National Association for Biomedical and Diagnostic Technologies,
Medical Equipment,
Services and Telemedicine

HEALTHCARE FACILITIES AND PRODUCT SPECIALISTS

ASSOBIOMEDICA GUIDELINES

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INTRODUCTION

These guidelines are targeted at associate companies of Assobiomedica, whose staff, considering the role performed, visits hospitals to both promote sales and provide technical assistance to medical staff.
These guidelines are targeted both at employee and non-employee staff (agents) who are called to cover the task of “Product Specialist”. Its scope is to describe workplace characteristics, the risks to which workers might be exposed and the correct rules of conduct.
Starting from the premise that often it is impossible (or, anyhow, extremely difficult) to define the action framework of the Specialist in the hospital, both for endogenous factors (knowledge of departments, freedom of circulation, direct relations) and for exogenous factors (difficulty in finding the contact person, lack of actual checks), it is necessary to define a series of potential risks to which staff are exposed and a series of prohibitions and recommendations that must be followed.

1. GENERAL PRINCIPLES

If the doctor requests it, the Specialist can be present during medical and surgical procedures and follow-up visits related to marketed medical devices, to provide the technical and application support required to optimise the use of the devices.
The presence of the Specialist in healthcare facilities presupposes coordination in terms of prevention and protection of workers in the workplace, pursuant to Art. 26 of Legislative Decree No. 81/2008 (see, in this regard, the recommended facsimile letter that should be sent to the healthcare facility, Enclosure Sub 1).
Concerning the presence of the Specialist in the operating theatre, it shall only be requested by the surgeon (even through the biomedical company) and subordinated to the authorisation of the Hospital Administration.
The Specialist shall be informed about the risks and Individual Protection Devices that are deemed to be necessary while performing his duties. This informative and training activity (specific training) shall be carried out either by the competent doctor or by other staff that is deemed suitable by the company.
Safety devices (caps, uniforms, masks, clogs…) shall be provided to the Specialist directly by the hospital to which he is assigned. The Prevention and Protection Department Manager (RSPP) shall ensure that the above specifications are implemented and that devices provided are both suitable and sufficient.
The Specialist shall be required to comply with all protocols of healthcare facilities where he performs his activity, making use of Individual Protection Devices that are placed at his disposal. He shall also immediately inform his company about any deficiencies and/or the absence of Individual Protection Devices, and make use, in this case, of the ones given him by the company.
The company shall, anyhow, provide its Specialists (employees and agents) with all Individual Protection Devices that are required for safe performance of their duties.

2. PREPARATION OF STAFF ACCESSING THE OPERATING THEATRE

Preliminarily it must be underscored that the company can obtain access for its Specialist (employee or agent) to the operating theatre only following evidence of specific professional training received by the same.
Even if it makes use of agents, the company shall provide evidence of having adequately trained the same concerning the risks and protocols to be followed, in order to ensure correct access both to healthcare facilities and to operating theatres.
If it makes use of agents, the company shall also ascertain the actual professional preparation of the same for the assigned duties and it shall guarantee their constant and specific training.
The assistance provided by the Specialist to the doctor shall then take place, as far as possible, preventively and outside the hospital framework.
The support given by the Specialist shall not, in any case, turn into clinical practice and medical assistance, which are the typical responsibilities solely of doctors.
Smooth function of the Surgery Unit shall depend on the conduct of staff assigned to it. Some basic rules shall be complied with to maintain a sterile environment and, especially, sterile operating theatres. Access to the Surgical Unit, even if limited to delivering a device, entails a series of procedures that are designed to establish and maintain conditions of low microbiological contamination. It is implemented through dressing in the filter area (clean but not sterile period).
If the Specialist is formally requested to perform assembly and/or disassembly operations of a specific surgical instrument during surgery, he shall have to perform the additional operations of disinfection of hand and forearm skin, and wear the special sterile devices (sterile period).

Dressing in the filter area (clean but not sterile period)
Access to the filter area first envisages shedding personal clothing and wearing a uniform provided by the hospital that usually includes the following items:

- *jacket* with short sleeves, and cotton, cloth or better still “non-woven fabric” *trousers* designed to facilitate movements; at the end of each surgical session, these clothes shall be left in the filter area for washing and even sterilisation;
- *footwear* has considerable importance because the soles are a vehicle for numerous germs; plastic clogs, whose washing and sterilisation are easier than for wooden ones, can be used;
- *caps and masks,* in disposable “non-woven fabric” material; their scope is to reduce possible contamination from hair, nose and throat.

Sterile period
It concerns staff participating directly in surgery (surgeons and instrument nurses) and the Specialist, if he is expressly requested to be available to perform any assembly and/or disassembly operations on specific surgical instrumentation.
Described below are the operations (and their implementation mode) that are most frequently performed in hospitals. If particular procedures are performed and different devices are used, the Hospital shall correctly instruct the staff involved.
Before proceeding with the typical operations of the sterile period, operating theatre staff shall be requested to wear an eye protection device (goggles, masks with eyeshade, eyeshades with an elastic band).
An essential moment in the sterile period is disinfection of hand and forearm skin because the skin is the site of various microbial flora.

Disinfection of these parts (performed in a special room that is adjacent to the operating theatre) is obtained through mechanical and chemical action. All personal belongings found on hands and forearms (e.g. watch, rings, bracelets) shall be removed.
A thorough wash with warm running water shall then be necessary, soaping with appropriate germicide substances, scrubbing hand and forearm skin up to the elbow with special sponges, and nails with special sterile brushes for a sufficient time for germicide substances to be effective (generally a few minutes) before thoroughly rinsing. The operation shall be repeated twice or thrice.
Opening and closing of water taps and use of the germicide dispenser, if they are not operated by photocells, shall be rigorously performed without using hands and forearms (using the elbows).
At the end of this operation, the person shall enter the operating theatre, taking care to keep hands above elbow level and not to touch the door with either hands or forearms (using either the elbow or the foot).
When entering an operating theatre, special attention shall be paid not to touch either sterile devices (instrument table, surgical instrument container, sterile protections for the patient, sheets) for the risk of causing contamination and loss of sterility, or non sterile objects for the risk of being contaminated and loosing hand and forearm sterility. It is a good rule to stand at least at a distance of one metre from any object.
Then the sterile gown is worn with the help of the instrument nurse who, in a frontal position, holds the open gown avoiding its contact with non sterile surfaces. A theatre assistant shall help with correctly tying the gown, maintaining its sterility. Sterile rubber gloves are then worn with the help of the instrument nurse who shall widen the upper edge to facilitate insertion of the hand.
The Specialist shall request and wear all the various protection devices (gloves, gowns, eyeshades) provided by the Hospital before starting his activity of assistance in the operating theatre. If relevant, latex-free Individual Protection Devices (gloves) shall be requested.
Gloves that are accidentally torn or pierced shall be promptly changed after washing the hands once again.
Maximum attention must be paid to prevent accidents that are caused by handling of sharp instruments and, in general, of contaminated instruments. If the Specialist has suffered an injury from accidental contact (even a slight wound or contamination particularly of the eyes) with potentially infected biological materials, he shall:

- immediately inform the Director or Coordinator of the department, specifying the site and occurrence mode of the event;
- follow the indications provided.

