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## REPORT OF THE ACCREDIA DIRECTIVE COUNCIL FOR 2018

Data at 31122018

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## The President's report

Over 2000 accreditations issued and more than 15000 assessment days performed on bodies and laboratories - these are figures which alone testify to the continued and substantial growth in Accredia's activities last year. In-depth analysis of the data is set out in detail further into this report, whilst here we offer an initial overview, with the influences exerted by various factors.

## Accredia and the Public Administration Authorities - a regenerating synergy

The Public Administrations have provided a considerable thrust through their policy of entrusting Accredia with more tasks and responsibilities. In 2018 the first accreditations were issued to inspection bodies enabling interested parties to operate in conformity with DPR 462/2001 for the verification of grounding systems.
The same is true regarding the Decree of the Ministry of Economic Development 93/2017, concerning the periodical verification of measuring instruments (in this case, access to accreditation is allowed also for calibration laboratories).
This upward trend is not due only to these new and certainly important factors, as well as those confirmed in the so-called regulated area. In 2018 the agreements were renewed with the Ministry of the Environment and Land and Maritime Protection for a range of activities; with the Ministry of Internal Affairs and the Ministry of Economic Development for the conformity of appliances burning gaseous fuels. Data amply reveal an increase in activities also for testing laboratories and calibration laboratories - the latter following a period of many years which had been relatively static.
There have also been developments in the area of fluorinated gases. The revision of EU Regulations led to the issue of a Legislative Decree (146/2018) whereby Accredia's activities will no longer be guided by specific Technical Regulations but by schemes approved by means of Ministerial Decrees.
It is important to stress the good work pursued in consultations between the Ministry of the Environment, the various trade associations, Unioncamere and the representatives of the accredited bodies, with Accredia performing a leading role, producing tangible benefits also for tens of thousands of mostly small-scale operators and businesses.

## Accreditation responding to new market demands

As we have seen, the number of assessment days performed has increased compared with the number of accreditations issued (in the period from 2010 to 2018 the former rose by $78 \%$ and the latter by $48 \%$ ) and thus one can reasonably conclude that conformity assessment bodies have grown in size and enlarged their staff structures in response to a market which has not been affected by crises.
In 2010 the average number of assessment days per body or laboratory stood at 7, whilst last year it had risen to 9, and, according to data for 2017 gathered by Accredia, the overall revenue deriving from accredited certification, inspection and verification activities touched a remarkable 431 million euro.
We often refer to "chains" when we are speaking about conformity assessment bodies, going upwards to the Accreditation Body as far as the technical standard. It is an important concept containing not only technical links in the chain of activities but also the need of the entire system to face society expectations in terms of quality, health, safety, the environment and indeed to boost economic growth. It is therefore encouraging to see that conformity assessment bodies are strengthening their structures and activities and this must have a positive knock-on effect whereby all operators can obtain a reliable, competent and impartial service provided by bodies and laboratories. Competitiveness should center around the evidence of higher quality and service efficiency, and not on the lowest available price.
In the light of this, Accredia has welcomed the new Public Procurement Code but has also dedicated considerable care, over recent years, to the very complicated application of the new normative framework, revisions to which are still the subject of ongoing discussion. Pending new legislation, Accredia is focusing on the creation of contracting Authorities to enable the correct use of conformity assessment in the preparation of public procurement tenders. In answer to this, a Memorandum of Understanding was signed with ITACA and UNI for defining the activities for the managing officers responsible for the procedures of the contracting Authorities.

## Renewal of Accredia's institutional bodies aimed at continuity

Two major developments took place in 2018. With the closure of the three-year period, all the institutional bodies have been renewed, apart from of the Board of Arbitrators which is due to lapse in 2021.
Starting from the Assembly in May, all fulfillments were duly carried out and with the broad agreement of the Members' representatives. The activities of the various committees were not interrupted and it should be highlighted that the process took place in continuity with past practices. This was achieved also in the system of the Sector Accreditation Committees, as well as regarding the Board of Auditors, the Appeals Commission and the Steering and Guarantee Committee. In addition to this, top management positions were re-confirmed for the President and the two Vice Presidents whose positions were renewed for the second mandate.
These decisions can certainly be interpreted in a positive light as a general sign of satisfaction with Accredia's progress and it is corroborated by the results of the customer satisfaction survey which, in 2018, was conducted on a basis of anonymity for the first time. The level of participation was of accredited bodies and the approval they expressed were very good and in line with previous years.
This satisfaction can undoubtedly be extended to another event which was crucial to the year: the EA Peer Evaluation which was conducted in November.

## Novelties and confirmations of the EA Peer Evaluation

This evaluation contained three major factors of unknown outcome: a) the key standard for accreditation, UNI CEI EN ISO/IEC 17011, had been issued only at the end of 2017 and without a transition period with respect to the previous edition; b) the standard UNI CEI EN ISO/IEC 17025, which alone covers $60 \%$ of the accreditations issued for tests and calibrations, was revised at the end of 2017; c) Accredia had requested participation in the new International Agreement of Mutual Recognition (EA MLA) of Reference Materials Producers accredited in accordance with UNI CEI EN ISO 17034, also issued recently.
Having stated these points and bearing in mind the considerable preparatory effort made by all staff members - which also involved the revision of many General Regulations for accreditation and other Procedures - the outcome was received with great satisfaction: the results of the activities of the sixteen peer evaluators (including the three IAF and ILAC observers and trainee observers) resulted in the raising of just one Nonconformity, with nine Concerns and 9 Comments.
We are therefore confident that the EA MAC Committee of May 2019 will reach a positive decision regarding Accredia's continued signatory status for all the Multilateral Agreements as well as the Agreement due to enter into force for Reference Materials Producers. When this is submitted to Accredia's bodies it will be possible to affirm that the proposed corrective actions implemented to address the findings have been accepted by the evaluation team.
On the worldwide level, in 2018 the signing took place of the new International Agreement of Mutual Recognition (IAF MLA) for the verification and validation of greenhouse gas inventories, reflecting Accredia's acknowledged competence in protecting public interests - an axiomatic factor of accreditation - from the issue of climate change to sustainable growth.

