handling shocks,<br>primarily for equipment-<br>type specimens | EN 60068-2-31:2008  |

# 11. Multi-part series

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Covered separately by the podcast:

 Link to the recording:

[“Instructions for multi-part standard series including the presentation of detailed informative Annex ZA/ZZ”](#)



## European Standardization Organizations

Drafting a detailed informative Annex Z under the Machinery Directive in practice including the quiz

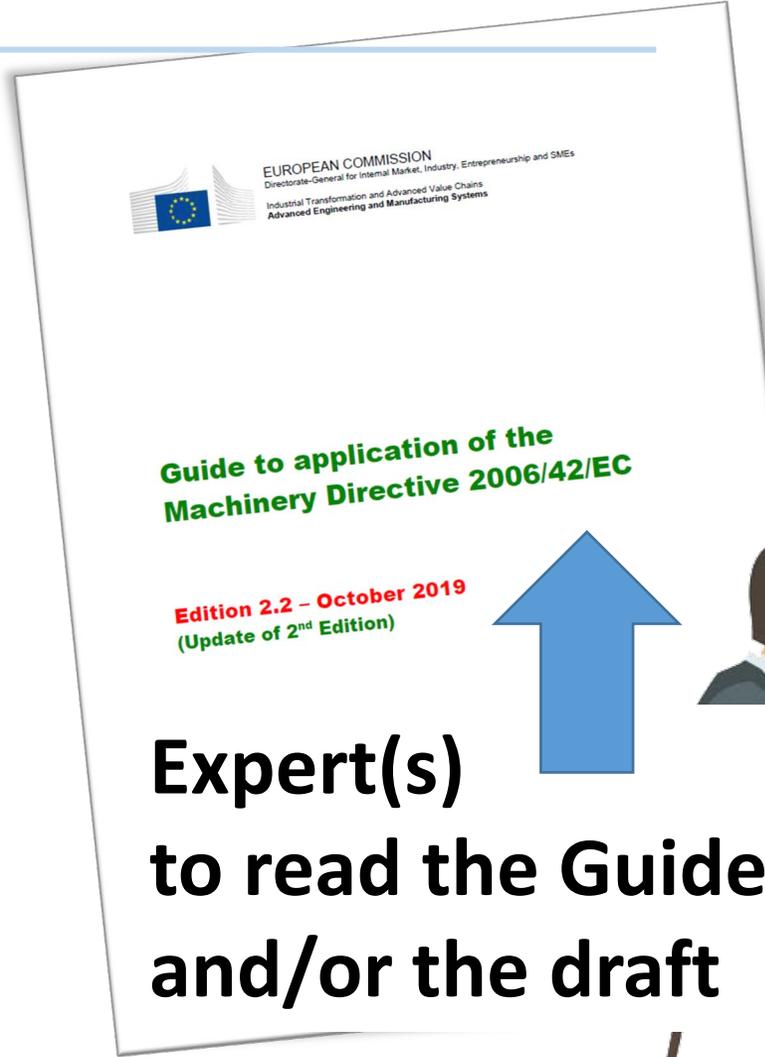
Aline Vecchia, Catherine Lubineau (AFNOR/UNM)



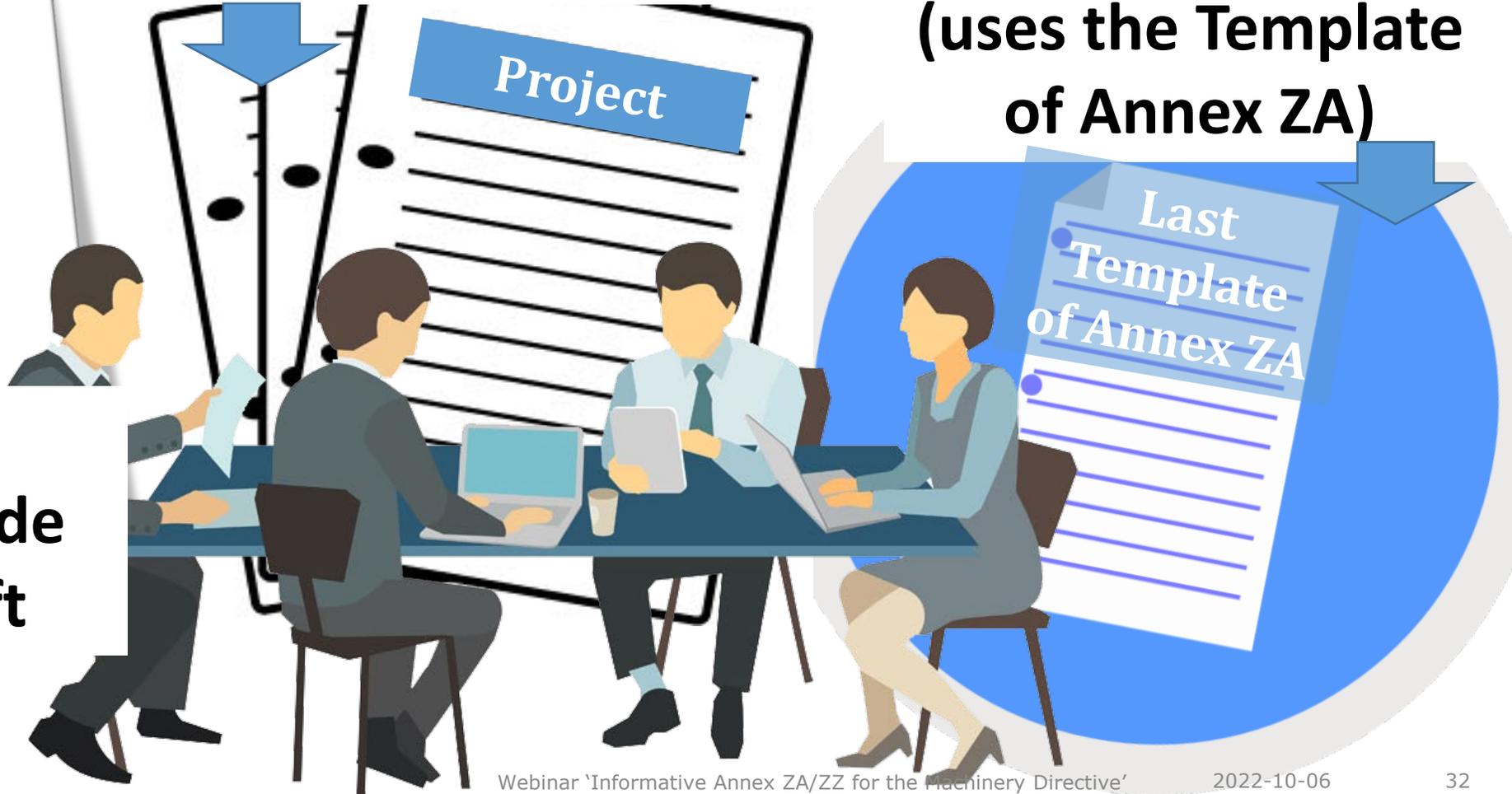
# Useful documents and organisation

**Convenor / experts  
(who know well the draft)**

**The WG Secretary  
(uses the Template  
of Annex ZA)**



**Expert(s)  
to read the Guide  
and/or the draft**





**1.1.2 Principles of safety integration**

*(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.*

*The aim of measures taken must be to eliminate or reduce risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.*

