

Risk assessment, and carcinogen mutagen for workers potentially exposed in the research laboratories of "Sapienza" University of Rome for Health Surveillance

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Article history

Received: January 21, 2017 Accepted: February 28, 2017 Published: March 13, 2017

Abstract

The following work is meant to represent the evaluation of risk factors for the health of exposed workers, arising from the management of carcinogenic and mutagenic substances, through the use of algorithms. In some places of work as a research laboratory, it is more suitable a theoretical and practical methodology (algorithm) which allows a "timely" exposure assessment. The methodology developed and used is able to determine the level of risk of exposure due to a single agent and / or to more agents. Results obtained by the algorithm, have shown an higher exposure to 1 for formaldehyde ($L_{canc} = 1.32$), while for acrylamide results obtained shows a lower exposure to 1 ($L_{canc} = 0.528$). Although the overall exposure level of studied workers higher value to 1 ($L_{canc} = 1.848$), the Occupational Medicine Centre of "Sapienza" - University of Rome, in agreement with the position taken by the Italian Society of Occupational Medicine and Industrial Hygiene applies health surveillance even in the presence of potential health risk reducing it among the general protection measures the health and safety of workers.

Keywords: carcinogenic and mutagenic risk, levels of exposure of workers, health surveillance of workers of research laboratories.

Introduction

The University laboratories are complex working reality, heterogeneous and dynamic, where assessing professional risk exposure is often difficult, particularly to chemicals and carcinogens. Italian Guidelines on Risk Assessment for chemical and carcinogens suggest that more than with feedback arising from environmental measurements, it is more suitable already a theoretical and practical methodology (algorithm) which allows to

obtain, in a simplified manner, an accurate exposure assessment [1].

Chemical risk assessment in research laboratories is complicated by factors such as the large number of agents to be considered, each present in small quantities, and the very short and erratic periods of exposure, all of which make reliable environmental and biological monitoring particularly difficult and at times impossible. In such environments, a preliminary evaluation procedure based on algorithms would be useful to establish the hazard

potential of a given situation and to guide the appropriate intervention [2].

This algorithm, already tested in the laboratories of the agency system ISPRA [1] (Institute for Environmental Protection and Research), ARPA (Regional Agency for Environmental Protection) and APPA (Provincial Agency for Environmental Prevention), was used for the similarity of all working environments heterogeneous and dynamic university, and not repetitive and constant such as those of the industrial sector.

The peculiarity of the activity in research laboratories, places the actors of the safety sector in the workplace (RSPP, Occupational physician, etc.), in front of reality different and very complex to evaluate the risk of exposure especially for:

- The quantities used;
- The frequency of use;
- The duration of exposure;
- The state and the temperature of the substances / mixtures.

The use of a carcinogen and mutagen is not, in itself, an effective health risk, since the risk of exposure, also depends on the substance of the management mode used during the working activity. In these particular research environments, it is therefore the most suitable choice of a theoretical and practical methodology (algorithm application) which allows to get a correct exposure assessment in a simplified manner for the protection of the operators of this sector.

The aim of this study was to assess the exposure to carcinogenic and mutagenic risk in the two substances (acrylamide and formaldehyde) from those used in a research laboratory "sample" "Sapienza" University of Rome, with the use of 'algorithm adopted by lines ISPRA Guide - Institute for Environmental Protection and Research.

Materials and Methods

In the lab "sample", the SDL (target board working) was administred to a homogeneous group of workers (trainees, laboratory technicians, graduate students) employed in a research laboratory, duly completed and countersigned by the Manager.

SDL were extracted from the frequency data and duration of exposure and the quantity handled, were also collected data on the use of personal protective devices and equipment commonly used. During the inspections have been verified the methods of use and handling and verified the labeling of containers of substances object of study and the presence of safety data sheets in the laboratory.

