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Bio-HyPP

Deliverable No	Title	Submission Due Date	WP/Lead
D1.10	Guidelines for health and safety, standardization and certification	31.05.2019	WP 1 / RINA
Short Summary	The main objective of this deliverable, is to provide a definition of a strategy and of measures to be undertaken towards standardization shall be issued, in the form of advices, best practices and implementation supports aiming to limit any potential risk and prevent any non-compliance with existing standards.		
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Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Table of Contents

Table of Figures

1 INTRODUCTION

The Bio-HyPP (GA No 641073) Horizon 2020 EU funded project aims to develop a full scale technology demonstrator of a hybrid power plant using biogas as main fuel in laboratory environment, in order to reach the goals of improving the efficiency of CHP systems while simultaneously widening the biomass feedstock base as well as increasing operational flexibility (Ref. [6], [7], [8] and [9]).

The present document constitutes Deliverable 1.10 "Guidelines for health and safety, standardization and certification" in the framework of Bio-HyPP project and refers to activities carried out within Task 1.6 "Health, safety, standardization and certification", under Work Package 1 "Hybrid Power Plant System Analysis".

This document supplies an overview of the current Regulations, Codes and Standards framework throughout Europe for what concerns the installation aspects referring to the Hybrid Power plant. With this overview, the document guides on what to keep in mind when aiming at standardization and certification. This document aims to support the Bio-HyPP Project consortium on these issues, with a particular focus on aspects related to the presence of fuel cells within the plant under development.

Active support and engagement from Bio-HyPP project partners and in particular from the industrial entities involved will therefore be indispensable to comply with existing legislative framework. Further studies must follow to analyse plant adequacy in terms of control and usability.

Fuel cells and, specifically, stationary applications (including FC-based Combined Heat Power, CHP) are being subject to an increasing standardization at an international and European level. These efforts have the aim of creating a common, normalized framework that would help them enter the market. The objective of this document is to identify the current international and the European standards, and European regulations related to FC-based CHP (Combined Heat Power) systems and to analyse their adequacy, in terms of content and usability.

At a standard level, focus has been on the installation aspect of these devices while, at a regulation level, attention has been addressed to the consequences on market perspectives.

Regulations, codes and standards provide performance requirements (effectiveness, reliability) with regards to the means (procedures, prevention, mitigation) used to achieve performance/safety targets. Moreover, they provide design criteria ensuring fitness for purpose by relating requirements to conditions of use and standard solutions for meeting the performance requirements or safety targets.

1.1 ACRONYMS AND DEFINITIONS

Acceptance Criteria	The level of health, safety and/or environmental performance deemed acceptable for a given period or phase of activities
ALARP	As Low As Reasonably Practicable
ATEX	ATmosphère EXplosibles
CE	European Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CHP	Combined Heat and Power
EC	European Commission
EFTA	European Free Trade Association
EN	European Standard
GAR	Gas Appliances Regulations
Hazard	The potential to cause harm or injury, damage to asset or to environment, production losses or increased liabilities
HAZID	Hazard Identification (Analysis) - Technique for early identification of potential hazards and threats
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
FC	Fuel Cells
PED	Pressure Equipment Directive
RCS	Regulations, Codes and Standards
Risk	The product of the probability that a specified undesired event will occur and the severity of its consequences.

2 OBJECTIVE

The main objective of this document on the basis of the current status of the Bio-HyPP Project, is to provide a definition of a strategy and of measures to be undertaken towards standardization shall be issued, in the form of advices, best practices and implementation supports aiming to limit any potential risk and prevent any non-compliance with existing standards. Standardization study has been focussed to preventively identify the way to remove market barriers, assuring safety, increasing the compatibility of products, systems and services and promotes common technical understanding. The application of this guidelines will remain a vast environment, for this reason, these activities must be supported by active engagement and input from partners of the Bio-HyPP Project.

Ensuring that the system complies with applicable norms and standards will therefore be an integral part of activities as well as taking actions toward preparing the system to acquiring the required certifications.

These guidelines provide guidance to appropriate behaviour, so as to ensure safety of people (workers, users and general public). They may also give information about codes, standards and regulations to be complied with and about the recommended way to meet those requirements. For example, it gives information related to material properties, adequate installation, and use of equipment and safety procedures. Guidelines may be intended:

- To authorities, who have to verify the conformity with applicable regulations and standards of a system and to approve it;
- To end-users of a given system, so that they can run the system in accordance with safety and performance requirements;
- To maintenance employers, so as to give them principles to observe during maintenance and cleaning up.

