	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.001 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 1	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : final inspection, quality management, intermediate inspections

Question :

Does final inspection and testing only refer to tests after manufacturing?

Recommended solution :

Although the wording of the directive suggests that the final inspection takes place after manufacturing, it seems clear that a quality management system for “design, manufacture, final inspection and testing” also contains appropriate intermediate inspections and tests during the product phase.

These activities are under the responsibility of the manufacturer and are to be differentiated from the direct conformity assessment carried out by the Notified Bodies.

Note: Production phase includes design, manufacture, inspection, testing and storage for the machinery

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.002 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 1	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : quality system, compliance with standards, accreditation

Question :

Is it necessary for the manufacturer to have a quality system according to ISO 9001:2000?

Recommended solution :

No, compliance with the requirements of EN ISO 9001:2000 normally provides a presumption of conformity to the relevant requirements of module H. However, since there are several additional requirements in the Annex X, compliance with ISO 9001:2000 alone is certainly not sufficient as such to demonstrate compliance with the requirements of the directive. On the other hand, compliance with the standard is not mandatory, but the quality system must comply with the essential requirements of Annex X: no more, no less.

Note: It should be noted that notification for Annex X is sometimes based on accreditation according to EN ISO 17021:2006 standards. Because these standards require ISO 9001:2000 it might be impossible for the Notified Bodies (NB) to accept a quality management system which is not complying with ISO 9001:2000. This might introduce discrepancies depending on the nationality of the NB.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.003 Revision : 3 Language : EN

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Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.1	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : application, quotation, selection of Notified Body

Question :

What is meant by application in the terms of clause 2.1 of Annex X and in particular the last bullet point?

Recommended solution :

It is not the intention of this requirement to restrict the manufacturer from obtaining several quotations, but simply prevent the practice of going from one Notified Body (NB) to another until one will issue certification. It is permissible for the Manufacturer to approach one or more Notified Bodies (NBs) and invite them to issue a quotation for providing the necessary assessment services required by Annex X of the Machinery Directive 2006/42/EC. The NBs 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 NB. Once the manufacturer has decided to select a single NB to provide the necessary services that manufacturer shall be required to enter into an agreement (e.g. a contract) with that NB. In that agreement the manufacturer declares that they have not entered into a contract with any other NB to provide similar services for the same category or categories of machine. The selected NB will then request (if not already provided) the remaining information specified within clause 2.1 of Annex X.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.004 Revision : 3 Language : EN

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Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.1 - 2nd indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : manufacturer, sub-contractors, conformity, supplier, subsidiaries

Question :

Do substantial subcontract activities of the manufacturer need to be identified?

Recommended solution :

Yes. Where the manufacturers sub-contract the whole, or a significant part, of either design, manufacturing, inspection, testing or installation (where installation is part of the deliverable) they shall declare this to the Notified Body they have selected to provide the services required. Significant in this context can mean an important activity which could have a bearing upon the final conformity of the product with the applicable legislation/standards (examples are full design of the machinery, manufacturing of an important subassembly having direct impact on safety). This does not apply to safety components (e.g. light curtains) or basic sub-assemblies procured completely from a supplier. The machinery manufacturer is responsible for obtaining from his sub-contractor the information and documentation required for the application of the Annex X. If the manufacturer is not able to provide the required documentation this shall be considered to be a major nonconformity. For important subcontracting the Notified Body shall be required to visit the sub-contractor site. This shall be made by the Notified Body or on behalf of the Notified Body. It is the responsibility of the machinery manufacturer to ensure access. The basic principle is that the same logic shall be applied to a virtual manufacturer and a real manufacturer. If relevant work has been performed by different Notified Bodies at the sub-contractor site, this should be taken into account.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.005 Revision : 3 Language : EN

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Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.1 - 3rd indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : representative model, categories of machinery, risks

Question :

Who is choosing the model and what is the category?

Recommended solution :

The headline of Annex IV is: “Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied”.

Categories are therefore defined, i.e. each group of machinery listed in one of the paragraphs from 1 to 23 or paragraphs 1.1, 1.2, 1.3, 1.4, 4.1, 4.2, 12.1, 12.2.

Annex X clause 2.1 - 3rd indent refers to “one model of each category” this model is a representative sample that displays all the major hazards identified with the machinery.

