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Digital transformation: Ensuring metrological traceability

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ABSTRACT

The digital transformation project for the calibration and testing laboratories of INTA is presented. It is intended to serve as the institute's single platform for integrating knowledge, capabilities and innovative metrology techniques, quality and testing systems, to produce highly efficient and reliable results while ensuring metrological traceability of R + D + i results. It provides the necessary data for decision support and aims to address many current issues faced by laboratories and testing centres. The project is developed across the following action areas: (a) Automation of quality assurance for measurements according to ISO/IEC 17043 standard; (b) Automation of data capture and analysis of calibration procedures for the Metrology and Calibration Centre (CMC) and various tests; (c) Digital services for remote auditing of measurement and testing services in accordance with ISO/IEC 17025 and ISO/IEC 17043 standards; (d) Evolution towards the flexibility and expansion of parameterization of the different modules to facilitate implementation in any type of INTA and Ministry of Defence (MoD) laboratories.

1. Introduction

The Metrology and Calibration Centre (CMC) at the National Institute of Aerospace Technology (INTA) took on the challenge of meeting the metrology and calibration needs of the institution, in a cross-cutting manner, providing metrology and measurement engineering services to the new model of configuration of INTA [1] after the integration in INTA of several MoD technological centres.

The CMC is located on the Torrejón de Ardoz campus, in the community of Madrid, and has a purpose-built building spanning over 4500 m^2, designed to minimize vibrations and other radio-electric disturbances, equipped with an advanced air conditioning system that ensures rigorous temperature and humidity control (24 hours a day, 365 days a year). Additionally, there is another building with similar features covering an area of 3740 m^2, situated on the La Marañosa campus, also in Madrid, housing dimensional, force and torque, and human factors laboratories.

Since the first accreditation by the British Calibration Service (BCS) in April 1972, which covered activities in the permanent laboratory for direct current and low-frequency electricity at the then electrical standards laboratory in Torrejón de Ardoz, to the current accreditation scope published by the Spanish accreditation body (ENAC), the CMC [2] in eleven metrological areas, three locations, and on-site calibration, the laboratory management needs have changed significantly. In addition to the previous activities, according to the ISO/IEC 17025 standard [3], in May 2010, the CMC also obtained ENAC accreditation as a calibration proficiency testing provider [4], in accordance with the ISO/IEC 17043 standard [5].

For all these activities, the CMC has an organic staff of 63 people, comprising 30 % senior professionals (including 7 PhD's), 14 % middle-level professionals, and 56 % laboratory technicians.

In the early days, traceability of records was obtained through a card for each item of equipment (both owned and client-owned) with a unique identifying number. These cards contained equipment and client data, as well as reference to the calibration procedure and calibration interval. The calibration history, including the date, calibration number, initials of the technician performing the calibration (or repair), and the approval of the qualified person, was added to this card. Certificates and reports were typed with a typewriter with carbon paper, and a copy was kept as a record of the document issued. Calibration sheets included the equipment card number and the standard used, with results, environmental conditions, entry and exit dates from the laboratory, measurement date, applied corrections, and signatures of the technician and supervisor. All stability correction graphs of the standards were kept on large graph sheets stored in plan drawers, identified with the standard card number.

Only the signed and approved original procedures were kept, and responsible individuals made annotations on them, which were dated and signed for consideration in subsequent reviews. Equipment entries and exits were recorded in huge entry and exit books, which included all equipment and accessory data and corresponding dates.

Regular participation in intercomparisons, usually bilateral ones organized by the BCS, was carried out. Through a concept called "Audit Via Traceability," standards which show predictable drift (such as voltage standards, standard resistances, etc.) had their value estimated on the expected calibration date based on available history and provided to the BCS before the standard was transferred to the external laboratory.

This simple system ensured, manually, access to all relevant calibration information without the existence of a formally documented quality system. The first quality manual was implemented following the introduction of ISO Guide 25 [6] and UNE 66-501-91 [7] in the early 90s.

As quality system requirements increased and began to require much

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more time for tasks other than purely technical ones, several tools were developed at INTA using internal resources. The first, called SISECA, was used for all document management and audit records. The second, called LaMeca, was used for equipment management, including their reception and handling. From there, a custom tool development was contracted to replace SISECA, and another commercial tool was utilized to replace LaMeca, both employing technologies no longer supported by the Institute's ICT environment.

