Horizontal Recommendation for Use sheets (RfUs)
of the European Coordination of Notified Bodies in the field of PPE 5ƛǊŜŎǘƛǾŜ уфксуск99 /

Number of RfU	Version	Reference	Keywords	Approved by Horizontal Committee	Approved by PPE Expert Group
00.001	01	Directive 89/686/EEC, Article: 12	Declaration of conformity	24/06/94	01/07/96
00.002	03	Directive 89/686/EEC, Annex: III, 2	Technical file, control and test facilities	31/05/96	03/06/97
00.003	01	Directive 89/686/EEC, Article: 7	EC type examination certificate, withdrawal	24/06/94	01/07/96
00.005	04	Directive 89/686/EEC, Article: 10.2	Type examination certificate	24/01/13	01/10/15
00.006	04		Sub-contracting, accreditation, acceptance of test results, competence of laboratories	31/05/96	03/06/97
00.007	04	Directive 89/686/EEC, Article: 10.5, 85/374/EEC	Retention, technical file, samples, liability	24/01/13	01/10/15
00.008	02	Directive 89/686/EEC, Annex: II, 1.4	User information, availability	24/06/94	01/07/96
00.010	01	Directive 89/686/EEC, Annex : II, 1.4	User information, conformity assessment	24/06/94	01/07/96
00.011	01	Directive 89/686/EEC, Annex III	Technical file	24/06/94	01/07/96
00.012	04	Directive 89/686/EEC, Article 10.2	EC type examination, application	31/05/96	03/06/97
00.013	03	Directive 89/686/EEC, Article 10.5, 10.6	Type examination certificate, withdrawal, extension, refusal	31/05/96	01/07/96
00.014	02		Certification, modified model	24/06/94	01/07/96
00.015	01	Directive 89/686/EEC, Article 8.2	Limited series, individual items of PPE	24/06/94	01/07/96
00.016	03	Directive 89/686/EEC, Article 10.4	EC type examination procedure, harmonised standards	31/05/96	03/06/97
00.017	01		Test reports	24/06/94	01/07/96
00.018	03	Directive 89/686/EEC, Article 10.4	Standards, deficiencies	31/05/96	03/06/97
00.019	01	Directive 89/686/EEC, Annex II, 1.4	User information	24/06/94	01/07/96
00.020	01		Testing of materials	24/06/94	01/07/96
00.021	01		Type examination certificate, modification of products	24/06/94	01/07/96
00.022	01		Identification of test samples	24/06/94	01/07/96
00.023	02	Directive 89/686/EEC, Article 11 A.1	Quality control, manufacturer	31/05/96	01/07/96
00.024	02	Directive 89/686/EEC, Article 11 A.2	Quality control, checks	31/05/96	01/07/96
00.025	02	Directive 89/686/EEC, Article 11 A.2	Quality control, application of CE marking	31/05/96	01/07/96
00.026	03	Directive 89/686/EEC, Article 11 A.2	11A checks, time interval, random	22/11/13	01/10/15
00.029	01		CE marking, categories	24/06/94	20/05/95
00.030	04	Directive 89/686/EEC, Article 11 A.2	Necessary checks	27/05/98	20/04/98
00.031	02	Directive 89/686/EEC, Article 11 B	Article 11B, withdrawal of certificates	22/11/13	01/10/15
00.032	01		Manufacturer, authorized representative	02/06/95	01/07/96
00.034	02	Directive 89/686/EEC, Article 10	Type examination: contents of technical file, technical documentation	01/06/95	18/11/97
00.036	03	Directive 89/686/EEC, Annex II, 1.4 (e)	Period of obsolescence	24/01/13	01/10/15

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00.038	03	Directive 89/686/EEC	Components from different manufacturers	27/05/98	20/04/98
00.046	04	Directive 89/686/EEC	Marking, standard reference, testing according to prEN	26/05/99	21/06/99
00.048	03	Directive 89/686/EEC, Article 11 A	Sampling 11 A procedures	04/06/97	20/04/98
00.051	04	Directive 89/686/EEC, Article II, 1.4	Use of pictograms	23/02/00	15/01/02
00.052	03		Test reports, designation of materials	04/06/97	20/04/98
00.058	03		Test reports, materials	04/06/97	20/04/98
00.061	03		Slip resistance, type examination certificate		18/11/97
00.064	03	Directive 89/686/EEC	Type examination for category I PPE	04/06/97	20/04/98
00.068	05	Directive 89/686/EEC	Revision of standard, validity, EC type examination certificate	26/05/99	21/06/99
00.074	04	Directive 89/686/EEC, Article 11 A	Change of certificate	04/06/97	20/04/98
00.075	04	Directive 89/686/EEC, Article 10.2, 11 A, 11 B	Distribution, type examination certificate	04/06/97	20/04/98
00.077	07	Directive 89/686/EEC, Annex II, 1.4	Information to users	05/05/06	31/07/06
00.080	02	Directive 89/686/EEC, Article 10	Production Plant		18/11/97
00.081	03	Directive 89/686/EEC, Article 1.2 (c)	Interchangeable components, EC type examination	27/05/98	21/06/99
00.086	08	Directive 89/686/EEC, Article 11 B	Composition of audit team; competency of auditors; knowledge of auditors	22/11/13	01/10/15
00.087	06		Quality assurance system	22/11/13	01/10/15
00.088	04	Directive 89/686/EEC, Article 11.B (2)	Quality Assurance System, Supervision, Frequency of Audits	05/01/98	20/04/98
00.089	03	Directive 89/686/EEC, Article 11.B (c)	ISO 9001/2/3:1994	05/01/98	20/04/98
00.090	04	Directive 89/686/EEC, Article 11.B (b) 11.A.3		22/11/13	01/10/15
00.092	02	Directive 89/686/EEC, Annex II, Article 1.4 (i)	Notified body reference, information supplied by the manufacturer	26/05/99	21/06/99
00.093	02	Directive 89/686/EEC	Element, CE marking	27/05/98	21/06/99
00.094	02	Directive 89/686/EEC	Harmonised standards, essential requirements, EC type examination	27/05/98	21/06/99
00.095	02	Directive 89/686/EEC, Article 10, 4 (b)	Technical file	26/05/99	29/11/99
00.096	06	Directive 89/686/EEC, Annex II, 1.2.1.1	Innocuousness of PPE	04/07/01	15/01/02
00.098	03	Directive 89/686/EEC, Article 10	Conformity to standard	23/02/00	15/01/02
00.099	02	Directive 89/686/EEC	CE marking, separate items of PPE, technical file	27/05/99	29/11/99
00.104	02	Directive 89/686/EEC, Article 8.4 a	Category; certification	23/02/00	15/01/02
00.106	04	Directive 89/686/EEC, Article 11.B.2	Re-assessment of approved quality system	02/12/04	30/06/05
00.107	02	Directive 89/686/EEC, Article 11.A.3	Sample selection	27/10/00	15/01/02
00.109	03	Directive 89/686/EEC, Article 11.A	11.A test clauses	05/05/06	31/07/06

Number of RfU	Version	Reference	Keywords	Approved by Horizontal Committee	Approved by PPE Expert Group
00.113	03	Directive 89/686/EEC, Annex III, Article 10	Test and Inspection of Production	12/12/02	11/06/03
00.114	03	Directive 89/686/EEC, Article 8.4, 11.A, 11.B	Manufacture	05/09/02	11/06/03
00.117	02	Directive 89/686/EEC, Annex II, 1.2.1.1	Information supplied by the manufacturer; sensitising or allergenic substances	05/09/02	11/06/03
00.118	02	Directive 89/686/EEC, Article 8	Categorisation; welding	05/09/02	11/06/03
00.120	01	Directive 89/686/EEC, Article 11.A.3	Category III product	06/09/02	11/06/03
00.122	03	Directive 89/686/EEC, Article 10 and 11 A	Retention of representative samples	03/12/04	30/06/05
00.123	06	Directive 89/686/EEC, Article 10 and 11 A	External testing	05/11/15	04/04/16
00.124	02	Directive 89/686/EEC	Boil-and-bite mouth guards	03/12/05	30/06/05
00.125	05	Directive 89/686/EEC, Article 11.A	Uniformity of production; Article 11.A	24/06/09	20/04/11
00.126	02	EN 17025, Clause 5.10.3.1 c.)	Uncertainty of measurement	26/08/05	31/07/06
00.127	03		Dedicated test method standards	24/01/13	01/10/15
00.128	02	Directive 89/686/EEC, Article 1, 2 c.)	Interchangeable components of breathing apparatus	05/05/06	31/07/06
00.129	02	Directive 89/686/EEC, Article 1, 2 c.)	Interchangeable components of breathing apparatus	05/05/06	31/07/06
00.130	02	Directive 89/686/EEC	Own-brand certificates	05/05/06	31/07/06
00.131	02	Directive 89/686/EEC	Standard template for report content covering annual assessment process	09/02/07	15/07/08
00.132	02	Directive 89/686/EEC	Sizing	09/02/07	15/07/08
00.133	02	Directive 89/686/EEC, Article 10 / 11	Traceability of article 10 technical file documents	09/02/07	15/07/08
00.134	02	Directive 89/686/EEC, Article 10, 11	Article 11 assessment, EC type examination certificate	09/02/07	15/07/08
00.135	04		11B minimum requirements	18/10/09	20/04/11
00.136	06	Directive 89/686/EEC, Article 10	EC type examination certificates; validity	14/11/14	01/10/15
00.137	03	Article 11 A.2, RfU sheet 125, 2B(iii) and 2B(iv)	Failure of 11A samples	31/08/09	20/04/11
00.138	03	Directive 89/686/EEC, Article 10	EC type-examination, certificate format	12/05/11	15/05/12
00.139	02	Directive 89/686/EEC	Marking, standard number	19/03/10	20/04/11
00.140	02		Product marking; reference to standards	19/03/10	20/04/11
00.141	02	Directive 89/686/EEC, Annex 2, 1.4	Information supplied by the manufacturer, address of manufacturer	19/03/10	20/04/11
00.143	02	Directive 89/686/EEC, Article 11.A.3		01/03/12	30/08/12
00.144	00		Instructions for use	22/11/13	01/10/15
00.145	00	89/686/EEC, Article 10 / Article 11A / 11B	Article 11A, 11B, non-conform product, unsafe design	22/11/13	01/10/15
00.146	01	89/686/EEC, Article 11A.2, RfU sheet 125, 2B(iii) and 2B(iv)	11A samples and process / production dormant	24/01/13	01/10/15
00.147	00	89/686/EEC, Article 11A.3	11A samples / frequency of specific tests	14/11/14	01/10/15

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.001 Revision 01 Language : E

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		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 12	Clause :	

Key words :

declaration of conformity

Question :

Which purpose does the declaration of conformity of the manufacturer serve?

Is it to be presented with each delivery of a PPE?

Solution :

The declaration of conformity has to be drawn up by the manufacturer to certify that the PPE placed on the market is in conformity with the directive; it is the basis for CE marking.

The general opinion is that the declaration of conformity is to be issued by the manufacturer only once and has to be kept with the documentation of the manufacturer.

This documentation has to be presented to the authorities on request.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.002 Revision 03 Language : E

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Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : III, 2 Article :	Clause :	

Key words :

technical file, control and test facilities

Question :

Which minimal requirements are to be established for the control and test equipment of the manufacturer?

