



INTEGRA LIFESCIENCES ITALY S.R.L.

Model of Organization, Management and Control
(pursuant Italian Legislative Decree 231/2001)

[TRANSLATED FROM THE ORIGINAL ITALIAN VERSION]

Special Part K

Health and Safety Management

1. Special Part Aim

This Special Part aims to define do's-and-don'ts as well as control activities that all Addressees are required to adhere to and execute whenever operating within activities and process listed in subsequent chapter 2, for the purpose of *i)* preventing the risk of specific "231" relevant crimes commission as well as of *ii)* assuring correctness and transparency in conducting business activities.

In addition, this Special Part aims to provide Supervisory Body and all other control bodies with relevant information to perform their control activities.

Addressees should adhere to, each to the extent applicable:

- Model of Organization, Management and Control, General Part;
- Standard of Business Conduct and Ethics;
- Delegation of Authorities in place;
- each and all other Company and Group documents addressing activities relevant for the Italian Legislative Decree 231/2001 compliance.

In general, all actions and behaviours in violation of existing and valid laws are forbidden.

2. Special Part Scope

This Special Part and, specifically, do's-and-don'ts as well as control activities detailed in subsequent chapters, apply to all Integra managers, employees and other professionals involved with the below listed processes:

- Employer;
- Prevention and Protection Service Responsible ("RSPP");
- Emergency management team;
- Safety Workers Representative ("RLS");
- Competent doctor;
- Other Function / Area Managers;
- Company Employees (employees and collaborators).

3. Applicable 231 crime

231 crimes theoretically applicable to Integra Lifesciences Italy S.r.l. are the following:

- manslaughter and serious or very serious injury committed in violation of regulations on health and safety at work (art. 25-septies Leg. D. 231/2001).

4. Do's-and-don'ts

All addressees must:

- comply with health and safety at work requirements, as well as scrupulously observe instructions given by people in charge in order to preserve health and safety of all workers;
- comply with company guidelines and procedures / protocols governing issues relating to health, hygiene and occupational safety;
- collaborate, through its representatives, in the assessment of all risks to health and safety at work;
- promptly report to the identified functions in line with the procedures defined in the Company procedures / protocols, any situations of danger and risk, accidents, occupational diseases or near miss situations (or near misses), and violations of the rules of conduct and business procedures;
- use, according to the instructions, equipment present in the workplace, as well as the individual and collective protection devices;
- do not remove or modify safety devices of machines and equipment or other signaling or control devices;
- do not carry out on their own initiative operations that may compromise safety of themselves or other workers or that may expose themselves, their colleagues or third parties to situations of danger;
- report any anomaly, situation or risk for safety and health different from those known or particularly significant;
- participate in the training sessions organized by the Company on occupational safety and health risks.

Furthermore, Company representatives who, due to their duties or functions, are involved in the activities in question, must:

- keep up-to-date and comply with the regulatory body and system of proxies in the field of health and safety;
- pursue risks elimination and, where this is not possible, their reduction to the minimum in relation to the knowledge acquired on the basis of technical progress;
- guarantee prevention planning, aiming at a complex that integrates the production and organizational conditions of the Company in a coherent way;
- pursuing the objective of "no harm to people" and risks reduction at the source;
- promote a health and safety culture involving all workers participate;
- guarantee respect for ergonomic principles in work organization, in the workplace design, in the equipment selection and in the working methods;
- reduce chemical and biological agents use in the workplace;
- guarantee adequate emergency measures definition to be implemented in case of first aid, fire fighting, evacuation of workers in case of serious and immediate danger;

- guarantee human resources suitability - in terms of number, professional qualifications and training - and necessary materials to achieve objectives set by the Company for the maintenance and/or improvement of workers' safety and health levels;
- guarantee the acquisition and management of the vehicles, equipment, plants and, in general, of the Company structures in compliance with the technical-structural standards of the law, also through a continuous (ordinary and extraordinary) maintenance process;
- define objectives for safety and health of workers, assessing risks associated with the activity carried out at the Company, identifying the hazards and risks introduced at the Company by activities carried out there by third parties, through an effective and preventive exchange of information and cooperation / coordination with the employer of external companies that may operate in the company;
- guarantee an adequate level of training and information to workers, as well as request that an adequate level of training and information be guaranteed by the employer of the third-party contracting / subcontracting companies within their competence and relative to the risks of interference, on the company safety management system defined by the Company and on the consequences deriving from a failure to comply with the law and the rules of conduct and control defined by the Company itself;
- promptly report to the Function identified according to law and/or internally any risk / danger signals / events regardless of their seriousness.

5. Management of activities related to health and safety in the workplace

Main activities, in the management of compliance with health and safety at work related to workers, are correlated with the potential failure to comply with regulations aimed at protecting workers' health and safety, or preventing accidents from which an event may arise harmful (death or injury), in particular:

- health and safety and accident prevention policies aimed at defining general commitments undertaken by the Company for the prevention of risks and the gradual improvement of health and safety;
- correct application of the provisions of the laws and regulations applicable to workplace safety and accident prevention;
- identification and assessment of health and safety risks for all categories of workers with particular reference to:
 - Risk Assessment;
 - procurement contracts;
 - assessment of the risks of interference and drafting of the Single Document for the Assessment of Interference Risks ("DUVRI");
 - Safety and Coordination Plans ("PSC"), Work Files and management of Safety Operational Plans ("POS") of contractors;

- setting objectives aligned with the general commitments defined in the policies referred to in the first point; drawing up of the programs to achieve these objectives with relative priorities, timing and attributions of the respective responsibilities in the field of health and safety at work;
- awareness of the Company structure, at all levels, in order to guarantee the achievement of the pre-established objectives, also through training planning;
- implementation of adequate monitoring, verification and inspection activities in order to ensure effectiveness of the occupational health and safety management system and accident prevention;
- implementation of the necessary corrective and preventive actions, based on the results of the monitoring;
- carrying out a periodic review by the Company management in order to evaluate effectiveness and efficiency of the Company management system for occupational safety and health protection and accident prevention, as well as the adequacy of this last compared to the Company reality.

In the management of the activities, all contacts involved will have to ensure that the following control safeguards are deemed to be formally traceable and documented (also for the purposes of the verification activities pertaining to the Supervisory Body) in order to mitigate potential risks-offense pursuant to Legislative Decree 231/2001.

The Company has implemented a system of established practices and procedures that regulate all work activities, integrated with aspects of health and safety at work.

5.1 Compliance with technical-structural standards of law relating to equipment, plants, workplaces as well as to chemical, physical and biological agents

The Employer, with the support of the RSPP and the competent Function involved, provides, for all the Company's operational sites:

- identify, following “Documento di Valutazione dei Rischi” (“DVR”) and subsequent updates, the compliance status (and any improvement actions) with respect to the technical-structural standards of law, equipment and plants (exclusively example, thermal and electrical systems, grounding, fire prevention), workplaces, chemical, physical and biological agents and the related implementation responsibilities;
- perform periodic checks on workplaces aimed at ensuring that legal standards are maintained over time;
- plan and conduct, or verify that qualified external companies / professionals make periodic and extraordinary maintenance of the machines and work equipment used, recording it in suitable documentation and in accordance with the instructions in the user manuals and maintenance of individual technological systems and information acquired from suppliers / manufacturers of machines and equipment;
- define security requirements that corporate responsible must first verify prior to the procurement of equipment, plants, chemical, physical and biological agents, for the development and implementation of products / services;
- guarantee continuous monitoring on the evolution of technical-structural standards and legislation.

5.2 Risks evaluation and preparation of related consequent prevention and protection measures, adopted methodology and mapping of identified risk factors

The Employer, assisted by the “RSPP”, with the support of the Competent Doctor and the “RLS”, conducts risks assessment for health and safety, in order to identify and implement the prevention and protection measures of workers, reducing levels the associated risks, in relation to the acquired knowledge and the defined priority.

This analysis is formalized in a specific document ("Risk Assessment Document" or "DVR", prepared for each Company operating site), as required by Legislative Decree 81/2008 and subsequent amendments and by the current legislation on health and safety at work. It contains the identification and assessment of risks for each Company task, the prevention and protection measures and the individual protection devices assigned to each worker as specified in the art. 28 paragraph 2 of Legislative Decree 81/2008, signed by the Employer.

The Employer, in collaboration with the aforementioned safety representatives, provides for:

- assessing all risks associated with activities and duties of the Company's employees, preparing and formalizing risk assessment document;
- updating DVR for organizational and procedural changes, technical changes, changes made necessary by regulatory developments, as well as after significant accidents that highlight the need, in a short time and in any case no more than one month after the changes and changes have occurred;
- formalizing specific risk assessment for each task and/or activity performed by its workers with identification and assessment of each specific risk;
- assessing interference risks with third-party workers duties working at the workplace with the drafting of Single Document of Interference Risks - “DUVRI”.

The Employer also provides for:

- guaranteeing access and use right, without costs, for each worker to suitable Personal Protective Equipment (“PPE”) - and/or Collective - appropriate to the task performed, also ensuring the registration of the security devices assigned;
- ensuring the implementation of the methodologies for the analysis and classification of accidents and any dangerous events recorded;
- ensuring responsibilities definition for the implementation of measures to mitigate the consequences following accidents or non-compliance, as well as for the initiation and completion of corrective measures.

With particular reference to activities and services management provided by third parties at the plant and before starting work, a document is processed (in coordination with the Employer/s of the work of the third companies and/or contracting / subcontracting companies), to be attached to the contract, indicating the measures taken to eliminate or, where this is not possible, minimize interference risks, with a view to promoting cooperation and coordination between the Employers, also providing for the estimation of the relative burdens of preventive and protective measures aimed at the safety and health of workers.

This document, according to regulatory requirements, can be configured in:

- Security and Coordination Plan (“PSC”), in case of contracts within the scope of application of Title IV of Legislative Decree 81/08 - Consolidated Law on Safety at Work (or TUS), drafted by the Security Coordinator during the Design phase (“CSP”), appointed by the Customer subject;
- “POS” (Operational Safety Plan), provided by third parties under contract that fall within the scope of application of Title IV of the TUS. It is signed by the Employer of third parties and handed over to the Employer of the Company for the purposes of law of the case;
- “DUVRI”, for other types of contracts, prepared, as required by art. 26 of Legislative Decree 81/2008, by the commissioning employer.

5.3 Organizational activities, including emergencies, first aid, periodic safety meetings, consultations with workers' safety representatives

Company has a system of appointments and delegations that defines responsibilities, duties and powers regarding safety, accident prevention and occupational hygiene. The Employer provides for the maintenance and possible updating (and related communications and information flows) of the appointments of the RSPP and of the Competent Doctor; workers in charge of the implementation of fire prevention measures, evacuation of the workplaces in case of serious and immediate danger, rescue, first aid and, in any case, emergency management are assigned (first aid workers and employees to emergencies in the event of a fire, etc.). There is an Emergency Plan for all sites.

The Employer guarantees adequacy, effectiveness of role, independence as regards the competence and updating of the emergency teams, according to the State-Regions Training Agreement of 21 December 2011 (Published in GU No. 8 of 11/01 / 2012).

Also:

- managers in the field of workplace safety identified above exercise, for the area in which they are responsible, all the powers attributed and all obligations provided for by Legislative Decree 81/2008 and subsequent amendments, as well as by all other laws and regulations on safety, accident prevention and environmental hygiene applicable;
- all workers are appropriately trained (and trained during emergency exercises) on the references (both internal and external) to be contacted in case of emergency and the actions to be taken to ensure safe evacuation.

In particular, instructions and/or operating procedures are defined with the aim of:

- guaranteeing safety and health at the workplace;
- managing the contracted and subcontracted activities and the relative risks of interference;
- regulating information flows;
- guaranteeing operational activities perform and define instructions to conduct correctly and safely the activities related to each professional figure;
- guaranteeing correct management of emergency situations and provide for periodic emergency / evacuation tests.

The Employer, with the support of the RSPP guarantees that:

- as required by art. 35 of Legislative Decree 81/2008 at least once a year, periodic meetings in which all the key security figures participate are organized;
- continuous training, awareness and competence in the safety and health of all workers are ensured, for the general guidelines and the specific risks related to their job, as well as for the responsible staff, for their specific skills;
- accomplishment registration of the aforementioned activities is verified, as well as the archiving of the related documentation.

During annual meeting, the Employer submits at least the following topics for the examination of the participants:

- risk assessment document and prevention measures;
- accidents trend, occupational diseases and health surveillance;
- selection criteria, technical characteristics and effectiveness of personal protective equipment;
- information and training programs for workers, for the purposes of safety and protection of their health.