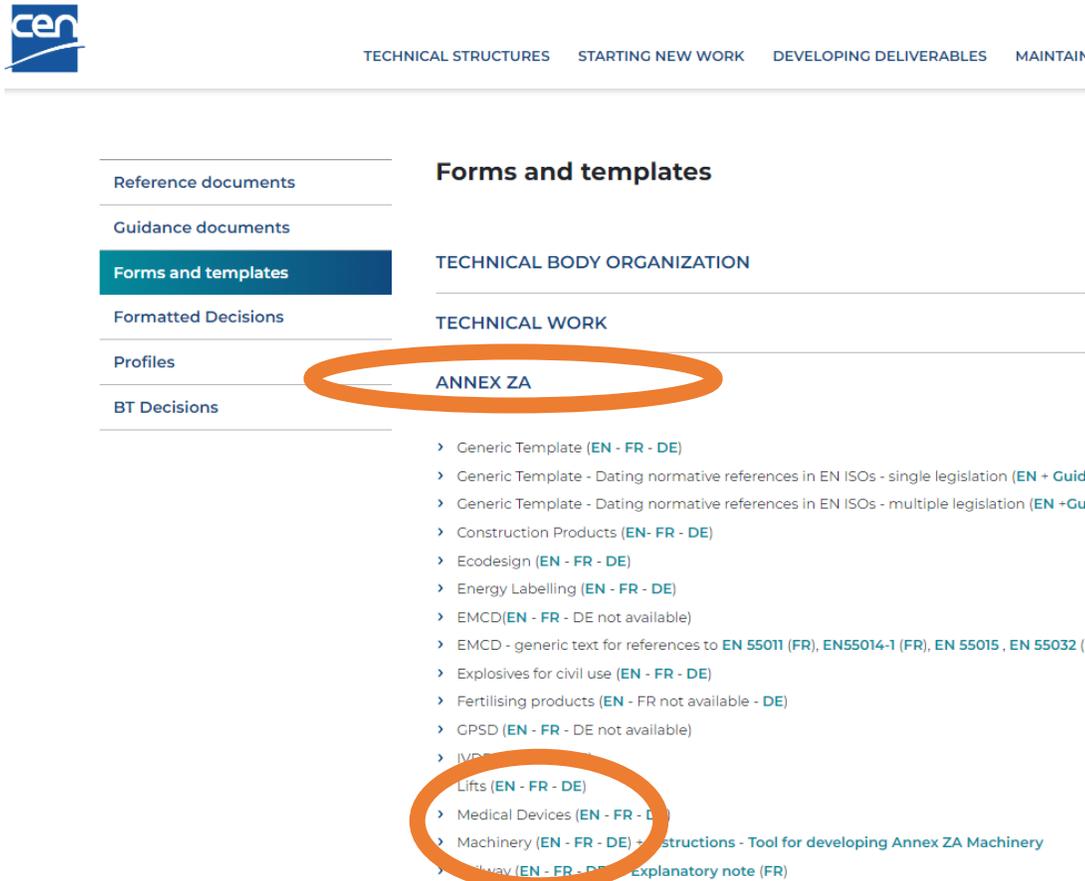
...

**§173 Principles of safety integration**

Section 1.1.2, setting out the principles of safety integration (sometimes referred to as *safety by design*), is a key section of Annex I. Section 1.1.2 sets out a basic methodology for designing and constructing safe machinery which is fundamental to the approach of the Machinery Directive.<sup>102</sup> General principle 2 states that this EHSR is applicable to all machinery. When applying the other EHSRs, the principles of safety integration set out in section 1.1.2 must be

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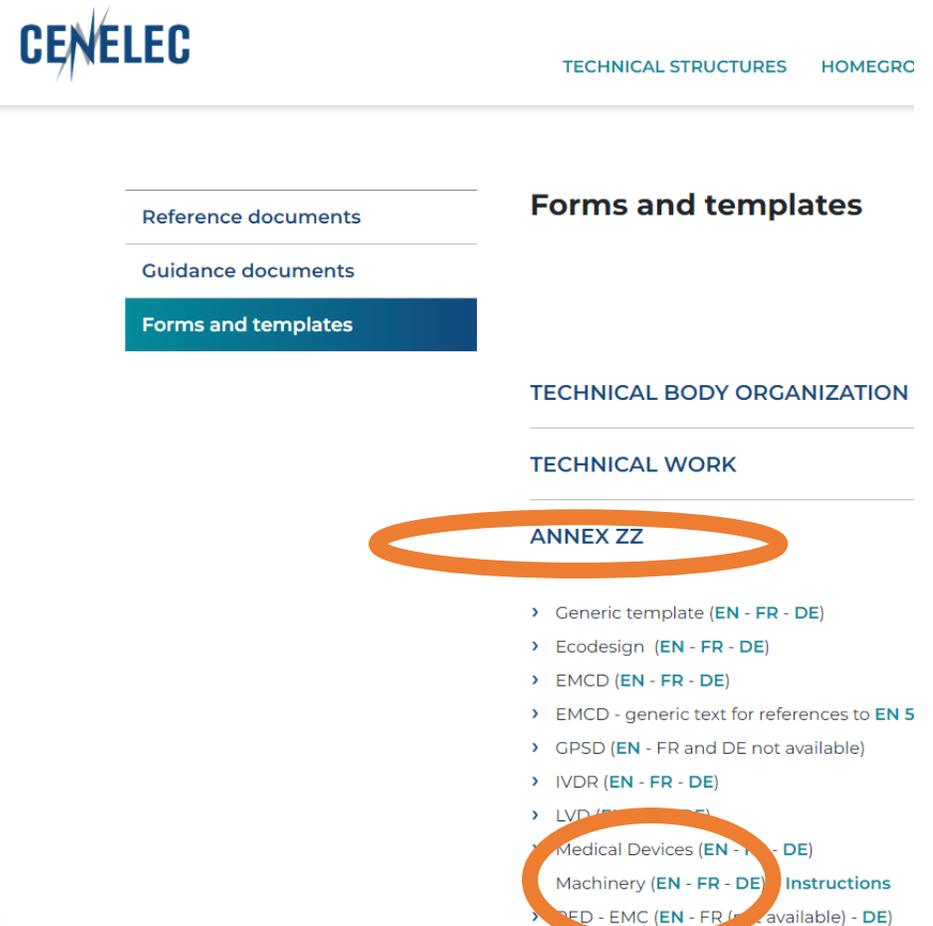
TECHNICAL BODY ORGANIZATION

