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Abstract: *This paper describes the Quality Management System (QMS) at the Istituto Nazionale di Ricerca Metrologica (INRiM), Italy. The QMS encompasses calibration and measurement activities (ISO 17025) in accordance with the Mutual Recognition Arrangement (MRA), to ensure the acceptance of national standards and calibration certificates among signatory countries. The system also covers testing activities for the Association for the Certification of Electrical Equipment (ACAE) and the Low Voltage Agreement Group (LOVAG), production of certified reference materials (ISO 17034), interlaboratory comparisons (ILCs, ISO 17043), and the provision of documentation using both standardized and in-house methods. The INRiM QMS does not cover research activities. In 2024, INRiM maintained 448 Calibration and Measurement Capabilities (CMCs) and, between 2022 and 2024, issued 5336 certificates, 173 test reports, and 337 ILC reports. The paper shows that the INRiM organization, where a QMS coexists within a research environment, has a positive impact on all INRiM activities.*

Keywords: *mutual recognition arrangement, quality management system, calibration and testing, reference material, interlaboratory comparisons, metrology institute*

1. Introduction

The Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA) Comité international des…(1999) is an international framework allowing national metrology institutes (NMIs) to demonstrate the international equivalence of their measurement standards and the mutual recognition of their calibration certificates and measurement reports. The way the CIPM MRA works is that NMIs participate in key comparisons (KCs) and supplementary comparisons (SCs) of measurement standards to demonstrate the equivalence of their capabilities. Based on the results of these comparisons, NMIs publish their calibration and measurement capabilities (CMCs) in the key comparison database (KCDB), which is maintained by the International Bureau of Weights and Measures (BIPM). These published CMCs signify that the participating NMIs measurement standards and calibration certificates are mutually recognized as equivalent. A further requirement to support the quality of the data in the KCDB is that the NMIs must implement a Quality

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Management System (QMS) in accordance with ISO/IEC 17025(2017). NMIs signatories of the CIPM MRA declare their Calibration and Measurement Capabilities (CMCs) and submit them to their Regional Metrology Organization (RMO) for review. Starting with the implementation of a QMS in conformity also with ISO 9001 (2015) forthe fulfillment of the CIPM MRA requirements, several NMIs extended the scope of their QMS to cover additional activities in response to the needs of both internal and external customers, in accordance with other relevant standards. For example, QMSs of the following NMIs cover:

- Federal Institute of Metrology (METAS Switzerland): General Quality System (QS) according to ISO 9001, (2015), Calibration and Testing (C&T), Reference Materials (RMs) production, according to ISO 17034, (2016), Conformity Assessment for Inspection bodies according to ISO/IEC 17020 (2012), Risk Management according to ISO 31000 (2018), Information security system according to ISO/IEC 27001 (2022).
- Physikalisch-Technische Bundesanstalt ((PTB Germany): QS, C&T, RMs production.
- National Physical Laboratory (NPL Great Britain): QS, C&T, RMs production, information security system and Proficiency Testing (PT) or Interlaboratory comparisons (ILCs) provider according to ISO/IEC 17043 (2023) all accredited by UKAS.
- Laboratoire national de métrologie et d'essais (LNE France): QS, C&T, RMs production, conformity assessment for bodies providing audit and certification of management systems according to ISO/IEC 17021-1 (2015).
- VSL National Metrology Institute, Netherland: C&T, RMs production and PT provider, all accredited by RvA.
  Instituto Português da Qualidade (IPQ) Portugal: QS, C&T.
- National Institute of Standards and Technology (NIST USA): C&T, RMs, PT provider and standard Reference data.
- INRiM, Italy: C&T, RMs production and ILCs provider.

