

# Structural accreditation of healthcare facilities: comparison of the requirements by Italian presidential decree 14/01/1997 and regional regulations. a proposal for updating the minimum environmental units at national level

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**Abstract.** *Background and aim:* The Italian Decree of the Republic’s President of 14<sup>th</sup> January 1997 is the reference norm related to the accreditation of public and private healthcare structures. This guideline establishes the minimum structural, technological and organizational requirements that each structure operating in the Italian territory must comply with. *Methods:* In occasion of the project work for the postgraduate training course in healthcare management by ALTEMS School, a team of researchers conducted a survey on the state of updating of the minimum structural requirements indicated in the norm (those relating to hospital facilities) with the ones adopted by the individual regions through the analysis of the most up-to-date regional regulations. *Results:* Precisely starting from the comparison of regional references and from the regulations on the subject of structural accreditation which suggest strategic environmental units and which address some key-aspects relating to the contemporary design of healing environments (i.e. semi-intensive care units, hybrid operating theatres, etc.), the outcome of the project work is to define a proposal to update the national reference document, also in the light of the currently changing needs in terms of hospital design. *Conclusions:* The research aims to become a starting milestone for future investigations. The team investigated – in this first phase – the functional areas listed in the norm, and the next step aims to extend the analysis also to the innovative functions (i.e., buffer spaces, hybrid operating theatres, sub-intensive care units, etc.) and/or introduced only the last years which have only been regulated in some regions. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key words:** Healthcare facilities, hospital design, accreditation, minimum structural requirements, environmental units, hospital functional design, Italian context

## 1 - The role of accreditation of healthcare facilities in Italy

### 1.1 Introduction

With the term “accreditation” we mean an evaluation process, carried out by an external body, which verifies the quality of assistance requirements, periodically updated with the contribution of scientific societies, professional associations and sector experts (1).

In Italy the accreditation of a healthcare facility can be requested voluntarily for guaranteeing a functional relationship with a client. It can be issued by a universally recognized impartial entity (in this case the accreditation is like a “certification”) or by the organization itself (2). The latter is the case of institutional accreditation in order to operate within the Italian National Healthcare System (INHS): it is mandatory to be able to carry out activities on behalf of the Local Health Agency (LHA) and it has the purpose of identifying potential providers of healthcare services on the basis of defined quality criteria.

Institutional accreditation is confirmed after an accurate analysis and inspection on-site by each region to the healthcare facilities located in its territory’ as the Italian Legislative Decree n. 502 in 1992 (3) and then the Legislative Decree n. 229 in 1999 stated (4).

It is well-known that the Italian Constitution provides for the legislative powers of the State and the regions for the health-protection. The Government determines the essential levels of assistance that must be guaranteed throughout the national territory; while the regions plan and manage healthcare services in autonomy within the territorial area of their competence (5).

In the Italian model, accreditation is only one of the stages of a long process that a healthcare facility must complete in order to become a provider of medical services for the INHS. The process begins with the authorization to operate, given by the Municipality to any private and public healthcare facility intending to establish itself, based on the minimum structural, technological and organizational

requirements listed in the Italian Decree of the President of the Republic (DPR) 14<sup>th</sup> January 1997 related to the minimum structural, technological and organizational requirements of public and private healthcare activities (6-8). Among the structural ones, it is required the compliance with the laws in force regarding anti-seismic, fire and acoustic protection, electrical and accident prevention safety, hygiene in the workplace, protection from ionizing radiation, elimination of architectural barriers, waste disposal’ etc. In addition to the general requirements, there are specific minimum requirements (technological equipment, organizational, etc.) for the various functional areas (8,9).

The accreditation, not disregarding the minimum requirements, requires documentation on the medical and administrative processes and on the outcomes guaranteed by the structure.

In conclusion, both region and LHA can establish contractual agreements with the accredited structure for the provision of services at the expense of the INHS (10).

### 1.2 Aims and scope

Starting from these premises’ referring to the fact that the DPR 14/01/1997 defined the general requirements and that each region can define additional indications, the aims and scope of the present paper is a survey of the current state of updating of the minimum structural requirements (8)-in particular those relating to hospital facilities- with those adopted by the individual regions through the analysis of the most up-to-date regional regulations.

This activity has been developed as a project work of the training course “Healthcare Management of a Hospital Unit” promoted by ALTEMS School by “Università Cattolica del Sacro Cuore” in Rome, with the involvement of some experts in the field’ a team of physicians and architects.

## 2 - Methodology

With the aim of proposing an update of the minimum requirements, the team did a comparison of the

contents related to DPR 14/01/1997 and the regional regulations. In particular, the method adopted:

- referring to the aims and scope of the project work related to “hospital design”, focuses only on structural requirements;
- among the minimum requirements, refers only to the spaces with any analysis on their dimensions;
- for facilitating the data collection, the data analysis and the outcomes of the present paper are focused on the list of the functional units (8).

