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# New Reference Practice For Safety Specialist On Machinery Directive Professional Profile

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#### Abstract

Reference Practices (PdRs) introduce technical prescriptions or sectoral application models of specific standards when there are no national, European or international standards or draft standards. They may contain good practices already in use in citizen/consumer services, sectoral applications of existing specifications, industry specifications, protocols for the management of proprietary brands, locally tested management models, nationally adopted CWAs. In this case, the Safety Specialist PdR has been developed and published in Italy to give a common reference to rule one specifical non-regulated by law profession: the Safety Specialist on Machinery design and Construction. This PdR falls under the category of "products of European standardization," as outlined in EU Regulation No. 1025/2012. In the paper, the new Italian PdR will be presented and explained in details: legal aspects, relevant definitions, knowledge, skills, autonomy, and responsibility requirements and elements for conformity evaluation. As a rule, the regulatory framework for professional activities also fits within the context of the European Union, serving as a useful tool for the mobility of individuals and the removal of barriers to the free movement of human capital. The official publication of this PdR at the end of 2023 (UNI/PdR 151:2023), allows the application of it as a common basis for training and validation of competences for this new professional activity.

Keywords: machinery directive, safety specialist professional profile, safety of machinery

# 1. Introduction

Professions not regulated by law are those that can be practiced without the need to be listed in a register or a reference order and without having to possess a specific qualification or training course, regulated and defined by, as an example, the Ministry for Education, Universities and Research Centers (MIUR in Italy). Reference practices, adopted exclusively at national level, fall under the category of "products of European standardization," as outlined in EU Regulation No. 1025/2012 (European Parliament and of the council, 2012). As a rule, the regulatory framework for professional activities also fits within the context of the European Union, serving as a useful tool for the mobility of individuals and the removal of barriers to the free movement of human capital.

They are documents that introduce technical specifications, developed through a streamlined process involving all the stakeholders potentially affected by the new PdR. In this case, the reference practice has been developed under the operational guidance of UNI by an ad hoc working group promoted by Italian FEDERMACCHINE (National Federation of Association of Manufacturers of capital goods). The reference practices are available for a period not exceeding 5 years, the maximum time from their publication during which they can be transformed into a regulatory document (UNI, UNI/TS, UNI/TR) or must be withdrawn.

This particular reference practice establishes the requirements related to the professional activity of the machinery safety specialist, i.e. an expert in the application of safety requirements stipulated by European

legislation concerning machinery, as well as other applicable European product legislation, norms, and relevant legal provisions, in the activities of design, manufacturing, conformity assessment and product documentation (see European Parliament and of the Council, 2006).

In the following paragraphs we will analyze this reference practice for safety specialist as UNI/PdR 151:2023. It has been ratified by the President of UNI (Italian standardization association) and came into effect in Italy on September 28, 2023.

There are already in the EU market some companies offering successful training and certifications for safety specialist as the CMSE by Pilz and TUV Nord (Certified Machinery Safety Expert) that are certificated worldwide, see Pilz (2023). These certifications are documents provided by private entities and are not recognized by national/international standards or legal acts.

No discussion on the quality of this type of course will be done in this paper, but the definition of a UNI/PdR 151:2023 has been done under some very important general rules/a general context for all the reference practices defined by UNI:

- ensure, during the pre-regulatory phase, constant monitoring of the relevant national and international legislative context, conducting periodic reviews of the developed regulations;
- ensure coherence with the European Qualifications Framework (EQF) and the National Qualifications
  Framework (NQF), with particular attention to terminology, expression methods of descriptors (i.e.,
  knowledge, skills, autonomy, and responsibility). Ensure also the application of the principle that "learning
  outcomes" are decisive rather than the path taken, to facilitate the portability of skills across formal,
  informal and non-formal domains;
- ensure, to the extent possible, the involvement of all relevant stakeholders at various levels (e.g., Regions
  and Ministries, representative business organizations, labour union representatives, consumer
  organizations, professional orders and associations, professional associations, conformity assessment
  bodies, non-governmental organizations, universities and research institutions, cultural associations, etc.);
- provide specific guidelines for relevant conformity assessment processes;

This general approach to regulations of "new professional skills" are very welcomed especially in the field of the application of safety requirements for machinery and general products and, as deemed by the authors, it is certainly helpful in disseminating knowledge of design of safer products and correct market entry practices for products. The content of UNI/PdR 151 (2023) will be described in detail in the next paragraphs.