Labeling and the safety data sheets of the evaluated substances were obtained symbology, the Hazard statements (H), the Safety Phrases (P) and physical characteristics. Moreover, for each carcinogen and mutagen, it was, applied the algorithm for each handled substance of individual workers applying the "Guidelines for the assessment of risk from exposure to Hazardous Chemical Agents and Carcinogens and mutagens agents" [1] and the model published in the following guidelines "Assessment of exposure to carcinogens / mutagens in research laboratories: integrated system of checklists, surveys and use of algorithms" [3].

The valuation methodology applied in these laboratories, considering the particularity of such working environments characterized by the use generally. Occasionally, in small amounts and for short time, a small number of carcinogens / mutagens compounds and prepared, for the detection of the level of worker exposure is that proposed by the Guidelines for the assessment of risk from exposure to hazardous chemical agents and agents Carcinogens and mutagens - 2011 [1], tested in the laboratories of the agency system ISPRA (Institute for Environmental Protection and Research), ARPA (Agency regional Environmental protection) and APPA (Provincial Agency for Environmental Prevention).

In the case of these laboratories, is to be considered, the particularity of such working environments characterized by the use generally occasionally, in small amounts and for short time, a small number of carcinogens / mutagens compounds and preparations [2].

To determine the risks of exposure to carcinogens and mutagens, they have been taken into account all the elements that characterize the exposure according to the following algorithm (Guidelines for the assessment of risk from exposure to chemical agents Hazardous and carcinogens and mutagens) [1].

L_{canc} is the level of exposure of individual workers to carcinogens and mutagens.

$L_{canc} = \sum_{i=1}^{n} (P_i * S_i * T_i * Q_i * E_i * F_i)/6.25$

From: Guidelines for the assessment of risk from exposure to chemical agents Hazardous and carcinogens and mutagens [1].

To the risk factors listed are assigned scalar values proportional to the degree of hazard. The product of the various indicators potential quantifies the i-th exposure substance. The values of the variables that make up the algorithm used are explained below.

Pi is the use factor and efficiency of collective protective devices during agent use carcinogenic / mutagenic.

Table 1 - Collettive protection factor - P

Risk categories	Hazard values
Close cycle	1
Functional hood	2
Potentially under the hood	5
No hood	10

Table 1. Collettive protection factor - P

Si is the factor physical state as it meets the physicochemical state of substance.

Table 2 – Physico-chemical state - S

Risk categories	Hazard values
Gel, compact solid	2
Non-volatile liquid crystals	5
Gas, steam, volatile liquid, fine powder	10

Table 2. Physico-chemical state - S

Ti is temperature factor is the process of Te corresponds to the temperature of the work process of Substance. For formaldehyde we used the value of 2. The FA boiling point is 98 ° C, is used at room temperature and in any case, in the presence of air conditioning system, at temperatures below 32 ° C. The same goes for Acrylamide.

Table 3. – Process temperature- T	
Risk categories	Hazard values
Tu<=0.3 Teb or solid	2
0.3 Teb < Tu < = 0.7 Teb	5
0.7 Teb < Tu	10

Table 3. Process temperature- T

Qi: this is the amount used Q factor value corresponding to the amount of the ith carcinogenic / mutagenic agent used in single manipulation.

Table 4. – Amount used - Q	
Risk categories	Hazard values
Q < 1g or Q < 1ml	2
1g or 1ml < = Q < = 50g or 50 ml	5
Q > 50g or 50 ml	10

Table 4. Amount used - Q

Ei is the value of life factor E corresponding to the handling time of carcinogenic / mutagenic in minutes / day

Table 5 – Handling time - T	
Risk categories	Hazard values
Daily fraction	Minutes/480

Table 5. Handling time - T

Fi is the frequency factor of use F corresponds to substance manipulation frequency in days / year.

Table 6 – Use frequency - F		
Risk categories Hazard values		
Use frequency	Days/200	

Table 6. Use frequency - F

The final result of the algorithm used to highlight the level of exposure for each individual substance to which they are exposed, no exposed or potentially exposed. Infact, if the exposure level Lcanc of an employee is less than 1, he is no exposed or potentially exposed while the exposure level Lcanc is more than 1 can be classified that operator exposed.