TECHNICAL WORK

**ANNEX ZA**

- > Generic Template (EN - FR - DE)
- > Generic Template - Dating normative references in EN ISOs - single legislation (EN + Guid
- > Generic Template - Dating normative references in EN ISOs - multiple legislation (EN +Gu
- > Construction Products (EN- FR - DE)
- > Ecodesign (EN - FR - DE)
- > Energy Labelling (EN - FR - DE)
- > EMCD(EN - FR - DE not available)
- > EMCD - generic text for references to EN 55011 (FR), EN55014-1 (FR), EN 55015 , EN 55032 (
- > Explosives for civil use (EN - FR - DE)
- > Fertilising products (EN - FR not available - DE)
- > GPSD (EN - FR - DE not available)
- > IVDR (EN - FR - DE)
- > Lifts (EN - FR - DE)
- > Medical Devices (EN - FR - DE)
- > Machinery (EN - FR - DE) - Instructions - Tool for developing Annex ZA Machinery
- > Railway (EN - FR - DE) - Explanatory note (FR)

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TECHNICAL WORK

**ANNEX ZZ**

- > Generic template (EN - FR - DE)
- > Ecodesign (EN - FR - DE)
- > EMCD (EN - FR - DE)
- > EMCD - generic text for references to EN 5
- > GPSD (EN - FR and DE not available)
- > IVDR (EN - FR - DE)
- > LVD (EN - FR - DE)
- > Medical Devices (EN - FR - DE)
- > Machinery (EN - FR - DE) - Instructions
- > PED - EMC (EN - FR (not available) - DE)

# Use case : EHSR\* 1.1.2 covered

\*Essential Health and Safety Requirements



## *1.1.2 Principles of safety integration*

*(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.*

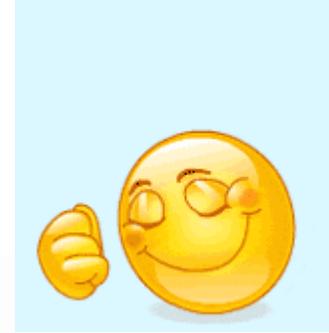
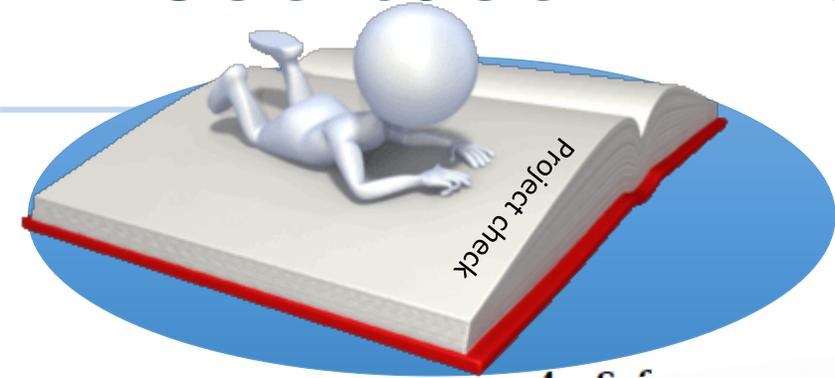
*The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.*

...

## **§173 Principles of safety integration**

Section 1.1.2, setting out the principles of safety integration, sometimes referred to as *safety by design*, is a key section of Annex I. Section 1.1.2 sets out a basic methodology for designing and constructing safe machinery which is fundamental to the approach of the Machinery Directive.<sup>102</sup> General Principle 2 states that this EHSR is applicable to all machinery. When applying the other EHSRs, the principles of safety integration set out in section 1.1.2 must be followed.

# Use case : EHSR 1.1.2 covered



**4.2 Safety d** **4.4 Access to operator's station**  
Access to the operator's station shall be provided by means of doors, shields

Unless otherwise specified in the standard, the requirements of ISO 13857 shall be applied.  
**4.5.1 Starting**

**4.5.1.1 Unauthorized starting or movement**  
Means shall be provided to render the machine inoperable to deter unauthorized starting or working of the machine. Key-type ignition switches, lockable master switches or other devices shall be used as protection. Lockable cabs can be used as protection.



Working release systems inoperative in order to prevent machine shutdown. Locking devices such as interlocking switches or provisions for padlocks satisfy this requirement. Controls or systems located within the cab.

Verification of conformity shall be by inspection.

Availability of controls being used as handholds.

# Use case : EHSR 1.1.2 covered

Table ZA.1 — Correspondence between this European Standard and Directive 2006/42/EC  
[2006 L157]

| The relevant Essential Requirements of Directive 2006/42/EC | Clause(s)/subclause(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                           |               |



# Use case EHSR 1.1.3 : not relevant



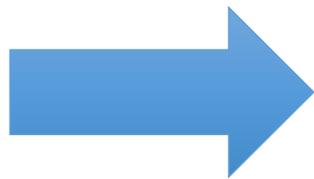
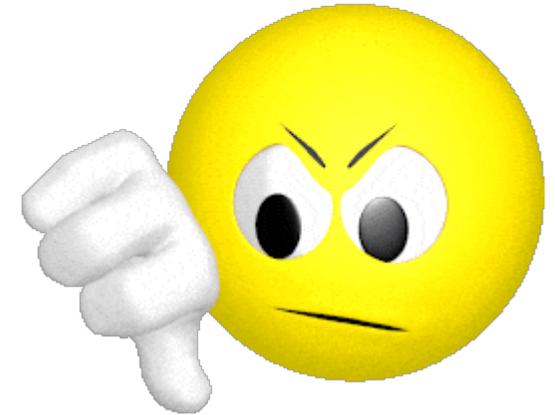
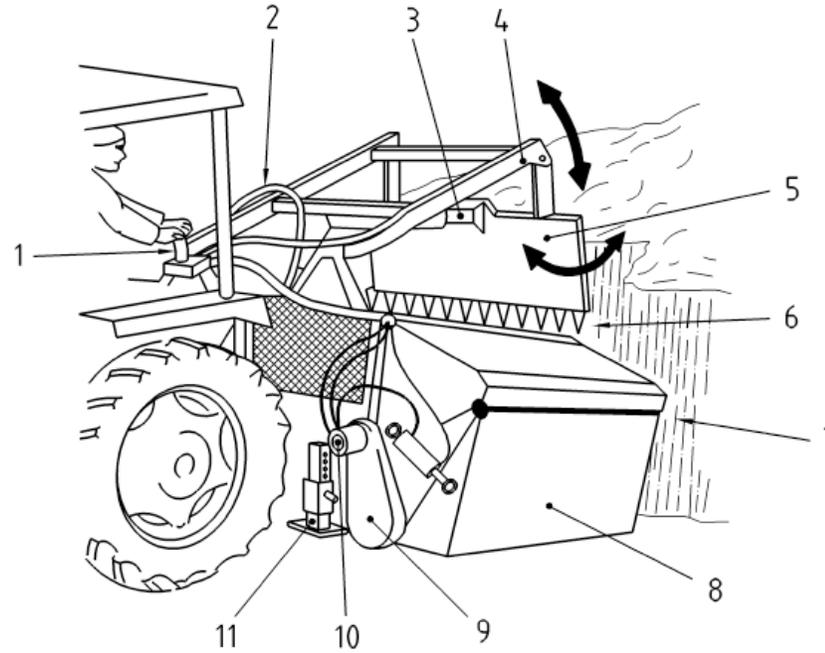
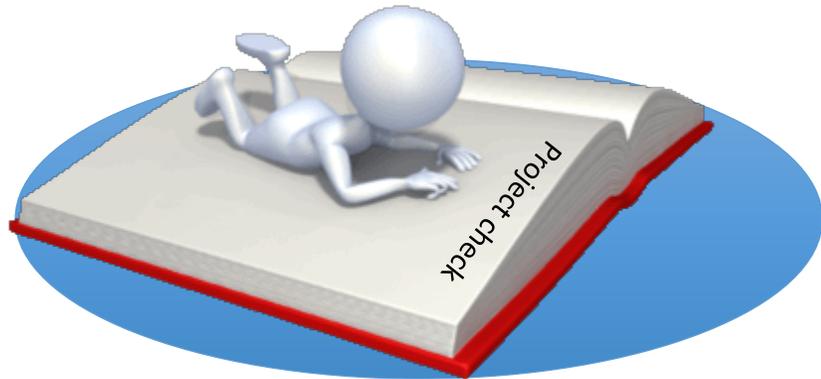
## *1.1.3 Materials and products*