Until this point, the initial systematic was still being emulated, only adapted to changing regulatory requirements and with a general quality system focused on paper and manual data processing, with countless spreadsheets, each increasingly complex.

The management of CMC, aware of the new approach that the new version of ISO 17025 [3] would bring, focussing on the use of information technologies to ensure compliance with standard requirements, embarked on the first step of the CMC's digital transformation, which would be the seed of the project described in this article.

In November 2016, work began on a proposal from a Spanish software development company, within the framework of the Centre for Industrial Technological Development (CDTI), co-financed by the European Regional Development Fund (ERDF), with a duration of 24 months, which concluded at the end of 2018 [8].

2. Project development

2.1. First steps

The starting point was the existing version of the WHITESTONE Calibry software [9], designed for managing equipment in calibration and testing laboratories. It was primarily intended for small and medium-sized enterprises offering calibration services to numerous industrial clients within a classic accredited laboratory environment. The software handles the reception of calibration and testing items, management of calibration processes, and storage of manually generated calibration certificates. In addition, it includes a basic portal for securely delivering calibration certificates to clients. This version served as the platform upon which the new processes to be developed in the new product were integrated for functionality.

2.2. Targets

The tool to be developed aimed to go beyond mere equipment management as another asset of a traditional laboratory, introducing as main technical differential elements the ones outlined as follows:

1. Automatic analysis of calibration data based on the requirements established in the UNE-EN ISO/IEC 17025:2005 Standard (which was in the final phase of the new revision published in 2017) for the following families:
   - Characterization of isothermal environments.
   - Calibration of dataloggers and temperature, humidity, and pressure recorders.
   - Calibration of dimensional metrology instruments.
2. Advanced application of correction factors with models allowing intelligent association between instrument families and their transfer functions.
3. Automatic identification of interpolation functions of reference standards and measuring instruments, based on the physical principles of their sensors.
4. Determination of the robustness of the statistical analysis used in the determination of reference values.
5. Estimation of measurement uncertainty based on the use of standards and instruments.
6. Drift analysis and prediction functions in cases of significant drift with reduced uncertainty.
7. Determination of reliable acceptance and rejection criteria based on calibration history.
8. Automatic data analysis for determining measurement series with dependent parameters to obtain values with minimal uncertainty.
9. Impact analysis of uncertainty propagation in cases of non-compliance with acceptance criteria and automatic data auditing.

In addition to the necessary work for the development of algorithms and implementation of the indicated processes, the new version would introduce significant usability aspects through the development of tools aimed at facilitating the use of the introduced improvements. Among these are those indicated in Table 1:

As a result of this project, software for automating analysis, result evaluation, and calculation of uncertainty of measurement was generated, improving its efficiency and ensuring results while guaranteeing metrological traceability.

The project emphasized the need for the study of measurements under standard conditions and methods, providing traceability to the International System of Units (SI) and the validity of calculations based on acceptance and rejection criteria established in measurement procedures.

2.3. Implementation

In this project, the role of INTA was also served as a pilot laboratory for data and procedure validation, leveraging both the technical and human resources necessary for the calibration and characterization of measuring instruments and isothermal media. Mandatory tests were conducted to assess the consistency of the results obtained, using real data and comparing the current methodology with the automated data evaluation and analysis implemented with this new software tool.

During the development of the project described in the previous section, the CMC had access to the tool in its different versions for conducting necessary tests, installed on the INTA servers. Once the project concluded and the intellectual property generated as a result of the project was evaluated, INTA obtained a perpetual, non-exclusive, non-transferable, and free license for the complete Whitestone Calibry software and its future modifications for the Institute's own metrology and calibration activities.

Having ensured the availability of this corporate tool in a sustainable way for the Institute, the CMC was ready for its implementation, having the most advanced tool on the market for managing all processes of ISO/IEC 17025:2017 applicable to calibration and testing activities. With this software tool, the entire calibration plan of the institution for measuring and testing instrumentation can be managed to ensure traceability to the SI of measurements made by INTA laboratories.

Once this milestone was achieved, the digital transformation of the CMC could be undertaken. The existing management processes are the result of evolution over several decades with incremental solutions to changes in regulatory or accreditation requirements and institutional development.

The nature of the service to be provided was analysed, and aspects of

Table 1
Most notable improvements introduced.

