



## **Reference 2024n17**

### **Adapted Guideline for a practical conformity assessment according to Module D of Annex II of the Directive 2013/29/EU in automotive industry**

This document gives guidance to the Notified Bodies for the application in automotive industry of the Module D as set out in the Annex II of the Directive 2013/29/EU. The application of this guidance is restricted to the case of manufacturer of pyrotechnic articles for vehicles (PAV) of category P1 or P2. Notified Bodies (NBs) under the Directive 2013/29/EU agree to follow the principles stated below as general guidance for their assessment according to Module D.

#### **1. Introduction:**

Pyrotechnic articles for vehicles (PAV) are in the scope of the Directive 2013/29/EU. For their certification, manufacturers select often the conformity assessment procedures Module B + Module D.

For PAV, harmonized standards series have been developed as ISO standards (cf. ISO 14451 series) to take into account the worldwide market of automotive industry.

The document 2015n18 *“Guideline for the practical application of the conformity assessment procedures (modules B, C2, D, E, and H) according to Annex II of the Directive 2013/29/EU - Approved during the meeting in Sofia, May 13th, 2015”* from the Forum of Pyrotechnic Notified Bodies gives general guidance regardless of the type of pyrotechnic articles or industry concerned. However, it was not written in view of pyrotechnic articles for vehicles at that time and is therefore not fully appropriate for application in the automotive field.

The document is created to adapt the applicability of audit sampling of multi-site organizations as compared to IAF MD1:2023 guide document by taking into account the specifications of automotive pyrotechnic industry .

#### **2. Description of a multi-site organization applied to the PAV industry**

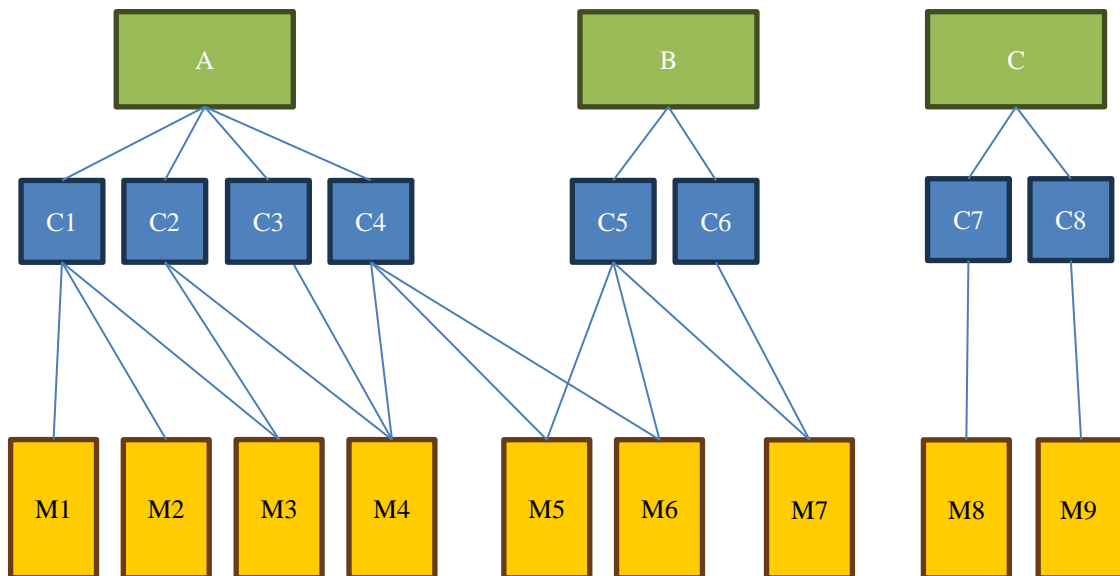
PAV manufacturing sites are usually organized in such a way that they are linked or operate under the supervision of a parent company. In this case it is possible to identify a manufacturer (as defined in the Directive) which will be responsible for the compliance of conformity of several manufacturing sites in charge of manufacturing the articles for it.

However, the actual situation can be a bit more complex when several manufacturers are using a same manufacturing site: the overall complexity of the PAV industry is depicted in the Figure 1 below.

This Figure 1 gives an illustration of the situation where A, B, and C are parent company but also manufacturer as defined in the Directive; each obtained different module B certificates C1 to C8. These manufacturers are manufacturing the articles for which they have a certificate in the manufacturing sites M1 to M9. For example, the manufacturer A holds 4 certificates module B (C1, C2, C3 and C4) and the production of articles from certificate C1 is made in 3 manufacturing sites M1, M2 and M3.



**Reference 2024n17**



**Figure 1**

**3. Definition of an Audit Group**

Since the Directive requires that the audit shall include an assessment visit to the manufacturer’s premises, the sole audit of only the manufacturer (as defined in the Directive) is impossible. So, some manufacturing sites, defined in this document as an Audit Group, shall be part of the Module D audit of a manufacturer. By considering the specific organization described previously in §2 and its Figure 1, the following table can be made:

Manufacturer/Applicant (Certificate holder level)	Certificate level	Production level	Audit Group
<b>A</b>	C1	M1, M2, M3	M1, M2, M3, M4, M5 and M6
	C2	M3, M4	
	C3	M3	
	C4	M4, M5, M6	
<b>B</b>	C5	M5, M6, M7	M5, M6 and M7
	C6	M7	
<b>C</b>	C7	M8	M8 and M9
	C8	M9	

**Table 1: allowed grouping from Figure 1**

Manufacturer A will be responsible of the manufacturing sites M1, M2, M3, M4, M5 and M6 for the products covered by the certificates C1, C2, C3 and C4. Therefore, the Module D of the manufacturer A audit shall be conducted by auditing A and the Audit Group M1 to M6, and include in its scope the products covered by the certificates C1 to C4.

