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DISSEMINATION OF ISO 9001: 2015 IN R&D ORGANIZATIONS

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ABSTRACT

Although there are case studies on the quality management systems in research centers – called here R&D organizations – none of these studies aimed to present the diffusion of ISO 9001:2015 certification in this group. In this sense, even in "The ISO Survey," there is no evidence regarding the diffusion of ISO 9001:2015 in R&D organizations. The purpose of this article is to analyze the diffusion of ISO 9001:2015 in R&D organizations, including its scope. Using data provided by different databases, it was possible to find cases to be studied and build a new database. In addition, the review of the quality management system scopes, based on ISO 9001: 2015, allowed their characterization. The database created enabled us to understand the diffusion of ISO 9001 and the objects of certification by R&D organizations worldwide. The present article attempts to be a relevant contribution to understanding ISO 9001:2015 in R&D organizations and the importance of this certification in this type of organization.

Keywords: ISO 9001; R&D; Quality Management System; R&D Organization.

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INTRODUCTION

According to the International Standard Organization (ISO), ISO (2020), ISO 9001 has certified "more than 1 million companies and organizations in over 170 countries", which can be tracked periodically with the ISO Survey publication. The ISO Survey of Management System Standard Certifications regarding ISO 9001:2015 shows the certification's global spread and evolution (ISO, 2019). However, the figures regarding the diffusion of ISO 9001 in R&D organizations are not clearly and distinctly presented.

This paper explores the application of ISO 9001 in the area of research and development (R&D). However, the approach of the paper is not about the R&D function but about organizations where R&D is one of their main activities. Throughout the paper, they will be referred to as "R&D organizations".

According to ISO (2020), there are applications based on ISO 9001 for some sectors of the economy, such as ISO 13485:2016, ISO/TS 54001:2019, and ISO 18091:2019. However, in this study, the focus is on ISO 9001.

Understanding the adoption of the standard and the scope in which it is being applied by R&D organizations is relevant. This topic is also significant because there are many stakeholders in the results delivered by universities and research institutions, which are examples of R&D organizations. The application of ISO 9001 in R&D organizations can increase stakeholder satisfaction, reduce organizational risks, improve governance, or be a management tool in search of better results within the scope in which it is applied.

This study is relevant since, as put by Vermaercke (2000a), quality assurance systems are rare in this environment and are a controversial topic that encounters barriers and resistance. As put by Mathur-De Vré (2000), it is a controversial topic that faces skepticism.

Although it is difficult, authors such as Biasini (2012) and Fàbregas-Fernández (2010) understand quality management as a way to demonstrate excellence. In this same vein, Vermaercke *et al.* (2000b) argue that competence can no longer be based on a management promise or reputation built over the years but on a well-structured operations management system (OMS).

In light of the above, two main research questions arise: how widespread is certification to the ISO 9001:2015 standard in R&D organizations and how have R&D organizations structured their certification scopes based on ISO 9001:2015?

In an attempt to answer the questions posed, this article presents an exploratory study of the application of ISO 9001 in R&D organizations globally. It is worth noting that this study opens a path but is not intended to be conclusive, given the insufficient data to make general statements.

R&D Organizations

This work explores the application of ISO 9001 in organizations in research and development (R&D) globally. These organizations conduct R&D activities that, according to the OECD (2015), include basic research, applied research, and experimental development. Furthermore, according to the Frascati Manual, OECD (2015), individuals, institutions, economic sectors, and countries, developed or developing, are affected in various ways by R&D results. This proves the relevance of R&D activities and, consequently, of organizations that perform R&D in a general and global manner. The question of the diffusion of the ISO 9001 standard in R&D institutions carries with it the question of this standard's application in this type of organization. In this way, the literature review searched the Scopus and Web of Science databases for studies similar to the one proposed here and found none with the same focus on R&D organizations.

ISO 9001 and R&D organizations

As per ABNT's (2015) presentation in the preface, the ISO 9001:2015 standard points out that its scope is related to organizations that wish to briefly implement a quality management system aimed at: "a) demonstrating that they can provide products and services that meet customer requirements; and b) seeking to increase customer satisfaction". The standard further states that its requirements are generic and can be applied to any organization, regardless of the type and size or the products or services in question.

However, it is worth highlighting the works found, divided into three groups: those that talk about the relevance of the theme of quality for R&D organizations; case studies or proposals about quality in R&D organizations; and those that deal with the diffusion of the ISO 9001 standard; the latter being more aligned with the purpose of this work. In this sense, the entire literature review was very important for the study design and to answer the questions proposed here.

First, works highlighting the importance of the topic "quality" for R&D organizations will be explored. As an example, we can cite the study by Mathur-De Vré (2000), which highlights that the history of quality focused on the production chain creates many difficulties in recognizing the contribution that a quality management system can provide to R&D

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activities. Biasini (2012) argues that the implementation of a quality management system in public research centers is still rare, mainly due to the widespread belief that quality assurance and control tend to limit the freedom of researchers, and points to the lack of a known international standard or guidelines for research laboratories. Presot *et al.* (2014) point out that quality is essential in research centers and universities, highlighting the need for a quality management system, as some researchers and sponsors question the traditional "peer review" system as the only means of research evaluation.

