

INTERFERENCE and RISKS ASSESSMENT DOCUMENT

Information document on the specific workplace hazards in the environments and structures of the C.R.O.M. "Oncological Research Center of Mercogliano" Prevention and emergency measures adopted

Aimed at contractors, workers and non-employee workers operating within the CROM (pursuant to art. 26 paragraph 1 b) Legislative Decree 81/08 as amended)

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INTRODUCTION

The objective of this document is to provide information on the specific risks present in the environments of the "Oncological Research Center of Mercogliano" (hereinafter referred to as CROM), managed by the IRCCS Istituto Tumori di Napoli - G. Pascale Foundation, and on the incidence of such risks with respect to the personnel assigned to activities entrusted to a contract or work contract within the CROM (e.g. maintenance, cleaning, etc.). It therefore collects the main safety indications prepared by the Institute in application of art. 26 of Legislative Decree 81/08.

It is clear that, for the pursuit of the best safety conditions in the work entrusted to non-employee personnel within the CROM, the activation of an information flow between the various subjects involved is of primary importance: Employer, Client, Employer of the **Contracting Company**, Manager / s of the structures involved in the works / contract, Administrative or technical structure responsible for managing the contract and the Prevention and Protection Service.

This document is configured as operational support in the context with this flow of information and constitutes fulfillment, by the client employer, with the obligation to provide contractors / self-employed workers with detailed information on the specific risks existing in the workplace in which they are intended to operate and on the related prevention and emergency measures adopted in relation to their activities according to the provisions of Article 26 paragraph 1 letter b.

The information and indications contained in this Document constitute fulfillment by the Employer of the obligation of cooperation and coordination of prevention and protection interventions to eliminate the risks due to interference between the work of the various companies involved in the execution of the overall work, in the event of the coexistence of several companies in the same workplace (Legislative Decree 81/08, art. 26 c. 2 letter b), process whose promotion is the responsibility of the client Employer (Legislative Decree no. Law 81/08, art. 26 c.3).

The aforementioned obligation does not extend to the specific risks inherent in the activity of contractors or individual self-employed workers, as established in c. 3 of art. 26 of Legislative Decree 81/08; However, it was considered useful to also report some indications relating to specific risks inherent in activities typically entrusted to contractors within the CROM: these indications with the result of the experience gained on the subject within the CROM, are intended only as suggestions - not exhaustive of all the possible risks inherent in these activities - aimed at the employers of contractors or self-employed workers.

There is talk of **interference** in the circumstance in which there is a "risky contact" between the customer's staff and that of the contractor or between the staff of different companies operating in the same company headquarters with different contracts.

Risks from interference can therefore be generated by:

- overlapping of several activities carried out by operators of different contractors;
- presence of risks from the customer's own work in the places where the contractor is expected to operate, additional to those specific to the contracted activity;
- placing the contractor's work in the client's workplace;
- particular methods of execution specifically requested by the client that involves additional risks compared to those specific to the contracted activity

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Pursuant to Legislative Decree 81/08 and subsequent amendments and of Resolution no. 3 of 5 March 2008 (Official Gazette no. 64 of 15.03.2008) issued by the Authority for the Supervision of public contracts for works, services and supplies - "Safety in the execution of contracts relating to services and supplies. Preparation of the single risk assessment document (DUVRI) and determination of safety costs "- the drafting of the DUVRI is not envisaged in the event that the contract consists of:

- mere supply of materials or equipment without installation or works and services whose duration does not exceed two days, provided that these do not involve risks deriving from the presence of carcinogens, biological agents, explosive atmospheres or the presence of particular risks (referred to in 'annex XI of Legislative Decree 81/08);
- services for which execution within the Contracting Authority is not envisaged, meaning by «Internal» all the premises / places made available by the same for the performance of the service, even if not the seat of its offices;
- services of an intellectual nature, even if performed at the contracting authority;
- contracts falling within the scope of Title IV of Legislative Decree 81/08 and subsequent amendments, for which it is necessary to draw up the Safety and Coordination Plan, the analysis of interfering risks and the estimate of the related costs are contained in the Safety Plan and Coordination and, therefore, in this case it does not appear necessary to draft the DUVRI.

SINGLE INTERFERENCES RISKS ASSESSMENT DOCUMENT (DUVRI)

• For each contracted contract for the supply of goods and services that includes interfering activities, the Client will process the DUVRI which indicates the measures adopted to eliminate the risk factors determined by the interference between concurrent activities carried out in the same work environment.

This document, drawn up pursuant to Article 26 of Legislative Decree 81/08 is shared with the Contractor and is attached to the contract or work contract.

- For all other cases not included in the previous point, which provide, in any case, the presence of interfering risks, this document is deemed to comply with the provisions of Article 26, paragraph 3 of Legislative Decree 81/08. In this case, the Institute will be responsible for making the necessary devices available to non-employee external operators (in any capacity in the company) to protect them from any risks associated with the activity carried out in the CROM.
- For works involving the opening of temporary or mobile construction sites, falling within the scope of Title IV of Legislative Decree 81/08, reference is made to the provisions of the same Decree, including therefore the preventive study of the aspects related to safety in design phase, at the expense of the figures provided, and compliance with the same legislation in the execution phase. In any case, the assessment of any critical safety aspects (eg "interference") is envisaged, with particular reference to the interface areas between the construction site and the normal activities of the structure.

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Contracting companies or individual self-employed workers, in communicating the **specific risks associated with their business**, must promptly and formally submit (to the Employer and the SPP) any proposals for integration to the DUVRI, where they believe they can better guarantee work safety, based on their own experience. In no case can any additions justify changes or adjustments to safety costs.

PREDISPOSITION OF DOCUMENTS RELATING TO WORK SAFETY

by the contractor/self-employed worker

For each contract, the contractor is required to prepare the safety documentation that describes the objective of the contract, the working phases and the expected times, the machines and/or equipment required, the materials, the workers employed and the working techniques. This documentation is used in order to highlight the technical and organizational measures to be implemented for the purpose of preventing and protecting their workers from occupational risks, but also for the protection of third parties, whose presence could determine a negative interaction with the activities performed.

The name of the manager or local contact person for the contract must be highlighted by the contractor employer.

This documentation is a binding element in relation to the activities to be carried out, the identification of responsibilities and the assumption of commitments relating to the protection of the health of all operators involved in carrying out the work.

The contractor company, before the start of activities, must declare in writing that he has read and informed his workers about the contents of this document.

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1 GENERAL PROCEDURES OF COORDINATION

This document, drawn up by the Prevention and Protection Service (SPP), is delivered by the Institute to the Legal Representative of the Contracting Company (or self-employed workers), pursuant to art. 26 of Legislative Decree 81/08 and subsequent amendments, in order to promote cooperation and coordination between the parties regarding the protection of health and safety in the workplace, and to indicate the measures adopted for the elimination of interference.

The organizational structures in charge of compliance with the regulatory obligations covered by this document are the following:

- **Technical Structures**: CS Building and Plant Design and Maintenance (hereinafter referred to as TS) for all maintenance interventions both on plants and structures and on equipment;
- The CS Good and Service Management (hereinafter referred to as GSM) for the supply of goods and services (Laundry, Surveillance, Cleaning and Canteen etc) and the CS Administrative Coordination of Research and hetero projects financed for research supplies;

It is therefore recommended, for any reference, doubt or need on the subject in question, to always refer to the figures indicated.

Annex I contains the names and contact details of the HSM, the Qualified Expert and all other consultants and / or internal professionals authorized to provide information on safety.

Where it has not been possible to eliminate the interference through organizational measures, or other measures borne by the CROM, the costs borne by the contractor are assessed separately.

1.1. THE RESPONSIBLE FIGURES FOR COORDINATION

The operational figures responsible for coordinating activities in order to avoid interference are:

- ***** The operator of the external company.
- ***** The internal contact person of the Institute / CROM for the specific activity.
- ***** The Responsible of the CROM Structure in which the activity takes place.

For the purposes of this document, the **Responsible of the Structure** means, unless otherwise specified: The organizational structures in charge of compliance with the regulatory obligations covered by this document are the following:

- **Technical Structures:** CS Building and Plant Design and Maintenance (hereinafter referred to as TS) for all maintenance interventions both on plants and structures and on equipment;
- the CS for Goods and Services Management of (hereinafter referred to as GSM) for the supply of goods and services (Laundry, Surveillance, Cleaning and Canteen, etc.) and the CS for Administrative Coordination of Research and hetero-funded projects for supplies for Research;

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The figure of the Responsible as identified above coincides, in most cases, with that of the Manager or Supervisor; for the sole purpose of coordinating the activities of external personnel, the function of Manager may, for the above, also be carried out by other professional figures, as this responsibility is limited to reporting to external personnel the presence of risk factors that each worker is required to know.

By **internal contact person** we mean the employee of a CROM Structure appointed by the Manager to follow a specific activity that requires the presence of external staff.

For maintenance activities, the internal contact person is always an employee of the ST / CROM, for the supply of goods and services, an employee of the SC Gestione Beni e Servizi / CROM, for the search an employee of the CS Administrative coordination of research and hetero funded projects / CROM.

The Operator of the external company must always be recognizable by an identification tag and must comply with the instructions and provisions of the Contact Person.

1.2. COORDINATION METHODS AND PERIODICITY OF MEETINGS

The coordination between the figures referred to in paragraph 1.1. happens:

- Through the preparation of rules and indications, at the time of drafting and formulating the contract.
- By submitting this document for information on its own risks and internal organizational methods
- Through what is expressly provided in the DUVRI, when the activities are considered to interfere with those of the client

For the development of particular organizational interventions, specific meetings are planned, which may consist of:

- Periodic meetings to assess the quality of the service and / or to check for any problems relating to safety
- Meetings convened in the event of problems arising (e.g. accidents, modifications or changes in the course of work, damage of various origins and management of related emergencies, etc.)
- Communications regarding organizational and managerial changes in the workplace or emergency plans.

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1.3 TYPES OF RELATIONSHIP BETWEEN CUSTOMER AND CONTRACTING COMPANIES

- external firms with occasional presence of operators
- external firms with continuous presence of operators
- external firms for the opening of temporary construction sites
- professionals, healthcare or not

In all the cases mentioned above and always at the same time as the start of the work to be carried out, the Operators of the contractor company must notify the Head of the Structure; where the intervention is carried out, directly or through the Contact Person, about the presence of external operators and the activity to be carried out, also to acquire any specific additional information useful for the correct and safe performance of the work assigned.

1.3.1 External Companies with occasional presence of their own operators

In the case of companies that carry out their activities at the "one-off" CROM:

- the operator goes to the center and requests the presence of the contact person who contacted him;
- the Contact Person, prior to the start of the work, carries out a joint inspection in the work area and illustrates any procedures or problems related to safety in the area of interest, as well as the procedures to be observed to eliminate the risk of interference with operators of other firms;
- during the execution of the work, the Contact Person, as far as he is concerned, checks compliance with the general or specific safety standards in relation to their applicability in the case in question;
- at the end of the intervention, a joint check is carried out to verify the correct and exhaustive performance of the work, the restoration of the pre-existing conditions and the absence of elements that could constitute a danger for operators and patients.

1.3.2 External companies with continuous presence of their own operators

In the case of companies with a continuous presence of their own staff working at the facility (e.g. cleaning company, catering, etc.), in addition to this Document, it is necessary to refer to the tender specifications, which necessarily includes the description of the types of work carried out.

A "Coordinator" responsible for coordination with the client, or with other contractors in order to eliminate any interference, is usually identified among the operators of the contractor.

The aforementioned "Coordinators", whose name must be formalized to the Structures referred to in paragraph 1.1 and to the Prevention and Protection Service, must:

- check that all the operators they are responsible for wear the identification tag;
- refer to the HSM for health and safety issues;

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- for particular works (eg structural or plant modifications, etc.), at the end of the intervention, carry out, together with a representative of the TS, an inspection to verify the correct and exhaustive execution of the works and the complete restoration of the initial conditions, or that no elements have been introduced that could constitute a danger to workers and users. Any anomalous situations encountered must be formally reported to the competent figures (Director of the Structure, ST, SPP);
- draw up and deliver to the Structures referred to in paragraph 1.1 any documentation of the interventions carried out.

1.3.3 Temporary construction sites

For works involving the opening of temporary or mobile construction sites, falling within the scope of Title IV of Legislative Decree 81/08, reference is made to the provisions of the same Decree, including therefore the preventive study of the aspects related to safety in design phase, at the expense of the figures provided, and compliance with the same legislation in the execution phase.