	New improvements implemented
1	Graphic tool for the development of measurement procedures and data analysis allowing users to generate automatic flows of complex automation processes.
2	Dynamic generation of test reports and calibration certificates allowing the necessary flexibility to adapt to regulatory or accreditation body requirements and specific customer requirements, especially to the various national variants of aeronautical regulations.
3	Intelligent graphical visualization of large-scale measurement data allowing easy visualization, spatial and temporal interpretation of data, as well as identification of anomalies and associated events.
4	User interface optimization on different display devices

the processes that were considered weaknesses or threats to the achievement of the CMC's goals and the associated risks were identified [10], to proceed with the optimization of CMC management processes.

The optimization was analysed from the following three perspectives: changes in the organization, the implementation of the new software solution, and the design and execution of new initiatives. These actions aim to take the first steps in mitigating the main risks identified in a realistic and manageable way to effectively operate as a single laboratory facing the client, with consistent procedures and maximum efficiency in processes.

It is worth noting that the implementation of this process is very complex due to resistance to change, which is common in an organization the size of INTA and especially in the public sector.

2.3.1. Changes within the organization

The changes implemented in the new organization are based on four main lines of action:

1. Establishment of a Technical Office (TO), responsible for all aspects of technical and administrative coordination, both internally and externally. It serves as the single point of contact with clients (internal from INTA and external).
2. Implementation of the concept of functional dependence within the CMC. For this purpose, the technical unit was created as an organizational element, understood as a "functional grouping formed by one or more services, laboratories, or units, which share a well-defined set of technical and human resources and are dedicated to the specific purposes of accreditation." Functionally, the CMC is organized into technical units to carry out activities covered by ENAC accreditation of the Centre. Some of the accredited activities also involve other departments of INTA, which are functionally dependent on the CMC.
3. Shared technical responsibility. Responsibility within the technical units is shared among all the heads of the departments that constitute the Technical Unit.
4. Single accreditation. In terms of administrative file management, the director of the Centre serves as the only interlocutor with ENAC, responsible for coordinating a single contracting file for the Institute's accreditation expenses. This once validated was subsequently transferred to the INTA Quality department, dependent of the same subdirectorate as the CMC. The CMC has assumed all the calibration functions of the Institute, joining various accreditation scopes into a single one. Thanks to the functional dependency created and the implementation of a single quality management system, run in a common tool, ENAC has accepted this initiative and has proceeded to grant the first consolidated accreditation scope with three locations plus one on-site, incorporating the described functional dependencies and encompassing four subdirectorates of INTA.

2.3.2. Implementation of the new software solution

The software platform comprises three main sections: the management environment, the user portal, and the management console. The first is used for comprehensive laboratory management, the second for client interaction, and the third for data exploitation through custom queries and analysis).

To implement the user portal, accessible from outside the INTA's Intranet, the IT department had to develop a secure access system meeting all the requirements of the Ministry of Defence.

The successful implementation of the solution at the CMC requires its integration with other corporate software, such as the management system implemented in SAP, the secure digital signature server, and the document repository based on SharePoint.

The first step was to unify all the document control in the management system. Document management allows documents to be incorporated into the platform and managed under approval policies, revision and version control, with established access permissions and relationships with other documents, regulations, and sections. From consulting documents, regulations and up to templates used in printing offers and calibration labels, Calibry manages each document under a quality document management system.

Through event logging, the platform provides a quality management system tailored to compliance with reference standards, ensuring service quality. These events function as individual entities but are related to one another, allowing for the creation of complex records while maintaining control and a simplified global view. In Calibry, events are divided into the following types: Audits, Deviations, Actions, Follow-ups, Complaints, Risks, Intercomparisons, and Validation of Results.

Except for Follow-ups (necessarily linked to Actions), each of these types can exist as isolated entities without any relationship to other events. The creation of links between events follows the relationship between types and event states outlined below:

- An Audits, when in the "open" state, enable the creation of Deviations.
- Deviations, when in the "open" state, allow the creation of Actions.
- Actions, when in the "Under Review" state, allow the creation of Follow-ups.

These associations among linked entities are depicted in the navigation tree present in the details tab of each event. Audits can contain links to other event types, thus always occupying the highest level of the hierarchical tree.