Second, studies concerning the implementation, structuring, or impacts of the implemention of quality management systems in R&D organizations worldwide will be explored. This occurs with the work of Fàbregas-Fernández *et al.* (2010) regarding ISO 9001:200 in a research center operating in the pharmaceutical field in Spain. Biasini's (2012) work addresses a quality management system inspired by ISO 9001:2008 and ISO/IEC 17025:2005 in a public research center in Italy. Martins *et al.* (2017) present a proposal for a standard for a research center in the biological area. The work of Presot *et al.* (2014) addresses quality perception after implementing a quality management system in the laboratories of an R&D organization in Brazil. Breustedt *et al.* (2011) show in their work how a quality management system based on ISO 9001 served as a basis for incorporating laboratories in need of accreditation into an institute in Germany. The work of Fontalvo and De La Hoz (2018) deals with a proposal for the design and implementation of quality management systems based on ISO 9001:2015 for universities with a view to accreditation by the Ministry of Education of Colombia.

There are projects related to the diffusion of the ISO 9001 standard, but most are concentrated in Europe. In this sense, Kozel *et al.* (2017) point out that European countries have played a leading role since the introduction of ISO 9001. In their work based on 2015 data, the authors also point out the most active countries in the implementation of ISO 9001: Italy, Germany, the United Kingdom, Spain, France, and Romania. In this sense, it should be noted that the referred work focuses on the diffusion of ISO 9001 in Poland and the Czech Republic. The authors also emphasize the importance of a database with more information for further studies, including the effects of certification on organizations. Sampaio *et al.* (2009a) also state that the spread of ISO 9001 certification began most vigorously in Europe and that these companies led their providers worldwide to adopt ISO 9001. The authors also comment on the results of the ISO Survey published in 2007, which presented the following countries in the top 10 positions in the number of certificates, from the highest to the lowest: China, Italy, Japan, Spain, the United Kingdom, the United States of America, Germany, India, France, and Australia. The authors also highlighted China's leadership due to its economic importance and its role in global trade, but again pointed out that five out of the top ten countries listed are European. In their study on the diffusion or evolution of ISO 9000 around the world, Sampaio *et al.* (2009b) present very relevant considerations on the dissemination of the standard in general and also highlight the historical role and primacy of European countries.

Finally, Llach *et al.* (2011), who also referenced other works mentioned here, present the geographic approach to diffusion. The authors have a new look at diffusion concerning economic sectors, using the ISO database in their ISO Survey from 1998 to 2008.

METHOD

This study proposes to explore the phenomenon of ISO 9001 application in R&D organizations and its diffusion worldwide through a multiple case study. Each R&D organization and its scope in the ISO 9001:2015 Certificate is a case in this exploratory multiple case study. The analysis of this diffusion and the conclusions depend on the databases used to identify the cases, the time and availability of data for analysis, and the database construction.

Here we have two competing propositions regarding ISO 9001:2015: the first, in which the standard applies to all types of organizations and is likely to be widespread in R&D organizations; and the second, in which the standard does not apply to R&D organizations, thus not being widespread in R&D organizations. In this case, the typical activities of R&D organizations, such as basic research, applied research, and technological development would not be appropriate for the ISO 9001 model, and thus certification in the standard would not be widespread in this type of organization.

Geographical diffusion can be examined since it is possible to identify cases on all continents and in several countries. The question can also be approached through the R&D organization's industry, based on its stated scope for its quality management system.

To answer the second question, the scopes that integrate the database created are analyzed individually to prepare a table that synthesizes the choice of R&D organizations to implement a certified quality management system according to the ISO 9001:2015 standard. This table was built after a textual analysis of all cases and the elaboration of a kind of Mind Map, which, according to Buzan (2009), "is a method of storing, organizing, and prioritizing information (usually on paper) using keywords and key images that trigger specific memories and stimulate new ideas". In this case, key images were not used, but rather keywords.

The methodology for this multiple case study will allow for exploring the scope and identifying processes, activities, or assignments that R&D organizations have included in their quality management system based on ISO 9001:2015. The Mind Map will be valuable to show the size of the field of study and the relevance of the proposal for this work.

According to Yin (2006), conducting high-quality case studies depends on three critical principles, namely: collecting evidence from multiple sources; creating a database; and maintaining a chain of evidence.

As Yin (2006, p. 134) puts it, the methodology proposed in this paper seeks to "make the process as explicit as possible, so that the results – the data collected – reflect a concern for construct validity and reliability, which would then validate further analysis".

The first stage of this study consisted of building a database to answer the research questions, which relied on the triangulation presented by Patton (1987) *apud* Yin (2006, p. 126). According to Yin (2006), "every case study project should strive to develop a presentable database so that, in principle, other researchers can review the evidence directly and not be limited to written reports". Thus, according to Yin's (2006) suggestion, for this study, the authors created a database by developing tables with the information gathered from the various sources consulted and which integrate the body of this work.

This base was built in stages, starting after a literature review and the study of theoretical articles about quality in R&D organizations and individual case studies about quality in these organizations.

As a complement, the study also relied on internet search tools using keywords to identify ISO 9001:2015 certified organizations, databases, or papers, such as case studies, referring to R&D organizations.

The database design includes the continent, country, name of organization, ISO 9001:2015 scope, and the link to the ISO 9001:2015 Certificate or scope description based on the standard. Thus, data regarding the existence of a quality management system based on ISO 9001 can be confirmed, certificates accessed, and scopes identified. The scopes of the organizations listed in this study are published in English. In this way, R&D organizations whose available certificates referred to this 9001:2008 were no longer included in the database. In addition, the organizations were no longer part of the database since it was not possible to identify the certificate in English. The choice of the English language was made to provide an analysis base that could be verified by other researchers.

