COMMISSION IMPLEMENTING REGULATION (EU) 2022/944

of 17 June 2022

laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [1], and in particular Article 100(8), point (a), thereof,

Whereas:

(1) Regulation (EU) 2017/746 lays down rules on European Union reference laboratories (the 'EU reference laboratories').

(2) The criteria that the EU reference laboratories are to satisfy are set out in Article 100(4) of Regulation (EU) 2017/746. The Commission is to lay down detailed rules in order to ensure compliance with those criteria.

(3) In order to ensure compliance with the criterion regarding adequate and appropriately qualified staff laid down in Article 100(4), point (a), of Regulation (EU) 2017/746, the EU reference laboratories should have a sufficient number of technical and scientific staff. Minimum levels of education and professional experience for that staff and the EU reference laboratory director should be specified. In order to ensure that the appropriate qualifications, knowledge and experience of the staff are maintained, the EU reference laboratories should be required to put in place a continuous training and education programme.

(4) In order to ensure compliance with the criterion regarding equipment and reference material laid down in Article 100(4), point (b), of Regulation (EU) 2017/746, the EU reference laboratories should be required to keep documentation demonstrating that they possess the equipment, including specimens and control materials, and reference materials necessary in order to carry out their tasks as set out in Regulation (EU) 2017/746. As specimens, control materials and reference materials may be short-lived, the EU reference laboratories should have an acquisition plan in place to ensure their continuous availability.

(5) In order to ensure compliance with the criterion regarding knowledge of international standards and best practices laid down in Article 100(4), point (c), of Regulation (EU) 2017/746, and given the variety and evolving nature of such international standards and best practices, the EU reference laboratories should identify which of those standards and practices apply to the activities within their scope of designation with a view to integrating them into their operating procedures.

(6) In order to ensure that EU reference laboratories can assume legal responsibility as organisations for the tasks listed in Article 100(2) of Regulation (EU) 2017/746, they should be established as legal entities. In order to ensure continuity of operations, EU reference laboratories should be economically viable and have sources of funding.

[1] OJ L 117, 5.5.2017, p. 176.

(7) As EU reference laboratories may receive a Union contribution in accordance with Article 100(6) of Regulation (EU) 2017/746, their administrative organisation should fulfil the conditions for recipients of Union funds laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([2]).

(8) In order to ensure compliance with the criterion regarding administrative organisation and structure laid down in Article 100(4), point (d), of Regulation (EU) 2017/746, the EU reference laboratories should have sufficient administrative staff and keep documentation demonstrating their structure and organisational procedures, as well as records of costs and fees levied and a yearly overview of the tasks performed.

(9) In order to ensure compliance with the criterion regarding confidentiality laid down in Article 100(4), point (e), of Regulation (EU) 2017/746, EU reference laboratories should ensure that their staff handles, stores and processes confidential information and data in an appropriate manner and should take measures to prevent undue disclosure of such information, in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council ([3]).

(10) In order to ensure compliance with the criterion regarding public interest and independence laid down in Article 100(4), point (f), of Regulation (EU) 2017/746, a competent authority should confirm that a laboratory for which a Member State or the Commission's Joint Research Centre submitted an application for designation as EU reference laboratory performs tasks of public interest in the proposed scope of designation.

(11) In order to ensure compliance with the criterion laid down in Article 100(4), point (g), of Regulation (EU) 2017/746 regarding the impartiality of staff, the EU reference laboratories should be required to put in place a policy to identify and prevent, on a continuous basis, any conflict of interest of their staff in relation to the fulfilment of the tasks of the EU reference laboratories.

(12) Considering the volume, specific nature and potential novelty of the laboratory testing that may be required from the EU reference laboratories within their scope of designation, those laboratories should be entitled to request support for laboratory testing activities from national reference laboratories and other laboratories established in a Member State (collectively referred to as 'external laboratories') or from other EU reference laboratories in terms of equipment and staff. This Regulation should establish the rules for the provision of such outsourcing that are necessary to ensure compliance with the criteria laid down in Article 100(4) of Regulation (EU) 2017/746. Regardless of the support received from any other laboratory, the EU reference laboratory requested to perform the task should bear the responsibility for the final opinions, findings or recommendations.