## 2. Content of the reference practice

In this paragraph, a detailed description of content of the UNI/PdR 151:2023 from legal aspects relevant for the introduction and utilization of this profession to elements for conformity evaluation.

For this reference practice, even if it has been implemented using the standardized format of all UNI reference practices, particular attention has been paid to avoid introducing elements or references to specific national regulations/laws that could limit its application even in other countries.

Only few references to national regulations have been introduced, such as legal references on how to produce certifications of work experience on safety of machinery, but those national aspects are very simple to be identified and adapted to other nations, especially in EU that has a common regulation for a lot of social and product aspects.

# 2.1. Legal aspects

The activity of the Machinery Safety Specialist can be of legal relevance in relation to various aspects connected to product compliance.

First, it is necessary to consider the main purpose of the expert, which is to provide economic operators with the necessary advice, based on his knowledge, skills and professional experience, to assess the conformity of machinery, as defined and regulated by European product regulation, to the essential safety requirements.

This fundamental activity, carried out through consultancy or technical/project collaboration or in other explanatory modes of the expert's professionalism, may involve:

the employer and machinery users, to assess the safety and conformity of work equipment to applicable
regulatory requirements, both during the purchase phase and at the time of their putting into service in the
workplace. It also includes evaluating safety aspects in relation to maintenance and adaptation obligations
assigned to users. Despite the CE conformity marking for machinery, the employer must verify the actual
compliance of machinery with safety requirements and ensure the maintenance of such conditions over

time, making necessary improvements and adjustments in terms of safety if required. In this regard, the expert may be called upon to provide his knowledge to assist the economic operator in this activity;

- the manufacturer, as defined by product regulations, see as an example the Blue Guide (European Commission, 2022), is the main party involved in risk assessment for the machine and the adoption of necessary measures based on safety integration principles and requirements contained in product regulations. This is to ensure machine compliance, both in the placing on the phase and during maintenance or modification, as well as in the creation of machine assemblies, etc.;
- the importer, as defined by product regulations and/or other EU norms, is subject to obligations and responsibilities similar to those of the manufacturer when placing a machine on the market;
- the distributor, as defined by product regulations and/or other EU norms, with reference to compliance verification obligations in the marketing and distribution of machinery;
- other entities to whom product regulations assign significant tasks concerning compliance (authorized representative, entity making substantial modifications to a machine, etc.).

Another fundamental activity for the Machinery Safety Specialist is providing expertise as a technical expert appointed by a judicial authority to evaluate the compliance of a machine in the case of an accident or dispute regarding supply, maintenance or other activities related to a machine. Similarly, the machinery safety specialist's activity can be helpful in judicial proceedings as a consultant for the parties involved in legal disputes.

Considering the importance of the expert's activity in the judicial context for the assessment of responsibilities, it is necessary for him to acquire adequate knowledge (within the limits of his competencies and professionalism), not only of specific product regulations, but also of legal norms applicable at both substantive and procedural levels. This ensures proper orientation and determination based on the objectives of his actions.

The machinery safety specialist's activity can also be highly relevant in relation to market surveillance proceedings, harmonized generally by EU regulations for all products, and specifically for machinery.

As known, market surveillance aims to prevent non-compliant and, therefore, unsafe or potentially dangerous machinery from putting or remaining on the market. Competent authorities can take particularly serious actions against manufacturers and economic operators for the withdrawal or recall of machinery from the market. Customs authorities also have specific tasks related to controlling the introduction of machinery into the market at the time of their entry into the EU territory. The expert can assist economic operators in managing these procedures, which can significantly impact their business activities.