The starting point, the first base to be explored, was the data from the IQnet (The International Certification Network) portal. Its electronic address, IQnet (2019), shows that it is a global network of certifying bodies in which it is possible to identify R&D organizations with a valid ISO 9001 certification and scope written in the English language. This database has a significant limitation regarding the study's objective, which has led to the search for other databases. This limitation lies in the fact that there are other R&D organizations certified by ISO 9001 but which are not included in the IQNet portal database. This is because inclusion in this database depends on the certifier's participation in IQNet. It also depends on the client's desire for certification to be included in the database. Thus, using only this database would allow a limited cut-off in the universe of R&D organizations.

The second database explored was the Ranking Web of World Research Centers portal. The Ranking Web of World Research Centers (2020) is an initiative of the Cybermetrics Lab, a research group of the *Consejo Superior de Investigaciones Científicas* (CSIC) in Spain. It adds breadth to the study by enabling a greater number of R&D organizations to be located around the world. However, it requires further exploration of each organization through their websites to verify that they fit the database design proposed in this work, despite the fact that R&D organizations do not always disclose the existence of ISO 9001 certification or its scope in their email addresses.

It is worth noting the explicit option in this paper to consider only ISO 9001:2015 certified institutions and not those with a certified quality management system based on ISO 9001:2008, a non-certified ISO 9001-based system, or based on another benchmark.

The second stage refers to the analysis of the data collected about the cases found. This analysis was based on statistical surveys from the database built and on the analysis of the text of each scope of each case studied. In addition, the ISO Survey 2018, ISO (2019) was used as a comparison basis for the study of the diffusion of the standard in the world.

RESULTS

As explained, this multiple case study presents a data base that allows exploring further questions regarding the phenomenon of ISO 9001:2015 in R&D organizations.

The database was divided into three parts for presentation to allow further analysis by other authors. Through the methodology proposed in this work, 42 cases were identified for this multiple case study. **Table 1** presents a column indicating the numbering of each case, the continent, the country, and the name of the institution.

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Table 2 shows the numbering of each case and the text regarding the scope of the quality management system declared by the R&D organization.

Table 3 shows the indication of the numbering of each case and the link referring to the quality management system certificate based on ISO 9001:2015 or the scope of the one declared by the R&D organization.

The data explored from the constructed base presented in the tables above begin with the question of diffusion in R&D organizations. As presented in the methodology to seek worldwide representation, an R&D organization was sought in at least each continent and the largest group of countries possible. However, it was not the intention to exhaust or map all R&D organizations on all continents and countries within the other bases and data sources used earlier in the methodology.

Regarding the geographical issue, cases were identified in almost all continents except Oceania. However, the Melbourne Centre of Nanofabrication (2020) has this 9001 certification, but it was not possible to identify the scope or if there is a certification based on the 2015 version of ISO9001 either in the databases consulted or on the organization's website. Furthermore, it shows the limitations of design and methodological options of this study. The same behavior happened with other R&D organizations, which were left out of the constructed database since it was not possible to fulfill all the requirements of the methodology presented, such as the Institute of Ceramics and Building Materials from Poland, with the last available ISO 9001:2008 certificate. The existence of R&D organizations on all continents suggests their suitability and diffusion. The graph in **Figure 1** shows the distribution by continent.

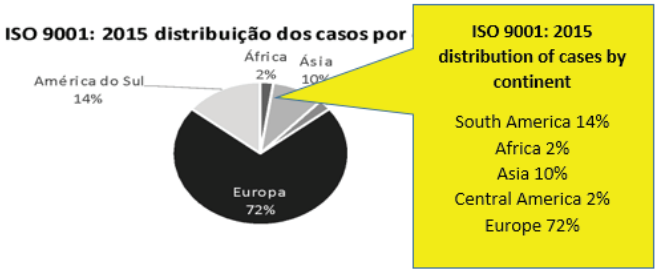

Figure 1. Distribution of cases per continent
Source: elaborated by the authors

Figure 1 shows a concentration of ISO 9001:2015 certifications in Europe, corroborating the placements of other authors cited in the literature review on the diffusion of ISO 9001. The present study explores which countries stand out in the identified cases in the constructed database. Cases were identified in 19 different countries, as illustrated by the graph in **Figure 2**.

Among the cases identified, Germany stands out, with 13 cases in this study, in addition to the prominence of Europe. The cases identified and distributed in almost two dozen countries worldwide also suggest the diffusion of ISO 9001 in R&D organizations, since the two dozen countries with the most certifications represent more than 85% of the total, according to ISO Survey 2018 (ISO, 2019).

Cases were found in developed and developing countries. Thus, the perception of the diffusion and adequacy of ISO 9001:2015 certification to R&D organizations is reinforced.

By collating the database constructed with the results of the ISO Survey 2018 (**Figures 3 and 2**), it is possible to see the similarity regarding the diffusion of ISO 9001:2015 certification, in general. According to the ISO Survey 2018, ISO (2019), the top 20 countries in terms of quantities of certificates in 2018, in descending order, are presented in the chart below, built on the basis of the sector table by country.