(13) The requirements laid down in the harmonised standard EN ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) are appropriate for EU reference laboratories. Therefore accreditation in accordance with that standard, the reference of which has been published in the *Official Journal of the European Union*, by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ([4]), should be a means for laboratories to demonstrate conformity with the relevant requirements of this Regulation.

(14) Considering that the Commission may only designate, as EU reference laboratories, laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation, Member States should be required to verify the compliance of the laboratories for which they intend to submit an application with the criteria laid down in Article 100(4) of Regulation (EU) 2017/746, as further specified in this Regulation, prior to submitting the application. The Commission's Joint Research Centre should verify that it complies with the criteria if it intends to submit an application for its designation as an EU reference laboratory.

([2]) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

([3]) Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

([4]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(15) The tasks that the EU reference laboratories are to carry out within their scope of designation are set out in Article 100(2) of Regulation (EU) 2017/746. The Commission is to lay down detailed rules to facilitate the application of that provision.

(16) In order to ensure clarity, certainty and transparency, tasks requested of EU reference laboratories by notified bodies and Member States should be performed in accordance with predetermined terms and conditions. Therefore, such activities should be covered by a contract between the requesting parties and the EU reference laboratories. With regard to the verification of performance, the verification of compliance with common specifications or with other solutions chosen by the manufacturer and the sample or batch testing referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746, the notified body should lodge a request with only one EU reference laboratory for a given task and device in order to prevent parallel assessments of the same device by several EU reference laboratories.

(17) In order to carry out the verification of performance, the verification of compliance with common specifications or with other solutions chosen by the manufacturer and the sample or batch testing referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746, the EU reference laboratories need information specific to the device to be tested. The notified body, as the requestor of the task, should be required to provide that information. In case the EU reference laboratory needs to clarify that information, any communication between the EU reference laboratory and the notified body should be documented in order to ensure independence of the EU reference laboratory and traceability.

(18) In order to enable testing of devices for which the manufacturer has specifically developed or prescribed equipment or reference materials, the notified bodies should ensure that the EU reference laboratories have access to such equipment and materials free of charge. To ensure correct use of the equipment and materials, the EU reference laboratory staff should have access to training in that regard.

(19) To ensure access to the market for safe and performing devices, the EU reference laboratories should not refuse requests from notified bodies for a contract to perform the tasks referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746 that are in their scope of designation.

(20) To ensure independence when carrying out the verification of performance, the verification of compliance with common specifications or with other solutions chosen by the manufacturer referred to in Article 100(2), point (a), of Regulation (EU) 2017/746, the EU reference laboratories should decide which tests are necessary taking into account the performance claimed and duly substantiated by the manufacturer.

(21) In order to ensure legal certainty, it is necessary to clarify the starting point for the period of 60 days which the EU reference laboratories have at their disposal for providing the opinion referred to in Section 4.9 of Annex IX to Regulation (EU) 2017/746 and Section 3, point (j), and Section 5.4 of Annex X to that Regulation.

(22) In order to operate in a transparent manner, the EU reference laboratories should provide sufficient reasons for their conclusions regarding the verification of performance, the verification of compliance with common specifications or with other solutions chosen by the manufacturer and the sample or batch testing referred to in Article 100(2), points (a) and (b) of Regulation (EU) 2017/746. Those reasons should be included in the opinions or findings provided by the EU reference laboratories.

(23) In order to ensure consistent assessments of devices and facilitate subsequent sample or batch testing by EU reference laboratories, the opinion referred to in Section 4.9 of Annex IX to Regulation (EU) 2017/746 and Section 3, point (j), and Section 5.4 of Annex X to that Regulation should contain recommendations on subsequent sample or batch testing to be carried out by the same EU reference laboratory or by other EU reference laboratories.