*The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.*

### **§178 Materials and products used**

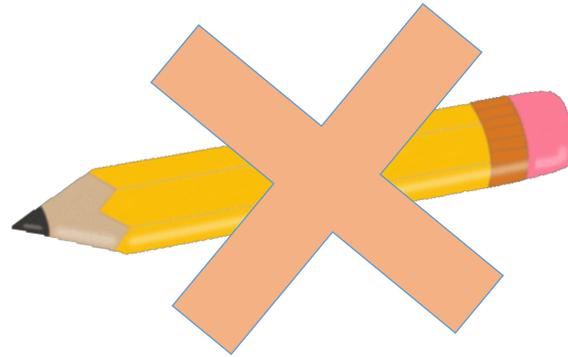
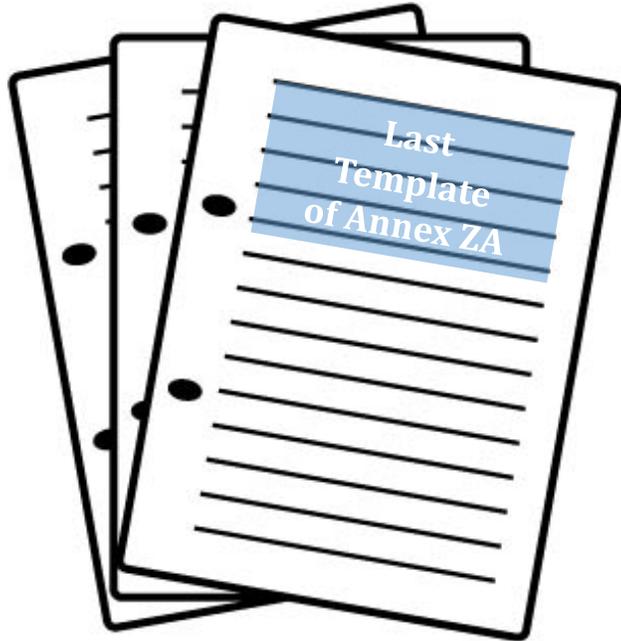
The requirement set out in section 1.1.3 deals with several kinds of risk:

# Use case EHSR 1.1.3 : not relevant



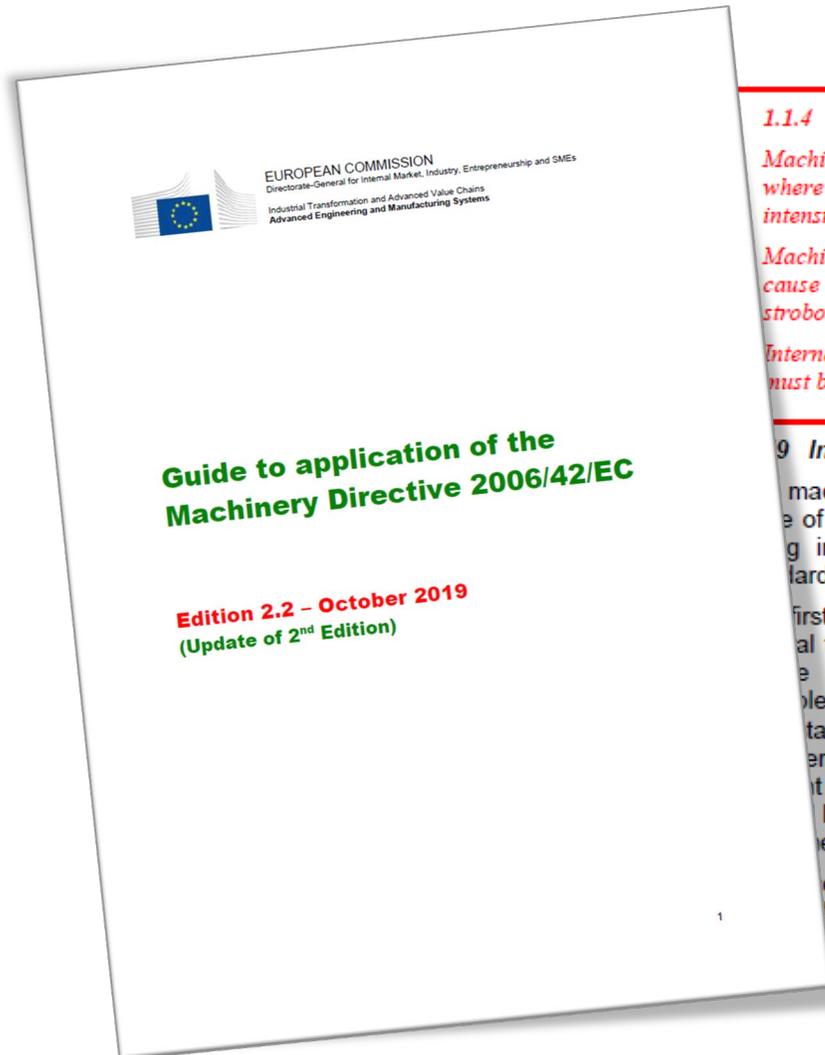
Having considered the list of risks intended to be covered, experts concludes that **this EHSR is NOT RELEVANT to the machines covered in the Scope**

# Use case EHSR 1.1.3 : not relevant



**Row EHSR 1.1.3 is not added**

# Use case : EHSR 1.1.4 : not covered



## 1.1.4 Lighting

*Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.*

*Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.*

*Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.*

## 9 Integral lighting

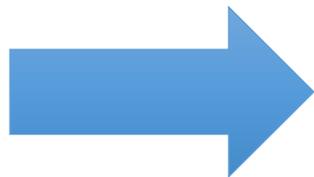
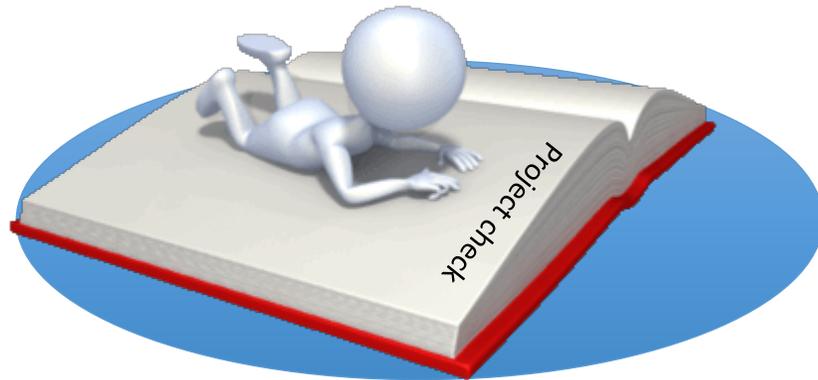
A machinery manufacturer is entitled to assume that the ambient lighting in the place of use is of normal intensity. Normal intensity can be judged, for example, by taking into account the levels for indoor and outdoor workplaces indicated in standards EN 12164, parts 1 and 2.<sup>105</sup>