Concerning the activities described above, the UNI/PdR 151:2023 Reference Practice identifies specific matters on which the Machinery Safety Specialist must acquire knowledge and skills to essentially meet the following criteria:

- the expert must know the legal norms, Essential Health and Safety Requirements (EHSR) specified by
  product regulations and technical standards necessary to achieve the presumption of conformity. Applying
  safety requirements means understanding the implementation of EHSR for different types of machinery
  based on their relevance and pertinence;
- respecting EHSR means knowing the obligations they entail and being able to apply harmonized technical standards to satisfy these EHSR. Knowledge of technical standards is an indispensable requirement for achieving the presumption of conformity for machinery;
- the Machinery Safety Specialist must be able to perform his activity for the assessment of machine
  conformity, both concerning design, construction and documentation of machinery, and in cases of
  modifications or updates. This includes situations where machinery may be subjected to criminal, civil, or
  market surveillance proceedings.

# 2.2. Relevant definitions

The Scope of UNI/PdR 151:2023 is to give the requirements related to the professional activity of the Machinery Safety Specialist which is defined in the PdR as:

"Natural person who possesses competence, knowledge and ability in the field of machine safety with reference to the design, construction, conformity assessment and documentation activities of machines".

For the purposes of the professional qualification of safety specialist on the Machinery Directive, two levels of specialization have been established within the PdR, namely the "basic level" and the "advanced level", according to which the knowledge and skills have been differentiated and must be verified for the purposes of the above-mentioned professional qualification.

Both the basic and advanced levels require the same basic knowledge and skills, but the advanced level requires greater skills.

At the advanced level, in fact, the ability is required not only to know whether the product complies with the requirements of the Machinery Directive, but also to know how to operate at a more in-depth technical level, such as (for detailed information refers to the aforementioned PdR):

- knowing how to define the functional interlocks;
- the characteristics of the electrical devices;
- the characteristics of the pneumatic and hydraulic systems of the product necessary to implement its functionality;
- to be able to define the level of performance of the safety functions necessary to adequately reduce the
  risk.

In other words, the advanced level specialist is required to have a marked proactive ability well beyond the simple verification of compliance with the technical-legal requirements.

For the purposes of evaluating the competence of the machine safety specialist (in terms of knowledge, skills, autonomy and responsibility), his learning is evaluated in formal, non-formal and informal terms, where the different learning methods are defined as follows (definitions partially taken from Council of the European Union, 2017):

- formal learning: learning that takes place in the education and training system and in universities
  and institutions of high artistic, musical and dance training, and which ends with the
  achievement of a qualification or a professional qualification or diploma, also obtained in apprenticeship
  or a recognized certification, in compliance with current legislation regarding school and university
  systems:
- *informal learning:* learning which, even regardless of an intentional choice, takes place in the carrying out, by each person, of activities in everyday life situations and in the interactions that take place therein, within the context of work, family and free time;
- non-formal learning: learning characterized by an intentional choice of the person, which takes place
  outside the systems referred to informal learning, in every organization that pursues educational and
  training purposes, including volunteering, of the national civil service and private social and business
  sectors.

Further relevant definitions contained in the PdR are the following:

- autonomy and responsibility: ability of the person to apply knowledge and skills autonomously and responsibly;
- competence: proven ability to use a structured set of personal, social and/or methodological knowledge, skills and abilities in work or study situations and in professional and personal development;
- knowledge: result of the assimilation of information through learning;
- learning outcomes: description of what a person knows, understands and is able to achieve at the end of
  a learning process;
- conformity assessment: demonstration that specified requirements relating to a product, process, system, person or organism are met.

All those definitions were essential on the developing of the UNI/PdR 151:2023 and to institute a common knowledge for this new professional profile.

#### 2.3. Knowledge, skills, autonomy, and responsibility requirements

The PdR establishes the specific tasks and activities to be performed by the machinery safety specialist, both for the basic and advanced level. The associated knowledge, skills, autonomy and responsibilities for both levels are outlined in the next two paragraphs.

#### 2.3.1. Tasks and activities of the professional figure

The Machinery Safety Specialist shall be able to determine which current legislation and technical standards apply to the product, with particular reference to:

- European legislation relating to machinery (for a complete list of relevant legislation see the references of UNI/PdR 151:2023);
- any other applicable European product legislation;
- technical standards applicable to the product, its parts/components or to safety aspects concerning the
  product.

Therefore, the Machinery Safety Specialist must be able to carry out the risk assessment of machinery, performing the following activities:

- identification of the intended use;
- identification of the space, use and time limits of the product and the environmental conditions in which it
  is to be used:
- identification of the relevant product life stages and, for each of them, identification of:
  - the persons involved;
  - the product limitations;
  - the reasonably foreseeable misuse;
  - the hazards present and the extent of the hazardous area related to them;
  - the situations in which people are exposed to the identified hazards;
  - the risk related to each identified hazard, in terms of severity of damage and probability of occurrence

In addition to this, the advanced level Machinery Safety Specialist must also be able to:

- determine the safety measures to be applied to adequately reduce the risk;
- · define the information to be provided to the user;
- identify where to affix the necessary safety information on the product;
- define how to prevent unexpected start-up.

Assessing the conformity of electrical, pneumatic, oil/hydraulic equipment is also part of the activities of the machinery safety specialist.

Of particular importance is also the evaluation of safety functions; the Machinery Safety Specialist must therefore be able to identify which functions are to be implemented as safety functions.

As already introduced in paragraph 2.2, the advanced level machine safety specialist shall also be able to define the specifications of the safety functions, determine its the performance level of the safety function that is appropriate to reduce the risk, ascertain that this performance level — including safety-related software, if relevant — has been achieved, and validate the safety functions.

The assessment of emissions from the machine — e.g. noise, vibration, radiation, etc. — is also part of the activities to be performed by the machine safety specialist.

A key part of the activities to be carried out by machinery safety specialists is the drafting of documentation concerning machinery and partly completed machinery, i.e.:

- declarations of conformity and declarations of incorporation;
- instructions for use and assembly instructions;
- technical files and relevant technical documentation.
- In the case of modifications to existing machinery, the Machinery Safety Specialist must be able to:
- define whether the modified machine or partly completed machine is to be subjected to a conformity
  assessment in accordance with European machinery legislation, or
- document the modification intervention, ensuring that it has been carried out in accordance with the relevant laws and regulations.

Finally, the work of the Machinery Safety Specialist must also cover legal aspects relating to product safety, including:

- the relevant legal provisions, concerning the safety and health of workers and accident prevention, specific to the country of use, applicable to products placed on the market prior to the entry into force of European legislation on machinery (and therefore not subject to this legislation);
- conformity assessment procedures for products, which may or may not include certification by notified bodies;
- · market surveillance procedures.

#### 2.3.2. Knowledge and skills

For the activities and tasks described above, the PdR defines the knowledge and skills that the professional figure of the machinery safety specialist must possess.

By way of example, the knowledge and skills, taken from Table 1 of UNI/PdR 151:2023, for some of the tasks are reported in Tables 1 to 5:

With this simple to read table format, the requirements for Machinery Safety Specialist conformity evaluation are very simple to be found.

Moreover, because of rapid change of relevant standards is expected, the check/maintenance of those tables is very simple to be done by national experts. In the tables below when a reference to the application guide for Machinery Directive is done by the European Commission, 2019 at its latest edition it is to be taken into account.

Table 1. Knowledge and skill for risk assessment task.