Similarities can be observed in the diffusion presented in the ISO Survey and this study. Except for China, the United States, South Korea, the Czech Republic, Malaysia, Romania, and Israel, where the applied methodology failed to identify cases for analysis, less than half of the 19 countries presented cases. When analyzing the ten countries where the ISO 9001:2015 standard is most widespread, only China and the United States are outside the scope identified by the methodology applied. In this sense, it is worth emphasizing that the absence of cases does not indicate the absence of R&D organizations in these countries. Moreover, it is also true that the segment of R&D organizations may not have a uniform diffusion in these countries.

Figure 4 shows the intersection between the sets represented by **Figures 2 and 3**: Italy; Germany, Japan, Spain, India, England, Brazil, Poland, Switzerland, and Portugal.

Analysis of the texts relative to the scopes presented in **Table 2** can also contribute to the question of diffusion. This is because diffusion can be approached through the sector in which the R&D organization operates based on its declared scope. The analysis of **Table 2** allows identifying that this is not a question of a specific area of knowledge or performance, even within R&D organizations. Within the cases identified, R&D organizations work in biotechnology, health, agriculture, nuclear energy, space, information technology, and chemistry, among other sectors and themes. This diversity reinforces the adequacy of ISO 9001:2015 and its diffusion in R&D organizations.

All the scopes of the identified cases were analyzed verbatim to answer the second question. The Mind Map technique presented a pattern that would enable an understanding of how the R&D organizations see the way the ISO 9001:2015

Table 1. List of identified ISO 9001 Certified R&D organizations

No.	Continent	Country	Name of Institution
1	Africa	Egypt	National Authority for Remote Sensing and Space Science
2	Central America	Costa Rica	Instituto Clodomiro Picado
3	South America	Argentina	Instituto del Cemento Portland Argentino
4	South America	Argentina	Universidade Nacional del Litoral
5	South America	Brazil	Embrapa Environment
6	South America	Brazil	Energy and Nuclear Research Institute - Nuclear Energy Center
7	South America	Brazil	Energy and Nuclear Research Institute - Radiopharmaceutical Center
8	South America	Brazil	Energy and Nuclear Research Institute - Research Reactor Center
9	Asia	India	CSIR- CGCRI Central Glass & Ceramic Research Institute
10	Asia	India	CSIR - SERC Structural Engineering Research Centre
11	Asia	Jordan	Royal Scientific Society
12	Asia	Japan	Semiconductor Energy Laboratory
13	Europe	Germany	Fraunhofer Institute for Laser Technology ILT
14	Europe	Germany	Fraunhofer Institute for Photonic Microsystems IPMS
15	Europe	Germany	Fraunhofer Institute for Telecommunications, Heinrich Hertz Institute HHI
16	Europe	Germany	Fraunhofer Institute for Microelectronic Circuits and Systems IMS
17	Europe	Germany	Fraunhofer Institute for Silicon Technology ISIT
18	Europe	Germany	Fraunhofer Institute for Wind Energy Systems IWES
19	Europe	Germany	Fraunhofer Institute for Machine Tools and Forming Technology IWU
20	Europe	Germany	Fraunhofer Institute for Computer Graphics Research IGD
21	Europe	Germany	Fraunhofer Institute for Material and Beam Technology IWS
22	Europe	Germany	Fraunhofer Institute for Manufacturing Technology and Advanced Materials IFAM
23	Europe	Germany	Fraunhofer Institute for Applied Solid State Physics IAF
24	Europe	Germany	Fraunhofer Institute for Nondestructive Testing IZFP
25	Europe	Germany	Karlsruher Institut für Technologie (KIT) DE Technik-Haus (TEC)
26	Europe	Austria	Austrian Institute of Technology
27	Europe	Spain	Institut de Recerca I Tecnologia Agroalimentaries
28	Europe	Spain	Universitat Autònoma de Barcelona - Plataforma de Produccíón de Proteínas
29	Europe	Spain	Universidad de Córdoba
30	Europe	Spain	Universidad de Málaga
31	Europe	Finland	VTT Technical Research Centre of Finland
32	Europe	France	Université Gustave Eiffel
33	Europe	France	IFP Energies Nouvelles (IFPEN)
34	Europe	France	Institut de Physique et Chimie des Materiaux de Strasbourg (IPCMS)
35	Europe	England	National Physical Laboratory (NPL)
36	Europe	Italy	AVANTEA SRL
37	Europe	Norway	Norwegian Institute for Air Research
38	Europe	Portugal	Association for Biomedical Research in Light and Image (AIBILI)
39	Europe	Portugal	University of Azores
40	Europe	Switzerland	AO Research Institute Davos
41	Europe	Poland	Institute for Chemical Processing of Coal
42	Europe	Serbia	Institute of Meat Hygiene and Technology

Source: elaborated by the authors

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Table 2. List of scopes of identified ISO 9001 certified R&D organizations