The first paragraph of section 1.1.4 requires the manufacturer to provide lighting integral to the machinery when normal ambient lighting is likely to be inadequate to ensure the safe operation of the machinery. Such lighting may be necessary, for example, at work stations that are likely to be in the shade or in enclosed or covered workstations or cabs. Such lighting may also be necessary where the visual tasks of operators require a higher level of luminance than is likely to be provided by the ambient lighting. The third paragraph of section 1.1.4 adds the requirement for integral lighting for internal parts to which access is frequently required for inspection, adjustment and maintenance purposes.

The second paragraph of section 1.1.4 concerns the design of the integral lighting, to ensure that it does not generate other hazards.

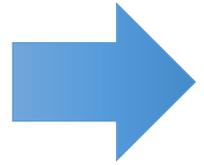
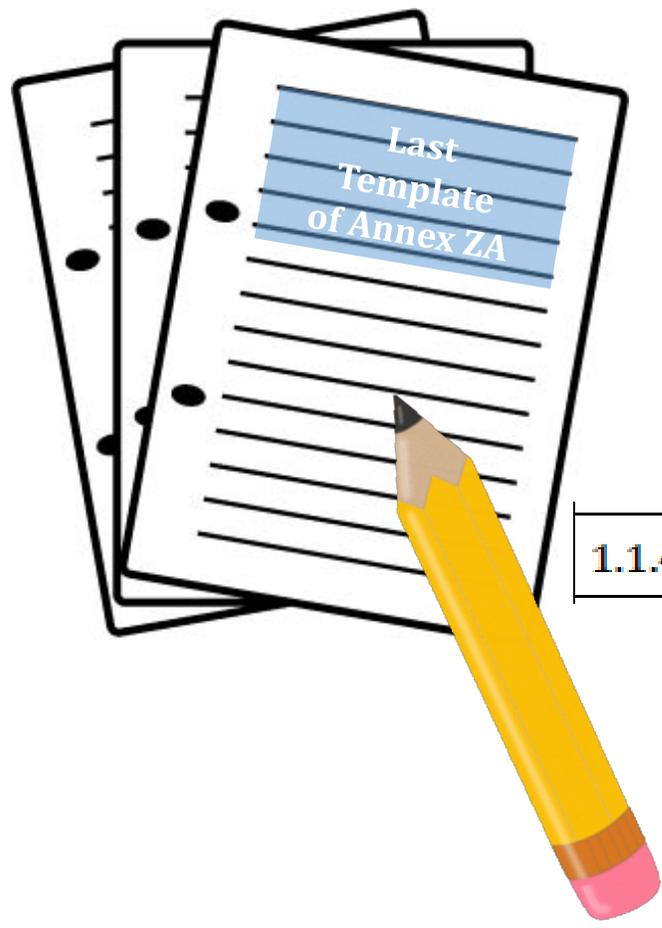
Technical conditions for integral lighting are given in standard EN 1837.<sup>106</sup>

# Use case : EHSR 1.1.4 : not covered



Having considered the explanations given to this EHSR, and hearing no solution for immediate inclusion in the draft (no consensus or no technical measure for the machines within the scope), experts concluded that **this EHSR is NOT COVERED**

# Use case : EHSR 1.1.4 : not covered



Row EHSR 1.1.4 is added

|                 |  |             |
|-----------------|--|-------------|
| 1.1.4. Lighting |  | Not covered |
|-----------------|--|-------------|



# Use case : EHSR 1.1.5 : covered



## **1.1.5 Design of machinery to facilitate its handling**

*Machinery, or each component part thereof, must:*

- *be capable of being handled and transported safely,*
- *be packaged or designed so that it can be stored safely and without damage.*

*During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.*

*Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:*

- *either be fitted with attachments for lifting gear, or*
- *be designed so that it can be fitted with such attachments, or*
- *be shaped in such a way that standard lifting gear can easily be attached.*

*Where machinery or one of its component parts is to be moved by hand, it must:*

- *either be easily moveable, or*
- *be equipped for picking up and moving safely.*

*Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.*

## **§180 Handling of machinery and parts of machinery**

The requirements set out in section 1.1.5 are to be applied in the light of an analysis of the different phases of the lifetime of the machinery concerned – see §173: comments on section 1.1.2 (a).

Section 1.1.5 applies to 'machinery or each component part thereof'. This does not mean that all parts of machinery must be designed for safe handling, but only those parts of the machinery, or the machinery itself, which may have to be handled separately.

Portable hand-held and/or hand guided machinery is subject to specific requirements – see §278: comments on section 2.2.1.

# Use case : EHSR 1.1.5 covered



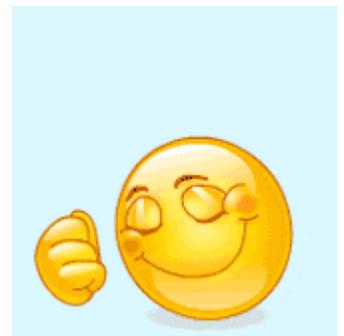
1.2.6 Stability in use and storage  
The machinery shall be designed to be taken into account during the design, in particular by limiting the equipping them with gripping means.

Functional test shall be carried out in a

Machinery fitted with wheels for manual displacement shall be designed in such a way as to prevent overturning.

Functional test shall be carried out in accordance with F3.

ISO 4254-1:2016, 6.2.1.1 and 6.2.1.3.



# Use case : EHSR 1.1.5 covered



|   |              |  |
|---|--------------|--|
| 1.1.5. Design of machinery to facilitate its handling | 4.2.5, 4.2.6 |  |
|---|--------------|--|