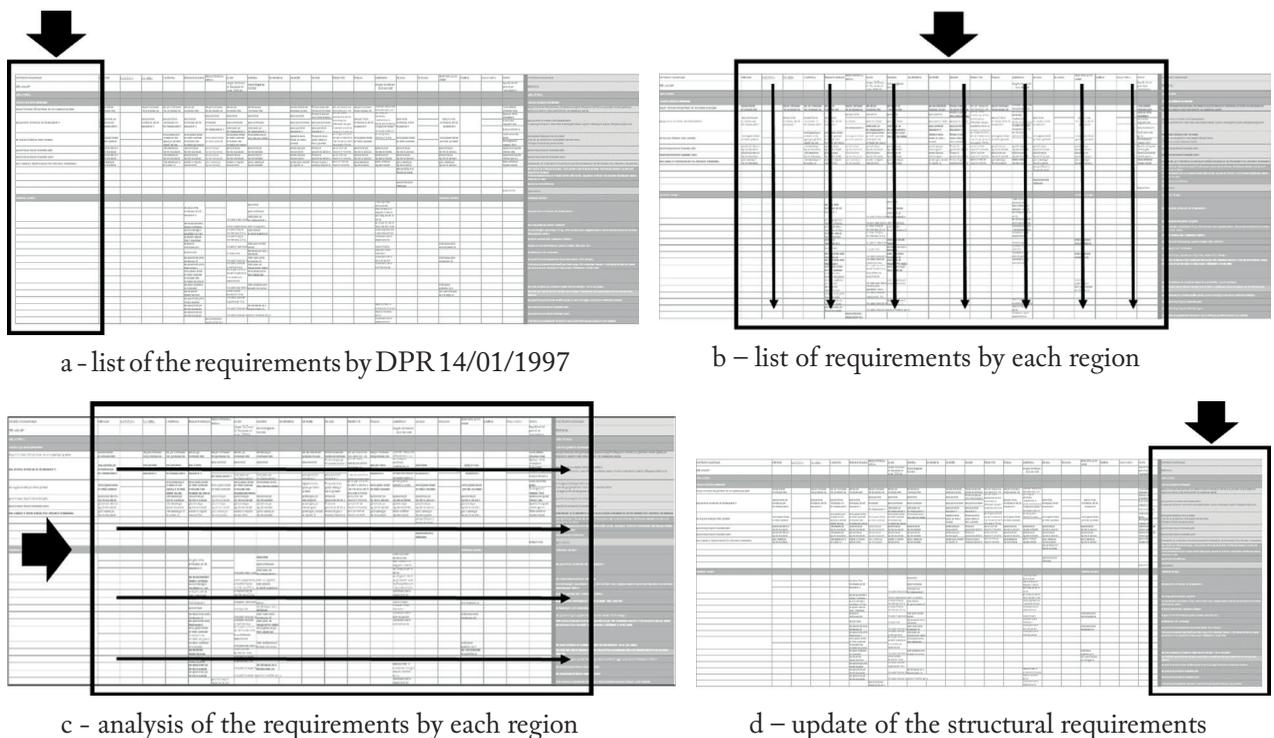
The entire team found the regulations of each Italian region (Figure 1a - see Supplementary file online). Each participant analyzed 2 regional regulations and filled in an Excel file that permitted to collect all the environmental units listed for each functional area (Figure 1b - see Supplementary file online). After the data collection, the team organized some specific meetings related to the definition of the structural

requirements for each Functional Area (Figure 1c and figure 1d - see Supplementary file online).

### 3 - Discussion

From the overall analysis, as Table 1 shows, the authors observed that Basilicata, Umbria and Aosta Valley have not any regulation about the accreditation, but they directly refer to DPR 14/01/1997 without any additional indications; instead, among the regions that have included a significantly greater number of specifications and recommendations, there are Abruzzo, Emilia Romagna, Liguria, and Piedmont.

In the following paragraphs, the team shows the results for each functional area selected. To facilitate reading and understanding of the next sections, the following abbreviations are given in Table 2.



**Figure 1.** Schematic organization of the methodological framework (see Supplementary file online).

**Table 1.** Analysis of the regional regulations related to the minimum structural requirements.

Analysis of regional regulations	ABRUZZO (11)	BASILICATA (12)	CALABRIA (13)	CAMPANIA (14)	EMILIA ROMAGNA (15)	FRIULI VENEZIA GIULIA (16)	LAZIO (17)	LIGURIA (18)	LOMBARDY (19)	MARCHE (20)	MOLISE (21)	PIEDMONT (22)	APULIA (23)	SARDINIA (24)	SICILY (25)	TUSCANY (26)	TRENTINO SOUTH TYROL (27)	UMBRIA (28)	AOSTA VALLEY (29)	VENETO (30)	
Outpatient area																					
Laboratory medicine																					
Diagnostic imaging																					
Rehabilitation area																					
Emergency room																					
Inpatient ward																					
Surgery block																					
DMCH-Inpatient ward																					
DMCH- Birth block																					
Intensive care unit																					
Nuclear medicine																					
Radiotherapy																					
Day hospital																					
Day surgery																					
Hospital pharmacy																					
Sterilization																					
Disinfection service																					
Mortuary service																					

**Legend**

- Several additional information in addition to DPR 14/01/1997
- Limited additional information in addition to DPR 14/01/1997
- Same information reported by DPR 14/01/1997

**3.1 Outpatient area**

Outpatient activity is an expanding service that plays a fundamental role in the more general process of dehospitalization, i.e. in the search for a system that identifies appropriate treatment modalities in relation to the real therapeutic needs (31,32). It guarantees an irreplaceable filtering and control activity, avoiding the use of indiscriminate and improper forms of hospitalization (33,34). Outpatient clinics are responsible

for providing specialist services (diagnostic, therapeutic and rehabilitative ones), pertaining to the various medical and surgical disciplines, which do not require hospitalization of the patient.

