GNB-CPD position paper from SG04 - EN 1317-5:2007

Certification of Road restraint systems - Part 5: Product requirements and evaluation of conformity for vehicle restraint systems

General scope, limitations and aim of this guidance for notified bodies

This position paper contains guidance for notified bodies (NBs) involved in the attestation of conformity of Road restraint systems according to EN 1317-5:2007. The purpose is to help NBs work equivalently and come to common judgments. This guidance contains informative material (which NBs should or may follow) and/or normative guidance (which NBs shall follow or at least work equivalently to as circumstances demand).

This guidance is thought necessary to provide clarity and completeness for NBs so that they can work equivalently. It supplements and makes practical for NBs the harmonized standard EN 1317-5:2007, approved Advisory Group guidance, and Standing Committee guidance in the form of GPs, which also apply - unless otherwise explicitly stated in this guidance. This position paper should not contradict nor extend the scope of the work and role of a NB, nor impose additional burdens on the manufacturer, beyond those laid down in the CPD and EN 1317-5:2007.

This guidance should be considered valid until the relevant standards are amended to include the guidance (as thought fit by the CEN/TC); or until guidance from Commission, SCC, and AG has changed on relevant matters. Whereupon, the paper should be considered for withdrawal/revision and be replaced by new guidance as necessary.

This position paper was considered approved in its original form by SG04 on 30 September 2009 and by Advisory Group on 2 January 2010. Revision 2 of this paper was prepared urgently, following discussions with the Commission Services, and approved directly by the GNB-CPD President on 15 July 2011. Revision 3 of this paper was approved by SG04 on 21 December 2011 and by Advisory Group on 19 February 2012.
Revision 3 of this position paper was produced to:

- Strengthen the importance of following the dated references to the 1998 editions of EN 1317 Parts 1-3 in Annex ZA of EN 1317-5:2007+A1:2008 (even though CEN has withdrawn these versions of the supporting standards (a replacement Section 2).
- Address the use of simulation through computational mechanics for assessing modifications to products (a new Section 4.4).
- Clarify which materials are acceptable under the FPC (additions to Section 6).

Paragraphs that have been changed from NB-CPD/SG04/10/074r2 are indicated as follows:

  new paragraph by a solid left border line, and;

  where previous paragraphs have been removed by 佢.

Revision 2 of this position paper was produced in response to a meeting between Commission Services, CEPMC and the GNB-CPD President, where the Commission Services explained that the dated references to the supporting standards EN 1317 Parts 1-3 in Annex ZA of EN 1317-5:2007+A1:2008 should be followed although CEN has withdrawn those versions of the supporting standards, and the references to EN 1317 Parts 1-3 in the body of EN 1317-5:2007+A1:2008 are undated.

Paragraphs in which the text has been changed from NB-CPD/SG04/10/074r1 are indicated by a single left border line.

Revision 1 of this position paper was produced, with the agreement of CEN/TC 226, to permit the use of current, 2010 editions of EN 1317 Parts 1-3 in place of the dated references to the 1998 editions in Annex ZA of EN 1317-5:2007+A1:2008. The 1998 editions are being withdrawn. Also the final paragraph of what is now section 4 (g), relating to soil conditions, has been changed.
1 Introduction

Paragraphs of the standards that are quoted hereinafter for ease of reference are written in small blue text. They are under the copyright of CEN and the Member States national standardization bodies.

2 Update of supporting standards

NBs shall use only the supporting standards in the edition mentioned by date in Annex ZA even if CEN has withdrawn such standards.

NOTE: CEN expects to issue the new edition of EN 1317 Part 5 in spring 2012. Following its publication by CEN, the standard will be cited in the Official Journal of the European Union (and listed on the Commission’s NANDO website), together with its date of applicability, and the end of any co-existence period with EN 1317-5:2007+A1:2008. When working to the new edition of EN 1317-5, NBs shall make reference to the new editions of the supporting standards (2010 editions) if and only if they are mentioned in Annex ZA of the new edition of EN 1317-5.

3 Definitions

Vehicle restraint systems (VRS)

Hereinafter the acronym VRS refers to vehicle restraint systems as defined by EN 1317.

Testing laboratories

**EN 1317-5  3 Terms and definitions**

For the purposes of this document, the following terms and definitions apply.

