TECHNICAL SHEETS FOR COORDINATION

HORIZONTAL RECOMMENDATION FOR USE SHEETS (RfUs)
Status in November 2024

Number CNB/M/ (1)	Revision (Rev)	Key words	Approved by Horizontal Committee of NBs(2) on:	Approved by Vertical Group of NBs(2) on:	Endorsed by Machinery Expert Group/MWG on:
00.001	41	Key addresses	18/12/2023	-	-
00.100	03	Recommendation for Use sheets (RfUs) - Content - Addressees	26/06/2013	-	22/11/2013
00.213	04	EC type-examination, safety relevant aspects, omission of tests	26/11/2009	-	09/04/2001
00.220	03	Guards	13/12/2011	-	23/04/2012
00.230	04	Low voltage, tests, report, declaration, electrical components	15/06/2010	-	30/12/2010
00.240	03	Internal arrangements, series production, quality assurance (generalization of CNB/M/03.003)	26/11/2009	-	08/06/1998
00.250	07	Notified bodies, operational procedures, duties, certificates	29/06/2016	-	31/01/2018
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00.252	03	EC type-examination, series manufacture, internal checks	14/12/2010	26/10/2010	23/05/2011
00.254	04	EC type-examination certificate, validity, renewal by original NB	18/06/2014	-	08/01/2015
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00.510	02	Remote assessment activities	31/05/2023	-	12/04/2024
00.511	02	Refusal to issue certificate, Withdrawal of a certificate, suspension of a certificate, Restriction of a certificate	18/12/2023	-	17/10/2024

(1): CNB/M/xx.xxx RERev yy = Coordination of Notified Bodies/Machinery/Numbering of the RfUs
R: Recommendation for Use E: English version Rev: Revision yy: index of the Revision
(2): NBs = Notified Bodies

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.001 Revision: 41 Language: EN

Number of pages: 4	Date: 20.02.2024	To be approved by: ☑ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☐ Machinery Expert Group	Approved on: 12.12.2016 18.12.2023 Endorsed on: -
Origin: Technical Secretariat			

Question related to: -	Article: -	EN/prEN: -	Other: -
Annex: -	EHSR (1): -	Normative clause: -	Other clause: -
		CEN TC concerned: -	

Key words: Key addresses

Question:

What are the key addresses of the European Co-ordination of the notified bodies for Machinery Directive?

Solution:

The key addresses of the coordination are given in the following pages.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

EUROPEAN CO-ORDINATION FOR MACHINERY AND SAFETY COMPONENTS
CHAIRMAN, VICE-CHAIRMAN, SECRETARIATS AND CONVENORS OF THE CO-ORDINATION GROUP FOR NOTIFIED BODIES

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EUROPEAN CO-ORDINATION FOR MACHINERY AND SAFETY COMPONENTS
CHAIRMAN, VICE-CHAIRMAN, SECRETARIATS AND CONVENORS OF THE CO-ORDINATION GROUP FOR NOTIFIED BODIES

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7	Removable transmission cardan shafts				
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10	This VG does not exist anymore				

EUROPEAN CO-ORDINATION FOR MACHINERY AND SAFETY COMPONENTS
CHAIRMAN, VICE-CHAIRMAN, SECRETARIATS AND CONVENORS OF THE CO-ORDINATION GROUP FOR NOTIFIED BODIES

V.G.or H.C N°	Title of the group	Convenor	Secretary	Organisation	Address
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14	Portable cartridge-operated fixing andimpact machinery				

EUROPEAN CO-ORDINATION FOR MACHINERY AND SAFETY COMPONENTS
OBSERVERS

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	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.100 Revision 03 Language: E

Date of first stage: 22/04/2013	To be approved by:	Approved on:
Origin: Horizontal Committee	☑ Vertical Group..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group....	26/06/2013 Endorsed on: 22/11/2013

Question related to: Directive 2006/42/EC	Article:	EN/prEN:	Other:
Annex:	ESR (1):	Clause:	Other clause:
		CEN TC concerned:	

Key words: Recommendation for Use sheets (RfUs) – Content - Addressees

Question:

What are the acceptable purposes/contents of the RfUs and who are the addressees of the RfUs?

Solution:

1) Before bringing a Recommendation for Use sheet to the attention of the Horizontal Committee and after to the Machinery Working Group of the European Commission, the writers of the RfUs must apply the following tests:

1.1) Does the Recommendation for Use sheet add value, i.e. does it provide additional information that is not available in the directive or the relevant harmonised standard?

The added values can be for example as follows:

a) to support the interpretation of requirement(s) of standards and provide a solution;
b) to provide a solution that supersedes a too generic requirement of a standard by providing an alternative solution for a specific application;
c) to provide an additional solution besides those from the standard to meet the goal(s) of the MD in an alternative way.

If the RfUs do not add value, the issues raised by the document should be included in the minutes of the meeting of the relevant Vertical Group but not presented as Recommendation for Use sheet.

1.2) Is the Recommendation for Use sheet of a horizontal nature, i.e. applicable to more than one Vertical Group? Such questions should be agreed and documented at Vertical Group level and passed to the chairman of the Horizontal Committee and the Technical Secretariat for agreement and submission as a horizontal document.

1.3) Are the wordings of the Recommendation for Use sheet clear and so that readers who have not attended the Vertical Group or Horizontal Committee meetings can easily understand the question and answer?

1.4) Are the RfUs consistent with the actual safety level to be applied (e.g. wording of directive, standard, decision of the Machinery Working Group, publication of the European Commission, etc)? It is not permissible to specify a level of safety below that described in the above documents. Where realization of an adequate safety level can be achieved by a solution not described in a harmonized standard, evidence shall be provided in a transparent and comprehensible way that the Vertical Group solution meets the requirements and is therefore acceptable. Such evidence should be sufficient to support the solution in the event of challenge from a Member State.

(1) Essential safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

1.5) If the level of safety specified in the applicable standard appears to be too low, or if an aspect of a standard that is doubtlessly wrong or seems to not fully meet the goal of the MD, the relevant interested parties (CEN/CENELEC TC, European Commission) shall be informed immediately.
Before decision is taken, the Vertical Group shall discuss the matter in order to reach a common agreement on how to proceed with the assessment of the conformity.
However, if the questions require an urgent solution the notified body who detected the possible deficiency(ies) or mistake(s) can start within the VG members a quick enquiry in order to collect answers within a reasonable period of time (less than 3 months).
If the question(s) are deemed to be of general interest, the Horizontal Committee shall also be informed.
The Member States and the European Commission are automatically informed through the minutes of the meetings of the Horizontal Committee.

2) The RfUs, “endorsed” by the Machinery Working Group shall be sent firstly by the Technical Secretariat (TS) to the NBs who are responsible for their implementation. The TS shall send the “endorsed” RfUs to the CEN/CENELEC TCs and to the European Commission in order to be uploaded in EUROPA Website.
The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that he said machinery meets the corresponding state of the art (Annex IX point 9.2). State of the art is described in the harmonised standards; RfUs provide explanations and rules for implementing the clauses of the harmonised standards.

3) The fact of a standard being transferred to the ISO does not change either its status or the status of RfUs.

4) If a manufacturer applies a technical solution described in a Recommendation for Use (RfU) which deviates from the technical solution described in a harmonised C-standard, he must submit an example of the machinery either for the EC type-examination referred to in Annex IX or for the Full quality assurance referred to in Annex X because the machinery would not totally comply with the harmonised C-standard.

	CO-ORDINATION OF NOTIFIED BODIES **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.213 Revision 04 Language: E

Date of first stage: 16/07/1998	To be approved by:	Approved on:
Origin: Horizontal Committee - Generalization of CNB/M/11.018	☑ Vertical Group ..... ☑ Horizontal Committee.....	26/11/2009
	To be endorsed by: ☑ Machinery Working Group.....	Endorsed on: 09/04/2001

Question related to: Dir. 2006/42/EC	Article:	EN/prEN: EN ISO 13849-1:2008	Other:
Annex:	EHSR (1):	Normative clause:	Other clause:
		CEN TC concerned:	

Key words: EC type-examination, safety relevant aspects, omission of tests

Question: Within the framework of an EC type-examination account should be taken of all safety-relevant aspects (category, electrical insulation, environmental factors as vibration, EMC etc.). In which well-founded cases exceptions from this rule are admissible?

Solution:

In general a test can be omitted if a negative influence of performance and safety is not expected. Some examples may demonstrate how omissions can be justified:

1. For indoor applications tests with limited temperature ranges (o to 50°C) are admissible.

2. If the type tested is used in an indoor application and foreseen to be mounted in an enclosure of P-rate IP 54 the IP-rate test can be omitted.

3. In the case that safety-related controls consist only of electromechanical components EMC testing for immunity can be omitted.

4. If the type tested is foreseen to be used with an external converting equipment with fulfils the power supply voltage interruption requirements the supply voltage can be omitted.

All restrictions in the field of applications shall be mentioned in the EC type-examination certificate. However tests of safety relevant aspects cannot be omitted within framework of an EC type-examination, if cannot be ensured that all given requirements are fulfilled.

Adaptation procedure: FORMAL ADAPTATION IN CONFORMITY WITH DIRECTIVE 2006/42/EC

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.220 Revision 03 Language: E

Date of first stage: 17/05/2011	To be approved by:	Approved on:
Origin: Generalisation of CNB/M/01.005/R/E Rev 03 from VG1 Woodworking machinery	☑ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group....	13/12/2011 Endorsed on: 23/04/2012

Question related to: Directive 2006/42/EC Annex: I	Article: ESR (1): 1.3.7 and 1.4	EN/prEN: Clause: CEN TC concerned:	Other: Other clause:

Key words: Guards

Question:

Asuming a machine meets all essential safety requirements of the directive. The manufacturer of this machine adds for any reason an additional guard. Shall this additional guard meet all the requirements of the directive as defined for guards in clause 1.4?

