Proposed Conformity Assessment Procedure of electrical and electronic equipment with respect to the restriction of hazardous substances

How to Produce Technical Documentation to demonstrate compliance with MINISTRY OF ENVIRONMENT NATIONAL COUNCIL OF ENVIRONMENT RESOLUTION Nº nnnn/2019 (“Brazil RoHS”)

1) Introduction

   a. Purpose of this Procedure

      The purpose of this procedure is to provide guidance to manufacturers who must produce technical documentation per Chapter 3, Article 7(III) in order to demonstrate that their products comply with the requirements of Brazil RoHS. Note that the form of the Technical Documentation (TD) follows that described in Section 4.2 of ABNT IEC 63000:2019.

      This procedure is to be used along with, not instead of, ABNT IEC 63000:2019.

   b. Goals of this Procedure

      The goals of this procedure are

      i. Describe the different sections of the Technical Documentation
      ii. Describe the information that is expected to be contained in each section
      iii. Provide guidance and tips on completing the sections, as needed

2) Technical Documentation Section Overview

   Section 4.2 of ABNT IEC 63000:2019 describes certain required elements of the Technical Documentation. This procedure expands that to consist of the following sections. Each section is described in more detail in Clause 3, below.

   a. Manufacturer Information
   b. General Product Description
   c. List of Standards and other technical specifications used to establish the Technical Documentation
   d. Bills of Materials/Parts Lists
   e. Evidence of Compliance
   f. Supplier and Material Risk Assessment Methodology (optional)
   g. Declaration of Conformity

3) Procedure/Guidance for Each TD Section

The requirements for each TD section are described below including, where necessary, options and guidance on how to complete the sections. ABNT IEC 63000:2019, Section 4.2 lists the general sections of the Technical Documentation. Section 4.3 describes the information the manufacturer will need in order to demonstrate compliance of the product. Figure 1, below, outlines the process to create the TD, along with the relevant sections of this document:

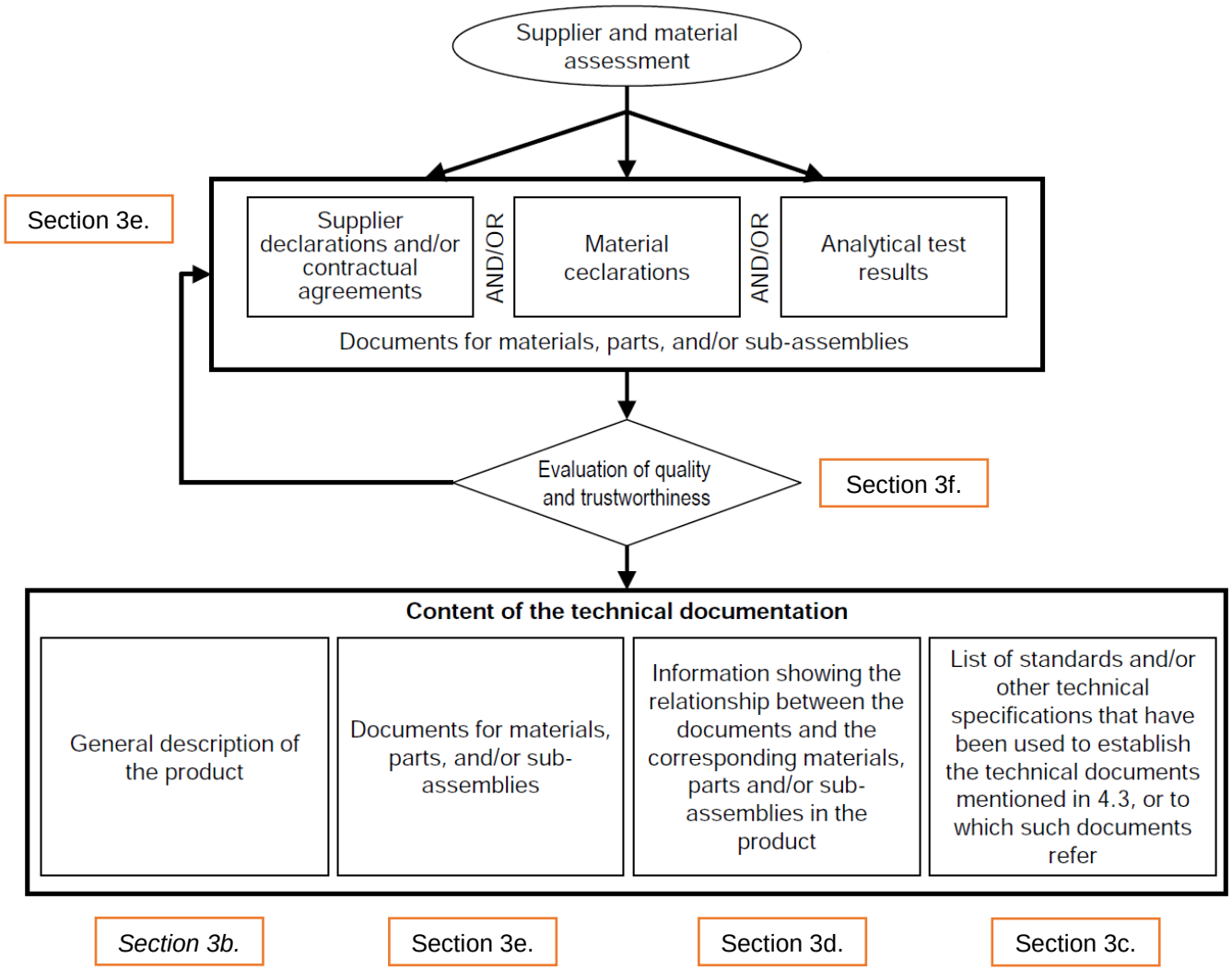

Figure 1. Flowchart from ABNT IEC 63000:2019

a. Manufacturer and, as necessary, Importer Information

   While not called out explicitly by ABNT/IEC 63000, this section is nevertheless required.

   i. Name/Address/Phone/Email Contact Information

      - For the actual manufacturer or brand owner of the product
      - Products imported into Brazil for sale on the Brazilian market must also provide contact information for the Importer and/or Distributor, as relevant.

b. General Description of the Product

   i. Briefly describe the product, including information about the intended use

   ii. Include a list of product lines including the names and identifying model numbers (if appropriate) for individual models, accessories and options covered in this TD. Describe how the models, accessories and options relate to each other. For example:

      - "Great Product 1: Basic" is the most basic version of the product.
      - "Great Product 1: Super" is the version with more memory.

   iii. Include photos, drawings, instruction guides, etc. as needed

   iv. List any exemptions taken (link to "Evidence of Compliance", as desired)

c. List of Standards and/or other technical specifications used to establish the Technical Documentation

   i. ABNT IEC 63000:2019 must be listed

   ii. List other industry standards used to achieve and maintain compliance; these can include (but are not limited to)

      - IEC 62321 (all parts), *Determination of certain substances in electrotechnical products*

        Where testing has been determined to be a necessary method of assessing compliance of a part or material to RoHS requirements (see below, Clause 3(f)), ensure that the tests are carried out according to the appropriate part of IEC 62321, as specified in IEC 63000, by

        - a third party laboratory accredited by the General Coordination of Accreditation (CGCRE) of the National Institute of Metrology, Quality and Technology (Inmetro) or by
        - foreign laboratories accredited to ISO/IEC 17025 by accreditation bodies, and preferably signatory to a mutual recognition agreement (MRA) to which Inmetro is a party.

      - IEC 62474 and/or IPC 1752A declaration standards,
      - IEC/TR 62476 "Guidance for evaluation of products with respect to substance-use restrictions in electrical and electronic products"
      - ISO 9001 or ISO 14001 business process management standards

   Provide a brief description of how the listed standards apply to the TD.

d. Bills of Materials/Parts Lists

i. Flat list of parts and materials. A simple parts list is acceptable. If the product is comprised of modules, sections or subassemblies, those may be represented by separate parts lists.