3.1 testing laboratory

competent laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products within the scope of this document. A laboratory accredited by a signatory of EA (European co-operation for accreditation) or the appropriate statutory instrument, within the scope of this document, in the territory where the test was executed may be presumed to be competent

Notified Certification Body (NCB)

A certification body notified by a Member State for the purpose of EN 1317-5.

Inspection Body (IB)

An inspection body that is either accredited or notified.

4 Initial Type Testing (ITT)

4.1 Path to ITT

The ITT is carried out under the responsibility of the NCB.
The path to certification for a new VRS is summarised as follows:

a) The manufacturer produces a prototype VRS either using the existing production lines (option 1) or by setting up a new production line (option 2).

b) The NCB is informed by the manufacturer that a new VRS is being prepared.

c) The NCB or the IB inspects the design and installation manual of the VRS to check for consistency.

An installation manual (see EN 1317-5 §5.4 c) shall be submitted by the manufacturer to the NCB that, in turn, will deliver it to the laboratory designated for the ITT. This manual shall contain sufficient information to enable the system to be installed although it is not required to be the final version as the manual may evolve following the ITT. The final version of the manual must, though, be consistent with the installation of the ITT test item.

The minimum set of information to be included in the installation manual is defined in EN 1317-5 §5.4.

The language of the Installation manual shall be agreed upon by the manufacturer and the NCB.

If necessary the manufacturer shall provide a translation of the installation manual.

d) The manufacturer, under the control of the NCB or the IB, collects all the necessary parts to set up a VRS to be tested for ITT.

e) The NCB or the IB inspects the documents accompanying the incoming materials, takes the necessary samples for material testing and makes any measurements necessary to check consistency of the parts with the design.

f) The manufacturer packs all the parts to be delivered to the testing laboratory. The NCB or IB seals the packages.

The ITT shall always be representative of the current production in terms of material types, geometric dimensions and other properties (chemical, physical, mechanical, etc).

The NCB shall assess the origin and documentation of the material properties according to the standard indicated in the design of the VRS.

g) The testing laboratory performs the ITT.

The installation of the VRS to be tested at the laboratory should be carried out under the surveillance of the manufacturer. In particular the following should be precisely respected (with tolerances suitable to the purpose for which the VRS has been designed):

- height of the main longitudinal components from the ground;
- pitch of any posts;
- torque of each bolt and applied tension;
- spacing between elements of modular systems;
- types of anchorages;
- position of particular components.

In order to achieve consistency between the ITT and the installation manual, the laboratory shall check and report the consistency of the installation with the manual. (See EN 1317-5 §6.2.1.3.b and §5.4).

The soil and foundation reports relating to the ITT shall include a description of the soil conditions and the foundations as described in 5.4 f). The NCB shall check that the soil conditions for testing are in agreement with the technical description.
In EN 1317-5 see:

5.4 f) description of the soil conditions and/or foundations suitable for the system;

6.2.1.3 Evaluation report of test item
d) soils and foundations report relating to the ITT,
e) verification that the product is installed in accordance with the specified layout in accordance with 5.4;

8. Installation of road restraint systems

The manufacturer shall provide an installation manual for the installation that will achieve the performance declared for the ITT.

... The use of the system relative to soil and other conditions of installation shall be defined by the manufacturer.

Annex ZA.2.2 EC Certificate and declaration of conformity
e) particular conditions applicable to the use of the product (e.g. provisions for use under certain conditions);

h) Either before or after the ITT the material samples (if any) are tested either by the NCB, a notified laboratory, or a laboratory under a long-term contract to the NCB. See NB-CPD/AG/03/005r2 for further details of the conditions under which NBs may use testing facilities other than their own.

i) The FPC of the new lines (option 2 above) is inspected by the NCB or the IB.

j) The ITT report is sent by the testing laboratory to the manufacturer and to the NCB.

k) If an IB is involved its report is sent to the manufacturer and the NCB. As an option the NCB shall take care of sending one original of the IB report to the manufacturer.

l) The NCB decides whether to certify the product based on the results of ITT, the material testing (if any) and the FPC inspection.

In case of failure of a test in the ITT, the VRS shall not be re-tested unless it is revised (in terms of design or layout) or the manufacturer can show that the first test failed due to conditions independent from the VRS itself (for example: ground conditions, strong vibrations due to accelerometer mounting, etc). In this case all the test reports shall be submitted to the NCB.