Solution:

Yes.
Any part of a machine regarded as a safety guard shall meet all the requirements of the directive as defined for guards in clause 1.4.

E.g.:
A manufacturer fits a fixed guard, which prevents access to a hazard area, with an interlocking not required by the directive or the relevant standards. The interlocking might be understood as a safe shut off of all hazard movements of machine parts behind the fixed guard and the user may omit turning the power switch. Both the fixed guard and the interlocking shall comply with the relevant requirements in annex I of the machinery directive.

(1) Essential safety requirement
Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.230 Revision 04 Language: E

Date of first stage: 06/06/1997	To be approved by:	Approved on:
Origin: Horizontal Committee - generalization of CNB/M/11.022	☐ Vertical Group..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group..	15/06/2010 Endorsed on: 30/12/2010

Question related to: Dir. 2006/42/EC	Article:	EN/prEN:	Other:
Annex: I	EHSR (1): 1.5.1	Clause:	Other clause:
		CEN TC concerned:	

Key words: Low voltage, tests, report, declaration, electrical components

Question:

To what extent can a notified body accept certificates for electromechanical components of machinery?

Solution :

The intention is to create a document that may be used by all Notified Bodies to determine the acceptability of electrical components.

EXAMPLES

I. The list of components given in the columns is non exhaustive and only meant as indication.

2. In all cases, the actual use of the component has to be considered and it has to be decided if it is used as a functional or as a safety component.

3. It should be checked whether the declaration and/or certificate of conformity with a specific directive (EMC, Low voltage) or a standard allow to cover the specific requirements of the machinery directive for the component concerned.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

AVAILABLE COMPONENT INFORMATION	COMPONENT IS USED AS:		
	FUNCTIONAL COMPONENT	SAFETY RELATED COMPONENT	SAFETY COMPONENT (not covered by Annex IV)
	Failure of the component does not decrease the safety level	Failure of the component causes a limited decrease of safety	Failure leads to unacceptable decrease of safety
Manufacturer's specifications No conformity mark and no reference to compliance with standards	Y	N	N
Manufacturer's specifications with reference to a standard No conformity mark No declaration of Conformity	Y	Y(1)	N
Manufacturer's specifications +Declaration of Conformity	Y	Y	Y
Voluntary conformity marks	Y	Y	Y(2)
	EXAMPLES Plugs and sockets(3) Cables Push-buttons Pilot lights Switches/contactors/timers El. Magnetic valves Temp. controls Motor start capacitor	See below (A)	See below (B)

In all cases it is assumed that components operate within their specified limits
Y= The notified body may accept the component with the information certificate provided
N= The notified body shall not accept the component as such other types of certificate or additional testing are needed

(1) if manufacturer states in writing that he has followed the standard
(2) only if test report shows that the safety functions have been checked as well
(3) strictly speaking plugs and sockets outlets for domestic use are not under the low voltage directive.

(A): EXAMPLES Transformers. Temp. limiters. Position Switches without positive opening operation. Motor protectors. Overload protectors. Main power switches. Power supply units. Fuses
(B): EXAMPLES: see Machinery Directive Annex V (Note: some of the safety components listed in Annex V are also listed in Annex IV)

	CO-ORDINATION OF NOTIFIED BODIES **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.240 Revision 03 Language: E

Date of first stage: 30/09/1996	To be approved by:	Approved on:
Origin: Horizontal Committee - generalization of CNB/M/03.003	☐ Vertical Group..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group..	26/11/2009 Endorsed on: 08/06/1998

Question related to: Dir. 2006/42/EC	Article:	EN/prEN:	Other:
Annex: IX-Point 2 et Annex VII-A 1, b)	EHSR (1):	Clause:	Other clause:
		CEN TC concerned:	

Key words: Internal arrangements, series production, quality assurance

Question:

In the EC type-examination requested dossier what shall "the internal arrangements for maintaining the conformity of machines and safety components manufactured in series" contain? What are the acceptance criteria for the Notified Body?

Solution:

Annex IX point 2. and Annex VII-A 1. b) require that the technical dossier contains the internal arrangements established to ensure that the conformity of machines and safety components manufactured in series meet the requirements of the Directive.

The notified body cannot require the manufacturer to present a quality manual conforming to the series EN ISO 9-000 standards (preferably 9001). If the firm has set up such a system it is enough to have a copy of the certificate. Otherwise, the notified body will satisfied with a commitment from the manufacturer to ensure the homogeneity of manufacturing together with a concise description of the means of control. The controlling may rest on :

- foreign bought parts, components,
- during production,
- final check before delivering the machines/safety components.
- check list for the final check
- external compliance

Adaptation procedure: FORMAL ADAPTATION IN CONFORMITY WITH DIRECTIVE 2006/42/EC

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.250 Revision 07 Language: E

Date of first stage: 02/12/1999	To be approved by:	Approved on:
Origin: Horizontal Committee	☐ Vertical Group ☑ Horizontal Committee..... To be endorsed by: ☑ Machinery Working Group....	29/06/2016 Endorsed on: 31/01/2018
Question related to: Directive 2006/42/EC Annex: XI ESR (1):	EN/prEN: Clause: CEN TC concerned:	Other:
Key words: notified bodies, operational procedures, duties, certificates:		

Question: What are the operational procedures and duties of a notified body once it has been requested to issue an EC type-examination certificate

This revision 07 is a textual modification of the previous version as a result of remarks at the HC-meeing #45 during 28-29 June 2016 in Warsaw. The modification is in par. 2.3 shown by tracked changes.

Solution:

The rights and duties of a notified body are defined firstly by the Directive itself. Some useful indications can be found in guides published by the European Commission, and specially the "Guide to application of the machinery directive – 2006/42/EC" Reference to these guides is sometimes made in this "Recommendation for Use". The main purpose of this document is to highlight some aspects which are specific to the activities of a notified body acting within the framework of the Machinery Directive.

(1) Essential safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use

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3.2. Components and safety components manufactured by specialised firms and included by the machinery manufacturer in his product

3.3. Parameters considered to be less critical

4. EC Type-examination certificate

5. Organisational procedures

5.1. How can it be assured that the manufacturer has not presented the same file to two or even several notified bodies? How can it be assured that the manufacturer does not re-submit a file having been the subject of a previous EC type-examination certificate refusal decision?

5.2. How to harmonise the practical interpretation of the Directive when the product does not comply with an harmonised standard

5.3. What action should be taken if deficiencies and/or mistakes in standards are detected ?

5.4. For how long must the EC type-examination files be stored by the notified body?

1. BASIC PRINCIPLES

As a starting point, it is felt important to confirm some principles

- It is not possible to carry-out an EC type examination for machinery not listed in annex IV. However, a notified body can carry out a voluntary examination for a machinery not listed in annex IV on request of an applicant or a manufacturer. In this case, the notified body shall not mention its European identification number on the voluntary examination-certificate[1]
- A body does not need to be notified for all machinery/safety components covered by Annex IV[2]. The notified body must know which harmonised standards apply to the machine examined and must know how to apply them. If the solutions proposed by the manufacturer differ from the requirements of the standards, the notified body shall make sure that the safety level of these solutions is not lower than the level recommended by the harmonised standards.
- The task of a notified body in the field of Machinery is restricted to an examination of conformity with the Machinery Directive.

  The notified body, as per Article 14 of Directive 2006/42/EC, which is responsible for carrying out the EC type-examination procedure defined in Article 12 (3) (b) and Article 12 (4) (a) for a machine specified in Annex IV, is only required to carry out the operations defined in the above mentioned Article and in Annex IX.

  In particular, where a machine or one of its components is subject to Community Directives other than the Directive 2006/42/EC, there is no requirement to check whether these other Directives are being respected. In which case, the notified body must draw the attention of the contractor to his obligation to complete his technical file (also termed technical documentation or technical construction file) with reference to other Directives applicable to the machine.

  In effect, the manufacturer must ensure that these other Directives are being respected, and pursuant to Article 5 (4), the CE marking affixed by him or his authorised representative (article 5 (1) (f)) in accordance with article 16 means that the machine also conforms to the provisions of those Directives[3].

  If other Directives (low voltage, EMC, etc.) apply to the machine or to some of its components, that is the manufacturer's problem (See also CNB/M/11.025/R/E). In other words, supplying an EC type-examination certificate does not necessarily mean that the machinery may carry the CE marking as it may not conform with the EMC Directive. However, the notified body should draw the attention of the manufacturer to the existence of other Directives which apply to his product.

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[1] This is the text of CNB/M/00.105/R/E Rev 01 now replaced by this Recommendation for Use

[2] European Commission - Responses given by the services of the Commission after consultation of the committee set up by the Directive,
to some questions relating to the implementation of the Directive - question 6 - June 97

[3] Useful information on the directives that may apply in a complementary way to machinery can be found in § 89 of the "Guide to the application of the machinery directive 2006/42/EC"

Secondly, here are a few guidelines with regard to the essential requirements that the notified body must actually verify. This will be defined in more detail under paragraph 2.3.

- The notified body must carry out a thorough examination of the risk assessment performed and documented by the manufacturer.
- In certain cases the notified body takes into account data provided by the manufacturer (test reports, certificates, etc.). This will be discussed with more details in paragraph 2.2. hereafter.
- The notified body does not normally have to deal with certain criteria such as, for instance testing vibrations in the case of motor vehicle lifts.

2. TYPICAL CONTENT OF AN EC TYPE-EXAMINATION

Based on the general information defined above and the field information provided by several Vertical Groups, a list defining the "typical" content of an EC type-examination has been established for "simple" machines (without sophisticated electronic steering.....). The aim is to consolidate the practical consequences of the general principles as implemented today. Of course, every type of machine is specific. Some of the examinations are critical for certain machines and not relevant to others. For instance, the calculation of stability is not critical for a heavy press and can be very important for a lifting platform.

