

**ROYAL DECREE 39/1997 of 17th January,  
by virtue of which  
THE REGULATIONS FOR PREVENTION  
SERVICES ARE APPROVED**

Regulations for Prevention Services and subsequent amendment

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MINISTERIO  
DE TRABAJO  
E INMIGRACIÓN



INSTITUTO NACIONAL  
DE SEGURIDAD E HIGIENE  
EN EL TRABAJO

**ROYAL DECREE 39/1997 of 17<sup>th</sup> January, by virtue of which the Regulations for Prevention services are approved.**

Regulations for Prevention Services and subsequent amendment

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## Stated Purpose

Spain's Act 31/1995 of 8th November has brought a new focus, already announced in its preamble, to the prevention of risks at work, which, in the new legal conception, is not limited to a number of enforced corporate obligations or correcting hazardous situations that have already appeared, but is now integrated into the company's activities and decisions of which it must be a part right from the outset of the corporate project.

Thus, the new approach to the prevention of risks starts with the planning thereof based on an initial risk assessment inherent in the work and the subsequent adoption of measures that are appropriate to the nature of the risks detected.

The need for these phases or aspects to receive specific treatment by appropriate regulatory means is established in Article 6 of Spain's Prevention of Risks at Work Act 31, according to point 1, letters d) and e) of which, the Government will regulate, by means of the corresponding regulatory rules, the procedures for evaluating risks to workers' health and safety and the organizational types, operation and control of Risk Prevention services, in addition to the capacities and abilities required of such Services and of the workers appointed to carry out preventive activities, this latter requirement being already contained in EEC Directive 89/391.

This Royal Decree responds to the fulfilment of the legal precept, in which those aspects that make possible the prevention of risks at work are the subject of treatment from a new perspective, that is, as an activity forming an integral part of a company's activities at all its hierarchical levels, based on a plan that incorporates the technique, organization and conditions of work, to all of which are to be applied the same principles of efficiency, co-ordination and participation that have shaped the Act.

Consequently, it is covered in the first place the risks assessment, as the basis for the next step of planning whatever preventive activity may be necessary, via one or other of the organization modalities that, following Article 31 of the Act, are regulated in this Regulation, in accordance with the company's size and the risks and danger of the activities conducted by it.

The suitability of the preventive activity which, as a result of the assessment, the employer has to adopt, is guaranteed by the twin mechanism that is regulated in this Regulation: on the one hand, the accreditation by the Labour Authorities of external prevention services, as a way of guaranteeing the adaptation of their resources to the activities that they are going to carry out and, on the other, the prevention system's audit or external assessment when this activity is undertaken by the company using its own resources.

In connection with the necessary capacities and abilities for conducting the preventive activity, this regulation establishes the necessary adaptation between required training and the functions to be carried out, establishing the necessary minimum training for performing the functions specific to preventive activities, which are broken down into three levels: basic, intermediate and higher, in the last of which are included the preventive specialities and disciplines occupational health, safety at work, industrial hygiene and ergonomics and applied psychosociology. The current non-existence of academic or professional qualifications corresponding to the aforementioned training levels, with the exception of the occupational medicine speciality, has been allowed for in the Royal Decree, which contemplates the temporary possibility of alternative certifications of the required training, until the corresponding qualifications have been established by the competent education authorities.

By virtue thereof, at the proposal of the Minister of Labour and Social Affairs, having heard the National Commission for Health & Safety at Work and consulted the most representative trade union organizations and business associations, previously approved by the Ministry of Public Administrations, in accordance with the State Council and after the deliberations of the Council of Ministers in their meeting held on 17th January, 1997

## **CHAPTER I General Provisions**

### **Article 1. Integrating preventive actions into the company**

1. Occupational risk prevention, as an action to be developed within the company, must be integrated into its general management system, both into all the company's activities and at all hierarchical levels, through the development and implementation of an occupational risk prevention plan whose structure and content are set out in the following Article.

Integrating prevention into all the activities of a company means that it must be integrated into all its technical processes, work organisation and conditions under which work is performed.

Integrating it at all hierarchical levels implies that all hierarchical levels are assigned and must assume the obligation to include risk prevention in any activity they carry out or order and in any decision they take.

2. The workers and their representatives must contribute to integrating occupational risk prevention into the company and cooperate in adopting and complying with preventive measures through the participation granted to them in Chapter V of Act 31/1995 of 8 November on Prevention of Occupational Risks.

The participation referred to in the previous paragraph includes consultation on the implementation and application of the company's occupational risk prevention Plan, the assessment of risks and the subsequent planning and organization of prevention, as appropriate, as well as access to the corresponding documentation, under the terms of Articles 33 and 36 of Act 31/1995 of 8 November on Prevention of Occupational Risks.

3. Preventive actions in the company shall be implemented by means of any of the types listed in Chapter 3 of this Royal Decree.

### **Article 2. Occupational risk prevention Plan**

1. The Occupational Risk Prevention Plan is a tool for integrating the company's preventive action into its general management system and for establishing its occupational risk prevention policy.

The occupational risk prevention plan must be approved by the company's management, endorsed by all its organizational structure, especially by all its hierarchical levels, and known by all its workers.

2. The occupational risk prevention plan shall be enshrined in one document that shall be made available to the labour authority, health authorities and the workers' representatives, and include the following items, as extensively as the size and nature of the company warrant:
  - a. The name of the company, its productive activity, the number and the characteristics of its workplaces, the number of workers and their characteristics relevant to occupational risk prevention.
  - b. The organizational structure of the company, with the identification of duties and responsibilities of each of the levels in its hierarchy and the corresponding channels of communication between them, in relation to occupational risk prevention.
  - c. The organization of production regarding the identification of the different technical processes and practices and organizational procedures within the company, as related to occupational risk prevention.

- d. The organization of prevention in the company, indicating the prevention model chosen and the existing representative bodies.
  - e. The policy, objectives and goals that the company wishes to reach in matters of prevention, as well as the human, technical, material and financial resources that will be available for this purpose.
3. The instruments that are essential for managing and implementing the occupational risk prevention Plan are risk assessment and prevention activity planning, which the employer must carry out in the manner set forth in Article 16 of Act 31/1995 of 8 November on Prevention of Occupational Risks, and in the following Articles of this resolution.
  4. Companies with up to 50 employees that do not undertake any of the activities listed in Annex I may collate their occupational risk prevention Plan, risk assessment and prevention activity planning into a single document.

This document shall be short and easy to understand, be fully adapted to the activity and the size of the company and set out the appropriate operational measures to integrate prevention into the company's activity, risk involving jobs and the specific measures for preventing or mitigating them, ranked by level of risk, as well as the time limit for implementing them.

## **CHAPTER II Risk Assessment and Planning of the Preventive Activity**

### **Section 1 Risk Assessment**

#### **Article 3: Definition**

1. The assessment of risks at work is the process that is aimed at estimating the importance of those risks that it has not been possible to avoid, providing the necessary information for the employer to be in a position to take the appropriate decision on the need for adopting preventive measures and, in this case, the type of measures that must be adopted.

Whenever, as a result of the assessment, the adoption of preventive measures proves to be necessary, must be made very clear the situations in which it is necessary:

- a. To eliminate or reduce the risk by means of preventive measures at source, organizational, collective protection, personal protective equipment or workers' training and information.
  - b. To regularly control the working conditions, organization and methods, and the workers' state of health.
2. As set forth in Article 33 of the Prevention of Risks at Work Act, the employer must consult the workers' representatives, or the workers themselves in the absence of representatives, on the assessment procedure to be used in the company or work centre.

#### **Article 4: General Content of the Assessment**

1. The initial assessment of the risks which have not been possible to avoid must be applied to each one of the posts within the company in which such risks exist. For this purpose, the following must be taken into account:
  - a. Existing and forecast working conditions, as defined in point 7 of article 4 of the Prevention of Risks at Work Act.
  - b. The possibility that the worker who occupies such a post or is going to occupy it is particularly sensitive to one or other of such conditions, by virtue of his/her personal characteristics or known biological state.

In particular, in accordance with the provisions on risk assessment as stipulated in Article 26.1 of Act 31/1995 of 8 November on Prevention of Occupational Risks, Annex VII of this Royal Decree includes a non-exhaustive list of agents, procedures and working conditions that can negatively affect the health of pregnant or breastfeeding workers, of the unborn or breastfeeding child, in any activity likely to involve a specific risk of exposure.

In any case, pregnant workers shall not carry out activities likely to involve a risk of exposure to the agents or working conditions contained in the non-exhaustive list in Annex VIII, Part A, when, in accordance with the conclusions of the risk assessment, they might endanger her safety or health or that of the unborn child. Similarly, a worker who is breastfeeding shall not carry out activities likely to involve a risk of exposure to the agents or working conditions contained in the non-exhaustive list in Annex VIII, Part B, when the assessment shows that they might endanger her safety or health or that of the breastfeeding child. In the cases included in this paragraph, the measures described in Article 26 of Act 31/1995 of 8 November on Prevention of Occupational Risks shall be adopted, in order to prevent exposure to the risks indicated.

2. On the basis of this initial assessment, reassessment must be made of those posts that could be affected by:
  - a. The choice of working equipment, chemical substances or preparations, the introduction of new technologies and the modification of the conditions in the work place.
  - b. A change of working conditions.
  - c. The hiring of a worker whose personal characteristics or known biological state make him/her particularly sensitive to the conditions of the post.
3. The assessment of risks will be carried out with the intervention of competent staff, in accordance with the provisions of Chapter VI of this Regulation.

#### **Article 5: Procedure**

1. Based on the information obtained on the organization, characteristics and complexity of the work, on raw materials and the work equipment that already exists in the company and on the state of health of the workers, dangerous elements will be established and the workers who are exposed to them will be identified, then assessing the existing risk in accordance with the objective assessment criteria, based on the technical evidence that exists or has been agreed on with the workers, so that a conclusion can be reached as to the need for eliminating or controlling and reducing the risk.

For the purposes established in the foregoing point, the information received from the workers on the topics indicated must be taken into account.

2. The assessment procedure adopted must give confidence in its result. In the case of doubt, the most favourable preventive measures, from the prevention point of view, must be adopted.

The assessment will include the taking of any measurements, analyses and tests that may be considered necessary, with the exception of those operations, activities and processes in which direct expert professional appraisal allows to reach a conclusion without the need to perform them, provided that the provisions of the foregoing point are complied with.

In any case, should a specific regulation be applicable, the assessment procedure must comply with the concrete conditions established therein.

3. When the assessment requires the taking of measurements, analyses or tests and the regulations do not indicate or specify the methods that must be adopted, or when the assessment criteria contemplated in such regulations must be interpreted or determined in the light of other criteria of a technical nature, methods and criteria, as set forth in the following standards, if they exist, may be used:

- a. UNE Standards
- b. Guides published by the National Institute for Health & Safety at Work, the National Silicosis Centre and protocols and guides published by the Ministry of Health & Consumption as well as those from the competent Institutions of the Autonomous Communities.
- c. International Standards
- d. In the absence of the foregoing, other well-known prestigious bodies on the subject guides or other documented professional criteria, which complies with what has been established in the first paragraph of point 2 of this article and which provides an equivalent level of confidence.