Some notified bodies consider the verification of the manufacturer's control and test equipment a part of the type examination, others argue that this is not necessary, since article 10.4 (a) of the directive refers to the manufacturer's technical file, which according to annex III does not include the description of the control and test facilities.

Solution :

The requirements must be seen in connection with the technical file mentioned in the directive which must describe the control and testing. The notified body must be convinced that the system described is sufficient.

The verification of the control and test equipment of the manufacturer is required only in relation to quality control according to article 11 B.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.003 Revision 01 Language : E

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Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 7	Clause :	

Key words :

EC type examination certificate, withdrawal

Question :

On which basis can a valid EC type examination certificate be withdrawn?

Solution :

An EC type examination certificate has to be withdrawn as soon as the notified body gets knowledge of any circumstances indicating that the tested model of the PPE does no longer meet the requirements of the directive for reasons which had not been known at the time when the certificate was issued.

It is recommended to note on the document that the certificate is the property of the notified body.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.005 Revision 04 Language : E

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		☑ Standing Committee	.....01/10/2015

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.2	Clause :	

Key words :

type examination certificate

Question :

Is it possible to issue certificates for one and the same product to different applicants (such as manufacturer and other economic operators)?

Solution :

No, there can only be one type examination certificate for each single named product.

It was, however, acknowledged that the manufacturer can issue several declarations of conformity on the basis of this type examination certificate.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.006 Revision 04 Language : E

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		☑ Standing Committee	.....03/06/97

Question related to :	EN/prEN :	Other :
Annex : Article :	Clause : [other]	

Key words :

sub-contracting, accreditation, acceptance of test results, competence of laboratories

Question : Is it possible for a certification body to accept test data obtained by other than accredited laboratories?

Are test reports from authorities outside the Community acceptable for the purpose of CE marking?

If this is so, what is the minimum criteria to be used in judging their competency and how should they be monitored?

What quality control methods should be applied to sub-contracting laboratories?

Can the notified body use test reports on materials, items or components carried out by other specialised laboratories?

Can the notified body use reports on tests carried out by the manufacturer or the applicant?

Solution :

Under all circumstances, the notified body takes on the responsibility for test results/test reports it accepts as the basis for certification.

Therefore, it should generally be recommended to use test results from accredited test laboratories only.

As this will not always be possible, other sources of testing have to be used. Sub-contracting laboratories should meet the requirements according to ISO / IEC 17025, if this is not the case, the notified body has to ensure by other means that the test results are reliable.

The notified body itself will have to specify the conditions for the acceptance of other test laboratories to carry out the tests. In all cases, a sub-contracting laboratory must satisfy condition (3) of Annex V of the directive.

Quality control measures for sub-contracting test laboratories are important, the notified body itself is responsible for deciding how to proceed with this.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.007 Revision 04 Language : E

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Question related to : Directive 89/686/EEC	EN/prEN :	Other : 85/374/EEC
Annex : Article : 10.5	Clause : [other]	

Key words :

retention, technical file, samples, liability

Question :

For how long must the EC type examination files, reference samples and tested items be stored?

Solution :

The directive specifies that the technical file will have to be held at the disposal of the authorities for 10 years following the placing on the market of the PPE.

In addition, the specifications of the product liability directive (85/374/EEC) should be taken into consideration.

Note:

The technical file should be retained by the manufacturer and the notified body.

For the retention of samples see RfU 00.122.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.008 Revision 02 Language : E

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Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : II, 1.4 Article :	Clause :	

Key words :

user information, availability

Question :

Questions have been raised concerning the user information to be supplied by the manufacturer, especially with regard to protective gloves.

Some notified bodies seem to interpret the directive and EN 420 (protective gloves) to mean that it is sufficient, if the user information is available on request, whereas other notified bodies require the user information to be supplied with each item of PPE.

Solution :

The user information should be supplied with each item of PPE (the smallest commercial package available) as it is believed that this is the spirit of the directive and provides the information where and when it is most needed.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.010 Revision 01 Language : E

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		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : II, 1.4 Article :	Clause :	

Key words :

user information, conformity assessment

Question :

Notified bodies that carry out certification procedures for foreign manufacturers have to decide what language version of the user information will be checked in the framework of conformity assessment.

Solution :

The notified body can choose which languages it does accept for testing. Any translation is the responsibility of the manufacturer / authorized representative. It would be useful, however, to note in the test report which language version was checked.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.011 Revision 01 Language : E

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		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : III Article :	Clause :	

Key words :

technical file

Question :

What does the manufacturing technical file have to contain?

Solution :

A complete list of the information to be included in the technical file is laid down in annex III of the directive.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.012 Revision 04 Language : E

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		☑ Standing Committee	.....03/06/97

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.2	Clause :	

Key words :

EC type examination, application

Question :

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?

Solution :

The manufacturer will be asked for a written confirmation that he has not submitted the same file to another notified body and that the model presented for examination has not been the subject of any previous EC type certificate refusal decision.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.013 Revision 03 Language : E

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Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.5, 10.6	Clause :	

Key words :

type examination certificate, withdrawal, extension, refusal

Question :

How should:
- the EC type examination certificate
- the withdrawal of an EC type examination certificate
- an EC type certificate extension
- an EC type examination certificate refusal

be written?

Solution :

The general points to be included in the documents are laid down in the directive, the notified bodies being free to decide on the form of presentation.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.014 Revision 02 Language : E

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		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause : [other]	

Key words :

certification, modified model

Question :

What is the procedure to be applied to the examination of variants of a PPE?

Which criteria should be taken into account for the certificate?

Solution :

The notified body is free to decide whether it will grant extensions to existing certificates or it prefers issuing a new certificate for the variant to be certified.

A PPE is considered as a variant of a reference PPE 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 constituent materials, colour, assembly methods, manufacturing processes etc.
It will be useful to consider in the vertical groups what criteria allow for acceptance of a modified model, e.g. modifications with regard to accessories, colours, types of glues, an additional size, etc. which do not change the essential functions of protection.
It is the responsibility of the notified body to evaluate for each individual case if a given PPE 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 examples of these variants required for complementary checks and tests.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.015 Revision 01 Language : E

Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 8.2	Clause :	

Key words :

limited series, individual items of PPE

Question :

What is the EC type examination procedure for limited series and PPE manufactured singly?

Solution :

In the logic of the EC directives, the model of the PPE (prototype) has to be submitted to an EC type examination before serial production starts.

exceptions: pre-prototypes and research prototypes

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.016 Revision 03 Language : E

Number of pages : 1	Date : 14/07/97	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....31/05/96
		☑ Standing Committee	.....03/06/97

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.4	Clause :	

Key words :

EC type examination procedure, harmonised standards

Question :

What is the procedure to be applied to the EC type examination in the absence of test methods provided by the appropriate harmonized European standards?

Solution :

The notified body has to decide what will be the basis for testing against the requirements of the directive.

The manufacturer has to set the specification for the product and ask for certification against this specification. Under normal circumstances, the specifications of the manufacturer will remain strictly confidential.

The notified body is responsible for assessing whether or not the specification meets the applicable requirements of annex II and determining whether or not the submitted PPE does comply with the requirements.

It is recommended to refer to existing standards (national or ISO (international)) whenever possible.

If this is not possible, the notified body should identify the objectives to be reached in testing for conformity with the requirements and specify test procedures appropriate for the EC type examination.

The proposed method may be discussed with the notified bodies if this is necessary. If there is a general interest in a harmonization of the test procedure, the subject should be brought into the European standardization committee responsible.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.017 Revision 01 Language : E

Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

test reports

Question :

presentation of test reports

Solution :

It was generally agreed that no harmonized format is necessary for the presentation of test reports.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.018 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....31/05/96
		☑ Standing Committee	.....03/06/97

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.4	Clause :	

Key words :

standards, deficiencies

Question :

What action should be taken if deficiencies or mistakes in standards are detected?

Solution :

Deficiencies and mistakes in standards always have to be discussed in the relevant CEN/TC or WG. Therefore, as soon as any such mistake is recognized, the appropriate body has to be informed and asked to take action for a possible revision of the standard as soon as possible.

In addition to that, the problem should be discussed within the vertical group so that a general approach to the problem is laid down and the notifed bodies can agree how to proceed with the testing before a revision of the standard is published. The relevant TC or WG should be informed of any such interim solution.

If the problem is of general interest, the Horizontal Committee should be informed so that the subject can be discussed at Horizontal Committee level and, if necessary, with the relevant CEN authorities.

The European Commission will receive lists of the existing Recommendation for Use sheets for information.

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

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

PPE	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.019 Revision 01 Language : E

Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
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		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : II, 1.4 Article :	Clause :	

Key words :

user information

Question :

On which point should the verification on the information/instruction notice provided by the certificate applicant be focused?

Solution :

Within the EC type examination framework, the notified body ensures that the information/instruction notice from the manufacturer or applicant covers all the items of article 1.4 of annex II of directive 89/686/EEC modified and that it is presented in an accurate and understandable way.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.020 Revision 01 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

testing of materials

Question :

Is it permissible to carry out tests on materials, parts or components identical to those comprising the PPE instead of carrying out tests on the PPE itself? If so, what are the conditions to be met for type approval and for production control?

Solution :

It is possible to carry out tests on materials described in the standards with the sample taken either on the PPE itself or on a sample of the material if the manufacturer attests (in writing) that it is strictly identical to that used in the construction to the PPE and if the notified body can confirm the identity by examination of the reference PPE and the samples supplied. This procedure should be limited to a specific case as, for example, when referring to high cost PPE produced in small quantities.

The applicant has to supply one example of the PPE submitted to EC type examination so that the notified body can check that the materials or items put forward for testing are indeed identical to those composing the PPE.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.021 Revision 01 Language : E

Number of pages : 1	Date : 15/07/96	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other : Clause :

Key words :

type examination certificate, modification of products

Question :

What should the manufacturer or his authorized representative established in the Community do in the case of a modification to a PPE model having been the subject of an EC type examination certificate?

Solution :

The directive does not explicitly provide for the case of modification of a PPE model having been the subject of an EC type examination certificate.

The manufacturer or his authorized representative established in the Community has to inform the notified body that delivered the EC type examination certificate of any intended modification of the PPE.

The notified body then has to decide whether the modification does or does not require new type examination procedures.

If the modification only involves minor changes not affecting the safety characteristics of the product, the notified body informs the applicant that the EC type examination certificate will continue to be valid for the modified mode. It may then either deliver a type examination certificate extension or a new certificate.

If the modification consists of major changes to the product, the notified body has to inform the manufacturer or the authorized representative that the certificate cannot be transferred to the modified model. If the manufacturer intends to keep the modifications, he will be required to make a new official request for an EC type examination.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.022 Revision 01 Language : E

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		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

identification of test samples

Question :

What are the measures to be taken for the identification of tested models for any subsequent controlling inspection or expertises?

Solution :

There must be no ambiguity regarding the identification of the PPE having been submitted as a type (model) to a notified body for EC type examination.

PPE placed on the market are the subject of the tested type declaration of conformity.