For purposes of conformity assessment to Annex X, the Notify Body shall select a model that represents the most complex machine in each category form the complete list of the products manufactured.

Note: There is a mistake in the German edition of Annex X of the machinery directive. Annex X clause 2.1 - 3rd indent should read “für ein Baumuster” (“for one model”) instead of “für jedes Baumuster” (“for each model”).

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.006 Revision Language : EN

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Origin : VG13 Full quality assurance		X Vertical Group X Horizontal Committee X Standing Committee	2007-09-17 2007-12-04

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X. 2.1 3rd indent	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : EC declaration of conformity, technical file

Question :

Is it necessary to get a copy of the EC-declaration?

Recommended solution :

Yes. A copy of the EC declaration of conformity is a component of the technical file. That's why the applicant should submit a draft of the EC declaration of conformity to the NB.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.007 Revision 2 Language : EN

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Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X. 2.1 3rd indent	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : technical file, assessment on site, quality system

Question :

When has the technical file to be made available to the NB?

Recommended solution :

The technical file shall be made available to the NB before the assessment on site of the manufacturer is carried out. This is necessary, because the technical file will be used to validate the output of the quality system. The assessment of the quality system can only be positively finished if also the review of the technical file is positively finished. For this reason it is a recommendation for the machine manufacturer to submit the technical file as early as possible.

Note: When the NB has an experience on technical files related to specific categories of this manufacturer it may take it into account for the assessment of the technical files.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.008 Revision 1 Language : EN

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Origin : VG13 Full quality assurance		X Vertical Group X Horizontal Committee X Standing Committee	2007-09-17 2007-12-04

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X. 2.1 3rd indent	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : complete technical file, documentation, complex machinery, audit

Question :

Does the complete technical file have to be made available?

Recommended solution :

Yes. The complete technical file has to be made available to show that the quality system is capable of generating sufficient and complete documentation output according to the requirements of Annex VII, Part A.

For complex machinery, it might be difficult to submit a very voluminous and complete technical file before the audit on site. The content of the documentation to be sent before the audit can be reduced in agreement with the NB. During the audit all elements of the technical file must be available.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.009 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.1 - 4th indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : quality system documentation, quality management manual, certificates, audit reports, language

Question :

Shall the complete documentation according to Annex X clause 2.2 of the quality system be submitted to the Notified Body prior to the audit?

Recommended solution :

No, the applicant must make available a controlled copy of his quality management manual or any other type of documentation acceptable to the Notified Body (NB) in due time before the audit. This need not include all detailed processes but will focus on the procedures which were specifically developed in order to comply with the requirements of the directive. During the audit the complete documentation according to Annex X clause 2.2 must be checked.

The language of the provided documentation must be acceptable to the NB.

If the applicant requires the NB to take into account some elements already certified by another NB and or an accredited certification body, he shall provide the related certificates. Where appropriate the NB may require to review audit reports produced during the three last years.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.010 Revision: 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex: X clause 2.2 - 3rd indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : technical design specification, sample, manufacturing facilities, inspections, audit plan

Question :

What is the role of the Notified Body of reviewing the technical design specifications?

Recommended solution :

During the assessment of the quality system, the Notified Body will at first verify that the harmonised standards used by the manufacturer are the correct ones with regard to the different categories of machinery presented by the manufacturer. Care will be taken about the fact that there might be necessary to use different standards to cover the various types of machinery within one category.

The Notified Body will also pay attention to the procedures developed by the manufacturer in order to ensure that he uses the latest version of the relevant standard.

If harmonised standards are not used, or are partially used the Notified Body will evaluate the adequacy of the principles developed in order to demonstrate compliance with the requirements of the directive (see also CNB/M/13.009). The control of the effectiveness of these principles is made by the assessment of the technical file.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.011 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.2 - 2nd indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : harmonized standards, responsibility, design review

Question :

What is the role of the Notified Body for the assessment of the technical design specifications that do not comply fully with harmonized standards?

Recommended solution :

The Notified Body has to evaluate, whether the strategy for the selected means of the manufacturer is adequate to fulfil the requirements of the machinery directive. The manufacturer has to document the parts of a design which do not fully comply with harmonized standards and has to describe and justify (e.g. by risk assessment, use of approved practice, testing) the means that will be used to ensure that the essential health and safety requirements are fulfilled at least at an equivalent level of safety.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.012 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.2 - 3rd indent	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : design inspection, design verification, independence, level of confidence

Question :

Has the design inspection and design verification to be done by an independent person or department of the manufacturer?