The HSM must be promptly informed about the opening of construction sites, in order to be able to assess any critical aspects for safety (eg "interference"), with particular reference to the interface areas between the construction site and the normal activities of the structure.

1.3.4 External professionals working at the structure

For external staff employed in institutional activities, the risk assessments and procedures already in place for the internal staff of CROM apply, without prejudice to special procedures provided for by any external company providing such staff.

The demonstration of operation and after-sales assistance related to the supply of devices and/or equipment, apart from cases comparable to mere intellectual performance, must take place in the manner established by this document.



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2. INFORMATION ON SPECIFIC WORKING RISKS AND RELATED PREVENTION AND PROTECTION MEASURES

2.0 DESRIPTION OF THE WORKING ACTIVITY IN THE CROM



CROM is the acronym for Oncological Research Center of Mercogliano; the establishment and management of the Center is entrusted to the Institute (DGRC n.1630 of 13/10/2006); a memorandum of understanding regulates the relations between the Campania Region, the Province of Avellino and the Cancer Institute of Naples.

It is based in Mercogliano (AV) in Ammiraglio Bianco street in the so-called ex-I.P.A.I building spread over six levels (planimetric distribution attached) for a total of 11,846 square meters; the Province of Avellino has granted it free of charge for ninety-nine years to the Institute.

CROM, in compliance with regional planning, establishes close links and synergies with other public and private research and health care structures, and with universities, in order to develop and implement common programs.

The work carried out within the CROM is mainly aimed at research and study for the cancers cure.

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Nuclear magnetic resonance spectrometry (NMR)



Radiopharmacy Laboratory

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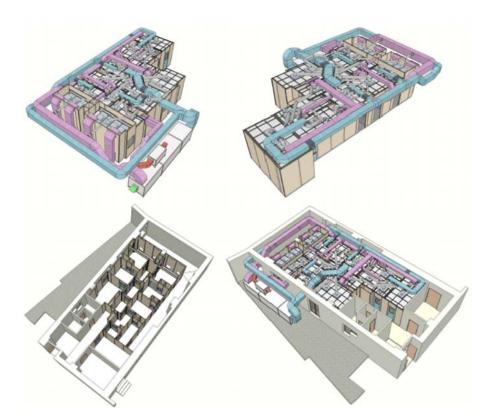


Research Activity – Animal Enclosure

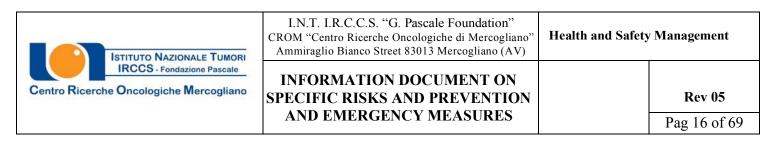


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Reasearch Activity - Laboratory







Training

The following are also carried out:

- Specialist services for external personnel (diagnostic laboratory for the determination of EGFR and KRAS mutations)
- Training (University Masters and post-graduate courses)
- Administrative management, control and planning of activities
- Technical activities related to building maintenance and plant and equipment maintenance
- Management of the acquisition of goods and services
- Production and Experimental Activities of the Radiopharmacy Laboratory with consequent physical surveillance of radioprotection of the environments, personnel and population at radiological risk by means of the Qualified Expert as established by current legislation
- Temporary storage and control of waste disposal.

The esteem of the people who attend the areas must therefore consider, in addition to the employees, also students, university professors, users, escorts, visiting researchers and suppliers.

The following is a review of the risk factors present in the working environment as a result of the CROM activities, where applicable the provisions for coordination of the different activities.

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2.1 EXPOSURE TO BIOLOGICAL AGENTS

The risk from biological agents in the health sector is to be presumed to be ubiquitous; in fact, potentially infected organic materials, tissue samples, blood, urine, liquids taken from patients or laboratory animals, etc. are also handled in the laboratory environments. Furthermore, in some laboratories, culture media are used on which proliferated viruses and bacteria.

All these materials can accidentally be found in traces, on the counters, on the floors, on the equipment, as well as on furniture and objects in the laboratory.

In regards to extremely rare events - and the control of the CROM operators in this regard is continuous - it is considered appropriate that any user / external operator / guest be aware of them.

2.1.1 Danger signs on biohazard

The areas and containers inside which materials can be found in which the presence of pathogens is ascertained or very likely are identified by specific signs.

Access to these areas and/or handling of containers is reserved for specifically trained and authorized personnel.

The biohazard symbol which may or may not be accompanied by indicative writings is the following.



2.1.2 Biohazard prevention measures

This Document intends to define brief recommendations useful for containing infections based on the scientific information available.

2.1.2.1 Universal precautions

First of all, it is necessary to constantly and correctly wash hands.

Barrier measures must be taken to prevent exposure to accidental contact with blood and other bodily fluids:

- use of Personal Protective Equipment (PPE) such as gloves, gowns, overcoats, masks, goggles or visors;
- use and correct disposal of needles and cutting edges;
- decontamination of surfaces soiled by potentially infected biological materials.

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2.1.2.2 Hand washing

The hands of health workers are the main vehicle for the transfer of pathogens; hand washing is the most effective way to limit this transmission and must take place:

- before the start of work;
- before putting on the gloves and after taking them off;
- before and after risky procedures;
- in case of biological or chemical contamination even if only suspected.

For further details, see the provisions of the Hand Hygiene Procedure.

2.1.2.3 Hands care

- nails must be neat, short, clean and without polish;
- the skin of the hands must be kept intact, also resorting to the use of barrier creams;
- during work activities you must not wear rings, bracelets, watches.

2.1.2.4 Rules of conduct in case of contamination of hands

- washing with water and liquid soap in dispenser for 30 seconds, followed by hand antisepsic with suitable disinfectant products;
- washing with antiseptic in a soapy detergent solution for 2 minutes.

For further details, see the provisions of the Hand Hygiene Procedure.

For further details, see the provisions of the Hand Hygiene Procedure.

2.1.2.4 Barrier measures

Gloves

- they must always be worn in case of possible contact with biological material, in cleaning and waste collection operations;
- before and after using the gloves, the operator must wash their hands with soap and water;
- so that the use of gloves does not itself become a vehicle for the dissemination of pathogens, it is necessary to use them only in operations where their use is required and must be thrown away after use.

Protective clothing

- the garment must be intact, clean and of adequate size;
- specific procedures must be developed that establish methods and times of use and the management of the garment after use (sanitization);
- the user must personally verify the integrity and cleanliness of the garment and suitability of the sizes; must ask for the change of the garment if it is soiled;
- disposable garments must be used (non-woven fabric overlays) to be used in operational situations that require greater exposure to biohazard.

Face and respiratory protection

- goggles, visors or screens are recommended when operations may expose eyes, mouth and airways to splashes of biological material;
- in specific cases it may also be necessary to protect the respiratory tract with suitable respiratory protective devices. For further details, please refer to the provisions of the PPE Handbook.

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2.1.3 Risks associated with the use of health equipment

2.1.3.1 Needles and sharps

- pointed, sharp and cutting tools must be considered dangerous, so they must be handled with care to avoid accidental injuries;
- all operators must take the necessary measures to prevent accidents caused by cutting edges (eg scissors, glassware, etc.) and needles;
- many injuries occur due to the incorrect elimination of needles: remember in this regard that it is FORBIDDEN to re-cap the needles; the syringes must be disposed of whole in the special yellow container;
- needles and cutting edges after use must be eliminated ONLY and EXCLUSIVELY in the appropriate resistant, rigid, waterproof containers, with hermetic final closure;
- disposal containers must be kept within reach during work operations in order not to postpone the disposal of needles or sharp and dispose of them at the same time as use.

2.1.3.2 Cleaning maneuver of tools and equipment

The washing maneuvers of the instruments are particularly at risk and except in extreme cases in which it is not possible to avoid the manipulation it is advisable to wash with mechanical means.

In no case must the operators of the Companies perform sanitization or decontamination of the laboratory equipment for the execution of the tests, of the safety cabins, laboratory instruments, work surfaces or other surfaces on which there are biological samples, if not explicitly authorized by the Laboratory Manager.

2.1.4 Precautions against biohazard in cleaning and sanitizing operations

As a general assessment of biological risk, it can be said that, during the cleaning of environments (or maintenance activities in general), the possibility of biological contamination is usually very low.

In fact, the guarantee of adequate safety conditions for personnel of external companies operating within the workplace is ensured, by the application of the essential safety precautions commonly adopted in every healthcare environment, the application of which is controlled by the **Laboratory Manager**. More specifically, each laboratory manager (see paragraph 1.1) must favor the performance of the activities of the operators of external companies by avoiding their accidental exposure to biological agents, ensuring that **the personnel assigned to ordinary**, extraordinary **cleaning or maintenance** operations in general must always observe the following:

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- before starting any ordinary, extraordinary or maintenance cleaning operations in general, you must contact the Manager or Contact Person to request information on any specific risks or on the need to adopt particular prevention measures;
- under no circumstances must the laboratory equipment be sanitized or decontaminated for the execution of the tests, the safety cabinets, the laboratory instruments, the worktops or other surfaces on which there are biological samples, unless explicitly authorized by the Laboratory Manager.
- must wear suitable work uniform, complete with non-slip footwear, possibly water-repellent and closed completely or at least in the front part; it is advisable to avoid the use of slippers or clogs, which do not guarantee complete coverage of the forefoot or which do not guarantee correct fit during work. The use of open footwear can cause an injury as a result traumas due to accidental blows in points such as the wheels of the beds, the edges of the doors, etc.;
- must, before the normal cleaning operations, wear gloves (domestic type), to be replaced according to the rooms to which they are dedicated (possibly differentiated by color: 1 pair for hospitalization areas, 1 pair for bathrooms). All operators must be duly informed on the correct maintenance procedure for the gloves supplied (cleaning after use, evaluation of wear, etc.)
- must wear, whenever the head of the Laboratory reports it, protective devices such as overcoats and masks suitable for the type of work, made available by the contractor,
- if the protection of the respiratory tract is necessary to prevent exposure to infectious agents, the personnel must be equipped, by the company, with respiratory protection devices suitable for the purpose and must be suitably informed about their correct use and maintenance.

2.1.5 Precautions against biohazard in handling and storage of medical waste

The personnel assigned to handling and transporting the containers of medical waste not similar to urban waste to the storage place may be potentially exposed to the risk of biological contamination, due to puncture, cut or accidental contact with material, following incorrect handling procedures. biological content in the waste. In order to avoid this possibility, it is necessary that the workers involved in waste handling are properly informed, by their respective employer, of the nature of the materials they have to transport.

It is absolutely forbidden:

- open the containers and insert your hands, or overturn them with the risk of spillage of the material contained, handle the containers without having worn suitable protective gloves provided by the employer; the use of protective gloves is also recommended for cleaning the trolleys used for transport;
- touch visibly dirty or damp containers with bare hands; in this case, report the inconvenience to the laboratory managers so that it is possible to replace the container safely.

It is recommended to use a work uniform to wear during the collection and storage of non-urban waste and suitable non-slip footwear, to prevent accidents.

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2.1.6 Precautions against biohazard associated with maintenance and technological services

In general, it should be noted that, without prejudice to compliance with basic hygiene rules, the risk of contracting pathologies of infectious origin in the CROM environments for the staff, internal or external, operating in this sector is not higher than the same activities carried out in other workplaces. Therefore, for these personnel the possibility of contracting pathologies of infectious origin in the workplace is to be considered extremely low.

2.2 DANGEROUS SUBSTANCES

2.2.1 Generality

In all hospital sectors, chemical substances are in use, albeit in limited quantities and for limited uses. Among the first measures suitable for the prevention of incongruous exposure are:

- adequate reporting of risks related to the use of chemical substances, with particular regard to the presence of adequate labeling on all containers,
- the presence of the Safety Data Sheets (SDS) of the substances used
- correct information for operators who use said substances.