The conformity of INRiM's QMS with the relevant standards according to ISO/IEC 17025(2017), ISO 17034, (2016), ISO/IEC 17043 (2023) is self-declared. This means that INRiM has not undergone accreditation or certification by an external accreditation body (AB). Such an approach is permitted under the CIPM MRA, as INRiM is a NMI. Other NMIs participating in the MRA have made the same choice. This self-declarationis formally stated on the first page of the INRiM Quality Manual. However, the absence of a formal accreditation implies that INRiM is periodically subject to re-evaluation through peer reviews. These peer reviews are carried out by personnel and experts from other NMIs — that is, by peer-level staff, in accordance with the CIPM MRA rules. For RMs production and ILCs provider activities, the INRiM QMS includes additional requirements defined in specific internal procedures, which are applied in addition to the general requirements for compliance with ISO/IEC 17025 (2017). INRiM is also a qualified laboratory within the Association for Certification of Electrical Equipment (ACAE), a network of qualified testing laboratories. ACAE is a certification body active in the fields of electrical low-voltage and high-voltage equipment. An ACAE-qualified laboratory is authorized by ACAE to carry out tests consistent with its technical capabilities and equipment. ACAE qualification implies the compliance by the laboratory to the requirements of ISO/IEC 17025 (2017), and ACAE specific

requirements. The qualification process consists in the verification by ACAE assessors, documental and onsite, of the compliance to ISO/IEC 17025 (2017) if the laboratory is not accredited by an independent AB, and to the specific ACAE requirements. The maintenance of the qualification requires annual surveillance. An insightful analysis of national Quality Infrastructures (QIs), including NMIs, is given in Rab et al. (2021), where it is demonstrated that stronger Quality Infrastructures are generally associated with more robust economies. NMIs play a central role in National Quality Infrastructures (NQIs) through their connections with scientific and legal metrology, as well as with conformity assessment and accreditation bodies. These include organizations such as the Bureau International des Poids et Mesures (BIPM), the Comité International des Poids et Mesures (CIPM), the International Organization for Standardization (ISO), the World Trade Organization (WTO), the International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum (IAF). NMIs often participate in committees with such organizations sharing and transferring advances in technology allowing these organizations to update their rules and accreditation/certification criteria. Other significant examples of quality systems implemented by some NMIs operating in specific areas can be found in literature Asanovic et al. (2018), Kok (2023) and Mandal et al. (2021).

2. INRiM: A Research and Metrology Institute

INRiM is a national public scientific research organization supervised by the Ministry of University and Research. It serves as Italy's NMI, together with the Istituto Nazionale di Metrologia delle Radiazioni Ionizzanti of ENEA (INMRI), which is responsible for ionizing radiation quantities. INRiM was established in 2006 merging the Istituto Elettrotecnico Nazionale "Galileo Ferraris" (IEN) with the Istituto di Metrologia "Gustavo Colonnetti" (IMGC), which was previously part of the National Research Council (CNR). INRiM performs scientific research in metrology and develops advanced measurement standards and methods. As a signatory participant of the CIPM-MRA, INRiM maintains the national measurement standards to ensure the metrological traceability and legal validity of the measurements across industry, commerce, scientific research, healthcare, and environmental protection. The INRiM NMI Role encompasses metrology activities for both internal and external clients, including C&T, ILCs provider and RMs production. INRiM also promotes the knowledge transfer (KT) and advancements in measurement and materials science, aiming to enhance national technology, quality of life, and public services. The INRiM scientific structure is led by a Scientific Director, and it is organized into three Departments:

- Applied metrology and engineering (AE).
- Metrology of innovative materials and life sciences (ML).
- Quantum metrology and nanotechnology (QN).

Figure 1 shows the current INRiM organizational chart, highlighting that the QMS board and system operate at the highest level, reporting directly to the INRiM President.