(24) Notified bodies should establish a plan for sample or batch testing in order to ensure appropriate product verification. In order to allow the notified bodies to benefit from the expertise of the EU reference laboratories in the context of the sample or batch testing referred to in Article 100(2), point (b), of Regulation (EU) 2017/746, the EU reference laboratory should be given the opportunity to propose changes to the notified body's plan for sample or batch testing, including the reasons for such changes. To ensure coherence in the assessment of the device, the

final plan established by the notified body should take into account all relevant information, including the recommendations on sample or batch testing set out in the EU reference laboratory opinion referred to in Section 4.9 of Annex IX to Regulation (EU) 2017/746 and Section 3, point (j), and Section 5.4 of Annex X to that Regulation and the results of any previous sample or batch tests performed on the device.

(25) Having regard to Section 4.13 of Annex IX to Regulation (EU) 2017/746 and Section 5.2 of Annex XI to that Regulation (EU) 2017/746, logistic arrangements should be made to ensure sufficient time for the EU reference laboratory to perform the testing and provide its findings to the notified body, taking into account the need for the notified body to communicate a possible decision to the manufacturer within the timeframe agreed with the manufacturer, but not later than 30 days after reception of the samples.

(26) The tasks referred to in Article 100(2), points (c), (d), (f), (g), (h) and (i), of Regulation (EU) 2017/746 may concern horizontal matters which should be treated in a harmonised manner. Therefore, where a task falls within the scope of designation of more than one EU reference laboratory, all of those EU reference laboratories should be involved in fulfilling that task.

(27) Where requests from notified bodies for tasks referred to in Article 100(2), points (c), (d) and (g), of Regulation (EU) 2017/746, concern more than one notified body, they should coordinate with each other to ensure consistent conformity assessments of devices across the Union.

(28) In order to enable the EU reference laboratories to set up and manage a network of national reference laboratories as referred to in Article 100(2), point (e), of Regulation (EU) 2017/746, it should be specified how such national reference laboratories are to be identified and how the networks are to be established and managed.

(29) For the purposes of the task referred to in Article 100(2), point (h), of Regulation (EU) 2017/746, namely to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order, the EU reference laboratories should maintain a public list of such materials and procedures within their scope of designation, as such information is of general interest to the relevant actors across the Union.

(30) The assistance, advice, contributions and recommendations provided by EU reference laboratories should follow relevant standards. Should this not be the case, for example as a result of limited availability of materials that comply with relevant standards, EU reference laboratories should, in order to ensure transparency, provide an appropriate justification for the use of methods, practices and materials that diverge from those standards.

(31) To perform their tasks in a harmonised manner, it is essential that the EU reference laboratories exchange experience on specialised topics. To that end, the EU reference laboratories should, within the network of EU reference laboratories referred to in Article 100(5) of Regulation (EU) 2017/746 (the 'EU reference laboratories' network'), form sub-networks corresponding to a specific device, category or group of devices or a specific hazard related to a category or group of devices, or covering other specific topics. The sub-networks should regularly compare test results to ensure the consistency of those results across EU reference laboratories.

(32) In order to ensure that the EU reference laboratories carry out their tasks in a harmonised manner, common rules of procedure for all EU reference laboratories should be established in agreement with the Commission. Those common rules of procedure should be publicly available, for reasons of transparency, and reviewed regularly to ensure that they are efficient and up-to-date with the state of the art.

(33) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

CHAPTER I

CRITERIA FOR EU REFERENCE LABORATORIES

Article 1

Staff

1. The EU reference laboratories shall document and justify the knowledge and experience requirements for staff, including the director, the scientific and the technical staff, needed to fulfil the EU reference laboratory tasks in the field of specific devices, categories or groups of devices, or specific hazards related to a category or group of devices for which the EU reference laboratories are designated ('scope of designation').

