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I SISTEMI DI QUALIFICAZIONE DELLE IMPRESE

*Modelli organizzativi, certificazione e qualificazione delle imprese:
buone pratiche per l'ottimizzazione dei processi e la selezione
degli operatori virtuosi nel settore della sanificazione del tessile
e dello strumentario chirurgico*

EXECUTIVE SUMMARY

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Report: Structure and Scopes

Being the service sector of textile sanification, surgical instruments, and related medical services characterized by a considerable organizational complexity, by the fragmentation of the production process, and by a plurality of cost centres (widespread use of contractors), it is often exposed to distorting effects on competition, among which and above all, social dumping, as well as, inevitably, issues related to accidents at work and occupational illnesses.

An unfair competition, due to the widespread attitude in the sector to handle the certificates of professional-technical suitability – which should indeed constitute the essential requirements to operate in the market– as a matter of mere formalities and procedural paperwork, therefore failing to become a guarantee of real organizational capability to conduct all production processes in a safe and competitive manner.

On this subject, the need to define a selective/barring system in the market for non-virtuous operators is high; this can be done by assessing their suitability through the evaluation of substantial elements related to the actual organization of work within the enterprise, to the structure of training courses, and to the valorization of the acquired skills, along with the adoption of organizational and contractual standards, including contract work, to be guaranteed through certification procedures.

In regards to health and safety at work, in light of the above considerations, the choice made by the legislator to include the textile sanification and surgical instruments sectors within the “pilot sectors” aimed at the definition of a qualification system for enterprises and self-employed as per art. 27 legislative. decree no. 81/2008 is no coincidence; the scope is to improve the workplace environment from existing risks, also taking into account the guidelines proposed by joint committees.

To that end, the research seeks to identify best practices expedient to optimize the production processes and the selection of the operators, outlining a prevention framework typical of the regulatory model *by objectives*, projected -on the one hand- towards the valorization of the certification of employment and works or service supply contracts (as provided by legislative decree 276/2003, the so-called Biagi law), and the experimentation of organizational models and -on the other hand- towards the construction of an enterprise qualification system, envisaged to detail selection criteria for the operators on the market.

The present report is divided into 5 sections. The first one, in addition to a brief description of the relevant sector, maps out the risks and outlines the *social dumping* phenomenon, framing both the characteristics of the system and its peculiar criticalities.

The second one-focusing both on the labour market evolution and on the novel production systems that have brought about new risks for health and safety at work- analyses, instead, the enterprise qualification system, pointing out its origins, its state of the art, and the need to define it also on a normative basis.

The third section addresses the fundamentals behind the creation of an ideal qualification system, that is certification of employment and works/service supply contracts, and certification of the production processes and products to validate their quality. These are all substantial elements aimed to foster fair competition, setting high safety standards for enterprises, and ensuring a guaranteed quality of service. In addition to this, the fourth part deals with the organizational and work management models, advancing the possibility to subject them to certification to enhance safety and health protection of workers.

The fifth and last section describes the experimental activity undertaken within the five pilot enterprises, and constituting –in all its phases of study, actual application, and shared considerations for the drafting of a Presidential Decree– the basis for building up a qualification system in the sectors of textile sanification and surgical instruments.

Issues and Perspectives of Intervention

As already mentioned, many problem areas have been encountered on this subject.

Above all, the wide implementation of best practices is definitely obstructed by the unfair methods of competition adopted by some operators in the market to avoid the costs arising from an attentive and qualitative production, thus disregarding the sectorial collective agreement, and neglecting to comply with the technical requirements on hygiene standards of the finished products.

It needs to be said that this market distortion is made possible by the lack of mandatory regulations imposing adequate levels of service quality and safety for both operators and end-users.

To date, these fundamental concerns are left to the social responsibility choices of each enterprise; the virtuous operators are obviously called to face hardships because of the unlawful conduct of others which, having the only scope of lowering costs and final prices, ignore altogether quality and safety requirements. Thus being the cause of outright social dumping.

By contrast and in perspective, it seems that the only viable means to overcome these difficulties is the enterprise qualification.

In fact, the introduction of the enterprise and self-employed qualification system in the sectors of textile sanification and surgical instruments may contribute, on the one hand, to improve service quality to the enterprises, and may become, on the other hand, a driving force towards the implementation of best practices in relation to the lawful management of employment relationships and safety protection.