Referring again briefly to the transition to the new standard UNI CEI EN ISO/IEC 17025, in line with expectations, testing laboratories and calibrations laboratories are moving ahead with due caution (of about 1,400 interested parties at the end of 2018, fewer than ten had completed the transition) despite Accredia's efforts concerning training and informing, which also involved many stakeholders.

## Increased activities for accredited bodes

In 2018, from an economic point of view, the progress made in the previous year influenced by the reductions in the pricelist decided by the Directive Council has continued. Owing to this decision, revenue showed a notable downturn, closing post-tax at $€ 100,409$ and constituting $0.5 \%$ of total revenue.
Increased activities have also inevitably meant that Accredia has had to enlarge its staff.
Hiring new staff members has, in turn, made it necessary to have more office space: in Rome a new apartment has been purchased (near the head office in Via Saliceto), and in Milan an agreement was reached with the owner of the building in Via Tonale to rent a part of the $7^{\text {th }}$ Floor

## Collaboration for transparency and privacy

Amongst the events which occurred last year there was also the renewal of the Compliance Body for the prevention of crimes, with the confirmation of the position tasked for supervising compliance with the three-year plan for transparency and the fight against corruption.
Once again, Accredia intends to commit to the highest levels, in line with its ethical principles, adopting tools in accordance with the laws conceived for the Public Administration Authorities, in spite of the fact that Accredia is a private entity with the participation of these Authorities.
This commitment was repeated also for the application of the new EU Regulation for the protection of personal data (GDPR). In this case, with the aim of providing greater protection to all operators involved despite the fact that it is obligatory, the Directive Council chose to nominate a DPO (data protection officer) in charge of data protection (external and independent). The new law refers at many points to certification and accreditation as instruments for attesting conformity of the processing of personal data, such as to induce Accredia and the Guarantor to set up a permanent working group.
Two General Vice Directors were appointed, one with powers to act as substitute, together with a revision of staff structures decided by the Directive Council for the Certification and Inspection Department. The intention is to offer greater assurances for business continuity, safeguarding the prerogatives of the structure, to which complements should be added to the Members for the good results accomplished.

## The international network, cooperation and reputation

Having mentioned the excellent results of the EA evaluation, we should also acknowledge the efforts of staff who participated in the international activities of accreditation bodies, with the confirmation of Emanuele Riva as Vice President of IAF, as well as a number of international projects: Twinning in Azerbaijan in support of the creation of an accreditation system in line with EU Regulations and policies, the Taiex project with the government of Serbia providing support for the correct interpretation of laws for the implementation of EU rules, and finally the UNIDO project for the accreditation of four certification bodies in Benin, Ivory Coast, Niger and Senegal.

## Innovative ways of communicating quality

To conclude, the communication activities undertaken by Accredia were also of a sustained nature. Starting with the implementation of the plan for 2018-2019, emphasis was placed on communication with the consumer, with the opening of a new social profile on Facebook, the experimental use of television through a TV spot planned in a two-weeks advertising campaign on Channel La7 which was very successful in terms of contacts, in addition to social impressions.
Also in 2018, communication had the support of the contents of the Accredia "Osservatorio" which created new studies such as the notebook "Occupational health and safety certification" made in collaboration with Inail and Aicq, and "The Circular Economy for public policies. The role of certification" made with the contribution of the Institute of Management of the Sant'Anna High School in Pisa.
Communication is an activity aimed at promoting above all the culture of quality which, in the training and improvement of the competences within Accredia, are two central pillars on which this objective can be built. Finally, 2018 was also the year of the development and improvement of a high-value tool: the Databases, which are Accredia's statistical treasure, concerning accreditations and certifications. Beginning with a general revision of the coherence of their contents throughout the various databases, a number of agreements were signed - intended for research objectives - with third parties for obtaining data, including agreements with the Banca Intesa and ISTAT. Thanks to the agreement with the latter the data of accredited bodies and certified companies entered into the national statistical production in the service of institutions and of the market.