The following is recommeded:

- the alphanumeric reference of the models must be provided by the manufacturer with an indication of its meeting
- the photographs needed for correct identification of the PPE must accompany the certificate and a copy of these photographs must be archived with the file by the notified body
- an example of the PPE in a finished state can be archived by the notified body when this is possible
- if this is not possible, representative samples will have to be stored.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.023 Revision 02 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....31/05/96
		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A.1	Clause :	

Key words :

quality control, manufacturer

Question :

Article 11 A of the directive refers to "a manufacturer", but who is "a manufacturer"?

Solution :

Agreement that the manufacturer in this context must at least carry out the final assembly of the PPE. This is necessary due to the responsibility to ensure homogeneity of production, which can only be achieved through controlling the manufacturing process.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.024 Revision 02 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....31/05/96
		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A.2	Clause :	

Key words :

quality control, checks

Question :

At what frequency should the required "necessary checks" (as referred to in article 11 A) be carried out?

Solution :

A minimum of one per year, the year starting from the date of issue of the certificate.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.025 Revision 02 Language : E

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		☑ Horizontal Committee	.....31/05/96
		☑ Standing Committee	.....01/07/96

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A.2	Clause :	

Key words :

quality control, application of CE marking

Question :

Should the checks referred to in article 11 A.2 be carried out before the application of the CE marking or afterwards?

Solution :

As a minimum the manufacturer must have entered into a formal agreement with a notified body for assessment against 11 A. This is explicit in article 12 of the directive, whereby the EC declaration is drawn up before the application of the CE marking and part of the declaration states which body is/will be supervising the 11 A procedure.

The amending directive covering the application of the CE marking requires the number of the notified body responsible for administering article 11 to be added to the marking. It would appear sensible for notified bodies to have checked a company's control procedure before agreeing to its number being marked on the product.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.026 Revision 03 Language : E

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Origin : Horizontal Committee, Article 11 ad hoc group		☑ Ad hoc group	.....21/11/2013
		☑ Horizontal Committee	.....22/11/2013
		☑ Standing Committee	.....01/10/2015

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A.2	Clause :	

Key words :

11A checks, time interval, random.

Question :

What does "random" mean (in article 11 A.2)?

Solution :

For on-site assessments and sampling, the interval between visits to be varied, and for remote sampling selection without the manufacturer's advance knowledge, where possible. Where samples are to be selected from distributors, warehouses etc. it will be necessary to arrange visits directly with the people concerned.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.029 Revision 01 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/06/94
		☑ Standing Committee	.....20/05/95

Question related to : Annex : Article :	EN/prEN : Clause :	Other :

Key words :

CE marking, categories

Question :

CE marking according to the directive 93/68/EEC does not provide for a clear distinction between categories I and II. Is it possible to amend the provisions on CE marking so as to include a distinction, as this is considered to be helpful to the user?

Solution :

At the moment there is no intention to change the situation by another amending text.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.030 Revision 04 Language : E

Number of pages : 1	Date : 15.12.2009	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....27/05/98
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A.2	Clause :	

Key words :

article 11 A , necessary checks

Question :

What are the necessary checks required under article 11 A.2?

Solution :

Each certified model to be selected by the notified body at least once per year. The notified body has an obligation to sample and test products that adequately represent the products within the family / group of products.

The selected sample(s) must be checked for compliance with the type described in the EC type approval certificate and the relevant basic requirements of the directive.

That means, the compliance with 11 A is checked by every model tested once a year, no assessment of the manufacturing process.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.031 Revision 02 Language : E

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Origin : Horizontal Committee Article 11 Ad hoc group		☑ Ad hoc Group.....	.....21/11/2013
		☑ Horizontal Committee	.....22/11/2013
		☑ Standing Committee	.....01/10/2015

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 B	Clause :	

Key words :

Article 11 B, withdrawal of certificates

Question :

What procedure should be followed in the event of failures during 11 B assessments?

Solution :

In the event of failures in 11 B assessments, the notified body concerned has to decide in each individual case, taking into account the reasons that lead to the failure and the risks involved.

In serious cases, e.g., major nonconformities issued against either the system or the product, the notified body should proceed to withdraw their 11B approval; in that case the Member State giving notification will have to be informed.

NOTE: The failures can concern both quality system failures and product performance failures.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.032 Revision 01 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....02/06/95
		☑ Standing Committee	.....01/07/96

Question related to : Annex : Article :	EN/prEN :	Other : Clause :

Key words :

manufacturer, authorized representative

Question :

The directive always refers to the manufacturer or his authorized representative established in the Community. Can manufacturers worldwide act equivalent to companies in the Communnity?

Solution :

The PPE group of the Standing Committee 89/392/EEC stated that the directive 89/686/EEC does not distinguish between the manufacturer's location inside or outside the EEA. Only (authorized) representatives need to be based in the EEA.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.034 Revision 02 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....01/06/95
		☑ Standing Committee	.....18/11/97

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : III Article : 10	Clause :	

Key words :

type examination: contents of technical file, technical documentation

Question :

Which documents are part of the technical file / technical documentation mentioned in the directive?
Annex III of the directive makes a distinction between the technical documentation, which has to be maintained by the manufacturer for submission to the authorities, if need be, and the technical file, which has to be submitted to the notified body in the framework of type examination.
The description of the control and test facilities and the instructions of the manufacturer are part of the technical documentation, but not of the technical file. This means, however, that it is not possible for the notified body to assess the suitability of the test facilities or of the instructions of use during type examination.

Recommended solution :

It should be noted that there is no on-site assessment of the test equipment of the manufacturer under article 10 procedures.

However, the description of the test equipment as well as the instructions for use are important for the assessment of the conformity of a product with the directive. Therefore, they have to be considered to be a part of the technical file.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.036 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....24/01/2013
		☑ Standing Committee	.....01/10/2015

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : II; 1.4 (e) Article :	Clause :	

Key words :

period of obsolescence

Question :

There are a few items of PPE for which a definitive life can be stated. In general, the time for which an item of PPE can be used is dependent upon many and varied effects; for example storage, maintenance, conditions and frequency of use, etc.

This presents a problem for manufacturers required to state a period and for notified bodies in assessing whether or not this requirement is complied with.

A practical solution is required which satisfies the spirit of the Directive and supplies the necessary information to the user.

Recommended solution :

All relevant information on the period of obsolescence and/or instructions to enable the user to assess and inspect the item to determine whether or not the item can continue to be used shall be given.

Individual vertical groups may define more detailed specifications for different types of PPE.

(see annex II, 2.4)

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.038 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....27/05/98
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

components from different manufacturers

Question :

Should a notified body agree to issue an EC Type Examination for a product submitted by manufacturer "A" which includes interchangeable components produced by a manufacturer "B" where the product requires to be tested as a complete device?
for example:
a) filters for an air powered device
b) chemical protective clothing without a hood and/or boots
c) helmet mounted ear muffs

Recommended solution :

A notified body is responsible for reviewing the Technical Documentation for compliance with the relevant requirements of the Directive. Provided the client's documentation submitted covers all the applicable requirements the notified body may perform or arrange for the necessary tests to be carried out and if found satisfactory issue an EC Type Examination Certificate.

Note: It is the manufacturer "A"'s responsibility to monitor that each subsequent product is in conformance with that tested for the EC Type Examination and that the product manufactured by "B" remains the same and compatible with his tested product.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.046 Revision 04 Language : E

Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group	.....
		☑ Horizontal Committee	.....26/05/99
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

marking, standard reference, testing according to prEN

Question :

If only a prEN is available at the time of EC type approval, can the product be marked with the standard number „EN ...“?

Where the EC type examination is issued against a prEN, can EN be marked on the product, once the standard is ratified?

Recommended solution :

Marking with a standard reference is not mandatory by the directive.

Where a manufacturer decides to mark a standard or prEN on his product, the following principles apply:

As long as no final standard exists or the final standard is not identical with the prEN, the marking cannot be "EN ...".

If the ratified EN is identical to the prEN, then „EN ...“ may be marked on the product.

Where the ratified EN is not identical to the prEN, then „EN ...“ cannot be marked on the product.

Marking with a prEN is not recommended. However, where a manufacturer decides to mark with the prEN used for the EC type examination then it should be fully identified by year and/or issue.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.048 Revision 03 Language : E

Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11 A	Clause :	

Key words : sampling 11 A procedures

Question :

What sampling procedures are possible for 11 A procedures for small series of PPE, e.g. 10 PPE manufactured per year, especially if the tests are destructive tests?

Recommended solution :

If the 11A option is taken, sufficient testing must be undertaken by the notified body. It is up to the notified body to decide how sampling could be done.

If the manufacturer does not want to follow the 11A route, the only option is the quality system route 11B.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.051 Revision 04 Language: E

Number of pages: 1	Date: 04.09.02	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 23.02.00 ☒ Standing Committee 15.01.02

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: II, 1.4 Article:	Clause:	

Key words:

use of pictograms

Question:

Is it possible to mark a product with a pictogram described in an EN standard when the verification of essential requirements has been made against another EN standard or other technical specification ?

Solution:

It is possible to use the pictogram even if the standard used is not the EN standard where the pictogram is described.

The notified body, in reviewing the manufacturer's instructions for use (information supplied by the manufacturer), must ensure that the meaning of the pictogram is clearly defined in respect of the essential health and safety requirements of the directive.

NOTE: 'Pictogram' refers to the pictorial presentation; this does not include the EN number or performance levels. These must not be used if the EN is not the basis for testing.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.052 Revision 03 Language : E

Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

test reports, designation of materials

Question :

In test reports, materials are often only referred to by a single, mostly commercial reference name. In many cases, however, this name covers a variety of materials different by structure and weight (for fabrics) or by origin and thickness (for leather).

Is it possible to have a uniform and clear "finger print designation" of materials in test reports in order to make an evaluation easier?

For this purpose, we propose to use the elements as given below:

- aramid twill 2/1 - 270 g/m²
- cow split 1.3 - 1.5 mm.

Recommended solution :

A unique reference number or name identifying the material must be the same in the technical file and in the test report.

The technical file should contain a documentation of the material, i. e. a sample or a proper identification.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.058 Revision 03 Language : E

Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

test reports, materials

Question :

How old can test reports be when they are used for type examination?

Recommended solution :

This is the responsibility of the notified body.

The general view is that there should be no time limit for previous tests.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.061 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☐ Horizontal Committee	.....
		☑ Standing Committee	.....18/11/97

Question related to : Annex : Article :	EN/prEN :	Other :
	Clause :	

Key words :

slip resistance, type examination certificate

Question :

Does slip resistance have to be considered an essential requirement for safety, protective and occupational footwear?

Recommended solution :

Slip resistance is a general feature of safety, protective and occupational footwear.

Notified bodies have to carry out slip resistance testing, unless the manufacturer clearly claims in his product specification and in the user information that the footwear does not meet this requirement.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.064 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

type examination for category I PPE

Question :

Could PPE which do not belong to categories II or III be submitted to an EC type examination on a voluntary basis?

Recommended solution :

Only PPE belonging to categories II or III can be submitted to an EC type examination procedure leading to the issue of an EC type examination certificate.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.068 Revision 05 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....26/05/99
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

revision of standard, validity, EC type examination certificate

Question :

When a new version of an EN standard is published, are manufacturers obliged to get their products tested to the new/revised version or can they continue to sell their product(s)?