3 REGULATIONS, CODES AND STANDARDS

The first part of this report is dedicated to the presentation of global context and issues for Regulations, Codes and Standards (RCS). First and foremost, we propose to clarify the meaning of RCS, on a general basis. Then, we identify the different documents related to RCS and explain how they are connected. Finally we highlight the issue of definitions, which is of paramount importance in a RCS context (Ref. [2]).

Regulations, codes and standards (RCS) are a key part of the development and running of any industry. This document will look at the ways in which RCS affect fuel cells and the fuels they use as the technologies begin to commercialise (Ref. [5]). Codes and standards are influential as they feed into and form the basis for legislative regulations; it is important to look at all levels of RCS (shown in Figure 3.1) when assessing industries and technologies that are still developing.

Figure 3.1: Regulations, Codes and Standards (RCS) pyramid (Ref. EC Network of Excellence for Hydrogen Safety "Hysafe",Template for Hysafe Website Dedicated to RCS and WP16: link: http://www.hysafe.org/download/878/D27template.pdf)

Regulations, Codes and Standards refer to different levels of "coding". Based on the recent report issued by the standardization body CEN – CENELEC (the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC)). We clarify the meaning of Regulations, Codes and Standards in what follows:

- Regulation: Regulations are the highest level of "coding", because they do not only contain descriptions of the physical and operational features of the given technology or product, but also performance standards and limit values (tolerances) to be complied with, and implicit restrictions for the use of non-standard or non-compliant items or systems. Regulations are needed to ensure that public goods such as safety, security, sustainability, health, interoperability, are not unduly compromised by the use of a given product or system over its complete life-cycle. Authorities, e.g. local, national, or international governments, provide compelling regulations to protect the public, workers, and environment from dangers and hazards. A European Community Directive is an example of a regulation. This is a collective legislative act requiring Member States to achieve a particular result without dictating the means of achieving that result. In addition to the EC directives the European countries typically have their own national or local regulations for producing parts, e.g. pressurized equipment and equipment intended for use in explosive atmospheres. National or local regulations for the use of such equipment may also apply.

- Code: Codes (also referred to as "codes of practice") usually explain the basic functions of an equipment or product for safe handling and problem-preventive maintenance in order to guarantee trouble-free operation. These codes usually share at least some basic elements that are built around the generic features and functionality of the technology, and build a common understanding among the people how to deal with this type of product or system. In that case, the codes (of practice) are not a mandatory document, unless the codes were validated by decree. The notion "Code" can also be used differently: it then refers to a collection of rules made binding by a local or national government. In that case, the code is mandatory. In Europe, the difference have to be made clearly between "Codes" and "Codes of practices".
- Standard: A standard is a document that sets out requirements for a specific item, material, component, system or service, or describes in detail a particular method or procedure. Standards facilitate international trade by ensuring compatibility and interoperability of components, products and services. They bring benefits to businesses and consumers in terms of reducing costs, enhancing performance and improving safety. Standards are developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders -including businesses, consumers and environmental groups, among others. The formal definition of a standard is a "document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. There are several different types of standards. Basically, standards include requirements and/or recommendations in relation to products, systems, processes or services. Standards can also be a way to describe a measurement or test method or to establish a common terminology within a specific sector. Standards are voluntary which means that there is no automatic legal obligation to apply them. However, laws and regulations may refer to standards and even make compliance with them compulsory. As an example, the ATEX - Directive 2014/34/EU (related to explosion protection) states that it is mandatory under European law for all equipment for use in a potentially explosive atmosphere to conform to specific safety standards. Only accredited standards can become mandatory. Each European country has its own national standards organization, which can accredit standards. Once the standard is accredited, it can be set mandatory by ministerial decree.

Regulations, Codes and Standards are not equivalent, as regards their coverage, but also as regards the way they are designed.

While standards are developed by standardization organizations, through thorough development processes, involving workgroups put together by a wide range of interested parties, codes may be developed by a few or only a single company or association. Due to their more extensive development process, standards generally have a wider acceptance than codes.