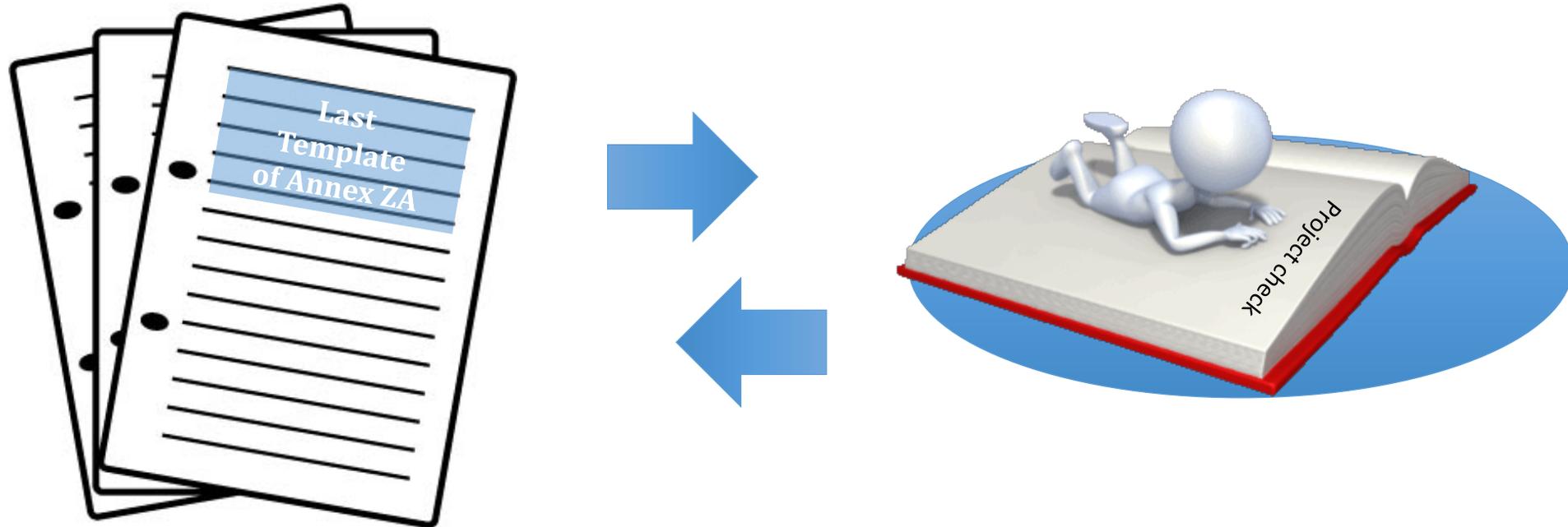
# Check each of the EHSR up to 6.5

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 i 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⌘  |               |

# Check each of the EHSR up to 6.5



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

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

# WARNING

**Update Annex Z at each stage AND be sure that in Annex Z :**

- the project clauses and subclauses numbering is up to date;
- the modifications introduced in the project are reflected





**CENELEC**

Let's try a simple quiz...  
*Respond to the questions...  
and see how smart you are!*

# Quiz: Question 1

What do you think, is there any template to fulfill?



# Quiz: Answers to Question 1

## ► Is there any template to fulfill?

1: Yes : it is only available to TC secretaries



2: No template exists : I draft my own annex Z



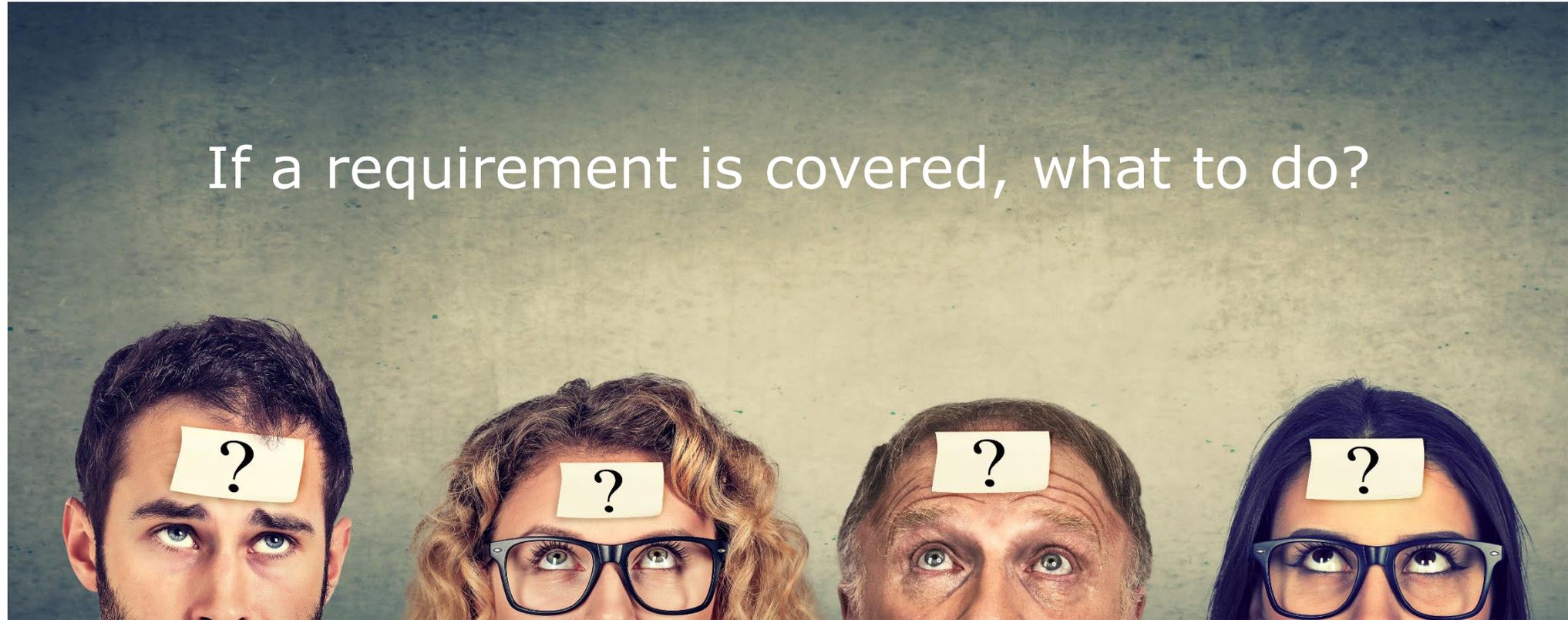
3: Yes : on CEN BOSS and CENELEC Boss



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<https://boss.cenelec.eu/reference-material/FormsTemplates/Pages/>

# Quiz: Question 2



# Quiz: Answers to Question 2

## ► If a requirement is covered, what to do?

1: I add as many rows as there are numbers of sub clauses in the standard



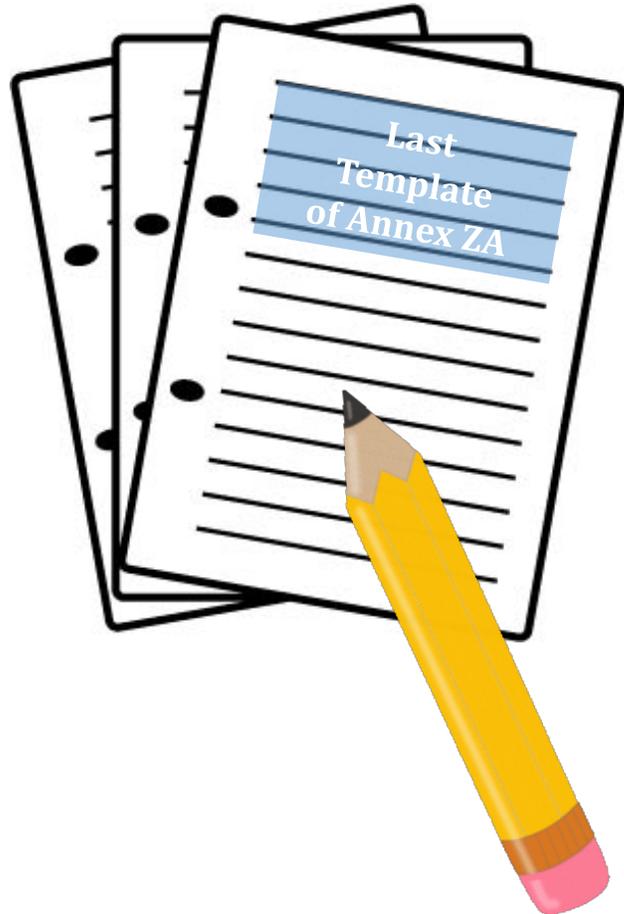
2: I do not add it because the content of the project is sufficient