Eng. Giuseppe Rossi
President of Accredia


Financial results

## FINANCIAL STATEMENT 2016-2018

| BALANCE SHEET | 2018 | 2017 | 2016 |
| :--- | ---: | ---: | ---: |
| ASSETS |  |  |  |
| Intangible assets | 814 | 543 | 559 |
| Tangible assets | 9,771 | 7,750 | 7,991 |
| Long-term investments | 599 | 568 | 467 |
| Short-term receivables | 5,290 | 5,442 | 5,333 |
| Long-term receivables | 66 | 209 | 308 |
| Liquid assets | 1,945 | 4,114 | 3,633 |
| Other assets | 524 | $\mathbf{2 5 6}$ | $\mathbf{2 4 7}$ |
| TOTAL ASSETS | $\mathbf{1 9 , 0 0 9}$ | $\mathbf{1 8 , 8 8 2}$ | $\mathbf{1 8 , 5 3 8}$ |


| LIABILITIES |  |  |  |
| :--- | ---: | ---: | ---: | ---: |
| Capital and reserves | 9,525 | 9,425 | 9,279 |
| Severance indemnity reserve | 1,672 | 1,524 | 1,473 |
| Short-term payables | 5,954 | 5,795 | 5,372 |
| Long-term payables | 1,854 | 2,130 | 2,406 |
| Other liabilities | 4 | 8 | $\mathbf{8}$ |
| TOTAL LIABILITIES | $\mathbf{1 9 , 0 0 9}$ | $\mathbf{1 8 , 8 8 2}$ | $\mathbf{1 8 , 5 3 8}$ |


| INCOME STATEMENT | 2018 | 2017 | 2016 |
| :--- | ---: | ---: | ---: |
| Production value | 20,156 | 19,284 | 19,182 |
| Production costs | 19,908 | 19,018 | 18,204 |
| Difference between production value and production costs | 248 | $\mathbf{2 6 6}$ | $\mathbf{9 7 8}$ |
| Financial income and expenses | 8 | 6 | 3 |
| Pre-tax income | $\mathbf{2 4 2}$ | $\mathbf{2 7 2}$ | $\mathbf{9 8 1}$ |
| Income tax | 142 | 126 | $\mathbf{4 0 2}$ |
| Net income | $\mathbf{1 0 0}$ | $\mathbf{1 4 6}$ | $\mathbf{5 7 9}$ |

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## Accredia

Assessment activities ..... 14
Assessors and experts ..... 14
Accreditations ..... 14
Complaints ..... 16


## ASSESSMENTS

The total number of accredited certification, inspection and verification bodies, testing laboratories and calibration laboratories stands at 1,776, showing an increase of 4.5\%. These are Accredia's results for 2018, providing a service of competence, impartiality and independence for all market operators (Table 1).
Assessment activities, which grew in all three Departments, exceeded 15 thousand days, with an average annual increase of $6 \%$. The rise in the number of accredited bodies rose a little less than the number of assessments performed by Accredia. Seen over the 2010 - 2018 period, reflect a conformity assessment market increasingly concentrated on large-scale operators (Figure 1).

Table 1 - ASSESSMENT ACTIVITIES 2015-2017 - MAN-DAYS/ACCREDITED BODIES

| Department | 2016 |  | 2017 |  | 2018 |  |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Man-days | Accredited <br> bodies | Man-days | Accredited <br> bodies | Man-days | Accredited <br> bodies |
| Testing laboratories | 8,707 | 1,160 | 8,675 | 1,168 | 9,420 | 1,222 |
| Certification and inspection | 4,639 | 342 | 4,927 | 351 | 4,999 | 365 |
| Calibration laboratories | 680 | 174 | 871 | 180 | 901 | 189 |
| Total | 14,026 | 1,676 | 14,473 | 1,699 | 15,320 | 1,776 |

## ASSESSORS AND EXPERTS

Ensuring a high level of competence in the conduct of assessments of accredited bodies and laboratories, over 544 assessors and technical experts operate in all sectors of conformity assessment (Figure 2). At December 31, 475 assessors performed assessments; of these 316 operated for testing laboratories, medical laboratories and PTPs, 81 for the Certification and Inspection Department and 78 for calibration laboratories and RMPs. The assessors were supported by a technical team of 58 experts for highly specialized sectors for certifications, inspections and verifications and 11 experts for calibrations.

## ACCREDITATIONS

The number of accredited bodies continues to grow, confirming a positive market trend in conformity assessment with good long-term prospects (Figure 3).
In the period from 2010 to 2018 the number of accredited bodies and laboratories rose annually by a total of $48 \%$. This trend is strongest for certification, inspection and verification bodies.

Figure 1 - ASSESSMENT ACTIVITIES PER DEPARTMENT 2016-2018 - MAN-DAYS


Figure 2 - ASSESSORS PER DEPARTMENT 2016-2018


Figure 3 - ASSESSMENT ACTIVITIES 2010-2018 - ACCREDITED BODIES (index number 2010=100)


An overview of accreditations issued in 2018 for the various schemes reveals a situation of great diversity, reflecting the multiple needs in the market for conformity assessment (Figure 4).
The rise from 179 to 188 accreditations of calibration laboratories and from 119 to 133 in the case of inspection bodies in one year reflect growing demand for reliable services required by businesses and professionals for their investment choices.

## COMPLAINTS

An analysis of the complaints and remarks received over the year is important for progress continuity and for keeping up Accredia's reputation amongst accredited bodies and stakeholders. Efficiency and effectiveness of the AB's activities are the founding stones of trust and credibility of the entire conformity assessment system (Figure 5).
Alongside the growth in accreditation activities there was also a rise in the number of complaints and remarks - a total of 223 , which is 43 more than the previous year, most of them received by the Certification and Inspection Department which also handles remarks concerning certified organizations under accreditation.