Recommended solution :

No, unless it is required by the quality system of the manufacturer or an applied standard. This directive, and others such as the PE-Directive and Lift Directive, and the current issue of the standard ISO 9001:2000 do not explicitly require independence of persons or departments carrying out the design inspection and review. The manufacturer shall at least define responsibilities and competence for these persons and traceability of their actions. The manufacturer shall plan the inspection and review which shall be carried out under controlled conditions (instructions, checklists etc.). The final inspection shall include checking whether the design inspection and review has been performed correctly.

Note: It is good practice to have design inspection and design verification performed by a person not directly involved in this design process.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.013 Revision 2 Language : EN

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Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X. 2.2 3rd indent; 2.3 1st sentence	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : product complexity, validation, competency

Question :

How has the NB consider the complexity of the product?

Recommended solution :

The complexity of annex IV products may vary substantially. A circular saw with electro-mechanical control components only is for example less complex than a Logic Unit to ensure safety functions realized with several microprocessors (hardware and software) to control a work tool machine. The validation of the applied design process and the validation of the specific product need an adequate level of detail and therefore an adequate amount of time, which means that the conformity assessment process needs more time for complex products. At least one of the members of the audit team shall have appropriate competence in the technical field and in the corresponding ESHR of the MD.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.014 Revision : 3 Language : EN

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Origin : Horizontal Committee			

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.2 - 6th indent; clause 2.3 - 1st sentence	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : competency qualification of personnel, product specific requirements

Question :

How shall the Notified Body assess the qualifications of the manufacturer's personnel?

Recommended solution :

The Notified Body shall ensure that records are available to demonstrate the competencies of personnel undertaking tasks which could affect the conformance of the product with the relevant legislation/standards. Competency shall include, but not be limited to, product knowledge, experience of particular processes and awareness of the applicable quality system procedures, the relevant standards and the directive.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.015 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.2 - 7th indent; clause 2.3 - 1st sentence	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : machinery design, quality, compliance

Question :

How shall the Notified Body assess the means of monitoring the achievement of the required design and quality of the machinery?

Recommended solution :

There are two parts to this question:

In the first instance, the Notified Body (NB) has to check demonstrated "design" compliance with the requirement of the machinery directive. This compliance is assessed by sampling, mainly by examination of the representative technical files as defined by Annex X of the directive. In addition to the ability of the manufacturer to prepare an adequate technical file, it is important to assess the procedures developed in order to ensure that the different versions of the machinery will still comply with the requirements, taking into account the evolution of the state of the art.

In the second instance, the NB has to check the existence and application of procedures for effective control of the conformity of produced machinery to the "approved" design. These procedures must also ensure monitoring of subcontracted and/or licensed design and production. The manufacturer has to ensure that test or check result data are recorded and that annexed documents remain available for a period of ten years from the last date of manufacture of that product.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.016 Revision : 3 Language : EN

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Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.3	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : existing certification, conformance, certified quality system

Question :

Can the NB fully rely on an existing certificate (e.g. for ISO 9001:2000)?

Recommended solution :

No. A quality system certified to ISO 9001:2000 alone cannot be considered adequate to demonstrate conformance with the requirements of Annex X. An ISO 9001:2000 certified quality system must be adapted to integrate the additional requirements of the Machinery Directive (in particular Annex X) , but it is up to the Notified Body (NB) undertaking the assessment to determine the extent to further modification. Only a NB can issue certification of conformance with Annex X of the Machinery Directive and such NBs must take full and sole responsibility for such certification.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.017 Revision 1 Language : EN

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Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X.2.3	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : auditors, experts, competency

Question :

Must the team of the auditors consist of at least two persons?

Recommended solution :

No. The number of auditors shall be adequate for the size of the company or to the number of the people involved and the complexity and number of categories of machinery. If the auditor´s competence doesn't cover the scope, additional experts shall accompany the auditor(s). In this context the expert(s) shall not be regarded as an auditor.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.018 Revision 1 Language : EN

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Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X.2.3	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : EHSR, technical file, review

Question :

How deep shall the review of the technical file be if the purpose is to ensure its compliance with the relevant HSR?