Each department is structured into scientific sectors (SSs) encompassing research and metrology activities relevant to their respective fields. The AE Department is primarily focused on metrology activities, with its SSs covering Mass and related quantities, Length, Electrical and electronic measurements, and Thermodynamic quantities. The QN Department is specialized in the metrology of Time and Frequency, as well as Photometry. The ML Department is responsible for Acoustics, Ultrasound, and Magnetism. Recently, a structural change at INRiM mandated that all Departments

participate in the institute's three core tasks: Research, NMI and KT Roles. In the INRiM's previous organization, scientific Departments and SSs were primarily involved in research activity. Within this framework, research outcomes were not always directly aligned with metrological applications, nor were they readily accessible to the Department exclusively in charge of the NMI and KT roles. This change was proposed by the INRiM Scientific Council, subsequently explained and discussed with the personnel and agreed by most of the researchers. Finally, it was ratified by the INRiM Board of Directors. This change has significantly enhanced the internal KT, as researchers and technicians can now participate in all the three tasks, facilitating the application of research findings to metrology activities (C&T) especially for external customers.

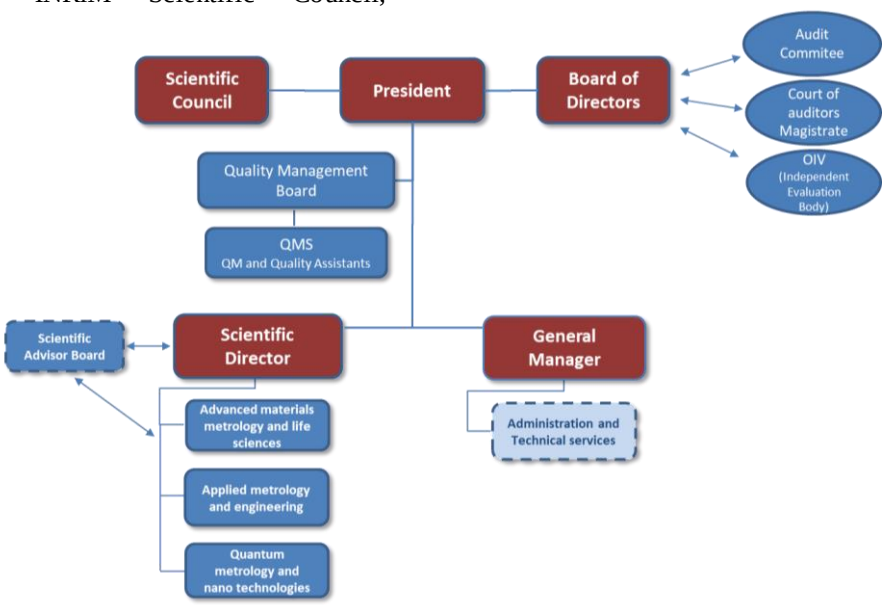

Figure 1. INRiM Organization chart.

Before the structural change the research results were primarily aimed at scientific publication and, to a lesser extent, at knowledge transfer, since the latter activity took time and resources away from research work, on which researchers were evaluated. Therefore, the Department in charge of the NMI and KT roles received fewer results to transfer to external users. Previously, researchers were focused on only the research task, with little or no cross-task involvement. Today, researchers and technicians contribute to all three tasks, enabling the seamless application of research outcomes to NMI and KT activities. An additional benefit of this new organization is the shared use of instrumentation across tasks, whereas in the past, equipment and personnel were strictly allocated to specific Departments and roles within INRiM. INRiM Departments provide also technical support to the Italian accreditation body for calibration laboratories, ACCREDIA-DT, providing expertise and technical assessors for the accreditation processes. The INRiM QMS was originally formed through the integration of the QMSs of IEN and IMGC, the two institutes that originally participated since 1999 to the CIPM MRA. In the early years, efforts were focused on harmonizing the two pre-existing QMSs to develop a unified INRiM QMS. However, this transition