Figure 4 - ACCREDITATIONS FOR THE VARIOUS SCHEMES IN 2018


Figure 5 - COMPLAINTS AND REMARKS MANAGED - 2016-2018


## 04 <br> Testing Laboratories Department

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Testing laboratories, medical laboratories and PTPs ..... 25
Complaints ..... 25


## THE DEVELOPMENT OF SECTORS

In 2018, Accredia invested in the training and improvement of the competences of the Department in view of the many novelties in the field of accredited tests, starting from the publication of the new standard UNI CEI EN ISO/IEC 17025:2018. This involved major update activities to support laboratories in the application of this standard and to continue to ensure high standards of quality through the involvement of staff, of assessors and members of the Sector Accreditation Committees.
For testing laboratories new areas of activity were opened, reflecting the growing reliability and reputation of conformity assessment activities such as the accreditation of Vulnerability Assessment tests performed on IT infrastructures for identifying any security failures which could involve the breach, loss or acquisition of data and information.
The management of mandatory accreditations for drinking water for people in conformity with the Decree issued by the Ministry of Health on 14.06 .2017 is a particularly significant case. Accreditation regards individual tests or groups of tests, for internal and external laboratories, as well as the validation of methods of analysis adopted in the field of verification of water quality.
With regard to collaboration between Accredia and institutions, the resolution of the Autonomous Province of Trento which introduced the requirement of accreditation in compliance with UNI EN ISO 15189 for all the medical laboratories in the province, whether they be part of a health care company or private. Collaboration between the province and Accredia will permit the rationalization and simplification of controls on health structures, ensuring uniform methods and procedures for the benefit of both users and medical staff.
In the light of growing interest in international standards, Accredia has set up and trained a team of experts in the various disciplines of laboratory medicine and has made significant agreements with sector institutions and stakeholders in order that accreditation issued by Accredia is gradually introduced alongside the accreditation of institutions throughout the national health system.
Innovation, transparency and effectiveness have been the key words with which Accredia has performed the updating of instruments and procedures. Amongst the novelties, the online application for accreditation which, by means of the dedicated portal enables laboratories to apply for accreditation, to make changes to personal details, variations to tests and to the applications for accreditation and extension of accreditation. Novelties also for assessors, with the introduction of the Application 3A, a platform for the management of assessments at laboratories, enabling the reporting of on-site assessment activities and the management of post-assessment activities.


#### Abstract

ASSESSMENT ACTIVITIES The long-term prospects for assessment activities of the Testing Laboratories Department have increased considerably, with a rise of 92 files on 2017, concerning 1,197 testing laboratories, 11 medical laboratories and 14 PTPs. The volume of first accreditation activities has almost doubled - from 48 to 89 out of a total of 1,334 files managed, including re-accreditation, surveillance and supplementary assessments (Figure 6). At the close of 2018, accredited laboratories mostly performed tests in the chemical and biological sectors, accounting for $70 \%$ of accreditations (Figure 7). Compared with 2017 there were 71 fewer accreditations in the mechanical sector, whilst those for emissions against UNI CEN/TS 15675 were up from 58 to 117.


Figure 6 - ASSESSMENT FOR ACCREDITATION OF TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS - 2010-2018 - TYPE OF ASSESSMENT - NUMBER OF FILES


Figure 7 - DISTRIBUTION OF ACCREDITED TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS PER SECTOR - 2018


The technical and system assessors carried out 5,495 and 3,811 assessment days respectively, and assessors with both qualifications performed 52 assessment days (Figure 8).

Figure 8 - ASSESSMENTS FOR THE ACCREDITATION OF TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS 2018 - TYPE OF ASSESSMENTS - TOTAL MAN-DAYS


In the comparison between the types of assessment, the effort was greater for system assessors for document examinations, whilst technical assessors operated mostly on-site (Figure 9).

## ASSESSORS

At the end of 2018 , out of 316 professionals undertaking inspection activities, competences were concentrated in the chemical and biological sectors, in keeping with the sectors in which accredited laboratories have greatest involvement (Figure 10). These sectors alone constitute almost 70\% of the specializations of the Department's assessment team.

Figure 9 - ASSESSMENTS FOR THE ACCREDITATION OF TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS-2018 - MAN-DAYS DEDICATED TO ON-SITE ASSESSMENTS AND DOCUMENT EXAMINATIONS


Figure 10 - ASSESSORS OF THE TESTING LABORATORIES DEPARTMENT PER SECTOR OF COMPETENCE - 2018


Figure 11 - REGIONAL DISTRIBUTION OF TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS - 2018


## TESTING LABORATORIES, MEDICAL LABORATORIES AND PTPS

Over 1,200 accredited laboratories and PTPs are concentrated in the northern regions, mostly in Lombardy, the Veneto and Emilia Romagna. At the end of 2018 these three northern regions represented almost $40 \%$ of all accreditations (Figure 11). Compared with last year the number of accredited testing laboratories in Emilia Romagna and Veneto has grown by $14 \%$ and $7 \%$ respectively, whilst the number of accreditations in Campania has diminished by 3\%.

## COMPLAINTS

In 2018 the number of complaints and remarks received by the Testing Laboratories Department rose significantly. 41 of them were deemed well-founded (Figure 12). The majority of the files handled regarded the activities of accredited laboratories, while 15\% regarded Accredia's activities (Figure 13).