Annex A of this position paper contains a list of applicable standards for material testing.

NOTE The list is not complete. The FPC of the manufacturer shall include the tests necessary to assess the properties affecting the performance of the VRS. See chapter 5 of this position paper on FPC.

4.2 Criteria to be followed to accept test results with particular reference to EN 1317-2

NOTE: this section applies only if following EN 1317-2:1998. Its content has been taken into account in EN 1317-2:2010.

In EN 1317 Part 2 the working width “W” is defined in §3.4 and illustrated in Figure 1, but requires careful interpretation.

The maximum lateral position of the VRS, used to evaluate the working width “W”, and the maximum lateral position of the vehicle, are two different measures that shall be reported separately by the testing laboratory.
NOTE Document CEN TC 226 TG1/TW1 N859 (to be incorporated in the revision of EN 1317-2) gives the following explanation.

<<It is absolutely clear that the maximum lateral position of the barrier is used to evaluate the working width and the maximum lateral position of the vehicles is a different measure that shall be reported separately.

Unfortunately in Figure 1 e) the measure W is indicated in the wrong position, in contradiction with the text. This is an error coming from a previous draft.

CEN/TC 226 in its last meeting approved the interpretation of WG1 and decided to send you this for clarification.>>

With reference to EN 1317-2 §4.1

4.1 General
After testing in accordance with the vehicle impact test criteria defined in Table 1 the safety barriers shall conform to the requirements of 4.2 and 4.6; and the test vehicle shall conform to the requirements of 4.3, 4.4 and 4.5.

The test parameters on which acceptance criteria shall be assessed, are listed in Table 5 as a function of the containment level.

When during a test, after the end of the impact subsequent collisions of the vehicle with the safety barrier may occur, these subsequent collisions shall not be considered for performance or acceptance.

Vehicle deformation is not a mandated characteristic in Table ZA.1 of EN 1317-5.

With reference to EN 1317-2 §4.2

4.2 Safety barrier behaviour
The safety barrier shall contain and redirect the vehicle without complete breakage of the principal longitudinal elements of the system.

No major part of the safety barrier shall become totally detached or present an undue hazard to other traffic, pedestrians or personnel in a work zone.

Elements of the safety barrier shall not penetrate the passenger compartment of the vehicle.

Deformations of, or intrusions into the passenger compartment that can cause serious injuries are not permitted.

Ground anchorages and fixings shall perform according to the design of the safety barrier system.

The principal longitudinal elements of the VRS (EN 1317-2 §4.2, 1st paragraph) are those elements which are designed to carry a significant part of longitudinal forces in any of the tests of cars and heavy vehicles.

In order to define the “major part of the safety barrier” the testing laboratory should locate, identify and record in the test report, all detached parts with a mass greater than 2 kg. They shall be considered as “major parts”. Attention shall be paid by the NCB to whether the installation manual is consistent with “detached parts”.

The performance of ground anchorages and fixings should be in line with the design and the installation manual prescriptions and shall be checked by the NCB body on the basis of the Laboratory test report.

With reference to EN 1317-2 §4.3

4.3 Test vehicle behaviour
The centre of gravity of the vehicle shall not cross the centreline of the deformed system.

The vehicle shall remain upright during and after impact, although moderate rolling, pitching and yawing are acceptable.
The vehicle shall leave the safety barrier after impact so that the wheel track does not cross a line parallel to the initial traffic face of the safety barrier, at a distance $A$ plus the width of the vehicle plus 16% of the length of the vehicle within a distance $B$ from the final intersection (break) of wheel track with the initial traffic face of the safety barrier.

A movement (rolling, pitching, yawing) is “moderate” when it does not imply roll over (including roll over of the vehicle onto its side).

With reference to EN 1317-2 §5.2.1

5.2.1 General

The vehicles to be used in the tests shall be production models representative of current traffic in Europe, having characteristics and dimensions within the vehicle specifications defined in EN 1317-1.

The tyres shall be inflated to the manufacturers recommended pressures. The condition of the vehicle shall satisfy the requirements for the issue of a certificate of road worthiness with respect to tyres, suspension, wheel alignment and bodywork. No repairs or modifications shall be made that would alter the general characteristics of the vehicle or invalidate such a certification. The vehicle shall be clean and mud or deposits which may cause dust on impact shall be removed prior to testing. Marker points shall be placed on external surfaces of the test vehicle to aid analysis.