No.	Scope
1	In respect of Performing Research and Development and Providing Services in Remote Sensing and Space Applications
2	It includes the processes of production of therapeutic imnunobiologicals, biological, biomedical, and biotechnological research as well as social action in the subject of ophidism.
3	Provision of training, technical assistance, technological transfer, studies, and research services provided.
4	Consultancy and authorization of highly specialized services to third parties (SAT) and educational services to third parties (SET); control over the distribution, preparation, and authorization of fund settlements for the provided services; consultancy, registration, and maintenance of UNL's members' intellectual rights; monitoring of the Intellectual Property Rights registration procedures; strategic information management that is required by R&D results valorization; invention patents' applications drafting and experts' opinions about Industrial Property; management of innovation and technological modernization projects within Universidad Nacional del Litoral's scope; project development that includes the coordination of the parts involved; work planning statements; follow-ups of the projects backed by different financing institutions; technology transfer processes management, including the valorization and promotion of services offered and results generated by UNL's members.
5	Research, development, and technology transfer at the interface between agriculture and the environment.
6	Provision of technological services in energy and nuclear systems.
7	Research and development, production, quality control, and commercialization of radiopharmaceuticals and production of radioisotopes in a cyclotron.
8	Operation and Maintenance of the IEA-R1 Reactor and provision of Irradiation services.
9	Research & Development, consultancy, testing and analysis services in the areas of glass, fibre, ceramics and other related materials.
10	Research & Development, analysis, design, testing and evaluation of structures, structural components, special structures, and providing post-graduate research training.
11	Provision of Mechanical materials Testing; Provision of Automated chemical Materials Testing; Provision of Construction Materials Testing; Provision of Industrial Chemistry Materials Testing; Provision of Environmental & Food products testing; Provision of air quality studies and projects; Provision of climate change studies and projects; Provision of real-time water quality monitoring; Provision of water quality projects and studies; Provision of projects and studies in environmental management (environmental and social impact assessment, environmental auditing, cleaner production, hazardous material management, risk assessment, and life cycle assessment); Provision of Applied Research, Technology & Knowhow Transfer and Adaptation, Technical Services & Consultations to Both Private And Public Sectors And Training In Renewable Energy and Energy Efficiency; Testing of Household appliances for energy labeling; Provision of Analysis & Design of Buildings & Building Systems; Provision of Studies & Consultation Services; Engineering Supervision & Project Management, and assessment of green buildings and issuing certificates according to the Jordan Green Building Guide. Analysis, assessment, and rehabilitation of existing buildings, including seismic retrofitting and geotechnical studies; Provision of development and updating of building codes and manuals; Provision of construction project quality control; Training services; Software Quality Assurance and Compliance services; Software Testing Services; Provision of Accredited Training for EC-Council; Development of Applications and Software; Mobile Applications' Development; Requirement Analysis Studies.
12	Research & Development of crystalline thin film integrated Circuits, Liquid crystal and EL displays, Semiconductor TFTS, solar cells, batteries, and wireless elements, seeking patents and exercising intellectual property rights for the above developments.
13	Research and development for laser, plasma, and laser-driven sources, as well as their application in industry and science; scientists and engineers training and qualification.
14	Microsystems research, development, and manufacturing; appropriate semiconductor and microsystem processes; integrated actuators and sensors; and consultation in these areas.
15	Research, development, and production in the fields of photonics and electronics.
16	Research, Development, Production and Distribution of Microelectronic Circuits, Electronic Systems, Microsystems, Sensors and Actuators, Test Equipment and Technologies, and Consultation in these Fields.
17	Development of electronic components and systems on the basis of micro and nanotechnologies.
18	Applied research and development in the field of wind energy with the following research topics: Product Development all the way through Prototype Technology Development and Optimization The Assessment of Technologies and Studies Evaluation in Test Centers.
19	Application-oriented research in production technology for automobile and mechanical engineering.
20	Execution of application-oriented research and development projects and customer-specific adaptations.
21	Research and development in the field of Surface Engineering/Coatings and Laser Materials Processing with the research areas PVD and Nanotechnology, Chemical Surface and Reaction Technology, Thermal Coating and Build-up Technologies, Surface Treatment and Joining, Laser Ablation and Cutting, and Microtechnology.
22	Product-oriented development of materials, mechanical engineering, processes, and production technologies for adhesive bonding technology, surface technology, and paint/lacquer technology characterization and simulation of materials and technologies Adhesives development Training courses in adhesive bonding technology, fiber composite technology, and electromobility Casting technologies Metallography, thermal analysis, powder measurement technology, and trace analysis testing laboratory for material testing, corrosion testing, paint/lacquer technology, and materialography analysis.
23	Research and development for semiconductor-based devices, circuits, and components with functionality based on quantum mechanics and classical physics principles for applications in sensor technology, electronics, and optoelectronics.