Figure 12 - COMPLAINTS AND REMARKS MANAGED BY THE TESTING LABORATORIES DEPARTMENT - 2016-2018


Figure 13 - SUBJECT OF COMPLAINTS AND REMARKS - 2018


##  <br> Certification and Inspection Department

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## THE DEVELOPMENT OF SECTORS

2018 was concluded with the transition set by IAF regarding quality management certification in accordance with the new ISO standards of 2015. At the deadline of September 15, 93\% of certified companies had completed the transition to the standard UNI EN ISO 9001 and $97 \%$ to UNI EN ISO 14001, in line with levels internationally.
Privacy was a sector which was given considerable importance by the Certification and Inspection Department, with participation in a UNI work table for the preparation of a publicly available specification UNI 43:2018 concerning the processing of ICT personal data in compliance with EU Regulation 679/2016 GDPR, and the start-up of a new certification scheme of the Data Protection Officer (DPO) on the basis of the standard UNI 11697:2017.
The effectiveness of accredited certification had a demonstrable result in another context of great public interest: occupational health and safety, with the implementation of the first international standard for management systems, UNI ISO 45001, to which businesses and public entities, already holding certification to BS OHSAS 18001 have begun the transition process.
The increase and diversification of Accredia's activities with regard not only to the market but also to society in general, can be seen in the new anti-bullying certification scheme, in accordance with the publicly available specification UNI 42:2018. Thanks to the collaboration of the interested parties, including associations of parents and all types of schools, Italy is a world leader in promoting an accredited certification system for managing these phenomena.
The Budget Law of 2018 testifies to the credibility given to accreditation as a strategic instrument for the process of technological and digital transformation with the confirmation of the measure of hyper depreciation in support of the "Industria 4.0" plan, restating the role of accredited certification for obtaining fiscal advantages.
In 2018 Accredia continued to develop accreditation in areas of major interest for the consumer, such as organic production and animal welfare. Through collaboration with the Ministry of Health and the Ministry of Agriculture, Food, Forestry and Tourism, and the sector associations, the Certification and Inspection Department actively took part in the definition of common rules to strengthen the role of accredited certification in sectors of public interest.

## ASSESSMENT ACTIVITIES

Assessment activities for the accreditation of certification, inspection and verification bodies increased in 2017 by $2 \%$ for a total of 4,820 assessment days performed, 89 more than the previous year (Figure 14). Alongside this growth, there was a $9 \%$ fall in assessment days performed for recognition of foreign bodies operating in IAF sector 28 (construction) and for cross frontier assessments (assessments carried out for accreditation bodies operating in a different country). In this case the commitment by the Department was, respectively, 98 and 81 assessment days delivered (Figure 15).

## Certification and Inspection Department

Figure 14 - ASSESSMENT ACTIVITIES FOR THE ACCREDITATION OF BODIES - 2010-2018 - MAN-DAYS


Figure 15 - ASSESSMENT FOR RECOGNITION AND CROSS FRONTIER ACTIVITIES PERFORMED BY BODIES - 2010-2018 - MAN-DAYS


The workload of the Certification and Inspection Department's assessment team rose especially with regard to document examinations and on-site assessments, whilst witness assessments were down on 2017 (Figure 16).
$70 \%$ of assessment activities for accreditation consisted of surveillances and extensions. In $11 \%$ of the cases they were for renewals, whilst first accreditations and supplementary visits accounted for $6 \%$ of activities (Figure 17).

Figure 16 - ASSESSMENT FOR ACCREDITATION OF BODIES - 2010-2018 - TYPE OF ACTIVITY - MAN-DAYS


Figure 17 - ASSESSMENT FOR ACCREDITATION OF BODIES 2010-2018 - TYPE OF ASSESSMENT - MAN-DAYS


## ASSESSORS

The Department used 81 assessors and 58 technical experts for assessment activities. At the end of 2018 the competence of assessors, in line with the situation regarding accreditations, was concentrated in product, QMS and inspection schemes requiring, in the case of inspection schemes, an increase in the competences of the assessors (Figure 18). 7 additional assessors were used exclusively for the accreditation of inspection bodies.

Figure 18 - COMPETENCES OF THE ASSESSORS OF THE CERTIFICATION AND INSPECTION DEPARTMENT - 2018


Legend - Accreditation schemes

PRD - Certification of products/services
QMS - Certification of quality management systems
INSP - Inspection
PRS - Certification of persons
EMS - Certification of environmental management systems
OH\&S - Certification of occupational health and safety management systems
EMAS - Certification for environmental verification activities (EC
Reg. 1221 2009)

EnMS - Certification of energy management systems
FSM - Certification of food safety management systems
GHG/ETS/MRV - Verification of GHG emissions. Voluntary and mandatory sectors
EPD - Environmental product declaration
ISMS - Certification of information security management systems
ITSM - Certification of management systems for IT services
QMS Aerospace - Certification of quality management systems aerospace sector

| Accreditation scheme | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| QMS - Certification of quality management systems | 85 | 89 | 90 | 91 | 92 | 92 | 95 | 95 | 96 |
| EMS - Certification of environmental management systems | 37 | 42 | 37 | 40 | 40 | 39 | 40 | 40 | 39 |
| ENmS - Certification of energy management systems | 2 | 7 | 7 | 10 | 12 | 12 | 13 | 13 | 14 |
| OH\&S - Certification of occupational health and safety management systems | 17 | 21 | 23 | 26 | 29 | 27 | 27 | 30 | 31 |
| ISMS - Certification of information security management systems | 9 | 10 | 10 | 10 | 10 | 11 | 12 | 13 | 14 |
| ITSM - Certification of management systems for IT services | 1 | 1 | 2 | 3 | 4 | 4 | 5 | 5 | 7 |
| FSM - Certification of food safety management systems | 12 | 12 | 11 | 11 | 10 | 10 | 12 | 13 | 14 |
| PRD - Certification of products/services | 63 | 66 | 84 | 149 | 171 | 195 | 203 | 212 | 212 |
| PRS - Certification of persons | 15 | 15 | 23 | 28 | 29 | 37 | 40 | 49 | 52 |
| INSP - Inspection | 52 | 57 | 62 | 64 | 79 | 97 | 109 | 119 | 133 |
| EPD - Environmental product declaration | 4 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |
| EMAS - Certification for environmental verification activities | - | - | - | 15 | 15 | 15 | 15 | 15 | 15 |
| GHG/ETS/MRV - Verification of GHG emissions | - | - | - | 1 | 15 | 12 | 12 | 11 | 10 |
| Total | 297 | 324 | 355 | 454 | 513 | 558 | 590 | 622 | 644 |