The vehicle shall not be restrained by the control of the steering or any other means during impact and whilst the vehicle is in the exit area as defined in 4.3 (e.g. braking, anti lock brakes, blocking or fixing).

Repairs shall not modify vehicles with respect to the initial configuration and shall be limited to those necessary to make the vehicle acceptable for roadworthiness. Testing laboratories shall take into consideration this item.

NOTE This item has been discussed by CEN TC 226/WG1, which approved the view above given.

4.3 Use of historical data

The evaluation report (required by EN 1317-5 §6.2.1.3) shall be written in part by the NCB and in part by the testing laboratory, and made available when evaluating historical data. Items a) to c) should be under the control of the NCB and items d) and e) under the control of the testing laboratory.

6.2.1.3 Evaluation report of test item

The evaluation report shall comprise the following information:

a) verification that materials are as specified by the manufacturer in accordance with 5.2;

b) verification that geometries and dimensions are as specified by the manufacturer in accordance with 5.2;

c) verification of protective treatments, if any;

d) soils and foundations report relating to the ITT;

e) verification that the product is installed in accordance with the specified layout in accordance with 5.4.

When this report is missing or the available data do not include all the necessary test results, the NCB shall exercise technical and/or engineering judgement in deciding whether to accept the historical data. It is the responsibility of the NCB to either accept historical data or to require a new ITT if judged necessary.

Historical data are assumed to have validity regardless of the exact positioning of the accelerometers in the vehicle, provided they are near its centre of gravity.

The manufacturer shall provide all the records of acceptance on incoming (raw) materials used for the then current production of the “old” VRS. Problems may arise when material test results of the previously tested VRS are missing from historical data. In this case it may be necessary to take into account the declaration of product characteristics issued by the producer of the material. These
data shall be compared with those obtained by the continuous control of purchased material in the FPC.

NOTE EN 1317-5 §6.2.1.7 is ambiguous; “this document” should be interpreted as

6.2.1.7 Use of existing impact test reports (historical data)

In order to facilitate the use of existing road restraint systems which have been tested in accordance with EN 1317 before the availability of harmonized European Standards and to avoid unnecessary duplication of cost and possible delays, which could result in lower safety for users, existing systems may be accepted as meeting regulatory requirements without new impact tests by the use of historic data under the following conditions:

a) road restraint system shall have been assessed by a testing laboratory in accordance with the current existing or a former version of EN 1317-1, EN 1317-2 + EN 1317-2/A1, EN 1317-3 or ENV 1317-4 or a prEN 1317 standard, and the test results and possible additional information shall show that the road restraint system conforms to the requirements of this EN 1317-5:2007+A1:2008;

b) provisions of this clause shall be invoked within 3 years after the end of the co existence period.

CE marking is applicable only to VRS that are placed on the market (existing vehicle restraint installations do not need to be CE-marked). If a manufacturer wishes to use the ITT from a previous approval procedure to seek CE marking for a VRS, it must be traceable to current production. Moreover the FPC of the current production must be certified by a NCB.

NOTE Most of the crash tests performed in the past were carried out without material analysis of the prototype. This means that these products have been approved in the past through an ITT performed according to the edition of EN 1317 in force at the time of testing but are lacking part or all of the material information. For this reason they may not be declared as compliant with EN 1317-5: 2007. Nevertheless, if the manufacturer supplies suitable supporting information about the materials, the ITT results can be accepted by the NCB. To this end the test results shall have “traceability” to the current production and to the previous production.

For historic test results to be accepted for CE marking purposes, the laboratory that performed the test should have been able to satisfy the Member State’s requirements as to its competence at the time of testing. This might be expressed as being accredited by a particular authority at the time of testing, e.g. as set out in EN 1317-5 §3.1

When a VRS under examination is identical to the one tested, the NCB can certify the product:

- “immediately” if the testing is positive, the material is known and the inspection of the FPC and the factory has shown no nonconformities
- If the NCB has concerns that the material of the prototype is not representative of the current production, it may be able to resolve these concerns by requesting additional documents or tests.

NOTE Identical means that design, drawing, dimensions, tolerances, materials and layout must match.

