

Environmental quality of the operating theaters in Campania Region: long lasting monitoring results

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Parole chiave: Sale operatorie, monitoraggio ambientale, Regione Campania, Italia

Abstract

Background: The health risk level in the operating theaters is directly correlated to the safety level offered by the healthcare facilities. This is the reason why the national Authorities released several regulations in order to monitor better environmental conditions of the operating theaters, to prevent occupational injuries and disease and to optimize working conditions. For the monitoring of environmental quality of the operating theaters following parameters are considered: quantity of supplied gases, anesthetics concentration, operating theatres volume measurement, air change rate, air conditioning system and air filtration. The objective is to minimize the risks in the operating theaters and to provide the optimal environmental working conditions. This paper reports the environmental conditions of operating rooms performed for several years in the public hospitals of the Campania Region.

Methods: Investigation of environmental conditions of 162 operating theaters in Campania Region from January 2012 till July 2014 was conducted. Monitoring and analysis of physical and chemical parameters was done. The analysis of the results has been made considering specific standards suggested by national and international regulations.

Results: The study showed that 75% of the operating theaters presented normal values for microclimatic monitoring, while the 25% of the operating theaters had at least one parameter outside the limits. The monitoring of the anesthetics gases showed that in 9% of measurements of nitrous oxides and 4% of measurements of halogenated was not within the normal values.

Introduction

Italy, as a member of the European Union has to adjust the national laws relating to health and safety. Therefore, from the 90s to today, the continuous alignment with European standards (directives) allowed the updating and the integration of the national legislation. The main change has been to the transposition of Directive 89/269/EEC (the so-called Framework Directive)

through Title I of the Legislative Decree n. 626/1994 (1). However, the “Consolidated Security”, the Legislative Decree n. 81/2008 (2), the repeal of the Legislative Decree n. 626/1994 (1, 3), imposed a path, forced and gradual, characterized by interventions “of prevention”, which draw more and origin “from the arrangements and general principles” applicable to “source of risk”, as required, in particular, Art. 15 of Legislative Decree n. 81/2008 (2): prevention should be

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understood as a continuous process in which standardize the whole business reality (2).

The attention of the legislature and jurisprudence increasingly rigorous focuses especially in the health sector, with full involvement in business decisions, organizational and management and with the absolute empowerment of all roles and functions, starting from the top of the corporate structure that through a synergistic effort must ensure the prevention of accidents and occupational diseases.

The operating room (OR), given the specific nature of the activities, has always been considered a “risk environment” for both patients (surgery is a critical event in the clinical history of an individual), as for health care professionals who work there and therefore are exposed to multiple factors potentially dangerous. In operating rooms (ORs), the extent of the risks is closely correlated with the degree of security provided by the facilities, installations, the equipment, protective devices and last but not least, information and training operators.

In 2009, the Institute for Prevention and Occupational Safety (ISPESL) has updated a pre-existing document Guidelines of 2002 (5, 6) for the definition of safety standards and environmental health departments operators: through an innovative definition of structural, technological and instrumental in the operating department, environmental hygiene requirements, and a new provision in the chapter devoted to audits of the environmental characteristics and plant for monitoring the effectiveness of preventive measures, the Guidelines represent an operational tool for the regions to pursue optimum levels of safety and protecting the health of the operators and users and to implement the obligations required by current legislation (5, 6).

Guidelines ISPESL 2009 (5) summarize the regulatory framework regarding the safety of operating rooms and include the recommendations of ISO 7730 in 2006 on

the determination of the PMV and PPD in moderate thermal environments (7), Legislative Decree. n. 81/2008, on aspects of health and safety at work (2), the Decree of the Ministry of the September 18, 2002 on fire safety in the workplace (8), the DPR n. 37/1997 on structural, technological and organizational requirements for the exercise of health activities by public and private structures (9), the DGR n. 7301/2001 (10) and the Circular of the Ministry of Health no. 5/1989 related to occupational exposure to anesthetic gases and vapors (11).