Standards and codes, unlike regulations, are not legal documents, yet standards may be included or referred to in regulations and, through the regulation, may be made legally binding. In this case the standard is said to be harmonized with the regulation and becomes a harmonized standard. However, the use of these standards remains voluntary. Manufacturers, other economic operators, or conformity assessment bodies are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements.

4 GUIDELINE FOR HEALTH AND SAFETY, STANDARDIZATION AND CERTIFICATION

As far as standards development is concerned, since fuel cells are electrochemical devices, this falls to European Committee for Electrotechnical Standardization (CENELEC) in Europe and International Electrotechnical Commission (IEC) at on international level (Ref. [1] and [3]).

The most relevant regulation for FC-based Combined Heat and Power (CHP) systems is related to the European Conformity (CE) marking. CE marking is a conformity marking that is adopted inside the European Union, and the countries belonging to the European Free Trade Association (EFTA), which states that a product has been assessed before being placed on the market and meets the EU safety, health and environmental protection requirements. These requirements are stated in a set of European Directives that deal with different aspects of product development and product characteristics (Ref. [2]).

This chapter reports a general overview of the already existing International and European Regulations, Codes and Standards that deal with fuel cell (and hydrogen) activity.

4.1 EUROPEAN DIRECTIVES AND CE MARKING

The European Union introduced a series of measures to ensure the free movement of goods throughout the European Union (EU) and the European Free Trade Area (EFTA). New Approach Directives are examples of these measures (Ref. [4] and [5]).

These Directives aim at controlling product design and, above all, at ensuring technical harmonization of product safety requirements across Europe, so as to guarantee a high level of protection to the public.

The CE marking symbolizes that the marked product fulfils all applicable provisions (or requirements) of applicable directive(s) that provide for CE marking (essential requirements, harmonized standards and specific dispositions), and that the product has been subject to the appropriate conformity assessment procedure(s) contained in the directive(s). The scope of the CE marking regime is laid down in the relevant harmonization directive(s), and can only be applied by the legal entity responsible for the conformity of the product. The CE marking is neither a mark of origin nor a quality mark.

Installed fuel cell systems must be CE marked and comply with a set of EU directives, so:

- ATEX Equipment Directive (Directive 94/9/EC, amended by Regulation (EC) No 1882/2003 and Regulation (EU) No 1025/2012). This Directive applies to any equipment (electrical or non-electrical) or protective system designed, manufactured or sold for use in a potentially explosive atmosphere.
- Pressure Equipment Directive (PED) (Directive 97/23/EC, amended by Regulation (EC) No 1882/2003 and Regulation (EU) No 1025/2012). This Directive applies to the design, manufacture and conformity assessment of pressure equipment with a maximum allowable pressure greater than 0.5 bar above atmospheric over the temperature range it has been designed for.
- Low Voltage Directive (LVD) (Directive 2006/95/EC). This applies to electrical equipment designed for use with a voltage rating of between 50 and 1,000 V for AC, and between 75 and 1,500 V for DC.
- Electromagnetic Compatibility Directive (EMC) (Directive 2004/108/EC). This Directive applies to commercially available equipment, or combinations of equipment made into a single unit, intended

for an end user and likely to generate electromagnetic disturbance, or the performance of which is likely to be affected by such a disturbance.

- Gas Appliances Directive (GAD)(Directive 2009/142/EC). This applies to appliances that burn gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing, and which have, where applicable, a normal water temperature that does not exceed 105°C. This is not applicable to fuel cells as no fuel is burnt, but the Directive also covers such components as safety, and regulating and controlling devices, which may be fitted to the gas side of a fuel cell or a reformation unit to generate hydrogen.
- Machinery Directive (Directive 2006/42/EC, amended by Regulation (EC) No 596/2009 and Directive 2009/127/EC). This applies to machinery, interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, removable mechanical transmission devices and in part to completed machinery. This Directive does not apply to the fuel cell installation itself, but could apply to the associated equipment that is necessary to operate the installation, e.g. a hoist for lifting gas cylinders.

The PED (Pressure Equipment Directive) has been applicable in Europe since December 1999 and mandatory since end of May 2002. It applies to all stationary vessels with a service pressure of more than 0.5 bar and a PV (pressure water capacity) of more than 50 bar. In case of fuel cell applications, it may be particularly relevant for all pressure vessels (cylinders) and safety accessories (valves, flexible hoses, connectors). This Pressure Equipment Directive allows the same design for the pressure vessels and associated accessories to be used everywhere in the EU. This Directive only defines the "essential requirements" which are given in its Annex 1. Detailed requirements are given in the harmonized standards (e.g. those prepared by CEN). These EN standards are not mandatory, other procedures or "state of the art" can be used by the manufacturer in order to demonstrate to the notified body that the essential requirements are fulfilled.