Recommended solution :

Current certificates remain valid. However, manufacturers have a responsibility to keep abreast of changes and to modify their products in the light of these changes to continue to supply safe products, which may necessitate the issue of a new certificate.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.074 Revision 04 Language : E

Number of pages : 2	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11A	Clause :	

Key words :

article 11A, change of certificate

Question :

When controls carried out in accordance with article 11A give performance level classification figures, for example, lower than those stated in the EC type examination certification, should the original EC type examination certificate be changed?

Recommended solution :

The EC type examination certificate cannot be altered, only withdrawn and a new one be issued to cover the new lower performance levels. The product in this case has to get a new identification.

The procedure set out in the Directive should be followed. (Reference Article 11A, para 4 & 5)

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.075 Revision 04 Language : E

Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....04/06/97
		☑ Standing Committee	.....20/04/98

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10.2, 11 A, 11 B	Clause :	

Key words :

distribution, type examination certificate

Question :

How should files concerning PPE likely to have several product identifications be processed?

Recommended solution :

There are two acceptable situations.

1) The original manufacturer or his authorised representative remains responsible for placing the equipment on the market

   The manufacturer is the certificate holder, and established the declarations of conformity.

   The technical construction file indicates the different forms of product identification and markings as well as the trade name of the distributors. The various versions of the instruction handbook are subject to EC type-examination (with the exception of direct translations into foreign languages).

2) The distributor or importer, acting as a manufacturer, is responsible for placing the equipment on the market

   Being responsible for placing the equipment on the market, the distributor / importer must request an EC type examination.

   The certificate or the extension to the certificate is established in the trade name of whoever is responsible for placing the equipment on the market. He, in turn, established the declarations of conformity in his name.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.077 Revision 07 Language: E

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Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 05.05.06 ☒ Standing Committee 31.07.06

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: II, 1.4 Article:	Clause:	

Key words:

information to users

Question:

What is the responsibility of the notified body in checking the information to users ?

Solution:

The notified body shall verify that the equipment can be used in complete safety for its intended purpose (directive, article 10 (4) b). In order to do this, the notified body shall check that the claims of the manufacturer on the area and limits of protection of the product are in line with the technical specification used and with the relevant essential safety requirements. One of the essential safety requirements is to supply all relevant information as required by annex II, clauses 1.4, 2 and 3. The notified body must check that the information is given in accordance with these requirements and that it does not contain misleading statements and obvious mistakes concerning the protection provided. The manufacturer has the final responsibility for the accuracy of the content including translations.

Note : Claims of compliance with standards other than harmonised European standards that have the same scope as those used as a basis for type examination or claims that are not related to user protection, e.g. value for money etc., are the sole responsibility of the manufacturer.

Explanatory note: *The Recommendation for Use was originally agreed in the Horizontal Committee on 23 May 2003. Confirmation and re-submission to the PPE Expert Group on 5 May 2006.*

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.080 Revision 02 Language : E

Number of pages : 1	Date : 15/01/98	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group..... ☑ Horizontal Committee ..... ☑ Standing Committee	....18/11/97

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10	Clause :	

Key words :

Production Plant

Question :

Do certificates only cover PPE made at the production plant(s) specified either on the certificate or associated documents? If no, is the certificate holder free to sub-contract production to any alternative plant, without reference to the Notified Body, and apply the CE marking on the basis of the original certificate and declaration?

Recommended solution :

The Type Examination certificate is linked directly to the production plant(s) specified at the time of application.

- Only products made at the specified site(s) are covered by the certificate and these can be CE marked following the drawing up of the necessary declaration.

- If alternative production plants are to be used, the Notified Body who issued the original certification must be informed. The N.B. decides, in agreement with the manufacturer, what level of verification testing, if any, is required before amending the certificate and/or the technical file.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.081 Revision 03 Language : E

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Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....27/05/98
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 1, 2 (c)	Clause :	

Key words :

interchangeable components, EC type examination

Question :

Should interchangeable components be submitted to an EC type examination?

Recommended solution :

Yes, an EC type examination certificate can be issued in accordance with Article 1;2 c.

The notified body shall carry out sufficient evaluation and/or testing to verify their suitability for the stated equipment in its final assembly.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.086 Revision 08 Language: E

Number of pages: 1	Date: 21//11/2013	Approval by : Approved on :
Origin :Horizontal Committee, Article 11 ad hoc group		☒ Ad hoc group 21/11/2013 ☒ Horizontal Committee 22/11/2013 ☒ Standing Committee 01/10/2015

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 11 B	Clause:	

Key words:

composition of audit team; competency of auditors; knowledge of auditors

Question:

How should the audit team be composed?

Solution:

The audit team must include at least the following

Experience and knowledge of the relevant quality system requirements (e.g. ISO 9001) and the product technology concerned.

Knowledge of the type examination certificates which are applicable to the scope of the assessment.

Access to and knowledge of the applicable Recommendation for Use sheets.

Knowledge of the status of the standards applicable to the scope of the assessment (amendments, revisions, drafts, final drafts etc.).

Note: The audit team can either be a single person with the required knowledge, skills etc., or a number of different people making up a team.

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

(5): EU Commission

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.087 Revision 06 Language: E

Number of pages: 1	Date: 23/03/2010
Origin : Horizontal Committee, Article 11 ad hoc group	

Approval by : Approved on :

- ☒ Ad hoc group 21/11/2013
- ☒ Horizontal Committee 22/11/2013
- ☒ Standing Committee 01/10/2015

Question related to: Annex: Article:	EN/prEN: Clause:	Other:

Key words:

quality assurance system

Question:

Must existing certificates relating to QA-Systems (ISO 9001) be accepted by a notified body?

Solution:

No; but the notified body is able to take into account existing certificates relating to QA-systems (ISO 9001) if it is convinced of the qualification of the certification body (accreditation, mutual recognition and others). In all cases the notified body must add product and regulation-related aspects.

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

(5): EU Commission

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.088 Revision 04 Language : E

Number of pages : 1	Date : 15.12.2009	Approval by :	Approved on :
Origin : VG12 Certification of Quality Systems, article 11B HC ad-hoc committee		☑ Vertical Group..... ☑ Horizontal Committee ..... ☑ Standing Committee	.....29/11/95 .....05/01/98 .....20/04/98

Question related to : Directive 89/686/EEC Annex : Article : 11.B (2)	EN/prEN : Clause :	Other :

Key words :

Quality Assurance System, Supervision, Frequency of Audits

Question :

What frequency of audits is necessary to fulfil the obligation arising from Article 11 B (2) of Directive 89/686/EEC?

Recommended solution :

A supervision frequency of at least once a year.

See also RfU no. 00.106.

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

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

PPE	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.089 Revision 03 Language : E

Number of pages : 1	Date : 27/08/98	Approval by :	Approved on :
Origin : VG12 Certification of Quality Systems, article 11B HC ad-hoc committee		☑ Vertical Group ☑ Horizontal Committee ☑ Standing Committee	.....29/11/95 .....05/01/98 .....20/04/98

Question related to : Directive 89/686/EEC Annex : Article : 11.B (c)	EN/prEN : Clause :	Other :

Key words :

Question :

When must ISO 9001/2/3: 1994 be used as the harmonised standard?

Recommended solution :

The certification and procedures, of notified bodies and manufacturers, which reference ISO 9001/2/3, must reference the 1994 version by the end of 1998, at the latest.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.090 Revision 04 Language : E

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Origin : Horizontal Committee, Article 11 Ad hoc group		☑ Article 11 Ad hoc.....	.....21/11/2013
		☑ Horizontal Committee	.....22/11/2013
		☑ Standing Committee	.....01/10/2015

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11.B (b) / 11.A.3	Clause :	

Key words :

Question :

Must the "appropriate tests" be as specified in the product standard or product specification?

Recommended solution :

The manufacturer's routine/regular inspections and tests can be supplemented by alternatives, providing that the manufacturer can prove there is sufficient correlation. Where this is the case, the compulsory test/inspection programme against the product standard/specification can be less frequent.

Where alternative methods are used, they shall be described in the manufacturer's quality system documented procedures.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.092 Revision 02 Language : E

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		☑ Horizontal Committee	.....26/05/99
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : II Article : 1.4 (i)	Clause :	

Key words :

notified body reference, information supplied by the manufacturer

Question :

1. Has information on the notified body who certifies a PPE product to be included in the user information?
2. What is the correct interpretation of the PPE Directive as amended?

Recommended solution :

1. Yes. Reference 93/68/EEC (Article 7, para. 7) which amends section 1.4 requiring „the name, address and identification number of the notified body involved in the design stage of the PPE;“
2. The details to be included in the manufacturer's user information must be that of the notified body responsible for the issue of the EC type examination.

   It should be noted that in some cases more than one notified body may be involved, i. e. combined PPE. In such cases the information supplied would be for each notified body involved.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.093 Revision 02 Language : E

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		☑ Horizontal Committee	.....27/05/98
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

element, CE marking

Question :

May an element (e. g. attachment element, steel toe cap) which is not sold to the end user be CE marked?

Recommended solution :

No, these elements are items that are supplied to a manufacturer for the manufacture of PPE.

Note: Certain items may be CE marked under another directive.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.094 Revision 02 Language : E

Number of pages : 1	Date : 31/05/99	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....27/05/98
		☑ Standing Committee	.....21/06/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

harmonised standards, essential requirements, EC type examination

Question :

When carrying out an EC type examination, what is the responsibility of the notified body when the applicable product harmonised standard does not address all the relevant Health and Safety Requirements?

Recommended solution :

Where a relevant product harmonised standard does not address all the relevant Health and Safety Requirements the manufacturer must identify those not addressed in the standard and also state how these are dealt with in his Technical File. The notified body is responsible for confirming that all the relevant Health and Safety Requirements have been identified, listed and adequately dealt with when carrying out their review, inspection and testing for the EC Type Examination.

Note 1: A product harmonised standard gives a presumption of conformity with those Basic Health and Safety Requirements which it identifies for the product and addresses.

Note 2: It must be remembered that the Directive is the law and must be complied with whilst standards are one means by which a manufacturer may demonstrate his compliance with the Directive's requirements.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.095 Revision 02 Language : E

Number of pages : 1	Date : 11/12/99	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....26/05/99
		☑ Standing Committee	.....29/11/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 10, 4 (b)	Clause :	

Key words :

technical file

Question :

How should the inspection body „verify“ that the model is the product described in the manufacturer’s technical file?

Solution :

The inspection body is seen as the notified body in terms of the directive.

The generally accepted action in order to verify that a PPE model has been produced in accordance with the manufacturer’s technical file is to conduct a visual comparison between an example of the model and a description of the model. The objective of the comparison is to ensure that, in general terms, the product is as described and that there are no obvious differences in general form or materials.

Note: The description of the model may take various forms, e. g. general assembly drawings, component drawings, photographs, material descriptions, etc.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.096 Revision 06 Language: E

Number of pages: 1	Date: 04.09.02	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 04.07.01 ☒ Standing Committee 15.01.02

Question related to: Directive 89/686/EEC Annex: II, 1.2.1.1 Article:	EN/prEN: Clause:	Other:

Key words:

innocuousness of PPE

Question:

What should notified bodies require from the manufacturer to demonstrate compliance with annex II, 1.2.1.1 ?

Solution:

Compliance may be demonstrated by a written declaration confirming that the submitted PPE does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health, if present; a list of these substances has to be submitted as part of the technical file. Tests as required by harmonised standards will not be affected.