That is an approach aimed to promote cultural growth, where virtuous enterprises become the norm, and the radius of action of the non-virtuous ones is reduced.

Under a complementary profile, the introduction of the enterprise qualification system in the sector of textile sanification could allow public and private clients to identify, among the many present on the market, those enterprises focused on the quality of their production, on the correct management of employment relationships, and on the safety protection of their workers. All of this, in order to contain the insidious phenomenon of unfair competition, put in place by operators willing to decrease their prices by offering poor service, and thus massively eroding the market shares of virtuous enterprises.

Peculiarities and Criticalities of the Sector

The Industrial Integrated System of Textile and Medical Goods and Services (from now on the “System” or the “Sector”) concerns industrial enterprises providing the following services:

- rental of textile and sanification;
- rental of medical devices, sanification, and sterilization;
- supply, rental, reconditioning and maintenance of work clothing and personal protective equipment (“PPE”);

by means of machinery and automatic equipment only, excluding the mere manual intervention during the processes.

The customers are large entities (i.e. hospitals, communities, hotels, restaurants, barracks, schools, pharmaceutical, chemical, and textile enterprises), which externalize the service in order to focus their resources on the main objectives of their activity.

This is an industrial process of high organizational complexity and social discretion, because:

a) the processing cycle is aimed to satisfy the needs of collective realities quantitatively high in number;

b) the activity performed by the industrial enterprises of the sector is not limited to the sole hygienization phase, yet – by means of rental – it encompasses also the supply of decontaminated and sterile goods.

The above mentioned production process sophistication affects accident prevention, and is kept under control by a gradual diffusion of a “safety culture” among the sector enterprises and an increased automation of the industrial processes.

In fact, a study conducted by *Inail* (National Institution for Insurance against Accidents at Work), referred to the period between 2000 and 2009, has registered a 14,4% reduction of accidents. By contrast, a number increase has been registered for occupational illnesses. Among the highest sources of risk exposure, we count:

1. accidental contact with infected clothing coming from hospitals;
2. wounds caused by sharp objects;
3. chemical exposure (corroding acids, detergents, products to remove stains, etc.);
4. dragging by moving parts of machinery (press, kiln, ironing press, etc.);
5. electrocution and muscle and bone problems.

Due to the complexity of the production process and the social discretion of the impacted collective needs, it is fundamental for the enterprises of the sector to operate according to optimal productive and organizational standards, apt then to guarantee a quality service/product to the customer.

With regard to the organizational profile, the correct and integral application of the CCNL by enterprises of the Industrial Integrated System of Textile and Medical Goods and Services is certainly a clue for accountability. In fact, the compliance with CCNL guarantees the implementation of suitable organizational solutions put in place by the enterprise and decided by consensus of the social parties.

Within this regulatory framework, the role of the category bilateral body is central. EBLI has been elected by trade unions and enterprise representatives as the start point for the analysis of the factors affecting the market for the enterprises in the textile sanification and surgical instruments sectors, with particular regard to the workers’ condition.

However, with regard to production, enterprises may reach an optimal quantitative level if they comply with:

- a) environmental regulations (legislative decree no. 152/2006);
- b) best practices guaranteeing the actual elimination of microbiological contamination and, therefore, the hygienic safety of the products handled.

To this end, enterprises are more and more seeking a range of different certifications to guarantee high production standards, and compliance with relevant technical requirements. Precisely:

- *UNI EN ISO 9001:2008 Quality Management System;*
- *ISO 14001:2004 Environment Management Systems – Requirements and guidelines;*
- *SA 8000:2008 Corporate Social Responsibility;*
- *OHSAS 18001:1999 Workers' Health and Safety Management;*
- *UNI CEI EN ISO 13485:2004 Medical Devices – Quality Management Systems.*

The control of microbiological contamination is undoubtedly crucial, and is regulated by the UNI EN 14065:2004 norm (according to *Assosistema* guidelines). The compliance with the norm, in fact, allows to create a control system apt to obtain the RABC certificate (Bio-Contamination Analysis and Control System).

In particular, the above-mentioned control system prevents the so-called cross-contamination by means of:

- a) total separation of clean and dirty laundry, through a physical barrier, both in the entrance and exit phase of the products handling;
- b) regulation and limitation of personnel and equipment transit between the dirty and the clean area.

The enterprise qualification system.