2. The EU reference laboratories shall have staff that fulfils the requirements referred to in paragraph 1 and document how those requirements are fulfilled.

3. The EU reference laboratories shall have a sufficient number of the staff referred to in paragraph 2 in relation to the volume of the tasks that the EU reference laboratories are to carry out in their scope of designation.

4. The EU reference laboratories shall put in place a continuous training and education programme for their staff.

Article 2

Equipment and reference materials

The EU reference laboratories shall keep up-to-date documentation containing:

(a) an explanation of which equipment, including specimens and control materials, and reference materials are necessary to carry out the tasks assigned to them within their scopes of designation;

(b) evidence that they possess the equipment and a sufficient quantity of the reference materials referred to in point (a);

(c) a plan for the procurement of the specimens, control materials and reference materials referred to in point (a).

The EU reference laboratories shall make the documentation referred to in the first subparagraph available to the Commission, upon its request.

Article 3

International standards and best practices

The EU reference laboratories shall keep up-to-date documentation containing:

(a) a list of international standards and best practices, including common specifications, that apply to the tasks assigned to them within their scopes of designation, and a justification of the relevance of such standards and practices where that relevance is not obvious;

(b) evidence that they have integrated the international standards and best practices referred to in point (a) into the operating procedures for the relevant tasks.

The EU reference laboratories shall make the documentation referred to in the first subparagraph available to the Commission, upon its request.

Article 4

Administrative organisation and structure

1. The EU reference laboratories shall identify at least one person within its management as having overall responsibility for the performance of the tasks set out in Article 100(2) of Regulation (EU) 2017/746.

2. The EU reference laboratories shall have sufficient administrative staff to provide the necessary administrative support for performance of the tasks set out in Article 100(2) of Regulation (EU) 2017/746, in relation to the volume of those tasks.

3. The EU reference laboratories shall establish and keep up-to-date documentation containing the following:

(a) evidence of their status as a legal entity;

(b) where they are part of a larger organisation, a description of the activities of that organisation, its organisational structure and governance;

(c) where they are, directly or indirectly, controlled by other entities, the identity of such entities and their controlling position;

(d) a description of their internal organisational structure with clearly allocated responsibilities and reporting lines;

(e) a description of their operating procedures, including management and performance of tasks, management of staff, a staff substitution plan, as well as registration of documentation and correspondence with external entities;

(f) a declaration that none of the situations for exclusion set out in Article 136 of Regulation (EU, Euratom) 2018/1046 apply to them;

(g) evidence of their sources of funding and of economic viability without financial assistance from the Union;

(h) detailed records of the calculation of the costs and the corresponding fees levied for each task they are requested to perform;

(i) a yearly overview of the tasks performed.

The EU reference laboratories shall make the documentation referred to in the first subparagraph available to the Commission, upon its request.

Article 5

Confidentiality

1. EU reference laboratories shall have a confidentiality policy that includes the following:

(a) the type of information that shall be considered confidential;

(b) rules for the appropriate secure handling, storage and processing of confidential information and measures to prevent undue disclosure;

(c) rules for sharing of confidential and non-confidential information with staff, and the public;

(d) rules for granting access to confidential information to a competent authority of a Member State upon its request in the context of market surveillance or vigilance activities by the competent authority;

(e) rules for sharing confidential information, on the initiative of the EU reference laboratory, with a competent authority of a Member State and with the Commission where the EU reference laboratory has reason to believe that such sharing is in the interest of protection of public health.

2. EU reference laboratories shall put in place and document measures to ensure that the staff complies with the confidentiality policy referred to in paragraph 1.

Article 6

Public interest, independence and conflicts of interest

1. Member States shall confirm that laboratories for which they have submitted an application for designation pursuant to Article 100(1) of Regulation (EU) 2017/746 will perform their tasks as EU reference laboratories in the public interest and in an independent manner within their proposed scopes of designation. That confirmation shall be included in the application.