This list sets out the points that need to be taken into consideration in view of the specific nature of each type of machine. As we point out when presenting the list of documents to be supplied by the manufacturer, these points are sorted in logical rather than chronological order.

2.1. General

- Contract (mutual obligations).Although a contract is not explicitly foreseen in the directive, this might be a good way to confirm mutual understanding of regulatory duties for both parties, for instance the duty of the applicant to inform the notified body which retains the technical file of all modifications of the approved type. (Annex IX paragrap 6).
- Acceptability of the request and completeness of the technical file as provided by the applicant (manufacturer, authorised representative.....)
  One of the issues is related to the obligation for the manufacturer to include in its application a written declaration that the application has not been submitted to another notified body (Annex IX second paragraph, second bullet point).
  It has to be clear that the intention of this requirement is not to restrict the manufacturer from obtaining several quotations, but simply prevent the practice of going from one Notified Body to another until one will issue EC type approval. It is permissible for the Manufacturer to approach one or more Notified Bodies and invite them to issue a quotation for providing the necessary assessment services required by Annex IX of the Machinery Directive 2006/42/EC. The Notified Bodies that have been approached may require the manufacturer to supply relevant information to enable them to prepare the required quotation. This information may be submitted verbally or in written form as required by the Notified Body. Once the manufacturer has decided to select a single Notified Body to provide the necessary services that manufacturer shall be required to enter into an agreement (e.g. a contract) with that Notified Body. In that agreement the manufacturer declares that they have not entered into a contract with any other Notified Body to provide similar services for the same machine. The selected Notified Body will then request (if not already provided) the remaining information specified within clause 2 of Annex IX (sse also 5.1. in this RfU)
- Verification by the body that the machine has been built to in conformity with the applicable essential requirements of the Directive and/or the applicable harmonised standards when the manufacturer has made reference to them.

2.2. Documents to be supplied by the manufacturer (and to be verified by the notified body)

In current practice it is important to point out that the technical file as described in Annex VII of the Directive has not always been completed when the manufacturer requests an EC type-examination. In many cases the technical file is modified during the course of the type examination itself: it is the notified body that requests the additional information and/or the necessary corrections in order to be able to issue a certificate of conformity for the machine.

In the final stage the technical file must contain a set of information that must be properly identified. It must be possible to link the plans, drawings, certificates, etc unequivocally to the machine or family of machines that is the subject of the EC type approval certificate.

- Drawings, stress/stability calculations (limited to critical components)
- Sufficient documents for validation of electric, hydraulic and pneumatic circuits. The documents can be circuit diagrams (including interfaces/connections), functional description of the circuit diagrams, component lists…..
- Manufacturer's declarations and/or certificates[4] related to other Directives applicable to some safety/safety related components (EMC, Low Voltage, Pressure....).
    - See Section 3.1. hereafter for the acceptability of certificates.
    - The notified body should draw the attention of the manufacturer to the existence of other Directives which apply to his product.
- Other certificates, test reports (noise, safety components.....). They may be included in the technical file. The acceptability of certificates/test reports is made under the responsibility of the notified body[5] using a ranking of criteria defined as follows
    - Notification (a report established by a notified/competent body acting in the field of its notification/designation may not be rejected).
    - Accreditation (pay attention to the scope of accreditation)
    - Reputation (may be given consideration)
    - For parameters considered to be less critical, a test report of the manufacturer himself (for example on noise emission) can be taken into account by the notified body (see section 3.3. hereafter)
- Manufacturing procedures (when critical for safety aspects), internal measures for conformity of series production.
- The risk assessment carried out by the manufacturer and the safety measures applied, with indication of the residual risks.
- If all risks identified by the risk assessment of the manufacturer are described in the harmonised standard published in the Official Journal of the European Union the risk analysis may mention this as a result of this risk assessment process
- List of standards applied
- List of essential safety requirements applied (or, at least, list of the essential safety requirements which are not covered by the harmonised standards used by the manufacturer)..
- Instruction manual/safety related instructions (intended use, foreseeable misuse....)
- Declarations of incorporation for included partly completed machinery and the relevant assembly instructions, if appropriate

2.3. Language required for the documents of machinery

The files and correspondence referring to the EC type-examination procedures shall be drawn up in an official language of the Member state where the notified body is established or in a language acceptable to it.

The instructions must be drafted in one or more Official Community languages. The words “Original instructions” must appear on the language version(s) verified by the manufacturer or his authorised representative. (Machinery directive, Annex I, 1.7.4.1. (a).[6]

The notified body may require for carrying out an EC type-examination documents, including the technical file that are prepared in a language understood by the notified body. The notified body is ~~not~~ responsible to check one of the “original instructions” ~~translations of the manual instructions~~.

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[4] As applicable

[5] The notified body decides which are the critical components and which are the acceptable certificates/test reports. A general requirement is that “Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators”. (see Article 8 (10) of Regulation 765/2008/EC). It should also be clear the in so doing the notified bodies shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of the directive

[6] This is the text of CNB/M/00.207/R/E Rev 03 amended to take the new requirement of the directive into account and now replaced by this Recommendation for Use

2.4. Inspections (tests, measurements, visual checks.....as applicable)

- Correspondence between the actual machine (safety component) and the machine as described in the technical file
- Validate (by analysis and, if necessary, by testing), the safety functions and categories of the safety-related control systems, in normal operation and in the case of faults, taking into account all operating modes of the machine.
- Protective devices, safeguarding method
- Warnings
- Conformity of markings
  - Marking as requested by Machinery Directive
  - Indications or marks which are presented in the file as a factor of conformity of components to certain critical requirements of directives or European standards : electrical components (see CNB/M/00.230/R/E), mechanical components (ropes,....), hydraulic components (pipes,....)
  - Identification of the manufacturer (also for components....)
- Overload test
- Mechanical resistance
- Measurement of critical properties (e.g. dimensions, temperatures, pressure, speed)
- Stopping time between the moment the protective device (emergency stop, light curtain...) is actuated and the moment the machine stops (if necessary)
- Checking of electrical, pneumatic, hydraulic equipment

2.5. Documents to be issued by the notified body

- Test/inspection report : no standardised presentation has been provided but a full identification of all the components of the report is required in the spirit of the EN ISO 17000 and EN 45000 series. This report describes i.a. the examinations performed by the notified body, the certificates taken into account and the product examined (full identification, photo's, plans…..). The element of the file provided by the manufacturer must be identified univocally. In case of dispute in the future, the report must make it possible to define as completely as possible the machine or the safety component submitted by the manufacturer
- EC type approval certificate.

3. SUBCONTRACTING – ACCEPTABILITY OF CERTIFICATES, REPORTS AND DATA SUPPLIED BY THE MANUFACTURER

For such a wide-ranging Directive as the Machinery Directive, this is one of the most delicate points. It is important to ensure the credibility of the conformity assessment process . There are two important basic rules

- Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the relevant requirements set out in Annex XI of the directive and shall inform the notifying authority accordingly
- Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established

3.1. Electro-technical components subject to the low voltage and EMC Directives.

The conditions for subcontracting do not apply if the work concerns a product that is shown to fulfil the requirements put on it according to the applicable Directive(s). An example of such a product is an electro-technical component that is within the scope of the EMC and the Low Voltage Directives. The conformity assessment procedures foreseen for the component by the relevant Directives have to be accepted by a notified body in charge of the evaluation of a final product containing this component. This is true provided the administrative duties foreseen in the Directive for the manufacturer of the component are fulfilled (CE marking, declaration of conformity, instruction handbook etc…)

It is mandatory to follow the conformity assessment procedures set out in these two Directives. There is therefore a trend towards acceptance of the manufacturers data. For components with a significant bearing on the safety of the machinery, the body will also obtain a declaration from the manufacturer or a voluntary conformity mark.

The guide concerning the Low Voltage Directive states that the notified body in the field of machinery will take into account the results of the conformity assessment procedures of the "Low Voltage" Directive which apply for the intrinsic electrical safety aspects of the electrical component of the machinery (conformity with point 1.5.1. of Annex I of the Machinery Directive).[7] It is also stated that direct examination by the notified body will apply, i.a. to all risks arising from the way in which the electrical components are incorporated into a machinery and ensure their proper functioning.

The notified body remains fully responsible for the appropriateness of components and certificates. If the manufacturer defectively assembles components for which the required characteristics have not been documented/certified as far as the safe operation of the machinery is concerned, this gives rise to a fundamentally unacceptable situation whether or not the components carry the CE marking.

In terms of practice, two basic questions have been answered by the European Coordination of Notified Bodies. Both of the answers have been accepted by the Machinery Committee.

3.2. Components and safety components manufactured by specialised firms and included by the machinery manufacturer in his product.

Certain manufacturers are specialised in the manufacture of components and safety components of machinery. Such components are found in several types of different machinery produced by manufacturers throughout the world. Consequently, the machines will be submitted to various notified bodies. Although such components may have a significant bearing on the safety of machinery, it would seem exaggerated to carry out all of the tests required to demonstrate the reliability of the component all over again. Despite the fact that it is aimed specifically at presses, Recommendation for Use CNB/M/03.013/R/E gives some guidelines which can be applied to all types of machinery. Notified bodies may take into account certificates drawn up by other notified bodies for the same machines and/or by a laboratory/body which is accredited in a specific domain.