## CERTIFICATION, INSPECTION AND VERIFICATION BODIES

At the close of 2018 there were 644 accreditations for 365 certification, inspection and verification bodies - up on 2017 by 22 accreditations and by 14 bodies (Table 2).
The most significant rise occurred in the inspection scheme with 14 new accreditations, also as a result of new commitments bestowed by the Public Administration Authorities which recognized Accredia's competence for the issuance of accreditations in conformity with Law DPR 462/2001 for the verification of grounding systems and Law DM 93/2017 for the periodical verification of measuring instruments.

## FOOD \& WINE CERTIFICATION BODIES

The trust of consumers in the quality of products lies at the heart of the agri-food market, guaranteed by a regulated system of control on a European level to ensure the conformity of products with recognized rules. This system is based not only on the vigilance of the Public Authorities but also on the activities of control bodies authorized by the Ministry of Agriculture, Food, Forestry and Tourism which must also be accredited if they are private.

In 2018, accreditation activities were delivered on 46 control bodies (Figure 19) for products bearing the PDO, PGI and TGS marks, for wine producers and for organic producers. In the organic sector Accredia's activities increased by about 10 days (Figure 20).

Figure 19 - ACCREDITED CONTROL BODIES FOR PDO, PGI, TGS AND ORGANIC CERTIFICATION -2017-2018


Figure 20 - ASSESSMENT ACTIVITIES OF PDO, PGI, TGS AND ORGANIC PRODUCT CONTROL BODIES - 2017-2018 - MAN-DAYS


## AUTHORIZED AND NOTIFIED BODIES

The Public Administration Authorities have given Accredia new responsibilities of accreditation in the mandatory area, bringing a substantial increase of assessment activities to the AB's workload (Figure 21).

The decision of the Ministry of Economic Development to make accreditation compulsory for authorized inspection bodies against DPR 462/2001, has led to the issuance of five new accreditations, and verification activities for the subsequent metrological controls in accordance with Law DM 93/2017 have resulted in a rise of 20 in the number of bodies accredited for the purpose of authorization.

Figure 21 - ACCREDITATION OF BODIES FOR AUTHORIZATION AND NOTIFICATION - 2017-2018


Legend - Provisions for authorization and notification of bodies

| Lifts - Directive 2014/33/EU | Noise - Directive 2000/14/EC |
| :--- | :--- |
| Metrological controls - DM 93/2017 | Gas appliances - EU Reg. 426/2016 GAR |
| PED - Pressure equipment - Directive 2014/68/EU | Simple pressure vessels - Directive 2014/29/EU |
| Machines - Directive 2006/42/EC | Hot water boilers - Directive 92/42/EEC |
| PPE - Personal protective equipment - EU Reg. 425/2016 and | Toys - Directive 2009/48/EC |
| Directive 89/686/EEC | Electrical checks - DPR 462/2001 |
| ATEX - Protective equipment for potentially explosive atmospheres - | Fiscal verifications for the customs agency |
| Directive 2014/34/EU | NAWID - Non-automatic weighing instruments - Directive 2014/31/ |
| Lifts and goods lifts - DPR 8/2015 | EU |
| T-PED - Transportable pressure equipment device - Directive | RED - Radio and telecommunications equipment - Directive 2014/53/ |
| 2010/35/EU | EU |
| EMC - Electromagnetic compatibility - Directive 2014/30/EU | ETS - Electronic toll service - Decision 2009/750/EC |
| MID - Measuring instruments - Directive 2014/32/EU | Cableway installations - EU Reg. 424/2016 and Directive 2000/9/EC |

A positive trend is recorded for all bodies operating in compliance with the various EU Directives and which use accreditation to obtain ministerial authorization and notification from the European Commission.

## CERTIFICATIONS

At the end of 2018 there were over 106 thousand MS certifications (quality, environment, occupational H\&S, information, food safety etc.) issued by accredited bodies and about 140 thousand public and private company sites (Figure 22).

Figure 22 - MANAGEMENT SYSTEM CERTIFICATIONS - 2016-2018 - CERTIFIED SITES, COMPANIES, CERTIFICATES


Compared with 2017 there was a decrease of $7.6 \%$ in the number of certified sites for QMS in conformity with UNI EN ISO 9001, whilst all other certification schemes showed a rise. In the case of certified energy management systems to UNI CEI EN ISO 50001 there was an increase of 45\% (Table 3).
These developments reflect both market saturation in some sectors, to which bodies showed their ability to react by diversifying their offer of certification and also the transition to the standards ISO 9001 and ISO 14001 of 2015, which certified companies against the old editions had to carry out.