In the last decades, the textile sanification and surgical instruments sectors have undergone a consistent transformation, as it has occurred in many other industries. Break through technological evolutions, globalization, decentralization of production, as well as socio-cultural, legislative and organizational factors, have caused the need for high specialization, innovation drive, employment flexibility, and most of all outsourcing.

In light of this, three organizational factors lay the foundations of the main issues related to health and safety management: enterprise fragmentation (many tasks that were before performed by the same enterprise are now outsourced); substantial reduction of enterprise medium size; scattering of activities among different premises, often far from each other.

As previously indicated, the changes occurred in the labour market and within the enterprise organization models, along with the rise of new problems related to health and safety at work, have opened new challenges in the prevention field.

Actually, the normative developments on health and safety that have come one after the other, particularly in recent years, have demanded to analyze the relationship of this topic with the organization of work, moving along two binaries. On one side the “organization of work *versus* health and safety”, in the most traditional sense that sees it as a potential risk factor; on the other side, the “organization of work *for* health and safety”, where organization is considered to be an

essential element, even at a procedural level, to effectively implement suitable prevention practices and policies within the enterprise.

Lastly, with legislative decree no. 81/2008, the prevention system within the enterprise has been inseparably linked to the enterprise overall organizational model, and all its parts, subjects, competencies, functions, controls, responsibilities, sanctions must be coordinated within a clear organizational framework, and must answer to criteria of rational organization, efficiency, and effectiveness.

The individuation of an enterprise and self-employed qualification system falls within this scope.

The task to identify the sectors and criteria for the definition of the enterprise and self-employed (as per art. 27 in Consolidated Law – *Testo Unico*) qualification system has been assigned to the Permanent Advisory Committee on Health and Safety at Work

In this project, the textile sanification and surgical instruments sector is pointed out by art 27 legislative decree no. 81/2008 among those “pilot” sectors, expedient to the creation of a prototype intended to further develop into a Presidential Decree (*DPR*).

The rationale of this choice is the need to consider, on one hand, the impending obligations set forth by the legislation on those sectors seriously affected by dumping phenomena, by extremely high accident rates, and by the frequent use of service supply contracts; on the other hand, the need to modernize and increase the level of contractual, organizational, professional, and educational standards of many sectors characterized by services mainly performed through the contribution in personnel of the operator, with a minimal enterprise organization, in an essential framework of economic dependence.

As an example, the Committee -in outlining the indispensable and preferential requirements, cross-cutting all the concerned productive sectors- has expressly indicated the certification of employment and service supply contracts among the preferential conditions for enterprise qualification.

The bilateral bodies have been involved more in terms of health and safety. They may now select the virtuous operators on the market, issuing, on request, an attestation of adoption and effective implementation of the organizational models and safety management as per art. 30 of the decree.

It stands to reason that the adoption of particular organizational and safety management models provides a benchmark to measure the enterprise virtuosity, thus performing a sort of “natural selection” among the operators.

Certainly, the more virtuous enterprises will have a better qualification, will distinguish themselves on the market, and will be in the position to enjoy a series of benefits, as:

- preferential right in public tenders (for contractors and sub-contractors);
- access to incentives, subsidies, public funding;
- benefits linked to a more credible and effective reputation on the market, with regard to different stakeholders as customers, suppliers, Public Administration, competitors, scientific communities, positively impacting on productivity and competitiveness.

It is therefore clearly affirmed that the selection of operators on the market for public or *inter privates* tenders, will require a verification of the actual possession, by the beneficiaries (contractors and sub-contractors), of essential requirements related to:

- management and organizational reliability (suitable and effective organizational and management models);
- employment and service supply contract genuineness;
- actual and effective training courses;
- compliance with higher corporate social responsibility standards.

Clearly, the main objective underlying the adoption of a “qualification system” is the individuation of measures of greater protection in comparison to the general provisions laid down within the *Testo Unico* regarding the workplace, to be applicable to the higher accident risk sectors, aiming at bringing down the risk rates.

The Certification of contracts and organizational standards

The certification of employment and service supply contracts, and of organizational standards, as disciplined by legislative decree no. 276/2003, is undoubtedly a fundamental element in the creation of an enterprise qualification system. As a way of introduction, before addressing this procedure more in detail, it is important to review all the existing forms of certification of quality.

The Certifications of Quality

Any employer aiming to operate in the market is aware that to make his enterprise and products successful he must obtain one or more Certifications of Quality.