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

(3): (5):

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

PPE	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.098 Revision 03 Language: E

Number of pages: 1	Date: 04.09.02	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 23.02.00 ☒ Standing Committee 15.01.02

Question related to: Directive 89/686/EEC Annex: Article: 10	EN/prEN: Clause:	Other:

Key words:

conformity to standard

Question:

Is it possible to certify a product in compliance with a standard where one or more requirements of the standard are not satisfied?

Solution:

No.

NOTE: The product may be certified in compliance with the essential health and safety requirements of the directive.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.099 Revision 02 Language : E

Number of pages : 1	Date : 11/12/99	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Vertical Group.....	.....
		☑ Horizontal Committee	.....27/05/99
		☑ Standing Committee	.....29/11/99

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article :	Clause :	

Key words :

CE marking, separate items of PPE, technical file

Question :

The manufacturer produces a range of products that can be used individually and in combination.

1. Is it possible to submit one technical file containing the designs etc. for all of these products?
2. In such a case, can each product separately bear the CE marking?

Recommended solution :

1. It is possible to submit one technical file only for all products.
2. Yes, each product must be CE marked.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.104 Revision 02 Language: E

Number of pages: 1	Date: 04.09.02	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 23.02.00 ☒ Standing Committee 15.01.02

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 8.4a	Clause:	

Key words:

category; certification

Question:

How should the word 'emergency' in the English language version of the Directive be understood?

Solution:

It should be understood as in the original French version, which says 'intervention'.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.106 Revision 04 Language: E

Number of pages: 1	Date: 12.07.2005	Approval by : Approved on : ☒ Vertical Group 01.12.2004 ☒ Horizontal Committee 02.12.2004 ☒ Standing Committee 30.06.2005
Origin : Article 11 A / B ad hoc committee		

Question related to: Directive 89/686/EEC Annex: Article: 11.B.2	EN/prEN: Clause:	Other:

Key words:

re-assessment of approved quality systems

Question:

Shall approved quality systems be re-assessed ?

Solution:

Yes, at a recommended frequency of every third year, with surveillance audits being performed at a frequency of at least one per year, reference sheet 00.088.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.107 Revision 02 Language: E

Number of pages: 1	Date: 04.09.02	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 27.10.00 ☒ Standing Committee 15.01.02

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 11.A.3	Clause:	

Key words:

sample selection

Question:

What is the minimum requirement(s) to be applied to the method of obtaining samples for testing under Article 11.A ?

Solution:

As a minimum, the notified body or an independent representative of the notified body, shall visit a location agreed with the certificate holder (manufacturing site, importer, distributor, retail outlet), and shall randomly select the samples from the available stock.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.109 Revision 03 Language : E

Number of pages : 1	Date : 26.10.06	Approval by :	Approved on :
Origin : Article 11 A/B ad hoc group		☐ Vertical Group	.....
		☑ Horizontal Committee	05.05.06
		☑ Standing Committee	31.07.06

Question related to : Directive 89/686/EEC	EN/prEN :	Other :
Annex : Article : 11.A	Clause :	

Key words :

11.A test clauses

Question :

When an EC Type Examination is based upon a withdrawn standard, should the 11.A testing be conducted against the withdrawn standard or the current version ?

Recommended solution :

Whilst the type examination certificate remains valid, the 11.A testing should be against the edition of the standard used as a basis to demonstrate conformity with the Directive.

(Cross reference sheet 00.068 concerning the validity of Type Examination Certificates.)

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.113 Revision 03 Language: E

Number of pages: 1	Date: 15.12.2009	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 12.12.02 ☒ Standing Committee 11.06.03

Question related to: Directive 89/686/EEC Annex: III Article: 10	EN/prEN: Clause:	Other:

Key words:

Test and Inspection of Production

Question:

How is the phrase 'control AND test facilities' in annex III, 2 to be understood?

Solution:

As a minimum, the system described should include a summary of how often the manufacturer will carry out the inspections and tests required by the standard or specification, e.g. batch tests, annual tests, receiving inspections etc.

The system should clearly show that the manufacturer checks and confirms continuing compliance against all applicable requirements over a stated period / frequency and uniformity with the tested type (which must be assessed as satisfactory by the notified body).

See also RfU 00.002.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.114 Revision 03 Language: E

Number of pages: 1	Date: 22.08.03	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 05.09.02 ☒ Standing Committee 11.06.03

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 8.4, 11.A, 11.B	Clause:	

Key words:

manufacturer

Question:

There are various references in the Directive to a 'Manufacturer', but what is the accepted definition of a manufacturer?

Solution:

According to the Blue Book, the Manufacturer to has to be defined as

- any natural or legal person who takes responsibility for designing and manufacturing a PPE with a view to placing it on the Community market under his own name;
- any natural or legal person who assembles, packs, processes or labels ready-made products with a view to their being placed on the Community market under his own name;
- any natural or legal person who changes the intended use of a product in such a way that different essential requirements will become applicable;
- any natural or legal person who customises, modifies or rebuilds a PPE.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.117 Revision 02 Language: E

Number of pages: 1	Date: 22.08.03	Approval by : Approved on :
Origin : Horizontal Committee		☒ Vertical Group 5 11.04.02 ☒ Horizontal Committee 05.09.02 ☒ Standing Committee 11.06.03

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: II, 1.2.1.1 Article:	Clause:	

Key words:

information supplied by the manufacturer; sensitising or allergenic substances

Question:

Should the manufacturer of PPE display all substances with sensitising or allergenic potential in the "information supplied by the manufacturer", if the PPE is designed to get (even if only partly) in close skin contact with the user, or if parts of the PPE may be released and taken up via the inhalation route by the user?

Solution:

Yes. The PPE directive 89/686/EEC, annex II, 1.2.1.1 (suitable constituent materials) requires that "PPE materials and parts, including any of their decomposition products must not adversely affect user hygiene or health".

In case that PPE contains substances which are known to be potentially sensitising or allergenic, the manufacturer has to display each individual relevant substance in the information supplied by the manufacturer to give a warning to all potentially concerned users.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.118 Revision 02 Language: E

Number of pages: 1	Date: 22.08.03	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 05.09.02 ☒ Standing Committee 11.06.03

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 8	Clause:	

Key words:
categorisation; welding

Question:

1. Does welders' PPE have to offer protection against "electrical risks" in the aim of the directive (article 8.4 a), line 7) ?
2. What is the category of welders' PPE?

Solution:

1. No.
2. Welders' PPE are in category II.

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

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.120 Revision 01 Language: E

Number of pages: 1	Date: 22.08.03	Approval by : Approved on : ☒ Vertical Group (Art. 11 group) 05.09.02 ☒ Horizontal Committee 06.09.02 ☒ Standing Committee 11.06.03
Origin : Horizontal Committee		

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 11.A.3	Clause:	

Key words:

category III product

Question:

A PPE is classed as category III because the manufacturer claims one or more product features that qualify category III.

Can the tests required under article 11.A be limited to performance against this / these requirements?

Solution:

No. Once a PPE is claimed to meet performance requirements that qualify category III, for whatever reason, the entire PPE item is classed as category III and not just single performance requirements.

There should be no difference in approach between all category III PPE with respect to deciding which performance requirements should be tested on 11.A samples.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.122 Revision 03 Language: E

Number of pages: 1	Date: 12.07.2005
Origin : BSIF	

Approval by : Approved on :

- ☐ Vertical Group
- ☒ Horizontal Committee 03.12.2004
- ☒ Standing Committee 30.06.2005

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 10 and 11A	Clause:	

Key words:

retention of representative samples

Question:

Is there any requirement in the PPE Directive for notified bodies to retain samples of the equipment that they have type-examined (Article 10) or tested during the annual control of the final product (Article 11)?

Solution:

No.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.123 Revision 06 Language: E

Number of pages: 1	Date: 22.10.2015	Approval by : Approved on :
Origin : BSIF		☐ Vertical Group ☒ Horizontal Committee 05.11.2015 ☒ Standing Committee 04.04.2016

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 10 and 11A	Clause:	

Key words:

external testing

Question:

When a notified body uses external testing facilities, what selection criteria should be applied?

Solution:

Selection should be made upon the following general principles in descending order of acceptance:

1st option - Laboratory based within the EU / EFTA, accredited by an organisation which is part of the European accreditation system or covered by a mutual recognition agreement.

2nd option - Laboratory based outside of the EU / EFTA, accredited by an organisation which is part of the European accreditation system or covered by a mutual recognition agreement.

3rd option - Independent laboratory without recognised accreditation. The notified body will be responsible for both initial and surveillance direct auditing to confirm that the relevant standard is complied with and maintained - ISO 17025.

4th option - Use of manufacturers' test facilities is only to be accepted where the testing is supervised by the notified body staff. The test report is either issued under the notified body's authority or the manufacturers report clearly states the conditions under which the testing was carried out including the involvement of the notified body staff.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.124 Revision 02 Language: E

Number of pages: 1	Date: 12.07.2005	Approval by : Approved on :
Origin : Horizontal Committee (submitted by SATRA)		☐ Vertical Group ☒ Horizontal Committee 03.12.2005 ☒ Standing Committee 30.06.2005

Question related to: Directive 89/686/EEC	EN/prEN:	Other: BS DD 253
Annex: Article:	Clause:	

Key words:

Boil-and-bite mouth guards

Question:

Is it possible for a Notified Body to issue an EC Type Examination Certificate for a part completed product, in particular, mouth formed mouth guards (often termed Boil and Bite mouth guards) which require the end user to mould the mouth guard to its final shape by following a set of simple instructions supplied with the guard ?

Solution:

Yes – Provided that if the user instructions are followed (in every way that they can be interpreted) it always results in a compliant product.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.125 Revision 05 Language: E

Number of pages: 2	Date: 20.04.2011	Approval by :	Approved on :
Origin: Horizontal Committee Article 11 Ad hoc group		☒ Article 11 Ad hoc Group ☒ Horizontal Committee ☒ Standing Committee	16/10/2008 24/06/2009 20/04/2011

Question related to: Directive 89/686/EEC Annex: Article: 11.A	EN/prEN: Clause:	Other:

Key words:

Uniformity of production, article 11.A.

Question:

What is the correct interpretation of the requirements of article 11.A?

Solution:

See attached.

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

(5): Article 11 Ad hoc group, EU Commission

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

Article 11A interpretation, 1st December 2004, Article 11 ad-hoc committee. Revised 16th October 2008

EC quality control system for the final product.

1.
A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-examination certificate and with the specification / standard referenced on the EC type-examination certificate.

2.
A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at a minimum of one per year, starting from the date of initial certificate issue.
Before the CE mark can be applied to PPE to be covered by this article, the manufacturer, as a minimum, must have entered in to an agreement with a notified body for the administration of this article.
The necessary checks shall include both 2A and 2B: -

2 A.

Selection of product samples by the notified body, or an independent representative of the body. Selection shall be made at a location agreed between the notified body and manufacturer.

The samples shall be randomly selected from available stock and be representative of the certified range. The samples shall be examined by the notified body to confirm that the manufactured PPE is as type-examined and remain in conformity with the standard or specification referenced on the corresponding valid type-examination certificate.

AND

2B.