contributed to delays in the full implementation of the system and in the automation of its processes, particularly when compared to other NMIs of similar standing. The INRiM QMS does not encompass research activities, as no formal standards for research currently exist. Nevertheless, in Biasini (2012) it is stated that some organizations published schemes and guidelines for quality in research, but these were not generally accepted. Moreover, quality systems are often perceived as limiting the autonomy of the researchers. In academic environments quality-related activities are typically not prioritized, with research and teaching taking precedence (Grochau et al., 2010). However, the application of QMS principles to research and development (R&D) remains a topic of ongoing debate, with potential benefits highlighted in the literature Grochau et al. (2010), Cammann & Kleiböhmer (1998). The INRiM QMS was generally accepted by researchers, as its implementation was required for participation in the CIPM MRA and because it does not directly govern research activities, but only those related to the NMI role (calibration & testing, reference materials, proficiency testing provider). The current INRiM organization, in which a QMS coexists with research activities and where scientific and technical personnel are involved in all three INRiM tasks, appears to be successful in terms of scientific productivity, dissemination of measurement units, and technology transfer, while preserving the scientific autonomy of researchers. This is demonstrated in Table 1 reporting the figures for INRiM's three core tasks from 2019 to 2024. The table shows that, starting from 2021, when the organizational change was implemented, the outcomes of research (no. of scientific publications, first column), of certificates and reports (NMI role, second column), and no. of patents (part of the KT role, third column) for the most part increased, presumably benefiting from the new organization.

Table 1. no. of the three INRiM tasks from 2019 to 2024.

Year	Publications in indexed journals	Documents for external customers	Patents
2019	167	1802	0
2020	176	1749	3
2021	175	2116	4
2022	194	1980	4
2023	205	2042	5
2024	208	1824	10

2.1. Documents for the INRiM QMS

The INRiM QMS documentation system consists of 24 general procedures and of 236 technical procedures that support the activities of 63 laboratories across various fields at INRiM. The QMS is primarily focused on the requirements outlined in ISO/IEC 17025 (2017) concerning the C&T activities, which represent the core service for both internal and external customers. Additional requirements concern the RMs production and ILCs provider activities. Therefore, specific additional requirements are detailed in dedicated management procedures. For example, the procedure "Additional requirements to perform activity of ILC provider according to ISO/IEC 17043:2023" defines a flow chart of the activities to perform ILCs and gives requirements for:

- Designing and planning an ILC.
- Determinate assigned values.
- Distribution, handling, storage labelling of the travelling standards.
- Instructions for participants.
- Data analysis.
- Evaluation of the performances.
- Reporting.

In ISO/IEC 17043 (2023) and in Galliana et al. (2020) rules to evaluate the ILCs results are given.

Instead, the procedure "Additional requirements to perform activity of RM and Certified RM (CRM) producer according to ISO 17034 (2016) gives requirements for:

- RMs production planning.
- RMs production control, moving, handling, storage.
- Measurement procedures, data integrity, traceability of the results, instrumentation.
- Evaluation of homogeneity and control of stability.
- RMs characterization.
- Assignment of property values and uncertainties.
- RMs documents and labels.
- Distribution.

2.2 The LATFC laboratory

Among the INRiM's laboratories, the Laboratorio Alte Tensioni e Forti Correnti (LATFC)-High Voltage and High Power Laboratory - stands out for its specialization and capabilities. LATFC's mission focuses on research and calibration of measurement systems, as well as on the testing of electrical equipment, including switchgear and controlgear assemblies, busbar systems, insulators, circuit breakers, fuses, contactors, instrument transformers, and similar devices. LATFC performs high-current tests such as short-circuit, withstand and prospective current tests, endurance tests, and temperature rise tests. It also performs high-voltage tests, including power-frequency tests (at 50 Hz) in both dry and wet conditions, as well as lightning and switching impulse tests. Under the ACAE qualification, LATFC is authorized to carry out the following verifications: short-circuit conditions, dielectric withstand verification, temperature rise, overload releases, under-voltage and shunt releases, auxiliary circuits, mechanical operation, operational performance capability, lifting tests, and degrees of protection. Through its ACAE qualification, INRiM plays a key role in electrical safety and regulatory compliance by actively participating in European and international networks, such as LOVAG, the Low Voltage Agreement Group. The collaboration between INRiM - the only NMI laboratory recognized by LOVAG and certification networks such as LOVAG represents an effective model of integration between scientific metrology and technical conformity assessment. This synergy contributes to a safer, more efficient, and more competitive European electrical market. It enhances the product quality, fosters trust in the EU market, reduces business costs through mutual recognition, and supports innovation by ensuring that emerging technologies are both measurable and certifiable. LATFC is subject to regular surveillance by ACAE in accordance with ISO/IEC 17025 (2017), as well as the applicable IEC and EN standards relevant to the qualified tests. ACAE imposes additional requirements for laboratories performing tests on its behalf. Specifically, laboratories must follow the guidelines of the procedure "Current Technical Decisions", available through the IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE), which provides authoritative interpretations of the applicable rules. Furthermore, the measurement uncertainty associated with the tests must comply with the IECEE CB OD-5014 document: Instrument Accuracy Limits for low-voltage tests and with the Short-Circuit Testing Liaison procedure: "Handling of Measurement Uncertainties in Testing and Test Documents for high-voltage". ACAE signed an agreement with INRiM, outlining the criteria for operating as an ACAE-accredited laboratory.