The Certification of Quality is a guarantee for the stakeholders of the operating ways of the enterprise: by choosing a certified enterprise in a given sector, the customer is reasonably sure that the enterprise will be able to guarantee, with continuity over time, products and services in compliance with set agreed requirements.

In addressing the topic of the Certification of Quality and compliance to norms apt to guarantee the Quality Management System (QMS), it is necessary to consider the ISO 9000 certifications.

The ISO 9000 certifications identify a series of norms and guidelines, developed by ISO (International Organization for Standardization), which propose a quality management system, devised to monitor the enterprise processes and improve the organization’s efficiency and effectiveness, as well as the customer’s satisfaction.

At present, the only norm among the ISO 9000 in relation to which an enterprise may be certified is the ISO 9001:2008, representing therefore the worldwide acknowledged benchmark for the certification of the quality management system for the organizations operating in all productive sectors of all sizes.

The general principles, as pinpointed and explained by ISO, are:

- customer orientation: the priority is given to satisfy the customer’s explicit and implicit needs, and even to surpass their expectations;
- leadership;
- personnel involvement, that constitute the essence of the organization;
- the process approach, in order to achieve the desired result with the higher efficiency when the resources and activities are managed as a process;
- continuous improvement as steady permanent objective of the organization;
- analysis and information data as a base for decisions;

- relationship interdependence as a benefit to improve the capacity to add value.

The SA 8000 is a valid example to demonstrate how the market is now ready to use certifications also in the labour law field.

Art. 30 legislative decree no. 81/2008, entitled Organization and Management Models states that «At the first application, the company organizational models, defined in accordance with the UNI-INAIL guidelines for an health and safety management system (SGSL) in the workplace dated 28 September 2001, or with British Standard OHSAS 18001-2007, are presumed to be compliant with the requirements of the present article where applicable».

This norm represents an important example where certification issued by a private third party (therefore not a public body) is highly considered by the legislator, to the point of presuming compliance with the law for the corresponding parts.

Obtaining certification according to OHSAS 18000 means:

- to perform a detailed analysis of actual and potential risks, associated with the specific activity involved;
- to study adequate solutions to avoid that those risks become actual injuries;
- to guarantee a continuous and effective internal training;
- to constantly control the adopted solutions, that is implementing solutions that are actually functional and applicable to the structure and peculiarities of the activity.

The verification and monitoring of those solutions will allow the enterprise to enhance its techniques, and to steer towards the objective of continuous improvement.

Certification of Employment and Service Supply Contracts

Certification – introduced in our legal system by law no. 30/2003, and regulated by legislative decree no. 276/ 2003, as successively amended– meets a basic need for legal certainty and trust between the parties of an employment relationship in relation to the terms agreed. This, to overcome a widespread sense of instability in employment relationships, and in the way the employment contract is performed, creating increased areas of conflict and, in several cases, aggravating the legal disputes between employer and inspection bodies, with particular regard to the correct qualification of employment contracts.

Thanks to the increased information given to the worker by the certifying bodies, the certification of contracts should allow to overcome the information asymmetries often inherent in those relationships, thus mitigating the confrontational dynamics and the conflict between the parties, and therefore favoring a gradual, virtuous reduction of legal disputes on the different aspects regulated.

The scope pursued by the legislator with the introduction of this legal tool is sustainable and regulated flexibility, i.e. associated to a guarantee of genuineness and transparency. This to allow, at the same time, for:

- a reduction in labour disputes;
- a decrease of undeclared employment;
- a guarantee of adequate information to the parties of the contract;
- a reduction of the risks and costs associated to tax evasion and contributive or retributive with holdings, thus disseminating a culture of legality and fight against irregularities.

Hence, certification becomes an expedient tool in the correct dissemination of the so-called flexible labour contracts introduced by legislative decree no. 276 del 2003.

In respect of the aspects deemed relevant in the present analysis, art. 27 of the Health and Safety Consolidated Text has become particularly important, since it can be inferred that each organizational model concerning manpower can be evaluated by the relevant commissions of certifications.

In a forward-looking strategy that goes beyond the formal aspect of the relevance of certification during a judicial process, and is more consistent with the practice of some commissions seeking authoritativeness over authority, certification may be interpreted in light of corporate social responsibility (RSI o CSR).

Today, in fact, there is a wide perception, stronger than the practice and reiterated by some enterprises, of unlawful use of certain employment contracts and this situation originates, as a consequence, the workers' opposition to new employment forms that are perceived as associated to a precarious status.