#### **Article 6: Revision**

1. The initial assessment referred to in Article 4 must be revised whenever a specific provision establishes this.

In any case, the assessment of the affected posts must be revised whenever harm to the health of the workers has been detected or it has been noticed in the regular controls, including those relating to health surveillance, that the prevention activities may be inadequate or insufficient. To this end, the results of the following must be taken into account:

- a. Investigation into the causes of the harm to health that may have occurred.
  - b. Activities for reducing the risks referred to in point 1.a) of article 3.
  - c. Activities for controlling the risks referred to in point 1.b) of article 3.
  - d. Analysis of the epidemiological situation according to the data provided by the health information system or any other available sources.
2. Without prejudice to the provisions of the previous point, the initial assessment must also be revised with the frequency that is agreed upon between the company and the workers' representatives, particularly taking into account the deterioration of the elements used in the production process with the passing of time.

#### **Article 7: Documentation**

For each of the posts for which the assessment reveals a need to take some kind of preventive measure, the documentation referred to in paragraphs b) and c) of Article 23.1 of Act 31/1995 of 8 November on Prevention of Occupational Risks shall contain the following information:

- a. Identification of the post
- b. The existing risk or risks and the list of affected workers
- c. The result of the assessment and the appropriate preventive measures, taking into account the provisions established in Article 3
- d. Reference of the assessment criteria and procedures and of the measuring, analysis and test procedures used, in those cases in which the provisions of point 3 of article 5 are applicable

#### **Section 2 Planning the Preventive Activity**

##### **Article 8: Need to Plan**

Whenever the assessment's results reveal hazardous situations, the employer must plan the appropriate preventive activity with the aim of eliminating and controlling or reducing such risks, in accordance with an order of priority based on their importance and the number of workers exposed to them. When planning this preventive activity, the existence of legal provisions relative to specific risks, where applicable, must be taken into account as well as and the principles of preventive action described in Article 15 of the Prevention of Risks at Work Act.

## **Article 9: Content**

1. At any event, the planning of the preventive activity will include the necessary human and material resources, in addition to the allocation of the economic resources that are needed to achieve the proposed objectives.
2. Likewise, the emergency and health care measures established in Articles 20 and 22 of the Prevention of Risks at Work Act, must be integrated into the planning of the preventive activity, in addition to providing information and training to the workers on risk prevention and the co-ordination of all these aspects.
3. The preventive activity must be planned for a set period, establishing the priorities and phases of its development in accordance with the importance of the risks and the number of workers exposed to them, in addition to their regular follow-up and control. In the event that the period in which the preventive action is developed exceeds one year, an annual programme of activities must be drawn up.

## **CHAPTER III Resources organization for developing the Preventive activities**

### **Article 10: Types**

1. The organization of the necessary resources for the development of preventive activities will be carried out by the employer in accordance with the following types:
  - a. Personally assuming the activity
  - b. Appointing one or several workers to carry it out
  - c. Establishing an internal prevention service
  - d. Resorting to an external prevention service
2. According to the terms and conditions set forth in Chapter IV of Act 31/1995, of 8 November on Prevention of Occupational Risks, internal prevention service shall be understood as the company's human and material resources that are necessary to carry out the preventive activities, and external prevention service shall be understood as the prevention service provided by a specialized enterprise that reaches an agreement with the company to perform the preventive activities, to provide the advice and support that it requires in accordance with the types of risk, or both activities together.
3. The prevention services will have an interdisciplinary nature, understanding by such the co-ordinated combination of two or more technical or scientific disciplines on the subject of the prevention of risks at work.

### **Article 11: Personal assumption of preventive activities by the employer**

1. The employer may personally undertake the implementation of prevention activities, with the exception of those related to the surveillance of workers' health, under the following circumstances:
  - a. The company has up to ten workers.
  - b. The activities carried out in the company are not included in Annex 1.
  - c. The employer's professional activity are normally carried out in the workplace.
  - d. The employer has the necessary capacity to perform such preventive activities, in accordance with Chapter VI.
2. Workers' health surveillance and those other preventive activities not personally assumed by the employer must be covered by using any of the other preventive organization types established in this Chapter.

### **Article 12: Appointment of Workers**

1. The employer will appoint one or several workers to take charge of the preventive activity within the company.
2. Those preventive activities for which the appointment of one or several workers is insufficient must be implemented through one or more internal or external prevention services.
3. Irrespective of the provisions established in the foregoing point, the appointment of workers will not be obligatory whenever the employer:
  - a. Assumes personally the preventive activity, as indicated in [Article 11](#)
  - b. Resorts to an internal prevention service
  - c. Resorts to an external prevention service

#### **Article 13: Capacity and Resources of the Appointed Workers**

1. In order to conduct the preventive activity, the appointed workers must have the capacity for the functions to be performed, as established in [Chapter VI](#).
2. The number of workers appointed, in addition to the resources that the employer places at their disposal and the time made available to them for carrying out their activity must be sufficient to fulfil their functions adequately.

#### **Article 14: Internal Prevention service**

The employer must set up an internal prevention service in any of the following cases:

- a. When the company has more than 500 workers.
- b. In the case of companies with between 250 and 500 workers, when the corporate activity is one of those included in [Annex I](#).
- c. Whenever, in the case of companies not included in the foregoing points, the Labour Authorities so decide, subject to a report by the Labour and Social Security Inspectorate and, if applicable, by the technical bodies responsible for risk prevention in the Autonomous Communities, depending on the danger inherent in the activities carried out or the frequency or severity of the diseases and injuries in the company, except in the case that the company chooses to reach an agreement with an external specialized company, as provided for in [Article 16](#) of this regulation.

Taking into account existing circumstances, the Labour Authority's decision will fix a term, not above one year, in which the company that chooses an internal prevention service must establish such a service. Up until the date specified in the decision, the company's prevention activities must be outsourced from an independent specialized enterprise, with the exception of those activities that are gradually assumed by the company with the appointment of workers up until their full integration in the prevention service will be set up by the company.

#### **Article 15: Organization and Resources of Internal Prevention services**

1. The internal prevention service will be a specific organizational unit and its members will devote their activities in the company exclusively to the prevention service's object.
2. Internal prevention services must have at their disposal the installations and human and material resources that are necessary for the performance of the preventive activities that are going to be conducted in the company.

The service must incorporate at least two of the preventive specialities or disciplines established in [article 34](#) of this Regulation, implemented by experts with the required training for the functions to be carried out, as established in [Chapter VI](#). These experts will act in a co-ordinated way, particularly in connection with the functions relating to the preventive design of posts in the company, the identification and assessment of risks, prevention plans and worker training plans. Likewise, the service must incorporate the necessary personnel with the required training to carry out the basic and intermediate level functions established in the aforementioned [Chapter VI](#).

Without prejudice to the necessary co-ordination referred to in the foregoing paragraph, the health activity, whenever it exists, must have for the development of its function within the prevention service, an appropriate structure and resources for its specific nature and for the confidentiality of personal medical data, having the obligation of fulfilling the requirements established in the applicable health regulations. This health activity will include the specific functions set forth in point 3 of article 37 of this regulation, the activities attributed to it by virtue of Spain's General Health Act and any others that may correspond to it in the field of the prevention of risks at work by virtue of its specialization. The activities of the prevention service's personnel will be co-ordinated in accordance with protocols or other existing methods that establish the objectives, procedures and responsibilities in each case.

3. When the prevention service's scope of activity is applied to more than one work centre, the situation of the different centres in relation to the service's location must be taken into account in order to ensure that the service's resources match the existing risks.
4. Any preventive activities not assumed by the internal prevention service must be outsourced from one or more external prevention services.
5. Each year, the company shall prepare and make available to the competent labour and health authorities and the Safety and Health Committee the annual report and the annual programme for the prevention service referred to in Article 39, section 2), and paragraph d) of the Act on Prevention of Occupational Risks.

#### **Article 16: External prevention services**

1. The employer must outsource to one or several independent prevention services, which will collaborate with each other whenever necessary, when any of the following circumstances exists:
  - a. When the appointment of one or several workers is insufficient to carry out the prevention activity but when the circumstances that impose the obligation of establishing an internal prevention service do not exist.
  - b. When, in the case referred to in letter c) of article 14, the employer has chosen not to establish an internal prevention service.
  - c. When the preventive activity has been partially assumed in accordance with the terms and conditions set out in point 2 of article 11 and in point 4 of article 15 of this Regulation.

2.- In accordance with Article 33.1 of Act 31/1995 of 8 November on Prevention of Occupational Risks, the workers' representatives shall be consulted by the employer prior to taking the decision to outsource the preventive activities to one or more external prevention services.

On the other hand, in accordance with Article 39.1. a) of the above Act, the criteria to be taken into account when selecting the entity to which the service will be outsourced, as well as the technical details of the outsourcing agreement, shall be discussed, and agreed to if appropriate, within the Safety and Health Committee of the company.

#### **Article 17: Requirements to be met by specialised entities to act as external prevention services**

1. Specialised entities may act as external prevention services provided the following requirements are met:
  - a. They shall have the necessary organization, facilities, personnel and equipment for the performance of the activity.
  - b. They shall take out a guarantee to cover potential liabilities.
  - c. They shall have no business, financial or any other link with the outsourcing companies, other than those related to their performance as prevention service, that may affect their independence and influence the results of their activities, except as provided for in Article 22.

- d. They shall directly assume the performance of the functions contained in Article 31.3 of Act 31/1995 of 8 November on Prevention of Occupational Risks, which have been outsourced to them.
2. To act as an external prevention service, specialised entities shall be accredited by the labour administration, subject to approval of the public health administration in matters pertaining to health. The accreditation shall be aimed at ensuring compliance with the operational requirements referred to in the previous section.

#### **Article 18: Material and human resources of specialised entities acting as external prevention services**

1. Specialised entities acting as external prevention services shall have the necessary facilities and material and human resources to properly carry out the preventive activities which they have been outsourced, bearing in mind the type, extent and frequency of the prevention services they must provide, the type of activity carried out by the workers of the companies that have outsourced them and the location and size of the workplaces in which these services will be provided, in accordance with the terms of the implementing provisions of this Royal Decree.
2. In all cases, said entities shall:
  - a. Be accredited in the preventive specialities or disciplines of occupational medicine, safety at work, occupational hygiene, and ergonomics and applied psycho-sociology by the labour authority that is competent.
  - b. Have at least one technician with the necessary qualifications to perform high level duties, as provided for in Chapter VI, for each of the preventive specialities or disciplines referred to in the previous paragraph, except in the case of occupational medicine, for which, at least, one specialist physician in occupational medicine or with a university diploma in Occupational Medicine and one occupational ATS/DUE (Spanish acronyms equivalent to Health Technical Assistant and Registered Nurse, respectively) shall be required. They shall also have the necessary personnel with the required training to perform the basic and intermediate level duties provided for in Chapter VI, depending on the characteristics of the companies covered by the service. Experts in the fields above mentioned shall act in a coordinated manner, particularly regarding preventive work-place design, risk identification and assessment, prevention plans and workers' training plans.
  - c. Have a minimum of facilities and implementation means, both in the territorial and professional areas in which they operate, needed for testing, check-ups, measurements, analyses and assessments common in the practice of the specialties referred to above, and for carrying out basic training and dissemination activities, in accordance with the terms of the implementing provisions of this Royal Decree.
3. Without prejudice to the necessary coordination referred to in section 2 of this Article, the health activities to be implemented within the framework of the prevention service will have available the structure and the means appropriate to its specific nature and to the confidentiality of personal medical data.

#### **Article 19: Functions of specialised entities acting as prevention services**

1. Specialised entities acting as prevention services shall be able to provide the company with advice and support as required in regard to the outsourced activities, the responsibility for implementing them lying with the company itself. This shall be understood notwithstanding the specialised entities directly assuming their due share of responsibility in regard to the development and implementation of activities such as risk assessment, health surveillance or any other outsourced activity.

2. The entities shall directly assume the performance of those functions set out in Article 31.3 of Act 31/1995 of 8 November which may have been outsourced to them, and shall contribute to the effectiveness of the integration of preventive activities in all business activities and at all hierarchical levels, without prejudice to the fact that they themselves may:
  - a. Subcontract the services of other professionals or entities when necessary to carry out activities that require specialised knowledge or highly complex facilities.
  - b. Have the facilities or material resources, whether through renting or any other similar business deal, deemed necessary to perform the service correctly and within an appropriate time-limit, without prejudice to the obligation to have the minimum resources referred to in Article 18 permanently at their disposal.

## **Article 20: Outsourcing the Preventive Activity**

1. Should the employer, for lack of sufficient own resources to carry out preventive activities, have to outsource one or several external prevention services, the provision of said services shall be agreed in writing. This agreement shall provide, at least, the following information:
  - a. Identification of the specialised entity that, for that particular activity, will be acting as external prevention service.
  - b. Identification of the company that will be provided with said activity, and of the company workplaces for which this activity is contracted. In the case of companies operating under the rules of health and safety at construction sites, the scope of the agreed activities shall be explicitly extended to all the company's worksites.
  - c. Preventive specialty or specialties covered by the agreement, indicating for each of them the specific functions that will be assumed from among those listed in Article 31.3 of Act 31/1995 of 8 November, and the specific activities to be carried out for developing said functions, throughout the duration of the agreement. These actions shall be implemented in accordance with the prevention activity plan and the annual programme proposed by the service and approved by the company. Unless the activities are carried out with the company's own preventive resources and this is specified in the agreement, said agreement shall record:
    1. Where the object of the agreement is the specialty of safety at work, the commitment of the external prevention service to identify, assess and propose corrective measures, where appropriate, taking into account all existing risks of this nature within the company, including those arising from the conditions of machinery, equipment and facilities, and verifying that they receive adequate maintenance, without prejudice to the certification and inspection activities under work safety regulations, as well as those arising from the general conditions of the company workplaces, buildings and service and safety facilities.
    2. Where the object of the agreement is the specialty of industrial hygiene, the commitment of the external prevention service to identify, assess and propose corrective measures, where appropriate, taking into account all existing risks of this nature within the company, and to assess whether there is a need or not to measure, without prejudice to the fact that these measurements may or may not be included in the financial terms of the arrangement.
    3. Where the object of the arrangement is the specialty of ergonomics and applied psycho-sociology, the commitment of the external prevention service to identify, assess and propose corrective measures, where appropriate, taking into account all existing risks of this nature within the company.
    4. The commitment of the external prevention service to review the assessment of risks in those cases required by law, particularly when the health of workers has been harmed.

5. In the case of companies with worksites subject to the rules of health and safety at construction sites, the actions to be developed in accordance with the applicable regulations shall be specified.
  - d. The obligation of the prevention service to monitor and assess, at the intervals required by the existing risks, the implementation of the preventive activities arising from the assessment.
  - e. The obligation of the prevention service to include, in its annual report on the activities carried out in the contracting company, an assessment of how effectively occupational risk prevention has been integrated into the company's general management system by means of the introduction and implementation of the occupational risk prevention plan in relation to the agreed preventive activities.
  - f. The commitment of the prevention service to allocate each year the human and material resources needed to carry out the activities agreed to.
  - g. The company's commitment to inform the external prevention service of any work-related health damage.
  - h. The company's commitment to inform the external prevention service of any activities or duties carried out with other preventive resources and/or entities, in order to facilitate cooperation or coordination between them all.
  - i. The duration of the agreement.
  - j. The financial terms of the agreement, with an expressly stated list of the preventive activities or functions not included in said terms.
  - k. The obligation of the external prevention service to provide advice for the employer, the workers and their representatives and the specialised representative bodies, under the terms of the applicable regulations.
  - l. The specific preventive activities that are legally required and are not covered by the agreement.
2. Without prejudice to the terms of Article 28.2.b), specialised entities acting as prevention services shall make available to the labour and health authorities an annual report that shall include separately the companies or workplaces they have provided services for during that time, indicating in each case the nature of said services. They shall also provide the companies for which they act as prevention services with the annual report and programme referred to in Article 39 section 2.d) of the Act on Prevention of Occupational Risks, so that they can be made known to the Safety and Health Committee as provided by said Article.

#### **Article 21: Joint prevention services**

1. Joint prevention services may be set up among those companies carrying out activities simultaneously in the same workplace, building or shopping centre, provided the functioning and effectiveness of the service is guaranteed in accordance with the terms of Article 15, section 3 of this resolution.

The establishment of joint prevention services among companies of the same productive sector, or group of companies, or companies carrying out their activities in an industrial estate or limited territorial area may also be agreed upon in collective bargaining or in agreements such as those referred to in Article 83, section 3 of the Workers' Statute, or, in their absence, by a decision taken by the companies concerned.

Companies that have the legal obligation to have their internal prevention service can not form part of the joint prevention services set up by the companies in a specific sector, although they may do so if this service is set up by companies belonging to the same corporation.

2. The agreement setting up joint services, to be adopted after consultation with the workers' legal representatives in each of the companies concerned, under the terms of Article 33 of Act 31/1995 of 8 November on Prevention of Occupational Risks, shall expressly state the minimum conditions under which this prevention service must be implemented.

Indeed, in accordance with the terms of Article 39.1.a) of said Act, the terms under which this prevention service must be implemented shall also be discussed, and, where appropriate, agreed to, by each of the Safety and Health Committees of the companies concerned.

In addition, the agreement setting up the joint prevention service shall be reported in advance to the labour authority of the area where its main facilities are located if said agreement has not been decided by collective bargaining.

3. These services, whether or not they have a distinct legal personality, shall be considered as the companies' internal services and shall comprise, at least, three preventive specialities or disciplines. To be set up, these services shall have a minimum of human resources equivalent to those required for external prevention services in accordance with the provisions of this Regulation and its implementing rules. As for material resources, the reference shall be those required from external prevention services, adapted to the activity of the companies. The labour authority may make requests as to the adequate allocation of human and material resources.
4. The prevention activities of joint services shall be limited to the participating companies.
5. The joint prevention service shall make available to the labour and health authorities the information about the companies that have set it up and the degree and form of participation of each one.

#### **Article 22: Social Security's Mutual Insurance Companies for Accidents at Work and Occupational Diseases acting as prevention services**

The activities of the Social Security's Mutual Insurance Companies for Accidents at Work and Occupational Diseases as prevention services will be conducted in the same conditions as those applicable to external prevention services, but taking into account the specific regulations that are applicable to these Institutions.

Such functions are different and independent from those relating to cooperation in the management of the Social Security granted to them under the terms of Article 68 of the Consolidated Text of the General Law on Social Security, approved by Royal Legislative Decree 1/1994 of 20 June.

#### **Article 22 bis. Presence of preventive resources.**

1. In compliance with Article 32 bis of Act 31/1995 of 8 November on Prevention of Occupational Risks, the presence of preventive resources in the workplace, whatever the type of organizing such resources, shall be necessary in the following cases:
  - a. When risks may be aggravated or modified, during the process or activity, owing to the concurrence of various operations being carried out in succession or simultaneously and making it necessary to monitor whether the work methods are being correctly applied.
  - b. When the following hazardous or especially risky activities or processes are carried out:
    1. Work involving a particularly high risk of falling from a height, owing to the particular nature of the activity carried out, the processes used, or the work environment.
    2. Work involving a risk of burial or engulfment.
    3. Activities in which the machinery that is used does not have a CE declaration of conformity because at the time when it was placed on the market such declaration was not mandatory and that are of the same type as those for which the legislation on the marketing

of machinery requires the intervention of a notified body in the certification process, when the protection of the worker is not sufficiently guaranteed, even when the regulatory measures have been adopted.

4. Work in confined spaces. For these purposes, 'confined space' means a place with limited entering and exiting openings and unfavourable natural ventilation, in which toxic or inflammable pollutants may accumulate or in which there may be a lack of oxygen, and that is not intended to be continuously occupied by workers.
5. Work involving a risk of drowning, except as provided under section 8.a) of this Article, referred to underwater work with diving equipment.
  - c. When their presence is required by the Labour and Social Security Inspectorate, if circumstances so require, due to working conditions detected.
2. In the case referred to in paragraph a) of the previous section, the occupational risk assessment, whether the first or subsequent ones, shall identify those risks that may be aggravated or modified by the concurrence of consecutive or simultaneous operations.

In the cases referred to in paragraph b) of the previous section, the occupational risk assessment shall identify jobs or tasks inherent in the job linked to dangerous activities or processes or involving special risks.

In both cases, the way of ensuring the presence of prevention resources on the premises shall be described in the prevention activity planning referred to in Articles 8 and 9 of this Royal Decree.

In the case referred to in paragraph c) of the previous section, without prejudice to compliance with the requirements of the Labour and Social Security Inspectorate, the employer shall immediately review the workplace risk assessment should this not include the risk situations that have been detected, and modify the prevention activity planning when this does not include the need for the presence of prevention resources on the premises.

3. This presence may be ensured by any of the persons referred to in Article 32 bis, sections 2 and 4 of Act 31/1995 of 8 November on Prevention of Occupational Risks, the employer being obliged to provide his/her workers with the necessary information to enable them to identify such persons.

Those people whose presence is required on the premises shall be allocated a working space in which they will be able to perform their own functions, that being a safe place that does not origin additional risk factors to them or any other worker of the company, and they shall remain in the workplace as long as the situation that required their presence persists.

4. The presence of such persons on the working premises is an additional preventive measure whose aim is to monitor that preventive activities are carried out in relation to the risks arising from the situation that determines their need in order to ensure adequate control of said risks.

This monitoring shall include verification of the effectiveness of the planned preventive activities and the adequacy of these activities in relation to the risks which they aim to prevent or to unforeseen risks arising from the situation that determines the need for the presence of preventive resources.

5. Where, as a result of monitoring, poor compliance with the preventive activities is observed, those persons whose presence is required shall:
  - a. Give the necessary instructions for immediate and correct compliance with preventive activities.
  - b. Make any such circumstances known to the employer so that he/she adopts the necessary measures to address deficiencies, if they had not yet been addressed.

6. Where, as a result of monitoring, an absence, a shortage or a lack of suitable preventive measures is observed, those whose presence is required shall make these circumstances known to the employer, who shall immediately adopt the necessary measures to address said deficiencies and modify the planning of preventive activities and, where appropriate, the occupational risk assessment.
7. The presence of preventive resources in the workplace may also be used by the employer in cases other than those provided for in Article 32 bis of Act 31/1995 of 8 November on Prevention of Occupational Risks, insofar as it is compatible with the fulfilment of their functions.
8. The terms of this Article are without prejudice to the measures under the specific prevention provisions related to particular activities, processes, operations, jobs, equipment or products to which the terms of those resolutions shall apply, as is the case, among others, of the following activities or jobs:
  - a. Underwater work with diving equipment.
  - b. Work involving exposure to ionizing radiation.
  - c. Work carried out in caissons with a compressed-air atmosphere.
  - d. Work involving a risk of explosion due to the presence of explosive atmospheres.
  - e. Activities in which explosives are handled, transported or used, including pyrotechnic articles and other objects or instruments containing explosives.
  - f. Work involving electrical risks.
9. Where several concurrent companies carry out in the workplace the concurrent operations referred to in section 1.a) of this Article, or dangerous or particularly risky activities or processes, as referred to in section 1.b) above, the company or companies carrying out said operations or activities shall appoint the preventive resources that are to be present in the workplace, and said preventive resources shall cooperate with each other and with the other preventive resources and the person or persons responsible for coordinating the preventive activities of the employer who is the owner or in charge of the workplace.
10. The application of the terms of this Article shall not exempt the employer from complying with the other obligations in relation to his or her duty to protect his or her workers, as provided for in Article 14 of Act 31/1995 of 8 November on Prevention of Occupational Risks.