5.4 Procurement and supplies management

In general, works assignment to third parties is governed by Company procedures and by relevant legislation, with regard to criteria for the verification of the requisites, methods of assignment and planned controls.

Supplier qualification process conduct by the Company imposes request and verification with the support of the RSPP, the possession of the technical-professional suitability requirements of the contractor or self-employed workers for carrying out the activity as well as the acquisition of specific documentation such as registration with the Chamber of Commerce, as indicated in art. 26 Obligations connected to public works contracts or supply contracts (in the case of service and maintenance contracts) and art. 90 Obligations of the client or the person responsible for the work of Legislative Decree 81/2008 (in the case of contracts operating in temporary or mobile sites).

The Employer, with the support of the RSPP, guarantees during the execution of the works:

- cooperation between Employers for the implementation of measures to prevent and protect against the risks at work of accidents on the work activity subject to the contract;
- coordination of measures to protect and prevent risks to which workers are exposed (reciprocal exchange of information also to reduce the risks due to interference - if they arise - between the work of the various companies involved in the execution of the overall work).

In the case of contracts under Title IV of Legislative Decree 81/2008, the Customer, or the Head of Works, if identified, must comply with art. 90 Obligations of the client or of the person responsible for the work of Legislative Decree 81/2008, during the construction period of the building site.

5.5 Health surveillance activities

The Employer is responsible, with the support of the competent Function involved and the "RSPP", for ensuring to the Doctor in charge the necessary conditions for the health surveillance of workers employed by the Company, providing them with adequate space for the execution of their competence and for the

registration of the fulfillment of the legal obligations indicated below, as well as for the archiving of the related documentation.

The Competent Physician, provided that it is not at the expense of the mandatory assessments required by law, is in charge of assessing the adequacy and possibly updating the surveillance program based on any eventual needs. In particular, the Competent Doctor must, as required by art. 25 of the TUS:

- collaborate with the Employer, with the Prevention and Protection Service and with the RLS in the risk assessment;
- plan and conduct: (i) preventive assessments to verify absence of contraindications to the work, for the purpose of assessing their suitability for the specific task, (ii) periodic checks, aimed at checking the state of health of workers and express the assessment of eligibility for the specific task;
- establish, update and keep the health and risk record of each worker;
- visit workplaces at least once a year and produce relative report of the checks carried out;
- collaborate in training and information activities;
- collaborate in the preparation of the First Aid service;
- formalize and communicate to the worker the results of the analyzes performed, containing assessments of suitability or unfitness, releasing two copies (one to the worker and one to the Employer for filing);
- participate in the periodic safety meeting pursuant to art. 35 of the TUS, reporting on the visits made, the trend of accidents and occupational diseases, etc.

The health surveillance obligations refer to all employees of the Company.

Company can promote awareness and training actions for third-party collaborators.

5.6 Information, training on health and safety at work

The Employer, with the support of the RSPP, the competent Function involved and possibly with the support of professionals specialized in the subject, ensures that the necessary actions are activated to:

- prepare Annual Training Plan with the identification of training needs for workers;
- organize and provide training programs for newly hired / change workers;
- organize and provide specific and periodic training programs also for particular groups (e.g. fire prevention and first aid);
- record training activities and keep summary tables of the training conducted during the year with relative documentation (attendance sheets of the participants, possible learning verification cards, distributed teaching material);
- carry out periodical checks aimed at verifying the level of learning and awareness in the field of worker safety, by formalizing and filing results sharing with the "RLS";
- organize emergency simulation and evacuation tests at least annually;

- communicate to suppliers and contractors detailed information on the specific risks existing on the Company's sites as well as behavior and control rules adopted, defined in this document and in Company procedures;
- organize necessary training and information of workers after regulatory updates and as a result of organizational, technical or procedural changes with impact on work activities for safety purposes.

5.7 Supervisory activities about compliance with workers' safety procedures and instructions

Employer supervises the correct execution of the delegated activities; supervision is also performed through the inspections conducted by the RSPP, as well as by the Physician in charge at the workplace.

5.8 Implemented registration system

Relevant documentation on health and safety is managed in paper and computerized form (database and Company management programs).