Recommended solution :

Compliance with the essential health and safety requirements can only be ensured, if the technical file is reviewed in a similar manner to that required for module B, but without a detailed product inspection.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.019 Revision :3 Language : EN

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Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.4	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : product changes, changes of quality system, significant changes, contract

Question :

Is the planned change of the product covered by the planned change of the quality system?

Recommended solution :

One of the tasks of a Notified Boy (NB) in assessing and approving a full quality system is to review the technical file(s) for one model of each category of machinery referred to in Annex IV. A change of the quality system does not necessarily cause a change in the product nor - conversely - does a change of the machinery necessarily result in a change of the quality system. So the manufacturer shall only inform the NB about significant changes of the relevant technical files which may have implications on the quality system as well as direct changes of the quality system. It is recommended that contractual agreement between the NB and the manufacturer foresees the duty of the manufacturer to provide information on product changes and new products to the NB.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.020 Revision : 3 Language : EN

Number of pages : 1	Date : 2008-01-28	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.3	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : notification, report, certificate

Question :

How should a Notified Body notify its decision?

Recommended solution :

The Notified Body (NB) shall inform the Manufacturer or Authorised Representative of their assessment decision following the visit via a written report and/or an approval certificate. If this is not provided at the end of the assessment visit itself, the written report of findings and/or approval certificate should be submitted to the Manufacturer or Authorised Representative within a reasonable timeframe, normally within one month. Where approval certification is being withheld, the written report shall contain sufficient information and reasoned judgement to enable the Manufacturer or Authorised Representative to identify and take appropriate corrective action prior to requesting a further assessment visit. Whether issued via written report or an approval certificate, the NB shall ensure that certification is supported by a scope of approval, this will define exactly what has been approved in terms of products, manufacturing locations and any particular limitations.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.021 Revision : 3 Language : EN

Number of pages : 1	Date : 2008-01-28	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 3.3	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : audit frequency and duration, surveillance audits

Question :

How often have surveillance audits to be done by Notified Bodies?

Recommended solution :

The period between the audits should not be longer than 12 months. The duration and frequency of surveillance audits shall be determined by the Notified Body taking into account the complexity of the Manufacturer (e.g. number of sites, complexity of manufacturing processes, how much work is sub-contracted etc.), the products involved (e.g. the number and variety of individual products) and production volumes (e.g. higher volumes may require more frequent/longer visits). Also the former experience with this manufacturer may influence the duration and frequency of surveillance audits.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.022 Revision 1 Language : EN

Number of pages : 1	Date : 2007-10-08	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		X Vertical Group X Horizontal Committee X Standing Committee	2007-09-17 2007-12-04

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X.3.4	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : unannounced visits, contracts

Question :

Are there additional conditions for unannounced visits?

Recommended solution :

Annex X of the directive indicates some of the reasons which might induce the need of unannounced visits. The frequency of these visits is a matter for the NB to determine at its discretion and, as appropriate following co-ordination with other notified bodies, but should not be unreasonable.

A duly motivated complaint made to the NB by the Commission, a Member State, a manufacturer, another NB or any interested party is one of the factors which could trigger the need for an unexpected visit.

It is recognised that the NB may carry out tests (or have them carried out) on the product where this is necessary to verify the quality system. Such tests should generally be confined to instances where clear evidence demonstrates that there is reasonable doubt about the effectiveness of the quality system to ensure that the machinery made under it conforms to the essential requirements of the directive.

It is recommended that contractual agreement between the NB and the manufacturer foresees the possibility of these visits.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.023 Revision 1 Language : EN

Number of pages : 1	Date : 2007-10-08	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		X Vertical Group X Horizontal Committee X Standing Committee	2007-09-17 2007-12-04

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X.4	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : obligation to preserve

Question :

Does only the technical file referenced in to 2.1 of Annex X need to be kept available for the national authorities, for a period of ten years?

Recommended solution :

No. The manufacturer must also comply with Annex VII, 2.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.024 Revision 2 Language : EN

Number of pages : 1	Date : 2008-01-28	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 4	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : obligation to preserve, quality assurance system documentation

Question :

Shall the Notified Body check whether a manufacturer of the machine keeps each version of the quality assurance system documentation for at least 10 years?