The notified body shall identify any instances of production not being homogeneous by one of the following:

(i). Once per year, carry out on-site review of company production and test records. Review to take place where at least the final assembly of PPE is carried out.

(ii). Once per year, carry out an on-site audit of the production control. Audit to take place where at least the final assembly of PPE is carried out.

(iii). Once per year, take sufficient samples to evaluate production non-homogeneity.

(iv). Submission of samples throughout the year, each sample smaller in size the in (iii), based upon production information supplied by the manufacturer, to evaluate production non-homogeneity.

NOTE: Evidence of non-homogeneity to be in the terms of conformity with the PPE Directive, essentially all results to be in conformity with the applicable specification / standard. No measurement of deviation, spread of results, trends etc.

The test chosen to evaluate non-homogeneity to be a simple, straightforward, objective test, directly related to the performance of the product.

3.
Where a body is not the body that issued the relevant EC type-examination certificate, it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the production control or conformity of samples.

4.
The body of which notification has been given shall provide the manufacturer with a report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-examination certificate or the referenced standards / specifications, the body shall take measures appropriate to the nature of the fault or faults recorded, and inform the Member State which gave notification thereof accordingly.
Where appropriate, withdrawal of EC type-examination certificates and / or authority to use the notified body number shall be considered.

5.
The manufacturer must be able to present, on request, the report of the body of which notification has been given.

Notes: -

Appropriate tests performed by the manufacturer may not be as specified in the standard. Where this is the case, evidence of correlation must be available.

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.126 Revision 02 Language: E

Number of pages: 1	Date: 26.10.06	Approval by : Approved on :
Origin : INSPEC		☒ Vertical Group ☒ Horizontal Committee 26.08.2005 ☒ Standing Committee 31.07.2006

Question related to: Annex: Article:	EN/prEN: 17025 Clause: 5.10.3.1 c)	Other:

Key words:

Uncertainty of measurement

Question:

When notified bodies commission testing on test laboratories complying with EN/ISO/IEC 17025, and the reference specification includes pass / fail criteria, does the notified body have to make a specific request for uncertainty of measurement to be included in the test report?

Solution:

No.

EN/ISO/IEC 17025 includes a clear requirement for uncertainties of measurement to be available and reported where the uncertainty might affect compliance with pass / fail criteria. In such cases, the test laboratory has to include the uncertainty.

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

(3): (5): Article 11 A/B Ad hoc group

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.127 Revision 03 Language: E

Number of pages: 1	Date: 24 January 2013	Approval by : Approved on :
Origin : BSIF / Advisory Panel		☐ Vertical Group ☒ Horizontal Committee 24/01/2013 ☒ Standing Committee 01/10/2015

Question related to: Annex: Article:	EN/prEN: Clause:	Other:

Key words:

Dedicated test method standards

Question:

Product standards often refer to specific standards or other sources for the specification of test methods. Changes in the test method can result in differences with regard to the interpretation of test results for the assessment of the product, e.g. with regard to performance levels. What should notified bodies do when a test method standard is revised?

Solution:

As long as the product standard has not been revised, the old test method should be used.

NOTE 1: Notified bodies should try to make sure that product standards contain only dated references to test method standards.

NOTE 2: If a test method standard has been revised, the consequences for the interpretation of test results should be discussed, and an amendment to the product standard be proposed as quickly as possible, if necessary.

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

(5): EU Commission

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.128 Revision 02 Language: E

Number of pages: 1	Date: 26.10.06	Approval by : Approved on :
Origin : Exam / Advisory Panel		☐ Vertical Group ☒ Horizontal Committee 05.05.06 ☒ Standing Committee 31.07.06

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 1, 2 c)	Clause:	

Key words:

Interchangeable components of breathing apparatus

Question:

Who can apply for EC type examination of interchangeable components in the meaning of Article 1, 2 c) of the Directive 89/686/EEC?

Solution:

The manufacturer of the interchangeable component must be identical with the manufacturer of the complete PPE or protective equipment, or there must be a contractual agreement between them, which authorises the manufacturer of the interchangeable component.

(see also RfU 00.038, rev. 03)

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.129 Revision 02 Language: E

Number of pages: 1	Date: 26.10.06
Origin : Exam / Advisory Panel	Approval by : Approved on : ☐ Vertical Group ☒ Horizontal Committee 05.05.06 ☒ Standing Committee 31.07.06

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 1, 2 c)	Clause:	

Key words:

Interchangeable components of breathing apparatus

Question:

Do interchangeable components of protective equipment that was placed on the market before the end of the transition period fall under the scope of Directive 89/686/EEC?

Solution:

Even if the original equipment is not CE marked, such interchangeable components fall under the scope of the PPE Directive.

The suitability of the component for the intended use of the PPE in the protective equipment must be assessed and certified. The notified body must have access to the complete documentation concerning the whole equipment (test reports and certificates, if existing).

A simple certificate confirming equivalence with the part to be replaced is not enough.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.130 Revision 02 Language: E

Number of pages: 2	Date: 26.10.06	Approval by : Approved on :
Origin : Article 11 Ad Hoc Group		☒ Article 11 Ad hoc group 03.05.06 ☒ Horizontal Committee 05.05.06 ☒ Standing Committee 31.07.06

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article:	Clause:	

Key words:

Own-brand certificates

Question:

How should applications for own brand certificates be dealt with?

Solution:

See attached

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

(3): (5):

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

Own Brand manufacturers type-examination certificates, Article 10.

Any person / company / organisation placing a product on to the market in their own name is the manufacturer of that product within the terms of the PPE Directive. It then follows that the manufacturer must make an application in their own name and be issued with certificates that support the CE marking of the PPE.

It is common practice for original manufacturers to offer their product to one or more companies who wish to sell the product as their own. There will be no identifiable link back to the original manufacturer in the market place.

The product offered for sale by the own brand manufacturer will be identical to the original product except for marking and probably user instructions. All other elements of the technical file can be applied to the own brand product.

The own brand manufacturer will be required to raise and sign an EC declaration before placing CE marked product on the market. This will include a statement covering article 11 for category III PPE.

The own brand certificate will only remain valid while the cross-referenced original certificate remains valid.

As the own brand manufacturer is legally responsible for ensuring that the product(s) meet the requirements of the directive, it is necessary for the minimum acceptable level of control and responsibilities to be established with the PPE notified bodies.

Proposed conditions to be fulfilled before the granting of certification for an own brand product: -

1. The original manufacturer to hold a valid type-examination certificate and if category III, to provide evidence of current 11.A or 11.B supervision.

2. Written agreement to be submitted, signed by both parties (original manufacturer& own brand manufacturer), covering the following:
   - Confirmation that the PPE subject to the current application is physically identical to product xxx, which is covered by type-examination certificate yyy.
   - Any difference between the original submission and this application to be listed.
   - Confirmation from the original manufacturer that only product fully compliant with type-examination certificate xxx will be supplied to own brand manufacturer yyy as the specified model.
   - Confirmation that the original manufacturer will advise the own brand manufacturer of any changes affecting the validity of either the type-examination certificate and for category III PPE, the article 11 supervision.
   - Any proposed changes to the product will be sent to both the notified body and the own brand manufacturer before proceeding with the change.
   - Confirmation that the original technical file will be made available to the own brand manufacturer's notified body to support their application for certification and for category III PPE, article 11 documents.
   - Confirmation that both the original manufacturer and own brand manufacturer will inform each other of any incidents involving the products covered by the agreement

3. A copy of the EC type-examination certificate from the original manufacturer plus any documents that differ from the original technical file, e.g. marking and user information and access to the original technical file.

   The notified body should review the user information and labelling of the own brand manufacturer in order to confirm it meets the requirements of the Directive.

   A copy of the technical file amendments is then to be maintained by the own brand manufacturer and will be subject to review by the notified body during any ongoing surveillance activities.

4. For category III PPE, the article 11 notified body will decide during the review of the own brand manufacturer's submission, activities etc, whether or not the premises of the own brand manufacturer need to be visited in the article 11 supervision.

5. The type-examination certificate issued to the own brand manufacture will identify them as the manufacturer and will only reference the model identity as used by the own brand manufacture. It is proposed that the original certificate does not need to be referenced on the certificate, but the NB holds this information, should it be required.

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.131 Revision 02 Language: E

Number of pages: 3	Date: 18.08.2008	Approval by : Approved on :
Origin : Article 11 Ad Hoc Group		☒ Article 11 Ad hoc group 07.02.07 ☒ Horizontal Committee 09.02.07 ☒ Standing Committee 15.07.08

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article:	Clause:	

Key words:

Standard template for report content covering annual assessment process

Question:

What are the minimum requirements for the report content when implementing Recommendation for Use sheet 00.125, rev. 02?

NOTE:

Sheet 125 clearly specifies that 2 separate activities are required when assessing article 11.A, namely: -

1) Annual selection of samples to confirm continued compliance with the reference standard / specification and the type-examined

AND

2) Annual assessment of the production control to determine any evidence of non-homogeneity.

Solution:

See attached pages 2 and 3

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

(3): (5):

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

Confidential **Report number and date:**

Article 11.A Annual Surveillance Report

Notified Body – name / address / number:

Certificate holder: **Period covered by report:**

General Reference Documents:

Recommendation for use sheet, 125, revision 02. PPE Directive 89/686/EEC, Article 11.A

EC Type-examination certificate numbers covered by the surveillance:

Harmonised standards / technical specifications within the scope of the surveillance:

A. Annual assessment of product compliance with standard / specification and type-examined, reference 2A of sheet 125

1. Location(s) visited and dates:

a. Selection carried out by…….. Relationship to notified body……..

2b. Company representative, name and position……..

3. Relationship of company visited to type-examination certificate holder

Certificate Holder Production site Importer Secondary production site
Distributor Retail Outlet

European office of same company Other (please specify)

List of PPE
- available
- not available
- not selected
- selected plus lot / batch numbers

4. Attached reference documents

Visit report, number xxxxxxx **Test report, number yyyyyyy**

5. Sample selection was positive / negative. Product testing was positive / negative

6. Sample selection and testing demonstrated compliance with the reference specification / standard and type-examined, yes / no.

B. Annual assessment of production not being homogeneous, reference 2B of sheet 125

1. Method employed to perform assessment, please specify:

2B(i) - On-site review of production and test records.
2B(ii) - On-site audit of production control.
2B(iii) - Production non-homogeneity assessed by selection of a single, large sample.
2B(iv) - Production non-homogeneity assessed by assessment of samples throughout the year.

2a. Assessment(s) carried by …… Relationship to notified body. ……..

2b. Company representative, name and position……..

Confidential **Report number and date:**

Article 11.A Annual Surveillance Report

3. Attached reference documents.

Visit report(s), number xxxxxxx Test report(s), number yyyyyyyy

4. According to our judgement, the assessment concluded that production was not homogeneous, yes / no.

Justification of nonconformities

Conclusion of notified body:
Overall conclusion of the annual surveillance, positive / negative.

Signature…….. Name and position …….. Date ……..

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.132 Revision 02 Language: E

Number of pages: 1	Date: 15.08.2008	Approval by : Approved on :
Origin : Vertical Group 1 – Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 09.02.07 ☒ Standing Committee 15.07.08

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article:	Clause:	

Key words:

Sizing

Question:

A manufacturer declares sizes or size ranges for a PPE he submits for EC type examination. What action does the notified body have to take?