## **CHAPTER IV Accreditation of Specialized Enterprises as External Prevention Services**

### **Article 23: Application for Accreditation**

Specialised entities wishing to be accredited as prevention services shall apply to the competent labour authority in the place where their main facilities are located, and they shall state the following:

- a. Name or company name, tax ID number and Social Security contribution account code.
- b. Aspects of the prevention activity that they wish to carry out, specifying the types of activity that they are able to implement.
- c. Territorial and professional area in which they intend to operate and the forecast number of companies and number of workers to which they have the capacity to offer their prevention services, depending on the planned human and material resources.
- d. Forecast workforce requirements to carry out the preventive activities, duly justified, which shall be effective the moment it shall start providing services, indicating their professional qualifications and time dedication, and specifying the territorial area in which they will offer their services.
- e. Information on facilities, instrumental means and their respective locations.

- f. The commitment to take out an insurance policy or an equivalent financial guarantee to cover liabilities for a minimum of 1,750,000 Euros, which shall become effective when the entity begins to provide services. The amount of cover shall be adjusted annually in line with the Consumer Price Index, without said amount constituting the limit of the service's liability.
- g. Contracts or agreements to be established with other entities, if appropriate, to carry out activities that require specialised knowledge or highly complex facilities.

#### **Article 24: Competent authority**

1. The competent labour authority regarding the accreditation applications submitted by those specialised entities wishing to act as prevention services is the competent authority of Autonomous Community or Autonomous City where the entity's main facilities are located. Said labour authority shall also have the power to revoke this accreditation, where appropriate.
2. The accreditation granted shall be sole and valid throughout Spain, in accordance with the procedures regulated hereinafter.

#### **Article 25: Accreditation Process**

1. After receiving the application referred to in Article 23, the labour authority shall send a copy to the competent health authority of the place where the main facilities of the specialised entity are located, for the purposes provided for in Article 31, Section 5 of Act 31/1995 of 8 November on Prevention of Occupational Risks. This health authority shall notify the labour authority its decision on the approval of the project in terms of health requirements.
2. At the same time, the competent labour authority shall request a report from the Labour and Social Security Inspectorate and the Autonomous Community technical bodies specialised in preventive matters or, in the case of the Autonomous Cities of Ceuta and Melilla, the National Institute for Safety and Hygiene at Work, and any other report that may be deemed necessary on any of the issues not provided for in the previous section.
3. The competent labour authority shall request a compulsory report from all the Autonomous Communities in which the entity has indicated that it intends to carry out its activities. The competent health authority shall do likewise with regard to the health authorities concerned and in relation to the verification of compliance with health requirements.

The report from the concerned labour authorities shall address the adequacy of the material and human resources that the applicant's will have, and shall contain their decision on the admissibility or inadmissibility of the accreditation.

4. After receiving the application, the requested labour authorities shall, in turn, request a report from the Labour and Social Security Inspectorate and its technical territorial bodies specialised in occupational health and safety matters, and any other report that may be deemed necessary.
5. Based on the decision of the health authority and the reports issued, the labour authority shall, within three months of receipt of the application at the registry of the responsible administrative body, issue and notify its decision to either accredit the entity or reject its application for accreditation. This time limit shall be extended to six months in the case referred to in Section 3.

Failing to issue an express decision within this time limit, the application shall be deemed to be rejected, by administrative silence, in accordance with Article 31.6 of Act 31/1995 of 8 November on Prevention of Occupational Risks.

6. A positive decision by the competent labour authority shall apply when compliance with all conditions contained in Article 23 has been verified.

This positive decision, which shall specify the areas of activity of the specialised entity, shall be notified to the labour authorities concerned, and such data shall be recorded in the Register referred to in Article 28.

7. An appeal against an express or implied decision of the labour authority may be lodged with the appropriate next higher level of authority within one month.

#### **Article 26: Continuation of the operational requirements.**

1. The specialised entities shall comply, at all times, with the requirements to act as prevention services established in this Royal Decree and its implementing provisions.

To ensure compliance with this obligation, the specialised entities shall notify the competent labour authority of any change affecting said operational requirements.

2. The labour and health authorities may check, within the scope of their powers, that the requirements for carrying out the activities of the service are being met, notifying the labour authority that granted the accreditation of any deficiencies found during these checks.
3. If, as a result of the checks carried out, either directly or through the communications referred to in the previous paragraph, the labour authority that granted the accreditation finds that the requirements referred to in the previous paragraph are not being complied with, it may totally or partially revoke the accreditation previously granted in accordance with the procedure specified in Article 27. This revocation or partial suspension shall be deemed to refer only to the territorial scope of the specialised entity where deficiencies were found.
4. Furthermore, accreditation may be revoked by the competent labour authority, as a result of a penalty for a serious or very serious infringement by the specialised entities acting as external prevention services, in accordance with Article 40.2 of the Act on Social Order Infringements and Sanctions in the consolidated text approved by Royal Legislative Decree 5/2000 of 4 August. In this case, the revocation proceedings shall begin only after a firm administrative decision verifying the existence of a serious or very serious infringement.

#### **Article 27: Revoking accreditation.**

1. The competent labour authority shall start the revocation proceedings by means of an agreement, which shall be notified to the concerned entity and which shall contain the proven facts and the irregularities found or the testimony of the firm decision imposing a penalty for a serious or very serious infringement by the specialised entities acting as external prevention services, in accordance with the Article 40.2 of the Act on Social Order Infringements and Penalties in the consolidated text approved by Royal Legislative Decree 5/2000 of 4 August.
2. Preliminary verifications before opening proceedings on the continuation of the operational requirements to be met by the external prevention service may be started *ex officio* by the labour or health authorities or as a result of reports issued by the company's bodies of participation and representation of workers' specialized in occupational risk prevention
3. Should the authority carrying out these verifications be other than the labour authority that accredited the external prevention service, it shall submit to the latter a report-proposal specifying the facts established and the irregularities detected.
4. Where appropriate, the competent labour authority may request the labour and health authorities in the various territorial areas of action of the specialised entity to submit any reports it may consider necessary, which shall have to be submitted within 15 days.
5. After the preliminary verifications and the required reports, the competent labour authority shall notify the specialised entity of the agreement referred to in Section 1 and give it fifteen days to object.

6. If, after the objection stage, new actions are added to the case, the specialised entity shall be heard again so that it can formulate new objections, in response to the proceedings, within a term of ten days, following which the case will be ready for a decision.
7. The decision will be issued not later than six months from the date when it was agreed to open the case for revocation in accordance with section 1 and shall state one of the following:
  - a. The accreditation is maintained.
  - b. The accreditation is totally or partially suspended where the case is opened owing to the circumstance referred to in section 3 of the previous Article.
  - c. The accreditation is definitely revoked where the case is due to the concurrence of the circumstance referred to in section 4 of the previous Article.

In the case of paragraph b), the decision shall fix the period within which the entity is to meet the conditions and requirements in order to restart its activities and expressly warn that, otherwise, the accreditation shall be finally revoked. Should the specialised entity notify the competent labour authority of its compliance with said conditions or requirements within the period fixed in the decision, the competent labour authority shall, after carrying out the necessary verifications, issue a new decision within three months at the latest removing the suspension agreed on or definitely revoking the accreditation.

8. The decision shall be notified to the specialised entity, the other health and labour authorities involved and the Register referred to in Article 28 in which the revocation or suspension of the accreditation shall be recorded, as appropriate, under the appropriate entry.
9. If no decision is issued six months after the date on which the opening of the case for revocation referred to in section 1 was agreed on, without computing any interruptions attributable to the entity, the case shall expire and the proceedings shall be closed, proof of which shall be issued at the request of the interested party.
10. Similarly, if no express decision has been issued within three months from the date on which the specialised entity notified the labour authority of its compliance with the conditions and requirements established in the decision suspending the accreditation, the proceedings shall expire and the decision stating this shall order the closure of the proceedings with the effects referred to in Article 92 of Act 30/1992 of 26 November on Legal Regulations for the Public Administrations and the Common Administrative Procedure.
11. An appeal against the decisions of the labour authority may be lodged with the appropriate higher body in the hierarchy within the periods fixed in Article 115 of Act 30/1992 of 26 November.

#### **Article 28: Register**

1. For each of the competent bodies of the Autonomous Communities or of the General State Administration, in the case of the Autonomous Cities of Ceuta and Melilla, a register shall be established in which shall be entered the specialised entities accredited as prevention services, as well as the individuals or specialised bodies authorised to carry out audits or evaluations of prevention systems in accordance with the terms of chapter V of this resolution.
2. Regardless of the competent labour authority that issued the accreditation, registers shall be configured so that:
  - a. Citizens can look up specialised entities accredited as external prevention services or as auditing bodies.
  - b. Specialised entities can meet their obligations to provide data on their compliance with the operational requirements to the competent labour authorities.

- c. The labour authorities, health authorities, Labour and Social Security Inspectorate, the National Institute for Safety and Hygiene at Work as well as the territorial technical occupational safety and health bodies can have access to all data available on the specialised entities accredited as external prevention services or auditing bodies, regardless of the authority that issued the accreditation.
3. The bodies referred to in section 1 shall send to the Ministry of Labour and Immigration's Directorate General for Labour a copy of every entry made into their respective registers within eight working days.
4. The information contained in the registers of the competent authorities shall be incorporated into a database that shall be managed by the Ministry of Labour and Immigration's Directorate General for Labour.
- The configuration of this database shall enable the registers of the Autonomous Communities to comply with the functions assigned to them in section 2.
5. The mutual relations between the labour authorities shall be governed by the principle of cooperation and in accordance with that established in Article 4 of Act 30/1992 of 26 November on Legal Regulations for the Public Administrations and the Common Administrative Procedure.
6. Data contained in Registers shall be managed in accordance with the terms of Organic Act 15/1999 of 13 December on the Protection of Personal Data. Personal data may not be used for purposes other than those for which they were collected.

## CHAPTER V Audits

### Article 29: Scope of Application

1. Audits or external assessments will be obligatory in the terms and conditions established in this Chapter when, as a result of the assessment of risks, companies are obliged to carry out preventive activities to avoid or reduce work-related risks.
2. The companies that have not outsourced the prevention services to a specialised entity shall have their prevention system audited or externally evaluated.

Similarly, companies that carry out preventive actions with internal and external resources shall have their prevention system audited or externally evaluated in accordance with the terms of Article 31 bis of this Royal Decree

3. For the purposes of the previous section, companies with up to 50 employees whose activities are not included in Annex I, which carry out preventive actions with own resources and whose preventive systems are manifestly efficient without their needing to be audited due to their limited number of employees and the scarce complexity of their preventive actions, shall be deemed to have complied with the obligation of an audit after filling in and submitting to the labour authority a notification of the concurrence of the conditions that make it unnecessary to conduct an audit according to the model set forth in Annex II, provided the labour authority has not applied the provisions under section 4 of this Article.