3.3. Parameters considered to be "less critical"

For parameters considered to be "less critical", the task of notified bodies is essentially to verify the credibility of the data provided by the manufacturer

EC type-examination for all machines entering into the field of application of Annex IV must include verification of all the essential requirements stated in Annex I and applicable to the machine. This includes the requirements which are recognised as not constituting the basis of this examination :

- either by checking that the requirements directly applied by the manufacturer are adhered to
- or by checking that the harmonised standards have been used correctly, as regards the essential requirements covered by the standards, when the manufacturer has made reference to them

Taking noise as an example, the essential requirement aimed at in point f of section 1.7.4 of Annex I : the notified body must, in general, abide by the declaration of the manufacturer as stated in the instruction manual and should not:

- carry out the measurement again
- or require a certificate by a third party if the measurements and the equipment used comply with the relevant standards

At the meeting of 4 July 1993, the 89/392 Committee (currently 2006/42 Committee) stated that the role of the notified body should be limited to

- verifying that all measures have indeed been taken to ensure that noise has been reduced to the lowest possible level by isolating the transmission components for instance (Essential health and safety requirement 1.5.8.)
- verifying that the manufacturer has indeed indicated in the instruction manual both the noise level and the methods used to reach the result shown

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[7] European Commission - Guidelines on the application of Council Directive 2006/95/EC Electrical equipment designed for use within
certain voltage limits) – Comment 30 – August 2007

asking for explanations from the manufacturer where the emission level is badly indicated or where the stated emission level is clearly at odds with reality. In this case, the notified body should carry out further measurements and, afterwards, refuse the EC type-examination if the lack of compliance is confirmed. Systematic verification of the emission level is, however, not envisaged.

4. EC TYPE-EXAMINATION CERTIFICATE

As far as EC type-examination certificates are concerned,two issues have been dealt with by the European co-ordination of notified bodies

A. Is it possible to put different variants of a machine on the same certificate ?

B. Is it possible to issue EC type-examination certificates for the same product to different applicants ?

The answers are as follows

4.1.1 Procedure to be applied to the EC type-examination of variants of a machine or a safety component - Criteria to be taken into account for the certificate

The normal procedure is to put a family in one certificate. However, the notified body must verify if the range of products of the manufacturer presents a similar series of risks and/or technical solutions. If not, we are dealing with separate types which are covered by separate certificates. A machine or a safety component is considered as a variant of a referenced machine or safety component only if it differs on points which have no noticeable influence on the expected performances. The variants can correspond to differences relating in particular to dimensions, shape, nature of constituents materials, colour, assembly methods, manufacturing processes etc.

It is the responsibility of the Notified Body to evaluate for each individual case, if a given machine or safety component can effectively be considered as a variant. In case of doubt, it will carry out any check, measurement or test considered to be useful.

In every case and for each of the variants, the applicant will provide the Notified Body with a detailed description indicating the differences in comparison with the reference model and the number of samples of these variants required for complementary checks and tests.

4.1.2. Is it possible to issue EC type-examination certificates for the same product to different applicants ?

It is possible to issue other EC type-examination certificates for the same product which has an existing EC type-examination certificate provided the following rules are observed:

- The request shall be made to the notified body which issued the original EC type-examination certificate giving all relevant information to ensure the product is the same. The new applicant must obtain official authorisation from the owner of the original certificate, a copy of which must accompany the request.
- The new applicant shall be considered as a manufacturer and shall conform with the requirements of Annex IX, in particular point 6 (duty to inform the notified body about any modification made or planned on the type of machinery approved).
- To eliminate ambiguities between the original certificate and the new one, the references of the product must not be the same, the information for use and trade documents must accordingly be changed. The notified body has the responsibility to verify the new documents and to confirm the product is the same as the one originally approved.
- The new EC type-examination certificate should be issued by the same notified body as the original certificate ensuring full traceability of each document.

In this matter, the legislation on intellectual property and the patent and trade mark laws have to be observed.

5. 0RGANISATIONAL PROCEDURES

Four subjects have been broached in this context :

- How to ensure that the manufacturer does not attempt to resubmit a file that has already been rejected elsewhere
- How to harmonise the practical interpretation of the Directive when the product does not comply with an harmonised standard
- What to do when it is discovered that the application of a standard poses a problem
- How long should one retain files that relate to an EC type-examination.

5.1. How can it be assured that the manufacturer has not presented the same file to two or even several notified bodies? How can it be assured that the manufacturer does not re-submit a file having been the subject of a previous EC type-examination certificate refusal decision?

This question is in relation with the paragraph 2 from Annex IX of the Directive . The answer not applicable for the quotation process (see 2.1. of this RFU).

The manufacturer will be asked to confirm (an example of a confirmation form is attached) that he has not submitted the same file to another notified body and that the model presented for examination or a very similar one has not been the subject of any previous EC-type certificate refusal decision.

For the future, an information system is considered to be useful. The Commission should be asked by the Horizontal Committee whether the Directive provides a legal basis for establishment of such a system.

The aim of the confirmation Form is to make the manufacture aware of his(her) responsibilities.

" A body which refuse to issue an EC type-examination certificate shall so inform the other notified bodies. ..." The problem is that this information must be given very quickly to all other competent notified bodies (for example by FAX). If this is so, all notified bodies know what are the rejected machines. But this supposes that the list of European notified bodies is always up to date and sent in time to all notified bodies.

Confirmation form (example)

In the name of .....
(name of the company)

the undersigned.....certifies
(name of the undersigned)

- That the following Machinery or Safety Component for Machinery:

.....
(type of the Machinery or Safety Component according to Annex IV of MD 98/37/EC (previously 89/392/EEC amended)

.....
(identification of the product including designation of series or type, serial number and year of construction) whose manufacturing technical file is enclosed herewith, with the view of being granted an EC type-examination certificate, has not been subject of a previous EC type-examination certificate refusal decision

- That no request of a similar nature concerning the same model has been submitted to any other Notified Body for the granting of EC type-examination certificates.

Done at.....Date.....

(signature) (position of the undersigned) (seal)

Note : "A manufacturer cannot set notified bodies in competition with each other on technical questions by requesting an EC type-examination certificate from several notified bodies in the hope that at least one of them will issue such a certificate. However, this does not prohibit competition on the grounds of cost. A manufacturer located in one Member State may select a body notified by another Member State"[8]

5.2. How to harmonise the practical interpretation of the Directive when the product does not comply with an harmonised standard

If everyone interprets the Directive in his own way, it would be nothing short of miraculous if all of the solutions found were inter-compatible. In the event of flagrant divergences, there is always a risk that the safeguard clause would raise its head, which is not the desired objective.

The harmonised standards and the data sheets of the European co-ordination of notified bodies make it possible gradually to set a level acceptable to all parties involved (public authorities, manufacturers, etc.). Providing an operational summary of this “technical jurisprudence” applicable within the framework of the EC type-examination is one of the tasks of notified bodies.

One of the first questions raised during the meeting of the notified bodies was related to this topic. The question was "Are there any methods or procedures available for testing the achievement of adequate safety if the product is not in accordance with the harmonised standard? What and how can it be done? The notified body cannot always wait for the next meeting of the vertical group or horizontal committee to discuss the problem[9]".

The answer is based on common sense and personal contacts. We have no official regulation for the time being other than ESR's, but we can rely on :

- experience of some notified body ("ringing round")
- completing a technical sheet "proposal for enquiry"
- informative report and discussion in the vertical group
- compliance with national specifications/standards.

5.3. What action should be taken if deficiencies and/or mistakes in standards are detected ?

Question concerning possible deficiencies and/or mistakes in standards shall be brought to the attention of relevant CEN/CENELEC Technical Committees for possible solution.

Before decision is taken, the Vertical Group shall discuss the matter in order to reach a common agreement on how to proceed with the testing.

However, if the questions require an urgent solution the notified body who detected the possible deficiency(ies) or mistake(s) can start within the VG members a quick enquiry (by fax) in order to collect answers within a reasonable period of time (10 days).

If the question(s) are deemed to be of general interest, the Horizontal Committee shall also be informed.

The Member States are automatically informed through the minutes of the meeting of the Horizontal Committee.

5.4. For how long must the EC type-examination files be stored by the notified body?

Directive 98/37/EC did not give explicit limitation to the notified bodies concerning the retention of the EC type-examination files.

In order to ensure some degree of coherence with respect to Annex V paragraph 4 b of directive 98/37/EC, the notified bodies were advised to keep the file for fifteen years after the last intervention of the notified body.

The 2006/42/EC directive now states that the manufacturer and the notified body shall retain a copy of the certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of the issue of the certificate (Annex IX, 9.3. third paragraph)

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[8] J-P Van Gheluwe - Community legislation on machinery - Comments on Directive 98/37/EC - Section 822 - 1999 Edition

[9] This is the text of CNB/M/00.204/R/E Rev 01 now replaced by this Recommendation for Use

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.251 Revision 06 Language: E

Date of first stage: 09/11/2010		To be approved by:	Approved on:
Origin: Horizontal Committee		☐ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group....	28/06/2012 Endorsed on: 17/01/2013
Question related to: Directive 2006/42/EC Annex: IX	Article: 12.3 b), 12.4 a) ESR (1):	EN/prEN: Clause: CEN TC concerned:	Other: Other clause:

Key words: EC type-examination of a modified Machinery

Question:

How must a Notified Body (NB2) deal with an application of an assessment of conformity (EC type-examination) for a modified machinery while the base machinery was assessed by a Notified Body (NB1) who is different from NB2 and who delivered an EC type-examination certificate to the base machinery?

Solution:

The manufacturer has to address the NB1 when he makes changes to a machine (see Machinery Directive); NB1 will assess what impact the intended modifications may have on the validity of the EC type-examination certificate he issued. If NB1 reaches the conclusion that machinery, when subject to the envisaged modifications, will no longer be covered by the original EC type-examination certificate, he will inform the manufacturer about his conclusion.

If the manufacturer decides to go ahead and implement the envisaged changes, he must change the type and he has to make a new application in order to assess conformity with essential health and safety requirements of the Machinery directive. Such application may in this case be made to other NB2 that the manufacturer chooses. NB2 is responsible for the whole new type and it's up to the NB2 to accept technical files, certificates (e.g. for type approved Annex IV safety components) and /or test reports.