Solution:

If a manufacturer submits a PPE for certification, declaring sizes or size ranges for the product, the notified body has to check whether the declared sizes are correct. The test report shall state the tested sizes or size ranges, and it is recommended that the certificate clearly states the approved sizes or size ranges.

PPE outside the size or size ranges covered by the EC type examination must not be CE marked.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.133 Revision 02 Language: E

Number of pages: 1	Date: 15.08.2008	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 09.02.07 ☒ Standing Committee 15.07.08

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 10/11	Clause:	

Key words:

Traceability of article 10 technical file documents

Question:

What are the minimum criteria to guarantee the traceability / identification of documents within the technical file approved for an EC type examination certificate?

Solution:

In order to assure the notified body that carries out Article 11 procedures that the technical file as well as the model of the information supplied by the manufacturer, which are part of the technical documentation that must be presented by the manufacturer, correspond to the documents assessed during the EC type examination, the notified body that carries out the EC type examination will send back to the certificate holder at least a copy of the marking of the PPE and of the information supplied by the manufacturer. These documents must be dated and identified.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.134 Revision 02 Language: E

Number of pages: 1	Date: 15.08.2008	Approval by : Approved on :
Origin : Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee 09.02.07 ☒ Standing Committee 15.07.08

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 10, 11	Clause:	

Key words:

Article 11 assessment, EC type examination certificate

Question:

Should the notified body that carries out EC type examination for a category 3 product check, as part of its responsibilities according to articles 10 (1) and 10 (5), that an Article 11 assessment is present or in process?

Solution:

Yes.

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

(3): (5):

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.135 Revision 04 Language: E

Number of pages: 6	Date: 20.04.2011	Approval by :	Approved on :
Origin : Horizontal Committee, Article 11 Ad hoc group		☒ Ad-hoc Committee ☒ Horizontal Committee ☒ Standing Committee	18.10.2009 18.10.2009 20.04.2011

Question related to: Annex: Article: 11B	EN/prEN: Clause:	Other:

Key words:

11B minimum requirements

Question:

What are the minimum requirements that systems complying with 11B have to cover?

Solution:

The minimum requirements are as attached pages, 2 to 6.

NOTE: Recommendation for use sheet 00.119 is replaced by this sheet and will therefore be withdrawn.

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

(5): EU Commission

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

The system shall be documented in the form of a manual, procedures and supporting work instructions or similar. The scope of the system shall be specified.

The system requirements are limited to category III PPE, CE marked under the PPE Directive 89/686/EEC

Heading, with reference to ISO9001:2008	Comments
4 Quality management system **4.1 General requirements** Comply with Clause 4.1 of ISO 9001:2008 The quality system ensures compliance of the product with the product described in the EC-Type Examination Certificate(s). System shall be documented in the form of manuals, procedures and work instructions.	Shall include or reference quality objectives. Clear identification and control mechanisms for any outsourced processes to be documented, especially applicable where the company does not manufacture the PPE. Cross reference clauses 7.4.1
4.2 Documentation requirements Comply with Clause 4.2 of ISO 9001:2008 **4.2.1 General** Complies with Clause 4.2.1 of ISO 9001:2008 **4.2.2 Quality manual** Complies with Clause 4.2.2 of ISO 9001 :2008 **4.2.3 Control of documents** Complies with Clause 4.2.3 of ISO 9001:2008	To include technical file documents, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards.
4.2.4 Control of quality records Complies with Clause 4.2.4 of ISO 9001:2008 At least the following documents are retained for at least 10 years after supply of the last item: Those arising from regulatory requirements Training records Inspection and test data Calibration data	Retention period to clearly specify period after supply of the last production item.
5 Management responsibility **5.1 Management commitment** Complies with Clause 5.1 of ISO 9001 :2008	
5.3 Quality policy Complies with Clause 5.3 of ISO 9001:2008	
5.4 Planning **5.4.1 Quality objectives** Complies with Clause 5.4.1 of ISO 9001:2008 **5.4.2 Quality planning** Complies with Clause 5.4.2 of ISO 9001:2008 The quality system ensures compliance of the product with the EC-type examination certificate(s) All adopted elements, requirements and provisions are documented in a systematic and orderly manner in the form of written policies, procedures and instruction.	

5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Complies with Clause 5.5.1 of ISO 9001:2008 The following shall be defined: A. Need to liaise with notified body responsible for the EC type-examination in case of changes to the design defined in the EC-type examination certificate and the technical documentation B. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes of quality system. C. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes made to the product or technical file **5.5.2 Management representative** Complies with Clause 5.5.2 of ISO 9001 :2008 **5.5.3 Internal communication** Complies with Clause 5.5.3 of ISO 9001:2008	Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.
5.6 Management review **5.6.1 General** Complies with Clause 5.6.1 of ISO 9001:2008 A. Intervals should be at least every 12 months, but with a maximum of 14 months B. Top management chairs the review C. The authorized person(s) participate(s) in the review **5.6.2 Review input** Complies with Clause 5.6.2 of ISO 9001:2008 **5.6.3 Review output** Complies with Clause 5.6.3 of ISO 9001 :2008	The review and audit systems must include those departments / positions responsible for compliance with the PPE Directive.
6 Resource management **6.1 Provision of resources** Complies with Clause 6.1 of ISO 9001 :2008 **6.2 Human resources** **6.2.1 General** Complies with Clause 6.2.1 of ISO 9001:2008 **6.2.2.Competence, awareness and training** Complies with Clause 6.2.2 of ISO 9001 :2008 **6.3 Infrastructure** Complies with Clause 6.3 of ISO 9001 :2008 **6.4 Work environment** Complies with Clause 6.4 of ISO 9001 :2008	To include all personnel involved in those system elements covered by these requirements.
7 Product realization **7.1 Planning of product realization** Complies with Clause 7.1 of ISO 9001:2008	

7.4 Purchasing. **7.4.1 Purchasing process** Complies with Clause 7.4.1 of ISO 9001:2008 Manufacture, tests and final inspection sub-contracted (the responsibility to ensure compliance to specific requirements cannot be sub-contracted) A. Subcontractor has been selected after an evaluation has demonstrated the capability of ensuring compliance with all specific requirements B. The evaluation has been performed by one of the following methods; - third party quality system certification - documented evaluation which provides objective evidence of the capabilities - documented site assessment to ensure all relevant capabilities C. Where the features affecting the type of protection cannot be verified at a later stage, the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure that relevant controls are available, documented, understood and effective D. Suppliers not used for a period of one year are re-evaluated prior to placing of the contract E. Ability of supplier is reviewed at least once a year	The Notified Body is responsible for ensuring that the manufacturer's quality system complies with Article 11B requirements, and this may include on-site assessment of any sub-contracted activities which potentially impact upon conformity with the EC Type Examination and / or Article 11B.
7.4.2 Purchasing information Complies with Clause 7.4.2 of ISO 9001:2008 **7.4.3 Verification of purchased products** Complies with Clause 7.4.3 of ISO 9001:2008 A. Verification arrangements are implemented if purchased product can compromise the type of protection B. Routine tests or inspections confirmed with declaration of conformity.	
7.5 Production and service operations **7.5.1 Control of production and service provision** Complies with Clause 7.5.1 of ISO 9001:2008 Requirements contained in the EC-Type Examination Certificates are considered. **7.5.2 Validation of processes for production and service provision** Complies with Clause 7.5.2 of ISO 9001:2008 **7.5.3 Identification and traceability** Complies with Clause 7.5.3 of ISO 9001:2008 Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained **7.5.4 Customer property** Complies with Clause 7.5.3 of ISO 9001:2008 **7.5.5 Preservation of product** Complies with Clause 7.5.4 of ISO 9001 :2008	7.5.1 and 7.5.2 shall only apply where activities are carried out with respect to confirming compliance with standard / specification / type. Traceability is not required. Identification of product is required to cover type, model, part number etc.

7.6 Control of measuring and monitoring devices Complies with Clause 7,6 of ISO 9001 :2008 If the certificate of the calibrated instrument does not bear the accreditation logo of a national authority then the certificate shall contain the following: -an unambiguous identification of the item calibrated -traceability to (inter)national standards -the method of calibration -a statement of compliance with any relevant specification -the calibration results -the uncertainty of measurement, where relevant -the environmental conditions, where relevant -the date of calibration -the signature of the person under whose authority the certificate was issued -the name and address of issuing organization and the date of the certificate -a unique identification of the calibration certificate	
8 Measurement, analyses and improvement **8.1 General** Complies with Clause 8.1 of ISO 9001:2008	
8.2 Measuring and monitoring **8.2.2 Internal audit** Complies with Clause 8.2.2 of ISO 9001:2008 The audit program addresses the effectiveness of the elements of the quality system described in this standard. The audits should be carried out at least every 12 months, but within a maximum of 14 months **8.2.3 Monitoring and measurement of processes** Complies with Clause 8.2.3 of ISO 9001:2008 **8.2.4 Measurement and monitoring of product** Complies with Clause 8.2.4 of ISO 9001 :2008 The system shall include inspection and testing from purchased material to finished product, to the extent necessary to demonstrate continued compliance with the type-examined and the reference product specification, normally a standard. These activities shall be carried out by the manufacturer on a regular basis and shall be linked to production volumes, time or both. To include correct marking of the product, including the CE mark format and user information to include NB details.	
8.3 Control of nonconformity Complies with Clause 8.3 of ISO 9001 :2008 a) There shall be a system for the customer to be identified b) The manufacturer takes action if nonconforming product has been supplied to a customer c) In case of b) the manufacturer informs the customer and the Notified Body responsible for 11.B supervision. d) In case of b) and the nature of the nonconformity could affect user protection, and if not possible to trace the product, then additional actions shall be taken to inform the users, for example, notices placed in appropriate publications e) Product concessions that could affect user safety are not permitted. All concessions to be documented and authorised.	
8.4 Analyses of data Complies with Clause 8.4 of ISO 9001:2008	

8.5 Improvement **8.5.2 / 8.5.3 Corrective action / Preventive action** Complies with Clause 8.5.2 of ISO 9001:2008	To include customer complaints, warranty returns and returned products

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.136 Revision 06 Language: E

Number of pages: 2	Date: 28.09.2011	Approval by :	Approved on :
Origin : Horizontal Committee		☐ Ad-hoc Committee ☒ Horizontal Committee ☒ Standing Committee	 14.11.2014 01.10.2015

Question related to: Annex: Article: 10	EN/prEN: Clause:	Other:

Key words:

EC type examination certificates; validity

Question:

How shall revisions to standards which form the basis of EC type examination certificates be dealt with?

Solution:

Type examination certificates issued or amended after approval and publication of this Recommendation for Use sheet shall have a maximum validity of 5 years.

All certificate renewals shall reference the version of the standard(s) that is/are current at the time of renewal.

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

(5) EU Commission

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

Review of Article 10 Certificates

The standard validity period for certificates is a maximum of 5 years from the date of original issue or date of re-issue. Any amendment, modification, revision, extension etc. of a certificate shall not change the original expiry date. The expiry date will be stated on each certificate

Changes to any of the referenced standards during the 5 year period of the certificate will not affect the validity of the certificate, unless the presumption of conformity of a standard is withdrawn for safety concerns.

Certificates will not be renewed automatically.