The labour authority shall record and organise all notifications according to the activities carried out by the companies and provide global information on the companies concerned to the institutional participatory bodies in the field of safety and health.

4. Taking into account the notification established in the foregoing point, the documentation established in Article 7 and the company's individual situation, and in the light of data on the diseases and injuries rate of the company or sector, information or other circumstances that reveal the danger of the activities carried out or the prevention system's unsuitability, the Labour Authority, subject to a report of the Labour and Social Security Inspectorate and, where applicable, the technical bodies responsible for prevention in the Autonomous Communities, may require an audit to be carried out on the companies referred to in the aforementioned point, in accordance with the provisions set forth in point 2.

### **Article 30. Concept, content, methodology and time limit**

1. The audit is a management tool that seeks to give a true and fair view of the company's occupational risk prevention system, by evaluating its effectiveness and detecting those deficiencies that may lead to non-compliance with the current regulations to allow making decisions aimed at perfecting and improving it.
2. In order to give effect to what has been stated in the previous section, the audit shall undertake a systematic, documented and objective study of the prevention system, containing the following:
  - a. A check on how the initial and periodic risk assessment was carried out, a study of its results and a verification of said results in case of doubt.
  - b. A check on the extent to which the type and planning of preventive activities match the terms of the general regulations, as well as the applicable regulations on specific risks, bearing in mind the results of the assessment.
  - c. A study of the matching between the procedures and methods required to carry out the necessary preventive activities and the employer's resources, whether own or outsourced, also bearing in mind the way in which they are organized or coordinated, where appropriate.
  - d. On the basis of the above, an appraisal of the integration of prevention into the company's general management system, both in all its activities and hierarchical levels, through the establishment and implementation of the Occupational Risk Prevention Plan and the assessment of the effectiveness of the prevention system to prevent, identify, assess, correct and monitor occupational risk at all the stages of the company's activities.

For these purposes, the extent to which prevention has been incorporated into the company's management, into the modifications to equipment, products and company organization, in the maintenance of facilities or equipment and in the supervision of potentially hazardous activities, among other aspects, shall be weighed up.

3. The audit shall be carried out in accordance with the technical specifications that have been or may be established and shall take into account the information received from the workers. Whatever the procedure used, the methodology or the minimum reference procedure shall include at least:
  - e. A study of the documentation concerning the occupational risk prevention plan, the assessment of risks, the planning of preventive activities and any other information on the company's organization and activities that may be necessary to carry out the audit.
  - f. A field analysis aimed to check that the documentation referred to in the previous paragraph reflects faithfully and accurately the real situation of the company as far as prevention is concerned. This analysis, which may be carried out using sampling techniques when necessary, shall include workplace visits.
  - g. An assessment as to whether the company's prevention system complies with occupational risk prevention regulations.
  - h. Conclusions on the effectiveness of the company's occupational risk prevention system.

4. The first audit of the company's prevention system shall be carried out within twelve months after the preventive activities' planning becomes available.

The audit shall be repeated every four years, except for activities included in Annex I of this Royal Decree, in which case it shall be carried out every two years. These revision periods will be extended two more years in those cases in which the company's preventive organisation model has been agreed with the specialised representatives of the company's workers. In any case, it shall be repeated whenever required by the labour authority, on the basis of a report from the Labour and Social Security Inspectorate and, where appropriate, from the technical prevention bodies of the Autonomous Communities, in the light of diseases and injuries data or any other circumstances indicating that the results of the last audit need to be reviewed.

5. In accordance with Article 18.2 of Act 31/1995 of 8 November on Prevention of Occupational Risks, the employer shall consult the workers and allow them to participate in the audit as provided by Chapter V of said Act.

In particular, the auditor shall request information from the workers' representatives about the different items which, as provided by section 3, make up the content of the audit.

#### **Article 31. Audit report**

1. The results of the audit shall be the subject of a report that the company which underwent the audit shall make available to the competent labour authority and the workers' representatives.
2. The audit report must include the following items:
  - a. Identification of the auditing person or body and the audit team.
  - b. Identification of the company that underwent the audit.
  - c. Aim and scope of the audit.
  - d. Date when the audit report is issued.
  - e. Documentation on which the audit is based, including information received from workers' representatives, which shall be included in the report.
  - f. A summary description of the methodology used to carry out the audit and, if appropriate, identification of the technical regulations used.
  - g. A description of the different items that were audited and audit results for each one of them.
  - h. Conclusions on the effectiveness of the prevention system and the employer's compliance with the obligations laid down by the regulations on occupational risk prevention.
  - i. Signature of the person responsible of the person or audit body.
3. The contents of the audit report shall reflect faithfully the real verified situation of the company any alteration or falsification of the report being prohibited.
4. The company shall adopt the necessary measures to remedy any deficiencies shown by the results of the audit and which indicate non-compliance with the regulations on occupational risk prevention.

#### **Article 31 bis. Audit of the prevention system whose preventive actions are carried out with internal and external resources**

1. The audit of the prevention system of companies whose preventive actions are carried out with internal and external resources shall assess all preventive actions carried out by the employer with own resources and their integration into the company's general management system, bearing in mind the implications for

this system of a mixed form of organization, as well as the way in which internal and external resources are coordinated under the occupational risk prevention plan.

2. The audit contents, methodology and report shall match the object set forth in the previous paragraph.

### **Article 32: Requirements**

1. The audit must be carried out by natural or legal persons that, in addition, are in possession of sufficient knowledge on the materials and technical aspects of the subject audited and have adequate resources for the purpose.
2. Natural or legal persons carrying out the audit of a company's prevention system shall not have any business, financial or other type of link with this company, other than those related to their acting as auditors that may affect their independence or influence the results of their activities.

Similarly, said persons shall not carry out for that company or any other company any coordination activities of preventive actions, nor any activities as a specialised entity to act as a prevention service, nor maintain with the latter any business, financial or other type of link, except for the following:

1. An agreement with an auditing person or body with one or more external prevention services to carry out preventive activities in their own company.
2. A contract to carry out the audit of the prevention system of an employer whose company carries out external prevention services.
3. When the complexity of the verifications to be carried out makes it necessary, the persons or entities commissioned to carry out the audit may use the services of other professionals that have the know-how, resources and installations needed to carry them out.

### **Article 33: Authorisation**

1. Specialised persons or bodies wishing to audit prevention systems shall need to be authorised by the competent labour authority in the place where their main facilities are located, after submitting an application to said authority, which shall contain the requirements laid down in Article 23 a), c), d), e) and g).
2. The labour authority, after receiving any reports which it may deem necessary, shall make a decision to authorise or reject the application within three months from the date on which the application was lodged in the Register of the competent administrative body. If no decision has been issued by the end of this period, the application may be deemed to have been rejected.
3. The terms of Articles 24 and 25 regarding accreditation as well as those of Article 26 regarding the continuation of the conditions for authorisation and for the cancellation, where appropriate, of previously granted authorisations, shall be applicable to audit authorisation.

### **Article 33 bis. Voluntary audits.**

1. Without prejudice to compliance with the terms of this chapter, companies may voluntarily subject their prevention systems to an audit or an external evaluation so that decisions may be taken to perfect and improve them.
2. Voluntary audits may be carried out when an external audit is not legally required or, when being legally required, these are made more frequently or with a broader scope than those set forth in this Chapter.
3. Voluntary audits of a company prevention system that are in line with the terms of sections 2, 3 and 5 of Article 30, Article 31, 31 bis, Article 32 and Article 33 of this Royal Decree shall be taken into account in the programmes referred to in Article 5.3 of Act 31/1995 of 8 November on Prevention of Occupational Risks.

## CHAPTER VI Functions and Qualification Levels

### Article 34: Classification of Functions

In order to establish the necessary capacities and abilities for assessing risks and conducting the preventive activities, the functions to be performed will be classified into the following groups:

- a. Basic level functions
- b. Intermediate level functions
- c. Higher level functions, corresponding to the preventive specialities and disciplines of occupational medicine, safety at work, industrial hygiene and ergonomics and applied psychosociology.

The functions described in the following articles will act as a guideline for the various training projects and programmes developed for each level.

These projects and programmes must conform to the general criteria and minimum training content established for each level in Annexes III to VI.

### Article 35: Basic Level Functions

1. The basic level of the preventive activity comprises the following functions:
  - a. To promote safe conducts and the correct use of work and protection equipment and to foster the interest and co-operation of workers in an **integrated** preventive action.
  - b. To promote, in particular, basic preventive actions, such as orderliness, cleanliness, signs and general maintenance, and to carry out their follow-up and control.
  - c. To carry out elementary risk assessments and, where applicable, to establish preventive measures of the same level that are compatible with their training grade.
  - d. To collaborate in the assessment and control of the company's general and specific risks, making visits for this purpose, handling complaints and suggestions, recording data, and carrying out as many similar functions as may be necessary.
  - e. To act in the event of emergencies and first aid, managing the first interventions for the purpose.
  - f. To co-operate with the prevention services, where appropriate.
2. In order to perform the functions referred to in the previous point, it will be necessary:
  - a. To be in possession of minimum training, with the content specified in the programme referred to in Annex IV and which will have a duration of not less than 50 hours, in the case of companies that conduct any of the activities included in Annex I, or 30 hours in all other cases and with a distribution of the timetable that is appropriate to each training project, respecting that established in points A y B, respectively, of the aforementioned Annex IV, or
  - b. To have professional or academic training that qualifies them to hold equivalent or similar professional responsibilities to those required by the activities referred to in the previous point, or
  - c. To demonstrate not less than 2 years' experience in a company, institution or Public Administration involving the holding of equivalent or similar levels of professional responsibility to those required by the activities referred to in the previous point.

In the cases contemplated in paragraphs b) and c), the pre-existing qualification levels must progressively be improved in those cases in which the preventive activities to be carried out make this necessary, by means of basic level training within a framework of ongoing training.

3. The minimum training referred to in paragraph a) of the previous point will be justified by means of a certificate of specific training on the prevention of risks at work, issued by a prevention service or public or private enterprise with the capacity to conduct specific training activities on this subject.

### **Article 36: Intermediate Level Functions**

1. The functions that correspond to the intermediate level are as follows:
  - a. To promote, in general, prevention within the company **and to promote the integration of the prevention in it.**
  - b. To carry out risk assessments, with the exception of those specifically reserved for the higher level.
  - c. To propose measures for the control and reduction of risks or, in light of the results of the assessment, to raise the need for applying the higher level.
  - d. To carry out workers' informative and basic training activities
  - e. To monitor compliance with the risk control and reduction programme and to personally carry out the working condition control activities that have been assigned to them.
  - f. To participate in the planning of the preventive activity and to direct the actions to be implemented in the event of emergencies and first aid.
  - g. To collaborate with the prevention services, when applicable.
  - h. Any other functions that may be assigned to it as auxiliary, complementary to or in collaboration with the higher level.
2. In order to perform the functions referred to in the previous point, it will be necessary to be in possession of minimum training with the content specified in the programme referred to in Annex V and which will have a duration of not less than 300 hours and a distribution of the timetable that is adequate to each training project, while respecting what is set forth in said Annex.