2.3 INRiM results reports for C&T, RMs and ILCS provider activities

The technical documents issued by INRiM in the framework of its QMS are related to the CMCs in the Appendix C of the CIPM MRA https://www.bipm.org/kcdb/and/or to other activities made by INRiM as NMI according to the Italian law 273/91 instituting the Italian calibration system (SNT). Specifically, the issued documents are:

- Calibration certificates: concerning the calibration of a measurement standard, instrument or system.
- Measurement certificates: concerning a measurement activity.
- Test reports: concerning test activities on products or devices according to procedures and specifications defined by technical standards and/or agreed with customers.
- ACAE Test reports concerning test activities issued in the framework of the ACAE qualification.
- Certificates of CRM: concerning Reference Material Certification activities.
- Information sheets of RM: concerning the produced Reference Material.

On the first page and inside of the calibration and measurement certificates covered by CMCs, the CIPM MRA logo[1] and the CIPM MRA note[2] are respectively reported. Calibration and measurement certificates not covered by CMCs but issued in the capacity of the NMI designated under Italian Law No. 273 include the annex "ILAC Annex P10". This annex provides customers with the information required to ensure traceability in compliance with the same document. These certificates are issued for internal instruments.

2.4 Surveillance of the C&T, RMs and ILCS provider activities by the INRiM QMS

The C&T, RMs, and ILCs provider activities are monitored by the INRiM QMS through various methods, in accordance with the established QMS procedures as:

- Application of quality assurance to results, requiring laboratories performing these activities to monitor the validity of their results at planned intervals and to ensure that the monitoring results are accurately recorded.
- Participation in national and international comparisons.

The technical foundation of the CIPM MRA is based on the results of scientific key comparisons conducted by the Consultative Committees of the CIPM, the BIPM, and the RMOs. These results are published by the BIPM after approval and are maintained in the BIPM Key Comparison Database (KCDB). The comparisons identify the participants and their individual results, and they serve as technical evidence to support the processes of the CIPM MRA. INRiM has participated in 229 key comparisons (29 as pilot laboratory) and 86 supplementary comparisons (7 as pilot). The purpose of key comparisons is to validate the main techniques and methods in a given measurement field and to extend their applicability at the regional level (RMO key comparisons). Supplementary comparisons are conducted to meet specific needs not addressed by key comparisons. INRiM also participates in pilot studies, which aim to establish measurement parameters for emerging fields or new instruments, or are conducted as training exercises.

- Internal audits, conducted to verify that the elements and activities of the QMS comply with established requirements, documented procedures, and relevant standards.

[1] CIPM MRA

[2] This certificate is consistent with the capabilities (CMCs) that are included in Appendix C of the CIPM MRA drawn up by the CIPM. Under the CIPM MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in the KCDB. For details see https://www.bipm.org/kcdb/.