Since they are mainly related to daily users, in structural terms the outpatient clinics are not related to the hospitalization areas. They are in an area directly accessible from the main street, where the user from the welcoming area reaches the corresponding waiting area where the visit/procedure will be carried out.

**Table 2.** List of the abbreviations of the regions.

Region	Abbreviation	Reference
ABRUZZO	AB	11
BASILICATA	BA	12
CALABRIA	CAL	13
CAMPANIA	CAM	14
EMILIA ROMAGNA	ER	15
FRIULI VENEZIA GIULIA	FVG	16
LAZIO	LA	17
LIGURIA	LI	18
LOMBARDIA (LOMBARDY)	LO	19
MARCHE	MA	20
MOLISE	MO	21
PIEMONTE (PIEDMONT)	PI	22
PUGLIA (APULIA)	PU	23
SARDEGNA (SARDINIA)	SA	24
SICILIA (SICILY)	SI	25
TOSCANA (TUSCANY)	TO	26
TRENTINO SUD TIROLO (TRENTINO SOUTH TYROL)	TST	27
UMBRIA	UM	28
VALLE D'AOSTA (AOSTA VALLEY)	VA	29
VENETO	VE	30

The outpatient clinics must be connected to the diagnostic areas and the flows of daily users and inpatients should be differentiated (35). This functional area should guarantee large areas reserved for waiting and nurse stations adjacent to the entrances, sub-waiting areas in correspondence with the nursing services and outpatient clinics shared with inpatients. A second access should be set up for patients who have to undergo examinations or specialist visits and further accesses reserved for staff and goods, coinciding with the staff working areas and the storages (36).

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 3).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing offices for the department and a space for reporting as Sicily suggests (25).

### 3.2 Laboratory medicine

In addition to clinical chemistry, hematology, microbiology, this area includes histology and cytology and all other analytical methods on biological samples (37). It also has undergone and will be subjected to great changes in the next years, particularly in the sector of molecular biology and in automation and robotisation one, with the consequent possibility of re-organization and dislocation of activities (38).

To accentuate their flexibility and professional synergies, the laboratories should be merged into a rather large common area with the possibility of expansion, and they should share common services, secretariats and offices (39).

This area includes a large central space for regular activities and an emergency laboratory 24/7, and other spaces for specialties.

**Table 3.** Analysis and outcomes of outpatient area.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
ambulatory with separate area for undressing																						ambulatory
spaces for reception and administrative activities' and waiting area																						spaces for reception and administrative activities' and waiting area
separate toilets for users and staff																						separate toilets for users and staff
storage for clean materials																						storage for clean materials
storage of dirty materials																						storage of dirty materials
storage of materials, equipment, etc.																						storage of materials, equipment, etc.
																						offices
																						space/room for reporting
																						Archive

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 4).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular a waste storage and management (15,17), storage of clean materials (13), a reception area' staff changing room with toilet and dirty material storage (18), separate spaces for the storage of biological samples and any toxic, flammable and potentially dangerous reagents and a room for washing and sterilizing materials (22).

### 3.3 Diagnostic imaging

This specific area merges together all Diagnostic imaging tests related to the traditional radiology (Radiology, Magnetic Resonance, etc.) and the nuclear

medicine and endoscopy which are treated separately due to the related functional spatial features (40).

The functional area must be equipped with at least two entrances for patients subdivided into one for outpatients and inpatients (41), as well as another reserved for healthcare staff and goods (42).

As every functional area, a welcoming area with a reception should be set up in correspondence with the access of daily users; in addition, in this space it should be guaranteed the main waiting area and secondary ones should be localized in proximity of diagnostic rooms. As well as for inpatients, a waiting area for stretchered and wheelchair patients must be created (42,43).

Each diagnostic room should be equipped with a toilet and double changing room, between the waiting area and the room itself, to allow greater efficiency and



**Table 5.** Analysis and outcomes of diagnostic imaging.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
waiting area																						waiting area
spaces for reception, administrative activities and archives																						spaces for reception, administrative activities and archives
separate toilets for staff and users																						separate toilets for staff and users
radiodiagnostic room with changing rooms for users																						a diagnostic radio room, with changing rooms and the presence of toilets
room for the execution of ultrasound examinations, if present																						room for the execution of ultrasound examinations, if present
room for the conservation and treatment of sensitive materials																						room for the conservation and treatment of sensitive materials
space for reporting																						space for reporting
spaces for medical and technical staff																						spaces for medical and technical staff
storage for clean materials																						storage for clean materials
storage for dirty materials																						storage for dirty materials
storage of materials, equipment, etc.																						storage of materials, equipment, etc.
																						room/space for the collection and storage of harmful toxic waste until its removal, if produced
																						Computed Tomography (CT) room with changing rooms (if CT equipment is present)
																						a room for MRI diagnostic tests, if provided, with changing rooms
																						staff changing room with toilet
																						area dedicated to archives and/or with advanced systems

shorter waiting times, as well as a control area for staff and an additional access for inpatients (42,43).

In general, the nurse stations must be placed outside the diagnostic rooms; communicating with each other and pertaining to the service area where the departments, reporting areas, support areas' etc. are located.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 5).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular a clearly marked room for the storage of harmful toxic waste until its removal (15,17,18), Computed Tomography room (23,25), a room for MRI diagnostic tests (23,25), staff changing room with toilet (18), etc.