2. EU reference laboratories shall have a policy to ensure that the members of their staff do not have financial or other interests in the *in vitro* medical device industry, which could affect their impartiality with regard to the performance of their tasks.

The policy referred to in the first subparagraph shall include steps to prevent, identify and resolve conflicts of interest and shall be made available to the Commission upon request.

3. An EU reference laboratory shall not be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices within its scope of designation, nor the authorised representative of any of those parties and shall not be involved in the design, manufacture or construction, marketing, installation, use or maintenance of the devices within its scope of designation.

An EU reference laboratory shall not act as a notified body for devices within its scope of designation.

Within its scope of designation, an EU reference laboratory shall not perform any tasks related to conformity assessment under Regulation (EU) 2017/746 on request by a notified body, other than the tasks referred to in Article 100(2) of Regulation (EU) 2017/746.

4. An EU reference laboratory shall not enter into collaboration with a device manufacturer or a notified body concerning a joint commercial exploitation if such collaboration falls within its scope of designation.

Article 7

Outsourcing of testing and access to equipment from other laboratories

1. Where the volume of laboratory testing for a task assigned to an EU reference laboratory within its scope of designation so requires, it may outsource the testing or part of the testing to national reference laboratories and other laboratories established in a Member State (collectively referred to as 'external laboratories') or to another EU reference laboratory by way of a contract.

2. Where the volume, specific nature or novelty of a task assigned to an EU reference laboratory so requires, it may enter into a contract with an external laboratory or another EU reference laboratory to obtain access to specific additional equipment or materials that are needed for carrying out the task.

3. An EU reference laboratory may only conclude contracts referred to in paragraph 1 with external laboratories that fulfil the following conditions:

(a) their competence for fulfilling the tasks covered by the contract, including staff and equipment, satisfies the requirements set by the EU reference laboratory;

(b) they put in place and document the measures referred to in Article 5(2) to ensure that the staff involved in the performance of tasks covered by the contract complies with the confidentiality policy referred to in Article 5(1);

(c) they confirm the absence of conflict of interest in accordance with the policy of the EU reference laboratory referred to in Article 6(2) as regards the activities covered by the contract.

4. The EU reference laboratories shall make the contracts referred to in the first subparagraph available to the Commission, upon its request.

5. The EU reference laboratory shall have the overall responsibility for the results of tests and the fulfilment of tasks within its scope of designation, regardless of any support received from external laboratories or other EU reference laboratories in accordance with this Article.

Article 8

Accreditation

1. Member States or the Commission may presume that laboratories that are accredited in accordance with the harmonised standard EN ISO/IEC 17025, the reference of which has been published in the *Official Journal of the European Union*, by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008, are in conformity with the requirements set out in the following provisions of this Regulation:

(a) Article 1;

(b) Article 2(1), point (b);

(c) Article 4(1) and (2) and Article 4(3), points (a), (d) and (e);

(d) Article 5(1), points (a) to (c) and Article 5(2);

(e) Article 6(2);

(f) Article 7(3), points (a) to (c).

2. The scope of the accreditation referred to in paragraph 1:

(a) shall cover the methods of laboratory analysis or testing which are relevant to the scope of designation of the EU reference laboratory;

(b) may comprise one or more methods of laboratory analysis or testing or groups of methods;

(c) may be defined in a flexible manner, so as to allow the scope of the accreditation to include modified versions of the methods used by the laboratories when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratories' own validations and without a specific assessment prior to the use of those modified or new methods by the national accreditation bodies.

Article 9

Verification of compliance with criteria

1. Before submitting an application for designation of a laboratory in accordance with Article 100(1) of Regulation (EU) 2017/746, the Member States shall verify that the laboratory complies with the criteria set out in Article 100(4) of that Regulation, as further specified in Articles 1 to 7 of this Regulation.

2. Before submitting an application to be designated in accordance with Article 100(1) of Regulation (EU) 2017/746, the Commission's Joint Research Centre shall verify that it complies with the criteria set out in Article 100(4) of that Regulation, as further specified in Articles 1 to 7 of this Regulation.