Concerning in particular the chemical risk in OR, the Guidelines ISPESL 2009 (5) reserve a unique attention to the exposure related to the use of anesthetic agents: in the current legal framework, the Circular of the Ministry of Health n. 5 of 14 March 1989 “Occupational exposure to anesthetic in the operating room” (11) is the only reference that addresses the regulatory aspects of hygiene associated with general anaesthesia, providing specific occupational exposure limit values (Threshold Limit Value, TLV) and analytical methods to determine the levels of environmental contamination by anesthetic gases in OR.

In addition, the Guidelines ISPESL 2009 (5) aim to ensure an adequate level of organizational management through the availability of technological and structural supports, which were designed to: 1) ensure and verify the significant parameters for correct operation of the OR from the hygienic/systemic/structural point of view; 2) adopt, where necessary procedures and/or alternative proven effective; 3) implement all preventive and corrective actions to achieve adequate quality standards and appropriate (5). Therefore, the verification activities of the environmental and systemic characteristics in OR aim to assess and monitor the potential chemical pollution, physical and microbiological ascertaining so the adequacy of the preventive measures put in place (4, 12, 13).

A study of Montuori et al. (2007) shows that repeated environmental controls over time lead to the reduction of the number of ORs with concentrations of anesthetic gases above the limits established by the legislation (14).

The verification activities are performed by controlling the assembly retaining anesthesia by monitoring of ambient air pollution by estimating the risk of exposure to anesthetic agents, by the evaluation of the microclimatic conditions and the degree of thermal comfort of OR and by biological monitoring in the case in which the marks of actual and/or potential exposures (15, 16). In the OR, the particular interest to pollution anesthetic gases and vapors is related to the proven toxic action of these substances, resulting in risk for all staff professionally exposed (anesthesiologists, surgeons and nurses OR) (17-19).

The safe performance of OR can be achieved through the environmental monitoring aimed to determine: quality of medical gases, environmental concentration of the anesthetics, proper number of the number of air exchange per hour, efficiency of the air conditioning system and air filtration.

All the above mentioned tools, both technical and organizational, are necessary in order to eliminate or reduce as much as possible the risk, and the severity of potential damage for the workers and the patients.

Therefore, the present study has set itself the objective: 1) to evaluate the time course for the period January 2012 - July 2014, the parameter indicators of environmental quality of OR in different public hospitals in the Campania Region for which the Department of Public Health of the University of Naples "Federico II" for several years performing environmental monitoring activities, ordinary and extraordinary; 2) to evaluate the effectiveness of environmental monitoring activities through the comparison with the results of previous studies conducted

by the Department of Public Health on ORs of the same territory (12-14).

To the best of our knowledge, the studies conducted on the subject are few, therefore our results further emphasize the importance of environmental controls in achieving high quality standards (5).

Materials and methods

The study was based on the collection of data describing the structural, functional and organizational characteristics of each health-care facility and measured on-site data of physical and chemical monitoring parameters indicative of the environmental quality of OR. The regional health organization in Campania is divided in 7 Local Health Authorities (AASSLL), from which 3 in the province of Naples, 1 in Salerno, 1 in Caserta, 1 in Avellino and 1 in Benevento; 6 hospitals (AAOO), 3 university hospitals (AAOOUU), 2 Institutes of Hospital Care (IRCCS), for a total of 294 OR. The survey involved 162 environmental OR (55% of total public OR) of 43 hospitals (PPOO) afferent to 6 AASSLL, IRCCS 1, 4 AAOO and 1 AOU and predicted a quarterly or half-yearly basis. Regarding the physical risk in OR, environmental surveys were directed to the verification of the microclimatic conditions and the degree of thermal comfort of OR. As required by DPR n. 37/1997 (9), from DGR n. 7301/2001 (10) and the Guidelines ISPESL 2009 (5), the O.R. must be equipped with environmental conditioning that ensures the following microclimatic characteristics: air temperature $20 \div 24$ °C; relative humidity 40 to 60%; air velocity 0.05 to 0.15 m/s; $-0.5 \leq \text{PMV} \leq +0.5$ (PMV: predicted mean vote); $\leq 10\%$ PPD (PPD: probable percentage of dissatisfied); air exchange/hour (outside air without recirculation) 15 v/h, in order to dilute and contain pollutants potentially present and/or produced in OR (5, 9, 10). The measurement of microclimatic

parameters was performed with the aid of a microclimatic station model "BABUC A" by LSI Lastem Company, accompanied by specific probes whose accuracy is ± 0.15 °C for the air temperature, $\pm 2\%$ for relative humidity, ± 5 cm ($0 \div 0.5$ m/s), ± 10 cm ($0.5 \div 1.5$ m/s), 4% (> 1.5 m/s) to air velocity. The microclimatic station was positioned in the vicinity of the surgical field in order to verify the thermal homogeneity of the environment and to evaluate the conditions of exposure of the operating team.

The indices of microclimatic thermal comfort, PMV and PPD, were processed using the program "MICROCLIMA" by LSI Lastem Company. In particular, for the evaluation of comfort, a metabolic equivalent of task (MET) and a moderate thermal impedance of the standard type clothing (CLO) have been considered. The measurement of the number of air exchanges was performed using, as needed, the speed probe vane and/or the hot wire anemometer probe, connected to the same microclimatic station "BABUC A". The accuracy of the speed probe vane is 5% with a threshold value of 0.2 m/sec while the accuracy of the hot-wire anemometer probe is ± 5 cm ($0 \div 0.5$ m/s), ± 10 cm ($0.5 \div 1.5$ m/s), 4% (> 1.5 m/s) with a threshold value of 0.1 m/sec. For the purpose of calculating the number of air exchanges/hour were considered both the volume of the air generated by the system and the dimension of the examined OR. As for the chemical monitoring, environmental surveys were directed to the determination of the environmental concentration of gaseous anesthetics, nitrous oxide (N_2O) and volatile (sevoflurane). Within the current legislation, the Circular of the Ministry of Health n. 5/1989 (11) adopts TLV provided by the American Conference of Governmental Industrial Hygienists (ACGIH) for nitrous oxide, such as time-weighted average (time-weighted average, TWA) of 50 ppm (TLV-TWA) for OR constructed and/or refurbished after 1989 and 100 ppm (TLV-TWA) for OR

constructed and/or refurbished before 1989. Relatively to halogenated, the Circular of the Ministry of Health n. 5/1989 (11) takes the limit of 2 ppm (TLV-Ceiling) recommended by the National Institute for Occupational Safety and Health (NIOSH) (20, 21). For the assessment levels of environmental contamination by anesthetic gases in the OR a multiple gas analyzer of "Brüel & Kjaer" model 1302 was used. The principle of measurement is the infrared photoacoustic, connected to a multipoint sampler of "Brüel & Kjaer" model 1303, ancillary instrumentation that achieves in real time the environmental concentration of anesthetics monitored in most areas of the OR; the above instrumentation has a detection limit of 0.03 ppm for N_2O (the repeatability of the measured value is 1%), 0.01 ppm for sevoflurane (repeatability of the measured value is 1%). The environmental surveys of anesthetic gases in monitored OR were made mainly in the vicinity of the anesthesia trolley, more specifically, the position occupied by the team of customary operating during the intervention and at the height of the airways of the staff more exposed. Environmental sampling of anesthetic gases, with an acquisition of programmed data in intervals of 2 minutes, was performed before actual use of anesthetic apparatus to search for any losses in the anesthesia circuit in the high and low pressure, and during use of same and the duration of the operating session in order to evaluate the entity of the environmental concentration of anesthetic gases.

Results and considerations

The data relating to both the public hospitals in the Campania region that the number of OR monitored are described in detail in Table 1. The number, type, and the results of the environmental controls carried out in the period between January 2012

Table 1 – Public hospitals and operating rooms of the Campania Region monitored in 2012-2014.

	Public hospitals		Operating rooms	
	Total N.	Monitored N. (%)	Total N.	Monitored N. (%)
Campania	61	43 (70)	294	162 (55)
Napoli	31	30 (97)	149	109 (73)
Avellino	5	4 (80)	33	10 (30)
Benevento	3	1 (33)	25	14 (56)
Caserta	8	8 (100)	31	29 (93)
Salerno	14	0 (0)	56	0 (0)

and July 2014 at the ORs in the Campania Region are listed in Table 2. Table 2 shows that, in the period between January 2012 and July 2014, at 162 operating rooms of public health facilities in the Campania Region, were made 981 monitoring microclimate, 911 measures of air exchanges/hour, 1,281 checks on the dispersion of anesthetic gases.

With regard to the results of microclimatic monitoring and verification of the number of air exchanges, Table 2 shows that of 981 values of air temperature (AT) determined in the period January 2012 - July 2014 was found, by comparison with the limits conventionally taken as reference (5, 7, 8), a percentage of unfitness 6% (N= 55): the average value found in OR unfit for exceeding

Table 2 - Number, type and result of environmental controls in the period 2012-2014 in the operational theaters of the Campania Region.

Type of control	Total controls N.	Out of limits N. (%)	Range Out of limits	Average \pm SD Out of limits
microclimatic monitoring	981	249 (25)*		
Air temperature ($^{\circ}$ C)	981	55 (6)	24.4 - 30.3 (a) 19.1 - 19.5 (b)	25.7 \pm 3.2 (a) 19.3 \pm 0.2 (b)
Relative humidity (%)	981	146 (15)	60.3 - 75.3 (a) 22.4 - 38.8 (b)	65.2 \pm 10.6 (a) 32.3 \pm 9.2 (b)
Air velocity (m/s)	981	48 (5)	– 0 - 0.04 (b)	– 0.03 \pm 0.02 (b)
PMV	981	51 (5)	+ 0.54 - 1.79 (a) - 0.59 - 0.69 (b)	+0.89 \pm 0.33 - 0.63 \pm 0.03
PPD	981	56 (6)	10.9 - 45.6	20.1 \pm 4.5
Air changes/hour	911	136 (15)**	1.5 - 14.6	9.8 \pm 3.7
Anesthetic gases	1282	75 (6)***	–	–
Nitrous oxide (ppm)	396	35 (9)	53.6 - 296.6	118.8 \pm 38.7
halogenated (ppm)	886	40 (4)	2.16 - 20.0	7.60 \pm 1.9

* Limits adopted: Air temperature (20-24 $^{\circ}$ C); Relative humidity (40-60%); Air velocity (0.05-0.15 m/s); PMV (\pm 0.5); PPD (\leq 10%)

(a) unfit for exceeding the upper limit

(b) unfit for exceeding the lower limit

** Limits adopted: \geq 15 Air changes/hour

*** Limits adopted: TLV-TWA of 50 ppm for Nitrous oxide and TLV ceiling of 2 ppm for halogenated

the upper limit of temperature (AT: 24 °C) is 25.7±3.2 °C (range: 24.4÷30.3), the average value found in ORs unfit for exceeding the lower limit of temperature (AT: 20 °C) is 19.3±0.2 °C (range: 19.1÷19.5).

With regard to the values of relative humidity (RH), from Table 2 it is clear that on 981 determinations there was a percentage of unfitness equal to 15% (N= 146): the average value found in ORs unfit for exceeding the upper limit of relative humidity (RH: 60%) is 65.2±10.6 % (range: 60.3÷75.3), the average value found in ORs unfit for exceeding the lower limit of relative humidity (RH: 40%) was 32.3 ± 9.2% (range: 22.4 ÷ 38.8). As regards the air velocity (AV) a percentage of unfitness equal to 5% (N = 48) has been detected: the average value found in ORs unfit for exceeding the lower limit of air velocity (AV: 0.05 m/s) is 0.03 ± 0.02 m/s (range: 0÷0.04).

With regard to thermal comfort indices PMV and PPD, from Table 2 is visible a non-conformity of respectively 5% (N = 51) for the PMV and 6% (N = 56) for the PPD: the average value found in OR unfit for exceeding the upper limit of PMV (+ 0.5) is +0.89 ±0.33 (range: +0.54 ÷ +1.79), the average value found in ORs unfit for exceeding the lower limit of PMV

(- 0.5) is -0.63 ± 0.03 (range: -0.59 ÷ 0.69); the average value found in OR unfit for exceeding the limit of PPD (10%) was 20.1 ± 4.5 (range: 10.9 ÷ 45.6).

Finally, with regard to air exchanges, a total of 911 measurements were performed, with only 15% (N = 136) not complying with the reference (6): in OR unfit, the number of spare parts AIR-average returned was 9.8 ± 3.7 (range: 1.5 ÷ 14.6).

The trend in the percentage of non-conformities in the detection of the main microclimatic parameters (temperature of dry air, relative humidity, air velocity, PMV, PPD, and the number of air exchanges), can be highlighted by Figure 1. It would seem to prove a slight improvement trend, probably due to the technical interventions carried out over the years and aimed at bringing the standards required by law.

Regarding the evaluation of environmental pollution by anesthetic gases, from Table 2, can be seen that in total 1282 determinations of gas anesthetics were performed, of which 396 for N₂O and 886 for sevoflurane. Analysis of the data shows that, for the detections of N₂O there was a non-conformity of 9% (N = 35), in reference to the TLV-TWA 50 ppm taken as the limit for ORs constructed and/or refurbished after 1989 (11) and the

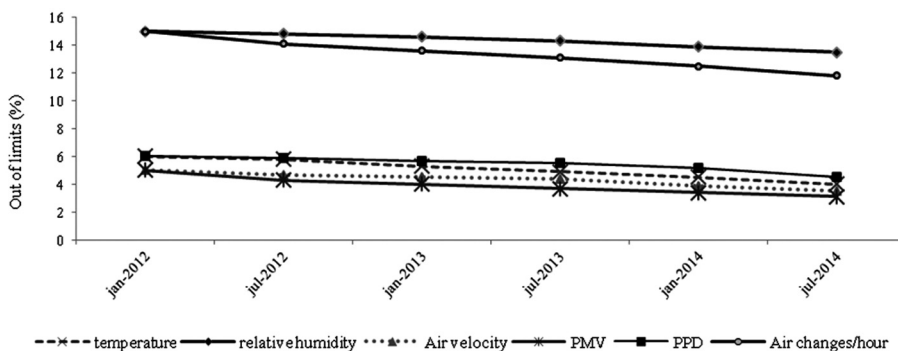


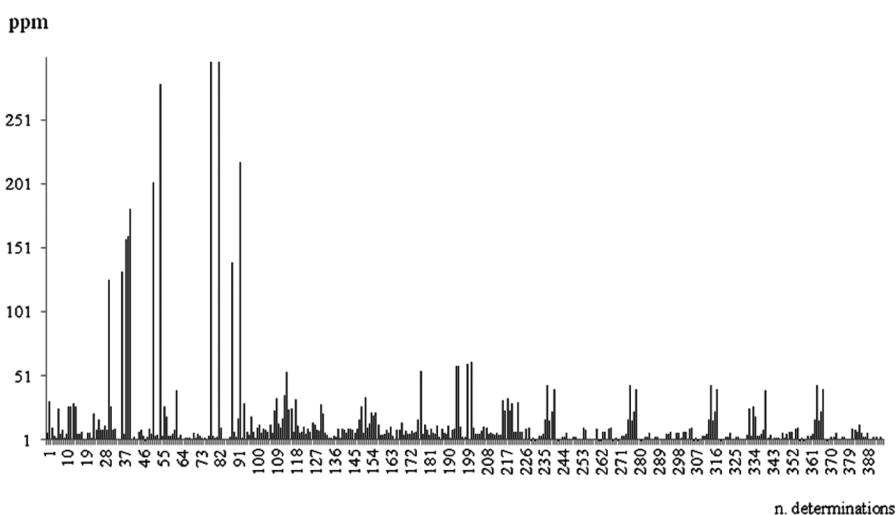
Figure 1 – Trend in the percentage of not conforming in the detection of the main microclimatic parameters indices of thermal comfort and Air changes/hour distributed annually.

concentration is found to average 118.8 ± 38.7 ppm (range: $53.6 \div 296,6$); for the detections of sevoflurane was observed a non-conformity of 4% (N = 40), in reference to the TLV-Ceiling 2 ppm taken as the limit for OR (11) and the average concentration was 7.60 ± 1.9 ppm (range: $2.16 \div 20.0$) (19, 20).

Figures 2a and 2b show the distribution of average values of nitrous oxide and

sevoflurane encountered during the detections during the study period; for both anesthetic gases, it is confirmed the progressive reduction of pollution levels, and it was noted that, in the smaller percentage, the concentrations remain unsuitable due to the dispersion in the delivery system and/or evacuation of gases. Figure 3 shows the trend of the percentage of OR with values

a) Nitrous oxide



b) Sevoflurane

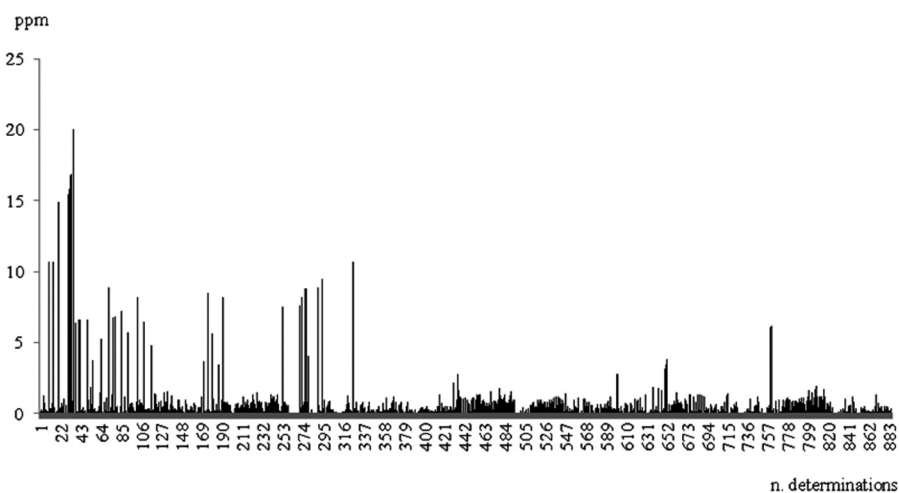


Figure 2 - Distribution of average values of nitrous oxide (a) and sevoflurane (b) encountered during the detections related to the period examined.

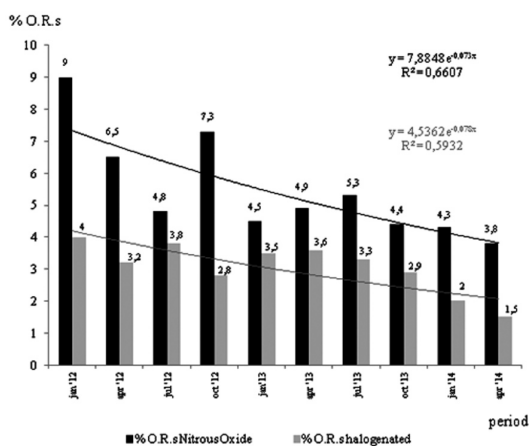


Figure 3 - Trend of the percentage of ORs with values of N₂O concentration higher than 50 ppm and concentration values of halogenated higher than 2 ppm.

of N₂O concentration greater than 50 ppm and concentration values of halogenated than 2 ppm during the period January 2012 - July 2014, every three months. As can be seen from Figure 3, during the time the value of the percentage OR that do not respect the TLV for both gases decreases, from 9% to 3.8% for N₂O and from 4% to 1.5% for halogenated, with a considerable reduction in the percentage of OR with values out of bounds. The regression curve that best approximates the data is found to be an exponential curve with equation: $y = 7.9 * e^{-0.073x}$ (correlation coefficient equal to -0.807) for nitrous oxide, and $y = 4.5 * e^{-0.078x}$ (correlation coefficient equal to -0.819) for the halogenated, valid obviously in the study period. The level of statistical significance for correlation coefficient ($p < 0.05$) is obtained by analyzing these parameters, taking into consideration the variability for the number of intervals.

Conclusion

Analyzing the data, you may find that the environmental concentration of anesthetic

gases found in different OR are maintained at low levels and and monitored microclimatic parameters are mainly appropriate.

The comparison of the results of the current study, with those of the study on the environmental quality of ORs in the Campania Region (2007), showed a reduction in the number of controls that exceed the limits of the environmental concentration of anesthetic gases of about 60% and a reduction in the number of unsuitable controls regarding the microclimatic monitoring (12) of about 50%.

This evidence is further confirmed by the results obtained in a study of the assessment of the effects of the environmental monitoring of the concentration of anesthetic gases in ORs (2008) which shows a reduction in the number of ORs with environmental values of anesthetic gases that exceed the standards, from 40% to 15% after a sequence of periodic controls (14).