The following indications shall generally apply:

a) in case of a prick or a cut: increase bleeding of the lesion; cleanse thoroughly with soap and water; disinfect the wound with 5% chloroxidant (e.g. Amuchina) or an iodine-based product;

b) in case of contact with conjuctiva: wash the face with water; rinse the conjunctiva with abundant water;

c) in case of contact with the skin: cleanse skin thoroughly with soap and water; disinfect skin with 5% chloroxidant (e.g. Amuchina) or an iodine-based product;

d) in case of contact with oral mucous tissue: wash face and mouth with water; rinse the oral cavity with a solution of water and 5% chloroxidant (e.g. Amuchina).

Always visit the Emergency Department. If the biological material belongs to either an HIV positive patient or one who is at risk of HIV, visit the Emergency Department within 1 hour.

In the hospital framework the Specialist CAN

- provide a technical opinion and information on the correct and safe use of technical devices;
- provide only information published in the manual and/or in the instructions for the use of technical devices;
- support the doctor to ensure optimal use of devices and equipment;
- set device functions following instructions given by the doctor and under his supervision;
- transfer to the doctor the information/experience of other doctors, but only to help the doctor develop his own independent opinion;
- describe device characteristics and differences with rival products, always with the utmost transparency.

In the hospital framework the Specialist CANNOT:

- make a diagnosis; he shall only answer questions on technical devices asked by the doctor;
- actively and directly participate in the medical procedure; in no case shall the Specialist touch the patient; in this regard, it must be said that active participation, if any, of the Specialist in surgical procedures is an illegal criminal action in every way;
- programme/reprogramme a device without the direct supervision of the doctor, unless expressly and directly requested by the doctor, and only following his specific indications;
- write in the clinical records of the patient;
- directly interact with the patient without the presence of the doctor, providing opinions or information about technical devices;
- provide information that is not present in the manual, instructions for use, literature or official documentation of the company that employs him.

Healthcare surveillance of the Specialist

The Specialist, like other workers who operate in the healthcare sector, must be subject by the company to all medical check-ups that are deemed necessary by the competent doctor.

If the Specialist is an agent, the company shall require him to undergo all healthcare examinations envisaged by the corporate protocol.

The company shall be required to perform a periodical follow-up check of healthcare documentation produced by agents.

Failure of the agent to undergo healthcare controls envisaged by corporate protocols shall entail termination of the contract with the company.

3. RISK ANALYSIS

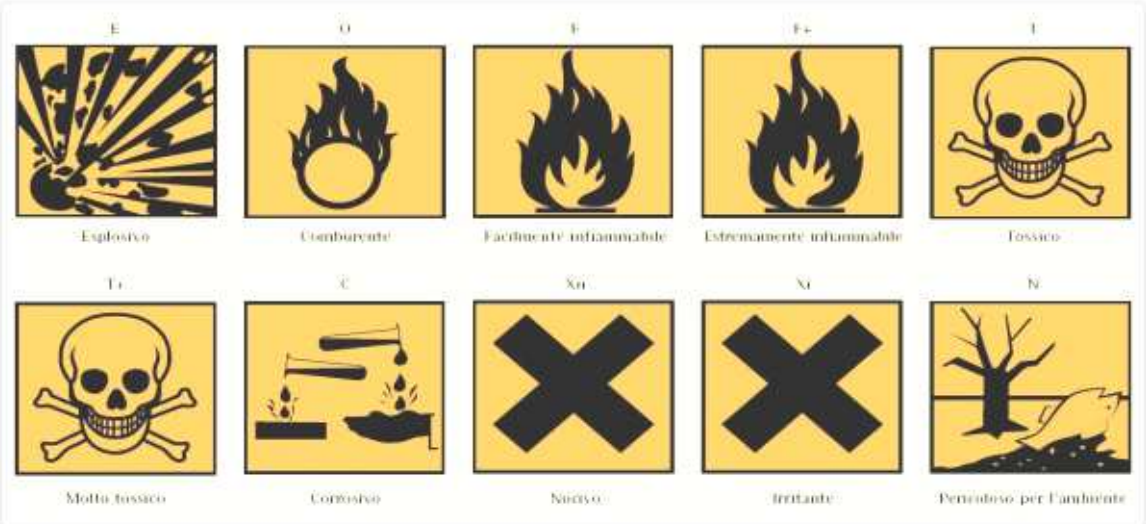
The Specialist is professionally exposed to all risk factors that are commonly present in hospital frameworks and in operating theatres where he might be called to provide assistance.

Besides the correct professional training and health check-ups envisaged depending on the specific duties performed, the Expert shall always be given the Single Document of Risk Evaluation (DUVRI) of the hospital to which he is assigned, and the said document shall be adequately explained to him.
Concerning risks resulting from slipping and tripping, including gas, electricity and any involvement in a fire (risks that do not directly result from the activity of the Specialist), refer to indications provided by the hospital (signs and floor plans indicating exodus tracks and directions, collection points and sites in case of an emergency and fire-fighting tools and equipment, such as fire extinguishers and fire hydrants).

3.1 EXPOSURE TO CHEMICAL AGENTS

The phrase 'chemical risk' designates potential exposure (for ingestion, contact with skin, inhalation) to chemical agents that could cause poisoning, allergies or intoxication.
Early information on the hazards, if any, of a chemical product is given by the symbol and by the danger sign that shall be published on the product label.
Symbols provide a classification of the hazardous nature of substances contained on the basis of their chemical and physical (e.g. explosive, highly or easily inflammable...), toxicological (e.g. toxic, hazardous, irritant…) and echo toxic properties. This symbol does not offer any immediate indication. It only draws the attention of those who use a certain product.

Chemical Risk Symbols



Chemical products that are relevant for hygiene and therapeutic requirements are used inside the operating theatre: detergents, disinfectants, sterilising agents and anaesthetic gas. These products can be inflammable, irritant or toxic.
Detergents, disinfectants and sterilising agents are stored in cabinets, and are generally available on operating theatre trolleys and fittings for cleansing and disinfection of the operator and of the patient, and for cleaning the premises.