3. The Member States or the Commission's Joint Research Centre shall document the verification referred to in paragraphs 1 and 2, and its outcome, in the application.

CHAPTER II

TASKS OF THE EU REFERENCE LABORATORIES

Article 10

Contracts between the EU reference laboratories and requesting parties

1. For tasks requested by a notified body or a Member State, the EU reference laboratories shall conclude a contract with the requesting party prior to performing the task. That contract shall set out the terms and conditions for performing the task, including the time schedule. That contract shall be concluded with:

(a) the notified bodies for the tasks referred to in Article 100(2), points (a), (b), (c), (d) or (g) of Regulation (EU) 2017/746;

(b) the Member State for the tasks referred to in Article 100(2), points (c) and (d), of Regulation (EU) 2017/746.

2. An EU reference laboratory may only refuse requests from notified bodies to conclude a contract to perform tasks referred to in Article 100(2), points (a) or (b) of Regulation (EU) 2017/746 where those tasks fall outside its scope of designation.

3. Where a contract has been concluded between a notified body and an EU reference laboratory, the notified body shall make the contract available to the authority responsible for the notified body upon request.

Article 11

Requests from notified bodies regarding tasks referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746

1. For each device and each task referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746, a notified body may conclude a contract as referred to in Article 10(1), point (a), of this Regulation with only one EU reference laboratory.

2. The notified body shall provide to the EU reference laboratory all the documentation related to the device and other relevant information in its possession which are necessary to fulfil the task referred to in paragraph 1. That documentation shall be available in any official Union language acceptable to the EU reference laboratory.

3. The EU reference laboratory may request the notified body for clarification of the submitted documentation and information. The EU reference laboratory shall keep a record of such requests.

4. The notified body shall ensure that the manufacturer provides to the EU reference laboratory free of charge any equipment and reference materials developed or prescribed by the manufacturer for a particular device for the purposes of testing that device, provided that the EU reference laboratory does not already possess such equipment. Where the manufacturer permits the use of the device with equipment made available by different manufacturers, the notified body shall ensure that the manufacturer provides the EU reference laboratory with equipment from at least one of these manufacturers and with a justification for the choice made. The manufacturer may also provide any other commercially available equipment or reference materials to the EU reference laboratory free of charge for the purposes of testing the manufacturer's device.

The equipment or reference materials referred to in the first subparagraph shall either be sent to the EU reference laboratory or, in duly justified circumstances, be made available to the EU reference laboratory on the premises of the manufacturer.

The notified body shall ensure that the manufacturer provides training to the staff of the EU reference laboratory on the use of the equipment referred to in the first subparagraph, where such training is deemed necessary by the EU reference laboratory in order to operate the equipment.

5. The notified body shall immediately inform the EU reference laboratory of any new information related to the device that has come to its knowledge and that may have an impact on the fulfilment of the task referred to in paragraph 1.

Article 12

Verification of performance and compliance with common specifications or with other solutions chosen by the manufacturer

1. For the purposes of the task referred to in Article 100(2), point (a), of Regulation (EU) 2017/746, the EU reference laboratories shall verify the performance of a device and its compliance with applicable common specifications or with other solutions chosen by the manufacturer against the performance claims duly substantiated by the manufacturer in the performance evaluation report.

2. The EU reference laboratories shall decide which laboratory tests are necessary in order to verify the performance of the device and its compliance with the common specifications or with other solutions chosen by the manufacturer as set out in paragraph 1. EU reference laboratories shall provide, in their opinion, reasons for the choice of tests.

3. EU reference laboratories shall verify the performance of the device and its compliance with common specifications or with other solutions chosen by the manufacturer as set out in paragraph 1 based on the results of the laboratory tests referred to in paragraph 2.