(1) Essential safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.252 Revision 03 Language: E

Date of first stage: 05/06/2009	To be approved by:	Approved on:
Origin: Generalisation of CNB/M/11.048/R/E Rev 01 from VG11 Safety components	☑ Vertical Group..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group....	26/10/2010 14/12/2010 Endorsed on: 23/05/2011

Question related to: Directive 2006/42/EC	Article:	EN/prEN:	Other:
Annex: IX	ESR (1):	Clause:	Other clause:
		CEN TC concerned:	

Key words: EC type-examination, series manufacture, internal checks

Question:

Article 12 lists as one possible procedure for assessing the conformity in its point 3 (b) the following:
"The EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3."

Does a Notified Body carrying out an EC type-examination also have to assess these internal checks, i.e. all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file?

Solution:

Reminder: "EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive."

No, the type-examination procedure described in Annex IX does not include the "assessment of conformity with internal checks on the manufacture of machinery" (Annex VIII).

According to Annex VII, point 1 b) "for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive" are part of the technical file.

Part of work of a Notified Body in performing an EC type-examination is to examine the technical file (see Annex IX, point 3.1). Therefore in case of series manufacture of a machine the Notified Body has to check also the measures foreseen by the manufacturer. The Notified Body has to check whether such measures exist and whether they seem appropriate, but does not have to perform production surveillance.

(1) Essential safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.254 Revision 04 Language: E

Date of first stage: 29.8.2013		To be approved by:	Approved on:
Origin: Horizontal Committee		☐Vertical Group..... ☑ Horizontal Committee..... To be endorsed by: ☑ Machinery Working Group....	18/06/2014 Endorsed on: 08/01/2015
Question related to: Directive 2006/42/EC	Article:	EN/prEN:	Other:
Annex: IX 9.3	ESR (1):	Clause:	Other clause:

		CEN TC concerned:

Key words: EC type-examination certificate, validity, renewal by original NB

§400 of the Guide to the MD states in matters of section 9.3 of annex IX:

“When reviewing an EC type-examination certificate, the Notified Body shall examine the technical file for the machinery in the light of any significant evolution of the state of the art over the elapsed five-year period.”

Question:
What are the minimum information and types of documents the NB has to request from the client when it wants to review the validity of the EC type-examination certificate?

Answer:
A manufacturer who considers his machine not to be modified and who wants to renew his EC type-examination certificate shall be requested to send to the notified body a written request which shall be accompanied, at least, by the following information and documents:

- Confirmation of the name and location of the current manufacturer,
- Confirmation that there were no modifications made to the machine with respect to the former type-examination, including all versions, components and optional assets,
- Pictures and drawings of the current machine,
- Confirmation that the manufacturer has received no complaints related to the safety of the machine during the last five years.

The manufacturer is free to send any additional documents supporting his request for renewal. The NB is in the responsibility to request further documents of its own choice.

All documents shall be examined in relation to the requirements of the current version of the Machinery Directive.

If the NB is convinced that the machine has not been significantly modified and still complies with all requirements of the Machinery Directive, it will renew the EC type-examination certificate according section 4 of Annex IX. In any case it is at the liberty of the NB to not rely on the documents but to carry out verifications on a sample of the machinery.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.255 Revision 03 Language: E

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Origin:	☐ Vertical Group..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group....	10./12/2013 Endorsed on: 15/04/2014

Question related to: Directive 2006/42/EC	Article:	EN/prEN:	Other:
Annex: I	ESR (1): 1.2.1	Clause:	Other clause:
		CEN TC concerned:	

Key words: Performance Levels, categories, SILs, hardware fault tolerance

Question:

Some type-C standards define requirements on the safety-related parts of the control systems as follows:

"Safety-related parts of control systems shall be designed so that they comply
- with **PL d** with structure **category 3** as described in ISO 13849-1:2006, or
- with **SIL 2** with a **hardware fault tolerance of 1** with a proof test interval of not less than 20 years, as described in IEC 62061:2005."

Will a safety-related part of a control system complying with **SIL 3** with a **hardware fault tolerance of 0** fulfil this requirement?

Solution:

No.

The probability of a dangerous failure, expressed either in PL or in SIL is one requirement.

The structure of the safety-related parts of the control system, expressed in categories or in hardware fault tolerance, is another requirement.

Both requirements have to be fulfilled independently.

(1) Essential safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.256 Revision: 05 Language: EN

Number of pages: 1	Date: 20.11.2024	To be approved by: ☐ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Expert Group	Approved on: - 29.05.2024 Endorsed on: 17.10.2024
Origin: Horizontal Committee			

Question related to: Directive 2006/42/EC	Article: -	EN/prEN: EN ISO/IEC 17025:2018	Other: -
Annex: IV - all	EHSR (1): -	Normative clause: -	Other clause: -
		CEN TC concerned: -	

Key words: EC type-examination, external test facilities, laboratory, manufacturer

Question:

Q1) Is the Notified Body allowed to use external test facilities (e.g. provided by manufacturer) for EC type-examination procedure according to Machinery Directive Annex IX?

Q2) Is the Notified Body allowed to accept test results from other laboratory (without supervising / witnessing) provided by laboratories mandated by manufacturer for EC type-examination procedure according to Machinery Directive Annex IX?

Note 1: Subcontracting ('Blue Guide' (2016/C 272/01), cl. 5.2.5) is not considered to be covered by this RfU.

Solution:

To Q1:
External test facilities (e.g. manufacturers' test facilities) are only to be accepted where the testing is supervised / witnessed by the notified body staff. The content of the test report has to be in alignment with clause 7.8 of EN ISO/IEC 17025 including details of the involvement of the notified body.

To Q2:
Yes, the following options can be accepted:

1. Laboratory accredited by a signatory to the ILAC accreditation system for the scope of testing:
   In this case the test results from this test laboratory can be accepted.
2. Independent laboratory without recognised accreditation:
   In this case the NB has to assess the test facility by an initial and by surveillance audits for the scope of testing to confirm, whether it follows the requirements of EN ISO/IEC 17025.
   Note: In some circumstances, there could be no other solution as to take non accredited laboratories. For example, very specific test is provided only by few laboratories which are not accredited. Or there are no available accredited laboratories, or to choose the accredited laboratory could conduced to abnormal additional cost (sending the samples to far locate countries).

Note 2: This RfU is not applicable to Safety-Components covered by VG11 – this topic is covered by CNB/M/11.067.

(1) Essential health and safety requirement
Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.301 Revision 03 Language: E

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	To be endorsed by:	Endorsed on:
	☑ Machinery Working Group..	08/06/1998

Question related to: Dir. 2006/42/EC	Article:	EN/prEN: EN 1005-2: 2003/A1 :2008	Other:
Annex:	EHSR (1):	Clause:	Other clause:
		CEN TC concerned:	

Key words: Component, manual handling

Question: What criteria should be taken into account when evaluating if a component can be transported by hand?

Solution:

The principal criteria to be taken into consideration are :

. the mass of the component

by component we mean all components used during the maintenance

. the dimensions of the component.

The maximum permitted mass per person is worked out according to the maximum distance between lifting and laying, as per the following table, and under no circumstances can exceed 25 Kg (in accordance with Directive 90/269/EEC, see also EN 1005-2:2003/A1:2008 safety of machinery. Human safety performance Part 2: Manual handling of machinery and component parts of machinery). Otherwise, standardised gripping devices which can be used in conjunction with slings, hooks, lifting rings or more simply cut holes must be foreseen for handling, and the instruction handbook should give all the necessary instructions.

Regardless of their weight, machine components which are more hazardous due to sharp areas, bulky shapes, slippery lubricated surfaces, etc. must be fitted with appropriate devices to ease handling.

Adaptation procedure: FORMAL ADAPTATION IN CONFORMITY WITH DIRECTIVE 2006/42/EC

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

Where the mass of a component to be handled is not obvious, (a strengthened, heat insulating guard for example), an indication regarding its sturdiness must be affixed to the guard itself.

The notified body should ensure that the instruction handbook gives all the details pertinent to the handling of these components.
The mass of components exceeding 25 Kg must be mentioned in the instruction handbook.

MASS (m) (kg)	MAXIMUM DISTANCE BETWEEN LIFTING AND LAYING (m)	
	HORIZONTAL DIRECTION	VERTICAL DIRECTION
0<m<=	1,2	1
10<m<=	1	0,8
15<m<=	0,8	0,6

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.302 Revision 04 Language: E

Date of first stage: 30/09/1996	To be approved by:	Approved on:
Origin: Horizontal Committee	☐ Vertical Group ..... ☑ Horizontal Committee.....	26/11/2009
	To be endorsed by: ☑ Machinery Working Group..	Endorsed on: 08/06/1998

Question related to: Dir. 2006/42/EC	Article:	EN/prEN:	Other:
Annex: I	EHSR (1): 1.5.4	Clause:	Other clause:
		CEN TC concerned:	

Key words: Machinery, Errors of fitting

Question:

How can the prevention of errors of fitting components making up machinery or errors of connection likely to leaf to a risk be ensured? What criteria should be retained to ensure that the instructions of the manufacturer prevent errors of fitting or connection?

Solution: Ensure that in the documentation:

1°) in the case of pre-fitting

- the "pre-fitting" of items or couplings has already been carried out by the manufacturer. In these circumstances the handbook must provide the information necessary for any possible dismounting operation as well as on the risks likely to result from an error of fitting where there is the possibility of interchangeability..

2°) without pre-fitting

- the items or couplings are fitted with polarizing slots in the case where "pre-fitting" has not previously been carried out. These devices should be strong enough not to break or deform if incorrect fitting is attempted .
- the items or couplings must be identified by means of markings or distinctive colours when 'pre-fitting' and fitting of polarizing slots are not feasible. These markings must be affixed directly on the items and/or on their housing. If a direction of movement is required this should be indicated on the items and/or on their housing. The handbook must provide information regarding the risks likely to result from an error of fitting.