- Do not list quantities
- Be sure to list all sources, i.e., list different manufacturers for the same part separately.

ii. Include separate part lists for accessories as well as additional parts lists that address options or model-to-model variations covered by the same Technical Documentation.

iii. Add a column to the parts list with a short description of each line item

iv. Add a column to map individual parts to the compliance evidence (clause 3(e), below). This can be the name of the file or a hyperlink to it. In the example below, this is the "Compliance Document Name(s)" column.

v. Consider adding a column to identify supplier and/or part risk, as determined by clause 3(f), below. Can be as simple as indicating "High/Medium/Low", "H/M/L:", or a Red/Yellow/Green color code. All standard off-the-shelf components from major manufacturers can normally be considered low risk; as long as you specify materials for custom-designed items like enclosures, bezels, etc. and verify that the suppliers follow your requirements, they should be low risk as well. See below.

vi. Example

The first set of parts below is for "Great Product 1: Basic". This is (part of) the basic product. The second set represents an available upgrade: "Great Product 1: Super". These product names should be the same as listed for section 3(b)(ii), above. Each product name should be associated with a list of parts.

Product Name	Manufacturer	Manufacturer's P/N	Description	Compliance Document Name(s)	Supplier Risk (Optional)	Part Risk (Optional)
Great Product 1: Basic	PCB Manufacturing	1004566-01	PCB,FAB,Product 1	PCB Manufacturing 1004566-01 CofC.pdf	M	M
	Infineon	HYB18T512160BF-3.7	IC,DDR-2 SDRAM 512Mb	Infineon DDR 2 CofC.pdf	L	L
	Nanya	NT5TU32M16AG-37B	IC,DDR-2 SDRAM 512Mb	Nanya DDR2 FMD.pdf, Nanya DDR2 CofC.pdf	L	L
	Samsung	K4T51163QC-ZCD5	IC,DDR-2 SDRAM 512Mb	Samsung DDR2 CofC.pdf	L	L
	Texas Instruments	LP3891EMRX-1.2	IC,LDO Regulator	TI LP3891EMRX-1.2 FMD.xlsx	L	L
	Kemet	C1210C106K3PACTU	CAP,SMT, 10uF,25V	Kemet C1210 FMD & CofC.pdf	L	L
	MURATA	GRM32DR61E106KA12K	CAP,SMT, 10uF,25V	Murata GRM32 FMD & CofC.pdf	L	L
	ROHM	MCR03EZPFX4532	RES,45.3K OHM,0.1W	Rohm MCR03 FMD & CofC.pdf	L	L
	VISHAY	CRCW060345K3FKEA	RES,45.3K OHM,0.1W	Vishay CRCW0603 FMD & CofC.pdf	L	L

Product Name	Manufacturer	Manufacturer's P/N	Description	Compliance Document Name(s)	Supplier Risk (Optional)	Part Risk (Optional)
Great Product 1: Super	PCB Manufacturing	1004568-01	PCB,FAB,Product 1, Accesory 1	PCB Manufacturing 1004568-01 CofC.pdf	M	M
	Infineon	HYB18T4096160BF-3.7	IC,DDR-2 SDRAM 4Gb	Infineon DDR 2 CofC.pdf	L	L
	Nanya	NT5TU256M16AG-37B	IC,DDR-2 SDRAM 4Gb	Nanya DDR2 FMD.pdf, Nanya DDR2 CofC.pdf	L	L
	Samsung	K4T517743QC-ZCD5	IC,DDR-2 SDRAM 4Gb	Samsung DDR2 CofC.pdf	L	L

Figure 2. Example Parts Lists

e. Documents for materials, parts, and/or sub-assemblies: Evidence of Compliance

i. Defining requirements – Per section 4.3.2 of ABNT/IEC 63000, manufacturers must determine what type of documents will be required based on two factors:

- the probability of restricted substances being present, in materials, parts or subassemblies (the "Part Risk" column in Figure 2, above), and
- the trustworthiness of the supplier (the "Supplier Risk" column in Figure 2, above).