### 3.4 Rehabilitation area

The rehabilitation and physiotherapy areas are increasing their importance as a fundamental moment of the clinical process (33). This functional area is reserved for the preparation for interventions and immediate post-acute rehabilitation for inpatients or outpatients, before-during-after the hospitalization, suffering from disabilities deriving from orthopedic, neurological, pulmonary, cardiological, gastroenterological, etc. pathologies (44).

The rehabilitation service needs to be structured in two equipped areas: gym for group activities and another for individual therapies, as well as outpatient clinics.

The unit must be equipped with two entrances for daily users and inpatients; each access corresponds to a waiting, acceptance and storage area for wheelchairs. In addition, further access to the service should be reserved for staff and goods.

As many outpatient areas' the service activity needs to be fully scheduled, therefore waiting times both for internal and external users, will be minimal.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following mandatory rooms (Table 6).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular a

storage of clean and dirty materials and a storage for materials, equipment and instruments (11,17,23).

### 3.5 Emergency room

It is a strategic area of the hospital, where the critical situations need to be properly processed and identified and therefore it is an area for which every detail must be examined, especially as regards the system of relationships and priorities with the other hospital functional areas.

The flow of the patient is strictly related to his/her health status and type of assistance and any emergency hospitalization must interfere as little as possible with the rest of the hospitalizations scheduled in the election (45).

It is important that the entrance flows can be controlled directly from the nurse station, that the flow to the urgent treatment areas are wide, direct, fast and that they are not in any way hindered by the flow of less serious patients (46).

The Emergency Department is equipped with areas for stabilization and emergency intervention, boxes with technical beds for treatment, an observed waiting area for brief observation of patients, and its own hospitalization (prolonged observation - no more than 48 hours), an outpatient area and diagnostic services, plaster room, and support services (47-49).

The organization must allow for the immediate subdivision of accesses on the basis of urgency-emergency during triage process. It is essential to have direct and easy connections that facilitate the connection of the patient to the intensive care unit, the surgery block and the other diagnostic services (47,48).

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 7).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular the triage area (11,15,17,18), room dedicated to the reclamation and/or decontamination station (11), space intended for the decontamination, cleaning, disinfection and sterilization processes of reusable medical devices (11,15,17), plaster room (15,17,18), etc.

**Table 6.** Analysis and outcomes of rehabilitation area.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal
areas equipped for group activities (gyms), for static and dynamic activities																					areas equipped for group activities (gyms), for static and dynamic activities
areas equipped for individual activities (motor, respiratory, neuropsychological, etc. ones)																					areas equipped for individual activities (motor, respiratory, neuropsychological, etc. ones)
box (or small rooms) for massage therapy, physical and instrumental therapy and manipulations																					box (or small rooms) for massage therapy, physical and instrumental therapy and manipulations
area equipped for the treatment of communication/ integration disorders, if present																					area equipped for the treatment of communication/ integration and speech therapy disorders, if present area equipped for the treatment of speech, swallowing and language disorders area equipped for the treatment of cognitive-symbolic disorders, if present
ambulatories for specialist visits and clinical diagnostic-prognostic evaluations relating to the pathologies treated																					ambulatories for specialist visits and clinical diagnostic-prognostic evaluations relating to the pathologies treated
disabled toilets																					disabled toilets
toilets and changing rooms for staff																					toilets and changing rooms for staff
changing rooms for patients																					changing rooms for users/patients with toilets
spaces for reception and administrative activities' and waiting area																					spaces for reception and administrative activities and waiting area
																					separate storages for clean and dirty materials
																					storage of materials

**Table 7.** Analysis and outcomes of emergency room.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
hot bay																						hot bay
local for emergency management (shock room)																						local for emergency management (shock room)
ambulatory																						ambulatory
local for observation																						local for observation
waiting room for (ambulant) users																						waiting room for (ambulant) users with toilets
waiting room for stretchered users																						waiting room for stretchered users
nurses workplace																						nurses workplace
toilet staff																						toilet staff
toilets for users																						toilets for users
storage for clean materials																						storage for clean materials, equipment, etc.
storage for dirty materials																						storage for dirty materials with technical drain
spaces for reception, administrative activities and archives																						spaces for reception, administrative activities and archives
																						triage area for nursing evaluation
																						waiting room
																						storage for stretchers and wheelchairs
																						Room for the doctor on call
																						staff relaxation area
																						room dedicated to decontamination with storage of clean clothing for patients in a state of poverty
																						space for the decontamination, cleaning, disinfection and sterilization processes of reusable medical devices
																						room for corpses (bodies awaiting transfer)

Table 7 (Continued)

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal
																					plaster room
																					nurse coordinator room with the medicines
																					changing room
																					storage
																					office
																					supervisory system, with permanent presence
																					ambulatory for the management for the low-care codes

### 3.6 Inpatient ward

The optimal articulation of the Inpatient ward is based on standard units of 24-28 rooms that can be used as single' single as double use or double rooms' designed with all the comforts necessary to make the patient's period of hospitalization as least traumatic as possible (50-52).

Each inpatient ward should be equipped with support services such as a nursing station, the coordinator room, the relaxation room, clean and dirty storages, assisted bathroom, public and toilet staff, a living room, a medical room, etc.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 8).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular room for infected patients equipped with dedicated filter, toilet and sink for each room (16) and room for corpses (bodies awaiting transfer) (30).