In all circumstances the handbook must explain the fitting and dismounting phases, and the cautions must de drafted clearly.
Ensure by means of inspection that :

- the pre-fitting is in conformity with the documentation
- the polarising slots are efficient,
- the markings are adequate

Adaptation procedure: FORMAL ADAPTATION IN CONFORMITY WITH DIRECTIVE 2006/42/EC

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.502 Revision 06 Language: E

Date of first stage: 05/02/1999	To be approved by:	Approved on:
Origin: Horizontal Committee	☐ Vertical Group ..... ☑ Horizontal Committee..... To be endorsed by: ☑ Machinery Working Group.....	15/06/2010 Endorsed on: 30/12/2010

Question related to: Dir. 2006/42/EC	Article:	EN/prEN:	Other:
Annex: I	EHSR (1): 1.5.10 and 1.5.11	Clause:	Other clause:
		CEN TC concerned:	

Key words: EMC, Emissions, Immunity.

Question: How to take account of electromagnetic effects in the context of the machinery directive?

Solution:

Generally speaking, the machinery directive and the EMC directive are complementary (see the European Commission's compatibility guide mentioned below). Neither of the directives can be considered specific, given the different nature of the essential requirements defined by the two directives (radiation and employee safety for the machinery directive and electromagnetic compatibility for the EMC directive).

This being said, it should be borne in mind that there are two aspects to the problem:

- Emissions (not causing interference in the environment): this point is raised in paragraph 1.5.10 of Annex I of the machinery directive (risks due to radiation). It has two facets:
  - induced effects on the performance of machinery and equipment: : this aspect is covered by the EMC directive ;
  - the physiological effects on human beings : this aspect is adequately covered by, among others, the IRPA (1) and NRPB (2) guides. For conventional machines, there is normally no risk in this field.

  The analysis of these risks by the manufacturer is compulsory.

- Immunity (not being influenced by electromagnetic interference): this point is raised in paragraph 1.5.11 of Annex I of the machinery directive (risks due to external radiation). Electromagnetic interference also constitutes an external influence under paragraph 1.2.1. The manufacturer must ensure that the interference does not create a dangerous situation. According to the directive, there must not be:
  - the machinery must not start unexpectedly;
  - the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,
  - the machinery must not be prevented from stopping if the stop command has already been given;
  - no moving part of the machinery or piece held by the machinery must fall or be ejected;
  - automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded ;
  - the protective devices must remain fully effective or give a stop command.

  It is also clear that interference must not cause the machine to make sudden random movements.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

The manufacturer and any notified body which may be involved in the conformity assessment process must ensure that these rather particular aspects are properly dealt with. We should bear in mind that effects of interference on the machine are covered specifically by the EMC directive and not the machinery directive. The following are possible approaches:

- reports drawn up by competent EMC bodies;
- declarations of conformity to the EMC directive for components, apparatus, systems forming part of the machine;
- analysis of the electrical circuit to determine whether the electromagnetic interference is likely to create a dangerous situation. The designer may have decided to guarantee immunity by using electromechanical devices which are not vulnerable to interference. In this case of complex control circuits, the manufacturer must make a risk analysis to evaluate the effect of faults. This analysis is to be included in the technical file.

It is often impossible to verify by testing whether a large machine is immune. In this case, the immunity of the electronic control systems and safety components is to be checked.

(1) = International Radiation Protection Association
PO Box 662 - 5600 Ar - Eindhoven - Netherlands

(2) = National Radiological Protection Board
Chilton - Didcot - Oxon - United Kingdom

EUROPEAN CO-ORDINATION MACHINERY OF NOTIFIED BODIES	**CO-ORDINATION OF NOTIFIED BODIES** **MACHINERY DIRECTIVE 2006/42/EC + Amendment** **RECOMMENDATION FOR USE**	CNB/M/00.503 Revision 02 Language: E

Date of first stage: 05/02/1999	To be approved by:	Approved on:
Origin: Horizontal Committee	☐ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Working Group.....	29/06/2016 Endorsed on: 31/01/2018

Question related to: Dir. 2006/42/EC	Article:	EN/prEN:	Other:
Annex: I Annex VII.A.1.	EHSR (1): 1.7.4.3.	Clause:	Other clause:
		CEN TC concerned:	

Key words: sales literature

Question:

Is a NB during EC-type examination obliged to check sales literature (as far as available) if the information on emission data is identical to the information in the Operator's Manual (according to section 1.7.4.3 of the Machinery Directive (MD))?

Answer:

No.

According to the list in Annex VII and the relevant paragraphs in the Guide to the MD (§ 392 with advice on §§ 254 through 274 whereas § 275 relates to chapter 1.7.4.3) sales literature does not belong to the technical file.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.505 Revision: 02 Language: EN

Number of pages: 1	Date: 03.07.2023	To be approved by: ☐ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Expert Group ...	Approved on: - 14.06.2022 Endorsed on: 23.03.2023
Origin: Horizontal Committee			

Question related to: Directive 2006/42/EC and ON Directive 2000/14/EC	Article: 1.7.4	EN/prEN: -	Other: -
Annex: -	EHSR (1): -	Normative clause: -	Other clause: -
		CEN TC concerned: -	

Key words: airborne noise declaration, instruction manual

Question:

To which extent should notified bodies verify the instruction manuals relative to the information provided on airborne noise emission?

Recommended solution:

NB should use the attached checklist together with the given example to verify the instruction manuals for appropriate declaration of airborne noise emissions.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

Sample checklist for airborne noise emission declaration in instruction manuals in accordance with the Machinery Directive 2006/42/EC and the Outdoor Noise Directive 2000/14/EC (when applicable)

Nr.	Check	not applicable	yes, o.k.	not o.k.	Remarks
1 0	**Reduction of Risk due to noise emission**				
1 1	Has the manufacturer identified the main source(s) of noise emission on the machinery?				An easy check is not possible. It is obvious that only the design engineer of the machine manufacturer would be able to give an answer on these questions provided that he is competent in the field of machinery acoustics. Only in very obvious cases of ignoring principal rules on noise reduction at source and on the transmission path an adequate answer could be given by the inspector. However, it should be clear that the application of noise reduction measures itself, e.g. identified by visual checking, is not a proof of its effectiveness. This can only be verified by comparing noise emission values from the machine under test with the state of the art of comparable machines. As this kind of data is currently not available a check is almost impossible. However, the notified body should collect respective data in order to establish it´s own database with emission data to be shared with the other notified bodies.
1 2	Has he taken measures to reduce noise emission at source?				Note: A "no" here would not mean that the machine is not in line with the MD. Use "not applicable" instead, to indicate, that their is no need for additional measures for noise reduction.
1 3	Has he taken measures to protect operators and other exposed persons against noise emission?				see remarks to 1.2 above

2 0 Measurement of noise emission

2 1	Has a noise test code according to harmonized standards been used to carry out the above measurements?		As one of the major purposes of these values is to allow comparison of emission values from different machines of the same kind, it is essential to determine the relevant noise emission values under comparative conditions. These conditions are normally stated in harmonised standards such as European machinery safety standards providing references to B-standards which describe methods for the noise emission measurement, declaration and verification and give specifications on installation, mounting (assembly) and operating conditions during measurement. NB are requested to report any obstacles during their own application of noise test codes or by the manufacturers and, if applicable, commissioned institutes to the responsible TC for the standards. This is the only way to ensure that the TC has all the information required to correct or adapt the relevant standards during revision.
2 2	If no noise test codes according to harmonized standards has been used, have the most appropiate measurement methods for this kind of machinery been used?		The manufacturer has to determine operating conditions that will result in noise emission values which are reproducible and representative of the foreseeable conditions of use of the machinery under test. If there is more than one foreseeable operating condition, he should include at least the operating condition that will give rise to noise emissions in the upper part of the range. He should identify a noise emission measurement standard that best suits the environment in which to carry out the noise measurements. He should try to achieve ‘engineering grade’ (grade 2) accuracy. If not achieved or not achievable, reasons shall be stated and documented. Harmonised standards include ISO 11201 to 11205 for emission sound pressure level and ISO 3741 to ISO 3747 and the ISO 9614 Parts 1 to 3 for sound power level.
2 3	If no noise test codes according to harmonized standards has been used, have the operator positions around the machine been correctly identified?		There may not be well-defined workstations for a machinery. Where this is the case, the manufacturer must measure A-weighted emission sound pressure levels at a distance of 1 m from the surface of the machine and at a height of 1.55 m +/- 0.075 m from the floor or access platform. His noise declaration must include the position and maximum value of the measured noise emission value, that is, he must work out where noise around the machine is highest and report that highest value.
2 4	If no noise test codes according to harmonized standards has been used, have the uncertainties associated with the measurements of emission sound pressure level and sound power level been determined?		
2 5	Are the relevant recorded data included in the technical file?		What is to be recorded is detailed in the clause "information to be recorded" of all B-standards for noise emission measurement and all harmonized noise test codes.