These audits also address the resolution of nonconformities and complaints, the implementation of corrective actions, and the improvement measures. INRiM carries out approximately 50 internal audits each year across all laboratories covered by the QMS. These audits include the assessments of technical procedures, their implementation, and the overall adequacy and effectiveness of the laboratories.

- Assessments under international agreements as the European Association of National Metrology Institutes (EURAMET), Technical Committee (TC) Quality.

The CIPM MRA requires that RMOs review and monitor the QMSs of their participating NMIs. The responsibility for conducting these reviews lies within each RMO, under the authority of its respective technical committees or working groups. EURAMET TC-Quality has established a structured process for the continuous monitoring of the QMSs of its member NMIs. Once a QMS is approved by EURAMET TC-Quality, all signatory NMIs and Designated Institutes (DIs) under the CIPM MRA are required to submit an annual report to the TC-Quality on the current status of their QMSs. The review of these annual reports ensures that institutes are maintaining their QMS, regularly reviewing their services, and addressing any issues that could impact on their CMCs (such as the departure of key staff, loss of facilities or equipment, poor performance in comparisons, etc.) Additionally, a periodic review of the QMS, equivalent to the initial assessment, must be conducted at intervals not exceeding five years. To this end, INRiM, besides the QMS annual reports, presents a comprehensive five-year QMS activity report every five years to EURAMET TC-Q. This planned monitoring ensures that the QMS continues to cover the declared CMCs and that peer reviews remain valid.

- Peer visits performed by experts of other NMIs to INRiM facilities, activities and laboratories.

To this purpose, INRiM is involved in the EURAMET Project 1123, "On-site Peer Review CEM, INRiM and IPQ". This joint audit project aims to support the development and improvement processes of NMIs, providing a tool for better international recognition and strengthening confidence in the fulfilment of the CIPM MRA requirements. The involvement of metrological experts fluent in Latin-root languages for evaluating the quality documentation facilitates communication during the audit and reduces translation costs. The peer review program is scheduled to be carried out on annual basis. Started in 2009, the project involves a program of joint or cross-audits conducted each year. In general, each technical subfield is assessed every five years, while the overall QMS is reviewed every two years.

- Surveillance visits by the ACAE to the LATFC.

Surveillance is conducted at least annually to determine whether the LATFC laboratory still meets the requirements of ISO/IEC 17025 (2017) and of ACAE specific requirements Since INRiM is a non-accredited institution, the annual monitoring is carried out through inspections, planned in such a way that, within a three-year period, all the requirements of ISO/IEC 17025 (2017) are checked at least once.

- Analysis of risks and opportunities according to the relevant procedure “Risks and opportunities”. This analysis is reviewed every year during the management review.
- Continuous improvement of the QMS applying the relevant managing procedure “Improvement”, in which Key Performance Indicators (KPIs) are established and annually evaluate. They mainly concern: Performance adequacy, system compliance, product compliance and customer’s satisfaction.

For example, one of these KPIs is defined as the ratio between the no. of work orders completed during the year (purchase orders no. /year) and the no. of quotes issued during the year (quotes no./year).

- Management review outputs, which report on the effectiveness of the QMS and its processes, the improvement of the activities of the laboratories, the adequacy of resource provision, and any identified need for changes.

2.5 INRiM numbers in the years 2022-2024 for C&T, RMs and ILCS provider activities

The metrological areas covered by the MRA include: EM (Electricity and Magnetism), T (Temperature) TF (Time and Frequency), L (Length), M (Mass and related quantities), AUV (Acoustics, Ultrasound and Vibration), QM (Amount of Substance), PR (Photometry and Radiometry). As of the end of 2024, INRiM maintains 448 CMCs published in the KCDB, distributed across these metrological areas, as shown in Figure 2. In the following selected data on activities conducted under the INRiM QMS between 2022 and 2024, divided by metrological area, are provided.