Detergents and disinfectants can produce clinical manifestations that concern the skin in a localised or generalised manner (contact dermatitis) that can be either irritative or allergic.
Another possible source of risk is related to the use of latex gloves, which can cause either irritative or allergic dermatitis; the latter is due to soluble proteins that form the latex glove and corn starch that is used to easily slip on the glove.
Lastly, staff authorised to access operating theatres, as prescribed for healthcare professionals, is exposed to anaesthetic gases that are released into the environment during surgery.
Regarding the hazardous nature of anaesthetic gases and the potential prolonged exposure time, it has been deemed that the risk of exposure can be defined as “not moderate”.
Anaesthetics can induce loss of consciousness, encourage loss of muscle tone and control the response to pain stimuli.
To reach target organs, they can exploit either inhalation or an intravenous route.
Inhalation anaesthetics include: nitrogen protoxide (that at ambient temperature and at atmospheric pressure is already in a gaseous state); halogenates (fluids, volatiles that need vaporisation, which is obtained by mixing them with other gases).
As a rule, inhalation anaesthesia is administered by using nitrogen protoxide combined with oxygen and potentiated by a halogenated vapour.
Emission into the workplace mainly results from accidental loss of gas from anaesthetic equipment and from the related circuits, and when the patient is regaining consciousness. Anaesthetics are metabolised in the liver, and they are eliminated in urine.
Effects resulting from absorption of anaesthetics are closely related to the extent of exposure, and they can produce transitory alterations in some psychological functions such as alertness, attention and concentration.
Hospitals are required to ensure control and maintenance of anaesthesiological plants and equipment, and to perform periodical evaluations of conditions of exposure through environmental monitoring.

Prevention
Professional exposure to chemical products shall be maintained within the lowest possible levels.
There are collective protection devices (air exchange systems in rooms, dilution of chemical agents) and systems that capture pollutants at the source (suction hoods).
Periodic checks that the anaesthesiological unit is sealed shall be conducted through detection of the presence of anaesthetic gas, and by periodically checking the quality of air in the Surgery Unit, ensuring ongoing maintenance of air conditioning plants.
Besides complying with procedures indicated to him and using the assigned Individual Protection Devices, the Specialist shall enter the operating theatre after anaesthetic gases have been administered, and leave it before the patient regains consciousness, thus minimising his stay in the operating theatre.

SUMMARY SHEET OF CHEMICAL RISK

The specific prevention and protection measures for activities involving a chemical risk envisaged in articles. 224, 225, 226 and 227 of Legislative Decree No. 81/2008 are given below.

Art. 224 – Risk prevention measures

- *Risks resulting from hazardous chemical agents shall be either eliminated or minimised by adopting the following measures:*
- *a) plan and organise processing systems in the workplace;*
- *b) supply suitable equipment for the specific work and relevant appropriate maintenance procedures;*
- *c) minimise the number of workers who are or could be exposed;*
- *d) minimise the duration and intensity of exposure;*
- *e) ensure adequate hygiene measures;*
- *f) minimise the number of agents who are present in the workplace, depending on processing requirements;*
- *g) ensure appropriate working methods, including provisions that guarantee safe handling, storage and transport to the workplace of hazardous chemical agents and of waste containing the said chemical agents.*

Art. 225 – Specific protection and prevention measures

The employer shall ensure that the risk is either removed or reduced through replacement, if the nature of the activity allows it, with other agents or processes that, in conditions of use, are not or are less hazardous for the health of workers. When the nature of the activity does not allow elimination of the risk through replacement, the employer shall guarantee that the risk is reduced by applying the following measures, which shall be adopted in the following priority order:

a) plan appropriate working processes and technical controls, and use adequate equipment and materials;
b) appropriate organisational and collective protection measures at the source of the risk;
c) individual protection measures, including individual protection devices, if exposure cannot be prevented with other measures;
d) healthcare surveillance of workers, pursuant to articles 229 and 230.

Unless it can be proven with other means that an adequate level of prevention and protection have been achieved, the employer shall periodically, and whenever conditions influencing exposure are changed, measure agents that can be a health hazard.

When a limit value of professional exposure established by the current regulation is exceeded, the employer shall identify and remove the causes that have led to this excess by immediately adopting the appropriate prevention and protection measures.

The results of measurements specified in section 2 are enclosed with the risk evaluation documents and made known to representatives for the safety of workers.

Art. 226. Provisions in case of accidents or emergencies

To protect the health and safety of workers from the consequences of accidents or emergencies resulting from the presence of hazardous chemical agents in the workplace, the employer shall arrange for adequate intervention procedures to be implemented when the events occur. These drills include safety drills to be carried out at intervals depending on the processing mode, and entail making appropriate first aid equipment available.

In case of accidents or emergencies, the employer shall adopt immediate measures that are designed to attenuate their effects and, especially, centred on assistance, evacuation and rescue, and he shall inform workers about it.
The employer shall adopt the necessary provisions to set up alarm systems and other communication systems that are necessary to speedily report the accident or emergency.

Art. 227. Information and training for workers

The employer shall guarantee that workers and their representatives have:

a) data obtained through risk evaluation and additional information whenever important changes in the workplace produce a change in this data;
b) information on hazardous chemical agents that are present in the workplace, such as the identity of agents, safety and health risks, the related professional exposure limits and other regulatory provisions for agents;
c) training and information on precautions and appropriate actions to be implemented to protect themselves and other workers in the workplace;
d) access to every safety data sheet that is made available by the Marketing Authorisation Manager, pursuant to Legislative Decrees No. 52 dated 3 February 1997 and No. 65 dated 14 March 2003.

The employer shall ensure that information is provided adequately to suit the result of risk evaluation, and updated to take into account changes in circumstances.

3.2 EXPOSURE TO BIOLOGICAL AGENTS

Title No. 10 of Legislative Decree No. 81 dated 9 April 2008 (Single text of health and safety in workplaces) specifically regulates exposure of the worker to biological agents.
“Biological agent” is any microorganism, even genetically modified, cell culture and human intraparassite that could cause infections, allergies and intoxications.
Biological agents are divided into the following four groups, depending on the risk of infection:
group 1 biological agent: an agent that presents a low potential of causing diseases in human subjects;
b) group 2 biological agent: an agent that can cause diseases in human subjects and be a risk for workers. It is not very likely to spread in the community; effective prophylactic or therapeutic measures are usually available;
c) group 3 biological agent: it can cause severe diseases in human subjects and represent a serious risk for workers. The biological agent can spread in the community, but effective prophylactic or therapeutic measures are usually available;
d) group 4 biological agent: a biological agent that can cause severe diseases in human subjects, be a serious risk for workers, and can present a high risk of propagation in the community. No effective prophylactic or therapeutic measures are usually available.
If the biological agent classified cannot be unequivocally assigned to one of the two aforementioned groups, it shall be classified in the highest risk group of the two options.
The phrase “biological risk” designates potential exposure (for ingestion, contact with skin, inhalation) to biological agents (microorganisms, cell cultures and human intraparassites) that could cause infections, allergies or intoxication.

The risk of exposure to biological agents is generally present in hospitals, considering the possible presence of biological material produced by the patient (blood, serum, urine, faeces, sputum); this risk is particularly present in all departments, outpatients clinics, diagnostic rooms, Emergency Department and, especially, in operating theatres.
The Specialist is exposed to the biological risk especially through inhalation or accidental contact with organic secretions/fluids of patients presenting infectious diseases. The most frequent modes of exposure to biological agents can be: contact with mucous tissue (conjunctiva, mouth) or skin, a prick, cut or abrasion caused by objects (instruments) or equipment.
The principal routes of transmission are the following:

- haematic: hepatitis B, hepatitis C, AIDS (HIV), hepatitis delta;
- aerial: tuberculosis, meningococcal meningitis;
- orofaecal: salmonellosis, hepatitis A;
- contact with skin: scabies, pediculosis.