Manufacturer B will be responsible of group M5, M6 and M7 for the products covered by the certificates C5 and C6. Therefore, the Module D of the manufacturer B audit shall be conducted by auditing B and the Audit Group M5 to M7, and include in its scope the products covered by the certificates C5 and C6.



### Reference 2024n17

Manufacturer C will be responsible of group M8 and M9 for the products covered by the certificates C7 and C8. Therefore, the Module D of the manufacturer B audit shall be conducted by auditing C and the Audit Group M8 and M9, and include in its scope the products covered by the certificates C7 and C8.

#### 4. Definition of Valid Audit Group

A Valid Audit Group is an Audit Group which complies with the following requirements:

- Annual internal audits of each manufacturing site shall be carried out under the responsibility of the manufacturer. The scope of these internal audits shall explicitly include the conformity related to the Directive 2013/29/EU including point 3.2 to 3.5, 5. (following the format of Annex III) and 6. of Annex II, module D and the labelling requirements (Article 11.) and Directive 2014/58/EU.
- the manufacturer and all manufacturing sites are holding a valid certification according to IATF 16949
- a global QMS managed by the manufacturer, or by a common parent company to the manufacturer and all manufacturing sites, is applicable to all the manufacturing sites and includes at least the following:
  - General Quality Management policies
  - Processes and procedures for the production, final product inspection and testing of the pyrotechnic articles

Detailed work instructions, forms, templates etc. may not be part of the global QMS and may be managed by the local manufacturing sites.

#### 5. Frequency, audit cycle and sampling of manufacturing sites

For a Valid Audit Group, the recertification audit of the manufacturer must be performed with a periodicity of maximal 4 years (audit cycle), then recertification audit of each manufacturing site shall be audited at least once within the audit cycle. The sampling of the manufacturing sites within the audit cycle should strive for even distribution among the years.

For instance, from Figure 1, if the Audit Group of the manufacturer A meets the requirements for a Valid Audit Group, then the following audit cycle can be performed:

Audit Cycle n						Audit Cycle n+1
$t_0$	$t_0 + 8$ months	$t_0 + 16$ months	$t_0 + 24$ months	$t_0 + 32$ months	$t_0 + 40$ months	
A+M1	M2	M3	M4	M5	M6	A+M1

**Table 2: example of an audit cycle of a Valid Audit Group**

If a manufacturing site produces articles under the name of two or more different manufacturers, the production site should be audited only once within the audit cycle (in case all manufacturers are monitored by one Notified Body) when there is an agreement between the manufacturers: this agreement shall state that the audit can be carried out on behalf of several manufacturers at the same time or that the results of the audit can be used for other audits. If the manufacturers belong to a common parent company, such agreement can be established for all manufacturers as long as each legal entities involved jointly signed.

For manufacturing sites which do not meet the requirements to be part of a Valid Audit Group, their recertification audit must be performed with a periodicity of 2 years.

The sampling of the manufacturing sites within the audit cycle should strive for even distribution among the years.



## Pyrotechnic Notified Bodies (PNB) Forum of the Notified Bodies for Directive 2013/29/EU



### Reference 2024n17

If a manufacturer has only one manufacturing site, its recertification audit is performed with a periodicity of 2 years, or performed with a periodicity of maximal 4 years if it complies with the following requirements:

- its customers perform frequent audits of the manufacturing site with a periodicity of maximal 4 years. In addition, the manufacturer must perform annual internal audit and the scope of audits shall explicitly include the conformity related to the Directive 2013/29/EU including point 3.2 to 3.5, 5. (following the format of Annex III) and 6. of Annex II, module D and the labelling requirements (Article 11.) and Directive 2014/58/EU.
- the manufacturer is holding a valid certification according to IATF 16949.

For all PAV manufacturers, Surveillance audits may be conducted but are not required.

#### 6. Module D: Production quality assurance - procedure

The procedure for module D shall be the following:

- Definition of scope of audit (categories, generic types and articles) between company and NB
- Procedures for communication with the NBs for monitoring of the quality system regarding any relevant changes or the inclusion of new types shall be set up
- Review of quality management system
- Quality system should be certified against IATF 16949, ISO 9001 (or other applicable system standards) in all manufacturing sites
- Quality system shall comprise all relevant production steps (such as incoming goods inspections, traceability of initial substances, raw materials, chemicals, intermediate products, in-process inspections etc.) and the necessary test requirements with regard to final article inspection and testing
- Number of auditors typically 2 (due to reasons of impartiality and complexity with regard to technical and organisational/legal questions)
- Check of incoming goods inspections
- Check of traceability of initial substances, mechanical parts and intermediate products
- Check of in-process inspections
- Check of final end product, sampling and testing
- Check of nonconformity assessments carried out by the company and procedure on how to handle nonconforming articles/lots
- NB provides an abridged or draft audit report (requirements; oral or written) at the last day of audit
- NB draws up an audit report (incl. actions during audit, observations, and requirements) after the audit according to 2013/29/EU, Annex II, Module D, 4.3
- NB gives out certificate (with a defined time of validity aligned to the expected periodicity of audit and information on the respective categories, generic types and manufacturing sites) after the fulfilment of all requirements, if applicable

In addition, for the audit of the manufacturer responsible of a group, the following documents or equivalent must be reviewed:

- Organization chart and position of the manufacturer in the group,
- Identification of the Company member of the group and of a local correspondent (focal point),
- Results of the internal audit organized by the manufacturer at the manufacturing sites,

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive.