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MANAGEMENT AND SAFETY TO ELECTROMEDICAL EQUIPMENT

1.1 Introduction

The main objective of this paper is to define the subject of the planning and management of the technological patrimony, with particular regard to safety and to the prevention of electric risks due to use.
For the past twelve years is in charge of the functional set-up and management of electromedical equipments operating at St. Anna Hospital and associated periferical units.
Takes part in National Technical Commission for the study and application of electrical safety standards (CEI) to electromedical equipment and is a member of the Technical Commission of the Emilia Romagna Region.
In the last few years the region of Emilia Romagna has been dwelling on the problem of the management of technology and it has worked in order to render the process of innovation quicker and more efficient.
It has been trying to guide the UUSSLL along a common line as regards planning in the acquisition of quality products in the use of technology in the field of health and prevention, as well as in the means and forms of quality control in order to guarantee its improvement in time.

1.2 Management: an overview.

Managing technology means: working out planning arrangements in advance, considering that only highly qualified personnel who is fully conscious of the situation of the Health Board and who can relate with the different aspects of the organisation: sanitary, technical and administrative, will be able to cope.

GENERAL SUGGESTIONS FOR MANAGEMENT

PLANNING	
Technological Investment	Technological Maintenance
Evaluation: 1) Technical 2) Clinical 3) Economic - managerial	1) Maintenance 2) Safety

This means that there must be media information as well as government support in order to analyse and intervene on costs and benefits.
From this we can deduce that all decisions must carefully ponder the choice of technological investments that have to be taken from the various stand points of technical, clinical, managerial and economic considerations.
In many cases, experience has shown that, erroneously, requests coming from the various wards are sorted out bureaucratically and given precedence only on the declaration on the part of the ward itself that it is something needing urgent attention.
When planning one must consider the maintenance and safety of technological equipment.

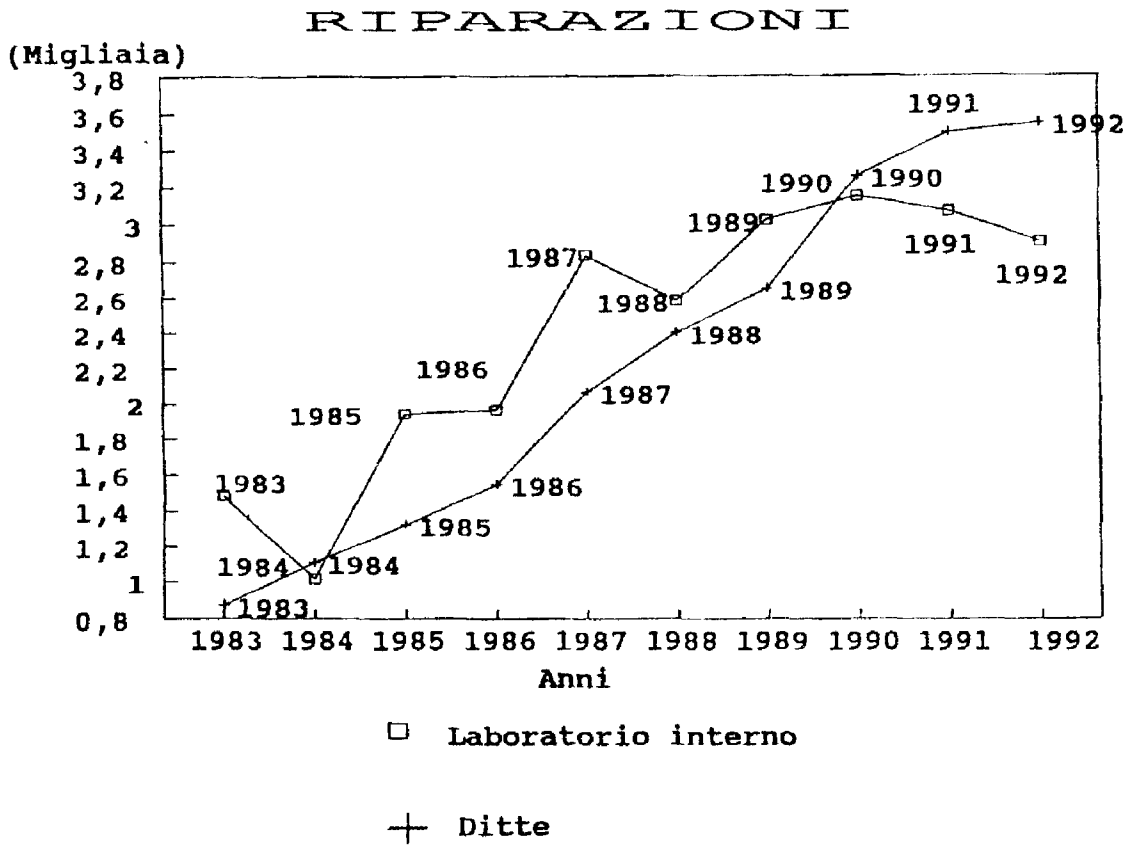
Another important feature is the management of technology.

MANAGEMENT	
Service	Equipment
1) Efficiency 2) Effectiveness	1) Maintenance 2) Safety 3) Advice

We must be very careful in making the right choices in labour organization so that the economic investment will yield a positive turn out as regards efficiency and effectiveness.
All equipment must be kept in good running order and routinely checked to safeguard its efficiency.
To this end, the presence of qualified technicians actively employed, who can satisfy all needs and can intervene with the suppliers and manufacturer in order to keeps standards high and up-dated, is absolutely compulsory.
The technical assistance service within the Hospital has the following tasks:
- first it provides in-house maintenance to machines
- secondly, works to ensure safety; in other words, effects acceptance controls to newly purchased machines and other tests to assure maintenance grade to machines in time, conforming to regulations and standards being introduced year after year
- offers consulting in connection with hospital needs.

BIOMEDICAL TECHNOLOGY MAINTENANCE	
<u>External Service (with Suppliers):</u>	<u>Inside Service:</u>
Contracts	Maintenance Safety Consultations

Maintenance should be divided in two stages: the first one involves the manufacturers who are called to intervene by contract, the second involves the inside services which answer to the required needs, such as: urgent maintenance, safety controls, various consultations.
This form of maintenance guarantees a better management, prevention of damages and a more efficient, total respect of safety.
Needless to say that without this kind of service it would be impossible to manage correctly all the technological features of a hospital from the inside.



As shown by the slides, approximately 6000 service calls are performed during the course of one year, of which 3000 effected by in-house Hospital staff; this means a considerable reduction in idle-machine-time and, financially speaking, a saving of money since supplier technicians charge ten times as much for servicing.
Another important point regarding equipment, dealt here in two essential words, is safety: to safeguard it, all equipment must be tested: when purchased and it must be periodically controlled in time.

EQUIPMENT SAFETY	
Testing for approval	Periodical control

When purchasing any equipment, it is important to verify that existing safety standards have been respected by performing safety checks immediately on delivery and, of course, routine machine controls must be conducted in time, especially to the most distinguishing and fundamental parameters.

1.3 Safety

The Technical Service of USL 31 of Ferrara has been working constantly in the last ten years on safety measures and it has been trying to enhance its experience in this field, pointing out the possible risks and planning the best solutions.

STANDARDS
IEC 601-1 C.E.I. 62-5 Particulars (62-..)

The basis is represented by the IEC 601-1 Standard published in Italy as CEI 62-5. An accurate study of these norms with the relative particulars has led to the development of the techniques for acceptance testing and periodic safety controls.
In matter of safety, we must take into account all those elements that even superficially come into contact with the patients and with the operators.
We have noticed that safety measures are often barely taken into consideration in hospitals and they are undervalued since, in most cases, people still reason according to an outdated mentality instead of keeping up with the evolution of technological progress, which advances day by day, and which helps us to march along to the forefront and maintain a vanguard position.

SAFETY IN EQUIPMENT

Hospitals	Equipment controlled
1	400
2	500
3	300
4	250
5	300
6	100
7	3500
8	1500

At present there are many existing situations in which nobody has questioned the safety of the electromedical equipment.
For this reason, we'd like to illustrate a detailed analysis concerning the safety of about 7000 parts of electric equipment (in particular: equipment from operating rooms, reanimation rooms, intensive therapy, ambulatories, etc.) functioning in eight hospital units in the region Emilia Romagna.
The equipment has been tested according to CEI norms and we have noticed, from the statistics that have been calculated, that the percentage of equipment that doesn't follow the prescribed norms is more or less the same in the small as well as in the large hospital unit (hospitals with 250 beds and hospitals with 1400 beds).

SAFETY CONTROLS	
- Equipment conforming to prescribed standards	4751
- Equipment not in the norm but modifiable within the accepted norms	1981
- Dangerous equipment, immediately declared out of order	114

First Unit
Equipment conforming to: 258 (64,5%)
Equipment not complying but liable to modification 130 (32,5 %)
Equipment out of order (not modifiable, dangerous) 12 (3 %)

Second Unit
Equipment conforming to: 328 (65,6 %)
Equipment not complying but liable to modification 162 (32,4 %)
Equipment out of order (not modifiable, dangerous) 10 (2 %)

Third Unit
Equipment conforming to: 203 (67,7 %)
Equipment not complying but liable to modification 91 (30,3 %)
Equipment out of order (not modifiable, dangerous) 6 (2 %)

Fourth Unit
Equipment conforming to: 169 (67,6 %)
Equipment not complying but liable to modification 77 (30,8 %)
Equipment out of order (not modifiable, dangerous) 4 (1,6 %)