Task	Knowledge	Skills	Level
assessment		Identify the intended use of the product.	Basic and
	relating to machinery	Determine the life stages of the product.	advanced
	EN ISO 7010	Identify hazards and dangerous situations considering the specific environment of	
		use (for example, residential or industrial) and the type of users (professional and/or non-professional).	
		Check whether the safety measures necessary to adequately reduce the risk have been correctly implemented, whether the necessary safety information has been correctly affixed to the product and whether the instructions have been drawn up in compliance with the applicable European product legislation.	
	EN ISO 13855		
	EN ISO 13857		
	EN ISO 14119		
	EN ISO 14120		
	ISO/TR 14121-2		
	EN ISO 14118	Determine the safety measures necessary to adequately reduce the risk.	Advanced
		Define the information needed by the user to implement further risk reduction.	
		Identify where to place the necessary safety information on the product.	
		Define how to prevent unexpected start-up.	
	EN ISO 14122-4		
	EN IEC 62046		
T. 1	W. I.I.	Table 2. Knowledge and skill for documentation tasks	Y 1
Task	Knowledge	Skills	Level
Drafting the declaration of conformity or incorporation	European legislation relating to machinery and corresponding application guide	Draw up the declaration of conformity or the declaration of incorporation of the product (or a homogeneous product family), in accordance with the legislation in force.	Basic and advanced
Drafting the instructions	European legislation relating to machinery and corresponding application guide EN ISO 20607	Draw up instructions for the product (or a family of homogeneous products) in accordance with the relevant essential health and safety requirements of European machinery legislation, taking into account the results of the risk assessment of the product.	Basic and advanced
Compiling the technical file or the relevant technical documentation	European legislation relating to machinery and corresponding application guide	Gather the documentation required by the legislation in force and organize it in such a way as to constitute the technical file or the relevant technical documentation of the product (or of a family of homogeneous products).	Basic and advanced
		In the case of series manufacture, define the internal procedures that must be applied in order to maintain the product's conformity with the provisions of European legislation relating to machinery.	
	Tab	ole 3. Knowledge and skill for modification of existing machinery	
Task	Knowledge	Skills	Level
Assessment of the impact of modifications	relating to machinery and	Determine whether the modification intervention is substantial, i.e. whether it requires the machine to undergo the CE marking procedure under European machinery legislation.	Basic and advanced
on existing machinery	corresponding application guide The 'Blue Guide' on the implementation	Define the procedure to be followed for CE marking of the modified machine in accordance with European machinery legislation.	

## 3. Relevant elements for conformity evaluation

The elements for conformity evaluation are contained in Annex A of UNI/PdR 151:2023, with specific reference to the third-party certification process (also known as "certification examination"), in accordance with UNI CEI EN ISO/IEC 17024. The aim is to ensure increasing uniformity and transparency and to develop a common framework for the professional figure introduced.

A minimum qualification of level 4 EQF is required according to the descriptors defining the levels of the European Qualifications Framework for both basic and advanced levels, see Council of the European Union (2017).

For level 4, the minimum learning outcomes are on Table 4 below.

Table 4. Learning outcomes for level 4 EQF.

Outcome type	Requests
Knowledge	Factual and theoretical knowledge in broad contexts within a field of work or study
Skills	A range of cognitive and practical skills required to generate solutions to specific problems in a field of work or study
Responsibility and autonomy	Exercise self-management within the guidelines of work or study contexts that are usually predictable but are subject to change.
	Supervise the routine work of others, taking some responsibility for the evaluation and improvement of work or study activities

It is to remember that the comparison at national level can be made using NQF levels. Guiding rules for conformity evaluation are:

- both factual and theoretical knowledge are necessary for conformity assessment. Especially for advanced level a proven unreplaceable experience on design, manufacturing, conformity assessment, and documentation of machinery is required;
- training must be delivered, ensuring at least 80% of the hours as direct in-person training and the remainder through synchronous learning methods courses; the on-line courses method is not considered effective for the safety specialist courses;
- for person with a level 7 EQF (as an example a master's degree in engineering), seeking certification, may be granted recognition of up to a fifty percent reduction in theoretical training based on a curriculum attesting to specific competencies in certain themes. The reduction of required hours must be evaluated separately for each point according to paragraph 2.3;
- it is possible to access to the advanced level both with or without the basic level in course of validity, the
  main goal of UNI/PdR 151:2023 is to give a certification on real knowledge, skills, responsibility and
  autonomy, not to evaluate persons on the basis of theoretical courses and theoretical knowledge.

Requirements related to non-formal and informal learning for Safety Specialist at basic level are in Table 5:

Table 5. Safety specialist – basic level.

Outcome type	Requests attendance to a training course of at least 44 hours on topics related to knowledge outlined on 2.3.2 a	
Theoretical knowledge		
Factual knowledge	<ul> <li>480 hours of specific practical internship, including the tasks and activities outlined in section 2.3.1,</li> </ul>	
	Alternatively,	
	<ul> <li>proven experience in the activities of designing, manufacturing, conformity assessment, and documentation of machinery, as well as consulting or applied research related to the contents of this reference procedure for at least 1 yea</li> </ul>	

The on-field experience in this basic level can be substituted with internship in the field of safety of machinery to enable the worker to have a factual experience in the field of safety of machinery with the assistance of industry experts.

Requirements related to non-formal and informal learning for Safety Specialist at Advanced level holding a valid certification as a basic machine safety specialist are in Table 6.