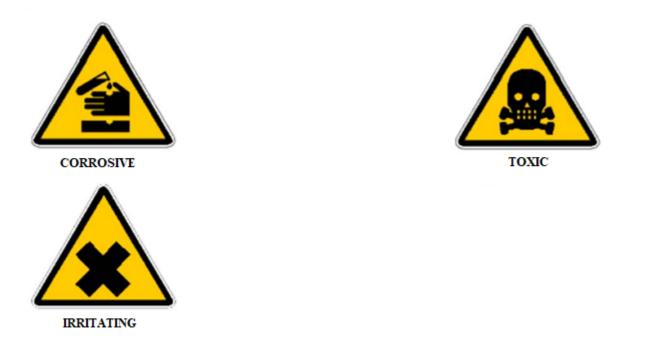
In details:

- in the Research Laboratories, more than in any other environment, concentrated acids and bases are used, toxic, irritating products, occasionally also carcinogenic, oxidizing and oxidizing, teratogenic or mutagenic, sensitizing, products incompatible with water or causing severe reaction with water. In these environments the prohibition, already present in the other areas of the center, to handle containers without authorization becomes even more stringent, as well as the duty to interface with the Manager.
- in the "plate development" environments where not already digitized automatic processors are installed that can only accidentally release chemical vapors whose quantity and toxicity, given the low quantities involved, does not cause problems, even considering the presence of suction systems, which provide for the normal air exchange

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2.2.2 Chemical risk signaling

There is no, or rather it is not applicable, a generic signal of chemical risk. Chemical risk indicators may, but not always, be present on laboratory reagent containers; the main signs are the following:



In all cases it is recommended to be careful in handling or using preparations which, if present, carry the following risk phrases on the label:

- T R45: can cause cancer
- T R49: can cause cancer by inhalation.
- Xn R40: possibility of a carcinogenic effect insufficient evidence
- T R46: can cause hereditary genetic alterations
- Xn R68: possibility of irreversible effects
- T R60: can decrease fertility
- T R61: can harm the unborn child
- Xn R62: possibility of risk of impaired fertility
- Xn R63: possibility of risk of harm to the unborn child

It should be noted that the drugs do not carry these risk phrases, as the reporting on pharmaceutical substances is not mandatory.

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2.2.3 New REACH signage

The new signals are mandatory from 1st December 2010, the date of application of the new REACH Regulation.

| Explosive |
|--------------------|
| Inflammable |
| Oxidizing |
| Gas under pressure |
| Corrosive |

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| | Harmful Irritating |
|---|-------------------------------|
| | Toxic |
| ^ | Harmful in the long term |
| | Carcinogenic |
| | Mutagenic |
| | Toxic for reproduction |
| | Harmful to the environment |

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2.2.4 Cryogenic gases and liquids

Many laboratory samples and cultures are stored at very low temperatures in liquid nitrogen (cryobank); many samples are stored in the laboratories, which are not equipped with a centralized nitrogen supply system.

Nitrogen is a gas which, if present in the environment in excessive concentrations, can quickly cause suffocation. In fact, although nitrogen is not a toxic gas, it is dangerous if it replaces the oxygen present in the environment. It should also be borne in mind that a small amount of liquid evaporating creates a large amount of gas.

Liquid nitrogen on contact can cause severe frostbite of the eyes or skin.

The two main safety aspects to consider in the use of liquid nitrogen are therefore adequate ventilation of the premises where one operates and eye and skin protection.

For safety reasons, it is forbidden to transport cryogenic liquid containers with a capacity greater than 250 cc together with people on lifts and goods lifts.

For the supply to the laboratories of the Center, the transport operator must place the container in the freight elevator, walk up to the destination floor and call the freight elevator.

The personnel who, having called the elevator to move between the floors, find it occupied by the nitrogen container, must close the door to allow the procedure to be completed.

2.2.5 Compressed gases and cylinders

Compressed gases are used in many healthcare settings. They can be found in containers (cylinders) of various sizes and in the pure or compound state (examples: oxygen, carbon dioxide and nitrogen).

Compressed gases can be toxic, flammable and explosive. These effects arise from the compression of the gas and the health effects that the chemicals themselves can have.

The control of this risk factor essentially involves the adoption of precautions in all phases of the use of compressed gases and handling of the related containers; these precautions are subject to specific training and information for health workers exposed to this risk factor.

Strict observance of the general behavioral measures reported in the appropriate paragraph of this document, together with compliance with the behavioral principles of workers, contained in particular in article 20 of Legislative Decree 81/08, are such as to minimize the incidence of this risk factor for the personnel of external companies and / or non-medical personnel called to operate in the areas where the same risk is present.

The only risk, however, associated only with the use of cylinders, remains the strictly accidental one due to collision and fall of the cylinder itself

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2.2.6 Chemical risk prevention measures

It is absolutely forbidden to manipulate, move, open containers of chemical substances that may be present in healthcare environments in which the companies are required to operate without justified reason and without the explicit authorization of the laboratory manager.

It is also absolutely forbidden to use, even temporarily and for the sole use of a single process, used containers of food liquids to store detergents, thinners, chemicals or in any case inedible products.

As regards the chemical substances that may still be present in the environments, attention is drawn to the fact that they - under the responsibility of the laboratory managers - are closed in containers labeled according to the law and any problem or accidental contact with they must be immediately reported to the laboratory manager himself, who will suggest the appropriate measures.

The introduction of hazardous materials and/or equipment (for example, flammable gas cylinders, chemicals, etc.) must be previously authorized by the figures referred to in point 1.1. In environments with chemical risk and in any case during work, it is forbidden to consume food and drinks, smoke or apply cosmetics, as these operations can favor the incorporation of any dispersed chemicals.

If to carry out the processing, the Contractor introduces and/or uses chemicals, it is mandatory:

- provide the Laboratory Managers with the safety data sheets of the chemicals used;
- read the safety data sheets that accompany the products, wear the personal protective equipment specified therein, follow the safety advice indicated on the labels and in the data sheets, and in particular avoid the dispersion of substances into the environment (atmosphere, earth or water) dangerous for man and / or the environment, as reported in point 12 of the safety data sheets of the products used regarding ecological information pursuant to Legislative Decree 52/97;
- never use unlabeled containers and if they are found, do not open and handle the contents;
- do not mix incompatible substances;
- remove the waste (debris, packaging, parts of machinery, etc.) deriving from the execution of the contracted activities and, more precisely, arrange for the collection, storage and final disposal which pursuant to Legislative Decree no. 152 of 2006, is the exclusive responsibility of the company for the management of special waste.

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2.2.7 Valuation of chemical risk

Without prejudice to compliance with the procedures, including those indicated on the safety data sheets of each preparation or substance, the chemical risk can be considered low for safety and irrelevant for the health of company workers.

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2.3 SYSTEMS AND ELECTRICAL EQUIPMENT

The main damage to health due to the electrical risk consists of painful shocks, deep burns (electrical and thermal), irregular heart rhythms, up to respiratory arrest and death.

Exposure can occur due to lack of maintenance of any electrical equipment, or due to careless use or lack of knowledge of the equipment and/or its controls. Atmospheres enriched with oxygen and water can contribute to making conditions riskier.

2.3.1 Installations

The operation of all CROM implants must always be guaranteed as the criticality on any of the implants can have consequences on patient safety.

This chapter provides information on the safety aspects of the systems, starting with the electrical system, in order to avoid risks for workers.

2.3.2 Electrical equipment

In the CROM there are:

- scientific equipment, some of which are powered by gases that are dangerous for their flammability or explosiveness, or for their oxidizing properties or toxicity;
- household appliances or similar appliances

Much of the electrical system of the CROM, and therefore many of the equipment present, are powered, in the absence of external mains supply, by an independent electrical source (Generator Set - UPS). Therefore, in any CROM environment, an equipment or an electrical system wire could be live even when the external supplier's network is inactive, or when it seems that "there is no power".

2.3.3 Provisions for the prevention of interference risks

- Any intervention on the CROM systems must be previously authorized by ST. Never carry out interventions and/or repairs on electrical systems or equipment if you do not have the specific knowledge and technical skills required by current legislation: tampering with a system or component makes them lose the manufacturer's warranty as well as an electrical system or equipment defined as safe can become dangerous following an incorrect intervention or repair.
- In order to ensure adequate containment of the electrical risk, the personnel using electrical systems and equipment must pay particular attention to ensure that they are in good condition, fully functional and not damaged. To avoid the risks associated with the use of broken or damaged equipment, its conservation status shall be periodically checked: any situation deemed unsuitable must be promptly reported to their superiors and to the TS, who will activate appropriate checks and interventions. The use of deteriorated electrical components (conductors with damaged insulation, broken enclosures, approximate electrical connections, broken plugs and sockets, etc.) considerably increases the risk of electrical contacts. Therefore, it is forbidden to use non-insulated cables or equipment and lines or circuits whose sectioning of the live parts does not allow direct or safe control of the sectioned parts.
- It is advisable that the connection of electrical appliances to the CROM network, for whatever reason, be preceded by a check of the same by the technical staff responsible for checking the equipment, to ensure compliance with current safety standards and compatibility with the hospital electrical network. Therefore, the use of devices that have not been previously authorized should be avoided and, above all, the connection to the electrical network of appliances for personal use must be checked and minimized.

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- Contracting companies that use electric tools or machinery to carry out their activities must only use equipment that complies with the regulations in force on the subject, and provide for their proper maintenance.
- Do not use electrical components that do not comply with the standards: all the safety of a system ends when electrical users (eg plugs, adapters, multiple sockets, extensions, portable lamps, etc.) that do not comply with the standards are used. All plug sockets used must be protected against direct contact, equipped with a cable retaining device, removable only by using a tool (eg screwdriver) and must not allow single-pole insertion of the plug.
- Do not use electrical components or machines for purposes not intended by the manufacturer: in these cases, improper use of the component can generate electrical or mechanical risk situations, not foreseen at the time of its construction.
- For everything concerning the power supply of electrical equipment, companies must acquire the necessary information from the TS and follow the instructions provided by the same.
- Particular attention should be paid to the possible use of electrical equipment or tools near medical gas supply points due to the increased risk of fire and/or explosion; in these cases, it is always necessary to ensure that there are no dispersions or dangerous situations, by asking the manager of the laboratory in which one operates for information. Similarly, unsuitable electrical equipment must not be used in conditions of increased electrical risk (e.g. with wet hands, on wet floors or in damp environments).
- Do not carry out cleaning operations on electrical machines with nebulised liquid detergents or with damp cloths, before having disconnected the power supply plug.
- Do not leave electrical equipment (cables, extensions, drills, etc.) abandoned on transit routes: in addition to causing obstacles and the risk of tripping and falling, they can be subjected to mechanical stresses not foreseen by the manufacturer with consequent risk situations.

In all environments the access procedures **must be agreed** with the Laboratory Representative.

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2.4 PHYSICAL AGENTS

For the following physical agents, given the absence of sources, no indication is deemed necessary pursuant to Article 181, paragraph 3 of the C.L.:

- infrasound
- ultrasound
- hyperbaric atmospheres

2.4.1 IONIZING RADIATIONS

2.4.1.1 Generality

Ionizing radiation is generated by radiogenic machines or radioactive sources.

X-ray machines pose a risk from ionizing radiation only when they are connected to the electrical network and are used in handwriting and / or scopy mode by delivering an X-ray beam.

The spelling modality assumes an emission duration, at each "click", of a few tenths of a second, the scopy modality presupposes a continuous emission which can be of the order of several minutes overall.

The risk of irradiation is associated with these modes of exposure.

The radioactive sources, on the other hand, maintain their danger until complete decay; the time required for decay is characteristic of each radioactive substance and in many cases can be particularly long. Radioactive sources, therefore, must always be adequately contained.

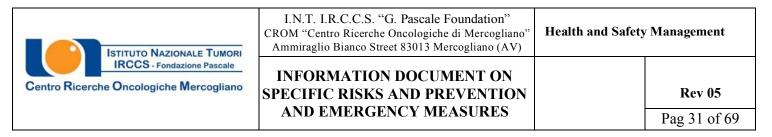
In particular, the "unsealed" sources present a danger not only of external radiation but also of internal radiation due to possible contamination, while the "sealed" sources are dangerous only for external

radiation, in the same way as an X-ray machine.

An "unsealed" source is dangerous both because it radiates externally and because it can be incorporated through ingestion, inhalation, skin contact and continue to irradiate critical tissues from within from very short distances. In this case we speak of the **risk of internal contamination**.

The use of ionizing radiation takes place under the supervision of the Qualified Expert, who is the professional in charge of assessing the risk and defining the protection standards and safety procedures. Medical surveillance is carried out by the Authorized Doctor or in specific cases by the Competent Doctor responsible for the medical surveillance of exposed workers.

Authorized doctors and qualified experts must be registered in special lists of names kept by the Central Medical Labor Inspectorate.



2.4.1.2 Areas of use of ionizing radiation - Signs of risk from ionizing radiation

In the radiopharmacy laboratory, radio drugs are produced (cyclotron and radiochemistry); there is a PET for small animals for research purposes.