Moreover, this section argues the "ordinary" inpatient wards, but several regions add some additional details about: pediatric inpatient ward (53,54); psychiatric inpatient ward (11,15,17,55); inpatient ward for infectious diseases; inpatient ward for oncology (11); nephrological inpatient ward (17); inpatient ward for rehabilitation (22).

### 3.7 Surgery block

The Surgery block must be in such a way as to be protected from any extraneous interference, in contiguity with other services, such as the intensive care units, the emergency department, the sterilization and the day surgery. In fact, a particular attention should be paid to defining the adequate level of contiguity between correlated functions, even if they are autonomous (56).

There are different distributive typologies' but the most common one is the double corridor scheme with clean and dirty corridors that permits to optimize the flows.

At the entrance to the Surgery block there are three separate areas:

- one for the patients, who access the sterile area through a patient transfer system;
- the other one for the staff who passes through changing rooms, equipped with toilets and showers;
- the goods' one' considering both the clean and dirty flows: a) the storages of sterile materials, equipment' etc. have access from the clean corridor, as well as the sub-sterilization room and the emergency laboratory; b) the dirty area is used by the cleaners and for carrying out the waste.

**Table 8.** Analysis and outcomes of inpatient ward.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
inpatient room																						inpatient room
ambulatory for visits and medications																						ambulatory for visits and medications
staff area																						staff area
nurse coordinator room																						nurse coordinator room
doctors' room																						doctors' room
living room																						living room
storage of clean materials																						storage of clean materials
storage of materials, equipment, etc.																						(at least) storage and conservation of medicines, medical devices, medication material
storage for dirty materials equipped with a sink and bedpan washer																						storage for dirty materials equipped with a sink and bedpan washer
kitchen																						kitchen with space for food distribution trolleys
toilet staff																						toilet staff
assisted bath																						assisted bath
waiting area for visitors																						waiting area for visitors with toilets
																						room for infected patients equipped with a filter area, toilets and sink
																						office for the doctor on call
																						room for corpses (bodies awaiting transfer)

Both dirty and clean materials' flows should be directly connected to the centralized sterilization service.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 9).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular: storage for clean materials (11); material preparation

area (16); relaxation area for personnel equipped with toilets and with the interposition of a filter area (11,16); coordinator room and medical staff room (18); drug storage (14).

**Table 9.** Analysis and outcomes of Surgery block.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal
patient filter area																					patient filter area
staff filter area																					staff filter area equipped with toilets, shower and face washer for biological risk
staff preparation area																					staff preparation area
user preparation area																					user preparation area
user awakening area																					user awakening area
surgery room																					surgery room
storage of surgical supplies and instruments																					sterile storage for surgical supplies and instruments
storage for dirty materials																					storage for dirty materials
																					storage for clean materials
																					plaster room
																					surgical instruments' washing area, if sterilization is not present
																					storage for material preparation
																					space for storing the current operating log and any clinical documentation
																					relaxation room
																					nurse coordinator room
																					local for extemporaneous anatomical-pathological examinations
																					staff working room
																					storage for medicine

*3.8 Department of Maternal and Child Health (DMCH) - inpatient wards and birth block*

The DMCH is made up of the sum and aggregation of the functions of the birth block, obstetric hospitalization and nursery. The access for patients and visitors should be unique and separate from the flows of the rest of the users of the hospital (35); from a common waiting area the users access the examination room, the delivery area - through a filter - as well as

the obstetric area and the nursery (57). Therefore the waiting area for relatives remains outside the service.

Women in labor access the Birth Block, following a medical examination which confirms the beginning of the birth process. Through a filter zone, the mother with only one parent is taken to the delivery room. This room has a neonatal area and a dedicated toilet attached (58).

After the birth, the mother should be moved to the post-partum observation area and then to the obstetric

**Table 10.** Analysis and outcomes of inpatient ward.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal		
inpatient room with toilets						■		■		■		■			■	■					■	inpatient room with toilets	
ambulatory								■		■				■	■							■	ambulatory equipped with a sink
staff working area								■		■				■	■								staff working area
nurse coordinator room								■						■	■								nurse coordinator room
doctors' office								■						■	■								doctors' office
living room								■						■	■								living room
storage of clean materials								■		■	■			■	■								storage of clean materials
storage of materials, equipment, etc.								■						■	■								storage of materials, equipment, etc.
storage for dirty materials equipped with a sink and bedpan washer								■		■	■			■	■								storage for dirty materials equipped with a sink and bedpan washer
kitchen								■		■				■	■								kitchen
toilets for staff								■		■	■			■	■								toilets for staff
waiting area for visitors								■			■			■	■								waiting area for visitors
assisted bath								■						■	■								assisted bath
																■	■						isolation room for presumed or current infectious diseases both for the mother and the newborn
											■												nurses/midwives working room
											■												ambulatory for the newborn
											■												Breast feeding room
											■												room for bottle preparation
															■								storage for dirty materials

inpatient ward. This last one area should be composed of single or double rooms' that must be treated with particular attention allowing rooming in or the simple presence of the cot in the room (59).