24	Research, Development, Qualification, and Application of Nondestructive Testing Technology and cognitive Sensor Systems
25	Scientific equipment production Support, Planning, and Control Mechanical fabrication/machining Mechanical production and assembly Wood and Plastics Machining Precision Engineering and Thermometry Welding technology Quality Control in Testing Technology
26	Austria's largest non-university research institution of a European format, specializing in the key infrastructure topics of the future: Energy, Mobility Systems, Digital, Digital Safety & Security, Health & Bioresources, Innovation Systems & Policy, Low-Emission Transport, Vision, Automation & Control, Technology Experience.
27	Research, development, and technological services in the food industry in the areas of: Animal Breeding and Genetics; Animal Nutrition and Welfare; Aquaculture; Animal Health; Production of Ruminant Food Technology; Product Quality; Food Security; Integrated Management of Organic Waste; Aquatic Ecosystems; Environmental Horticulture; Efficient Water Use; Postharvest Fruit Extensive Crops; and Sustainable Plant Protection.
28	Service on the design, production, and purification of recombinant proteins in different expression systems.
29	The knowledge transfer activities of the University of Córdoba include: management of research calls; international R&D calls; national collaborative research calls; technical advice for the creation of technology-based enterprises; analysis of patentability and management of the protection of intellectual property rights of research results; management of technological requests and dissemination of university capabilities; management of service contracts signed by university professors; and invoicing of contracts and agreements.
30	The promotion of agreements between the research groups of the UMA and the companies concerned; The promotion and management of European projects and collaboration National R+D+I. design and development of one's own technology transfer projects. design and dissemination of events management R&D+i. Technical advice on industrial and intellectual property; promotion and marketing of research results, UMA.
31	Research, new technology development, technology transfer, and commercialization (sites in annex).
32	Research, development, studies, expertise, product certification, testing, and training to and Through research for civil engineering materials and structures, geotechnical engineering and natural hazards, the environment, transportation system operation, and security.
33	Research and innovation in sustainable systems and technologies relating to energy, transport and the environment.
34	Provision of equipment, services, and training courses in: - Morphological and analytical characterization of materials by scanning electron microscopy (SEM +EDX) - Structural characterization of materials of powders, thin films, and single crystals using x-ray diffractometer (XRD) - Structural and analytical characterization of nanoscale materials by transmission electron microscopy (TEM) - Micro and Nanofabrication in STnano cleanrooms.
35	Research, development, advisory, consultancy, and training services relating to measurement and testing, and to the development, realization, validation, international consistency, maintenance, and dissemination of measurement and testing standards to deliver economic and social impact and support innovation. This includes the design, development, manufacture, maintenance, servicing, validation, and use of measurement equipment; environmental conditions such as specified clean rooms and techniques; software; data and knowledge transfer; and associated studies and investigations at NPL and remote sites. The provision of IT and administrative support services. The management of scientific and technical programmes and the manufacture of designated radiological equipment.
36	Animal reproduction biotechnologies service provision; Activities of production, scientific research, and education in the field of animal reproduction biotechnologies.
37	Research-based environmental-related services and products.
38	Research and Development in New Technologies for Medicine, with particular emphasis in the areas of Imaging, Optics, and Photobiology. Preclinical Studies of New Molecules with Potential Medical Use; Clinical Research Activities; Health Technology Assesment; Grading of Eye Exams; and Data Centre Activities.
39	University education (1st, 2nd, and 3rd cycle) and polytechnic education (1st cycle). Scientific investigation. Transfer of knowledge, technology and innovation
40	Research & Development
41	Research and development work, and expert and development services for the energy and coking industries in the areas of the processing of both using fuels; energy using biomass and waste; processing and using derivative carbonate products; energetic and environmental protection; science information and technology services; invention and standardization.
42	Scientific research, food testing, and testing of objects of general use, consulting, engineering, education.

Source: elaborated by the authors

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Table 3. List of links to scopes or certificates of identified ISO 9001 Certified R&D organizations

No.	Certified link or scope in English
1	http://www.narss.sci.eg/media/attachment/photo41pqzrm98f.pdf
2	http://www.icp.ucr.ac.cr/sites/default/files/20172/Certificado%20IQNet%202016_0.jpg
3	https://web.icpa.org.ar/wp-content/uploads/2019/04/CertificadosISO9001-14001_2018.pdf
4	https://www.unl.edu.ar/innovation/en/2020/02/04/cetri-litoral/
5	https://www.embrapa.br/documents/1355145/52592977/doc03010020200505094631.pdf/3553ec1f-d7af-24cf-c720-e5dd-14b076ac
6	https://www.ipen.br/portal_por/conteudo/institucional/arquivos/certificado_IQNET_CEN0001.jpg
7	https://www.ipen.br/portal_por/conteudo/institucional/arquivos/certificado_IQNET_CR0001.jpg
8	https://www.ipen.br/portal_por/conteudo/institucional/arquivos/certificado_IQNET_CRPq0001.jpg
9	https://twitter.com/official_cgcri/status/1085772580521299968
10	https://serc.res.in/quality-policy
11	https://www.rss.jo/wp-content/uploads/2018/12/RSS-Lloyds-Certificate-all.pdf
12	https://www.sel.co.jp/en/corporate/iso.html
13	https://www.ilt.fraunhofer.de/en/profile/management/quality-management.html
14	https://www.ipms.fraunhofer.de/content/dam/ipms/common/documents/ISO/ISO9001_2020_en.pdf
15	https://www.hhi.fraunhofer.de/fileadmin/Institut/About_us/Qualitaetsmanagement/Fraunhofer_HHI_Zertifikat_ISO_9001_ENG.pdf
16	https://www.ims.fraunhofer.de/en/Institute_/Quality-Management.html
17	https://www.isit.fraunhofer.de/content/dam/isit/de/documents19/Zertifikatengl.pdf
18	https://www.iwes.fraunhofer.de/content/dam/windenergie/de/documents/Zertifikate/ISO_9001_Fraunhofer_IWES_english.pdf
19	https://www.iwu.fraunhofer.de/en/about-Fraunhofer-IWU/quality-management.html
20	https://www.igd.fraunhofer.de/en/quality-management
21	https://www.iws.fraunhofer.de/content/dam/iws/en/documents/institute_profile/iso9001_2015_certificate_2019.pdf
22	https://www.ifam.fraunhofer.de/content/dam/ifam/de/documents/IFAM-Bremen/QM/Certificate_ISO9001-2015_Fraunhofer--IFAM_valid2018-2021.pdf
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30	https://www.uma.es/media/tinyimages/file/iqnet2017.pdf
31	https://www.vttresearch.com/sites/default/files/2020-01/ISO9001-2015_ENG.pdf
32	https://www.univ-gustave-eiffel.fr/fileadmin/Fichiers/Universite_Gustave_Eiffel/Documents/Certificat_ISO9001v2015_2014-64769-8_27janv2020.pdf
33	https://www.ifpenergiesnouvelles.fr/sites/ifpen.fr/files/inline-images/IFPEN/politique%20RSO/certificat_iso9001_if-pen_2019_VF.pdf
34	http://www.ipcms.unistra.fr/wp-content/uploads/2018/06/Certificat-iso-9001v2015_IPCMS.pdf
35	https://www.npl.co.uk/quality/iso-9001-cert.aspx
36	https://www.avantea.it/fileadmin/user_upload/ISO9001_2015_International.pdf
37	https://www.nilu.no/wp-content/uploads/2019/12/Sertifikat-NILU-9001.pdf
38	https://www.aibili.pt/ficheiros/AIBILI_ISO9001_Certificate.pdf
39	https://www.uac.pt/sites/default/files/certificado_2_apcer.pdf
40	https://www.aofoundation.org/what-we-do/research-innovation/about/quality-management
41	http://www.ichpw.pl/wp-content/uploads/2019/11/CERTYFIKAT-ICHPW-2019-kolor.pdf
42	http://inmes.rs/accreditation-and-certification/?lang=en