The distribution of certified sites (Figure 23) by product sector (IAF classification) underpins the predominance of construction. This distribution, which is constant over time, is conditioned by certifications issued in compliance with UNI EN ISO 9001 and sent to ANAC to check the requirements for operators intending to participate in tender bids.

[^1]| Table 3 - MANAGEMENT SYSTEM CERTIFICATIONS 2016-2018 - CERTIFIED SITES PER |  |  |  |
| :--- | :---: | :---: | :---: | :---: |
| STANDARD' |  |  |  |
| Certification standard | 2016 | 2017 | 2018 |
| QMS - Quality management systems (UNI EN ISO 9001) | 128,240 | 124,420 | 114,904 |
| EMS - Environmental management systems (UNI EN ISO 14001) | 21,616 | 22,160 | 22,301 |
| OH\&S - Occupational health and safety management systems (BS OHSAS 18001) | 15,461 | 16,860 | 17,103 |
| EnMS - Energy management systems (UNI CEI EN ISO 50001) | 1,315 | 2,322 | 3,363 |
| FSM - Food safety management systems (UNI EN ISO 22000) | 1,218 | 1,190 | 1,323 |
| ISMS - Information security management systems (UNI ISO 27001) | 926 | 1,205 | 1,631 |
| ITSM - Management systems for IT services (ISO/IEC 20000) | 81 | 108 | 193 |

Figure 23 - DISTRIBUTION OF CERTIFICATIONS PER MANAGEMENT SYSTEM - 2018 - FIRST TWENTY SECTORS


Legend - IAF certification sectors

01 Agriculture, fishing and forestry
02 Mining and quarrying
03 Food products, beverages and tobacco
04 Textiles and textile products
05 Leather and leather products
06 Wood and wood products
07 Pulp, paper and paper products
08 Publishing companies
09 Printing companies
10 Manufacture of coke and refined petroleum products
11 Nuclear fuel
12 Chemicals, chemical products and fibres
13 Pharmaceuticals

14 Rubber and plastic products
15 Non-metallic mineral products
16 Concrete, cement, lime, plaster etc
17 Basic metals and fabricated metal products
18 Machinery and equipment
19 Electrical and optical equipment
20 Shipbuilding
21 Aerospace
22 Other transport equipment
23 Manufacturing not elsewhere classified
24 Recycling
25 Electricity supply
26 Gas supply
27 Water supply

28 Construction
29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods
30 Hotels and restaurants
31 Transport, storage and communication
32 Financial intermediation; real estate; renting
33 Information technology
34 Engineering services
35 Other services
36 Public administration
37 Education
38 Health and social services
39 Other social services

## COMPLAINTS

There was a rise in the number of complaints received for a total of 156 , of which 116 were managed and closed during the year - 3 out of 4 (Figure 24). This result reflects the commitment given with respect to clients. $42 \%$ of the remarks received concerned directly organizations certified by accredited bodies, which were the object of half of the complaints. The dissatisfaction index regarding Accredia's work was less than 2\% (Figure 25).

Figure 24 - COMPLAINTS AND REMARKS MANAGED BY THE CERTIFICATION AND INSPECTION DEPARTMENT - 2016-2018


Figure 25 - SUBJECT OF COMPLAINTS AND REMARKS - 2018



# Calibration Laboratories Department 

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## THE DEVELOPMENT OF SECTORS

The development of international technical standards required a major commitment on the part of the Calibration Laboratories Department in 2018, with the revision of UNI CEI EN ISO/IEC 17025 concerning both testing and calibration laboratories and the fulfillment of the new standard UNI CEI EN ISO 17034 which has become the reference for the accreditation of Reference Material Producers (RMP), superseding the ISO Guide 34. This caused the revision of the management system and the conduct of transition activities as well as the organization of trainings for technical staff, assessors, experts and members of the Sector Accreditation Committee.
With the publication of this standard the production of reference material and of certified reference material was recognized on an international level for the first time and the accreditation of RMPs can benefit from the extension of the Agreements of Mutual Recognition at European level (EA MLA) and also worldwide (ILAC MRA).
With regard to the sectors, of the five accredited Italian producers the highest number operates mostly in the gas sector, followed by alcoholic solutions. New important frontiers and sectors are expected in the food sector as well as new materials used in superconducting and street lighting.
In the field of metrological traceability the role of accreditation has become increasingly important, with a resulting rise in the number of applications for calibration certificates coming from the market, in the industrial and manufacturing sectors along with a growing number of mandatory areas for the protection of public interests, from cash registers to speed cameras. The increase is also due to the birth of new typologies of calibration related to the introduction of innovative instruments such as the spectrum analyzer or the particle counter used in such sectors as emission gases and fine powders.
With regard to collaborations, in 2018 the Calibration Laboratories Department, together with INRiM, supported the international EMPIR project 17NRM05 EMUE, "Advancing measurement uncertainty - comprehensive examples for key international standards", with the aim of developing applicative models of uncertainty balances for use in the normative area.

## ASSESSMENT ACTIVITIES

## Accreditation files

After several years during which the accreditation of calibrations remained stable, 2018 saw a sustained rise, bringing the total to 189 accredited bodies, of which 188 are calibration laboratories, 5 are producers of reference materials ( 4 of these are also laboratories) (Figure 26). There were 9 more accreditations of laboratories than in 2017 and 27 more with respect to 2010 , underpinning the fact that the assurance provided by traceability at the basis of precise and reliable measurements is a value which the market always acknowledges.
There was a slight drop in the number of files managed due almost entirely to experimental on-site assessments which were 13 fewer than in 2017. In line with the growth trend of first accreditation activities recorded last year, surveillances showed an increase to reach a total of 108. Overall, the Department's assessment activities have almost doubled since 2010, going from 136 to 278 (Figure 27).