These two factors are rather poorly and incompletely described in ABNT/IEC 63000. Research and technical knowledge can, to a degree, be used to assess the likelihood of restricted substances being present in a given type of item. For instance, heavy metals like lead or cadmium, phthalates, and flame retardants like PBBs or PBDEs can be present in plastics and polymers. However, as stated in the standard, "organic substances in metals" will not be found, since the melting temperature of most metals exceeds the boiling or combustion temperature of organic substances (like PBBs, PBDEs or phthalates).

Work with your supply base management and/or procurement personnel to define supplier "trustworthiness". While ABNT/IEC 63000 fails to define trustworthiness, ISO defines it as "quality of being dependable and reliable".

Section 4.3.4 says "the manufacturer shall establish procedures that shall be used to evaluate the documents described in 4.3.3 in order to determine their quality and trustworthiness." These procedures may be included in the TD as desired. See clause 3(f), below.

ii. Defining the information to collect: desired information vs. minimum acceptable information

Per Figure 1, above, this can consist of

- Supplier declarations and/or contractual agreements, and/or
- Material declarations, and/or
- Analytical test results

ABNT/IEC 63000 section 4.3.3 describes what these are, but does not provide guidance for when to consider one or the other. The manufacturer should determine, potentially using IEC/TR 62476, what type of data is preferred from which suppliers. That may change based on the type of part, and part risk, or the type of supplier, and supplier risk.

For instance,

- for metal alloys based on standards (e.g. ASTM, DIN, etc.) provided by trusted suppliers and machine shops, perhaps only a contractual agreement is necessary.

On the other hand,

- new suppliers and new machine shops may be required to provide a material declaration or test results showing conformity with the standard (and with RoHS requirements) on a lot-by-lot basis until vetted[1] or fully approved.

Trusted suppliers may provide a declaration that states everything they provide to you complies with RoHS requirements. These declarations will list the parts/materials/items the supplier provides, any exemptions taken and will be signed and dated by a company representative.

[1] "Vetting" should be consistent with how the manufacturer approves new suppliers, expanded to include RoHS-specific requirements. For instance, this may be through a desktop or onsite audit that includes how the supplier orders sheet metal (or ingots, etc.) and approves incoming raw material for conformance with requirements.

Contractual agreements are typically depended on to ensure compliance for RoHS only for very low risk situations, primarily with strategic partners, like long-term contract manufacturers. While they may be legally appropriate, the people doing the actual work in the manufacturer's engineering and production groups may not know the specific requirements in the contract. Asking for documentation of compliance for any parts or materials provided by suppliers that are already contractually obligated to ensure compliance with RoHS is a sensible back-up or verification strategy.

Material declarations vary in terms of scope. They may meet a standard, such as IEC 62474, which requires listing substances with a mandatory reporting requirement if they are present at or above the reporting threshold. Or they may list every substance included in the part/material/item being provided by the supplier, along with the weight, location in homogeneous materials, and an indication of any exemptions taken. This is often called "Full Material Declaration", or FMD. Alternatively, they can simply be "Certificates of Compliance", or "CofCs", which state that a product complies with RoHS, defining whether or not any exemptions are used in order to comply and, if so, which ones. Again, these are dated and often signed by a company representative.

FMD may seem like overkill for RoHS however, for manufacturers who sell products in many markets, this may be the preferred level of documentation to request, along with CofCs. Different markets often have different substance-related regulatory and customer requirements and those requirements may change on a relatively frequent basis. In that case, knowing every substance used in a product will help a manufacturer to rapidly assess whether a product complies with requirements for a new market or for when a market's requirements change. Note that a specialized database is necessary to adequately manage and maintain this extensive and complex information.

In addition, manufacturers with products in many markets may find it useful to aggregate diverse regulatory and market product-related environmental and health-related requirements into a single internal standard. This standard is then shared with suppliers and their CofCs are then written against that standard, rather than specific regulatory requirements.