Therefore, with the evidence of the results, it can be argued that the environmental monitoring activities, although carried out at intervals of months apart, have certainly allowed the detection and early warning of risk situations allowing interventions in real time or, however, in a short time, in order to: a) correct any faults or lack of maintenance; b) direct the mode of choice and of use of substances to use anesthetic; c) arrangements for the proper space cooling; d) highlight risk behaviors. Through the execution of the above environmental monitoring activities you want, therefore, to find a mode of action useful to target interventions for periodic testing, suggest specific methodologies maintenance of facilities and equipment, and finally being able to sensitize health workers: indeed, in relation to structural, technological and instrumental risks, and environmental hygiene risk, some are expressly forbidden by the DPR 14/1/97 (9) as minimum requirements to be taken into consideration in the operating department. However, to date the Guidelines ISPEL 2009 (5) represent

for many the only way to fight the sources of risk related to departments operators. Different and many are, in fact, chemical and physical hazards, related to environmental and operating activities and the procedures for disinfection and sterilization, which should be carefully analyzed; however, epidemiological knowledge useful for testing, evaluation and the management of risk sources and their prevention in departments operators are still scarce. Routine control mechanisms performed, to verify the correct implementation of environmental procedures are important, as well as the collaboration between different professionals to identify the correct actions to be implemented in different situations. Taking into consideration all of the above mentioned, the , good management system which allows to control the environment should be based on well defined protocols and procedures particularly in critical areas of the main activities of assistance, on the implementation of a system for environmental monitoring and on the periodic reporting.

Riassunto

La qualità ambientale delle sale operatorie in Regione Campania: risultati di un monitoraggio pluriennale

Background: La partecipazione dell'Italia all'Unione Europea ha obbligatoriamente previsto l'adeguamento del quadro normativo nazionale, finanche in materia di salute e sicurezza sul lavoro, riservando una particolare attenzione al settore sanitario. Le strutture ospedaliere e, nello specifico, i complessi operatori, vista la peculiarità delle attività svolte, sono da sempre considerati "ambienti a rischio" sia per i pazienti che per gli operatori sanitari.

Nelle sale operatorie, l'entità dei rischi è strettamente correlata con il grado di sicurezza fornita dalle strutture, dagli impianti, dalle apparecchiature, dai dispositivi di protezione ed infine, ma non ultima, dall'informazione e dalla formazione degli operatori. L'espletamento in sicurezza della prestazione della sala operatoria può essere conseguita attraverso monitoraggi ambientali indirizzati a determinare: qualità dei gas medicinali, concentrazione

ambientale degli anestetici gassosi e volatili, idoneità del numero dei ricambi d'aria orari, efficienza del sistema di climatizzazione e di filtrazione dell'aria. La finalità è quello di agire con tutti gli strumenti disponibili, sia tecnici sia organizzativi, sulla fonte del rischio eliminando o riducendo, quanto più possibile, la probabilità e la gravità dei potenziali danni.

Il presente studio si è posto come scopo quello di valutare l'andamento temporale dei parametri indicatori della qualità ambientale delle sale operatorie in diverse strutture ospedaliere pubbliche della Regione Campania.

Metodi: I rilevamenti ambientali, come previsto dalle normative vigenti, sono stati eseguiti presso n. 162 sale operatorie di n. 43 strutture ospedaliere della Regione Campania relativamente al periodo Gennaio 2012 - Luglio 2014.

Risultati e considerazioni: Dall'analisi dei dati, si evince che il 75% dei rilievi microclimatici rientra nei limiti di riferimento con una percentuale di non conformità pari al 25%. Relativamente all'inquinamento ambientale da gas anestetici, è stata riscontrata una percentuale di non conformità pari al 9% per il protossido d'azoto ed al 4% per l'alogenato.

Conclusioni: I monitoraggi ambientali effettuati hanno senz'altro permesso di rilevare e/o segnalare tempestivamente situazioni a rischio consentendo interventi in tempo reale, o entro tempi brevi, al fine di riparare eventuali guasti od evidenziare carenze di manutenzione, migliorare le modalità d'utilizzo delle sostanze ad uso anestetico, predisporre un più idoneo condizionamento degli ambienti ed evidenziare potenziali comportamenti a rischio.

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