Figure 26 - CALIBRATION LABORATORIES AND RMPS - 2010-2018


Figure 27 - ASSESSMENT FOR ACCREDITATION OF CALIBRATION LABORATORIES AND RMPS -2010-2018 - TYPE OF ASSESSMENT - NUMBER OF FILES


## Assessments

With 901 assessment days delivered, 348 days for document examinations, 506 days for on-site assessments and 48 for experimental assessments, the total number of days delivered by the Calibration Laboratoires Department's assessors and technical experts grew by 30 in one year (Table 4). The highest rise was in the number of document examinations over the period 2017-2018.

Table 4 - ASSESSMENT ACTIVITIES OF THE CALIBRATION LABORATORIES DEPARTMENT -2010-2018 - MAN-DAYS

|  | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Document examinations | 87 | 210 | 198 | 167 | 199 | 317 | 197 | 315 | 348 |
| On-site assessments | 228 | 332 | 370 | 398 | 394 | 389 | 437 | 502 | 506 |
| Experimental assessments | 27 | 85 | 48 | 80 | 74 | 55 | 46 | 55 | 48 |
| Total | 342 | 627 | $\mathbf{6 1 6}$ | $\mathbf{6 4 5}$ | $\mathbf{6 6 7}$ | 761 | $\mathbf{6 8 0}$ | $\mathbf{8 7 1}$ | $\mathbf{9 0 1}$ |

On-site assessments remain the main element of assessment activities, involving system assessors (65.5\% / 175 days delivered) and technical experts ( $34.5 \%$ / 331 days delivered), in line with the previous year (Figure 28).

## ASSESSORS

89 assessors and technical experts coordinated by the Department ensure an assessment process of calibration laboratories in conformity with the international reference standards. Regarding specializations, the Legislative Decree 93/2017 of the Ministry of Economic Development for the periodical verification of measuring instruments, also provides for the authorization of accredited calibration laboratories, creating the need for new competences. At the end of 2018,16 assessors were undertaking these activities.

With regard to the periodical assessments, the highest number of assessors used was for the quantities "length and angles" and "mass", with 13 and 11 assessors required respectively (Figure 29).

Figure 28 - ASSESSMENT ACTIVITIES OF THE CALIBRATION LABORATORIES DEPARTMENT - 2018 - TYPE OF ASSESSMENT - MAN-DAYS


Figure 29 - ASSESSORS OF THE CALIBRATION LABORATORIES DEPARTMENT PER SECTOR OF COMPETENCE 2018


## CALIBRATION LABORATORIES AND RMPS

At the end of 2018 the calibration laboratories accredited by the Department were distributed by groups of quantities with few changes compared to the previous year (Figure 30). 40\% of accredited calibrations are operational for the three groups "length and angles", "electrical quantities" and "temperature and humidity", the latter with 5 more accredited laboratories than in 2017.

Figure 30 - DISTRIBUTION OF CALIBRATION LABORATORIES PER GROUPS OF QUANTITIES - 2018


On a national level the accredited calibration laboratories are concentrated in northern Italy, especially in Lombardy (37\%) and Piedmont (17), whilst in both Tuscany and Lazio the quantity stands at 6.9\% (Figure 31).

Figure 31 - REGIONAL DISTRIBUTION OF CALIBRATION LABORATORIES AND E RMPS - 2018


## CALIBRATION CERTIFICATES

The long-term trend, already positive, reflects growing demand for reliable measurements on the part of industry. It is no coincidence that the number of certificates issued by laboratories has risen the most, by 11,000 attestations (Figure 32). In 2018 there was a marked rise in the number of calibration certificates issued on the market, a little less than 150,000, with an annual growth rate of $15 \%$. Of considerable influence of this quantity there was the implementation of the Ministerial Decrees 937/2017 and "autovelox" (speed camera checks) (Figure 33).

Figure 32 - CALIBRATION CERTIFICATES PER REGION - 2017-2018


Figure 33 - EVOLUTION OF CALIBRATION CERTIFICATES - 2010-2018


## COMPLAINTS

The number of complaints and remarks received has remained relatively contained, in line with the number of accreditations (Figure 34). Out of a total of 14 received, the issue of dissatisfaction has tended to be the activities performed by accredited laboratories and only $14 \%$ of cases regarded the activities of the Department and/or of Accredia.

Figure 34 - COMPLAINTS AND REMARKS MANAGED BY THE CALIBRATION LABORATORIES DEPARTMENT - 2016-2018


Figure 35 - SUBJECT OF COMPLAINTS AND REMARKS - 2018
 $4-23$





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[^0]:    In thousands of euro.

[^1]:    ${ }^{1}$ The statistical reports of management system certifications are prepared on the basis of the data of certified organizations/companies and communicated to Accredia by the certification, inspection and verification bodies. Data are drawn up and aggregated according to three different categories:

    - Certified site: the certified site of the organization/company which may be an office, department, production unit of the certified organization. One organization may possess a number of certified sites;
    - Certified company: the unit/name of the company/organization holding management system certification which is unequivocally identified by a VAT or fiscal code number;
    - Certification: the specific code regarding procedure which, together with the date of first issue, identifies unequivocally the management system certification of the certified company.