In general, analytical testing is not an appropriate general approach for ensuring ongoing compliance of a product. It is very expensive and, ultimately, a test result is only valid for the part, material or lot being tested. Compliance of later parts, materials or lots cannot be assumed. However, when there is no other recourse – such as when a manufacturer is sole-sourced with a specific supplier and the supplier refuses to provide compliance information (i.e. a "trustworthiness" issue), or when the provenance of an item is unclear (i.e., a "part risk" issue) – then it may be used. It is also useful to verify compliance as a "spot check" or in situations where either the supplier or component risk is high (see below, section 3(f)).

Ultimately, this specific risk-based approach can be very challenging to implement since it requires each supplier and each part to be treated differently. Most manufacturers take the more practical approach of simply defining a desired set of documents to collect that will meet their requirements, then require the entire supply base to provide at least that level of documentation (but again, ask for more) and maintain it over time (e.g., request periodic – usually annual – updates). Suppliers that are outliers on "trustworthiness" or "part risk", which may be determined beforehand or after receiving information from them (or receiving no information), may be targeted for more specific and detailed information. The received information is then reviewed and the determination made whether to incorporate it into the TD or ask for additional information. Since this approach, too, is based on "the

manufacturer's assessment", it should be documented as part of the Supplier and Material Risk Assessment Methodology.

iii. Identifying resources to collect the data – consider internal vs. external resources

Depending on factors including number of unique parts and suppliers, internal business process and available internal resources, priority and cost a manufacturer may choose to collect compliance information from suppliers themselves or to outsource the task. Many service providers exist to support manufacturers in this effort.

iv. Collecting and Managing Information

Compliance information collected may be any combination of the types of information described above in 3(e)(i). Depending on what information was collected, storing and using it may require a very simple representation in an existing part management database, such as a single compliance flag, or it could require a sophisticated separate database.

As the supply chain and manufacturing processes are, at some level, in a constant state of flux, periodically review and refresh the information collected, per section 4.3.5 of ABNT IEC 63000.

v. Evaluating the Information

Procedures shall be established to evaluate the compliance documents received. These procedures include a risk assessment methodology, such as described above, assignment of trustworthiness risk to suppliers, assignment of risk to part types based on the probability that they contain RoHS substances, and a brief description of what to look for in each document collected.

Typically, the minimum acceptable information is the information that demonstrates compliance with the RoHS substance restrictions, including whether or not exemptions are used and, if so, which exemptions. The desired information may be more extensive, based on the manufacturer's markets, products and strategies.

vi. Building this Section and Mapping it to the BOM/Parts Lists (3d., above)

As a practical matter, the manufacturer should compile the data together and store it in a manner conducive to sharing it *en masse* with the requesting competent federal environmental authority. This can be, for example, a single (potentially very large) PDF file, or a compressed (e.g. "zipped") file containing a variety of document types organized in a manner determined by the manufacturer.

Regardless of how it is stored, each separate part/material/item from each separate manufacturer must have at least one document that demonstrates its compliance with RoHS. Section 3(d)(vi) above shows one way to map compliance files to their respective parts via the "Compliance Document Name(s)" (and perhaps folder). If a single large PDF file is used, perhaps an easier way to map the files to the parts is to simply use the page number that the compliance documentation starts at for the specific part.

f. Supplier and Material Risk Assessment Methodology (optional)

i. The documented methodologies, procedures and resources used for risk assessment may be included in the TD at the discretion of the manufacturer.

ii. When developing a risk assessment approach, consider (as noted above) that some of the restricted substances can inadvertently be found in certain part types and materials. This "contamination" can occur due to

- human error by the supplier,

- buying parts from unknown or disreputable sellers, or
- accidentally specifying a non-compliant part.

Put business processes in place to assess these risks and, when errors occur, to ensure that corrective action is defined and implemented.

g. Declaration of Conformity

   i. Per Resolution No. nnnn, Annex I, Sample of declaration of conformity for restriction of substances provided for in Chapter IV