The newborn will instead be moved to the nursery' that will be accessible only to the parents of the

newborns, under the supervision of the nursing staff. This area should be equipped inside with rooms for teaching breastfeeding, bathing the newborn and cord care. The nursery staff will take care of the care, management, feeding and handling of the newborns. The



baby room will be equipped with windows to allow visitors to see the babies.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms for the inpatient ward (Table 10).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example - an incubator in the neonatal care area (11,22,27), isolation room for infectious diseases, both for the mother and the newborn (26), nurses/midwives room (21), room for visitors (22).

Instead for the birth block the following rooms in Table 11 are expected.

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example - room for performing birth analgesia techniques (23), isolation room for infectious diseases, both for the mother and the newborn (18,23), storage of medicines and medical supplies (18,30), staff preparation (30), etc.

### 3.9 Intensive Care Unit

The Intensive Care Units (ICU) are composed of a specific area, with qualified personnel and equipment suitable for monitoring, treating and supporting the vital functions of patients in critical conditions. This service hosts critical users who need to be monitored continuously.

It is well known that ICUs have a strong connection with the emergency department, the surgery block, interventional radiology' as well as with the diagnostic services (34).

In ICU' three types of separate accesses need to be provided, all of them equipped with a filter: one for patients, one for staff and goods and another one for relatives and visitors. It includes:

- a protected area with the beds (both in single rooms and/or open space) and nursing stations;
- a second area made up of all the medical support services;
- a third sector is dedicated to relatives and visitors' composed of a waiting area and changing rooms' as well as meeting rooms with the medical staff.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 12).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example - meeting room with the parents (23), space for emergency laboratory diagnostic activities (24), ambulatory (22), separate toilet for users (11), preparation area for consumables (drugs, nutritional solutions) and surveillance area for direct visual control of patients (18).

### 3.10 Nuclear medicine

Nuclear medicine is a medical specialty involving the application of radioactive substances in the diagnosis and treatment of disease.

The functional must be equipped with several separate entrances, one for users (outpatient and inpatient) and the one for staff and goods. The system of accesses and flows for staff and goods requires great attention to avoid any type of contamination: it is essential to provide adequate access filters and spaces for decontamination in case of "accidents".

Therefore, the service should be divided into two areas:

- a "cold area" consisting of waiting, reception, any visiting rooms and support services;
- and a "hot area" which hosts a waiting area with services (whose wastewater is collected in decay tanks), staff work area and laboratories, administration rooms, PET, etc. suitably filtered and with controlled and isolated plant solutions

**Table 12.** Analysis and outcomes of Intensive Care Unit.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
filter area for inpatients																						filter area for inpatients
staff filter area																						staff filter area, also for relatives and consultants, with entrance to the area separated from the access of patients
inpatient room or box																						inpatient room or box
room for infected patients equipped with a filter area																						room for infected patients equipped with a filter area, toilets and sink
staff working room																						staff working room
nurse working room																						nurse working room, also for preparing infusion therapies, etc.
toilet staff																						toilet staff also with a shower
storage for clean materials, equipment, etc.																						storage for clean materials, equipment, etc.
storage for dirty materials																						storage for dirty materials with technical drain
visitors' waiting/living room																						visitors' waiting/living room
space for disinfection and washing of equipment and materials																						area for disinfection and washing of equipment and materials
room for the on-call doctor equipped with toilets																						room for the on-call doctor equipped with toilets
staff changing rooms																						staff changing rooms
storage for spare/sterile equipment																						storage for spare/sterile equipment
storage for bedding (pillows, sheets, blankets, towels and bath towels, etc.)																						storage for bedding (pillows, sheets, blankets, towels and bath towels, etc.)
Storage for medical gas cylinder																						Storage for medical gas cylinder
																						Meeting room
																						acceptance room



DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal
																					storage of radioactive waste
																					laboratory for “in vitro” diagnostic activity’ if present
																					ambulatory
																					therapy room
																					user toilets for the “cold” area
																					toilet staff
																					radiopharmacy laboratory for the storage and handling of radiopharmaceuticals and other radioactive products
																					waiting area for visitors/parents
																					in the case of high-dose therapeutic activity or experimental therapy, at least one shielded room for the inpatient equipped with an independent toilet with controlled drainage, with a filter
																					decontamination area with sink and shower equipped with drains for decay
																					staff room
																					storage for dirty materials
																					storage for clean materials
																					storage of materials, equipment, etc.
																					“hot” waiting room equipped with lead shielding to insulate for injected patients, equipped with toilets with controlled discharges

from the rest of the structure (the command-and-control area will be outside the diagnostic rooms).

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 13).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example - room used for the storage of radioactive waste (15,16,24), an ambulatory (15,17,20), a radiopharmacy laboratory for the storage and handling of radiopharmaceuticals and other radioactive products (15,17), decontamination area with sink and shower (18), staff room and a room for storing dirty and clean materials, as well as for equipment (11), presence of a “hot” waiting room equipped with lead shielding to insulate for injected patients, equipped with toilets with controlled drainage (15,21).

### 3.11 Radiotherapy

Radiotherapy is a high complexity service, where diagnostic, therapeutic and follow-up activities are carried out (60). The functional area needs to be subdivided into differentiated areas:

- the diagnostic area consisting mainly of outpatient rooms for diagnostic visits and follow-ups,
- a therapy area with bunkers for treatments and diagnostic studies (CT-simulator, etc.).

This functional area should guarantee two main entrances: one for outpatients and the other for inpatients (as well as users coming from other facilities); further access is required for staff and goods (possibly separate).

