TEAM-PRRC

The European non-profit organization of Persons Responsible for Regulatory Compliance

Position Paper N°2 on contracts and location

For Persons Responsible for Regulatory Compliance according to Article 15 of MDR (EU) 2017/745 and IVDR (EU) 2017/746

The information summarized in this document reflects the current understanding of the EU Requirements and may be subject to a regular change over the upcoming years.

Contents

I. Abbreviations

AR: Authorised Representative
EU: European Union.
IVDR: *In Vitro* Diagnostic Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices.
MDR: Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
MD: Medical Device
PRRC: Person Responsible for Regulatory Compliance
QMS: Quality Management System
SOP: Standard Operating Procedure
UDI: Unique Device Identifier

II. Presentation of TEAM-PRRC association

TEAM-PRRC was established in April 2020 and is the only European non-profit organization dedicated to Persons Responsible for Regulatory Compliance (PRRC), which originated from Article 15 of the EU MDR 2017/745 and EU IVDR 2017/746.

As mentioned in these regulations, the PRRC is a new role ensuring compliance of manufacturers and/or authorized representatives (AR). This role is known from other regulations where a similar position is described:

- General Data Protection Regulation with the Data Protection Officer
- The pharmaceutical industry with the Qualified Person
- The cosmetics industry with the Responsible Person.

The new requirement significantly impacts the resources and quality management system (QMS) of the previously mentioned economic operators.

Therefore, TEAM-PRRC is working on reasonable and practical solutions to support its members in implementing the requirements. The focus of this association is to share knowledge and experience on issues faced daily by PRRCs, develop and maintain a high level of professionalism and encourage harmonization in the interpretation of the requirements.

If you are fulfilling the minimum qualifications required by Article 15 you can join the association as an active member and benefit from:

- A secure professional practice because of the association's Code of Ethics;
- Proposals for solutions to your professional problems;
- Access to conferences and specialized training;
- Access to templates reflecting the minimum requirements;
- Access to a library of regulatory texts;

This position paper aims to:

- Explain the intent behind the role of the PRRC
- Describe the roles and responsibilities of the PRRC
- Explain the type of qualifications and extent of experience required
- Define the place of a PRRC in the QMS of the various organizations
- Describe potential methods to fulfill the legal obligations described in the MDR and IVDR
- Acknowledge the liabilities of the PRRC
- Give our position on Article 15, and MDCG 2019-07 guidance.

III. The use of an outsourced PRRC

The MDR states that (Article 15 §2):

"Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC (1) shall not be required to have the person responsible for regulatory compliance within their organization but shall have such person permanently and continuously at their disposal."

(1) *Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36): Enterprises which employ fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million*

Position of TEAM-PRRC:

In the case of micro and small enterprises and all ARs, an external PRRC is permitted and shall be continuously and permanently at the disposal of the manufacturer or the AR. To be compliant with this requirement, it might be necessary for the QMS of the manufacturer to anticipate the use of deputies or more than one PRRC could be designated (refer to Article 15§4):

"If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing."

The manufacturer and the AR need to have a written contract with their PRRC. It is also recommended that the PRRC be insured specifically against the situation where an organization wishes to prosecute for some perceived failings in the performance of the tasks set out in the contract.

Note: a suggested contract template for external PRRC is available for members of TEAM-PRRC.

IV. Designation of more than one PRRC

Referring to Article 15 §4, the responsibilities of each PRRC are detailed in writing. They can substitute for each other in case of absence. The mapping of responsibilities, including the provisions in terms of substitution, should be clear and communicated to and within the manufacturer or the AR.
Companies can use their own quality management system planning processes for determining how to split responsibilities, depending on the situation. Some examples for splitting responsibilities:

- Product groups (a PRRC for medical devices and one for IVDs);
- Production steps (e.g. a PRRC specific for sterilization);
- Locations (e.g. multiple production sites each have their own PRRC);
- Processes (e.g. a PRRC for the QMS related tasks and one for technical documentation)
- Combinations of the above.

V. Meaning of "permanently and continuously at disposal" of the company

The MDCG guidance 2019-7 states that:
"The micro or small enterprise may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria is met and the manufacturer can demonstrate and document how they can meet their legal obligations. For example, the PRRC may be part of an external organization, with which the manufacturer has established a contract laying down provisions so as to ensure the permanent and continuous availability of that party. The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (1)."