3 0 Noise emission data in user instructions

3 1	Have the noise emission values been declared in the dual number mode according to ISO 4871?		see example key 1
3 2	Do the instructions include the A-weighted emission sound pressure level L_{pA}, or an indication, that the level does not exceed 70 dB?		The A-weighted emission sound pressure level, L_{pA}, produced by the machinery at its workstation(s). This is the average A-weighted sound pressure level over a specific time, representative of a full work cycle of the machinery. Being an emission value, it excludes contributions from the environment of the machinery such as reflections of noise from walls or noise from other sources at the workplace. This quantity must be determined by measurement for all machinery using an appropriate test code, whether or not the machinery is considered noisy. If the measured value does not exceed 70 dB(A), the instructions must state this. If the measured value exceeds 70 dB(A), the measured value must be stated in the instructions. (see example key 2)
3 3	If $L_{pA} \geq 80$ dB: do the instructions include the A-weighted sound power level L_{WA} ?		The A-weighted sound power level, L_{WA}. This quantity represents the airborne sound energy per second radiated by the machine in space and thus characterises the machine as a noise source. It is the most important noise emission quantity and is independent of the environment in which the machine is placed. Since the measurement of the L_{WA} may be complex, this value only has to be measured and stated in the instructions if the L_{pA} at any of the workstations exceeds 80 dB(A). (see example key 3)
3 4	Do the instructions include the C-weighted emission peak sound pressure level L_{pCpeak}?		The peak C-weighted instantaneous sound pressure value, also known as the C-weighted peak sound pressure level, L_{pCpeak}. This is the maximum value reached by the C-weighted sound pressure over a specific duration representative of a full work cycle of the machine. This value is relevant for machinery that emits strongly impulsive noise. It only has to be stated in the instructions if the measured value exceeds 63 Pa (130 dB in relation to 20 µPa). L_{pCpeak} must be given in the manual if this is prescribed by the noise test code.
3 5	In the case of very large machinery: are the A-weighted emission sound pressure levels at specified positions around the machinery indicated?		To determine whether a given category of machinery is to be considered as very large, consideration shall be given both to the distribution and directivity of the sound sources on the machinery and the effort required to determine the sound power level, L_{WA}. Whether a given category of machinery is to be considered as very large is to be stated in the relevant noise test code. Where no noise test code exists, justification of the decision, that a machine is considered to be very large, needs to be stated in the manual. For such very large machinery, the statement of the L_{WA} can be replaced by a statement of the emission sound pressure levels, L_{pA}, at specified positions around the machinery. These positions must be stated in the manual as well.

3 6	Whenever sound emission values are indicated: are the uncertainties surrounding these values specified?		See example key 4
3 7	Do the instructions contain a reference to the approriate harmonized standard(s), which describes in the noise test code the operating conditions under which the measurement is to be made?		Where a noise test code specified in a harmonised standard states the operating conditions under which the measurement is to be made, a reference to the harmonised standard is sufficient to indicate the operating conditions and measurement methods used. (see example key 5). Harmonised noise test codes may allow several basic noise emission measurement standards and the manual should therefore indicate, which one was chosen, because reference to the harmonised noise test code only may not be sufficient to ensure traceability.
3 8	If the manufacturer has not used test methods according to harmonized standards, does he describe the operating conditions of the machinery during measurement and the measuring methods used?		It is not compulsory for a manufacturer to use harmonised standards. If a manufacturer does not use harmonised standards, he has to describe and indicate in the noise emission declaration the measurement method used and the installation, mounting and operating conditions applied during measurement. As this requires some effort the use of harmonised standards is preferred with the additional advantage of providing presumption of conformity with the essential requirements of the MD on noise. (see example key 6)
3 9	Do the instructions contain a statement related to the conditions, if the correctness of the declared emission values is to be checked?		See example key 7
3 10	Do the instructions contain a statement related to the correlation of the declared emission values and the exposition at the planned installation location?		See example key 8. The manufacturer should know that emission values obtained during standard tests underestimate or overestimate the noise hazard associated with typical use. Where this is the case, he should supplement a potentially misleading noise declaration with a range of noise emission values for foreseeable or typical in-use operating conditions, or otherwise make clear the noise likely during actual use. Where he knows the noise of the machine varies widely with application, he should inform the purchaser. In these cases, it is desirable to also inform the responsible TC so that the noise test code can be adapted (see also remarks to 3 15). Some harmonised standards may provide a fixed text of a warning of possible underestimation of noise emission to be inserted in the manual.
3 11	If the manufacturer has not used test methods according to harmonized standards, does he describe the workstation position(s) at which measurements were made?		See remarks to 3 8.

3 12	If the workstation(s) are undefined or cannot be defined: is the maximum A-weighted sound pressure level on a path around the machine and its position indicated?		
3 13	For machinery with emission sound pressure level above 80 dB(A) and for which both the MD and the OND apply: do the instructions include the garanteed A-weighted sound power level L_{WA} as well as the dual number emission sound pressure level?		Attention: A few noise test codes harmonised for the MD include a method for measuring sound power level, which differs from that specified by the OND. The manufacturer must use the method specified in the OND for determining the sound power level reported in the instruction manual. Regarding operating conditions for the determination of L_{pA}, they are those specified by the OND for the determination of L_{WA} unless there is a noise test code harmonised under the MD that has different requirements. Fortunately such situations are very rare. A manufacturer may make reference to the OND for L_{WA} and to a harmonised standard (that may contain a noise test code identical or not to the one in the OND for L_{pA}.
3 14	For machinery with emission sound pressure level above 80 dB(A) and for which both the MD and the OND apply: has the machine been marked with the garanteed A-weighted sound power level L_{WA}?		For some types of machinery the guaranteed sound power level must not exceed the permissible sound power level specified in the OND. These limits are defined in the Directive.
3 15	If the machinery is tested under conditions that produce noise emission values, which do not represent the actual noise emission levels when using the machine, does the manufacturer provide additional information to help the user assess and manage the noise hazard?		For example: *The declared A-weighted emission sound pressure level at the workstation of 76 dB was obtained with machine running (describe standard operating condition). When it is used to (describe here typical in-use activity), the A-weighted emission sound pressure level at the workstation can be up to 10 dB higher.* Note: Check the apropriateness of the noise test code in the harmonized standard!

Example to the checklist for airborne noise emission declaration in instruction manuals in accordance with the Machinery Directive 2006/42/EC and, if applicable, the Outdoor Noise Directive 2000/14/EC

	Declared dual-number noise emission values in accordance with ISO 4871	**Idle mode**	**Operating mode**
3	A-weighted sound power level L_{WA} in dB	96	110
4	Uncertainty K_{WA}	4	4
2	A-weighted emission sound pressure level L_{pA} in dB at operator position A	80	89
	A-weighted emission sound pressure level L_{pA} in dB at operator position B	78	88
4	Uncertainty K_{pA}	4	4
5	Measurement made in accordance with EN ISO 3744:2011 for sound power level and EN ISO 11202:2010, accuracy grade 2 for emission sound pressure level. Operating conditions in accordance with EN ISO 12345:2099, Annex XY,		
6	with the following deviations: feed rate 12 m/min, grooving tool diameter 200 mm.		
7	If the correctness of the declared emission values is to be checked, measurements shall be made using the same method and the same operating conditions as those declared.		
8	The figures quoted are emission levels and are not necessarily safe working levels. Whilst there is a correlation between the emission and exposure levels, this cannot be used reliably to determine whether or not further precautions are required. Factors that influence the actual level of exposure of the workforce include the characteristics of the work room and the other sources of noise etc. i.e. the number of machines and other adjacent processes. Also the permissible exposure level can vary from country to country. This information, however, will enable the user of the machine to make a better evaluation of the hazard and risk.		

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.506 Revision: 04 Language: EN

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Origin: Horizontal Committee			
Question related to: Directive 2006/42/EC	Article: -	EN/prEN: -	Other: -
Annex: IX	EHSR (1): A.1.(a) 8th and 9th indent	Normative clause: - CEN TC concerned: -	Other clause: -

Key words: Documents to be required for the assessment of the technical file in an EC type-examination procedure

Preamble:

Case 1

A machinery (belonging to Annex IV) incorporates a partly completed machinery, supplied by another manufacturer, accompanied by the following documents:

- Declaration of incorporation, issued according to clause 1.B of Annex II
- Assembly instructions, issued according to Annex VI

Case 2

A machinery (belonging to Annex IV) incorporates a number of safety components (e.g. two-hand control, emergency stop, etc.) for which the manufacturer has supplied an EC declaration of conformity based on the conformity evaluation procedure of clause 3.a) of article 12. For such safety components, the following documents are available:

- EC Declaration of conformity, issued according to clause 1.A of Annex II
- Instructions, issued according to clause 1.7.4 of Annex I

Question:

With reference to the above-mentioned cases, during the process of EC type-examination (Annex IX) has the notified body to require further documentation (e.g. detailed drawings, calculation notes, test reports, etc.) in addition to the previously listed documents?

Solution:

Usually no, as stated by Annex VII clauses A.1.(a) 8th and 9th indent (see Note 1) Such a request represents an access to information contained in the technical file of safety components (case 2) or in the relevant technical documentation of the partly completed machinery (case 1), but access to this information is allowed only to competent national authorities on the basis of a duly reasoned request.

However, if the Notified Body has concerns that the performance of the PCM or safety component may compromise the safety and conformity of the final machine, they shall request the manufacturer of the final machine to provide enough information to address those concerns. The manufacturer may need to refer back to the manufacturer of the PCM or safety component to provide adequate information.

Note 1:

- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.510 Revision: 02 Language: EN

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Origin: Remote assessment working group appointed by 54th Machinery Horizontal Committee meeting			
Question related to: Directive 2006/42/EC	Article: -	EN/prEN: -	Other: See reference documents mentioned in main text below.
Annex: IX Clause 3	EHSR (1): -	Normative clause: general CEN TC concerned: -	Other clause: -

Key words: Remote assessment activities

Question:

How should a Notified Body decide whether a remote conformity assessment activity is possible and how should it be carried out?

Solution:

See pages 2-5 of this document.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.

VG11 RFU CNB/M/11.067 concerns remote assessment for safety components and takes precedence over this document for those items only.

A remote assessment activity can be defined as the facilitation of a conformity assessment activity from a location other than being physically present at the assessment site. IAF ID 12:2015 Principles on Remote Assessment An assessment which combines remote and on-site assessment activities is referred to as a “Blended” or “Hybrid” assessment.