The reception area should be in proximity of patient access. After being accepted, the user will be directed to the corresponding waiting area (outpatient or treatment ones). Referring to the healthcare organization of the facility the functional unit could host the Health Physics services.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 14).

The team confirms the spaces suggested by DPR 1997 and it suggests introducing in particular - for example - “hot” waiting room (11,17), radiology space and storage for mobile equipment (22), a room for the packaging of immobilizers and a device for customizing the irradiation beam (24), dedicated room/space for the decontamination, cleaning, disinfection and sterilization processes of reusable medical devices (11).

### 3.12 Day hospital

It is perhaps the area that has undergone the greatest expansion in recent decades. It provides for the provision of diagnostic, therapeutic and rehabilitative services (multi-professional and multi-specialist ones) which do not involve ordinary inpatient recovery, and which require a regimen of prolonged medical and nursing assistance and/or observation (up to a maximum of 12H), not feasible in outpatient setting. Day hospitalization meets the psychological and social needs of patients, especially in the case of repeated or cyclical sessions (32).

Day hospital areas are preferably separate and autonomous with respect to the high care and low care hospitalization units. They meet the same requirements as ordinary inpatient wards; open spaces and/or single rooms should be provided, with toilets both for users and staff, nursing station, coordinator room, ambulatories and offices, storages for dirty and clean materials and toilet, etc.

In proximity to the main street, there should be the waiting and reception areas, while the outpatient clinics are located between these spaces and the inpatient area. An access should be guaranteed for staff and goods.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 15).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular -

**Table 14.** Analysis and outcomes of Radiotherapy.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
waiting areas for users																						waiting areas for users
spaces for reception, administrative activities and archives																						area for reception and administrative activities, archiving and delivery of reports
simulation room																						simulation room
therapy bunker																						therapy bunker
room for the conformation of the irradiation fields, for the containment and protection of the user during therapy, for dosimetric verification																						room for the conformation of the irradiation fields, for the containment and protection of the user during therapy, for dosimetric verification
ambulatory																						ambulatory
room for short drug treatments																						room for short drug treatments
room for the storage and handling of radioactive substances																						room for the storage and handling of radioactive substances'if present
separate toilets for staff and users																						separate toilets for staff and users, of which at least one for the disabled (controlled discharges for monitoring radioactive liquid waste)
changing rooms for users for therapy rooms and ambulatories																						changing rooms for users for therapy rooms and ambulatories
																						"hot" waiting room equipped with shielding system
																						offices
																						physics room
																						a darkroom with a collection system for the fixing and developing liquids to carry out the curie therapy activity



for example - storage of materials, equipment, instruments (11), and a living area for users (15,17).

### 3.13 Day surgery

This area includes patients for surgery or elective, invasive and semi-invasive diagnostic or therapeutic procedures, with limited hospitalization to daylight hours only. This functional area is destined to spread, and it is growing steadily (32).

The Day surgery is mainly composed of units with hospital beds and dedicated surgery rooms.

The access to the functional area is composed of the welcoming area with the waiting room and registration desk. Another access through pass-through changing rooms and/or filters is provided for staff and goods.

After acceptance, the patients move into the unit, and they have their own changing rooms, located between the entry and exit flows, directly connected both with the preparation and with the day inpatient beds.

The service should have its own internal surgery block, or it should have a direct connection with the general surgery block.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 16).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example- relaxation room for workers (22), changing room (as a filter) for the staff, a plaster room and observation area (17), equipment Storage (16,17), etc.

### 3.14 Hospital pharmacy

The hospital pharmacy is one of the key departments in hospitals that deals with procurement, storage, compounding, dispensing, manufacturing, testing, packaging, and distribution of drugs. The Pharmacy Service is required to have space for the storage of medicines, medical-surgical and sanitary devices, medication materials and specific drugs, medical-surgical and sanitary devices, medication materials and specific materials needed. The internal organization of the facility must enable separate paths of incoming and outgoing material, with independent accessibility from

the outside in relation to the general route system of the facility.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 17).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular material reception/registration space as several regions suggest and Toilet staff (11).

### 3.15 Sterilization

This area aims at sterilizing all the instruments used in the hospital. The sterilization area should be structured in three sectors: the arrival area of the dirty materials' the washing area, and the packaging area with a sterile storage. All three sectors should guarantee a filter for the access of the staff and in general the service will be equipped with changing rooms for staff. The service is directly connected to the surgery block with separate elevators for the clean and dirty flows.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 18).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example - a room intended for reception and washing of the instruments (15,17), presence of changing room for staff (21), room for administrative activities (11).

### 3.16 Disinfection service

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (61). Disinfection service is of paramount importance in the hospital as daily and terminal room disinfection reduces bioburden on the inanimate environment. This decreases the risk of cross transmission in the hospital (62).

The disinfection service must provide spaces for the treatment of personal effects, sheets, pillowcases, blankets bedclothes, and generally infected materials.

The internal organization of the spaces has to enable a distinct separation between the dirty and clean areas. The route must be progressive from the dirty area to the clean area.