### **Article 37: Higher Level Functions**

1. The functions that correspond to the higher level are as follows:
  - a. The functions indicated in point 1 of the previous article, with the exception of those indicated under the letter h).
  - b. The performance of those risk assessments that require:
    1. The establishment of a measuring strategy to ensure that the results obtained are really indicative of the situation being assessed, or
    2. An interpretation or non-mechanical application of the assessment criteria.
  - c. Training and information of a general nature, at all levels, and on subjects that are specific to its area of specialization.
  - d. Planning the preventive action to be implemented in those situations in which risk control and reduction involves the carrying out of different activities, requiring the intervention of different specialists.
  - e. The monitoring and control of workers' health, in the terms and conditions indicated in point 3 of this article.
2. **To carry out the duties listed in the previous section, it shall be necessary to have an official university degree and a minimum training certified by a university with the contents detailed in the programme referred to in Annex VI, of a duration of no less than six hundred hours and a timetable that is adequate to each training project, while respecting what is set forth in said Annex.**
3. The workers' health monitoring and control functions referred to in letter e) of point 1 will be performed by health professionals with technical competence, training and capacity justified in accordance with valid legislation and as established in the following paragraphs:
  - a. Those prevention services that perform workers' health monitoring and control functions must be have a doctor specialised in Occupational Medicine or with a diploma in Enterprises' Medicine, and an Enterprises' nurse, without prejudice to the participation of other health professionals with proven technical competence, training and capacity.
  - b. In terms of health monitoring, the health activity must encompass, in the conditions established by Article 22 of Act 31/1995 of 8 November on Prevention of Occupational Risks :
    1. An initial assessment of workers' health after being hired or after being assigned specific tasks involving health risks.

2. A health assessment of those workers who start work again after a long absence for health reasons, for the purpose of discovering its possible professional origins and recommending appropriate action to protect the workers.
  3. Monitoring of health at periodic intervals.
- c. Monitoring of health must be subject to specific protocols or other methods with respect to the risk factors to which the worker is exposed. The Ministry of Health and Consumption and the Autonomous Communities, after having heard the competent scientific institutions, and in accordance with the provisions of the General Health Law on the subject of the participation of social agents, will establish the specific content and frequency in each case.

At any event, medical examinations will include a medical-professional record, in which, in addition to anamnesis, clinical examination and biological control data and complementary studies depending on the risks inherent in the work, a detailed description of the post will be provided, the length of time in it, the risks detected in the analysis of working conditions and the prevention measures adopted.

It must also contain a description of the previous posts held, the risks that were present in them and the length of time for which each one was occupied, if available.

- d. The prevention service's health care personnel must know the diseases that occur amongst the workers and their absences due to ill-health, for the sole purpose of being able to identify any relationship between the cause of the disease or absence and the risks to health that may be present in the work place.
- e. In those cases in which the nature of the risks inherent in the work make it necessary, the workers' right to the periodic monitoring of their state of health must be prolonged beyond the termination of their labour relationship through the National Health System.
- f. The prevention service's health care personnel must analyze the results of the monitoring of the workers' health and assessment of risks, using epidemiological criteria, and will collaborate with the service's other members in order to investigate and analyze possible relationships between exposure to occupational risks and damage to health, proposing measures aimed at improving the working conditions and environment.
- g. The prevention service's health care personnel must study and evaluate, specially, the risks that could affect pregnant women and new mothers, minors and workers who are especially sensitive to certain risks, proposing adequate preventive measures.
- h. The prevention service's health care personnel at the work centre, if applicable, must provide first aid care and attention in emergencies to the victims of accidents or mishaps in the work place.

## **CHAPTER VII Collaboration with the National Health System**

### **Article 38: Collaboration with the National Health System**

1. As established in Article 10 of Act 31/1995 of 8 November on Prevention of Occupational Risks and article 21 of Law 14/86 on General Health, the prevention service will collaborate with primary and specialised health care services in the diagnosis, treatment and rehabilitation of work related diseases and with the competent Health Authorities in the health at work planned activities, with the units responsible for Public Health, as defined by the General Health Law, being in charge of co-ordination between the prevention services that act in this area and the Health System. This co-ordination will be developed by the Autonomous Communities within the scope of their authority.
2. The prevention service will collaborate in health and epidemiological campaigns organized by the Public Administrations responsible for health.

### **Article 39: Health Information**

1. The prevention service will collaborate with the Health Authorities to provide the Information Health System with data relating to Health at Work. The minimum data required for such information system will be established by the Ministry of Health and Consumption, subject to an agreement with the competent bodies of the Autonomous Communities, under the aegis of the National Health System's Inter-Territorial Council. Autonomous Communities, within the scope of their respective authority, may develop the aforementioned health information system.
2. The prevention service's health personnel will carry out epidemiological surveillance, implementing whatever actions may be necessary to maintain the Health at Work Health Information System within the scope of its field of activities.
3. Should the data on health or any other type of personal data be automated, it must be processed in accordance with Basic Law 5/1992 of 29th October.

### **First Additional Disposition: Basic Character**

1. This Regulation constitutes labour legislation, passed by virtue of Article 149.1.7 of the Spanish Constitution.
2. In connection with civil citizens in the employ of Public Administrations with an administrative or statutory relationship, this Regulation will be applicable in the following terms and conditions:
  - a) The Articles listed below are basic regulations within the meaning of Article 149.1.18<sup>a</sup> of the Constitution: 1, except for the references to Chapter V and Article 36 of Act 31/1995 of 8 November on Prevention of Occupational Risks, concerning the Health and Safety Committee, and Chapter III of this Royal Decree; 2; 3; 4, sections 1, 2 and 3, except for the reference to Chapter VI; 5; 6; 7; 8; 9; 10; 12, sections 1 and 2, except for paragraph a); 13, section 1, except for the reference to chapter VI, and 2; 15, sections 1, 2 and paragraphs one, 3 and 4; 16, section 2, except for paragraph two; 20, Article 22 bis, tenth additional provision, eleventh additional provision, twelfth additional provision.
  - b) Within the scope of Autonomous Communities and local bodies, the functions attributed to the Labour Authorities and the Labour and Social Security Inspectorate by this Regulation may be attributed to different bodies.

### **Second Additional Disposition: Integration in Prevention Services**

As provided for in letter d) of the Single Annulment Disposition of the Prevention of Risks at Work Act, personnel that belong to a company's medical services on the date such Law enters into force shall be integrated into that company's prevention services, once they have been set up, without prejudice to continuing to carry out those functions that were assigned to them and that differ from those specific to the prevention service.

### **Third Additional Disposition: Maintenance of the Preventive Activity**

1. The application of this Royal Decree will not affect the continuation of the health care activity that was being carried out in companies by virtue of the regulations governing company medical services that are repealed and their provisions for application and development, even when such companies do not set up prevention services.
2. Neither will the application of this Royal Decree affect the maintenance of the preventive activity carried out by the company's health and safety at work services in existence on the date Prevention of Occupational Risks Act is published, even when the circumstances envisaged in article 14 thereof do not exist.

#### **Fourth Additional Disposition: Application to Public Administrations**

1. Within the scope of the Public Administrations, the organization of the necessary resources for the development of preventive activities and the definition of the functions and qualification levels of the personnel that implement them shall be carried out in the terms and conditions regulated in the specific regulation that will be issued for the purpose, in accordance with the provisions of [Article 31](#), point 1 and the Act on Prevention of Occupational Risks and in the First Additional Disposition of this Regulation, subject to consultation with the most representative trade union organizations, in the terms and conditions established in Law 7/1990, of 19th July, on collective bargaining and participation in the establishment of the working conditions of civil servants.

In the absence of the aforementioned specific regulation, the provisions of this Regulation shall apply.

2. The obligations on the subject of audits contained in [Chapter V](#) of this Regulation will not apply to the Public Administrations.

The specific rules set forth in the previous point must establish adequate instruments of control for the purpose.

3. References to collective bargaining and agreements in Article 83, point 3, of the Workers' Statute contained in this Regulation shall be understood to refer, in the case of the administrative or statutory relations of personnel in the employ of the Public Administrations, to the agreements and covenants that are established in the terms and conditions set forth in Law 7/1990, of 19th July, on collective bargaining and participation in the establishment of the working conditions of civil servants.

#### **Fifth additional provision. Validation of duties and certificate of equivalent training**

1. Whoever, at the date when the Act on Prevention of Occupational Risks was published, was performing the duties described in [Articles 36 and 37](#) of this regulation and did not have the minimum training required in accordance with said provisions may continue to perform those duties at the company or body where he or she had been performing them, provided the following requirements are met:
  - a. An experience of no less than three years since 1985, carrying out the duties under [Article 36](#) of this regulation, in a company, institution or Public Administration. In the case of duties under [Article 37](#) an experience of one year shall be required from those who have a university degree or of five years from those who do not have one.
  - b. Proof of specific training in prevention of no less than one hundred hours, including training received and taught, at a reputable public or private organisation. The preceding paragraph shall not apply to healthcare personnel, who shall continue to be governed by their own specific regulations.
2. During 1998, professionals who, under the preceding section, had been performing the duties listed in [Articles 36 or 37](#) of this regulation at the date when the Act on Prevention of Occupational Risks was published, may be accredited by the competent labour authority of the place where the applicant is established, and shall be granted the corresponding certificate of equivalent training that will authorise them to perform the duties corresponding to this training, upon verification of compliance with the requirements established in this section.

In addition, during 1998, those professionals who, on the basis of the knowledge acquired and professional experience prior to the date when the Act on Prevention of Occupational Risks was published, when duly certified, have the necessary qualifications to perform intermediate or advanced level duties in any of the specialities of safety at work, industrial hygiene and ergonomics and applied psycho-sociology, may opt to receive this accreditation.

In both cases, in order to obtain the requested accreditation certificate it shall be necessary, applicants shall meet, at least and without prejudice section 3, the following requirements:

- a. An experience of no less than three years since 1985 in carrying out the intermediate or advanced level duties described in Articles 36 and 37, respectively, of Royal Decree 39/1997 of 17 January, to obtain the accreditation for the corresponding level.
  - b. To provide proof of specific training in prevention of no less than one hundred hours, including training received and taught, in a reputable public or private organisation, and
  - c. To have a first or second cycle university diploma if applying for advanced level accreditation.
3. In order to issue the certificate referred to in the previous section, the competent labour authority shall verify that the conditions required for the accreditation requested are fulfilled:
- a. By evaluating the documentary evidence of any diploma held by the applicant, and of the training programmes of attended courses which, within the limits referred to in the previous section, shall include the essential contents described in Annexes V or VI of this Royal Decree, as appropriate. This documentation shall be provided by the applicant, and shall accredit that he or she has satisfactorily passed said courses at a training institution of recognised credibility and reputation within its field.
  - b. By assessing and verifying the applicant's experience, which shall be appropriate to the functions proper to each level and, also, to the speciality that is to be accredited in the case of the advanced level, including any courses taught where appropriate, accredited by those institutions or companies where the applicant may have provided services; and
  - c. By verifying that the applicant has the necessary knowledge about those aspects that are not sufficiently proven under the terms of paragraphs a) and b) above, which complete the requirements under Annexes V or VI of this Royal Decree, by having him or her take and pass any necessary theoretical and practical tests in order to determine whether he or she has the skills and aptitudes required to perform the functions under Articles 36 or 37.

#### **Sixth Additional Disposition: Medical Examination of Workers Prior to Going to Sea**

In the case of the maritime-fishing sector, the provisions on the subject of training, information, education and medical examinations prior to going to sea, established in Royal Decree 1414/1981 of 3rd July, by virtue of which the Navy Social Institute is restructured, will continue to remain in force.