The Council Directive 90/396/EEC on appliances burning gaseous fuels (GAR) is based on the New Approach. The scope of the GAR is restricted to appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting and washing, i.e. the GAR covers mainly common consumer and commercial products. So-called fittings are also covered. Appliances specifically designed for use in industrial processes carried out on industrial premises are excluded. The GAR contains the essential requirements that an appliance must meet when it is placed on the Community market. It does not indicate how these requirements must be met, thus leaving flexibility to manufacturers regarding the technical solutions to be adopted. In order to facilitate market access, Harmonized Standards – the reference numbers of which have been published in the Official Journal – provide a presumption of conformity with the directive essential requirements. Using Harmonized Standards is voluntary. Standardization work is being coordinated by the CEN (Sector Forum Gas-SFG).

4.2 STANDARDIZATION

Though standards and regulations are frequently mentioned together, it should be remembered that they are two fundamentally different things. While regulations are mandatory for everybody within their domain, standards are not.

Standards facilitate the trade and use of goods or services. Their main role is to make components or services fit together: pressure cylinders with valves, valves with regulators and further equipment leading

the gas to the place of use. This, however, also involves safety issues, and so there is of course an interlink with regulations (Ref. [2]).

The basically clear distinction between regulations and standards stated above is somewhat softened by the fact that directives and other regulations may refer to standards. If this happens, the user is obliged to follow this standard, giving it a power similar to that of a regulation. But regulations usually contain some provision for the case that technical progress produces new products or applications not explicitly covered by the existing standards. These are required to meet the same safety objectives. Just the process to prove that they do is more tedious. While in the case of a conventional product the reference to the standards is enough, extensive test reports may be necessary for new ones.

Certification may be done initially on an individual basis only. As soon as the new product proves that there is a market for it, its manufacturers often develop appropriate standards and introduce them into the regulations. This may take time, but it is a general experience with new technologies.

The most important committee on standards for hydrogen technology is ISO TC 197 "Hydrogen Technologies".

European harmonized standards provide the detailed technical information enabling manufacturers to meet the essential requirements. A harmonized standard provides a presumption of conformity with the essential requirements covered by the standard. These standards – produced under a mandate from Member States through the Commission – give the technical measures to meet the essential.

5 MAIN INTERNATIONAL STANDARDS

In the following chapter the most referenced standards both at an international and a national level are described (Ref. [2] and [5]).

5.1 IEC 62282 SERIES

Regarding stationary fuel cell applications, IEC has issued the IEC 62282 series.

The IEC 62282-2 standard (Fuel cell technologies - Part 2: Fuel cell modules) focuses on fuel cell systems. In particular, it provides the minimum requirements for safety and the performance of fuel cell modules, and applies to fuel cell modules with different kinds of electrolytes. The standard only deals with dangerous situations that can involve people or the external part of these devices.

The IEC 62282-3 standard deals with stationary fuel cell power systems (FC-based CHP applications are also part of the scope of the standard). It is divided into three parts:

- IEC 62282-3-100: Stationary fuel cell power systems – Safety;
- IEC 62282-3-200: Stationary fuel cell power systems - Performance test methods;
- IEC 62282-3-300: Stationary fuel cell power systems – Installation;
- IEC 62286-3-400: Stationary fuel cell power systems - Small stationary fuel cell power systems with combined heat and power output.

Part 1 (Safety) regulates different safety aspects. It starts by setting a framework through a general safety strategy and, then further elaborates upon safety issues in the physical/operating environment, on materials, pressure equipment, the electrical system, electromagnetic compatibility, control and protective systems, pneumatic and hydraulic equipment, valves, rotating equipment, cabinets, thermal insulating materials, utilities and during installation and maintenance. The sections are dedicated to the definition of safety type tests and routine tests and to the marking, labelling and packaging requirements.

Part 2 (Performance test methods): The aim is to create a common set of test methods in order to evaluate the performance of stationary fuel cell power systems. Tests are proposed to measure their power output under stationary and transient conditions, to assess their electric and thermal efficiency and to evaluate their environmental characteristics.