Fifth Unit
Equipment conforming to: 210 (70 %)
Equipment not complying but liable to modification 87 (29 %)
Equipment out of order (not modifiable, dangerous) 3 (1 %)

Sixth Unit
Equipment conforming to: 65 (65 %)
Equipment not complying but liable to modification 34 (34 %)
Equipment out of order (not modifiable, dangerous) 1 (1 %)

Seventh Unit
Equipment conforming to: 2499 (59,4 %)
Equipment not complying but liable to modification 950 (27,1 %)
Equipment out of order (not modifiable, dangerous) 47 (13 %)

Eighth Unit
Equipment conforming to: 1019 (67,9 %)
Equipment not complying but liable to modification 450 (30 %)
Equipment out of order (not modifiable, dangerous) 31 (2,1 %)

Types of irregularities

Another analysis followed to evidence the type of irregularity detected in the various equipment such as:

A= lack of earthing

B= problem on the plug, supply cable, fairlead (plug not up to standards and dangerous, supply cablepeeled, dangerous, uncovered wires, chock missing with the consequence of slits in the rubber of the cable).

C= fuse or fuses missing

D= mechanical imperfections in the structure (danger of falling upside down, parts coming off, unprotected moving parts, ecc.).

E= switch missing or monopolar switch instead of required bipolar one (two phasesare used).

F= high resistance of the feeding cable (over 0,1 or 0,2)

G= problems of various nature (pedals not in the norm, high frequency currents, exceedingly low defibrillation energy, compulsory alarms missing or out of order, inefficient batteries, etc).

H= high leakage

Quite a few of the examined parts showed one or more of the afore mentioned inconveniences.

	A	B	C	D	E	F	G	H
First Hospital	16	40	71	2	32	15	14	4
Second Hospital	20	51	89	3	40	19	18	6
Third Hospital	11	28	50	2	23	10	11	4
Fourth Hospital	10	24	43	1	19	9	8	3
Fifth Hospital	13	20	40	3	28	15	8	2
Sixth Hospital	4	12	20	0	9	5	4	2
Seventh Hospital	122	320	500	10	230	120	100	30
Eighth Hospital	60	135	280	15	122	61	45	15

The statistics, deriving from an analysis of the technology present in eight hospital units, show immediately that the situation of the equipment presently in use is not acceptable for its low levels of safety measures and therefore in these cases a thorough control that will evaluate the "safety levels" is rendered absolutely necessary.

We must underline the fact that we have found 2095 equipment parts defective, of which 1981 were brought to acceptable safety standards, whereas 114 were considered out of order because they were not modifiable.
To the above figures we can add another significant number: 3% of the newly acquired equipment does not qualify according to legal norms.
This percentage is, however decreasing, and more recent percentages show a keener concern with the problem of safety by the producers and manufacturers.

EVALUATION
Efficiency
Safety
Costs
Maintenance

1.4 Conclusion

The organization must rely on a system of information that will allow the analysis and evaluation of its efficiency.
It must be provided with the instructions for its use, the safety measures necessary to manage the need to buy new technology and to substitute its parts.
This means that the buyer must be able to reason about economic matters, such as: up-dating the price of each single piece of equipment, the redemption plan to amortize the equipment, the prices and values of reeding the leases goods or those that have been bought on hire
Other important managerial elements are: programming the maintenance calendar, keeping track of guarantee deadlines, safety standards etc.
In order to obtain useful economic data for our purchases we can rely on a "price observatory" with standard maintenance contracts.
For more costly equipment we can consider its full potential and use, the costs of its management and the impact it can have on the organization as a whole and on its prospective operators.

BIOMEDICAL TECHNOLOGY COORDINATION AND CONTROL

External Service (with Suppliers)	HOSPITAL REQUEST	Inside Service

Therefore, it seems clear that the main concept to develop for a safe management is the need to employ highly qualified personnel, professionally prepared for its job

In this case we must favour a "pool" of professionally able workers who will be able to manage such an important organization.
This "pool" must function like a hinge or, like in other nations, the so.called technical interpreter highly specialized in its field that knows how to make technology function at its best.

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Dr. Ing. Zavarini Paolo Responsabile del Settore di Ingegneria Clinica dell'Ospedale di Ferrara Italy; da oltre venti anni sta lavorando nell'Ospedale sulla gestione delle apparecchiature elettromedicali.
Mi occupo della manutenzione, della sicurezza delle apparecchiature e degli stessi ambienti e mi occupo della gestione delle tecnologie biomediche in una Commissione della Regione Emilia Romagna.

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His principle concerns focus on maintenance and safety to equipment and hospital wards, dedicating much of his time to the study of biomedical technologies being a member of the clinical commission of the Emilia Romagna Region.