#### **Seventh Additional Disposition: Collective Bargaining**

In collective bargaining or the agreements referred to in Article 83, point 3, of the Workers' Statute, criteria may be drafted for establishing the human and material resources of internal prevention services, the number of workers appointed by the employer to carry out such prevention activities, if applicable, and the time and resources available to them for carrying out their activity, in accordance with the company's size, the risks to which the workers are exposed and their distribution within the company in addition to the planning of the preventive activity and training on the subject of prevention of the workers and the prevention representatives.

#### **Eighth Additional Disposition: Certification and Authorization Criteria**

The National Commission for Health & Safety at Work will be informed of the criteria adopted by the Labour and Health Administrations in connection with the certification of specialized enterprises that can act as prevention services and the authorization of private individuals and entities that wish to conduct the audit activity, for the purpose of being able to inform and formulate proposals aimed at an adequate co-ordination between the Administrations.

### **Ninth Additional Disposition: Supplementary Dispositions on the Subject of Administrative Procedures**

In connection with administrative procedures, for all matters not expressly set forth in this Regulation, the provisions of Law 30/1992 of 26th November on the Legal Regime of Public Administrations and the Common Administrative Procedure and of Royal Decree 1778/1994 of 5th August, by virtue of which such Law is adapted to the regulatory rules of the procedures for granting, modifying and cancelling authorizations, will apply.

### **Tenth additional provision. Presence of preventive resources on construction sites.**

Within the scope of application of Royal Decree 1727/1997 of 24 October, laying down minimum safety and health requirements at construction sites, the presence in the workplace of each contractor's preventive resources under the fourteenth additional provision of Act 31/1995 of 8 November on Prevention of Occupational Risks shall apply within the meaning of the single additional provision of Royal Decree 1627/1997.

### **Eleventh additional provision. Dangerous activities for the purposes of coordinating company activities.**

For the purposes of Article 13.1.a) of Royal Decree 171/2004 of 30 January, implementing Article 24 of Act 31/1995 of 8 November on Prevention of Occupational Risks, on the coordination of business activities, the activities or processes under Annex I of this Royal Decree shall be considered as dangerous or particularly risky.

### **Twelfth additional provision. Dangerous activities for the purposes of the consolidated Act on Social Order Infringements and Penalties, approved by Royal Legislative Decree 5/2000 of 4 August.**

1. For the purposes of sections 7 and 8.a) of Article 13 of the consolidated Act on Social Infringements and Penalties, approved by Royal Legislative Decree 5/200 of 4 August, the activities included in Annex I of this Royal Decree are considered as dangerous or as particularly risky, if any of the following concur:
  - a. A particular difficulty to control the interaction of the various activities carried out in the workplace that may pose serious or very serious risks.
  - b. A particular difficulty to avoid activities that are mutually incompatible from the workers' health and safety point of view from being carried out, either successively or simultaneously, in the workplace.
  - c. A particular complexity in coordinating preventive activities as a result of the number of concurrent companies and workers, the type of activities implemented and the characteristics of the workplace.
2. For the purposes of Article 13.8.b) of the Act on Social Order Infringements and Penalties, the activities referred to in Article 22 bis 1.b) of this Royal Decree are considered as dangerous or particularly risky.

### **First Temporary Disposition: Establishment of the Internal Prevention Service**

Without prejudice to the maintenance of those preventive activities that were being carried out in the company on the date on which this Regulation enters into force, those internal prevention services that must be set up by companies with between 250 and 1,000 workers, as per the provisions of letters a) and b) of Article 14 herein, must be operative by 1st January 1999 at the latest, with the exception of those companies that conduct any of the activities included in Annex I which must set them up by 1st January 1998.

Up until the date established in the foregoing paragraph, the preventive activities of the companies referred to must be outsourced from an independent specialized enterprise, with the exception of those services that are gradually assumed by the company through the appointment of workers, until their full integration in the prevention service that is set up.

### **Second Temporary Disposition: Accreditation of the Social Security's mutual insurance company for accidents at work and occupational disease**

To those Mutual Insurance Companies for Accidents at Work and Occupational Diseases that, by virtue of the authorization contained in the Second Temporary Disposition of the Prevention of Risks at Work Act perform functions corresponding to prevention services for their associated companies, the provisions of Articles 23 to 27 of this Regulation on the subject of certification and its requirements will apply.

### **Third Temporary Disposition. Training Certificate**

Without value.

### **Fourth Temporary Disposition. Temporary Application of Criteria for the Management of Risk Prevention in Public Hospitals and Health Centres**

Until such time as the provisions of the Fourth Additional Disposition, "Application to Public Administrations", have been developed, the prevention of risks in public hospitals and health centres will continue to be managed in accordance with the criteria and procedures that are in force until now, so that the functions of workers' health care and control and all other prevention activities, referred to in this Regulation, are guaranteed. To this end, preventive medicine activities will be co-ordinated with all the other prevention-related functions in order to achieve integrated and inter-disciplinary action.

### **Single Annulment Disposition: Scope of the Annulment**

All those dispositions of an equal or lower rank that oppose the provisions of this Royal Decree and, in particular, Decree 1036/1959 of 10th June on Company Medical Services and Order dated 21st November, 1959, by virtue of which the Regulations for Company Medical Services were approved, shall be annulled.

This Royal Decree does not affect the Special Dispositions on the prevention of occupational risks in mining exploitations contained in Chapter IV of Royal Decree 3255/1983 of 21st December, by virtue of which the Mining Statute and the rules for its application were approved, or the provisions of Royal Decree 2857/1978 of 25th August, by virtue of which the General Rules for the Mining Regime were approved, or Royal Decree 863/1985 of 2nd April approving the General Regulations for the Basic Rules of Mining Safety, and its supplementary Dispositions.

### **First final provision: Regulatory approval**

1. The Ministry of Labour and Immigration, on the basis of a previous report from the National Commission for Safety and Health at Work, is authorised to adopt all necessary measures for the implementation of the provisions of this Royal Decree.
2. The National Institute for Safety and Hygiene at Work shall compile and keep up to date a non-binding guide to drafting a single document containing the occupational risk prevention plan, the risk assessment and the prevention action plan, in accordance with Article 5.3 of this Royal Decree.

### **Second Final Disposition: Entry into Force (Amended by Royal Decree 780/1998)**

This Royal Decree will enter into force two months after its publication in the "Official State Gazette", with the exception of point 2 of article 35 which will enter into force twelve months after, and the point 2 of articles 36 and 37 of Chapter VI, that will enter into force 31st December, 1998.

Given in Madrid on 17th January, 1997  
JUAN CARLOS R.  
Minister of Labour and Social Affairs  
JAVIER ARENAS BOCANEGRA

## **ANNEXES**

### **Annex I**

- a. Work involving exposure to ionizing radiations in controlled areas, as per R.D. 53/1992 of 24th January, on health protection against ionizing radiations.
- b. Work involving exposure to toxic and very toxic agents, and in particular first and second category carcinogens, mutagens and other agents that endanger reproduction, as per R.D. 363/1995 of 10th January, by virtue of which the Rules on the notification of new substances and the classification, packing and labelling of hazardous substances were approved, and RD 1078/1993 of 2nd July on the classification, packing and labelling of hazardous preparations and the rules for the development and adaptation to progress of both Regulations.
- c. Activities in which high risk chemical products intervene and which are subject to the application of R.D. 886/1988 of 15th July and its amendments on the prevention of major accidents in certain industrial activities.
- d. Work involving exposure to group 3 and 4 biological agents, as per EEC Directive 90/679 and its amendments, on the protection of workers against risks relating to biological agents during their work.
- e. Activities for the manufacture, handling and utilization of explosives, including pyrotechnic articles and other objects and instruments containing explosives.
- f. Work specific to open cast and underground mining and borings on land or from marine platforms.
- g. Activities involving under water immersion.
- h. Activities in building construction, excavation, earth movement and tunnelling works, involving the risk of falling from a height or being buried.
- i. Activities in the iron and steel and shipbuilding industries.
- j. Production of compressed, liquated or dissolved gases and the heavy use thereof.
- k. Work producing high concentrations of silica powder.
- l. Work involving high voltage electricity risks.

**Annex II: Notification of the Existence of Conditions that mean that it is Not Necessary to Audit the Company's Prevention System**

Mr. ....  
 acting in his capacity as: .....  
 of the Company: .....  
 declares that it complies with the conditions established in Article 29 of the Prevention Services Regulations and, consequently, submits attached to this declaration those details that are specified before, for their registration and consideration by the competent Labour Authority.

Company Details

Newly incorporated or Already in existence	Fiscal Identification No. (NIF):
Corporate name:	Fiscal Identification Code No.(CIF):
Registered office (street):	Town:
Province: Postal Code:	Telephone No.:
Corporate activity:	Managing or collaborating entity for Accidents at Work and Occupational Diseases:
Type of work centre (workshop, office, warehouse):	No. of workers:
Risk assessment carried out on: ..... (date) .....	Built surface area (m <sup>2</sup> )

Data relating to Risk Prevention

Existing risks	Appropriate preventive activity

(Place, date, signature and company stamp)

### **Annex III: General Criteria for the Establishment of Projects and Training Programmes for Carrying out Basic, Intermediate and Higher Level Functions**

The preventive disciplines that will act as technical support will be those relating to Occupational Medicine, Safety at Work, Industrial Hygiene and Ergonomics and Applied Psychosociology, as a minimum.

The regulatory framework applicable to the prevention of risks at work will encompass all general international, EU and Spanish legislation, in addition to specific regulations deriving for the application of preventive techniques and their specification and development in collective agreements.

Training objectives will consist of the acquisition of the necessary technical know-how for developing the functions of each level.

Training must act as an integrator of all the different preventive disciplines that endow the training programmes with multi- and inter-disciplinary characteristics.

Training Projects will be designed with the criteria and singularity of each promoter and must establish general and specific objectives, contents, organization of the subject matter, specific methodology, assessment methods, timing recommendations and technical supports and resources.

Training Programmes, at the proposal of each promoter, and in accordance with the curricular projects and design, will establish objectives and contents within the course timetable, their methodological development, didactic activities and the criteria and parameters for assessing the objectives established for each program.