On the left is the navigation tree, on the right is the general information, and below are the linked deviations. Deviations can contain links to other event types, but their origin is not necessarily linked to another event. Actions can contain links to other event types, and their origin is not necessarily linked to the same, for example, a deviation generated from a non-conforming result (see Fig. 1).

When an Action is in the "Implemented" state, the platform allows for the automatic creation of Action Follow-ups, defining their periodicity and number. Follow-ups are always linked to an Action as their function is to verify its effectiveness.

The management of complaints follows a similar course of action to many other events, including the management of intercomparisons and ensuring the validity of results.

The platform integrates action on the basic pillars which allow to ensure metrological traceability, such as calibration procedures, personnel training and qualification, calibration plan, between-calibration control, and uncertainty budget. All of that is indispensable to demonstrate technical competence of laboratories [3].

Equipment management involves equipment registration in the platform and subsequent tracking of all actions performed on it, as well as its links and relationships with any other elements in the platform, regardless of whether they are under the laboratory's custody or not. From linking to offers to other items, to the automation of tasks such as calibration control and maintenance, the item is placed at the heart of management which includes a detailed historical and registration.

The platform automates the work order management process by incorporating its automatic generation triggered by dynamics and events such as accepting an offer or performing maintenance. Work orders are divided into different types that share general characteristics but possess unique features specific to their type. The types of work orders include Calibrations, Tests, Between-Calibration Controls, Maintenance, Repairs, and Metrological Requirements.

Work orders are created both via automation processes within the platform (e.g., when confirming that an offer has been accepted or when preparing batch calibration) and manually, and are centralized in the "List" option of the menu. Work orders allow for the registration of different types of actions: Note, Incident, and Supervised. Some of the actions have a direct effect on the work order's status.

Inputs are defined as the reception of items, indicating when they

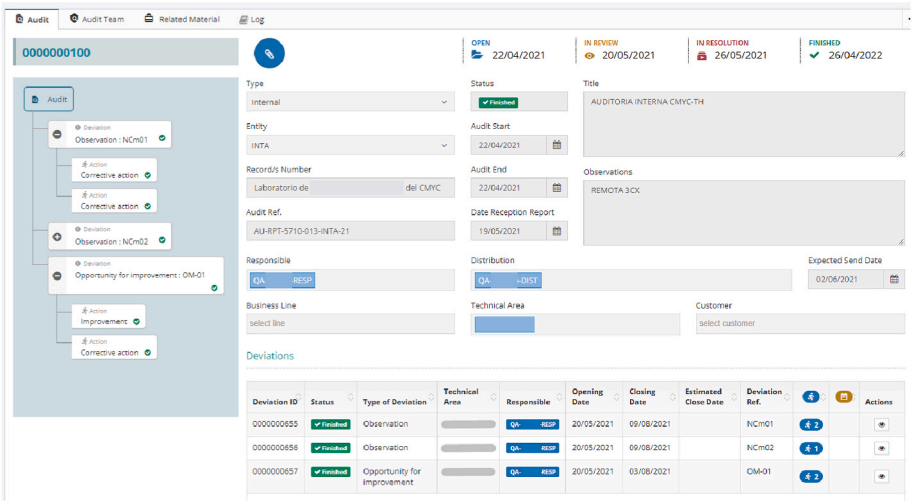


Fig. 1. Example of the comprehensive distribution of all information related to an audit event.

come into the laboratory's custody and linking them with pending offered services. Maintaining not only control over the items but also over the offers and their respective services.

Outputs handle the physical return of items to the client upon completion of work. This process directly connects with the items' inputs, allowing for precise control over their status and location, as well as any related offers and services for subsequent billing.

2.3.3. New initiatives

An interesting improvement integrated in this software, involved optimizing the registration of environmental conditions. Several solutions were studied, and finally the one offering the greatest flexibility of configuration and ease of calibration compatible with the laboratory's measurement systems was chosen. It was decided to acquire relative humidity and temperature sensors with digital sensors and wireless communication with a Gateway integrated into a subnet, which must satisfy all CMC needs. This model could be expanded to the rest of the INTA laboratories, thus providing a comprehensive service for monitoring laboratory environmental conditions incorporated into a quality management system for incidents and deviations. These Gateways also allowed communication with Modbus and other protocols, enabling the integration of other meters, such as those used in cleanroom quality control (differential pressure meters, particle counters, etc.) [11].