Position of TEAM-PRRC:

A PRRC employed internally to the company is, by virtue of their contract of employment, permanently and continuously available to that company.

When an outsourced PRRC is appointed, they also have to be permanently and continuously available. This means that:

- There is no duration limitation for the contract/agreement;
- The PRRC has to be prepared to carry out their responsibilities by being fully trained on related SOPs, authorized to perform each task and having access to the relevant documentation.
- The role of the PRRC is not intended to be an emergency response role. The timeframe for completion of planned activities should be agreed between the contract giver and PRRC along with the time period expected for response to communications outside the scope of planned activities.

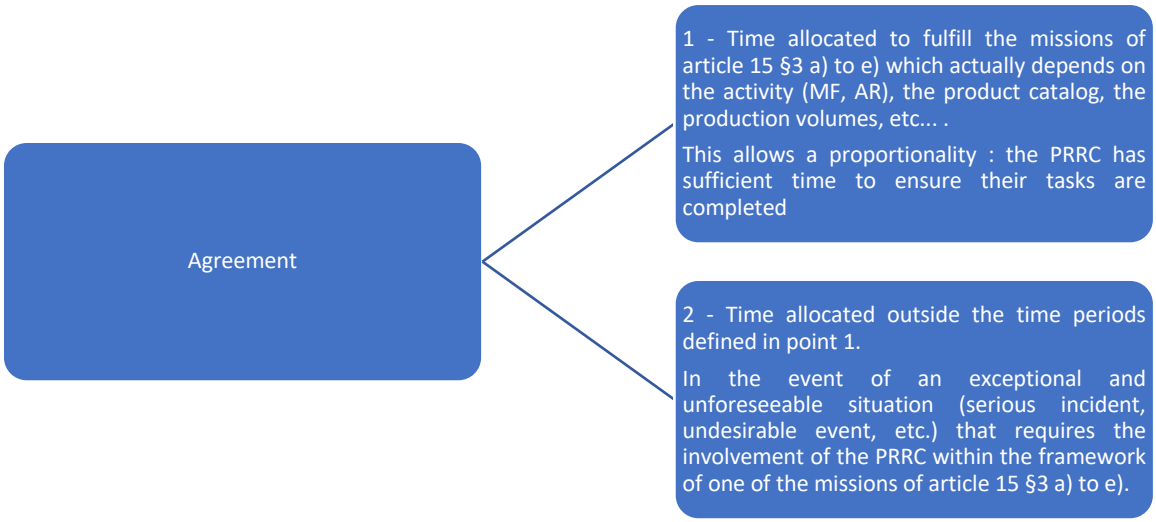
TEAM-PRRC's interpretation is that the hiring company should be able to reach their PRRC(s) during normal office hours. The availability regarding working time should respect the national employment laws. In addition, the availability should be proportionate to the manufacturer or AR activities. The criteria used to define the actual availability timeframes could include, but are not limited to the number of devices, the complexity of manufacturing processes, the frequency of design and manufacturing changes, the frequency of complaints, the vigilance history, the maturity of the QMS, the geographical locations of sites (also taking time zones into consideration) and the overall compliance level.

The outsourcing companies and the outsourced PRRC should agree on measures to delegate the responsibilities to a delegate when the PRRC is not available (sickness, vacations, pregnancy etc.). However, in the end the outsourcing company is responsible for ensuring the availability of the PRRC.

In case of an unannounced audit the involvement of the PRRC is not an expectation of Article 15. However, the outsourcing company should, in any case, be able to demonstrate the provisions for the PRRC are in place and effective, for example by reaching out to the PRRC and showing the auditors that a response has come back within the time period agreed between them.

Alternatively, when the PRRC is not available, (sickness, vacations, pregnancy, unexpected termination of contract etc.) the manufacturer or the AR must provide a replacement plan and/or designate a deputy. A procedure can be drawn up to cover the absence of the PRRC.

Creating robust contracts ensures there is no gap/misunderstanding and protects both the PRRCs and the company employing or contracting them. The contract should cover the items below:



VI. Meaning of "close linkage"

The MDCG guidance 2019-7 states that:

"Can the PRRC be located outside the European Union (EU)?