4. EU reference laboratories shall provide their opinion within 60 days after the latest of the following dates:

(a) the date of signature of the contract referred to in Article 10(1), point (a), by all contracting parties;

(b) the date of receipt of all the necessary documentation and information from the notified body as referred to in Article 11, paragraph 2, and clarifications referred to in Article 11, paragraph 3;

(c) the date of receipt of equipment from and completion of any training by the manufacturer as referred to in Article 11, paragraph 4;

(d) the date of receipt of the samples of the device to be tested.

5. The opinion of the EU reference laboratories shall be detailed and shall provide reasons for the conclusions and recommendations made.

The opinion referred to in the first subparagraph shall provide recommendations for testing referred to in Article 100(2), point (b), of Regulation (EU) 2017/746, including specimens to be tested, the number of samples of the device as well as the frequency for sample or batch testing by an EU reference laboratory, where there are no requirements adopted in accordance with Article 48(13), point (c), of Regulation (EU) 2017/746.

Article 13

Sample or batch testing

1. For the purposes of the task referred to in Article 100(2), point (b), of Regulation (EU) 2017/746, the notified body shall propose a sample or batch test plan for the device to the EU reference laboratory, taking into account, if applicable, the recommendations of the EU reference laboratory referred to in Article 12(5), second subparagraph, of this Regulation.

The EU reference laboratory may propose amendments to the test plan referred to in the first subparagraph. The EU reference laboratory shall provide reasons for such proposals.

The notified body and the EU reference laboratory shall agree on the final version of the test plan referred to in the first subparagraph. That plan shall comply with the applicable common specifications and any requirements adopted in accordance with Article 48(13), point (c), of Regulation (EU) 2017/746.

2. The notified body shall make available to the EU reference laboratory performing the sample or batch testing the following documentation:

(a) if applicable, the EU reference laboratory opinion issued after performing the task referred to in Article 100(2), point (a), of Regulation (EU) 2017/746, if that task was performed by a different EU reference laboratory;

(b) the findings of any previous sample or batch tests performed on the device by other EU reference laboratories in accordance with Article 100(2), point (b), of Regulation (EU) 2017/746.

The EU reference laboratory shall take account of the opinion and the findings referred to in the first subparagraph when proposing amendments to or agreeing on the final version of the plan referred to in paragraph 1.

3. The notified body shall, in agreement with the manufacturer, put in place logistic arrangements with the EU reference laboratory to ensure that the EU reference laboratory has sufficient time after the reception of the samples to perform the testing and provide its findings to the notified body. These arrangements shall take into account the time needed for the notified body to communicate a possible decision to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples.

4. The findings of the EU reference laboratory on the results of the sample or batch testing shall be detailed and include reasons for the conclusions made.

Article 14

Requests to perform tasks referred to in Article 100(2), points (c), (d), (f), (g) and (i), of Regulation (EU) 2017/746

1. The Commission may, on its own initiative or upon request from the Medical Device Coordination Group (MDCG), submit a request to carry out tasks referred to in Article 100(2), points (c), (d), (f) or (i), of Regulation (EU) 2017/746, to an EU reference laboratory or, where the request falls within the scope of designation of more than one EU reference laboratory, to the network of EU reference laboratories referred to in Article 100(5) of Regulation (EU) 2017/746 (the 'EU reference laboratories' network') or to a relevant sub-network referred to in Article 17(1) of this Regulation ('sub-network').

Member States may submit a request to carry out a task referred to in Article 100(2), points (c) or (d), of Regulation (EU) 2017/746 to an EU reference laboratory or, where the request falls within the scope of designation of more than one EU reference laboratory, to the EU reference laboratories' network or a relevant sub-network.

2. Notified bodies may submit a request to carry out a task referred to in Article 100(2), points (c), (d) or (g), of Regulation (EU) 2017/746 to an EU reference laboratory or, where the request falls within the scope of designation of more than one EU reference laboratory, to the EU reference laboratories' network or a relevant sub-network. Where the subject of the request concerns more than one notified body, those notified bodies shall coordinate the request.