In that respect, the existence of a legal tool that translates in a guarantee of respect for workers' rights impacts positively on the acceptance of new employment contracts, and opens up to an actual market flexibility by reducing the information asymmetries often penalizing the worker.

That is, for enterprises, workers, and for the system in general, investing in the creation of a virtuous circle generating wide-ranging advantages.

In other words, using certification- even through the new role with which it seems to have been invested by art. 27 of the Health and Safety Consolidated Act (*Testo Unico di sicurezza e tutela della salute dei lavoratori*)– to foster corporate social responsibility and promote the valorization of intangible assets means receiving by one's employees a stronger *commitment*, developing a sense of belonging, and sharing objectives and enterprise results, thus generating a positive reflection on work and speeding the spread of *positive word of mouth*.

The experience gained so far by the certification of employment and service supply contracts has shown the potential of this tool in several areas of operation broadening, in a certain way, its scope in comparison to the original objectives related to dispute resolution. That is not all. The practice of the commissions of certification have also highlighted as this potential derives and is explained by the voluntary nature of the procedure.

For those pursuing decentralization policies, certification allows for the possibility of an actual cost reduction and efficiency increase, with the guarantee, at the same time, of dealing with a reliable partner: in fact, certification awards the contractor a distinctive title on the market, acknowledging its "quality", and guiding the choice of possible partners through the reduction of the informative gap, translating in the end into an overall advantage for the economy thanks to the increased capacity to attract and hold investments. And these very last two factors transform the cost for certification into future profitability, and then investment.

This procedure represents then an essential factor for competitiveness, since it guarantees organizational flexibility in accordance with the norms and through their strategic use.

Besides, making the certification of one's employment or service supply contracts public, will decrease the likeliness of a situation of "moral hazard", that is the tendency of the contractor to hide any irregularity. This because the cost arisen from the damage of their image deriving by such a behavior, would be decidedly higher than the advantages gained through the irregularities.

Organizational management models and perspectives of certification

Another relevant element in the definition of the enterprise qualification is undoubtedly the adoption of an organizational and management model. At least with regard to health and safety at work, these models, above being likely to guarantee a reduction in accidents and occupational diseases by the careful use of business management models, offer the possibility to take advantage of the exemption effects within the meaning of legislative decree no. 231/2001 introducing the liability for the institution.

Further in detail, with regard to this last aspect, the necessary precondition to assess the institution's liability is the existence of a specific offence committed -by the management or by an employee- in the interest and to the advantage of the institution. This offence needs to be among the categories expressly laid out by decree 231 within the articles between 24 and 25 *duo decies*.

A "corporate offence" depends directly by the presence of an organized structure that not only ontologically defines the institution, but constitutes also the actual basis of the offence.

The best method to contain corporate crime is therefore to enact valid and effective organizational norms, and this scope is pursued through the adoption and effective application of the organizational, management, and verification models referred to in art. 6 and art. 7 of legislative decree no. 231/2001.

Firstly, these models fulfill their function through the individuation of the activities where offences may arise; once this prevention activity is completed, the model aims at identifying ad hoc protocols to support the decision-making process, relying on a preventive approach against certain types of offences.

Through its role within the system, the model performs two functions: a primary one, that produces the exemption effect, and a second one, that allows for a partial exemption effect, of a restorative nature.

The exemption function is achieved differently depending on the subject committing the offence (a subject belonging to the management or an employee). The restorative function takes obviously place in the *post delictum* phase, and consists in the possibility of an institution responsible of committing an offence (but lacking an organizational model, or having adopted a non-effective one), to receive a sanction reduction, up to a possible total exemption for the interdiction effects, providing the adoption of an organizational model, or the adjustment of an inadequate one.

Complementing the general provision of art. 6 legislative decree no. 231/2001, art. 30 legislative decree no. 81/2008, provides for a series of further specific requirements for the organizational model on health and safety at work, having to ensure in particular the existence, within the enterprise organization, of functions and procedures apt to guarantee the strict compliance to all legal obligations.

In addition to that, to fully perform its exemption function, the model must guarantee that the enterprise organization adopted with a prevention scope is actually enacted and respected, thus being effective and updated over time accordingly to the changes occurred within the enterprise.

For the parties meeting the set requirements, and at the first enactment phase, art. 30 of legislative decree no. 81/2008 states also the exemption value for the models complying with OHSAS 18001:2007 and UNI-INAIL 2001.