Part 3 (Installation): This part specifically deals with issues related to safety during the installation of a stationary fuel cell power system. These issues are grouped into five sections: siting, ventilation and exhaust, fire protection and gas detection, interconnections with site interfaces and environmental requirements. As the installation of such systems is influenced to a great extent by national regulations, the standard has the aim of creating a framework of what things should be considered, rather than being too specific. It also includes the requirements for the approval and maintenance tests that have to be performed after the system is installed.

Part 4 (Stationary fuel cell power systems, Small stationary fuel cell power systems with combined heat and power output) specifies requirements for construction, safety, installation, fitness for purpose, rational use of energy, marking and performance measurement of fuel cell power systems (with an heat input based on net calorific value of less than or equal to 70 kW) that act as a heating appliances supplying both electrical

power and useful heat. Furthermore, the direct connection to the mains (parallel operation) is also within its scope. Finally, it applies to both indoor and outdoor installations and Type Testing only.

These standards have been included in the European framework by CENELEC as IEC EN 62282-2 and IEC EN 62282-3 and the last update of both was in 2016.

5.2 EN 50465

The CENELEC/Standard Reference 105 technical body of CENELEC has been working on another standard that deals with the use of fuel cells as heating appliances (FC-based CHP systems). This standard is coded EN 50465 (last update in 2015) and it is the only standard that specifically addresses the issues of designing and manufacturing FC-based CHP systems.

EN 50465: Gas appliances - Fuel cell gas heating appliance - Fuel cell heating appliances of nominal heat input inferior or equal to 70 kW.

Section 4 of this standard states that fuel cell heating appliances are classified in categories according to EN 437. This standard regulates the test gases families, groups and ranges, as well as the gas appliance categories, on the basis of which of the previous test gases are suitable for them. The fuel cell heating appliance categories allowed in each Member State are given in the Annex A. Furthermore, another classification, based on CEN/TR 1749 (pertaining to the mode of air supply and evacuation of combustion products) is also given.

Section 5 is dedicated to construction requirements, and includes general construction (connection to gas and water pipes, use and servicing, soundness, air supply, etc.), conversion to different gases (the standard allows certain actions to convert the appliance from one gas family to another), materials and thicknesses (including material selection, thicknesses, welding, thermal insulation, control and safety devices, combustion product evacuation, etc.), gas circuits (composition and control), cooling and water circuits, electrical equipment (calls IEC EN 60335-2-102 (Household and similar electrical appliances - Safety. Part 2: Particular requirements for gas, oil and solid-fuel burning appliances with electrical connections)) and control systems (including adjusters as well as control and safety devices).

Section 6 deals with operational requirements, such as the soundness of the air supply and exhaust evacuation circuits, heat input and output, safety of operations (surface temperature limits, hot water temperature limits and control, exhaust temperature, etc.) and control systems.

Section 7 describes the test methods that should be used to check the requirements stated in sections 5 and 6.

Section 8 formally makes IEC EN 60335-2 (Household and similar electrical appliances - Safety. Part 2: Particular requirements for gas, oil and solid-fuel burning appliances with electrical connections), EN 50438 (Requirements for the connection of micro-generators in parallel with public low-voltage distribution networks) and IEC EN 61000 (Electromagnetic compatibility standard series) the reference standards for the electrical system and EMC.

Section 9 establishes the requirements for the marking, installation and operation instructions.

The standard also contains 11 informative annexes that complement the information.

In the same way as for the IEC 62282 series, it would seem necessary to have a better interaction with other reference standards as well as the treatment of issues that until now have not been considered.

6 CERTIFICATION

Certification of both manufacture and products is critical in any industry that wishes to sell to consumers. Commercial sales of fuel cells have only begun in the last five years and certification isa challenging area when presenting a product that utilises an unknown technology and is fundamentally different from its competitors. ISO 9001:2008 – Quality management systems is considered to be a benchmark of quality across all manufacture and conformance as it can ease the process of certification. It specifies requirements for a quality management system, where an organisation

- needs to demonstrate its ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements, and
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Other international standards, such as ISO 14001:2004 – Environmental management systems, although not directly related to the manufacture of fuel cells, can help instill good practices that can make the certification process easier.