3: I add the corresponding row in table of Annex Z



# Use case : EHSR 1.1.5 covered

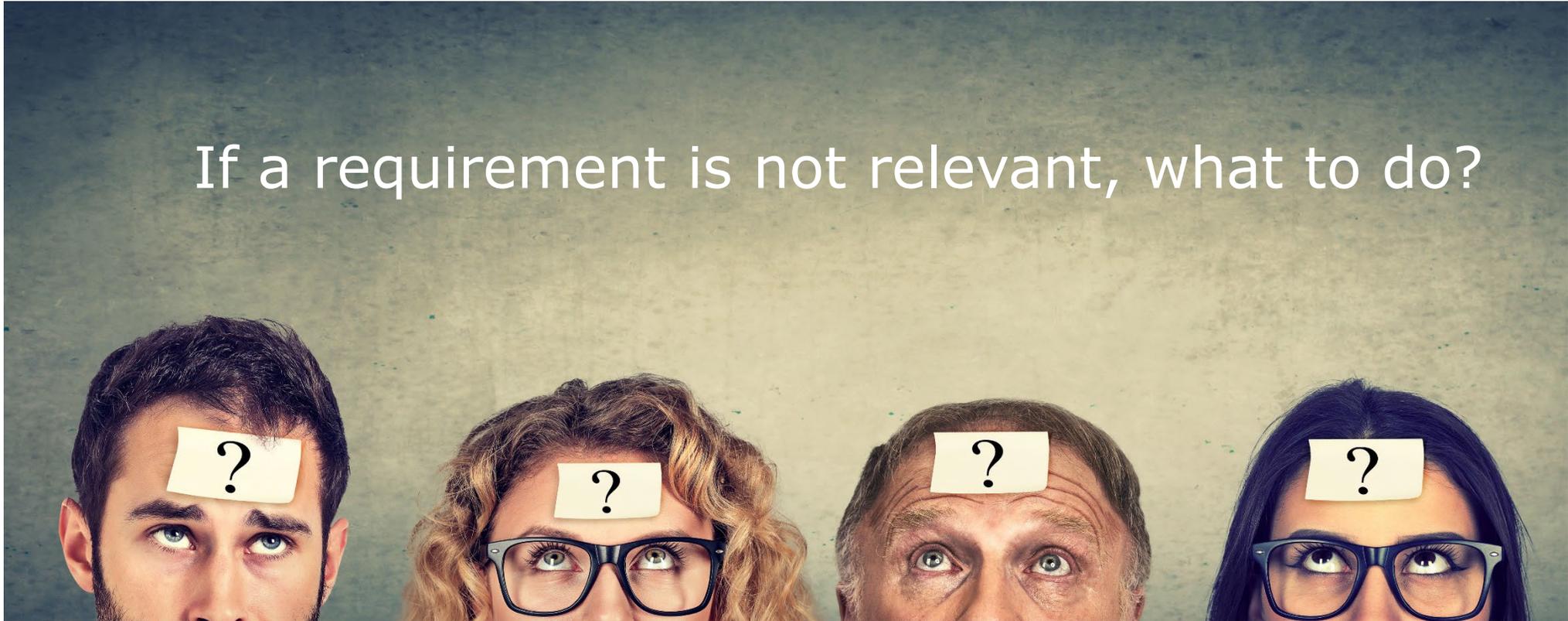


**Table ZA.1 — Correspondence between this European Standard and Annex 1 of Directive 2006/42/EC**

| The relevant Essential Requirements of Directive 2006/42/EC | Clause(s)/sub-clause(s) of this EN | Remarks/Notes |
|---|------------------------------------|---------------|
| 1.1.2. Principles of safety integration:                    |                                    |               |
| (a)   | 4, 5, 6                            |               |
| (c)   | 4, 5, 6                            |               |
| (d)   | 4, 5, 6                            |               |
| (e)   | 4, 5, 6                            |               |
| 1.1.3. Materials and products                               | 4.2.6.2.1                          |               |
| 1.1.5. Design of machinery to facilitate its handling       | 4.2.5, 4.2.6                       |               |

# Quiz: Question 3

If a requirement is not relevant, what to do?



## ► If a requirement is not relevant, what to do?

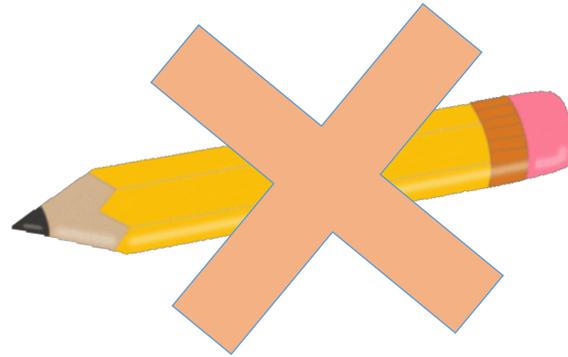
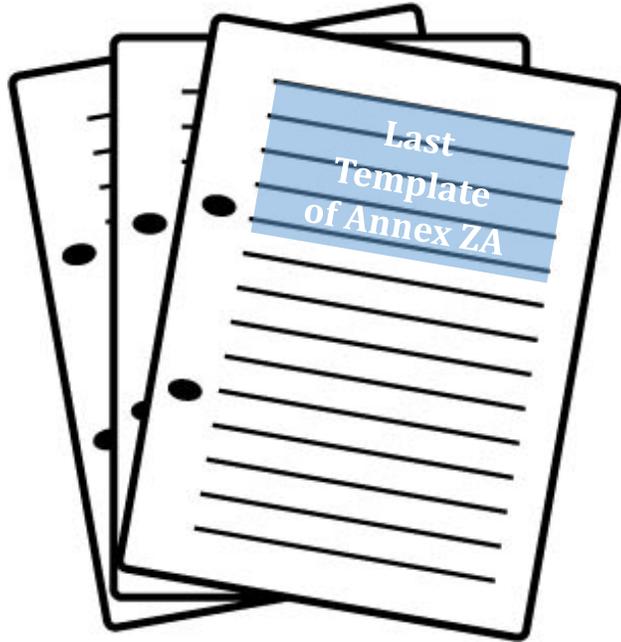
1: I add a row in the table and I write "not relevant" in the third column