Peculiar to the structure of the organizational model are the characteristics of:

- effectiveness;
- specificity;

- dynamism.

With the first two terms, reference is made to the need for the model to take into account all the peculiar characteristics of the institution, from size to history, to the capacity to adapt to possible changes within the prevention requirements, being the contextualization a key element for the judge when performing the review of legality.

A highly issue always debated is the relationship between the Risk Assessment Document (DVR), a compulsory element pursuant to art. 15, art. 28 and art. 29 of legislative decree no. 81/2008, and the management and organizational model *ex art.* 30.

As regards this debate, the analysis needs to focus on the issue of the possible coincidence between the two documents.

The universally renowned decision of the Court of Trani, local section of Molfetta, dated October 26, 2009 on the deaths in the *Truck Center* case, above being the first judgment asserting the liability of an institution for victims of accidents at work, has clarified this aspect in a definitive way.

In fact, art. 30 of the Consolidated Text (*Testo Unico*), paragraph 3, clearly provides for the verification, evaluation, control, and management of the risk, all elements undoubtedly non encompassed within the strictly evaluation obligations set forth with the DVR.

Essentially, the scope of model 231 is not limited to the risk mapping and management in regards to the accident prevention, but embraces also a monitoring role on the operating system, to guarantee a continuous verification of its effectiveness. This circumstance implies, as a consequence, a discrepancy between the subjects addressed by the DVR, and those addressed by the organizational, management, and control model.

Looking at the implementation of an effective organizational model within a medium, small, or very small enterprise, the Permanent Advisory Committee is working to develop guidelines aimed to be an incentive for the adoption and the effective implementation of the organizational models within the SME; anyway, the adhesion of these subjects to what stated by the Committee will not be compulsory, and they will be in the position to opt for different organizational solutions with a prevention potential, that might not be identical to the text written down by the social parties.

At present, this intervention– awaiting the definition by the Committee of actual simplified procedures for the adoption and effective implementation of organizational and management models for health and safety within the SME- can be seen as put in place by the *Circolare del Ministero del lavoro e delle politiche sociali* (Directorate-General for the protection of the working conditions Div. VI) of July 11, 2011.

In reason of the awaiting for the simplified procedures, the above measure –enacted April 20, 2011– aims to guide the small and medium enterprises that have implemented an organizational and management model on health and safety – or intend to – in accordance to the guidelines UNI-INAIL (2001) or BS OHSAS 18001:2007.

This operation has been put in place to allow the above subjects the possibility to assess the compliance of their model with the requirements set forth by art. 30 of legislative decree no. 81/2008 and, in light of this, to adjust it as to achieve a higher adherence to the norms.

Therefore, a model that meets the criteria listed in the above guidelines is considered compliant, for the corresponding parts identified in the comparison chart, with art. 30.

The connection between the certification provisions *ex* legislative decree no. 276/2003 (the so-called Biagi Law) articles 76 and ss. and legislative decree no. 81/2008 (so-called *Testo Unico*

Sicurezza) is certainly art. 27 of the Consolidated Text, entitled “Enterprise and Self-employed Qualification Systems”.

Ex art. 51, co. 3-*bis*, legislative decree no. 81/2008, even if not explicitly defined, it is possible to trace back the concept of attestation of adoption and effective implementation of organizational and management models issued by the bilateral bodies (*Organismi Paritetici*).

These provisions may be considered to outline the concepts of certification and acknowledgment of the organizational and management models.

The provision in art. 51, co. 3-*bis*, of legislative decree no. 81/2008, despite emphasizing the role of the bilateral bodies in regards to the acknowledgment of the organizational and management models, lacks though an exhaustive definition of the functions, profiles, and consequences of the attestation (*asseverazione*), to the point of only being able to define that concept *a contrario*, by means of its differences from certification.

An idea about the preferred direction on this topic, can be obtained by the consideration of the proposed amendment draft, presented in October 2010, for legislative decree no. 231/2001 (also known as AREL’s draft law).

This draft provided, along with the rest, for the introduction of a certification system devised for the organizational and management models, for the setting up of a purpose-built bar listing the authorized certifying authorities, and for the presumption of exemption of the certified models with regard to the liability for corporate offences.

At the same time, a certification system is available for each single procedure at the first stage, when the institution is working on adopting an organizational model, but has still not implemented it.