**Table 16.** Analysis and outcomes of day surgery.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal
waiting area																					waiting area with toilets, at least one of which is accessible to disabled people.
archive and recording space																					archive and recording space
operating room filter																					operating room filter
surgery room																					surgery room
staff preparation area																					staff preparation area
patient preparation area																					patient preparation area
awakening area																					awakening area
storage of sterile materials and surgical instruments																					storage of sterile materials and surgical instruments
ambulatory																					ambulatory
inpatient room																					inpatient room
kitchenette																					kitchenette
user toilets																					user toilets
toilet staff																					toilet staff
storage for clean materials																					storage for clean materials
storage for dirty materials																					storage for dirty materials equipped with sink and pan washer, equipment
																					staff working area
																					nurse coordinator room
																					staff changing rooms
																					storage for sterile materials
																					area for washing and local sterilization system
																					endoscopy room
																					diagnostic and/or interventional room
																					department offices
																					staff relaxation room
																					staff changing rooms equipped with toilets and shower and face washer for biological risk
																					plaster room
																					observation area
																					storage of materials, equipment, etc.
																					space for information relatives of patients

**Table 17.** Analysis and outcomes of hospital pharmacy.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
material reception/ registration space																						material reception/ registration space
storage for medicines and medical-surgical instruments																						storage for medicines and medical-surgical instruments
space for storing drugs																						space for storing drugs
space for chemical preparations																						space for chemical preparations
pharmacist office																						pharmacist office
cold rooms																						cold rooms
flammable storage																						flammable storage
																						spaces for the storage of perfusion solutions, toxic, corrosive and therapeutic gases in cylinders
																						toilet staff

**Table 18.** Analysis and outcomes of sterilization.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
spaces for materials’ reception, sorting, cleaning and preparation																						spaces for materials’ reception, sorting, cleaning and preparation
sterilization area																						sterilization area
staff filter, prior to access to the sterile materials area																						staff filter, prior to access to the sterile materials area
storage of sterile materials																						storage of sterile materials
storage for dirty materials																						storage for dirty materials
toilet staff																						toilet staff
																						space for materials’ reception and washing
																						staff changing room
																						space for administrative activities

**Table 19.** Analysis and outcomes of disinfection service.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal	
staff filter room, with toilets and changing rooms																						staff filter room, with toilets and changing rooms
pre-treatment and disinfection room																						pre-treatment and disinfection room
storage for materials to be treated																						storage for materials to be treated
storage for clean materials																						storage for clean materials
spaces for the storage of disinfectants and pesticides																						spaces for the storage of disinfectants and pesticides
space for administrative activities																						space for administrative activities

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 19).

In this case, the team confirms the spaces suggested by DPR 14/01/1997, without any additional information.

### 3.17 Mortuary services

This functional area provides for the observation, conservation and preparation of the corpses, the burial chambers, reserved spaces for funeral ceremonies and autopsy rooms.

The service should be equipped with separate external accesses' with a dedicated parking area' for mourners and the exit of the coffins. In correspondence with this access it is expected to include living rooms, toilets, a refreshment area' and the support spaces.

Users and relatives have access only to the burial chambers, because the observation area, preparation and cold storage areas are reserved for the staff in charge. Moreover' it is expected to guarantee an area for preparing corpses adjacent to the mortuary chambers.

Starting from these premises and from the analysis of the structural requirements, the team has listed the following rooms (Table 20).

The team confirms the spaces suggested by DPR 14/01/1997, and it suggests introducing in particular - for example- cold rooms or air-conditioned rooms for the corpses, a waiting area for mourners with toilets (15,17,26), a storage room for temporary conservation of anatomical specimens (11), etc.

### 3 - Conclusion

This study aims to be a starting point to define the future guidelines and strategies regarding the update of the minimum structural requirements for the accreditation of healthcare facilities.

Starting from this research activity, it is necessary to continue the considerations and strategies by expanding the study on all the functional areas of a healthcare facility. In fact, the team has only dealt with the functions mapped in the DPR 14/01/1997 but from 1997 other medical needs and related spaces become essential for the healthcare services.

In addition, the current analysis is focused, among the structural requirements, on the minimum environmental units and it lacks the dimensioning of the spaces, as well as of all the technological and organizational requirements.

**Table 20.** Analysis and outcomes of Mortuary services.

DPR 14/01/1997	AB	BA	CAL	CAM	ER	FVG	LA	LI	LO	MA	MO	PI	PU	SA	SI	TO	TST	UM	VA	VE	Proposal		
observation room (dead rest)	■				■		■	■			■										■	room for the observation and storage of corpses	
burial chamber																						■	burial chamber
staff working room	■						■	■			■											■	staff working room
toilet staff	■				■																	■	toilet staff
relatives' toilets	■						■	■			■											■	relatives' toilets (one of which is suitable for disabled users)
coffin funeral room	■										■											■	coffin funeral room
storage for materials	■				■		■	■			■											■	storage for materials
	■				■		■					■										■	cold rooms or air-conditioned rooms for the corpses
	■						■						■		■	■						■	the autopsy room must be equipped for the diagnostic check and for the eventual sampling of the anatomical parts, if present
					■		■									■						■	a waiting area for mourners with toilets
	■																					■	storage room and a room/area dedicated to the treatment/reduction and temporary conservation of anatomical samples, if there is a sector room

Therefore, the research activities can give rise to an update of the current regulations. This will continue the advancement of knowledge and competences within the field of healthcare design, which is critical for supporting interdisciplinary collaboration between healthcare facility managers and clinicians in the future planning, programming, and design of healthcare settings (63,64).

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