The metrological confirmation of the sensors would be carried out through the simultaneous automated calibration of a group of sensors using the humidity generators, dew point hygrometers, and temperature sensors belonging to the temperature and humidity laboratory of the CMC, as indicated in its calibration procedure. The result of the calibration is a file with the standard data and a file for each sensor under calibration. This calibration would be performed automatically. Subsequently, automatic analysis of the calibration data would be conducted with the automatic issuance of calibration certificates and updating of calibration factors in Calibry. The platform enables not only individual execution but also batch processing of items simultaneously [12].

As explained in the previous sections, one of the most demanded calibrations in the Institute, and one that is difficult to handle with available personnel, is the characterization of temperature-controlled environments 'in situ,' especially climatic chambers.

A formula was created that, leveraging the concept of functional dependence and the existence of the software solution, would change the business model in on-site calibrations. The change involves incorporating, with functional dependence, technicians from the department requesting the service (internal client) into our implementation of the quality system in the software tool, qualifying them to perform calibrations using our procedures and equipment, controlling the entire analysis and certificate issuance process from the central laboratory in Torrejón [13].

3. Future works

The significant achievements made in the digital transformation of CMC have been accomplished with limited internal resources and amidst a pandemic. To complete the work undertaken and make the final leap forward to a common corporate tool for the entire Institute, it is necessary to undertake a new project. This project utilizes the functionalities provided by the software solution but expands it to cover new functionalities, some of which are highly specific to the armament testing sectors. Additionally, it will provide a flexible infrastructure based on microservices, allowing the INTA Information and Communication Technology (ICT) department to develop and integrate interfaces suitable for the activities of the various departments of the Institute, integrated with other corporate tools.

The INTA's digitalization and integrated management plan is a strategic plan aimed at the digital transformation and modernization of the Organization, directing its activity towards a 360-degree vision of services. This plan aims to transform applications, infrastructures, and contents of the Organization's activities. However, it is not only a technological plan, as it also involves a change of perspective that proposes transforming the skills, training, and working methods of INTA's scientists and researchers.

This digitalization and integrated management plan responds to the INTA's strategic objective of integrated management and social responsibility to support participation in scientific and technical development programs. It must be supported by an organization that optimizes management and governance processes.

Within INTA, a series of actions are planned or already underway, with the primary goal of conducting a comprehensive review of functional and operational tasks, activities, and processes and integrating ICT Services into these activities and processes. Its objective is to close the gap between operational capabilities and ICT services, leveraging the possibilities offered by the latter to improve the quality and ease of use of these processes, and ultimately the efficiency of INTA. In this way, these means and services can contribute as efficiently as possible to the development of INTA's missions and tasks and the achievement of its high-level strategic objectives set out in INTA's Strategic Plan.

The plan aims to establish a renewed organization based on process management and knowledge-centred (data/electronic document) management, rationalizing its systems for better use of ICT. This plan takes a top-down approach, starting from the Strategic Objectives of the INTA Strategic Plan 2021–2025, to address the different associated strategies,

based on clearly defined lines of action.

Therefore, within Line LA1 – Transforming unit management processes into electronic ones, this project is born to create a DIGITAL TRANSFORMATION PLATFORM FOR TEST AND CALIBRATION LABORATORIES, INTAQALAB.

INTAQALAB aims to address many of the current challenges faced by laboratories and testing centres. On one hand, there are numerous technological challenges, summarized as follows:

- Technological obsolescence of support software applications for different tests and laboratories, making them vulnerable to various types of cyberattacks. There is currently a very high risk of data leakage from tests and laboratories; data espionage of sensitive data from State institutions; cyberattacks using ransomware, which could affect the availability of these support applications and the integrity and confidentiality of the data they handle.
- A high number of independent software applications implemented with different logical architectures and technologies (programming languages, communication protocols, etc.), making their management, maintenance, and support difficult and expensive (a "mushroom" model).
- Data dispersed and not shared among applications, services, or procedures, leading to duplications and inconsistencies in data, and greater difficulty in their governance and management.
- Knowledge about procedures and processes is very compartmentalized, and there is a lack of a global knowledge base of the institution's processes.
- Complicated management and governance of Classified Information.

On the other hand, some tests do not even have management applications, with procedures being performed manually and mainly using paper documentation.