Source: elaborated by the authors

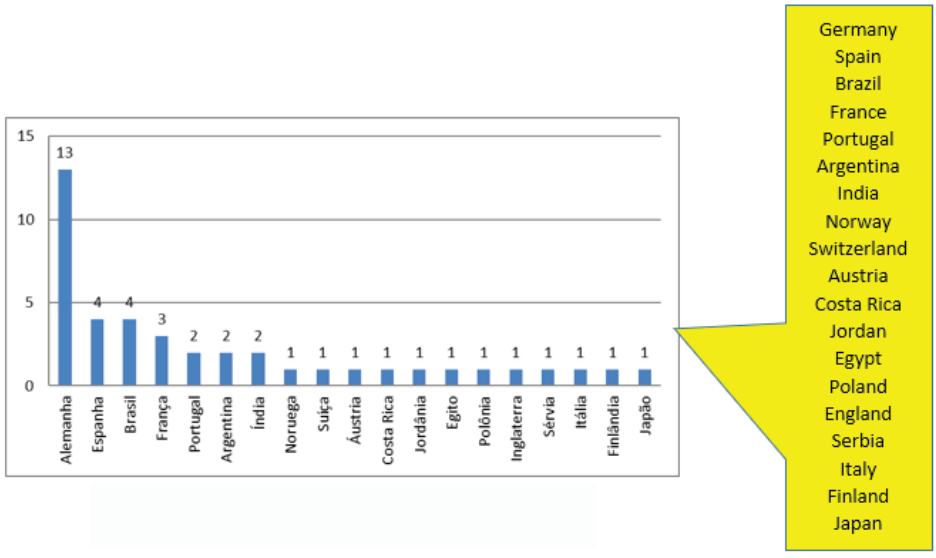

Figure 2. Distribution of cases by country of origin
Source: prepared by the authors from ISO Survey 2018 data

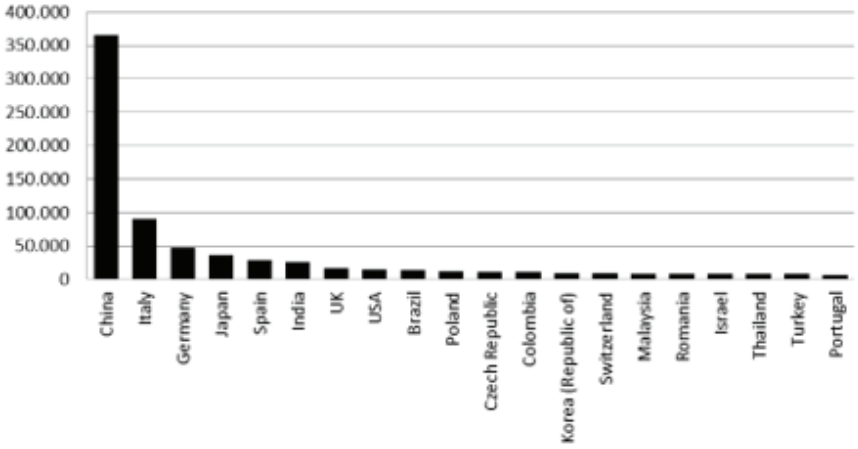

Figure 3. Top 20 countries with ISO 9001:2015 certification
Source: prepared by the authors from ISO Survey 2018 data

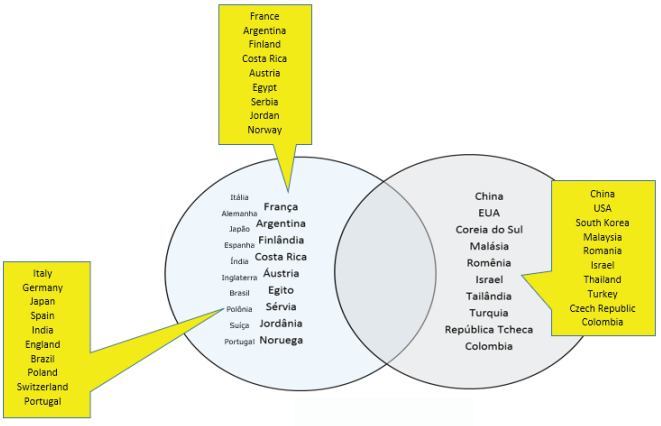

Figure 4. Venn's diagram
Source: elaborated by the authors

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standard applies to them. In other words, the aim is to identify where the standard adds value, helping R&D organizations fulfill their mission. However, before summarizing this analysis, here are some relevant observations.