6.1 Europe

A CE mark is a mandatory conformity mark for products to be sold in the European Economic Area. It confirms that a product conforms with all of the EC directives applicable to it. In some instances a user may self-certify; in others, particularly where a product is of potential danger, a Notified Body (an organisation accredited by an EU Member State to assess products against directives) must certify the product.

CE conformity marking concerns the design, manufacture, placing on the market and entry into service of a product. The CE marking must be affixed by the manufacturer or his agent established in the EC.

Depending on the directive concerned, certification is either through self-declaration or through examination and assessment by a notified body.

The manufacturer bears the ultimate responsibility for the conformity of the product. He has to issue a Declaration of Conformity which includes his identity, a list of EU directives he declares compliance with, a list of standards the product complies with, and a legally binding signature.

The basis of the conformity assessment is the Technical Construction File (also referred to in some directives as the technical file or the technical demonstration), which is a compilation of documents (as reported on Section 6.2) containing the product design and security measures that make it safe.

Prototype and demonstration units are not required to have CE marking.

6.2 EC Declaration of conformity of the Equipment

This declaration relates exclusively to the equipment in the state in which a product was placed on the market, and excludes components that are added and/or operations carried out subsequently by the final user. The EC declaration of conformity must contain the following particulars:

- Business name and full address of the manufacturer and, where appropriate, his authorized representative;

- Name and address of the person authorized to compile the technical file, who must be established in the Community;
- Description and identification of the equipment, including generic denomination, function, model, type, serial number and commercial name;
- A sentence expressly declaring that the equipment fulfils all the relevant provisions of the relevant directive(s) and where appropriate, a similar sentence declaring the conformity with other directives and/or relevant provisions with which the equipment complies. These references must be those of the texts published in the Official Journal of the European Union;
- Where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination and the number of the EC type-examination certificate;
- Where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system;
- Where appropriate, a reference to the harmonized standards used;
- Where appropriate, the reference to other technical standards and specifications used;
- The place and date of the declaration;
- The identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorized representative.

7 CONCLUSIONS

Within Task 1.6 of the Project, the assessment of the risk-based design for each system component has been done (i.e. for SOFC, MGT, reformer, burner, heat exchangers, piping, etc.), to aid future system exploitations and understand requirements for components certification. To this end, a Preliminary Hazard Identification and Risk Analysis (HAZID-RA) was carried out to qualitatively evaluate the possible events sequence which could transform a potential hazard into an accident (described in a confidential project document); and for each undesirable events or hazards, identify possible improvements, or preventive measures.

At the current state of the Bio-HyPP Project, the information in this document provides guidance on some safety aspects of the equipment. This is not a substitute for meeting applicable standards, codes and regulations. Relevant standards, codes and regulations are referenced, where available, and the document gives a listing of current codes and standards. As many standards and codes are currently in development (these activities are supported and developed by authorities, technical committees of international standardization and companies that have certified products) or only recently adopted, system designs have yet to be finalised by many manufacturers, it may be some time before we can reasonably expect equipment certification to these codes and standards. Certification, including CE marking, is not required for demonstration prototypes. The guidance provided in this document can facilitate demonstration and early market installations.

Fulfilling RCS is always a task specifically addressed for each product. Collaboration with experienced authorities or notified bodies is adviced. The global legislative landscape is vast and it can be a difficult task identifying all the relevant RCS that may impact certification of the Bio-HyPP project. Members of these authorities often sit in the working groups or technical committees of international standardization organisations. If there is an apparent lack of appropriate RCS for the Bio-HyPP project, working closely with them to develop standards or modify existing ones, based around the requirements of the final product, can be beneficial. It can aid market growth and will ensure that the designs and applications are standardized, easing future product introductions: a first mover advantage. Several companies that have certified products now have staff sitting on ISO and IEC technical committees, helping to shape future RCS.

As reported on this document, the Bio-HyPP project tries to ensuring that the system complies with applicable norms and standards. Technical solutions are therefore an integral part of activities toward preparing the system to acquiring the required certifications. However, certification is not needed for the demonstrator that shall proof functionality. Certification will be taken into account after the demonstrator design has been adopted to a market product.

A thorough and robust approach to design and manufacturing is also sensible. Working within guidelines common in the intended application areas and industries can ease certification as can having a facility that meets the requirements of international standards for manufacturing quality. It is also important to make sure that those you work with throughout the supply chain maintain a similar approach. RCS demands active involvement and input from all involved parties (manufacturer and installation site).

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