Therefore, it is considered necessary to expand the current calibration and test management system software to a unified technological platform for test and laboratory management, ensuring the security of the managed data and with a clear focus on standardizing the way tests are managed.

Furthermore, it will be necessary to implement other support systems within the scope of INTAQALAB to ensure the full objectives of the plan:

- The systems necessary to ensure proper governance and management of the unified technological platform.
- The implementation of a DEVOPS ecosystem, along with a microservices-based architecture, allowing the organization to continue the process of implementing INTAQALAB in all its testing and laboratory centres, being able to analyse, design, and implement their different needs in an agile and simple manner without being tied to a single development framework, as well as the creation and agile development of microservices allowing customization and communication with different systems and data acquisition equipment.

This new platform aims to address many of the current challenges faced by INTA's laboratories and testing centres. The following key areas of action are being developed:

- Automation of quality assurance for measurements according to UNE-EN ISO/IEC 17043 standard, providing digital quality assurance services for R&D laboratories and public administration and industry testing laboratories.
- Automation of the capture and analysis of calibration procedures at the CMC.
- Automation of the capture and analysis of product homologation tests specifically used in the Defence field according to ENAC RDE-12 [14].
- Automation of analysis of fuel and lubricant tests according to UNE-EN ISO/IEC 17025 standard.
- Automation of vehicle and component testing analysis, according to UNE-EN ISO/IEC 17025 standard.
- Automation of electromagnetic compatibility (EMC) tests and evaluation of human exposure to electromagnetic fields, according to UNE-EN ISO/IEC 17025 standard.
- Automation of power estimation tests in hydrodynamic test facility.
- Remote auditing of measurement and testing services according to the INTA's Quality Management System.
- Evolutions for improvements in the flexibility and expansion of the parameterization of all modules facilitating implementation in any type of INTA and Ministry of Defence laboratory.

It will enable the use of unique, reliable, and updated sources of data and information, especially of all the Institute's measurement and testing equipment used in its laboratories at different locations, improving access to information by standardizing processes in management systems and delocalizing workstations. It seeks to increase efficiency in the Institute's environmental management by eliminating paper formats and reducing unnecessary steps and procedures that consume resources and capabilities.

This platform aims to integrate innovative metrology and quality system knowledge, capabilities, and techniques to produce a highly efficient and reliable result, ensuring the traceability of results and providing the necessary data for decision support.

The implementation plan is divided into major blocks, each with a main milestone deliverable. Each of these blocks is divided into different phases with partial milestones. Each of the three main milestones will provide the final operational capability for the corresponding package.

It serves as a fundamental tool for the development of the Action Plan for the Digital Transformation of the MDEF [15,16]. It contributes to achieving the Strategic Objectives of this Plan, especially regarding the increase in productivity and efficiency in the internal operation of the Administration, the improvement of efficiency in the provision of ICT services, and the intelligent corporate management of knowledge, information, and data. These objectives are aligned with the ICT Strategy of the State General Administration (AGE) in this area [17] and with its continuation in the Plan for the Digitalization of Public Administrations 2021–2025 [18].

4. Conclusions

The evolution of the digital transformation of the Metrology and Calibration Center (CMC) of the National Institute of Aerospace Technology (INTA) has been presented, beginning with a software development project with a national company within the framework of CDTI, co-financed with ERDF funds, and following with its implementation in the CMC. The new approach of the CMC has been introduced following the optimization of its organization and the actions taken to realistically and feasibly mitigate the main identified risks to effectively operate as a single laboratory facing the client, through the standardization and simplification of processes, optimizing resource utilization through the incorporation of more efficient new technologies. This platform has enabled the enhancement of synergies among the different calibration and testing laboratories, maximizing resource usage, sharing common services, and reducing operational costs. This platform already has the necessary technological groundwork that confidently allows the development of new services to be proposed.

Other initiatives adopted as a result of the implementation of the new software tool have been listed, including the optimization of environmental conditions recording, automated calibration of instrument batches, characterization of temperature-controlled environments, and the achievement of a unique ENAC accreditation for different locations.

Finally, the project of an innovative digital software platform for the digital transformation of INTA, INTAQALAB, has been presented,

building on a new evolution from the current version of the INTA tool.

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CDTI is a Business Public Entity under the Ministry of Science, Innovation and Universities that promotes innovation and technological development of Spanish companies (https://www.cdti.es/en/about-us).

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