Regarding the scope, it is worth noting that the word "research" is present in all elements, except in the stated scope of the AO Research Institute Davos and by the University of the Azores.

The AO Research Institute Davos (ARI), as available on its website, states that "the Institute is one of the few academic research organizations that has achieved certification", corroborating what was presented in the introduction and the literature review of this paper.

The University of the Azores uses the term "scientific investigation", which is the closest version of its native language: "*Investigação e Desenvolvimento (I&D)*" (research and development - R&D), according to the UAc (2019) and within a system that also includes the teaching and transfer of knowledge, technology, and innovation. On its website, the university lists processes, including one related to Science and Technology, in which it is possible to identify the term "research and development (R&D)".

Another point to highlight in the results presented in **Table 2** is that the scope of the quality management system of R&D organizations goes beyond R&D, including technical services, under-graduation, graduation, technology transfer, personnel training, and intellectual property, among other activities, processes, or areas. **Table 2** presents universities and, thus, undergraduate processes also appear in its scope, being a possible object of another study on universities.

The following is **Figure 5**, which seeks to summarize the findings regarding the scopes of quality management systems, which, like the scopes in **Table 2**, are presented in English.

Figure 5 shows unexpected scopes such as production, operation, and maintenance – more recurrent in manufacturing or assembly. **Figure 5** also includes scopes beyond R&D, such as those referring to the relationships between R&D organizations and companies, such as knowledge transfer, technology transfer, consulting, product certification, testing, and analysis. Other relevant scopes for R&D organizations go beyond those already listed, such as the dissemination of organizational capabilities, academic entrepreneurship, promotion and dissemination of research results, intellectual property, and scientific research. One can add education, training, and qualification as possible scopes, often associated with universities but also with other R&D organizations, as for example, the cases of the Royal Scientific Society, the CSIR - CGCRI Central Glass & Ceramic Research Institute (2020), the CSIR - SERC Structural Engineering Research Centre (2020), and the Instituto del Cemento Portland Argentino (2019).

Therefore, based on the cases studied, it is observed that there are several opportunities for R&D organizations to apply ISO 9001:2015 to support their mission. **Figure 5** shows – within the cases studied – how R&D organizations

Figure 5. Mind Map on the scopes of R&D organizations
Source: prepared by the authors

have structured their certification scopes based on ISO 9001:2015. In this sense, this allows for several additional works to investigate the topic and broaden knowledge of the applicable scopes.

CONCLUSION

The present work sought to explore the suitability and scope of Quality Management Systems for R&D organizations. A database was built on ISO 9001:2015 in R&D organizations. Other authors can use this database to explore and refine their knowledge on the subject.

Regarding the first research question on how certification to ISO 9001:2015 is widespread in R&D organizations, the case studies showed a similar diffusion to what happens generally for ISO 9001, as shown in ISO Survey 2018. The case studies also show the prominent role of Europe in the application of ISO 9001 worldwide. In this sense, there are several factors that can be explored to understand this diffusion, including the historical ones already mentioned. In addition to the geographical issue, diffusion was observed within diverse areas of expertise or knowledge.

Concerning the second research question, about how R&D organizations have structured their certification scopes based on ISO 9001:2015, the objective evidence showed that R&D organizations invest in ISO 9001:2015 certification and that this investment covers the processes pertaining to R&D but is not limited to it. In this work, it is possible to highlight some additional processes in the scopes such as: service provision, technology transfer, and intellectual property management, as well as less expected processes such as production, operation, and maintenance. Further research can identify new scopes and expand the knowledge about these applications.

Still, on the scopes, Yin (2006) states that "the researcher is a vicarious observer, and documentary evidence reflects a certain communication between parties who are trying to achieve other objectives". As a result, further research into the scope is required. Based on this exploratory study, it is important to further investigate the scope of quality management systems in R&D organizations.

Future work can make use of the database built to develop other single or multiple case studies on aspects of these quality management systems, allowing an expansion of the body of knowledge on the subject and its applications to R&D organizations. Another relevant point for future work would be to study the impacts of certification on these organizations, as well as to carry out comparative studies among R&D organizations with and without ISO 9001 certification. In this sense, many of the questions presented by Sampaio *et al.* (2009a) for work related to ISO 9001 certification could be applied to R&D organizations, significantly expanding the understanding of what ISO 9001 certification represents, the impact, and the motivations for achieving or maintaining it. Again, based on the work of Sampaio *et al.* (2009b), we can propose reflection on the relationship between investments in R&D and the existence of certified R&D organizations, or their results compared to others. These reflections will allow a better understanding of the magnitude of the phenomenon of ISO 9001 certification in the R&D organizations that this work sets out to explore.

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