At the CROM you can find the following signs:



Risk of irradiation and contamination



Risk of irradiation

The sign, posted on the door of the radiochemical area of the cyclotron and of the radioactive waste room, may be accompanied by one of the following notices:

- **controlled area**: it means that the stay in the area indicated for the work carried out in a calendar year may lead to exceeding the limits established for workers; this applies during the delivery of the rays and access is forbidden to non-specifically authorized personnel.
- **supervised area**: means that the stay in the area indicated for the work carried out in a calendar year may result in exceeding the limits established for the population; in these areas during the delivery of the rays, it is not allowed to linger after finishing one's work.

Pregnant women cannot carry out activities in classified areas.

2.4.1.3 Standards for reducing the risk of ionizing radiations

The following paragraph shows the radiation protection standards and access procedures for interventions within the Radiopharmacy area.

If it is necessary to enter the laboratory or the storage of radioactive substances, make sure (by asking the laboratory managers for information) on the need or not to wear personal protective equipment.

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However, the incidence of this risk factor on the personnel of external firms, however operating in areas classified as at risk because:

- in the CROM all the radiation protection measures are already currently applied to safeguard, not only the health personnel in charge but also and mainly, the other employees and visitors, measures that therefore also protect any personnel of external companies and / or non-health personnel in any case called to operate in areas at risk;
- during the performance of the activities of external companies within the healthcare environments, no type of activity, and in particular radiological, must be in progress;
- for special cases in which access by external companies and / or non-medical personnel in the areas at risk will be necessary, the Head of the Laboratory will communicate the precautions against the risk of exposure to ionizing radiation, agreeing on times and methods of intervention, on the occasion of the preliminary contacts at the start of the works (see next paragraph radiation protection procedures for companies operating in a controlled and supervised area).

2.4.1.4 Radiation protection procedures for workers of external firms

The following points are the access regulations and radiation protection procedures for workers of external companies drawn up by the Qualified Expert:

- 1) Regulations for access to the Controlled Area;
- 2) Radiation protection procedure for workers of contractors operating in controlled or supervised areas for maintenance and / or calibration activities;
- 3) Radiation protection procedure for cleaning company workers operating in controlled or supervised areas of the functional area of nuclear medicine pursuant to Legislative Decree 230/95 and subsequent amendments.

1. RULES FOR ACCESS IN CONTROLLED AREA

- Access to the Controlled Areas, both for all workers and people of the public, must always be authorized by the Head of the Laboratory where the Controlled Area is located, after consulting the Qualified Expert.
- Access to the Cyclotron / NMR Area must always be accessible only via intercom and or appropriate Badges.
- Badges can be issued, by the Manager himself, only to personnel authorized to access the area.
- Can access to the Laboratory:
 - 1) Personnel on duty at the CROM specifically authorized and possibly classified by the Qualified Expert;
 - 2) The staff who cleans according to established procedures;

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- The personnel of the contractors <u>who must operate</u> in Controlled or Supervised Areas where radionuclides or radiological equipment are in operation (following the appropriate procedures established in the SIRAD);
- 4) The staff of contractors *who must NOT operate* in Controlled or Supervised Areas where there are radionuclides or radiological equipment in operation;
- 5) CROM staff and / or visitors who do not have to access the controlled and / or supervised areas.
- The personnel of the Contracting Companies who must access the controlled and/or supervised areas where radionuclides are present, must always be accompanied by a person in charge of the Functional Area where the Controlled Area is located. The person in charge assists the staff of the Contracting Companies to ensure compliance with the laboratory's internal radiation protection standards;
- During the activities carried out by the workers of the cleaning company, there must always be a person in charge to whom the cleaning company staff must refer for any problem;
- CROM staff and / or visitors who do not have to access the controlled and / or supervised areas must always be accompanied by a laboratory worker who assists in their correct stationing in rooms where there is no risk connected to exposure to ionizing radiation.
- Additional workers or members of the population will be able to access the Controlled Area only after the Head of the Functional Area has obtained the written consent of the Qualified Expert.
- The person in charge of the laboratory must allow the personnel who must operate in Controlled or Supervised Areas where there are radionuclides in operation only after verifying that the aforementioned staff is equipped with the direct reading electronic dosimeter issued by Health Physics.
- The persons in charge and workers of the contracting company are required to comply with the *safety regulations of the 600 MHz Nuclerar Magnetic Resonance Spectrometer AVANCE IVDr*.
- The persons in charge and workers of the contractor company are required to comply with the radiation protection procedure for the workers of contractors operating in controlled or supervised areas pursuant to Legislative Decree 230/95 and subsequent amendments for maintenance and / or calibration activities.
- The persons in charge and workers of the cleaning company are required to comply with the *radiation protection procedure for the workers of the cleaning company operating in controlled or supervised areas of the functional area of the Radiopharmacy pursuant to Legislative Decree* 230/95 and subsequent amendments.
- The persons in charge and the workers of the cleaning company are required to comply with the *safety regulations 600 MHz Nuclerar Magnetic Resonance Spectrometer AVANCE IVDr*.

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- Anyone who notices a fire must contact the telephone number 710 to alert the technical structure and verbally notify the person in charge.
- The person in charge must promptly implement the emergency procedures in the event of a fire in the Functional Area;
- Anyone inside the laboratory will have to follow in detail the instructions that will be provided by the evacuation coordinator, including the immediate evacuation order, in relation to the emergency procedures in the laboratory.

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2. RADIO PROTECTION PROCEDURE FOR THE WORKERS OF CONTRACTING COMPANIES OPERATING IN CONTROLLED OR SURVEILLED AREAS IN ACCORDANCE WITH D.LGS 230/95 AND SMI FOR MAINTENANCE AND / OR CALIBRATION ACTIVITIES

This procedure arises from the need of the Institute's Employer to fulfill the radiation protection obligations of the Technicians of the Contracting Companies of the Maintenance Service and / or Calibration of the X-ray sources installed and operating at the CROM, and, more generally, borne by the workers of the Maintenance Companies who carry out their work in a Controlled or Supervised area at the CROM.

This procedure applies only in cases where the workers of the Contracting Companies, for the performance of their activities, have the *absolute need to operate in Controlled or Supervised Areas where radionuclides are present.*

Each Director must ensure compliance with the provisions in must ensure compliance with the provisions of the DUVRI (Interfering Risk Assessment Document), by the Qualified Experts of the CROM and by the Qualified Expert of the Contractor.

Each Director must ensure compliance with the provisions of the radiation protection coordination document drawn up by the Qualified Experts of the Pascale Institute and the Qualified Expert of the Contractor.

The Health Physics Operating Unit is responsible for the management of direct reading electronic dosimeters.

The qualified expert is responsible for providing direct reading electronic dosimeters to the workers of the contractors for the activities that they must carry out in Controlled or Supervised Areas where radionuclides are present. If the contractor's staff is classified pursuant to Legislative Decree 230/95, the delivery of the direct reading electronic dosimeter will take place after the person in charge has received a copy of the medical suitability of the worker himself pursuant to Legislative Decree 230/95.

The Laboratory Director must first communicate the day, time and expected duration of the maintenance intervention to be carried out by the workers of the Contracting Companies in the Controlled or Supervised areas of the CROM.

In the laboratories, a Supervisor must be identified who must be present during the activities carried out by the workers of the Contractors.

The Laboratory Director must identify an adequate number of Supervisors who have the task of equipping the personnel of the Contracting Companies with appropriate electronic dosimeters with direct reading before the aforementioned personnel operate in Controlled or Supervised Areas where radionuclides or radiological equipment are in operation.

The persons in charge identified must be officially appointed by the Laboratory Director and accept the assignment in writing.

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The persons in charge identified must be officially appointed by the directors of the laboratories who must ensure that they are present during the activities of the workers of the contractors.

At the end of the intervention, the Contractor's worker must return the electronic dosimeter to the Head of Health Physics who transcribes the reading indicated by the electronic dosimeter on a special Register set up by the Director of the Health Physics Operating Unit. The register must include: date, contractor, contractor company worker, person in charge of health physics, effective dose read on the electronic dosimeter worn by the worker of the contractor company, signature of the person in charge and signature, for inspection, of the worker of the contractor company.

Each page of the Register must be signed by the Head of the Health Physics Operating Unit for acknowledgment. The Register must be kept by the Director of the Health Physics Operating Unit. On a monthly basis a copy of the pages of the Register used must be sent to the Qualified Experts and to the RHSM for the appropriate assessments of competence.

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3. RADIOPROTECTION PROCEDURE FOR CLEANING COMPANY WORKERS OPERATING IN CONTROLLED OR SURVEILLED AREAS PURSUANT TO D.LGS 230/95 AND SMI

This procedure arises from the need of the Employer of the Pascale Institute to fulfill the radiation protection obligations for the workers of the Cleaning Companies who carry out their work in the Controlled or Supervised Area at the CROM laboratories.

The Laboratory Director must ensure compliance with the provisions of the DUVRI (Interfering Risk Assessment Document), drawn up by CROM and the Cleaning Company.

The workers of the cleaning company must comply with the Internal Radiation Protection Regulations posted in the premises where there is a radiological risk, particularly in the "Controlled Areas" and therefore easily accessible by them.

The list of names of the staff of the Cleaning Companies who can work in the laboratories is identified in the staff, previously classified, equipped with specific PPE, trained and informed on specific risks, pursuant to art. 61, paragraph 3-e of Legislative Decree no. 230/95 and subsequent amendments.

Additional staff of the Cleaning Company that may possibly be used for activities involving the risk of exposure to ionizing radiation in Classified Areas, pursuant to art. 82 of Legislative Decree no. 230/95 and subsequent amendments he must also follow a specific training course and comply with the Internal Radiation Protection Standards.

The staff of the cleaning company that works in the laboratories must be subjected to Physical and Medical Radiation Protection Surveillance by the Company itself and all the formalities relating to the "coordination" referred to in Articles must also be guaranteed. 63 and / or art. 65 of Legislative Decree no. 230/95 and subsequent amendments

The Cleaning Company is required to communicate, in advance, the intention to change the list of Cleaning Personnel related to the laboratories.

The staff of the Cleaning Company that works in the laboratories is not assigned to cleaning technological equipment such as hoods, cells and technical material.

The Director of the Radiopharmacy / RIPU NMR Manager must identify an adequate number of Supervisors who must be present during the activities carried out by the workers of the Cleaning Company.

The persons in charge identified must be officially appointed by the Laboratory Director and accept the assignment in writing.

The director of the laboratory must ensure that at least one person in charge is present during the activities of the workers of the cleaning company.

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Access to the premises by the staff of the Cleaning Company must always take place with the authorization of the person in charge of radiation protection.

In presence of any contamination, the person in charge, following the internal radiation protection rules, must ensure that any contamination is eliminated before allowing the cleaning company worker to access the affected area.

The staff of the Cleaning Company, while carrying out the activities within the laboratories, must wear the specific PPE made available to them.

These PPE must be used exclusively in the aforementioned facility. The staff of the cleaning company is equipped with:

- Washable clogs supplied to each worker;
- Disposable TNT uniforms, of the type used in the operating room for visitor staff;
- Overshoes of the waterproof PPE type, of the type for supply in chemotherapy;
- Gloves, of the type used for the administration of radiopharmaceuticals to be worn over the gloves generally used for Cleaning;
- Disposable gloves (in compliance with the technical standard (UNI EN 241);
- Disposable uniforms (in compliance with the technical standard (UNI EN 1073).

All the equipment used for cleaning must be used exclusively in these premises and disposed of by the laboratory staff, according to the waste management protocol of the laboratories themselves.

2.4.2 ARTIFICIAL OPTICAL RADIATIONS

At the CROM laboratories there are germicidal lamps and transilluminators for gel plates that generate UV radiation.

Germicidal lamps are also installed on biological hoods in laboratories and are turned on only when the hood is properly closed (the hood glass is able to absorb the radiation).

The transilluminators can only be switched on if there are no personnel present in the surrounding radiation space (2 m), unless they are wearing the appropriate Personal Protective Equipment (mask). The UV sources of the analytical equipment are normally protected by screens that make the radiation inaccessible. However, during maintenance or adjustment, the beam may become accessible.

These adjustment operations should normally be carried out by the personnel of the company in charge of maintenance, equipped with the necessary training and, if necessary, with the appropriate PPE.

Unauthorized personnel must keep a safe distance during maintenance operations.

Class 3B and Class 4 laser equipment can be dangerous in case of direct beam exposure or even scattered radiation.