Table 6. Safety specialist - advanced level holding a valid base level.

Outcome type	Requests
Theoretical knowledge	attendance to a training course of at least 28 hours on topics related to knowledge outlined on 2.3.2 $^{\rm a}$
Factual knowledge	proven experience in the activities of designing, manufacturing, conformity assessment, and documentation of machinery, as well as consulting or applied research related to the contents of this reference procedure for at least 4 years, no necessarily continuous but within the last 8 years

In this case, the factual experience is necessary to achieve the certification and it is not possible to substitute it. The training courser shall be focused on advanced level topics and to updating past knowledge topic for, as an example, new standards and/or new requirements.

Requirements related to non-formal and informal learning for Safety Specialist at advanced level without a valid certification as a basic machine safety specialist are in Table 7:

Table 7. Safety specialist - advanced level without a valid base level.

Outcome type	Requests
Theoretical knowledge	attendance to a training course of at least 68 hours on topics related to knowledge outlined on 2.3.2 $^{\rm a}$
Factual knowledge	proven experience in the activities of designing, manufacturing, conformity assessment, and documentation of machinery, as well as consulting or applied research related to the contents of this reference procedure for at least 4 years, no necessarily continuous but within the last 8 years

The training courses in this case must be focused to all the necessary knowledge for the two levels. In this case, the factual experience is necessary to achieve the certification and it is not possible to substitute it.

The skills and qualifications needed for entities involved in training and certification processes are in Annex A.3 of UNI/PdR 151:2023 and no explanations are given on this paper. As a rule, the personal delivering training and certification shall have a proven experience on the field. There are no requirements about the separation between training and certification body, but if the same company is on charge of both the aspects it must demonstrate that all processes performed by the certification body are independent of training to ensure that confidentiality, information security and impartiality are not compromised.

# 3.1. Evaluation of competences

In formal learning, the methodologies and assessors are established according to the provisions of the equivalent NQF level of each country. For the conformity assessment related to the learning outcomes in nonformal and informal settings outlined in section A.2 of UNI/PdR 151:2023, knowledge, skills, autonomy, and responsibility, as specified in section 2.3.2, must be objectively and directly evaluated.

The overall assessment is based on the sequential completion of checks and exams specified in sections A.4.2 and A.4.3 of UNI/PdR 151:2023. Written exams are considered passed when achieving at least 60% of the maximum score. The analysis of the candidate curriculum vitae, written and oral examination and, for only advanced level, the solution of a "case study" is required to obtain the certification.

The maintenance for certification is biennial and based on documentation of the candidate presented to the certification authority. Certification renewal is every 6 years, detailed information on maintenance a renewal are in Prospects A.2 and A.3 of UNI/PdR 151:2023

#### 4. Conclusions

In this paper, the innovative UNI/PdR 151:2023 Reference Practice for Safety Specialists in Machinery has been introduced and explained, highlighting its key aspects. Like all Reference Practices, it delineates the

technical requirements necessary for obtaining certification as a Safety Specialist in Machinery—a new professional profile in Italy, at least for the time being.

This PdR falls under the category of "products of European standardization," as defined by EU Regulation No. 1025/2012. It is valid for five years and, hopefully, will be transitioned into a regular Italian standard. The tabular format of the main paragraphs, along with minimal references to national legislations and norms, ensures:

- ease of maintenance over time for updates, accommodating common changes in standardization and legislation within this field;
- simplified evaluation for other national bodies considering incorporation into their respective national standardizations, particularly within EU. The main definitions and requirements can be easily converted/ needs no conversion;
- quickly identifying the national references to legislation utilized, accessible through the references
  provided at the end of the text;
- the minimal formal qualification level to access to the certification is based on the European Qualifications
  Framework (EQF) and can be converted using each country's official conversion tables without requiring
  interpretation.

As a rule, the regulatory framework used for professional activities aligns with the European Union context, facilitating the mobility of individuals and eliminating barriers to the free movement of human capital. UNI/PdR 151:2023 is available for free download on UNI website, currently only in Italian language. Official courses for training and certification of knowledge, skills, autonomy and responsibility are already held on UNI training platform from the end of 2023.

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