Prevention
Having considered potential forms of contagion, the main methods of prevention shall now be taken into account: immunoprophylaxis, precautions and post-exposure prophylaxis.

a) Immunoprophylaxis
It belongs to the general programme of healthcare surveillance that, depending on indications provided to the competent doctor, is recorded in acts filed by the company and handled by the employer and by appointed corporate positions (RSPP and RLS).

b) Recommendations and Precautions
Biological fluids are one of the most important sources of infection. Hence, the need to adopt effective precautionary measures when coming in contact with biological fluids in order to avoid spreading infectious diseases.
Universal precautions shall be applied to: blood, tissues, bone fragments, liquor, pleural, synovial, pericardial, peritoneal fluid, etc.
Universal precautions envisage: a) washing hands, b) using gloves (Individual Protection Device), c) using protective gowns (Individual Protection Device), d) using protective masks, goggles and face covers (Individual Protection Device).

a) Washing hands

It is the simplest and most effective prevention method, basically to prevent the transmission of hospital infections. If this activity is performed with due attention, it reduces the risk of contagion by over 40%.
Hands are, by definition, a vehicle for transfer and contamination; hence, much care is required, if one happens to visit or stay in limited access areas such as operating theatres, in practicing thorough and accurate washing that is effective against occasional (or transitory) flora and resident flora.
Occasional flora includes microorganisms from the environment. It is acquired through contact. They survive for long periods (they are often antibiotic-resistant) but can be easily removed only by means of accurate washing.
Resident flora includes microorganisms that are normally present on the skin and in its crevices. They are scarcely virulent and rarely cause infections. In this case, mere

washing will not suffice, and a specific antiseptic shall be required to reduce the microbial load.
In case of accidental contact with blood or other biological materials, with contaminated equipment and objects, hands shall be immediately washed, and it would be better to use an adequate antiseptic. If gloves are worn, it is a good practice to, anyhow, wash the hands.

b) Using gloves

The use of gloves is very important, though it does not replace the need to wash hands, because gloves might have microscopic holes.
If sales staff is present in limited access areas of a hospital, the adoption of protective gloves does not respond only to the rationale of reducing the risk of transmission of infections, if any, but it forms a protective barrier to handling of any objects that are present in such environments.
If gloves are required:

- avoid rings and bracelets because they do not allow good hygiene of hands;
- avoid gloves from coming in contact with the sleeves of the protective uniform;
- avoid overstretching the gloves;
- pull them at the base of the fingers to slip them on;
- ensure that they are neither too tight nor too wide.

Used gloves shall be considered as disposable, not reutilisable and not washable. If one notices the presence of microscopic holes or damage, they shall be immediately replaced.
To ensure better protection especially for those who, to carry out a demonstration or to prepare various surgical instruments, need to handle and process the same (preparation, set up and control), high protection gloves (e.g. made of Kevlar) are recommended to avoid accidental pricks or cuts caused by extremely sharp components.
They shall be disposed of in special containers for such types of materials. Sales staff is absolutely forbidden to throw used gloves inside the hospital in common bins or containers for solid urban waste.

c) Using protective gowns

The scope of the gown is to prevent direct contact of clothes and skin with blood and other infected material. It is required whenever a person comes in contact with limited access areas and, particularly, inside operating theatres.
The gown is a disposable product. It is, therefore, forbidden to use the same garment repeatedly, and care is required to immediately replace it in case of holes or damage.

d) Using masks, goggles, protective facial shields (Individual Protection Devices)

These types of Individual Protection Devices are required to protect both the operator and the patient from exposure to pathogens that are transmitted by air.
The mask shall be correctly positioned on the face in order to cover both the mouth and the nose; strings shall be tied behind the nape, and it shall only be manipulated through the said strings. It shall never be lowered for any reason whatsoever.
It is mandatory to wear protective goggles and facial shields when performing all procedures that entail a risk of exposure of oral, nasal and conjunctival mucous tissues to either blood or other biological fluids (surgery, intubation, endoscopy, bronchoscopy and during washing of the said instruments). It is, generally, a good practice to resort,

in any case, to protective goggles or facial shields whenever manoeuvres entailing splashing or direct contact with biological materials are performed.
Gloves, protective gowns, masks, protective goggles and facial shields shall be correctly disposed of in the special containers that are usually found in hospital facilities.
All Individual Protection Devices shall be provided to the specialist by the hospital to which he is assigned. The Specialist shall, anyway, have his own Individual Protection Devices, which he shall use if the hospital is unable to provide appropriate ones.
Failing Individual Protection Devices, the specialist shall refuse to enter hospital facilities, and he shall immediately report the event to his company.

Post-exposure prophylaxis
Simple recommendations shall be taken into account in case of accidental contact with biological material.
In case of parenteral exposure, it is recommended to increase bleeding, immediately cleanse with soap and water and then disinfect the wound.
In case of contamination of mucous tissue, it is recommended to rinse thoroughly with running water.
In case of contamination of injured skin, it is recommended to cleanse thoroughly with soap and water and then completely disinfect the skin area concerned.

Pregnant workers
Pregnant workers who, acting as Product Specialist, might come in contact with sites (operating theatres, departments at risk of infection) that by definition present high risk factors, shall abstain from visiting departments at risk and especially operating theatres from the moment their pregnancy is ascertained, limiting their presence only to administrative departments in the hospital premises.

SUMMARY SHEET OF BIOLOGICAL RISK

The following summary sheet presents specific prevention and protection measures for activities involving a biological risk that are envisaged in articles 272, 273, 276, 277, 278, 279 of Legislative Decree No. 81/2008.

Art. 272. Technical, organisational and procedural measures

- *Avoid using hazardous biological agents, if the type of working activity allows it.*
- *Minimise the number of workers exposed, or potentially exposed, to the risk of biological agents.*
- *Adequately plan working processes.*
- *Adopt collective protection measures, namely individual protection measures if exposure cannot be otherwise avoided.*
- *Adopt hygiene measures to prevent and minimise accidental spreading of a biological agent outside the workplace.*
- *Use the biological risk sign published in Enclosure 45 of Legislative Decree No. 81/2008, and other appropriate warning signs.*
- *Process appropriate procedures to collect, handle and process samples of human and animal origin.*
- *Define emergency procedures to face accidents.*

- *Check the presence of biological agents in the workplace outside the primary physical containment, if necessary, or if the check can be technically implemented.*
- *Arrange the tools required to collect, store and dispose of waste in safe conditions by using adequate and identifiable containers, even after appropriately processing the waste.*
- *Define procedures for safe handling and transport of biological agents inside the workplace.*