Quality documents or records from the FPC at the time of testing (and if applicable ISO 9001 certification records) shall be used to support the declaration of the manufacturer as far as prototype materials are concerned. Other information can also be taken into account for judgement. The NCB or the IB should collect and consider all relevant evidence.

There are parts of VRS that do not have special requirements for strength or ductility. They are normally manufactured to specified minimum characteristics of standardised materials (e.g. steel S235 to EN 10025). VRS manufacturers normally make reference to the declarations and accompanying documents of the material suppliers, and no additional material testing is performed. In these cases the NCB may take into account the effect of the possible variation in material resistance on the performance of the VRS by exercising an engineering judgement if necessary.
4.4 Modified products

If there are modifications to the original product (e.g. the dimension of holes), refer to EN 1317-5 §6.2.1.5 "Modified products" and Annex A.

The use of simulation through computational mechanics is allowed only for VRS which have been modified (see Annex A.6 of EN 1317-5) and cannot be used as a substitute for the ITT. In this case the ITT will already exist and should always be the basis for the validation of the model.

Computational mechanics experts shall be approved by NBs according to their own procedure. In case a NB cannot claim to be competent to judge the computational mechanics output, an external independent specialist should validate the computational mechanics analysis.

The validation method should be applied according to the Computational Mechanics Europe Group document TR 16303 part 4.

5 Evaluation of conformity

With reference to EN 1317-5 §6.2.1.6

6.2.1.6 Characteristics

All characteristics in 4.1 shall be subject to initial type testing. Release of dangerous substances may be assessed indirectly by controlling the content of the substance concerned.

A potential release of a dangerous substance is zinc coating washed out by rain.

With reference to EN 1317-3 §4.3

4.3 system type tested crash cushions:

A System Type Tested Crash Cushion is a multiple performance product that can be assembled to form different models from the same set of components, to obtain different shapes and performances, with the same working mechanism for the system and its components.

A crash cushion shall never be considered as a system type tested crash cushion after tests on only a single configuration.

6 Factory Production Control (FPC)

The manufacturer’s FPC shall include a procedure (and a sampling plan) to evaluate that the characteristics of materials, components and parts used to manufacture the VRS are in compliance with the design and the performance the VRS shall have.

Only materials and components conforming to the VRS design specifications should be used to manufacture that VRS.

They should be newly produced, not derived from scrap or recycled material nor from dismantled VRS unless this is permitted in the design and the properties of these components can be identified and measured.

The sampling plan shall be consistent with the materials, components and parts being used.
The manufacturer should check geometric dimensions of the components (at least) once per lot (batch).

Material analysis shall be carried out to assess the compliance of materials and parts with the supplier’s declarations. In addition, there are certain parts of the VRS (commonly called “special parts” or “critical parts”) that shall be tested and evaluated continuously and according to the FPC sampling plan in order to assess their specific properties that provide the VRS with the required performance.

The NCB shall ensure that the manufacturer considers all appropriate parts as “critical”, and defines them as such in its FPC manual or equivalent documents.

**NOTE** the dynamic behaviour of the VRS under impact requires a component or a material to have defined lower and upper limits of resistance. Components and parts that must deform or must fail during impact are generally considered as “critical” and checked particularly rigorously.

It is a common practice for the main manufacturer (the one taking responsibility of the VRS) to subcontract the production of components of the VRS. There is no limit to the extent of subcontracting, and in some cases production of all of the components could be subcontracted.

In any case the subcontracted processes shall be part of the FPC system of the manufacturer. To this end the manufacturer shall demonstrate to the NCB or the IB that it has technical competence with regard to the design and “quality control” of processes, production and component characteristics.

If the manufacture of critical parts is subcontracted, the NCB or the IB shall also inspect the subcontracting manufacturers, unless the NCB has a contractual arrangement with another NB that inspects the production of those parts. For further details, see NB-CPD/AG/07/008 ‘Guidance to NBs on their duties in certifying (system 1+, 1, 2+ and 2) own brand labelled products and those involving significant subcontract manufacturing’. For non-critical parts manufactured by subcontractors, it may be sufficient to inspect the main manufacturer’s acceptance procedures for incoming parts, carried out at the premises as part of the FPC.

See EN 1317-5 §6.3.3.3.