Case Studies

In light of the analysis of the legal, contractual, and organizational framework in relation to the textile sanification and surgical instruments sectors, and of the gathering of legislation on the topic of certification of employment and service supply contracts, of enterprise qualification, and of organizational and management models, an on field research and trial activity has been performed through *case studies* within five “pilot enterprises” associated with *Assosistema*.

In particular, the context and impact analysis of each organizational model has been performed within each enterprise.

These enterprises were model enterprises for health and safety standards at work, as well as for organizational and contractual standards.

This activity pursued to recreate the starting point for the exam of the organizational, contractual, and prevention context, creating at the same time the conditions for an actual shared experimentation of the identified best practices, with the support of bilateral bodies and professional associations.

This analysis has been functional to build certification patterns for contractual and organizational standards tailored on the specific needs, sizes, and sector of the enterprises.

Operationally, training seminars- addressed to employers, top management, key personnel, and workers- have been held to raise awareness in the community and to promote information on the topics of the research, thus guaranteeing an active participation of the enterprise community in the creation of paths of organizational and productive excellence. This aim has been reached through a

dynamic process involving directly -firstly and foremost- the top management under a cultural profile.

After the consciousness-raising and training activity, five certification paths for the contractual and organizational standards have been developed in accordance with articles 76 ss. of legislative decree no. 276/2003.

This phase has been the direct consequence of the project aimed to outline and implement certification paths with parameters established according to the specific needs and characteristics of the carefully examined enterprises. It has also been functional to the actual experimentation of the models, and to the determination of the *case studies*, whose experimental results have been gathered.

Following a careful analysis of the employment and service supply contracts, an internal enterprise qualification system has been outlined and has been translated into a Presidential Decree draft to be submitted to the responsible bodies for its transposition and approval.

The draft of the decree highlights that the textile sanification enterprises and the surgical instruments enterprises have been identified only among those enterprises performing the whole production cycle with equipment and automatic machinery, ruling out any merely manual intervention during the production cycle, and validated in regards to hygiene safety of the products handled.

With regard to the effects of the acknowledgment of an enterprise qualification system, the possession of the requirements to obtain the qualification represents a preferential element in public tenders (contractors and sub-contractors), and for the access to incentives, subsidies, and public funding, always if linked to the same tenders.

For the sake of completeness, we must point out that the public authorities are required, when awarding public contracts, to perform a preventive verification of the possession of the necessary qualification of all interested parties.

As provided for in the DPR draft, the possession of the requirements for the enterprise qualification would concede a reduction in the premium to be paid to INAIL, and would constitute a title to obtain a tax credit, in the measure of a maximum 50% of the expenses faced to adapt the labour organization to the set requirements.

The DPR draft lists both the mandatory and the preferential requirements for the acknowledgment of the enterprise qualification.

Among the mandatory criteria to award the qualification, are included:

- a) compliance with the provisions referred to the workers' information and training;
- b) compliance with the provisions set forth in the Single Document of Contributory Regularity (Documento Unico di Regolarità Contributiva);
- c) the presence of personnel, mostly with open-ended contracts, and in percentage non lower than 30% of the workers, with at least a three-year experience in the sector, and with regard to the specific work or service performed.
- d) suitability to perform a specific activity, evaluated taking into account the compliance with the provisions regarding risk assessment, health monitoring, emergencies management measures, supply, possession, correct use, and maintenance of the personal prevention equipment and of work equipment, as per legislative decree no. 81/2008;
- e) the total application of the agreements or sectorial bargaining agreements, included the contribution payment to the National Bilateral Body (Ente Bilaterale Nazionale);

f) the adoption, according to the Assosistema guidelines, of a control system against bio-contamination, compliant with the requirements provided for by UNI EN 14065:2004, and the possession of RABC certification (Risk Analysis Bio-contamination Control);

g) the certification, in accordance with Title VIII, Chapter I, legislative decree no. 276/2003, of the flexible employment contracts in use;

h) the certification of each service contract or sub-contract, supply, sub-supply and transportation, in accordance with Title VIII, Chapter I, legislative decree no. 276/2003, and within the limits ex art. 27, legislative decree no. 81/2008.

Among the preferential criteria and requirements for the acknowledgment of the qualification are included:

a) the adoption and effective implementation by the enterprises of the organizational and management models in compliance with the provisions in art. 30 legislative decree no. 81/2008, and art. 6 and art. 7 legislative decree no. 231/2001.

b) the voluntary application of the Codes of Conduct and Ethics, and the development of corporate social responsibility actions.