Remote assessment activities provide the opportunity for increased efficiency, increased safety, better timing, inclusion of NB personnel that may not be easily accessible, and avoidance of travel delays and restrictions. IAF ID 12:2015 Principles on Remote Assessment

The use of remote conformity assessment activities is an option that can be used in certain cases or as a supplement to established procedures to replace some on-site conformity assessment activities by a Notified Body. It is important to assess the feasibility of individual “remote conformity assessment activities” rather than a complete “remote conformity assessment”.

Conditions for appointment of Machinery Notified Bodies do not exclude the possibility of remote conformity assessment activities, provided they are carried out under Notified Body control. ISO 17065:2012 does not exclude the possibility of remote conformity assessment activities.

Remote conformity assessment activities can be considered a normal option as part of an overall conformity assessment.

Remote conformity assessment activities must always provide an equivalent level of rigour and reliability to in-person on site assessment activities.

A Notified Body should in all cases make the choice of whether a remote conformity assessment activity is appropriate or not and should retain full responsibility for, and control of, the activity.

The decision to remotely conduct conformity assessment activities which traditionally have been conducted on site, should follow a risk-based approach to decide which activities can use remote assessment without compromising the rigour and reliability of the conformity assessment activity. Opportunities to mitigate or reduce any risks identified using additional measures should be considered and should be documented in the risk assessment.

The risk assessment which indicates that it is acceptable to use a remote conformity assessment activity as part of an overall conformity assessment should be included in the EC Type Examination documentation and should be available to the customer, to the conformity assessment body’s own employees, accreditation bodies, and the regulatory authorities. Annex A contains a recommended approach to remote conformity risk assessment.

The scope of a proposed remote conformity assessment activity should be reviewed during the planning phase and confirmed as practical and achievable, and adapted if necessary.

The conformity assessment body should provide a clear description of their remote assessment activity process, in their own QMS including the preliminary requirements, the different steps of the process, a guidance on the techniques to be used and the methodology adopted.

Additional training and qualifications may need to be carried out, covering the communication and information technology used in order to fully qualify the persons engaged in remote activities. Records of the persons qualified to supervise and carry out remote activities of different types should be maintained and updated by the Notified Body as described in their QMS.

An assessment plan should be developed in liaison with the manufacturer before any work is carried out and should include at a minimum:
• A detailed description of which activities will be carried out remotely, how the activity will be carried out and by whom, with an estimate of time required and proposed date and time that the assessment will be carried out.
• A detailed description of what communication facilities and other facilities such as calibrated measurement instruments, test weights, test materials must be provided
• An indication of what staff resources the manufacture must provide.
• The test/examination report produced as the result of a remote assessment activity should consider the requirements of ISO 17025 clause 7.8.2 and also include as a minimum:-
- The risk assessment used to justify use of remote assessment.
- Live-streamed and recorded video and audio, and test and activity reports as appropriate which provide evidence of an adequate test or examination.
Recordings of live streams, off-line videos and photographs provided by the manufacturer and any other evidence used as part of the remote assessment forming part of the final test report must be retained for at least 15 years after the date of issue of a certificate.[2006/42/EC Annex IX 9.3]

This document was compiled with reference to the following publications
- IAF ID 12:2015 Principles on Remote Assessment
- EA-2/21 G: 2022 Guidance on remote assessments
- CNB_M_0_2022_037V01 EA-2_21-Guidance-on-Remote-Assessments-rev00_18 Oct 2022
- TIC Council Guidance document on remote activities of conformity assessment
- IECEx OD 024 – Ed4.0 Operational Document

Annex A Recommended risk assessment method

The risk for each assessment activity should be considered separately, but different activities may be grouped together, for example, in a single test plan which covers several different activities.

The table below can be regarded as a “sliding scale”. The NB should assess and document where the activity they are assessing lies within the range of possible risk scores.

The individual risk scores for the four risk factors defined by the project should be added together. The Notified Body can then select an assessment method and person to carry it out to give a combined score with all factors added together which is then assessed against the following
Combined score 6 – 14 Remote risk assessment possible
Combined score 15 – 22 Remote risk assessment possible if other methods are not practicable with extra mitigations where possible
Combined score 23 – 30 Remote risk assessment likely to be unreliable and not recommended

Deviations from C type standard	**Score**	**Manufacturer experience See Note 2**	**Score**	**Complexity of equipment, test and examination required.**	**Score**	**Extent of assessment**	**Score**	**Proposed Method/Evidence**	**Score**	**Impartiality and experience of on site staff. See Note 1**	**Score**
Lower risk											
Defined by project								**Defined by Notified Body**			
Equipment aims for complete conformity with standard	1	Previous EC Type Examinations of this type of equipment with current examining NB	1	Small and simple	1	Minor further test or repeat test	1	Live streaming under continuous NB examiner supervision	1	Experienced NB staff but not authorised to examine this type of equipment	1
	2	Previous EC Type Examinations of this with a different examining NB or for different equipment	2		2		2		2	Experienced technical 3rd party	2
Deviations from standard	3		3	Medium size and complexity	3	Limited testing or examination	3	Continuous off-line Video + test/examination report only	3	Inexperienced technical 3rd party	3
	4	Experienced manufacturer but with no previous experience of EC Type Examination	4		4		4		4		4
Innovative equipment. Standard not very relevant	5	Inexperienced manufacturer with no previous experience of EC Type Examination	5	Large and complex	5	Complete new assessment against EHSRs or C type standard	5	Video highlights or Photo + test/examination report only	5	Manufacturer’s own staff	5
Higher risk											

Note 1. “Experienced” here means persons who have been specifically trained to carry out this type of examination and/or have carried out similar examinations before.
Note 2. “Experienced manufacturer” here means a manufacturer who has successfully made similar equipment before.

Annex B Some factors to be considered in remote assessment

Some hazards can be difficult to assess remotely, for example:
• Risk of cutting from sharp edges
• Risk of slips trips and falls during access to parts of equipment
The NB must consider how these can be adequately assessed.

The audio/video software or app used to perform the remote activity and means of connectivity is to be checked and accepted by the NB, if the NB is not providing them, in terms of:
• Quality of images and audio available to the examiner,
• Interoperability and compatibility of the technology, including formats,
• Consideration and fulfillment of cybersecurity requirements,
• Protection and confidentiality of the data transmitted, e.g., through encryption.

Where live-streaming is used for a remote assessment activity, proper preparation and planning of the remote assessment activity is to be done in advance of the activity and should include a pre-meeting and test to ensure that:
• The audio/video software or app used provides evidence of adequate quality.
• Internet connection is satisfactory in respect to the audio/video software or app used and proper communication capabilities are provided.
• Battery powered devices used have adequate duration and storage or suitable replacement batteries or charging facilities and storage are available.
• The on-site personnel operating the smart device and carrying out remote activities are properly skilled in using the technology.
• Adequate translation facilities are provided to ensure that efficient communication is maintained.

The possibility for the conformity assessment activities body to retain evidence, videos,
photos and audio recordings relevant to the object of the remote activity is to be considered an opportunity to avoid future potential risks for the NB to be involved in complaints, disputes, proceedings or potential accreditation suspensions/withdrawals.

	CO-ORDINATION OF NOTIFIED BODIES **Machinery Directive 2006/42/EC + amendments** **RECOMMENDATION FOR USE**	CNB/M/00.511 Revision: 02 Language: EN

Number of pages: 2	Date: 20.11.2024	To be approved by: ☐ Vertical Group ..... ☑ Horizontal Committee ..... To be endorsed by: ☑ Machinery Expert Group	Approved on: - 18.12.2023 Endorsed on: 17.10.2024
Origin: Horizontal Committee			
Question related to: Directive 2006/42/EC	Article: 14	EN/prEN: -	Other: -
Annex: IX EC Type-Examination	EHSR (1): -	Normative clause: general CEN TC concerned: -	Other clause: -

Key words: Refusal to issue certificate, Withdrawal of a certificate, suspension of a certificate, Restriction of a certificate.

Question:

Directive 2006/42/EC in

Article 14 clause 6 states

"6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available."

Note there is no requirement to notify other NBs in these cases!

And Annex IX "EC type-examination" clause 5 states:

"If the type does not satisfy the provisions of the Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available."

Under what circumstances shall a Notified Body issue a refusal to issue a certificate and how shall the refusal and also certificate suspensions, withdrawals and restrictions be advised to other parties?

Solution:

Once an application for certification is made and accepted by a Notified Body, a refusal to certificate shall be issued if an initial EC type-examination or an Annex X quality audit reports non-conformities and the manufacturer does not satisfactorily correct them within the time period agreed between the Notified Body and the manufacturer. There is no limit on the time period agreed and it may be extended at the manufacturer's request with the agreement of the Notified Body.

It is not necessary to issue a refusal to certificate if an application for certification does not proceed to certification for non-safety related reasons such as commercial problems or because the applicant no longer wishes to proceed with certification and withdraws their application.

A refusal to issue an EC Type examination certificate or a withdrawal, suspension or restriction of a certificate or quality system approval must be advised to an agreed contact in the member state which appointed the Notified Body.

Refusals to issue a certificate only shall also be advised to the Machinery Notified Body group Technical Secretariat who will post it in the

appropriate area of the Machinery Notified Bodies Group on CIRCABC. All members of the Notified Bodies group will be automatically notified of all new items posted on the group.

A notice of refusal to issue a certificate for an EC Type examination shall be sent to the Machinery Notified Bodies Technical Secretariat and should be in the following format

Date of Refusal (yyyy.mm.dd format to sort correctly by date)

Notified Body name and number
Manufacturer name and address
Equipment description and model name and/or number
Annex IV category of equipment refused
Brief description of reason for refusal. (Information provided must not include client confidential information.)

This RfU answers the problem of how to effectively advise other Notified Bodies raised in RfU 00.250 clause 5.1.

(1) Essential health and safety requirement

Note: According to point 6.6 of the Guide of the implementation of directives based on the New Approach and the Global Approach, the notified bodies apply as general guidance this recommendation for use.