Art. 273. Hygiene measures

- *Place adequate washrooms that are fitted with hot and cold water showers, and, if necessary, supplied with eye washes and antiseptics for the skin, at the disposal of workers.*
- *Provide workers with protective clothing or other appropriate garments that shall be placed in a place other than the one where civilian clothes are stored.*
- *Individual protection devices shall be checked, disinfected and cleaned after each use, also repairing or replacing defective ones before the next use.*
- *Working and protective clothing that can be contaminated by biological agents shall be removed when the worker leaves the work area, store separately from other clothing, disinfected, cleaned and, if necessary, destroyed.*
- *It is forbidden to take foods or drinks and to smoke in work areas presenting a risk of exposure.*

Art. 276. Specific measures for industrial processes

- *Except for what has been specifically envisaged in Enclosure No. 44, section 6 of Legislative Decree No. 81/2008, industrial processes entailing the use of biological agents belonging to groups 2, 3 and 4 shall adopt appropriate measures from those listed in Enclosure No. 48 of Legislative Decree No. 81/2008, taking into account the criteria specified in the previous point 273.2.*
- *Measures corresponding to at least those of third level containment shall be adopted in case of biological agents that have not been classified as yet, and whose use can give rise to a serious risk for the health of workers.*

Art. 277. Emergency measures

- *An emergency procedure that envisages at least the following points shall be arranged and adopted.*
- *If accidents that can cause dispersion in the environment of a biological agent belonging to groups 2, 3 or 4 should occur, workers shall immediately abandon the area concerned, which shall only be accessed by staff appointed to perform necessary interventions. They shall be obliged to use appropriate means of protection.*
- *The employer shall inform the competent surveillance body for the territory, the workers and the representative for safety at the earliest about the event, about the causes that triggered it and about the measures he plans on adopting, or which he has already adopted, to remedy for the situation that has been created.*
- *Workers shall immediately inform the employer or the director or the appointed person about any injury or accident related to the use of biological agents.*

Art. 278. Information and training

- *On the basis of knowledge available, workers shall be provided with information and instructions particularly concerning:*
  a) health hazards resulting from the biological agents that were used;
  b) precautions to be adopted to avoid exposure;
  e) hygiene measures to be observed;
  d) the function of protective working clothes and of individual protection devices and their correct use;
  e) procedures to be followed to handle biological agents belonging to group 4;
  f) the way of preventing the occurrence of injuries and measures to be adopted to minimise their consequences.
  Workers shall be ensured adequate training especially concerning details specified in the previous point 278.1.
  The information and training specified in previous points 278.1 and 278.2 shall be provided before workers are appointed to perform the activities in question, and repeated, at least every five years and, anyhow, whenever changes that affect the nature and degree of risks are implemented to processing.
- *Signs reporting the procedures to be adopted in case of an injury or accident shall be placed in a highly visible position in the workplace.*

Art. 279. Prevention and control

- *A specific healthcare surveillance protocol shall be implemented for the biological risk, pursuant to provisions in Art. 279 of Legislative Decree No. 81/2008.*

3.3 ACCIDENT RISK

The risk of accidents is scarcely important because the equipment used contains no parts that are in themselves dangerous, and premises do not usually have areas that present a risk of falling or slipping.

3.4 ELECTROCUTION RISK

The risk of electrocution is only correlated to the use of electric equipment, which is not relevant for the scope of this paper.

3.5 RADIATION RISK

Equipment that emits ionising radiations (brightness enhancers, optical instruments) could be used inside the operating theatre during surgery. These devices are used either by appointed staff or by the surgical team to obtain X-ray images.

The emission of radiations from a radiation generating device only occurs when a specific control switch is operated, and it ceases as soon as this action is interrupted; therefore, they entail a risk only during their actual use. The risk is especially related to the primary beam, which is emitted by the device along a precise direction, and to diffused radiation (that originates in objects and in walls, which are lit up by the primary beam) and to any escaping radiation emitted by the device in directions other than that of the primary beam. The principal aspects to be considered to reduce irradiation are:
shields: exposure to radiations diminishes considerably when the source is positioned behind a suitable material (e.g. lead); thicker the material and less quantity of radiation can penetrate the shield;
time: exposure to radiations is proportionate to time;
distance: exposure to radiations considerably diminishes as the distance from the source increases (e.g. when the distance is doubled, exposure is reduced by four-fold).
Ionising radiations that produce ions in the material they cross make the atoms concerned chemically unstable, triggering in living organisms biochemical processes that can cause biological damage to tissues/organs involved. There can be two types of biological damage: a) somatic damage to the person involved; b) hereditary damage that concerns the chromosomal heritage of the person involved, which is handed down to his descendants.
Product Specialists are potentially exposed to ionising radiations during the activity performed in customer premises, namely hospitals and medical centres.
Regarding the above details, associates shall appoint an Expert Qualified Manager for physical surveillance of radioprotection. The person shall establish the safety measures to be adopted. To this end, workers shall make use of specific Individual Protection Devices (protective gloves, if necessary, lead gown, protective lead goggles, special protective collar, dosimeters).

Regulations on Radioprotection
It is important for each Specialist to obtain information in advance about the specific procedures to be followed and the prevention and protection measures to be adopted for their personal safety during exposure to ionising radiations.
Specifically, the Specialist:

- shall ask the local appointed person/manager of the summoning facility in advance for information on protection measures in order to minimise exposure to X-rays (e.g. specialist who directs surgery);
- shall follow indications issued by the Manager, asking him to adopt the utmost care when using radiogenic sources in order to be able to move away to a correct position;
- shall inform the Division Director and/or Manager of the Prevention and Protection Department about any abnormal situations that might be found in the various plants, refraining from performing interventions when personal protection is not guaranteed.
- Only staff that have been classified by the corporate Qualified Expert shall be exposed to radiogenic risk and, if classified as “exposed worker”, they shall undergo a preventive medical examination and subsequent periodical follow-up examinations following which a statement of fitness shall be issued.
- The Specialist shall remain outside the Radiology Room during exposure (actual beam).
- If his presence is essential in the room during exposure, the operator shall stand as far from the source as possible and, anyhow, outside the direction of

the primary beam of irradiation and, if envisaged, behind the special protective barriers and, in any case, for the shortest possible time.

- The specialist shall avoid exposing any part of the body, including hands, to the direct beam.
- For any intervention that requires the presence of the Specialist in the Radiology Room, that is any intervention that might envisage exposure to radiation, the Specialist shall wear shielding individual protection devices (gown, parathyroid collar and goggles) provided by the company or by the appointed person of the room/Manager who shall be required to keep them available always and anyhow.
- Individual dosimeters prescribed by the Qualified Expert shall be used and stored as specified below.
- Staff shall comply with regulations and ensure observance of the same on the part of assistants, if any, informing them about the correct radioprotection procedures to be followed.
- Female workers shall immediately inform their Director and the Prevention and Protection Department about their pregnancy, and concurrently avoid entering supervised and controlled areas, and abstain from performing activities that can entail exposure to ionising radiations until 7 months after delivery. At the end of this period, if the person is confirmed as an exposed worker, and prior to exposure to radiations, she shall undergo an extraordinary medical examination that shall be conducted by the doctor appointed to issue a new statement of fitness.
- If new interventional techniques that imply new devices and, therefore, different levels of radiogenic risk are introduced, check in advance with the Director whether the Qualified Expert has evaluated working conditions and the doses they might entail.
- In case of doubt, the person shall contact the Qualified Expert and/or the Corporate Doctor through the Prevention and Protection Department.