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Systems of this type can also be present in the research laboratories associated with analytical instrumentation identified with the signs described below, also in this case the beam is accessible only in the case of particular maintenance interventions reserved for the assigned personnel.

2.4.2.1 Signs for optical radiatons

There is no specific signage for germicidal lamps and transilluminators.

The signal is displayed on the doors of rooms where class 3B and 4 lasers are present.



The laser sources present in the CROM can pose a risk only during maintenance operations that involve the suspension of the safety devices installed on the instruments.

The same pictogram may be present near the laser aperture of other equipment. These lasers are less dangerous but since their safety feature is based on the human eye's ability to react to stimuli, it is still a good idea not to look directly at a laser source.

By direct exposure to the laser beam, skin and eye burns can lead to blindness. Exposure to ultraviolet light can also cause cataracts.

2.4.3 ELECTROMAGNETIC FIELDS

Electrical maintenance workers can be exposed to magnetic induction fields generated by electrical installations with higher current draw.

Using as reference values those reported in Directive 2004/40 / EC, subsequently extended to 2012 by Directive 2008/46 / EC, considering the installed electrical power, magnetic induction field levels close to the action values can be present at most main electrical substation, in the position of the hands when operating the general low voltage switches, where the circulating current can reach or exceed 1000 A.

For reasons of electrical safety, these switches automatically open in case of failure without the intervention of personnel or, in case of maintenance needs, they are opened manually after having disconnected the main utilities served, then in conditions of low load, in order to not to generate overcurrents of opening potentially harmful to the plants themselves.

Staff exposure is therefore extremely unlikely.

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Portable radiofrequency and microwave telecommunication systems, including wireless computer networks, generate electromagnetic fields well below the action values.

2.4.3.1 Signage for electromAgnetic fields

The signal



indicates the presence of an electromagnetic field (frequency other than zero).

The values of these fields in the CROM are in any case below the action values considered safe by international standards.

The sign indicates the presence of conductors in which high currents pass.

2.4.4 MICROCLIMATE AND VENTILATION

Situations of thermal non-comfort can arise in all areas of the CROM, in particular during maintenance interventions; in case of construction site activities that foresee the decommissioning, even partial, of the systems in the summer season, appropriate measures must be studied to reduce the temperature in the work area.

Except for this clarification, the risk associated with the microclimate is to be considered low.

However, risk factors linked to the microclimate are only associated with situations of thermal stress.

2.4.5 ELIMINATION OF NOISE AND VIBRATION INTERFERENCES

Considering the sensitivity of the equipment installed at the CROM, the Management must be informed before using equipment capable of inducing significant levels of noise and vibrations on the structures, in order to agree on the times of the interventions.

2.5 EXSPLOSIVE ATMOSPHERES

In no work area is the formation of explosive mixtures possible in accordance with Title XI of the T.U. as:

- the use of flammable substances is limited to low concentrations; please note that the accumulation of flammable agents as a "backup" under the hoods of the laboratories is prohibited and that the possible use of ether to the sedation of laboratory animals must take place under a glass bell, using the minimum indispensable quantity;
- in the event of an oxygen leak, the procedures set out in the Emergency Plan apply.

Please note that the use of gas appliances, as per Presidential Decree 15/11/96 no. 61, is not subject to the provisions of the T.U.

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The formation of explosive mixtures from powders is not possible in any work area. Maintenance interventions using the oxyacetylene torch must be carried out only after ensuring the ventilation of the premises and removing combustible materials.

At the end of the work, the cylinders must be stored in the site area in a suitable and protected place.

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2.6 MANUAL HANDLING OF LOADS

2.6.1 Handling of loads

The manual handling of loads by unstructured external personnel mainly concerns the activities of pushing the cleaning trolleys, porterage and waste collection (cleaning service). The personnel in charge must be adequately trained on the correct methods of handling loads and subjected to health surveillance.

2.7 EQUIPMENT WITH VIDEOTERMINAL

Pursuant to Art. 174 paragraph 3 of the T.U. the workstations must comply with the requirements of Annex XXXIV; this requirement applies regardless of the time the workstation is used and the working relationship with the CROM. Please note that pursuant to point f) of Annex XXXIV the prolonged use of laptops requires the supply of suitable accessories to make the workstation compliant with standards (mouse, keyboard, screen, etc.). VDT personnel for more than 20 hours per week must undergo health surveillance.

2.8 SECURITY RISKS

2.8.1 FIRE RISK

The Legislator, in the Decree of March 10 1998 on Emergency Management, classified health structures as "High Fire Risk" Structures. Therefore, the risk of fire in the CROM is to be considered high. The structure complies with the current fire regulations referred to in the Decree of March 19 2015 G .U. General Series n.70 of 3-25-2015.

There are fire extinguishers, hydrants, compartment doors, fire detectors, gas leak detectors, alarm buttons, filter zones, safety exits, marked paths. Furthermore, flammable solvents are used in research laboratories; the execution of hot work, however agreed with the employees of the Technical Structure, must also be agreed with the laboratory managers, who must remove the materials at risk in advance.

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Rules of conduct

Each worker must carefully read the fire prevention and protection devices (e.g. fire extinguishers, hydrants, alarm buttons, etc.) and the specific rules of conduct (e.g. directions, plans with escape routes and meeting places) of the place in which he is called to operate.

In order to contain the risk of fire, the emergency routes and exits must be left free of any type of material; the fire-fighting devices must be correctly located and in good condition: any situation deemed unsuitable must be promptly reported to the TS for the necessary checks.

External companies, contractors and other non-employee operators are therefore invited to comply with the provisions of Ministerial Decree 3/10/98 and subsequent amendments, and, in particular, all possible organizational and management measures such as:

- respect for order and cleanliness;
- compliance with the smoking ban in all facilities;
- checks on security measures with the preparation of internal regulations on the measures to be observed;
- information and training of workers.

Paragraph 3.1 shows the emergency measures in case of fire.

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2.8.2 FALL AND IMPACT INVESTMENT RISKS

Risks of investment, fall and impact can occur in all internal and external areas of the CROM and in the common paths due to the presence of means of transport or other means or people (operators of contractors, workers and visitors) present in the company areas

2.8.2.1 External viability

The access of vehicles and people to the external spaces of the building involves the risk of injury connected to the simultaneous possibility of transit or parking of other people or to the passage of vehicles or equipment (forklifts, cars, trucks, electric or manual pallet trucks, etc.). Therefore, there may be risks of:

- investment of people with vehicles
- falling loads on people passing by during material loading and unloading operations
- slipping and falling (especially if it rains)
- tripping or impact due to materials present

The risk is aggravated by the reduced lighting in the evening.

Preventive measures

Circulation in the external road network of the CROM must be carried out strictly observing the rules of road traffic and the horizontal and vertical signs; the speed must be limited (at walking pace or at most 10 km / h); in any case, it is absolutely forbidden to stop at emergency exits, fire hydrants, fire extinguishers, motor pump attachments, paths for the disabled.

The access of vehicles with significant dimensions (over 35 quintals) must be coordinated with the Technical Structure. In case of necessary access of special or particularly bulky vehicles (eg mobile cranes, truck mixers, etc.) the presence of additional personnel of the Company must be provided for assistance in maneuvers in order to prevent accidents.

In the reversing maneuvers, in addition to the horn, another procedure must be envisaged that limits the risk of an accident (presence of another operator of the Company to assist in the maneuvers and / or camera with screen in the cabin and / or proximity sensors or other)

The stop, the loading / unloading activities must take place according to methods agreed with the customer. In the case of the simultaneous presence of several vehicles, each operator will wait for his turn according to the order of arrival without interfering with unloading activities during the completion phase and without hindering the viability of medical and / or private vehicles.

There is an obligation to turn off the engines in the unloading areas.

The operations of loading and unloading goods using a forklift truck or crane must be carried out with additional personnel on the ground who check that the operations take place without interference with people passing through the site; if a longer duration of the operations is foreseen, the loading and unloading area must be delimited with mobile barriers.

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Materials and equipment must not be deposited, even temporarily, along the transit routes or in the entrance courtyards; in case of impossibility to operate otherwise, they must be adequately reported.

Pay particular attention during the transit in the external areas in the winter season and always in case of rain.

2.8.2.2 Internal viability

The access of people to the internal premises of the building involves risks from:

- investment of people with materials transported along transit routes, especially corridors, and in elevators.
- falling of people due to stumbling or impact due to materials temporarily deposited along the transit routes.

The transport of materials in the lifts may involve the risk of people being run over while the car is running; furthermore, there is a risk of pinching the upper limbs when materials of considerable width are introduced in relation to the width of the cabin door.

Access to the elevators may present a difference in height that can cause tripping or real trauma from handling loads.

The floors of some rooms can be slippery: in this sense, the simultaneous and widespread presence of the staff of the cleaning company constitutes a danger, especially when the floors are washed or electrical appliances are used for cleaning (due to the presence of electrical cables on the floor).

Despite the continuous commitment to improvement, sometimes in the premises there may still be electric and telephone cables and multiple sockets which can cause tripping.

In some rooms there are narrow passages (width less than 70 cm) with the risk of hitting the edges, especially in technical rooms where the presence of pipes, valves, etc., constitutes a condition of increased danger.

Preventive measures

- considering the always possible presence of CROM personnel, the transport of equipment and materials along the internal routes must always be done with great caution, without prejudice to the safety of people and without causing damage to the structure.
- in the case of transport of bulky equipment in transit areas, the date, time and route to follow from the unloading area to the delivery point must be defined in advance with the Heads of the Structures involved in order to limit interference.
- In case of use of lifts for the transport of bulky and / or heavy equipment, it is necessary to check the capacity in advance, never carry out the transport in the simultaneous presence of people (not going up if other people are present and preventing them from climbing during the journey) and always keep the load still against the cabin wall during travel, carrying out the operation with two people. Always pay attention to the difference in height between cabin and landing; bulky material must be pushed without putting your hands into the interstice with the cabin and must be handled by two people.

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- In case of passage or parking in technical rooms, it is necessary to take the utmost care for the presence of obstacles with risk of tripping and falling or impact. It is absolutely mandatory to wear a helmet and safety shoes; at least two people must always be present, one of which has a mobile phone or radio to report emergencies.
- Materials and equipment must not be deposited, even temporarily, along the transit routes; in case of impossibility to operate otherwise, they must be adequately reported
- Avoid operating at the same time as the cleaning company operators; the latter are obliged to have slipped hazard signs on both access sides when the floor is wet.
- The operators of the CROM are sensitized to exercise caution and attention in the internal handling of trolleys or other mobile equipment.

2.8.3 BURN RISKS

This risk is present in the thermal power plant due to the presence of steam and hot water and can be achieved both by contact with materials, pipes and hot valves, and by the operators being hit by jets of high temperature fluids following valve breakage, equipment or other technical devices (e.g. condensate drains).

Preventive measures

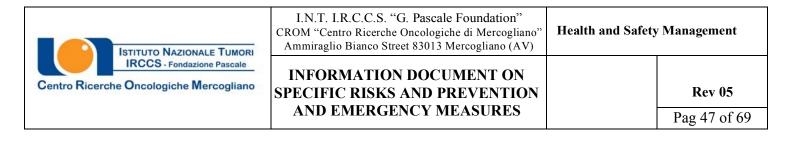
• Use specific ppe (protective gloves against thermal aggression; heat protective clothing).

2.8.4 ELECTRIC SHOCK RISK

This risk for those who use electrical equipment to be connected to fixed electrical system sockets, although very low and almost irrelevant, must be kept in mind in the case of obsolete electrical panels or sockets with unprotected pockets or for improper use.

The electrical systems are all protected against indirect contacts by a differential switch and earthing system. <u>Preventive measures</u>

- Any electrical intervention must be carried out by qualified external companies on mandate of the Technical Structure: never carry out interventions or repairs on electrical systems or machines if you do not have specific knowledge or the professional characteristics required by current legislation.
- Never use deteriorated systems (sockets disconnected from the wall or unsuitable for using the equipment)
- Contact the CROM Technical Structures for the deactivation of the electrical systems supplying the premises subject to the intervention.
- In the event of demolition works or works that may affect or interfere with the systems, it is necessary to inquire in advance of the presence of live conductors.
- Pay particular attention to inserting and disconnecting plugs in sockets with unprotected recesses.
- Always report situations of obvious danger (sockets disconnected from the wall, open electrical panels, etc.)