Recommended solution :

Yes, the Notified Body must check whether a machine manufacturer keeps all versions of his quality assurance system which has had an effect on any Annex IV product for at least ten years after the last of those products was manufactured.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.025 Revision : 3 Language : EN

Number of pages : 1	Date : 2008-01-28	To be approved by :	Approved on :
Origin : VG13 Full quality assurance		☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	2007-09-17 2008-06-10

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 4	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : last date of manufacture

Question :

What is meant by the last date of manufacture as used in Annex X?

Recommended solution :

The last date of manufacture is the date upon which the last of a 'defined product' type is CE Marked with the intention of placing it on the market (be this into service or the supply chain). 'Defined product' means one that has a specific and unique identification name/number and is identified as such within a particular Technical File. The relevant records shall then be retained for a period of ten years from this last date of manufacture.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.026 Revision Language : EN

Number of pages : 1	Date : 2007-10-08	To be approved by : X Vertical Group X Horizontal Committee X Standing Committee	Approved on : 2007-09-17 2007-12-04
Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : audit frequency and duration, assessment

Question :

Is there a minimum requirement for the time to be allocated to the assessment?

Recommended solution :

The duration and frequency of assessment visits shall be determined by the NB taking into account the complexity of the Manufacturer (e.g. number of sites, complexity of manufacturing processes, how much work is sub-contracted etc.), the products involved (e.g. the number and variety of individual products) and production volumes (e.g. higher volumes may require more frequent/longer visits). Annex 2 of IAF Guide 62 should be used as a basis for determining a minimum baseline duration for the assessment visit (auditor time) to which additional time shall be added based upon experience gained from similar modules in other EC Directives.

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 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.028 Revision 2 Language : EN

Number of pages : 1	Date : 2008-05-08	To be approved by : ☑ Vertical Group ☑ Horizontal Committee ☐ Standing Committee	Approved on : 2007-09-17 2008-06-10
Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X clause 2.1 - 3rd indent; clause 2.3 - 3rd paragraph	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words : technical file, sample, manufacturing facilities, inspections, audit plan

Question :

What is the role of the Notified Body in the review of the technical file?

Recommended solution :

The role of the Notified Body (NB) is to check whether the technical file fulfils the EHSR of the MD and to verify that the quality system can produce the product in conformance with the technical file. It is not the responsibility of the NB to test the product.

When studying the technical file(s) submitted by the manufacturer, the NB prepares the audit and possible inspections at the places of design, manufacture, inspection, testing and storage. This will allow him to send an audit plan to the manufacturer before his assessment.

There are two steps in the review of the technical file.

1. The NB will make a specific analysis of one technical file duly selected for each category of machinery and provided by the manufacturer in the context of section 2.1 – 3rd indent.
2. During the audit, the NB will also review the existing technical files according to section 2.3 – 3rd paragraph. The main purpose here is to check that the existing files are established with the same approach as the sample selected for deeper analysis.

Note: For an annex X conformity assessment there will be no sample of the type of machinery to be examined at the site of the NB. All checks of samples to confirm compliance with the technical file have to be witnessed at the manufacturing facilities. A precondition to do these checks is the knowledge of the technical file of the representative model.

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) Essential safety requirement (3) N° of CEN/TC (Secretary & Chairman) (5) To be specified
(2) Horizontal Committee (4) EEC Standing Committee 89/392

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 2006/42/EC as amended RECOMMENDATION FOR USE	CNB/M/13.031 Revision : 2 Language : EN

Number of pages : 1	Date : 2008-12-09	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2009-05-12 ..... Endorsed on : .....
Origin :			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words:

Question:

What are the duties of the Notified Body when a major non-compliance with Annex X or a major non-conformity of a product with Annex I is detected?

Note: A major non-conformity is the absence of, or the failure to implement and maintain, one or more quality management system requirements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the conformity of what the manufacturer is supplying.

Recommended solution:

The Notified Body suspends the approval of the quality system and requires the manufacturer to resolve the non-conformities within the shortest possible time. If these are not corrected appropriately, the Notified Body withdraws the approval of the quality system.

Note: There are information obligations for the Notified Bodies according to Article 14.6 of Machinery Directive.

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 2006/42/EC as amended RECOMMENDATION FOR USE	CNB/M/13.032 Revision : 01 Language : EN

Number of pages : 1	Date : 2008-08-21	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2007.09.17 ..... Endorsed on : .....
Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words: equivalence to Annex IX

Question:

How should licensed products/components be dealt with in Annex X?