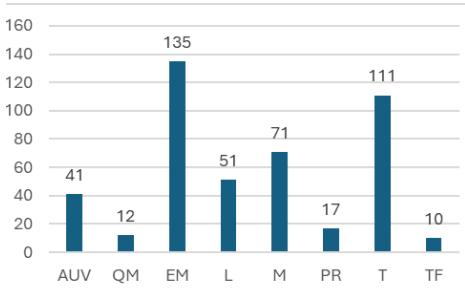

Figure 2. No. of the INRiM CMCs published at the end of 2024 on the KCDB

Figure 3 shows the percentage distributionof the INRiM's issued C&M certificates by metrological area over the three-year period 2022–2024, when 5336 certificates were issued.

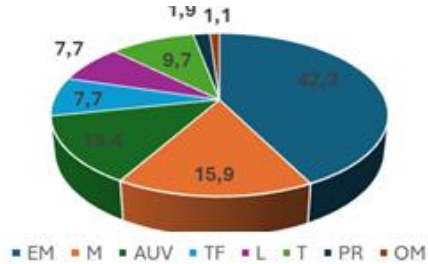

Figure 3. Percentage distribution of C&M certificates issued by INRiM per metrological area in the period 2022-2024.

Figure 4 shows the average number of ILCs provided by INRiM per metrological area in the period 2022–2024. During this period, INRiM provided 113 ILCs with an average of 54 participants per year and issued a total of 337 ILC reports.

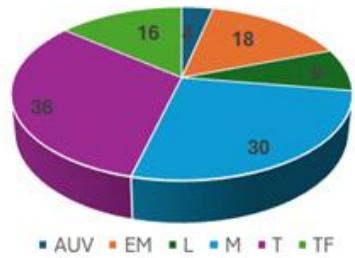

Figure 4 No. of ILCs provided by INRiM in the period 2022-2024 per metrological area

From Figures 4 and 5, it can be observed that the majority of the certificates were issuedby the EM area, while the majority of the ILCs were provided by the M and T areas. During the three-year period, INRiM issued 173 technical reports, most of which were provided by the EM area. In 2024 INRiM issued the first certificate for a RM Finally, Figure 5 shows the no. of documents issued by INRiM according to their typology in the same three-year period.

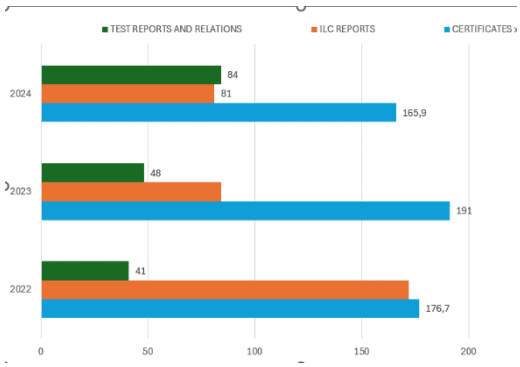

Figure 5. No. of documents issued by INRiM in the years 2022-2024 according to their typology

3. Discussion

This paper presented an example of an integrated QMS developed within a research institute to manage a variety of activities, excluding research,serving both internal and external stakeholders. The INRiM experience suggests that QMS and research activities can successfully coexist within a research environment, preserving scientific autonomy of the researchers whit potential mutual benefits. The collaboration between INRiM and LOVAG is an effective example of integration between scientific metrology and the conformity framework to improve the reliability of the electrical market. Furthermore, the peer review process under the CIPM MRA assessessing the conformity of the INRiM's QMS and of the laboratories represents a collaborative framework that facilitates the exchange of best practices, promotes mutual trust and reinforces international partnerships. This peer review process offers greater flexibility than aformal accreditation, being well-suited to meet the evolving needs of emerging and technologically advanced sectors, an essential characteristics for any research institution. On the basis of this integrated QMS, INRiM is strategically positioned to address the challenges of an increasingly interconnected context and to fully harness the opportunities arising from digital transformation Moreover, since July 2025, as a direct outcome of the QMS implementation, INRiM issue documents as certificates and reports in electronic forma

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