3 EMERGENCY MEASURES FOR COMPANIES AND SELF-EMPLOYED WORKERS

3.1. FIRE / EVACUATION

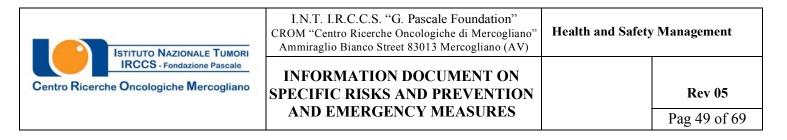
Conduct of any worker operating in the CROM

| Circumstance | Actions |
|-------------------------------|---|
| ALWAYS | Each worker must carefully read the fire prevention and protection devices (fire extinguishers, hydrants, alarm buttons, etc.) and the specific rules of conduct (indications, plans with escape routes and meeting places) of the place where he is called to operate. |
| IF A PRINCIPLE | Any worker who becomes aware of a start of fire or a danger in general is required to intervene immediately in the following way: |
| OF FIRE IS DISCOVERED | • contact by telephone no 710 - communicating the place and type of event; |
| | • if it is a fire principle and the worker has been trained, intervene using the nearest fire extinguisher; |
| | Follow the instructions of the emergency management staff (laboratory staff, first aid team, emergency teams, fire brigade); if requested: |
| INVOLVMENT IN AN EMERGENCY | • help keep calm, do not rush, do not scream, avoid panic situations; |
| | in the other case: exit the laboratory following the signs of the emergency exits and go to the collection point indicated in the plan affixed to the walls of the place where you are and wait for instructions; it is forbidden to return to the emergency rooms until the all-clear is notified. |
| | |



3.2 CHEMICAL RISK: ACCIDENTAL SPILLING OF CHEMICAL SUBSTANCES, PREPARATION OR WASTE

- open the windows and close the doors to the premises, alerting those present of the danger.
- immediately notify the manager of the Laboratory / service in which you work and your manager; if no one is present in the premises where the spreading took place, report the event to activate the procedures required for remediation.
- if present in the room, cover the spreading with inert material (sand or synthetic adsorbents); never use paper or rags.
- it is forbidden to pick up this material by hand.



3.3 RADIOLOGICAL RISK: SPILLAGE OF RADIOACTIVE SUBSTANCES

- immediately notify the manager of the Laboratory / service in which you work and their manager and jointly assess the danger of the situation and the protective measures to be implemented as well as the necessary PPE.
- if present in the room, cover the spreading with inert material (sand or synthetic adsorbents); never use paper or rags.
- it is forbidden to pick up this material with bare hands, without using protective gloves
- immediately notify the Qualified Expert for any necessary remediation interventions.

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4 CONDUCT MEASURES AND PRECAUTIONS TO BE TAKEN DURING THE PERFORMANCE OF WORKS OR SERVICES AT THE CROM

4.1. GENERAL CONDUCT MEASURES

The inevitable presence of a high number of risk factors, typical of every healthcare facility, which is a heterogeneous context where a fair number of very different activities can coexist, with the consequent problems of protecting the health and safety of the operators present, makes impossible to establish specific criteria and procedures for all possible situations.

However, it is considered appropriate to recall a series of general indications to which all external operators responsible for carrying out any type of work activity within the CROM structures and areas must comply: it should be noted that cases in which operators of a company find themselves operating together with other external companies (eg construction sites) cannot be excluded. For this purpose, **before starting work, the two companies must provide for mutual coordination in accordance with current regulations**, with particular reference to article 26 of Legislative Decree 81/08, in order to avoid dangerous interference (therefore to be agreed directly, to their load, with the other companies involved, at the moment, on site).

In any case, the Contractor's personnel in order to access and operate in the buildings and areas pertaining to the CROM must:

- compulsorily wear work clothes
- be identifiable by name, by affixing the company identification card to the work garment: compliance with the provisions of Article 26, paragraph 8, of Legislative Decree 81/08 is recommended: **all external operators must be equipped with special identification card, with the obligation to display this card**. No model card is established, however the following are required: photograph, personal details of the worker and indication of the company / employer;
- agree on the timing (days and times of access to the Client's premises) with the company references provided when signing the contract in order to avoid any interference with the activities of CROM and / or third-party companies;
- view the rapid evacuation plans in case of emergency affixed near the places where the works will be carried out and must physically view the escape routes before the start of the activities to be awarded;
- access the CROM areas scrupulously following the dictates communicated to them in order to avoid any interference with pedestrian and / or emergency routes;
- before the start of the works, all the necessary prevention and protection measures must be arranged and implemented aimed at protecting the safety of workers at work (provisional works, boundaries, fences, signs, personal protective equipment, etc.) both for own risks and for those specifically identified by the Client for the purpose of eliminating interfering risks; therefore, before starting work, if necessary, the work area must be fenced or in any case clearly and visibly delimited (using barriers, signs, two-colored tapes, etc.), whether it is excavation or underlying work that takes place in positions high, or when there is the possibility of causing damage to people who are passing by and these must be kept at a safe distance;
- carry out their role and their maneuvers in safety without causing damage to people or things;
- store the work material in the place indicated at the time of the award: the storage of products and / or equipment in places not identified and not authorized by the Client is not allowed and above all it is forbidden to clutter the paths with vehicles, materials and / or equipment exits and emergency

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exits and / or abandoning materials and equipment that may constitute a potential source of danger in transit and work places (unless this is done with proper authorization and in safe conditions) or in an unstable position (if this is indispensable, its presence must be duly reported);

- promptly remove containers, boxes, crates, baskets, rollers, empty pallets and waste;
- safe handling of material and, if necessary, with the help of suitable trolleys or Supervisor's aids;
- in case of interventions on systems and / or equipment and / or machinery, always consult the technical instruction booklets and / or the technical references of CROM before starting the work and make sure that the machine / system downtime cannot be prejudicial to the physical safety of staff, visitors and does not affect the organization of the individual sectors of the Client. If it is necessary to stop the machine / plant, the intervention must be scheduled with the technical and health representatives of CROM;
- comply with the prohibitions and limitations of safety signs, following the indications given by the appropriate specific monitoring signs (flammable storage, protected area, biological contamination, suspended loads danger, etc.) whether these are placed inside or outside CROM structures: it is necessary to strictly comply with the signs, signs, rules or procedures issued by the personnel assigned to the purpose or displayed and adopted by the CROM;
- it is mandatory to use the appropriate Personal Protective Equipment (PPE) provided by your Employer for each individual process, as well as to use machines, tools and tools that comply with current legislation;
- always use machines, tools and tools that comply with current laws;
- request the intervention of the Client's contact person, in case of anomalies found in the work environment and before proceeding with interventions in places with the presence of specific risks;
- immediately report any deficiencies in safety devices or the existence of dangerous conditions (working directly, in case of urgency and within the scope of their competences and possibilities, for the elimination of said deficiencies or dangers);
- in cases where it is necessary to remove power from parts of the electrical system subject to repair or overhaul work, or to interrupt the distribution of water, gas, etc. it is necessary to agree in advance times and methods with the staff of the Technical Structure;
- the custody of the equipment and materials necessary for the execution of the works within our offices is completely at the responsibility and risk of the contractor who will then have to provide for the related duties;
- it is necessary to transmit to the CROM any changes concerning safety not previously agreed;
- for alarm and / or emergency situations in general (eg fire, explosion, flooding) and in the event of evacuation, it is mandatory to strictly follow all the procedures (fire prevention, evacuation and first aid) given by the CROM staff present and, in any case, leave the work area if necessary, following the appropriate emergency routes, adequately prepared and marked, without generating panic, not before having switched off appliances and tools, closed gas cylinders in use, etc .;
- scrupulously follow the instructions on the use of mobile phones. For this purpose and in case of doubts or lack of reports on the matter, request authorization from the CROM staff;

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Please note that it is strictly forbidden:

- 1. to act on the work in progress;
- 2. access the premises with limited access to authorized personnel unless specifically authorized by the facility manager with the appropriate authorization which indicates the prevention and protection measures;
- **3.** remove or tamper in any way with the safety devices and / or protections installed on systems or machines or make changes, of any kind, to machines and systems owned by CROM without prior authorization:
- **4.** carry out, on its own initiative, maneuvers and operations that are not within its competence and which may therefore also compromise the safety of other people, on machines, equipment, plants or other owned by CROM without prior authorization;
- 5. carry out welding work, use open flames or smoke in places with a risk of fire or explosion and in all other places where there is a specific prohibition. For this purpose and in case of doubts or lack of reports, authorization should be sought from the CROM personnel; it is considered appropriate to underline that, according to the laws in force, it is absolutely forbidden to smoke within ALL the closed spaces of the CROM. In the case of welding work or the use of open flames, prior written authorization must be requested from time to time from the CROM representative;
- 6. clutter up pedestrian or driveways, corridors, escape routes, stairs, doors, emergency exits, etc. with materials of any nature;
- 7. perform any operation on moving parts (cleaning, lubrication, repairs, adjustments, etc.);
- 8. access, without specific authorization, inside electrical substations or other places where there are live electrical systems or equipment, valves, pressure vessels (cylinders), gas systems etc.;
- 9. access or remain in places other than those in which one's work must be carried out;
- 10. make changes of any kind to CROM machines and systems without prior authorization;
- **11.** use, in the workplace, garments or clothing which, in relation to the nature of the operations to be carried out, could constitute a danger for the wearer;

In addition, please note that:

- The toilets that can be used by the Contractor's staff are those reserved for users, appropriately marked and easily identifiable
- A telephone is available in the operating units and in the individual work sectors for both emergency and corporate communications, subject to the permission of the CROM personnel;
- For the use of mobile phones, it is necessary to strictly follow the instructions in this regard. For this purpose and in case of doubt or lack of specific reports, request authorization from CROM staff;
- For technical problems, the technical operators of the client company are available. Ask the staff present on site; Within the CROM premises, the emergency exits must not be obstructed;
- It is strictly forbidden to smoke and / or use open flames inside the CROM rooms and near the accesses, as regulated by specific signs;
- It is forbidden to throw butts, cigarettes and flammable material near the CROM areas;
- It is forbidden for any CROM worker and the Contractor to take alcohol or drugs in any quantity during working hours or to go to the CROM offices under the influence of alcohol or drugs.

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4.2 RESPECT FOR USERS

In the event of impediments of various kinds to the normal performance of work, it is necessary to refer to the Area Managers or Supervisors to report the problems encountered.

4.3 MAIN PRECAUTIONS TO BE TAKEN AGAINST INTERFERING RISKS

4.3.1 MAIN PRECAUTIONS TO PROTECT YOUR HEALTH AND SAFETY

It is always necessary to inform oneself in advance about the risks present in the place where one goes to lend one's work. If the activity to be carried out, according to the criteria and detailed indications in the current contract, involves potential access to all the premises and areas of the CROM, the existence of a particular risk within one of the aforementioned premises or areas, will be reported in advance by a Person in charge of the Structure or by his representative. If necessary, detailed information will also be provided on the type of protection to be adopted, or appropriate PPE will be made available. It is recommended to immediately report any injury to its employees in the context of the work carried out within the premises and spaces of the CROM. In the event of an accident (e.g. accidental contamination with biological liquids or chemicals, etc., which occurred at the CROM), the operator of the Company is recommended to report the incident immediately to the personnel of the Facility where the accident occurred, so that they can be undertaken the necessary interventions, remediation and / or prevention actions; then, subsequently, notify or inform the Company's Prevention and Protection Service and CROM about this.

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4.3.1.0 Precautions agianst biohazard

The intrinsic characteristics of the types of work carried out at the facility, despite the continuous prevention and protection activity, cannot exclude a potential risk of exposure to biohazard. Non-medical external personnel are therefore advised not to approach and not touch containers, syringes, bottles, etc. without authorization. and to promptly report any accidental contact or problem to the CROM staff present on site.