Use of dosimeters

The use of individual dosimeters prescribed by the Qualified Expert is mandatory, and any variation shall be approved by the Expert himself.

The position of individual dosimeters assigned by the Qualified Expert:

- if the operator has assigned <u>three dosimeters,</u> the one under the gown shall be shielded at the waist; the dosimeter over the gown shall not be screened, and it shall be placed over the gown near the neck; the dosimeter for the hands shall be worn on the wrist or fingers, and under shielding gloves, if any;
- if the operator has assigned <u>only one dosimeter,</u> it shall be placed near the pocket and under the shielding gown, and it shall always be worn inside the operating theatre.

Dosimeters shall neither be tampered with nor placed near sources of heat nor wet, and their use is mandatory during all work-related exposure and in all hospital premises.

If they are lost, they shall be immediately replaced, informing the Prevention Department.

They shall not be exposed to ionising radiations when they are not worn; therefore, they shall be stored far from sources of radiation.

They shall not be used in case of personal medical exposure, they are individual and they shall not be exchanged with colleagues.

4. CRIMINAL RISK IN THE ACTIVITY OF THE PRODUCT SPECIALIST

Before analysing the juridical consequences of the conduct of the Specialist, we shall first define the status of jurisprudence concerning healthcare liability.
Our juridical order deems the right to health as a basic constitutional right.
Article 32 of the Constitution establishes that "*the Republic protects health as a fundamental right of the individual, and a common interest, and guarantees free treatment for the destitute. Nobody can be obliged to accept a certain healthcare treatment unless it is legally established. The law can in no case violate the limits established by respect for the human person."*
Professional liability in the healthcare framework can generally result from inadequate performance that produces negative effects on the health of the patient, and it can entail consequences in terms of civil and criminal law, and professional ethics.
In the framework of civil law, the principal reference regulations are Art. 1176 of the Civil Procedural Code (diligent performance), Art. 1218 of the Civil Procedural Code (liability of the debtor), Art. 2043 of the Civil Procedural Code (compensation for an illegal event), Art. 2230 the Civil Procedural Code (professional services), Art. 2236 of the Civil Procedural Code (liability of the service provider).
From a criminal standpoint, the rules that are most commonly considered are specified in Art. 590 of the Criminal Procedural Code (accidental injuries), Art. 589 of the Criminal Procedural Code (culpable homicide), Art. 584 of the Criminal Procedural Code (involuntary manslaughter) and Art. 582 of the Criminal Procedural Code (personal – voluntary - injuries).
Violation of the rules of professional ethics can, instead, lead to sanctions issued by the competent Board of Directors of the professional association.
Criminal liability can normally be attributed either as wilful deceit or as misconduct.
A crime is deemed as malicious or intentional when the damaging or hazardous event, which resulted from the action or omission that determines the existence of the crime, by law, is foreseen and intended by the agent as a consequence of his action or omission.
The crime is deemed as misconduct or not intended when the event, even if it has been foreseen, is not intended by the agent and occurs due to negligence, carelessness or inexpertise, that is due to failure to abide by the laws, regulations, orders and discipline.
The healthcare operator shall not only implement appropriate conduct and cautions to forestall predictable damage (from an expert in the sector with average diligence), but he/she shall also abstain from performing all actions that can be a source of risk for the health of the patient, since they are intrinsically dangerous activities.
Jurisprudential trends that have followed in succession on the theme of healthcare liability can be summarised as described below.
The early phase - from the mid-'50s to the early '80s – limited medical liability only to macroscopic errors. It only acknowledged the so-called serious misconduct, whose concept was changed by the legislative provision in Art. 2236 of the Civil Procedural Code, a rule that regulates the liability of the service provider: "*if the service implies solving very difficult technical problems, the service provider shall not answer for damages unless in case of wilful deceit or serious misconduct."*
Regarding this first trend, it is worth mentioning the ruling dated 29 March 1963 issued by the 4th Section of the Court of Cassation, which decrees that "… *misconduct can only be found in an inexcusable error, precisely in the lack of general medical*

knowledge, in the lack of the necessary technical skill, in the trivial transgression of rules that regulate the art", and ruling dated 16 February 1987, always issued by the 4th Criminal Section of the Court of Cassation, which decrees that "*professional negligence of the doctor shall be evaluated by the Judge with a broad minded, understanding attitude. The exclusion of professional negligence is limited by professional conduct that is incompatible with the minimum required cultural standards and experience that shall be legally demanded of the person who practices the medical profession."*

Hence, the phrase "special difficulty" of surgery designates the facts by which one can judge a statement of criminal liability.

What does the phrase "particularly difficult technical problems" mean?

There are at least three feasible theories:

a) when the disease presents ambiguous symptoms that can lead to diagnostic and, hence, treatment errors;
b) when, despite clear and univocal symptoms, there are serious doubts about the aetiology, with unavoidable repercussions on the treatment to be administered, or contrasting treatments are planned due to the concurrent presence of multiple diseases and contrasting risks;
c) when the case seems to be exceptional because it has not been adequately studied and experimented as yet, and because it is still the focus of scientific debates with experimentations on diagnostic techniques and therapeutic treatments that have not been appropriately tested, and which differ depending on the school.

The evaluation must be conducted concretely, taking into account the special conditions in which the doctor is forced to intervene. It is evident that the special conditions in which the doctor had to intervene, without being able to consult specialists, and without either adequate equipment or qualified assistants cannot be neglected.

In the late '80s a different and more rigorous trend started to take off; it was inclined to criminally sanction even a slight misconduct on the part of a doctor. Starting from the assumption that not all surgical procedures can be deemed as "*particularly complex"*, the same judgement criteria that are normally adopted by criminal law (these criteria establish that even minor misconduct is a sign of criminal liability) had to apply to the medical class.

From the standpoint of medical liability for omissive conduct, that is for failure to intervene, in 1987 the Court of Cassation defined (Criminal Court of Cassation, 4th Section, 2 April 1987) how to recognise criminal liability only if "*reliable and evident chances of success that led one to believe that the life of the patient would most likely be saved"* were proven.

The most unfavourable interpretation for the medical class was reached in 1992: in a legal case for culpable homicide against two doctors for delayed diagnosis of a tetanus infection in a woman who had undergone Caesarean section, the Court of Cassation rejected the appeal of the two doctors against an adverse decision that acknowledged criminal liability and the existence of a causal link between their conduct and the death, despite the scarce 30% probability that their correct and speedy intervention would have produced a positive outcome.

