ExNB	Co-ordination of Notified Bodies Directive 2014/34/EU of the European Parliament and of the Council (ATEX) *Equipment and protective systems intended for use in potentially explosive atmosphere*	**Clarification Sheet** **N° ExNB/CS/015** **(replaces ExNB/CS/007)**

Guidance on the definition of "manufacturer" in relation to "local assemblers"

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Authorised by Chairman:	**Dr. Thedens**	**Date:**	**2020-02-13**
Date of application:	**2020-02-13**	**Signature:**	M. Thedens

Prenote:
"Local assemblers" are named as "LA" in this document; they work on the basis of a contractual cooperation between the manufacturer and the LA

1. Purpose

The purpose of this CS is to provide a coherent mechanism whereby such a normal industrial practice can be extended to the final assembly of some forms of Ex Products (e.g. Ex equipment, protective systems, safety devices, Ex components and their combinations).

2. Background Information

For simple cases where a manufacturer is fully responsible for the design of various assemblies, using components or sub-assemblies which are entirely within its control, the physical final assembly of such items is often performed at a remote location. This remote location is either owned by the manufacturer or being itself a contractor of the manufacturer.

Subject:	**Directive, 2014/34/EU Article No.**	**2 item 12**
	Directive, ESR No.	
	Directive, Module Annex No.	
	Standard, No.	

This ExNB Interpretation/Clarification Sheet has the sole purpose of clarifying the application of the EN Standards and/or of the requirements of Directive 2014/34/EU and related documents. It does not in any way change the content of the standards and/or of the requirements. It remains valid until an official answer is received from the European Commission of the relevant standardization bodies.

3. Procedures

3.1. In all cases where the use of a Local Assembler (LA) is envisaged, the manufacturer shall make an application to the NB that is responsible for the issue and maintenance of the QAN. The application shall be accompanied by the written procedure that the manufacturer intends to use to ensure that the product dispatched from the LA conforms to a design permitted by the certification documents and which describes the process to ensure that the requirements of this CS are complied with.

3.2. The NB shall process the application as an extension to scope of the QAN, seeking sufficient information that the proposed procedure can be correctly implemented. Whether this is done in association with a full QAN or as a desk exercise between full QANs. The location of the LA shall be addressed according to the QAN form clause (6) Manufacturing locations. This procedure does not mean or cover an own QAN for the LA, despite this the LA can be a holder of an own QAN.

3.3 Operation of the procedure shall be monitored along with all other relevant aspects as part of routine surveillance and assessment of the manufacturer, at which time evidence of correct operation of the agreed procedure shall be obtained. Where a manufacturer uses more than one Local Assembler, the NB assessment shall confirm that the internal audit process of the manufacturer audits the operation of procedures with every assembler. Anyway, the NB keeps the right for the on-site visit of the LA if necessary and without prior agreement of the manufacturer, e. g. in case of special requirements, testing for release or something other reasons.

3.4. The manufacturer’s written procedure shall include at least the following:

- A statement of how the contract is drawn up between the manufacturer and the assembler to ensure that the assembler accepts responsibility for its part in the process.
- The process used to ensure that the assembler is issued with all appropriate assembly instructions.
- The process used to transfer identified components of the permitted assemblies to the assembler, including evidence that the assembler has correctly received undamaged components and retains any necessary identification of the components prior to assembly.
- The process used to ensure that the assembler applies correct final marking to the assembly and includes relevant documentation with each assembly delivered to a customer.
- The process of final inspection to be employed by the assembler and the transmission of appropriate records to the manufacturer. These records shall be sufficient for the manufacturer to operate an efficient product recall system and will transfer any information related to customer complaints. Records shall also be transmitted and retained of any faulty items received from the manufacturer.
- The process for subsequently identifying which assembler finally placed the product on the market under the authority of the manufacturer. Note: The method

of identification is not prescribed by this CS but might include, for example, a code contained within the product serial number.

3.5. The following are noted as specific limitations in application of this CS:

3.5.1. The Local Assembler shall have either an appropriate QAN issued by an NB or an ISO 9001 Quality Management System Certificate issued by a certification body that has been accredited for the purpose by a member body of the IAF and which specifically covers activities related to the particular assembly process.

3.5.2. The Local Assembler shall not machine Flameproof (Ex d) Enclosures, but may add holes (for example, for cable entry devices or for switch operators) to an Increased Safety (Ex e) Enclosure as specified in technical documentation related to the (Ex e) Enclosure.

3.5.3. The Local Assembler shall use only parts supplied direct by the manufacturer unless, by prior agreement with the manufacturer, local sourcing of certain items is agreed. Such locally sourced items may include fully defined standard industrial items, such as screwed fasteners, or items clearly defined by reference to an ATEX Certificate, such as Component Certified terminals to be inserted in a junction box. Items which might directly affect the explosion protection (other than identified by an ATEX Certificate) shall not be locally sourced, for example gasket materials.

3.5.4. The manufacturer shall perform a physical inspection of a sample item produced by the assembler, prior to initiating production release of items of the same general type.

3.5.5. If internal wiring of equipment is included in the scope of the activity, routing and full definition of the wiring shall form part of the information provided by the manufacturer.

3.5.6. The manufacturer shall ensure, either directly or by a process agreed with the assembler, that all the assembler's personnel that will have an input potentially affecting conformity of the final product have adequate training in the relevant aspects of explosion protection, in interpreting the manufacturer's drawings and process instructions, and in the reasons why the documentation process is important. In particular, all personnel shall understand that failure to follow the manufacturer's detailed instructions, in any way, will result in the production of uncertified equipment.