## **Annex IV: Minimum Content of the Training Programme for Carrying Out Basic Level Functions**

### **A) Minimum Content of the Training Programme for Carrying Out Basic Level Functions**

- I. Basic concepts of health and safety at work
  - a. Work and Health: occupational risks. Risk factors
  - b. Work-related injuries. Accidents at Work and Occupational Diseases. Other work-related pathologies
  - c. Basic regulatory framework on the subject of the prevention of occupational risks. Basic rights and duties

Total hours: 10

- II. General risks and their prevention
  - a. Risks relating to safety conditions
  - b. Risks relating to the work environment
  - c. Workload, fatigue and lack of job satisfaction
  - d. Elementary systems for controlling risks. Collective and personal protection
  - e. Emergency and evacuation plans
  - f. Control of workers' health

Total hours: 25

- III. Specific risks and their prevention in the sector corresponding to the company's activity

Total hours: 5

- IV. Basic elements of the management of risk prevention
  - a. Public bodies involved in Health & Safety at Work
  - b. Organization of preventive actions: basic "routines"
  - c. Documentation: data collection, preparation and filing

Total hours: 5

- V. First Aid

Total hours: 5

### **B) Minimum Content of the Training Programme for Carrying Out Basic Level Functions**

- I. Basic concepts of health and safety at work
  - a. Work and Health: occupational risks. Risk factors
  - b. Work-related injuries. Accidents at Work and Occupational Diseases. Other work-related pathologies
  - c. Basic regulatory framework on the subject of the prevention of occupational risks. Basic rights and duties

Total hours: 7

- II. General risks and their prevention
  - a. Risks relating to safety conditions
  - b. Risks relating to the work environment
  - c. Workload, fatigue and absence of job satisfaction
  - d. Elementary systems for controlling risks. Collective and individual protection
  - e. Emergency and evacuation plans
  - f. Control of workers' health

Total hours: 12

- III. Specific risks and their prevention in the sector corresponding to the company's activity

Total hours: 5

- IV. Basic elements of the management of risk prevention
  - a. Public bodies involved in Health & Safety at Work
  - b. Organization of preventive actions: basic "routines"
  - c. Documentation: data collection, preparation and filing

Total hours: 4

- V. First Aid

Total hours: 2

## **Annex V: Minimum Content of the Training Programme for Carrying Out Intermediate Level Functions**

- I. Basic concepts of health and safety at work
  - a. Work and Health: occupational risks
  - b. Work-related injuries. Accidents at Work and Occupational Diseases: concepts, dimension of the problem. Other work-related pathologies
  - c. Working conditions, risk factors and preventive techniques
  - d. Basic regulatory framework on the subject of the prevention of occupational risks. Basic rights and dutiesTotal hours: 20
- II. Prevention Methodology I: General techniques for risk analysis, assessment and control.
  - a. Risks relating to safety conditions: Identification, analysis and assessment of the risks relating to:
    - i. Machinery
    - ii. Equipment, installations and tools
    - iii. Work places and spaces
    - iv. Handling, storage and transport
    - v. Electricity
    - vi. Fires
    - vii. Chemical products
    - viii. Toxic and hazardous waste
    - ix. Safety inspections and accident investigation
    - x. Preventive measures to reduce and eliminate hazards
  - b. Risks associated with the work environment:
    - i. Physical agents:
      1. Noise
      2. Vibrations
      3. Thermal conditions
      4. Ionizing and non-ionizing radiations
      5. Other physical agents
    - ii. Chemical agents
    - iii. Biological agents
    - iv. Identification, analysis and general assessment: Action methodology. The hygienic survey
    - v. Preventive measures for reducing and eliminating risks
  - c. Other risks:
    - i. Workload and fatigue: Ergonomics
    - ii. Psychosociological and organizational factors: Analysis and general assessment
    - iii. Environmental conditions: Lighting. Quality of indoor air
    - iv. Work station lay out and design.Total hours: 170
- III. Prevention Methodology II: Specific techniques for the follow-up and control of risks
  - a. Collective Protection
  - b. Signs and information. Packing and labelling of chemical products
  - c. Work standards and procedures. Preventive maintenance
  - d. Individual protection
  - e. Assessment and control of workers' health
  - f. Basic knowledge of statistics: accident ratesTotal hours: 40
- IV. Prevention Methodology III: Promotion of prevention
  - a. Training: Analysis of training needs. Adult training techniques
  - b. Communication, motivation and negotiation techniques. Preventive campaignsTotal hours: 20
- V. Organization and Management of Prevention
  - a. External resources relating to the prevention of risks at work
  - b. Organization of prevention inside the company:
    1. Integrated prevention
    2. Organizational models
  - c. Basic Principles of Prevention Management:
    1. Objectives and Priorities
    2. Assignment of Responsibilities
    3. Prevention Plan
  - d. Documentation
  - e. Actions in case of Emergencies:
    1. Emergency and evacuation plans
    2. First AidTotal hours: 50

## **Annex VI: Minimum Content of the Training Programme for Carrying out Higher Level Functions**

The higher level training programme consists of three parts:

- I. Compulsory and common subjects, with a minimum of 350 hours of classes
- II. Optional specialization, to be selected from amongst the following options:
  - A. Safety at Work
  - B. Industrial Hygiene
  - C. Ergonomics and Applied Psychosociology

Each option will have a minimum duration of 100 hours.
- III. Preparation of an end-of-course project or development of preventive activities in a work centre, according to the specialization selected, with a minimum duration equivalent to 150 hours

### I. Common Part

1. Fundamentals of the Techniques for Improving Working Conditions
  - a. Working conditions and health
  - b. Risks
  - c. Work-related injuries
  - d. Prevention and protection
  - e. Statistical bases applied to prevention

Total hours: 20

2. Techniques for the Prevention of Risks at Work

#### 1. Safety at Work:

- a. Concept and definition of safety: Safety techniques
- b. Accidents at work
- c. Accident investigation as a preventive technique
- d. Analysis and general assessment of the risk of accidents
- e. Safety standards and signs
- f. Collective and individual protection
- g. Statistical analysis of accidents
- h. Emergency & self-protection plans
- i. Analysis, assessment and control of specific risks: machines; equipment; installations and tools; work places and spaces; handling, storage and transport; electricity; fires; chemical products
- j. Toxic and dangerous waste
- k. Safety inspections and accident investigation
- l. Preventive measures to reduce and eliminate risks

Total hours: 70

#### 2. Industrial Hygiene

- a. Industrial hygiene. Concepts and objectives
- b. Chemical agents. Occupational toxicology
- c. Chemical agents. Assessment of exposure
- d. Chemical agents. Control of exposure: general principles; actions on contaminating sources; actions on propagation media. Ventilation: actions on individuals; individual protection; classification
- e. Specific legal regulations
- f. Physical agents: characteristics, effects, assessment and control: noise, vibrations, thermal conditions, non-ionizing radiations, ionizing radiations
- g. Biological agents. Effects, assessment and control

Total hours: 70

#### 3. Occupational Medicine

- a. Basic concepts, objectives and functions
- b. Occupational pathologies
- c. Health care
- d. Promotion of health in the company
- e. Occupational epidemiology and epidemiological research
- f. Health planning and information

- g. Life-saving and first aid

Total hours: 20

4. Ergonomics and Applied Psychosociology

- a. Ergonomics: concepts and objectives
- b. Environmental conditions in Ergonomics
- c. Conception and design of the post
- d. Physical workload
- e. Mental workload
- f. Psychosociological factors
- g. Structure of the organization
- h. Characteristics of the company, the job and individual characteristics
- i. Stress and other psychosociological problems
- j. Consequences of harmful psychosociological factors and their assessment
- k. Psychosociological intervention

Total hours: 40

3. Other Activities on the subject of the Prevention of Risks at Work

1. Training

- a. Analysis of training needs
- b. Plans and programmes
- c. Educational techniques
- d. Follow-up and assessment

2. Communication, Information and Negotiation Techniques

- a. Communication in Prevention: channels and types
- b. Information. Conditions for its effectiveness
- c. Negotiation techniques

Total hours: 30

4. Management of the Prevention of Risks at Work:

- a. General aspects of corporate administration and management
- b. Prevention Planning
- c. Prevention Organization
- d. Prevention Economics
- e. Special sectors: Construction, Extraction Industries, Transport, Agriculture and Fishing

Total hours: 40

5. Similar Techniques:

- a. Product safety and quality management systems
- b. Environmental management
- c. Industrial safety and prevention of property risks
- d. Road safety

Total hours: 20

6. Legal scope of prevention:

- a. Basic knowledge of labour law
- b. Spain's Social Security System
- c. Basic labour relation legislation
- d. Regulations on the prevention of risks at work
- e. Responsibilities on the subject of prevention
- f. Organization of prevention in Spain

Total hours: 40

**II. Optional Specialization**

- A. Area of Safety at Work : A minimum training of 100 hours must be justified, mainly consisting of in-depth study of the subjects contained in point 2.1. of the common part
- B. Area of Industrial Hygiene : a minimum training of 100 hours must be justified, mainly consisting of in-depth study of the subjects contained in point 2.2. of the common part.
- C. Area of Ergonomics and Applied Psychosociology : a minimum training of 100 hours must be justified, mainly consisting of in-depth study of the subjects contained in point 2.4. of the common part.

**Annex VII. Non-exhaustive list of agents, processes and working conditions that may have a negative effect on the health of pregnant or breastfeeding workers, of the unborn or breastfeeding child.**

**A. Agents.**

1. Physical agents where these are regarded as agents causing foetal lesions and/or likely to disrupt placental attachment, and in particular:

- a) shocks, vibration or movement.
- b) handling of loads entailing risks, particularly of a dorsolumbar nature.
- c) Noise.
- d) Non-ionizing radiation.
- e) Extremes of cold or heat.
- f) movements and postures, travelling, either inside or outside the establishment, mental and physical fatigue and other physical burdens connected with the activity of the pregnant worker who has recently given birth or is breastfeeding.

2. Biological agents. – Biological agents of risk groups 2, 3 and 4, within the meaning of the classification of biological agents under Royal Decree 664/1997 of 12 May on the protection of workers from risks related to exposure to biological agents at work, in so far as it is known that these agents or the therapeutic measures necessitated by such agents endanger the health of pregnant women and the unborn child and in so far as they do not yet appear in Annex VIII..

3. Chemical agents. – The following chemical agents, in so far as it is known that they endanger the health of pregnant or breastfeeding women, of the unborn or breastfeeding child, and in so far as they do not appear in Annex VIII:

- a) Substances labelled R40, R45, R46, R49, R68, R62 or R63 under the Regulation relating to the classification, packaging and labelling of dangerous substances, adopted by Royal Decree 363/1995 of 10 March, or labelled as H351, H350, H340, H350i, H341, H361f, H361d under Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, in so far as they do not yet appear in Annex VIII.
- b) Chemical agents in Annexes I and III of Royal Decree 665/1997 of 12 May, on the protection of workers from risks related to exposure to carcinogens at work.
- c) Mercury and mercury derivatives.
- d) Antimitotic drugs.
- e) Carbon monoxide.
- f) Chemical agents of known and dangerous percutaneous absorption.

**B. Processes.**

Industrial processes listed in Annex I of Royal Decree 665/1997 of 12 May, on the protection of workers from risks related to exposure to carcinogens at work.

## **Annex VIII. Non-exhaustive list of agents and working conditions presenting a risk to which pregnant or breastfeeding workers shall not be exposed**

### A. Pregnant workers.

#### 1. Agents.

##### a) Physical agents:

Ionizing radiation.

Work in hyperbaric atmosphere, e.g. pressurized enclosures and underwater diving.

##### b) Biological agents:

Toxoplasma.

Rubella virus.

Unless the pregnant workers are proved to be adequately protected against such agents by immunization.

##### c) Chemical agents:

Substances labelled R60 or R61 under the Regulation relating to the classification, packaging and labelling of dangerous substances, adopted by Royal Decree 363/1995 of 10 March, or labelled H360F, H360D, H360FD, H360Fd or H360Df under Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Carcinogenic and mutagenic substances included in table 2 and listed in the “Document on the limits to occupational exposure to chemical agents in Spain” published by the National Institute for Occupational Health and Safety, for which there is no limit given for exposure, in accordance with table III of said document.

Lead and lead derivatives in so far as these agents are capable of being absorbed by the human organism.

#### 2. Working conditions. –Underground mining work.

### B. Workers who are breastfeeding.

#### 1. Chemical agents:

Substances labelled R64 under the Regulation relating to the classification, packaging and labelling of dangerous substances, adopted by Royal Decree 363/1995 of 10 March, H360Df under Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Carcinogenic and mutagenic substances included in table 2 and listed in the “Document on the limits for occupational exposure to chemical agents in Spain” published by the National Institute for Occupational Health and Safety, for which there is no limit given for exposure, in accordance with table III of said document.

Lead and lead derivatives in so far as these agents are capable of being absorbed by the human organism.

#### 2. Working conditions. – Underground mining work.