However, the same year the Court of Cassation mentioned liability once again only in case of evident and reliable potential success of the omitted intervention. Criminal Court of Cassation, 4th Section, No. 371/1992: "*regarding criminal liability for professional negligence of the doctor, when seeking a causal link between the conduct*

of the defendant and the event, the criterion of certainty of the effects (of conduct) can be replaced by that of even a limited chance of the effects actually occurring, and of the adequacy of conduct implemented to produce them. Hence, causal relations exist even when the work of the doctor, if it is correctly and speedily performed, had no certainty but only a reliable and evident possibility of success that led to the belief that the life of the patient would most likely have been saved."

This deviating jurisprudential trend led the Court of Cassation to make a statement to the United Sections in the famous Franzese ruling dated 10 July 2002. This ruling acknowledged that the Judge could not automatically support the accusation of the existence of a causal link on the basis of the statistically calculated probability coefficient. He was, instead, required to check whether it actually applied to the concrete case with all the circumstances available, to prove that the omissive conduct of the doctor was a necessary condition for the damaging event with a high degree of rational credibility or logical probability in terms of procedural certainty.

The principle acknowledged by the ruling of the United Sections still applies today.

In case of liability for omissive conduct, the doctor shall answer criminal charges only if it can be stated with procedural certainty, hence beyond all reasonable doubt, that the dutiful action omitted by the doctor would have prevented the damage suffered by the patient.

Another relevant profile is the problem of defining the liability of the employee of a public facility. This issue has been repeatedly studied by jurisprudence.

Ruling No. 2144 dated 1988 explained the trend of the Supreme Court, creating an effective precedent for other rulings that followed.

With this ruling the Court of Cassation specified that the limitation of liability for cases of wilful deceit or serious misconduct established by the Single Text of Public Clerical Workers does not apply to the employee of a public institution who exercises a public service (including healthcare-related services).

But for the liability to be charged to the consultant, an abstract juridical obligation to prevent the event and the fact that omissive conduct was performed shall not suffice; it is, instead, essential to be able to reprimand the team leader for not abiding by the rules of diligence he was required to comply with.

The doctor who holds a leading position is, in the first place, required to adequately manage the distribution of duties within the competent department.

Legal literature and jurisprudence deem that the so-called *culpa in eligendo* applies when damage caused to the patient finds its primary cause in the wrong choice made by the medical director in assigning the duties to a certain doctor.

Another duty that is legally assigned to the doctor who holds a leading position is to ensure that his subordinate staff acts correctly and adopts precautions required to prevent damage to patients. Hence, another type of allegation is defined: the so-called *culpa in vigilando*.

The culpable conduct of the consultant in performing his supervisory duties can, in turn, be associated with either diagnostic evaluations, therapeutic activities or, anyhow, executive actions.

However, in recent decades the medical profession is being characterised by a trend toward specialisation and definition of a set of professional figures and competences. Hence, the issue of team liability comes into the limelight.

The importance of team liability is enlarged by the fact that every medical or surgical service is divided, in practice, into a series of healthcare operations that are, in turn, managed by various subjects.

For instance, the lead instrument nurse surveys the choice and sterilisation of instruments and operating theatre equipment, the lead anaesthetist surveys the entire phase that precedes surgery, and so on.
In fact, acts related to the position of the patient and correct administration of anaesthesia are usually performed by nurses who are not directly supervised by the consultant, but personally by the lead anaesthetist. The problem multiplies with a domino effect, reaching healthcare operators who have purely executive duties.
The keystone of a correct solution to the issue is, therefore, a carefully considered balance between two opposite requirements: on the one hand the need to protect the legal entrustment of the patient to the consultant, and on the other hand the supervisory duty of the team leader cannot be so intensive as to cause him to face the liability of any inaccurate service, regardless of the phase during which the said service was carried out by the operator who concretely provided it.
Careful conciliation and mediation between contrasting standpoints makes it seem appropriate to acknowledge that the consultant has a precise controlling capacity in all phases of hospitalisation.
However, it also seems legitimate that the blame on the doctor of any damage to the patient should be limited to the evident and controllable requirements of his subordinates.
In ruling No. 33619 dated 12 July 2006 the Criminal Court of Cassation acknowledged that "*every doctor is liable not only for compliance with the rules of diligence and expertise that are related to the specific and actual duties performed, but he shall also know and evaluate the activities of other team members in order to remedy to any errors implemented by others, as long as they are evident to an average professional because the various operations implemented converge toward a single final result."*
But what is the average reference standard to distinguish diligent service from one that is not diligent? It must first be specified that constant jurisprudence and unanimous legal literature trace medical service to the application framework of Art. 1176, Section 2 of the Civil Procedural Code.
Therefore, the diligence that can be demanded is not that of a "good father," but the specific diligence of a qualified debtor, taking into account the conduct and devices generally implemented by the average professional who belongs to the category that is considered from time to time.
And this is the crux of the issue: today the increasing specialisation demanded of every professional and, in particular, of every doctor, prevent focus only on compliance with the basic rules established by professional ethics in deeming a certain service as diligent. It is, instead, necessary to consider the average professional who possesses the same or a similar specialisation title, and even experience in the sector or field of intervention that concerns the concrete case as a reference parameter.
The principal element that characterises professional cooperation deserves some discussion: the trust each member has in the diligent work of the others.
In public service, as unanimously observed by legal literature, supported by jurisprudence on the subject, hierarchical relations, strictly speaking, are slowly making room to optimisation of the professional contribution and related liabilities of each operator.
Hence, the indications issued by the consultant to his assistants are not binding for the doctors, regardless of the fact that they are targeted for a specific case, and are generally given in advance. In fact, their qualification and professional skills are such that their decisional autonomy would be compromised in an unacceptable manner if they were required to passively follow the indications given by their superior.

It must, however, be said that the consultant could decide to take charge of the specific case. When this circumstance occurs, the health director is entirely liable for the health of the patient.
Concerning paramedic staff, they are exempted from liability if they can prove that they scrupulously followed the procedures established by their superior.
Jurisprudence has expressed contrasting opinions on medical liability regarding the theory that the consultant might leave the operating theatre in advance.
Recent rulings have confirmed the liability, on the one hand, of the doctor who was part of a healthcare facility where surgery was performed and who had performed all phases but, on the other hand, they have excused the circumstance of the doctor leaving in advance to respond to an urgent call that could not be postponed in order to assist other patients.
Along with the liability of the doctor and of paramedic staff, it is necessary to specify that even the hospital can be liable, and this liability is defined by analysing relations between the healthcare facility and the patients who entrust themselves to it.
The major part of legal literature and jurisprudence define actual contractual relations between the person who contacts the hospital and the hospital itself.
The moment the hospital admits the patient to its facilities, it enters into a professional contract according to which the hospital is obliged to carry out preventive diagnostic activities and to administer subsequent treatments in order to achieve the utmost improvements in the condition of the patient.
The Supreme Court, focusing on the surgical sector, has established rather precise rules to define the cases of liability of the hospital. The client who plans on obtaining compensation for damages resulting from invasive surgery that, despite its easy performance, had an undesirable outcome, shall only prove that:

a) the operation entailed no special difficulty;
b) the result achieved was worse than the initial situation.