If any company wishes to renew their certificate(s), written application is required to cover the following:

- Confirmation of the current company name and address
- Confirmation of current production address(es)
- Confirmation that there have been no changes to the product, including sub-components / sub-assemblies
- Copies of current product drawings and photographs, product marking and information supplied by the manufacturer
- The data resulting from the control and test facilities that have been used to check compliance of the PPE with the harmonised standards and / or other technical specifications
- For category 3 products information on Article 11 status

The manufacturer is free to submit any additional documents to support the application for renewal, e.g. independent product certifications, independent quality system certifications, etc.

The submitted documents will be reviewed against the requirements of the latest version of the PPE Directive after receipt of all the required information and data, and if the notified body is satisfied that the product has not changed and remains in compliance with all requirements, certification will be re-issued/renewed, retaining the same certificate number, to be valid for an additional maximum of 5 years.

Where deficiencies are identified, where possible, the company will be requested to address these before certification is re-issued.

If the notified body has any doubts about the current product being the same as that certified, they will be free to ask for more information, detailed drawings, photographs etc. plus if thought necessary, a sample of the model that is being questioned.

If the reference specifications / standards have been revised or amended and published in the Official Journal, the notified body will review the changes against the existing data, and any requirements not satisfactorily addressed will be covered by product testing before certification is issued. Where a certification is not based on a harmonised standard the technical specification shall be reviewed against the PPE Directive to take into account evolution in associated or applicable standards.

The earliest application can be made 12 months before the expiry of the certificate and to ensure continuity of the certificate the application for renewal shall be made at least 6 months before the expiry date.

Where the referenced standard(s) have been superseded / amended and published in the OJEU within 12 months before the expiry date of the certificate, the validity of a certificate may be extended by a maximum of 12 months to give the manufacturer sufficient time to comply with the revised / amended standard(s).

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/ 00.137 Revision: 03 Language: E

Number of pages : 1	Date : 20.04.2011	Approval by :	Approved on :
Origin : Horizontal Committee Article 11 ad-hoc group		☒ Vertical Group	31.08.2009
		☒ Horizontal Committee	31.08.2009
		☒ Standing Committee	20.04.2011

Question related to : Annex : Article : Article 11A.2 RfU sheet 125, 2B(iii) and 2B(iv)	EN/prEN :	Other : Clause :

Key words : Failure of 11A samples

Question :

What are the necessary actions following failures when samples are taken as required by recommendation for use sheet 125, sections 2B(iii) and 2B(iv), assessment of non-homogeneity?

Recommended solution :

The following steps should be taken:

1. Manufacturer asked to investigate the failure(s) and advise the notified body of their findings.
2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how.
3. Notified body to then determine what level of additional testing is required
4. Additional samples requested from the manufacturer and tested under the authority of the notified body
5. If additional samples pass the required testing, 11A considered completed.
6. If additional samples fail, steps 1 to 4 repeated.
7. If second set of additional samples fail, 11A certification to be withdrawn /not re-issued.

NOTE: If 11A body is not the article 10 body, article 10 body to be kept informed throughout the process.

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

(5) EU Commission

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

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.138 Revision 03 Language: E

Number of pages: 1	Date: 28.09.2011	Approval by : Approved on :
Origin : Advisory Panel		☐ Vertical Group ☒ Horizontal Committee 12.05.2011 ☒ Standing Committee 15.05.2012

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 10	Clause:	

Key words:

EC type-examination, certificate format

Question:

Each Notified Body uses its own format for EC type-examination certificates. Should a standard certificate format be used or should each certificate contain specified minimum information?

Solution:

The information provided on the certificate is of prime importance to the recipient and should provide all necessary information relating to the approval.

The following minimum information shall be entered on an EC type-examination certificate:

- Name and identification number of the notified body
- Name and address of the manufacturer
- Name and address of the authorised representative where the manufacturer is outside the EU / EFTA, where applicable
- Statement confirming compliance with the Directive. Where harmonised standards have been fully or partially applied as a basis for confirming compliance, the references shall be stated.
- Details of the equipment – type of PPE, model name / number / reference
- Where applicable, the recorded performance levels
- The necessary data for identification of the approved equipment or a clear reference to the technical file which contains this data
- Conditions of its validity, e.g. date of issue / date of any revisions / date of expiry
- Conditions attached to the issue and maintenance of the certificate, which for category 3 products shall include a reference to Article 11

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(4) EEC Standing Committee 89/392
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.139 Revision 02 Language: E

Number of pages: 1	Date: 20.04.2011	Approval by : Approved on :
Origin : Product marking with standard number		☒ Vertical Group ☒ Horizontal Committee 19.03.2010 ☒ Standing Committee 20.04.2011

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article:	Clause:	

Key words:

Marking, standard number

Question:

Can a product be marked with a national standard number in addition to the marking required by the EN?

Such marking can be confusing, e.g. if the publication date of the national standard differs from that of the EN.

Solution:

Yes, marking with additional standard numbers is possible.

If a product is marked with more than one standard number, the meaning shall be clearly explained in the information supplied by the manufacturer.

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

(5)

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(4) EEC Standing Committee 89/392
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.140 Revision 02 Language: E

Number of pages: 1	Date: 20.04.2011	Approval by : Approved on :
Origin : Vertical Group 2 “Respiratory protective equipment”		☒ Vertical Group ☒ Horizontal Committee 19.03.2010 ☒ Standing Committee 20.04.2011

Question related to: Annex: Article:	EN/prEN: Clause:	Other:

Key words:

Product marking; reference to standards

Question:

Is it allowed to use a defined term of a standard (e.g. FFP3) for marking a product without any reference to the standard?

Solution:

No.

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

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	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.141 Revision 02 Language: E

Number of pages: 1	Date: 20.04.2011	Approval by : Approved on : ☐ Vertical Group ☒ Horizontal Committee 19.03.2010 ☒ Standing Committee 20.04.2011
Origin :		

Question related to: Directive 89/686/EEC Annex: 2, 1.4 Article:	EN/prEN: Clause:	Other:

Key words:

Information supplied by the manufacturer, address of manufacturer

Question:

The Information for the user must contain the name and the address of the manufacturer. Can the manufacturer satisfy this requirement by publishing only his website and e-mail address?

Solution:

No.

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

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(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.143 Revision 02 Language: E

Number of pages: 1	Date: 1 March 2012	Approval by : Approved on :
Origin : Article 11 Ad hoc group		☒ Article 11 Ad hoc Group 16.11.2011 ☒ Horizontal Committee 01.03.2012 ☒ Standing Committee 30.08.2012

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article: 11.A.3	Clause:	

Key words:

Question:

Certain tests cannot be performed on samples of finished PPE, but require that materials or components are tested.

In such cases, how shall samples of materials/components be obtained in order to satisfy the requirement for samples to be selected and appropriate tests carried out?

Solution:

Where samples are selected from the production plant, the required material/component samples are to be selected at the same time as the finished PPE, either from the company warehouse or production line.

Where samples are selected from the importer or similar, advance notice shall be given that materials and components will have to be made available for selection, and size and quantity requirements specified in advance of the 11A visit.

In addition to the planned testing (referring to the PPE properties) carry out some appropriate test suitable to confirm the identity of the supplied material or component samples with the material present in the PPE itself.

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	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/00.144 Revision 00 Language: E

Number of pages: 1	Date: 22 November 2013	Approval by : Approved on :
Origin : Horizontal Committee		☐ Article 11 Ad hoc Group ☒ Horizontal Committee 22.11.2013 ☒ Standing Committee 01.10.2015

Question related to: Annex: Article:	EN/prEN: Clause:	Other:

Key words:

Instructions for use

Question:

What can notified bodies do to ensure that the information supplied by the manufacturer is legible?

Solution:

When checking the information supplied by the manufacturer, notified bodies should point out to the manufacturer that the printed version must be presented in a way that it is legible for the user.

They should make the manufacturer aware of relevant documents such as

- IEC 82079-1 “Preparation of instructions for use – structuring, content and presentation – Part 1: General principles and detailed requirements”, that specifies requirements for the presentation of instructions of use, e.g. font sizes;
- ISO IEC Guide 37:2012 “Instructions for use of products by consumers”;
- “Guideline on the readability of the labelling and package leaflet of medical products for human use” (version of 12/01/2009).

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

(3): (5):

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(4) EEC Standing Committee 89/392
(5) To be specified

	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/ 00.145 Revision: 00 Language: E

Number of pages : 1	Date : 21/11/2013	Approval by :	Approved on :
Origin : Horizontal Committee Article 11 ad-hoc group		☒ Ad hoc Group..... ☒ Horizontal Committee ..... ☒ Standing Committee	21/11/2013 22/11/2013 01/10/2015

Question related to : Annex : Article : Article 10 / Article 11A / Article 11B	EN/prEN : Clause :	Other :

Key words :

Article 11 A, 11 B, non-conform product, unsafe design

Question :

What procedure should be followed during article 11 examinations in the event of a non-conforming product where the non-conformity is related to the design of that product?

Recommended solution :

In the event of a non-conforming product where the non-conformity is related to the design of the product, the notified body doing the examination according to article 11 has to inform the notified body who issued the corresponding certificate according to article 10 about this non-conformity.

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

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	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/ 00.146 Revision: 01 Language: E

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Origin : Horizontal Committee Article 11 ad-hoc group		☒ Ad hoc Group..... ☒ Horizontal Committee ..... ☒ Standing Committee	24.01.2013 24.01.2013 01.10.2015

Question related to : Annex : Article : Article 11A.2 RfU sheet 125, 2B(iii) and 2B(iv)	EN/prEN :	Other : Clause :

Key words : 11A samples and process / production dormant.

Question :

What are the necessary actions where a manufacturer follows article 11A and production is dormant for a period, resulting in 11A not being able to be carried out?

Recommended solution :

1. 11A certification is covered by a separate certificate with a 1 year validity.

2. Where the11A certification is linked to article 10 or the article 11A certificate does not have a validity period.

Either:
11A supervision / sampling cannot be carried out due to no production, certificate remains valid and 11A process is activated when production starts or restarts, manufacturer to inform NB. 11A process to be satisfactorily completed before product is allowed to be placed on the market.

Or:
11A supervision / sampling cannot be carried out due to no production, certificate remains valid and 11A process is activated when production starts or restarts, manufacturer to inform NB. Product is allowed to be placed on the market while the 11A assessment is organised / carried out.

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

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	CO-ORDINATION OF NOTIFIED BODIES PPE-Directive 89/686/EEC + amendments RECOMMENDATION FOR USE	CNB/P/ 00.147 Revision: 00 Language: E

Number of pages : 1	Date : 14.11.2014	Approval by :	Approved on :
Origin : Horizontal Committee Article 11 ad-hoc group		☒ Ad hoc Group..... ☒ Horizontal Committee ..... ☒ Standing Committee	13.11.2014 14.11.2014 01.10.2015

Question related to : Annex : Article : Article 11A.3	EN/prEN :	Other :
	Clause :	

Key words: 11A samples / frequency of specific tests.

Question :

Is it acceptable for some of the required 11A tests to be carried once every two or three years instead of every year?

Recommended solution :

Yes, provided that the principle has been discussed and agreed by the applicable vertical group, and the tests that this principle could apply to have been specified by the vertical group.

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