**With reference to EN 1317-5 §6.3.3.4**

6.3.3.4 Traceability and marking

Individual road restraint systems shall be identifiable and traceable with regard to their production origin. The manufacturer shall have procedures ensuring that processes related to affixing traceability codes and/or markings are inspected regularly. Documented traceability records shall be available for at least 5 years from the date of manufacture.

Compliance with EN ISO 9001:2000, 7.5.3 shall be deemed to satisfy the requirements of this clause.

**NOTE** The term of 5 years may be short in those countries where the law foresees for the contractor a responsibility of 10 years over the finished work. It may be advisable for manufacturers to consider the legislation of the destination country of the VRS, in addition to that of the producing country. However, the responsibility of the notified body is limited to checking compliance with the harmonized standard.
The main elements of the VRS i.e. (at least) rails, posts, spacers, wire ropes and joints shall be marked in a permanent way in order to identify: the manufacturer; the production plant, and the production period. The complete VRS shall bear the identification of the manufacturer taking responsibility of the VRS (see Figure 1).

NOTE This identification may also include CE marking.

Figure 1 possible markings on a VRS and its components

NOTE In the figure: M is the manufacturer taking responsibility of the VRS; A and B are subcontracted producers of posts; C and D are subcontracted producers or rails and E is a subcontracted producer of bolts. Note that M is also producing posts.

7 Shared ITT results

The NCB needs to receive a copy of the original evaluation report released by the Laboratory.
Annex A  Material analysis

All materials used to produce any part of the VRS shall be in conformity with the design specifications of the manufacturer. If the characteristics of the various materials cannot be ascertained by documented evidence, suitable tests shall be carried out.

This annex gives the minimum of tests that should be carried out for relevant materials.

A.1   Steel

A.1.1  Steel used as parts of VRS

1. Steel sheets, coils, beams, bars and channels according to EN 10025: Hot rolled products of structural steels. Technical delivery conditions for non-alloy structural steels.

2. Steel hollow sections according to EN 10210 Hot finished structural hollow sections of non-alloy and fine grain steels - Part 1: Technical delivery conditions and EN 10219 Cold formed welded structural hollow sections of non-alloy and fine grain steels - Part 1: Technical delivery conditions.

3. Reinforcing steel (in bars, coils and/or fabricated shapes) according to EN 10080 Steel for the reinforcement of concrete - Weldable reinforcing steel or according to national standards applicable in the country of destination of the VRS.

4. Prestressing steel (in bars, strands and wires) according to EN 10138 Prestressing steels - Part 1: General requirements.


6. Washers according to the applicable EN standards.

A.1.2  Sampling

Samples shall be taken from raw materials that are traceable to the component being examined. Double sets of samples shall be taken in order to allow for a re-test if necessary. Samples shall be representative of nominal thickness/diameter/size and nominal strengths used in the components of the VRS.

A.1.3.  Testing

Tensile tests shall be performed according to the following standards:

- EN 10002-1:2001 ‘Metallic materials — Tensile testing — Part 1: Method of test at ambient temperature’

Bend and rebend test shall be performed according to EN 10080.
A.2  Timber; wood

Structural wood is often used as a covering for steel VRS. Nevertheless it contributes to the general strength of the VRS. Its characteristics shall be tested.

Timber can be used directly as a structural component for a VRS (for example posts). In this case characteristics are important and shall be known to the manufacturer.

Characteristics change from timber type to type and also from tree to tree (the characteristics of wood also change with its moisture content).

Examples of timber testing standards:

- EN 408 'Timber Structures – Structural timber and glued laminated timber – Determination of some physical and mechanical properties'
- ISO 3133: Wood – Determination of ultimate strength in static bending

A.3  Concrete

Concrete shall be sampled and tested according to EN 206-1 'Concrete – Part 1: Specification, performance, production and conformity'.

A.3.1  Sampling

Sample shall be taken from concrete at the time of pouring and cured according to the same process used for the VRS components.

A.3.1  Testing

Compression tests shall be carried out according to EN 12390-3 Testing hardened concrete - Part 3: compressive strength of test specimens).

A.4  Other Materials

Other materials, such as polyethylene, rubber and poly-methyl-methacrylate (Perspex, Plexiglas) shall be characterised according to their relevant material standards (if any) or the existing best laboratory practices.