3. The EU reference laboratory, the EU reference laboratories' network or the sub-network may collaborate with relevant national reference laboratories in order to perform the task.

4. Where, in response to requests under this Article, the assistance, advice or contribution provided by the EU reference laboratories contains elements that diverge from relevant standards, the EU reference laboratory, the EU reference laboratories' network or the sub-network shall state the reasons for that divergence in the documents describing the assistance, advice or contribution.

Article 15

Setting up of a network of national reference laboratories

1. The competent authorities shall inform the relevant EU reference laboratories of any laboratory designated as national reference laboratory in accordance with national law whose scope of designation is within the scope of designation of those EU reference laboratories.

2. Where the scope of designation of a national reference laboratory is within the scope of designation of an EU reference laboratory or a sub-network, that national reference laboratory shall be part of the corresponding network of national reference laboratories.

3. The EU reference laboratories or the sub-networks shall share relevant information and promote the use of common testing methods within their networks of national reference laboratories.

4. The EU reference laboratories shall publish on their websites lists of the national reference laboratories that form part of their network referred to in paragraph 2 and a list of the tasks of those national reference laboratories.

Article 16

Recommendations on suitable reference materials and reference measurement procedures of higher metrological order

1. The EU reference laboratories shall review the available reference materials and reference measurement procedures of higher metrological order falling within their scope of designation and publish recommendations on suitable reference materials and reference measurement procedures of higher metrological order on their website.

2. Where reference materials or reference measurement procedures of higher metrological order are relevant for more than one EU reference laboratory, the relevant EU reference laboratories' network or sub-network shall coordinate the review and agree on common recommendations.

3. The EU reference laboratories shall update the recommendations when new reference materials or new reference measurement procedures of higher metrological order become available.

4. Where the EU reference laboratories recommend reference materials or reference measurement procedures of higher metrological order that diverge from relevant standards, the EU reference laboratories shall state the reasons for that divergence in their recommendations.

Article 17

Sub-networks of EU reference laboratories

1. Where more than one EU reference laboratory is designated for a specific device, category or group of devices or a specific hazard related to a category or group of devices, those EU reference laboratories shall form a sub-network to the EU reference laboratories' network.

2. The EU reference laboratories may form other sub-networks for specific topics.

3. The sub-networks shall produce and keep up-to-date common procedures for the performance of tasks referred to in Article 100(2), points (a) and (b), of Regulation (EU) 2017/746.

4. At least every two years, the sub-networks shall determine which methods and materials, used for the performance of the tasks referred to in Article 100(2), points (a) or (b), of Regulation (EU) 2017/746, require proficiency tests to ensure the same results in the EU reference laboratories across the sub-network.

The sub-networks shall develop a methodology for the proficiency tests. The members of a sub-network shall perform the proficiency tests in accordance with the methodology developed by that sub-network and shall:

(a) report the results of the proficiency tests to the sub-network;

(b) ensure appropriate follow-up to the proficiency tests, including, if needed, corrective actions to adjust the methods and materials referred to in the first subparagraph to ensure consistency across the sub-network.

The sub-network shall inform the EU reference laboratories' network of the results of and any follow-up to the proficiency tests.

Article 18

Common rules of procedure

1. Upon a proposal from, and in agreement with the Commission, the EU reference laboratories shall adopt, by simple majority, common rules of procedure for all EU reference laboratories which shall cover at least the performance of the tasks set out in Article 100(2) of Regulation (EU) 2017/746.

2. The EU reference laboratories shall comply with the common rules of procedure referred to in paragraph 1 and make them publicly available on their websites.

3. The EU reference laboratories shall, in agreement with the Commission, review the common rules of procedure referred to in paragraph 1 at least every three years and update them to ensure that they are efficient and that they reflect state-of-the-art practice.

CHAPTER III

FINAL PROVISION

Article 19

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 June 2022.

For the Commission
The President
Ursula VON DER LEYEN