As to the location of the PRRC, it is important that a close linkage, of a permanent and continuous nature, is established between the PRRC and the manufacturing activities. For this reason, for manufacturers located outside the EU, it must be assumed that the PRRC should also be located outside the EU. On the other hand, for manufacturers located in the EU, it must be assumed that the PRRC should also be located in the EU."

Position of TEAM-PRRC about the meaning of "close linkage":

The PRRC should at least be located in the same continent as the manufacturer (or in the EU if the PRRC works for an AR). Geographically, the time zone should be also considered, although a few hours' time difference can be overcome. The geographical locations of sites also affect the justification for PRRC arrangements if they are located in several different time zones. In case of multiple locations where critical processes take place, appointing more than one PRRC should be considered. Ultimately the company appointing the PRRC(s) is responsible for justifying the choice of PRRC and their location with respect to their close linkage with the company.

VII. Case of the linked enterprise (legal entity)

The MDCG guidance 2019-7 states that:

"Organizations with more than one legal manufacturer under the parent company would need to ensure that each legal manufacturer has its own PRRC.[2]

[2] *In the context of Article 15, the obligation for having available within the organization at least one PRRC refers to the individual legal manufacturer."*

This implies that each legal entity shall appoint at least one PRRC.

Suppose a medium to large organization is linked to but entirely separate from a small medical device (MD) organisation. The medium to large organization is not involved in the day-to-day running of the medical device (MD) organisation. Can that MD company be considered a micro and small enterprise and appoint an external PRRC?

Position of TEAM-PRRC:

Under the strict definition of micro and small as given in Commission Recommendation 2003/361, the MD enterprise meeting the definition of small by itself does not exempt it from being considered a "linked enterprise". It may fall into the meaning of medium or large when taking the size of the linked organization into account. However, it should be noted that it is not just about staff numbers and turnover. The interpretation of micro or small also rests on whether the two enterprises have any of the following relationships:

- one enterprise holds a majority of the shareholders' or members' voting rights in the other;
- one enterprise is entitled to appoint or remove a majority of the administrative, management, or supervisory body of the other;
- a contract between the enterprises, or a provision in the memorandum or articles of association of one of the enterprises, enables one to exercise a dominant influence over the other;
- one enterprise is able, by agreement, to exercise sole control over a majority of shareholders' or members' voting rights in the other[1].

In the cases mentioned above, the two enterprises are considered to be linked, and the MD company would not be an independent company, therefore a PRRC is required to be employed within the company and not outsourced.

[1] Source : Commission Recommendation 2003/361/EC Article 3 section 3.

If none of these apply, it may still be possible to argue that the small enterprise does indeed qualify as small or micro in the meaning of Commission Recommendation 2003/361.

VIII. Professional indemnity insurance

Regarding the outsourced PRRC, no clause in article 15 nor in all the MDR provides information about professional indemnity insurance.

The only mention of financial coverage concerns the manufacturer:

- The MDR states in article 10 (obligations of the manufacturer) that:

"Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law."

- The MDCG guidance 2019-15[2] states that:

"Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Therefore, manufacturers shall, in a manner that is proportionate to the risk class, type of device and size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC[3], without prejudice to more protective measures under national law."

Position of TEAM-PRRC:

Considering Article 10 of the MDR and the MDCG 2019-15 guidance, the intent is that damages caused to natural (patients, user, …) or legal persons are indemnified. The PRRC should verify that all the activities described in Article 15 are effectively covered under the scope of the manufacturer's indemnity insurance.

The obligation of sufficient financial coverage is not mentioned for the authorized representative. However, Article 11§5 indicates that "the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer". In this case, the PRRC

[2] Source: MDCG guidance 2019-15: Guidance for Manufacturers of Class I devices; section 4.
[3] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

should verify that all the activities described in Article 15 are effectively covered under the scope of the authorised representative's insurance.

Regarding outsourced PRRCs, we highly recommend obtaining professional indemnity insurance that includes the cost of legal coverage.

Note: a suggested contract template for external PRRC is available for members of TEAM-PRRC and an adapted insurance has been negotiated specifically for those individuals taking on the role of an outsourced PRRC.