Recommended solution:

As a minimum the following requirements must be in place:

1. The own brand labelling manufacturers shall have their own Annex X certification and
2. The own brand labelling manufacturers shall have a legal cooperation agreement with the original manufacturer. The agreement should include: see NB-MED 3/7

Note: Own brand labelling means …. (NB-MED 2/7)

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 98/37/EC (formerly 89/392/EEC + amendments) RECOMMENDATION FOR USE	CNB/M/13.033 Revision Language : EN

Number of pages : 1	Date : 2008-08-21	To be approved by : X Vertical Group X Horizontal Committee X Standing Committee	Approved on : .....
Origin : Horizontal Committee			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X..2.3.	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words : quality system, audit plan

Question :

What kind of documentation is to be delivered to the manufacturer by the Notified Body (audit plan)?

Recommended solution:

The programming and planning of audits is an essential process in the satisfaction of the needs and expectations of both Notified Body and applicant.

An audit plan should be sent to the manufacturer. The audit plan should cover

- Identification of the applicable standard (for instance ISO 9001:2000) and type of audit (initial assessment, surveillance….)
- The dates of the audit
- The planned duration of each significant audit event
- Indication of the activities and clauses to be audited. Depending on the results of previous surveillance visits, focus can be set on some parts of the quality system concerned with design and/or manufacture (results of calculations, reports on the qualification of the personnel concerned ….)
- Identification of the audit team members
- Identification of the language of the audit
- Indication of the sites to be audited

The audit plan should be sent to the client at least five working days prior to the audit.

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 as amended RECOMMENDATION FOR USE	CNB/M/13.034 Revision : 2 Language : EN

Number of pages : 3	Date : 2008-08-21	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2009.05.12 ..... Endorsed on : .....
Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article : -	EN/prEN : -	Other : -
Annex : X	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words: certificate

Question:

What are the minimum contents of an Annex X approval certificate?

Recommended solution:

A certificate of an Annex X approval of a quality assurance system shall contain as a minimum, the;

- manufacturers name and address;
- scope of approval, including category and/or sub-category of machines according to Annex IV and generic product description
- limitations of the approval (if any);
- date of issue;
- date of expiry;
- issuing Notified Body; and
- person within the Notified Body authorising the certificate
- names and addresses of the sites which have been assessed.

The above reflects the minimum information necessary, but is not an exhaustive list.

An example certificate is attached to this RfU. The names and addresses of the sites assessed shall be listed in an annex to the certificate.

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified

Example Certificate

EC APPROVAL OF A QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Machinery Directive 2006/42/EC

This is to certify that the Full Quality Assurance System of:

<Company Name>
<Company Address>
<Company Address>

has been assessed against the requirements of Annex X of Machinery Directive 2006/42/EC and conforms to the requirements for the following scope of approval:

Design and manufacture of *<generic product description and any applicable limitations>*

This certificate is only valid when accompanied by a current schedule with the same number detailing the categories of machinery corresponding to this approval.

Approval is subject to the continued surveillance of the Full Quality Assurance System in accordance with the requirements of the above Directive. Unauthorised changes to the Full Quality Assurance System will render this approval invalid.

Authorisation is hereby given to use the Notified Body Identification Number in accordance with the requirements of the specified Directive in relation to the categories of machinery identified in this certificate and accompanying schedule.

Certificate No:	**<Certificate *Number*>**
Original Approval:	***<Original Issue Date>***
Current Certificate:	***<Subsequent Issue Date>***
Certificate Expiry:	***<Expiry Date>***
Notified Body Number	**<NB *Number*>**

_____

Issued by: ***<NB Signatory>***

EC APPROVAL OF A QUALITY ASSURANCE SYSTEM
CERTIFICATE <*Certificate Number*> SCHEDULE

In accordance with the requirements of the
Machinery Directive 2006/42/EC

<*Company Name*>
<*Company Address*>
<*Company Address*>

Only the following specific categories of machinery (as defined within Annex IV of the above Directive) are covered by this approval of a quality assurance system:

Annex IV Clause	Category Description

Schedule Issue: ***<Schedule Number>***

Date of Schedule Issue: ***<Schedule Date>***

Notified Body Number ***<NB Number>***

_____

Issued by: ***<NB Signatory>***

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 2006/42/EC as amended RECOMMENDATION FOR USE	CNB/M/13.035 Revision : 2 Language : EN

Number of pages : 1	Date : 2008-12-09	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2009-05-12 ..... Endorsed on : .....
Origin :			

Question related to : 2006/42 EC	Article :	EN/prEN :	Other :
Annex : X	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words: Subcontract

Question:

How should subsidiaries of the manufacturer be dealt with?