2: I do not do anything in annex Z

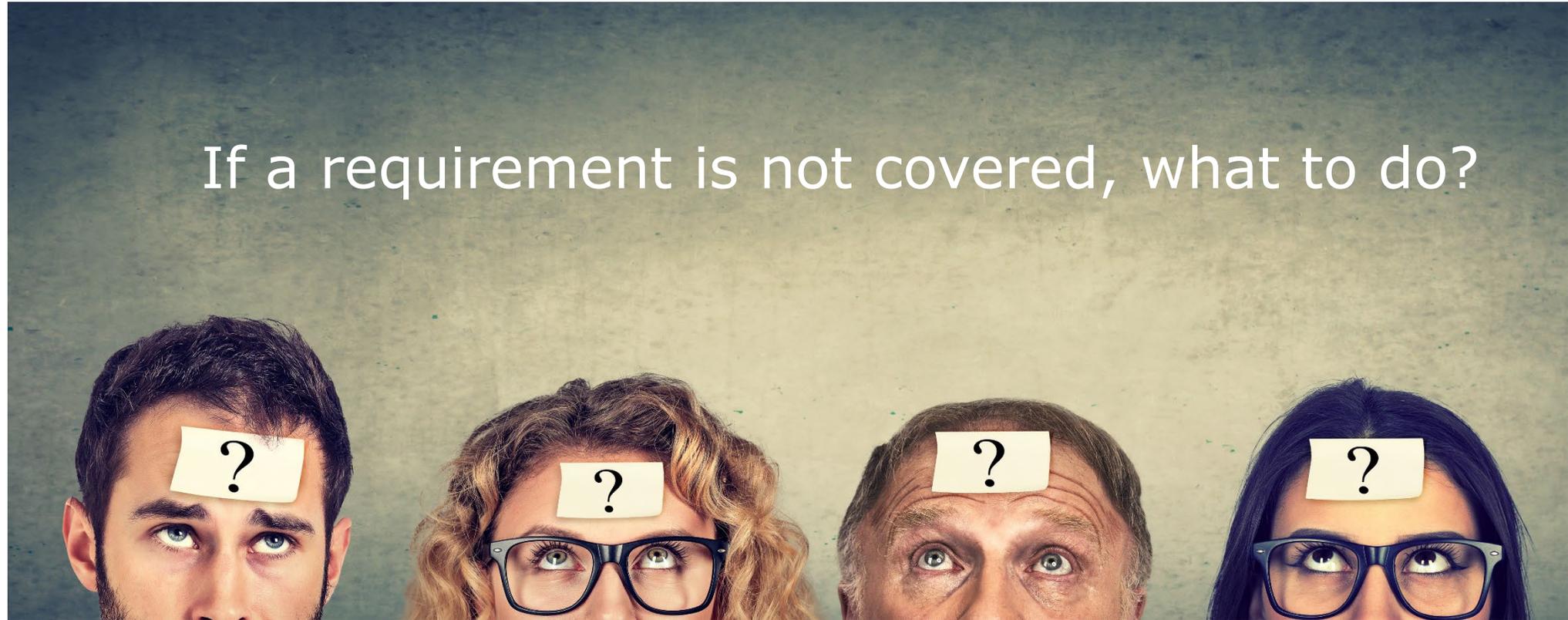


# Use case ESR 1.1.3 : not relevant



**Row ESR 1.1.3 is not added**

# Quiz: Question 4



## ► If a requirement is not covered, what to do?

1: I try to implement the corresponding requirements in the project in order to cover this requirement



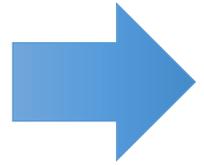
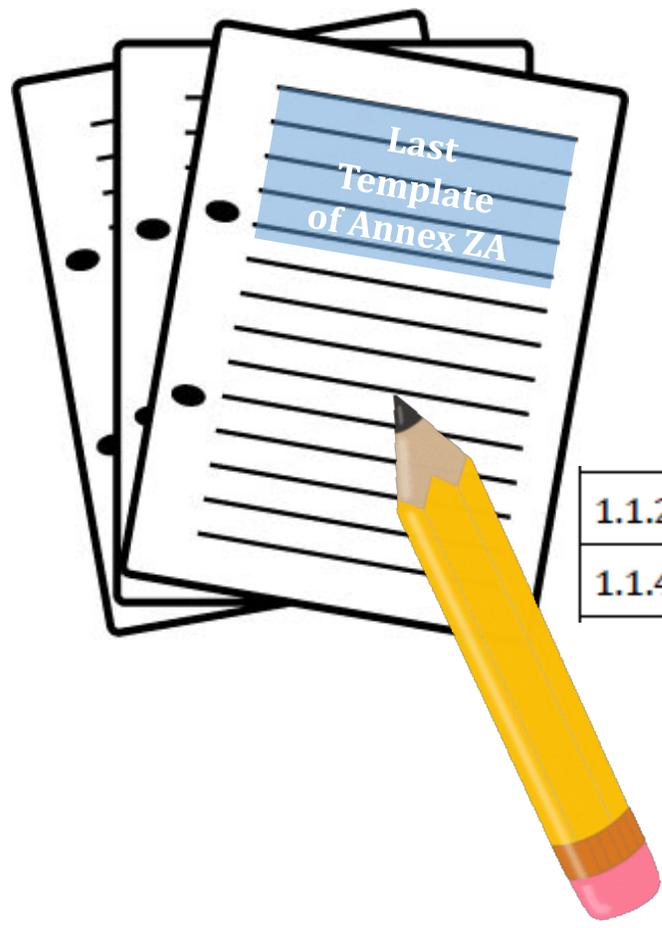
2: I do not do anything in annex Z



3: I add a row in the table and I write "not covered" in the third column



# Use case : EHSR 1.1.4 : not covered



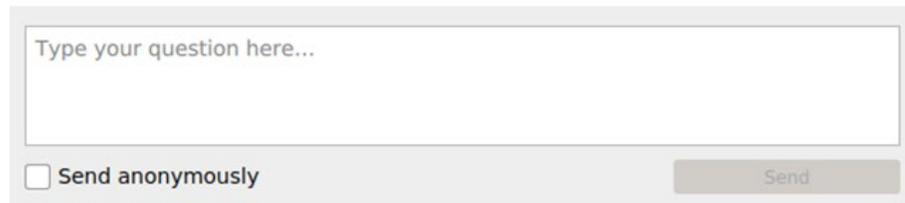
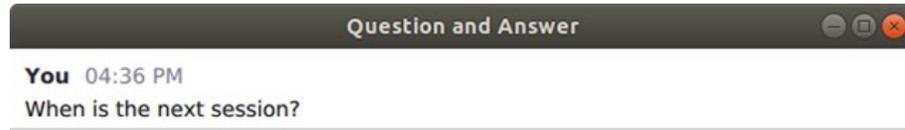
Row ESR 1.1.4 is added

|   |     |             |
|---|-----|-------------|
| 1.1.2. Principles of safety integration | 4.1 |             |
| 1.1.4. Lighting                         |     | Not covered |



# Question time

▶ Use the Q&A panel to submit your questions



Type your question here...

Send anonymously

Send



European Standardization Organizations

# Closing remarks

Frank Wohnsland (CEN-CENELEC Sector Rapporteur on Machinery)





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# Thank you for your participation!

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