Table 7– Exposure level for Lcanc substance per employee	
Exposed Lcanc> = 1	
Lcanc < 1	No exposed / Potentially exposed

Table 7. Exposure level for Lcanc substance per employee

The values Lcanc i obtained for each substance are added together to express the total exposure Lcanc i of each employee.

Table 8. – Total exposure level Lcanc per employee	
Lcanc> = 1	Exposed
Lcanc < 1	No exposed / Potentially exposed

Table 8. - Total exposure level Lcanc per employee

Based on the parameters used in this analysis, if the overall exposure level Lcanc (due to all the carcinogenic and mutagenic substances used by the worker himself) is less than 1, the worker will be classified as "unexposed" or as a precautionary measure "potentially exposed "and it can be said that prevention and protection measures in place in art. 237 D.Lgs.81 / 2008 [4] - Technical, organizational, procedural measures, are sufficient to contain the elements of risk, so the situation is under control and therefore we can say that there were no health risks and can therefore be applied as indicated in Legislative Decree no. 81/2008 [4], Articles. 242 - Health Surveillance and 243 - Enrolment in the register of complaints.

If according to the parameters used in this analysis it occurs that the overall exposure level Lcanc (due to all hazardous substances used by the worker himself) is greater than 1 can be classified that operator "exposed" and as a result will be worth the obligations under Articles. 237.242 and 243 of Legislative Decree no. 81/2008 [4] and subsequent amendments.

Results

As shown in the tables, the results obtained by the algorithm, have demonstrated for workers employed at the research laboratory "sample" of "Sapienza" - University of Rome, exposure to formaldehyde L_{canc} 1.32, while for acrylamide it was achieved an exposure level equivalent to L_{canc} of 0.528.

$$\begin{array}{c} L_{canc\;formaldehyde} = \frac{P^*S^*T^*Q^*E^*F}{6,25} = \frac{5^*10^*5^*5^*0,03^*0,22}{6,25} = 1,32 \\ & 6,25 \end{array}$$

$$L_{canc \ acrylamide} = \frac{P*S*T*Q*E*F = 5*10*5*2*0,03*0,22}{6,25} = 0,528$$

Exposure level for Lcanc substance per employee	
Substance: Formaldehyde	
Health risk	
FACTOR	SCORE
Collective protection P	5
Chemical-physical state S	10
Process temperature T	5
Used amount Q	5
Handling time E	0,03
Use frequency F	0,22
Level of exposure to the substance	1,32
Lcanc >1	Exposed

Table 9 - Exposure level for Lcanc formaldehyde per employee.

Exposure level for Lcanc substance per employee	
Substance: Acrylamide	
Health risk	
FACTOR	SCORE
Collective protection P	5
Chemical-physical state S	10
Process temperature T	5
Used amount Q	2
Handling time E	0,03
Use frequency F	0,22
Level of exposure to the substance	0,528
Lcanc<1	No exposed / "Potentially" exposed
TE 11 10 E 1 1C T	1 + 1

Table 10 - Exposure level for Lcanc acrylamide per employee.

As for the level of exposure, the analysis carried out at the research lab "sample" of "Sapienza" - University of Rome through the application of the algorithm, focused a value higher than 1, and therefore will implemented the obligations under Articles. 237, 242 and 243 of Legislative Decree no. 81/20083 and subsequent amendments.

Total exposure level Lcanc per employee	
Total health risk	
Exposure level for Formaldehyde	1,32
Exposure level for Acrylamide	0,528
Overall exposure level per employee	1,848
Lcanc >1	Exposed

Table 11 - Total exposure level Lcanc per employee

Conclusions

The proposed algorithm ISPRA is a simple tool to characterize the carcinogenic risk in research laboratories. While it provides a theoretical assessment, as stated by the editors, it allows a "timely" exposure assessment [1]. Its slenderness is well suited to the variability of university staff exposed to carcinogenic risks, for which a three-year periodicity of the risk assessment cannot be adapted to the specific working reality [6].