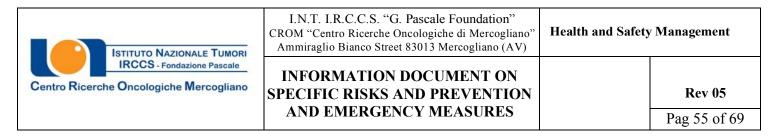
4.3.1.1 Precautions against chemical risk

- Always notify Executives and Supervisors of the workplace of their access
- Make sure of the need to use specific PPE that will be provided by CROM (unless otherwise provided for in the contract) and / or to observe particular procedures for access
- Avoid touching objects and tools of which you do not know the use and in any case without the authorization of the managers and supervisors of the laboratory / service
- During work interventions avoid coming into contact with unexpected places, activities, people, in order not to constitute an obstacle or danger for them; pay particular attention to the execution of the instructions relating to fire prevention (see specific section of this document)
- Apply the rules of hygiene, avoiding putting your hands to your eyes or mouth, eating and smoking
- It is a good idea to wear specific gloves during work operations, wash your hands after performing the surgery, cover any scratches or skin lesions with plasters or dressings
- Do not touch bottles and containers in departments and laboratories
- Refrain from carrying out dangerous operations near containers containing chemicals and in any case within the CROM laboratories
- It is forbidden to use products and chemicals present in the CROM departments

If the work to be performed involves contact with dangerous substances, it is mandatory to wear the PPE provided by your Prevention and Protection Service.

4.3.1.2 Precautions against radiological risk

- Access to the premises classified as radiological risk only the sources have returned and the Laboratory manager gives consent for access
- Make sure of the need to use any specific PPE that will be provided by the CROM (unless otherwise provided for in the contract) and / or to observe special procedures for access
- Avoid touching objects and tools of which you do not know the use and in any case without the authorization of the managers and supervisors of the laboratory / service
- During work interventions avoid coming into contact with unexpected places, activities, people, in order not to constitute an obstacle or danger for them; pay special attention to carry out the instructions relating to fire prevention (see specific section of this document)
- Apply the rules of hygiene, avoiding putting your hands to your eyes or mouth, eating and smoking It is good practice to wear specific gloves during work operations, wash your hands after performing the surgery, cover any scratches or skin lesions with patches or dressings
- Do not touch bottles and containers whose contents and dangers are unknown (always refer to the information on the product label) and in any case never without the authorization of the laboratory / service manager



• Refrain from carrying out dangerous operations in the vicinity of containers containing radioactive substances

4.3.1.3 Obbligation to wear personal protective equipment

All operators of external companies, contractors and other non-employee operators, are required, during their stay in the CROM, to make use of the personal protective equipment defined in the respective safety plans; in some cases, specific PPE may be indicated for access to particular environments: in this case, these will be provided by the client.

It is possible to view the document relating to all PPE adopted in the CROM at the Prevention and Protection Service.

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4.3.2 MAIN PRECAUTIONS TO PROTECT THE HEALTH AND SAFETY OF CROM PATIENTS, USERS AND STAFF

During the execution of works or supplies, it is possible to carry out:

- Risk of damage due to the production or dispersion of dust (also as a result of capture and diffusion by the ventilation systems): the danger is connected with demolition works, drilling walls, removal of false ceilings, furniture or other materials, brushing etc;
- Discomfort due to the production of noise: the danger is connected with the use of pneumatic hammers, breakers, small generators, hammers, chisels and operations to unload rubble;
- Risk of damage due to inadvertent service interruption of the electrical system, due to the insertion of high-power electrical equipment (which may cause the disconnection of the current due to overload) or due to involuntary interception of live cables during demolition or drilling of walls;
- Risk of damage due to unintentional interruption of the service of technological systems (water and heating): during the demolition of walls or installation, the piping supplying hot / cold water may be accidentally intercepted (with possible flooding);
- Risk of damage due to falling material during warehouse loading operations.

4.3.2.1 Precautions to be taken in case of works

It refers to compliance with the legislation regarding safety standards on construction sites: the drafting of the POS, which must always be sent to the Building and Plant Design and Maintenance Structure, the drafting of the PSC, in the cases and terms provided for by the decree, as well as, always where provided, the PIMUS for the use, installation and dismantling of scaffolding, etc.

In general, the construction sites for maintenance and restructuring interventions within the departments must guarantee:

- the clear delimitation of the construction site areas with prohibition of access to visitors and in any case to unauthorized personnel;
- the greatest possible separation between CROM and construction site activities, with particular reference to the introduction of dust, noise and vibrations.

Particular attention must be paid to the presence of the air intakes of the ventilation systems outside the building.

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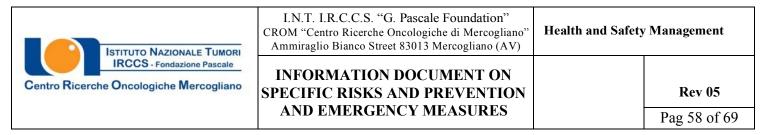
4.3.2.1.1 Height works

Access to coverage areas outside of the appropriate protections (railings, balustrades, etc.) is allowed only to employees who must carry out the required authorized interventions and only if equipped with appropriate Individual and Collective Fall Protection Devices, in compliance with current regulations.

4.3.2.1.2 Construction works that do not involve the drafting of PSC

It is necessary to take the following precautions in the case of construction works that do not involve the drafting of a specific PSC ("internal" room renovations, technological updates that involve the fixed installation of machinery and / or systems):

- Adopt all the precautions provided for in Annex II: (Guidelines for the protection of dust production and dispersion during works and for the prevention of Aspergylus infections)
- during the works, if necessary, the shutdown / disconnection of the air conditioning systems, fire detection, medical gases etc, must be planned with the Technical Structure and the ducts must be suitably protected;
- the intervention area must be completely isolated and circumscribed with barriers that extend from the floor to the ceiling, also including any false ceiling;
- the sealing of windows and / or other possible communication routes between the work area and the neighboring sanitary areas must be guaranteed; any holes in the walls made during the works must be repaired within the same day or temporarily sealed;
- the inlet vents of the air handling systems serving the neighboring sanitary blocks must be protected by installing additional metal grids and prefilters and scheduling more frequent maintenance;
- special signs must be provided for visitors and staff so that the passage takes place away from the work areas;
- special signs must also be prepared for workers' paths in order to guarantee a buffer zone to preserve in particular the access areas to the health buildings and in any case so as not to cross areas with patients, limiting the opening as much as possible and closing of the doors with the relative movement of air and dust;
- if possible, after assessing the places where the Hirer's activity must be carried out, a filter area must be prepared where the technicians, leaving the work area, can be subjected to dust extraction and shoe cleaning or otherwise they can wear protective clothing and over-footwears to avoid polluting areas where patients are present;
- specific areas dedicated to the storage of the equipment used must be identified;
- the schedules and timing of the work must be established with precision and communicated to the managers and / or referents of the health activities;
- the resulting material (rubble, electrical material, etc.) must be removed immediately following a well-defined path, avoiding the dispersion of dust, in closed containers or bags;
- the work area must be properly cleaned every day.



4.3.2.1.3 Obligation to contain environmental pollution

The underwriter is obliged to comply with all the rules and precautions that avoid environmental pollution of any kind:

- obligation to contain dust (see document in Annex II: Guidelines for the protection from the production and dispersion of dust during the works and for the prevention of Aspergylus infections)
- Exhausted materials or materials to be sent to landfills must be placed inside containers; for example, in the case of replacement of filters, when they are transported, to avoid unnecessary contamination in other areas, they must be contained in sealed bags or bags on which the material code is highlighted

4.3.2.1.4 Allaccio alla rete e/o lavori sull'impianto elettrico

If it is necessary to use the CROM electrical network, arrangements must be made in advance with the responsible and competent CROM technical staff.

Equipment with a power of less than 2 kW can be independently connected; for the others, and in any case always in case of doubt, it is necessary to contact the Technical Department.

In any case, it is mandatory to always contact the Technical Structure in advance in case you have to carry out operations that may involve the automatic operation of the switches for overload protection (insertion and starting of high power electrical equipment) or differential (presence of water or high humidity caused by the operations carried out) in laboratories where there are equipment which is essential to guarantee the continuity of energy supply electrical, (e.g. the refrigerator area).

Given the possibility of activities in progress, it may not be possible to globally deactivate all electrical systems, so it is likely that in the areas affected by the works there are live conductors; consequently, the Contractor's technicians must take all necessary precautions especially when and if the demolition operations must be carried out; during these processes, the Contractor must be equipped with appropriate protection devices as well as equipment suitable for detecting live cables even under traces. In case of interception of cables, the internal technical staff must be immediately notified.

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4.3.2.1.5 Wall drilling operations

The CROM is not always able to indicate the presence of pipes or electrical systems embedded in masonry. Before proceeding with the execution of holes in the walls it is therefore necessary:

- agree the intervention with the Technical Structures;
- ascertain, before drilling, the presence of any pipes or electrical systems recessed using appropriate instruments;
- that the company has its own instrumentation which it guarantees the quality.

4.3.2.1.6 Works on thermo-hydraulic systems and air treatment

During the operations of demolition, equipment installation, plant reconstruction according to the technical specifications for the introduction of new technologies, it may be possible to accidentally intercept the hot / cold water pipes and gas supply pipes.

In case of leakage of liquid or gaseous fluids, after having ventilated the rooms, it will be necessary:

- upstream dissect the pipes or plug the leak, for example by crushing the ends of the copper pipes;
- immediately notify the operators of the Technical Sector in order to limit the consequences and inefficiencies;
- in the event of a gas leak, ventilate the areas concerned and take the measures referred to in the safety data sheets.

The workers, before the demolition and / or installation operations must use suitable equipment to identify underground metal pipes.

In the event of an accident or emergency situation, the necessary precautionary measures must be taken (plugging the leaks, extinguishing fires, deactivating and removing electrical equipment if possible, etc.) before reaching the exit closest to the area of the works. The use of flammable or combustible substances, if provided for and authorized, must be limited to the bare minimum and operators must be informed about the related risks and precautions to be taken; operators must be equipped with fire extinguishers in a number and type appropriate to the type of substance used; the contractor company must in any case comply with the rules referred to in Ministerial Decree 10/3/98 and subsequent amendments.

Any particularities and information on electrical risks, gas leaks, fire and related safeguards will be provided by the referring structure for the contract.

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4.3.2.1.7 Obligation to contain noise / vibration pollution

The Contractor must contain noise emissions within the limits compatible with health care activities; therefore, he must use machinery and equipment that comply with the regulations for the control of noise emissions in force at the time of the work.

In the case of noisy work, he assumes the burden of circumscribing the rooms by means of paneling and shielding, closing doors and / or the adoption of suitable measures to limit the propagation of sound waves in the rooms used for healthcare activities;

The upgrading and maintenance of equipment and any building works must be conducted in ways that provide for the lowest impact in terms of vibrations; if it is unavoidable to use vehicles or equipment that cause significant vibrations, the contractor must agree with the CROM staff alternative strategies such as the deferral of work with respect to health activities or the transfer and / or reduction of the surrounding health activities throughout the duration of the works

4.3.2.1.8 Waste management

It is the Contractor's obligation to contain the environmental impact of waste from processing, demolition and supplies of materials (packaging, etc.).

4.3.2.1.9 Obligation to contain the fire risk

In the case of maintenance and renovation works, external companies must take into consideration the following issues related to the execution of the works:

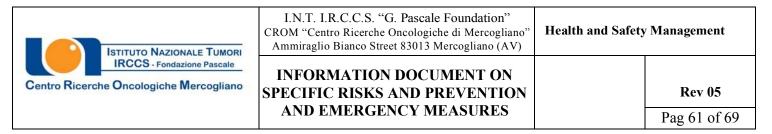
- accumulation of combustible materials
- obstruction of escape routes
- lock on opening of fire-resistant doors

At the beginning of the working day, it must be ensured that the exodus of people from the workplace is guaranteed; at the end of the work day, a check must be made to ensure that the fire prevention measures have been implemented and that the work equipment, flammable and combustible substances are secured and that there are no conditions for a fire to start.

Particular attention must be paid to places where hot work is performed (welding or use of open flames): a preventive inspection must be carried out to ensure that any combustible material has been removed or adequately protected against heat and sparks, portable fire extinguishers must be placed and, at the end of the activity, it is necessary to make sure that there are no residues of ignited materials and / or embers. Flammable substances must be stored in a safe and ventilated place; when they are used, smoking and the use of open flames must be prohibited.

Unused gas cylinders cannot be stored inside the workplace

Particular precautions must be taken in maintenance work on electrical systems and on those for the supply of fuel gas.