Recommended solution:

The Machinery Directive 2006/42/EC requires that the 'manufacturer' (e.g. *the person taking legal responsibility for placing the product on the market in their name*) fulfils the requirements of an appropriate Conformity Assessment Procedure.

One possible option for an Annex IV product is the Full Quality Assurance procedure under Annex X. In this instance the Notified Body must assess the 'manufacturers' quality system to determine conformity with the requirements of Annex X. This assessment must include a visit to all manufacturing sites pertinent to ensuring the conformity of the product with the specified requirements, including those of subsidiaries of the 'manufacturer'. In such circumstances the Notified Body shall include details of the subsidiary's address within the certificate of approval. This assumes that the subsidiaries are relevant to the certification.

If the subsidiary of the 'manufacturer' intends to place the product on the market in their own name then they are taking on the role of the 'manufacturer' and consequently must fulfil the requirements of an appropriate Conformity Assessment Procedure in their own right. Care shall be taken of the rights of the original manufacturer including intellectual property rights.

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 2006/42/EC as amended RECOMMENDATION FOR USE	CNB/M/13.036 Revision : 1 Language : EN

Number of pages : 1	Date : 2007-10-08	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2009.05.12 ..... Endorsed on : .....
Origin : VG13 Full quality assurance			

Question related to : 2006/42/CE	Article : -	EN/prEN : -	Other : -
Annex : X	EHSR (1) : -	Normative clause : - CEN TC concerned : -	Other clause : -

Key words: product

Question:

Is it possible to certify a full quality assurance system under Annex X before a product has been developed and manufactured according to this system?

Recommended solution:

There are two answers to this question depending upon whether:

a) it is the original assessment of a Full Quality Assurance System under the Machinery Directive 2006/42/EC: or
b) it is an assessment of the Full Quality Assurance System for an additional 'category of machinery'.

The answer to the above question would therefore be:

a) No. Because without having developed, manufactured and tested an appropriate product it would be impossible to demonstrate effective implementation of the required Full Quality Assurance System due to the lack of records and objective evidence;
b) Yes, providing that:
    a. effective implementation of the Full Quality Assurance System has already been adequately demonstrated for another 'category or machinery'; and
    b. this same system is intended to also be applied to the development and manufacture of the new 'category or machinery'; and
    c. the Notified Body has reason to be confident in the effective functioning of the existing Full Quality Assurance System.

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES Machinery Directive 2006/42/EC as amended RECOMMENDATION FOR USE	CNB/M/13.037 Revision : 1.0 Language : EN

Number of pages : 1	Date : 2009-05-12	To be approved by : ☑ Vertical Group ..... ☐ Horizontal Committee ..... To be endorsed by : ☐ Machinery Working Group	Approved on : ..... 2009-05-12 ..... Endorsed on : .....
Origin : VG13 Full quality assurance			

Question related to : 2006/42/EC	Article :	EN/prEN :	Other :
Annex : X clause 3.2	EHSR (1) :	Normative clause : CEN TC concerned :	Other clause :

Key words: surveillance, quality system, technical file

Question:

According to Annex X, 2.1 the manufacturer has to lodge an application for assessment of this quality system containing the technical file for one model of each category of machinery he intends to manufacture. Is it acceptable if in the process of approval of the technical file there is no possibility to see the product during the assessment of the quality system by the Notified Body?

Recommended solution:

No. At the very first audit the NB has to see at least one model of each category of machinery to assess the full quality assurance system. Where this model is different from the technical file that was audited a model of equivalent complexity has to be assessed at least once during each period of three years.

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.

Sent for information to: ☑ members of the VG ☐ other(s) VG ☐ HC (2) ☐ TC (3) ☐ SC (4) ☐ other (5)

(1) Essential Health and Safety Requirement
(2) Horizontal Committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) Machinery Working Group
(5) To be specified