The assumption of non diligent performance of the service will automatically apply when adequate evidence is provided for the aforementioned circumstances.
The hospital shall then be required to attempt to prove that the unsatisfactory result depended on one of the following causes:

a) a sudden and unpredictable event;
b) a particular physical condition of the operated patient that could not be detected even applying ordinary professional diligence.

Hence, the hospital shall incur in contractual liability outside the aforementioned cases for which it can provide redeeming evidence.
Hence, the prevalent trend leans toward equating the service provided by the hospital to the one provided by the freelancer who enters into a professional contract with the client.
Jurisprudence and legal literature that expound this parallel make it similarly applicable to all regulations that have been defined for professional service, including Art. 2236 of the Civil Procedural Code, which limits to the theory of wilful deceit or serious misconduct the liability of the professional, in case of particular difficulties.
The evaluation of the liability of the doctor, whose conduct did not meet averagely acceptable standards of diligence, shall consider the premises and equipment used by the healthcare operator.
The complex nature of healthcare service is such that the devices used shall be adequate from two standpoints. In the first place the decision must be weighted considering the requirements of the actual type of surgery that is about to be performed (e.g. the scalpel shall possess the appropriate characteristics and size for

the surgery during which it will be used). Furthermore, the equipment shall at least meet average technical standards, and it shall be sufficiently in line with technological progress.
The hospitals are required to place at the disposal of doctors premises that at least meet adequate standards, besides appreciable internal organisation and coordination.
If the negative outcome of surgery depended on structural deficiencies, the Law Courts of Rome (4th Criminal Section, Order dated 18.10.2000) have established that in such cases that the doctor who is called to answer for damage to the client can request the intervention of the hospital, and the latter shall be obliged to ensure that he is not convicted.
However, the Court of Cassation has repeatedly specified that structural deficiencies cannot, even indirectly, be the cause of liability of the doctor, if the condition of the patient was such as to deem that his transfer to another hospital would have been harmful. In such urgent circumstances, the healthcare operator can make use of redeeming evidence specified in Art. 1218 of the Civil Procedural Code: impossibility to precisely perform the duty for reasons for which he is not liable.
The jurisprudential trend, which has gradually become increasingly favourable to the medical class (to the point that criminal law deems surgery performed without the informed consent as legal), does not apply to the Specialist in any way.
It is, in fact, clear that the Specialist shall never and in no way touch the patient for any reason whatsoever.
If the Specialist actually participates in surgical procedures in some capacity, he shall answer for the crime of intentional lesions since this conduct is neither authorised by the patient (lack of consent), nor legitimated by the professional association or by the professional skills of the same.
It is clear that the crime of intentional lesions charged against the Specialist shall remain, regardless of the negative outcome of surgery.
It is then natural that the charge against the Specialist would extend to the surgeon in terms of contributory negligence, since he allowed the undue interference of a subject who was not authorised to perform surgery.
From the standpoint of compensation for damage (civil liability), the company represented by the Specialist could be called to answer for the damage caused by the same, unless there is evidence that the company has done everything within its power (particularly training activities) to prevent such conduct from being implemented.

Enclosure 1

Place and date

The General Manager
The Manager
The Prevention and Protection Department

Subject: coordination of prevention and protection of workers in the workplace (art. 26 of Legislative Decree No. 81 dated 9 April 2008 "Single text regarding the protection of workplace safety and health").

If requested by your healthcare operators, our employee/agent can be present in your facility (and especially in the operating theatre) to provide the technical and application support required to optimise the use of medical devices.

The activity performed by our staff, which shall follow indications provided by your managers, shall only entail technical and application support to your operators, and the length of time spent by our staff in your facility shall depend on the type of procedures performed and on your requirements, which cannot be scheduled at times.

During these activities, our corporate staff might be exposed to specific risks related to typical functions of your healthcare facility, such as, for instance: ionising radiations, electromagnetic fields, biological risk, presence of anaesthetic gas and any other risks that are either produced by your equipment or present in operating theatres.

Hence, the need to adopt coordination procedures and measures for safety and health in the workplace, pursuant to Art. 26 of Legislative Decree No. 81 dated 9 April 2008 ("Single text regarding the protection of workplace safety and health").

On its part, our company shall protect its employees pursuant to provisions regarding employers in Legislative Decree No. 81 dated 9 April 2008 "Single text regarding the protection of workplace safety and health".

Concerning exposure to ionising radiations, pursuant to provisions in articles 61, 75 and 83 of the aforementioned Legislative Decree No. 230/95, the Company shall make use of its Qualified Expert and competent/authorised doctors to:

- classify its staff by the activities performed;
- subject exposed workers to healthcare surveillance and to individual dosimetric surveillance for X-rays used in radiodiagnostics;
- inform employees, with reference to their duties, about the risks and general protection measures they should comply with, about the implementation modes of the work and about adequate radiogenic risk procedures (typically the specific risk related to radiodiagnostics in an operating theatre, e.g. neurological, orthopaedic, cardiological, angiographic and haemodynamic laboratory);
- Inform its employees that they shall be required to scrupulously follow indications on protection, protection and safety regulations and specific procedures that are issued by your managers and/or appointed persons.

We also declare that all employees are duly insured both for healthcare and welfare purposes, and that contributions are duly paid to welfare and healthcare institutions as established by the current regulation in terms of amounts and deadlines.

From another standpoint, we trust that you, pursuant to Legislative Decree No. 81/2008 and to the related regulation, as a party performing activities that entail a specific risk, shall handle the operative aspects related to protection from work-related risks that are directly related to the activity performed, both for staff and for medical equipment and/or devices that might be returned to us for analysis (e.g. disinfection against biological risk…). Moreover, pursuant to Art. 26, section 1, letter b) and section 3 of Legislative Decree No. 81/2008, we look forward to receiving information about specific and environmental risks, and about the risk resulting from any interferences with activities performed by other suppliers/operators.

Regarding the radiogenic risk, we particularly trust that, pursuant to Art. 65 of Legislative Decree No. 230/95, you shall:

- adequately inform our staff about risk areas and about protection and safety rules (that apply to both normal and emergency situations) that are effective in your facility;
- survey close compliance with the rules on the part of your staff;
- provide our staff with shielding individual protection devices, if they do not have their own.

Considering the above, and for any intervention that might expose our employees to specific risks, we wish to underscore the importance of preventing risks, including those related to biological risk, exposure to electromagnetic fields and to ionising radiations. We request you to provide our company with any additional information that might be useful in coordinating the safety of workers, including specific operative procedures for normal occupational situations and for emergencies, if any, that our staff is required to comply with both for personal safety and for the safety of persons who are present.

For any further clarifications and additional information you might require, please contact the **Prevention and Protection Department of your company (contact persons).**