4.3.2.2 Precautions to be taken in case of material delivery operations

Companies that supply CROM with materials and products of various kinds must comply with the following provisions to prevent the risk of material falling during unloading, transport and storage:

- the pallet used for loading the material must comply with current safety regulations and applicable technical standards (see ISPM 15 "Regulation of wood packaging material in international trade EPAL)
- the pallets must be handled with a forklift or transpallet
- the dimensions of the European pallets are: length 120 cm; width 80 cm; height 15 cm.
- The type of pallet (dried epal, storage, semi-heavy, light, etc.) must be commensurate with the capacity of the transported load; the use of used pallets is allowed only if they are in good storage conditions
- the pallet must keep the entire load raised from the ground by at least 15 cm
- when assembling the pallet, the method that guarantees the best stability and strength must be used. The packages should be stacked on top of each other, because this is what gives the pallet the maximum strength
- Pay the utmost attention to loading packages of different sizes, because often the discrepancy may not allow the correct stability of the load on the pallet, with consequent movement during transport, loading and storage operations and the risk of the material falling with possible damage to the present (operators, employees and passing people)
- The delivery / collection paths of materials etc must be agreed in advance and must take place at times when the presence of users is minimal

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5. CONCLUSIONS

CROM requires you to strictly fulfill the following requests:

- comply with the obligations specifically provided for by current legislation on health and safety at work;
- comply with current environmental regulations as far as applicable.

and to guarantee:

- a correct behavior of the staff replacing those who do not observe their duties;
- the execution of works with capital, machines and equipment owned and in compliance with current safety regulations and good practice standards;
- to regularly fulfill the obligations for social security and insurance.

In general, the workers of the contractors, in carrying out their duties, must:

- proceed with care when handling materials
- maintain a limited speed when traveling with operational vehicles
- increase the visibility and identification of vehicles (eg with headlights on or flashing lights)
- separate risk areas with barriers or similar
- use acoustic or visual signals where possible
- respect the road signs displayed

The Institute requires you to comply with all the provisions set out in this Document.

The contractor must undertake to implement the provisions indicated as well as to provide the staff assigned to the interventions provided for in the contract, precise instructions, instructions and adequate information / training, for safe access to the various environments and sectors of activity of the CROM.

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Annex I

Names and contact details of all professionals entitled to provide safety information

| CLIENT COMPANY NAME | NATIONAL INSTITUTE FOR THE STUDY AND TREATMENT OF CANCER "GIOVANNI PASCALE FOUNDATION" I.R.C.C.S. OF PUBLIC LAW F.C. 00911350635 |
|---------------------|--|
| REGISTERED OFFICE | Mariano Semmola Street - 80131 NAPLES |
| | CROM OPERATIVE HEADQUARTER: Ammiraglio |
| | Bianco Street – 83013 Mercogliano (AV) |

Employer: General Manager

Emergency Center -710-Tel. 082-51911710 Tel. 081-5903350

Health and Safety Manager Tel. 081-5903806

Health and Safety Management Tel. 081-5903806

Occupational Physician: Tel. 081-5903646

Authorised Physician

Tel. 081-5903304

Qualified Expert

Dr. F. Cammarota Dr. L. Baldassarre

Workers Representative:

Dr. A. Marfella Dr. M. Napolitano Dr. Marco Correra Dr. Cecilia Cavaliere

Activity: SANITARY- RESEARCH

Dr. Attilio A.M. Bianchi

Eng. Francesco Florio E-mail: <u>f.florio@istitutotumori.na.it</u>

Eng. Fabio Florio E-mail: <u>fa.florio@istitutotumori.na.it</u>

Dr. Simona Menegozzo Email: <u>s.menegozzo@istitutotumori.na.it</u>

Dr. Biagio Pecori E-mail: <u>b.pecori@istitutotumori.na.it</u>

E-mail: <u>espertiqualificati@istitutotumori.na.it</u>

E-mail: <u>a.marfella@istitutotumori.it</u> E-mail: <u>m.napolitano@istitutotumori.na.it</u> E-mail: <u>m.correra@istitutotumori.it</u> E-mail: <u>c.cavaliere@istitutotumori.it</u>

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Annex II

1 INTRODUCTION

A lot of dust can be produced during the building renovation and construction activities in health facilities; this can also be contaminated by a ubiquitous fungus, Aspergillus spp, which has been isolated from unfiltered air, ventilation systems, horizontal surfaces, food and ornamental plants. Therefore, before starting construction works, the probability that workers will be exposed to dust, even possibly containing a high load of Aspergillus spp spores, must be assessed during the works, with the consequent need to develop a plan for prevent such exposures.

2 PURPOSE

The purpose of these Guidelines is to minimize the production of dust from renovation or construction activities in progress in the Center and prevent its spread in the areas where there are operators, with particular regard to those at higher risk. Provide precise technical - preventive information to be included in the tender specifications relating to the performance of services or works that may produce dust.

Identify functions and responsibilities relating to the surveillance and verification of the correct application of these Guidelines.

3 FIELD OF APPLICATION

These Guidelines should be inserted in:

- Works contract specifications, within which they represent binding requirements
- Drafting of coordination plans in the design and / or execution phase, within which they represent binding requirements

They must be used as:

- technical operational reference for the personnel involved in carrying out the work
- evaluation reference on the work of contractors in the CROM
- organizational / managerial address for the Department Managers involved

4 WORKS CLASSIFICATION

Hospital construction works can be classified into:

• works outside the structure: these are essentially construction works for new pavilions or elevations, as part of specific expansion projects; they are mostly working of great magnitude and duration;



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• **internal works**: that is, renovations involving departments or services of the structure. An evaluation scale of the possibility of producing dust by a construction site can be intuitively constructed on the basis of the extent and duration of the work itself, assuming that as these parameters increase, the exposure to dust also increases; obviously, further indicators of the risk of exposure are the carrying out of said works in active departments or services (with the simultaneous presence of operators and users) or inactive and the possibility or not of having access to the site from the outside;

The greatest risk would materialize for:

- demolition and / or renovation of an entire sector that is not active
- demolition work carried out in active sectors or affecting inland areas, when the demolition involves a large area or when the duration of the work exceeds two days
- work of any size and duration involving higher risk departments
- works that involve the shutdown of aeraulic systems
- decoration / painting works involving the smoothing / peeling of surfaces> 10 m2

5 PREVENTIVE MEASURES

They essentially consist of measures for:

- reduce the production of dust on construction sites
- contain the dispersion of dust from construction sites
- reduce the exposure of operators to construction site dust

5.1 MEASURES TO REDUCE DUST PRODUCTION ON SITE

They are borne by the operators of the companies and concern any type of work producing dust in any construction site, both external and internal to the structure:

- The surfaces of the areas intended for demolition or for any other work that produces dust must be moistened during the activities; similarly, all the aggregates to be removed must be thoroughly wetted, subject to the precautions for possible risks deriving from the presence of liquid
- 2. The rubble must be removed at the end of each working day, using the center's paths only when there is no other viable alternative.



5.2 MEASURES TO CONTAIN THE DISPERSION OF DUST FROM CONSTRUCTION SITES

These measures are also borne by the operators of the companies and vary according to the type of work depending on whether the construction site is external or internal to the structure, and in the latter case, in active or inactive departments

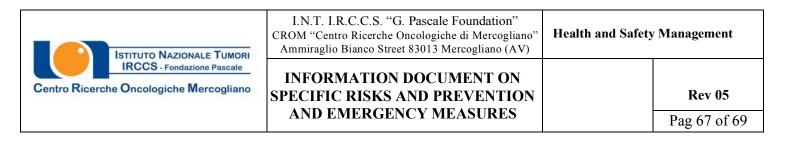
5.2.1 Behavioral rules for professionals

- personnel working on construction sites outside the structure cannot have access, in work clothes, to the internal areas of the structure used by users or staff
- the staff working on construction sites inside the structure must limit as much as possible access to the internal areas of the structure used by users or personnel in work clothes, especially if clearly contaminated; said staff must be clearly recognizable by users and health workers by wearing clothing and identification tags that allow the identification of the company they depend on.

5.2.2 Measures for external construction sites

As a rule, these are works of great size and duration.

- The construction site areas must be delimited with adequate dust containment systems, with nonflammable and airtight material, both on the ground (up to a height of 2 meters) and also along any scaffolding and scaffolding, where a lot of dust is produced
- Any external chutes for discharging the aggregates must be closed, perfectly sealed at the junction points between the elements; the collection on the ground of the discharges must take place in a sealed cage or in any other system that guarantees the containment of dust as much as possible, a thorough cleaning of the site area must be carried out at the end of each working day, removing all debris and other residues after having thoroughly moistened them
- If the works are carried out near water tanks or cooling towers, these must be adequately protected and the water quality of the systems must be checked if necessary.
- If the work is carried out near the external AHU outlets of aeraulic systems, it is necessary to periodically check the state of contamination and, if necessary, provide for the external cleaning of the air intakes and replacement of filters.



5.2.3 Measures for internal construction sites

5.2.3.1 Mesures for larger internale contruction sites

- The internal construction site area must be sealed with maximum tightness systems for dust, especially if the premises are completely insulated, as occurs in the case of a renovation of an entire laboratory, in the entrance / exit areas from the construction site, sheets must be placed / carpets to always be kept moist; in high-risk departments it is mandatory to set up a real antechamber to the construction site area. The access path to the site must be as separate as possible from the areas with the greatest personnel transit
- The windows and doors of the construction site area must be kept closed at least during the execution of the activities with the greatest production of dust, the passage points of the systems and the vents of the ventilation system in the construction site must be sealed
- Give preference to the preparation of external scaffolding or winches for handling the material. In case the removal of the rubble can only take place using the internal paths, those at least risk for patients must be identified, allocating lifts for the exclusive use of the site (and indicating the temporary intended use with clearly visible signs on the doors of the 'lift) and only if this is not possible, it will be possible to allow the transit of hermetically sealed trolleys, subject to agreement on the time (before or after the one of greater intensity of the health activity) and on the routes, which must be as short as possible and subjected to continuous and immediate cleaning.
- If the work is carried out near external AHU outlets of aeraulic systems, it is necessary to ensure the implementation of barriers with maximum tightness around the site, periodically check the state of contamination, clean the external air intakes and replace the filters and possibly check the air quality of the system served.

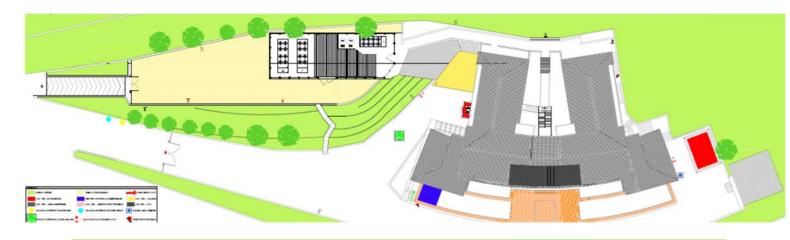
5.2.3.2 Measures for smaller internal construction sites

This typology includes a whole series of works for which, as a rule, a real construction site is not prepared, but there is a need to implement measures to contain dust:

- Isolate the area as much as possible
- In the entrance / exit areas from the construction site, sheets / carpets must be placed and always kept moist.

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Annex III CROM Floor plans – Internal viability





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Annex IV – Acceptance form and acknowledgment of the information document.

INFORMATION DOCUMENT FOR CONTRACTING COMPANIES. SELF-EMPLOYED WORKERS. SERVICE PROVIDERS AND OTHER NON-EMPLOYED OPERATORS OPERATING AT I.N.T. CROM "ONCOLOGICAL **RESEARCH CENTER OF MERCOGLIANO" - IRCCS G. PASCALE FOUNDATION OBJECT:** CONTEST ORDER N. ON REF. THE UNDERSIGNED____ BORN IN ON FISCAL CODE_____ IN QUALITY OF OF THE COMPANY SITES IN VAT NUMBER DECLARES to have read the content of the information document and the rules and precautions to be implemented therein and that it will inform its workers so that they apply it. The information document was consulted at the web address: http://www.istitutotumori.na.it/IstitutoPascale/DocUnicoValutazioneRischi CROM.pdf _____

(Place e date)

(full stamp and signature of the declarant)

P.N. The aforementioned document must kindly be returned by the Contractor, contractor or other external operator within 7 days from the date of receipt; in the event of failure to return within the aforementioned term, the silence of the recipient will be interpreted and considered as implicit acceptance and acknowledgment of the contents of the aforementioned document pursuant to and for the purposes of articles 26 and 36 of Legislative Decree 81/08

| PLEASE SEND THIS DOCUMENT TO: | | | | |
|---|-----|------------|--|--|
| Director of CS Management of Goods and Services | fax | 0815903842 | | |
| □ Director of CS Administrative coordination of research and hetero funded projects | | | | |
| | fax | 0815903827 | | |
| Director CS Building and Plant Design and Maintenance | fax | 0815903807 | | |

Naples Cancer Institute - Pascale Foundation - Mariano Semmola Street - 80131 Naples