In fact, there is no universally approved method in the scientific literature to identify subjects exposed to carcinogen mutagen and divide them in classes according to intensity of exposure [6]. A proper risk assessment still provides exposure measurement and presupposes the existence of limit values with which to compare the results [7]. This process although necessary, however, is long, complex and expensive in terms of human and economic resources.

The algorithm's effectiveness in identifying exposed workers, once verified by comparison with environmental measurements, could be a good reference to define which workers subjected to visit or at least to address the priorities of the health surveillance [8].

A proper risk assessment envisages that all the safety measures, both on a collective and individual are made and in some cases must include the exposure measure, which presupposes the existence of limit values with which to compare results [9].

The occupational physician can also make use of this tool to address the priorities of the health surveillance, obtaining a first screening of workers exposed and potentially exposed.

The population in this study, as result of the risk assessment has shown a level of exposure to health, has been subjected to health monitoring for the use of carcinogenic / mutagenic substances. Then the employer is required to apply all the measures and the general principles of prevention consist of [10,11,12]:

- 1) specific measures of prevention and protection to be implemented in relation to all present knowledge of the community 'scientific and all' technology offerings in accordance 'with the provisions of art. 15 and art. 18 of the aforementioned Legislative Decree 81/2008 [10];
- 2) health monitoring and medical records and risk;
- 3) inscription on the register of carcinogens.

The worker instead classified "not exposed" or as a precautionary measure "potentially exposed" could not be

applied as indicated in Legislative Decree no. 81/2008 Art. 242 - Health Surveillance and Art. 243 - Enrolment in the register of complaints [4];

Remaining that the Occupational Medicine Centre of "Sapienza" - University of Rome, in agreement with the position taken by the Italian Society of Occupational Medicine and Industrial Hygiene applies health surveillance even in the presence of potential health risk reducing it between general measures of health protection and safety of workers.

References

- Linee guida per la valutazione del rischio da esposizione ad Agenti Chimici Pericolosi e ad Agenti Cancerogeni e Mutageni – Centro Interagenziale "Igiene e Sicurezza del Lavoro" 2ª edizione Gennaio 2011;
- 2. Strafella E et al, "LaboRisCh: an algorithm for assessment of health risks due to chemicals in research laboratories and similar workplaces" Epidemiol Prey; 2008 Nov-Dec;32(6):315-8
- 3. "Assessment of exposure to carcinogens / mutagens in research laboratories: integrated system of checklists, surveys and use of algorithms" Journal Industrial Hygiene vol. 33 n. 3 July 2008.
- 4. D.lgs. 9 aprile 2008, n. 81 Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO-Attuazione dell'articolo 1 della Legge 3 agosto 2007, n. 123 in materia di tutela della salute e della sicurezza nei luoghi di lavoro. (Gazzetta Ufficiale n. 101 del 30 aprile 2008 Suppl. Ordinario- (Decreto integrativo e correttivo: Gazzetta Ufficiale n. 180 del 05 agosto 2009 Suppl. Ordinario n. 142/L) VERSIONE AGGIORNATA SU www.lavoro.gov.it Temi e priorità Salute e Sicurezza;

- 5. Linee guida per la formazione continua e l'accreditamento del medico del lavoro. La Sorveglianza Sanitaria, Pavia, 2003).
- Martines V et al "Algorithm for assessment of exposure to asbestos" - G Ital Med Lav Ergon. 2010 Apr-Jun;32(2):154-61.
- 7. Forni A, Bertazzi PA. "Epidemiology in protection and prevention against environmental mutagens/carcinogens. Examples fron occupational medicine." Mutat Res, 1987.
- Pira E et al, Linee Guida per la sorveglianza sanitaria degli esposti ad agenti cancerogeni e mutageni in ambienti di Lavoro vol. 1 e 2 . PIME editrice, Pavia 2003.
- F. Benvenuti, A. Di Mambro, R. Lombardi, S. Giambattistelli, "ISPESL Linee Guida per la Valutazione del rischio, D.Lgs. 626/94: applicazione alle strutture del Servizio Sanitario Nazionale"; Allegato al nº 1 dei Fogli di Informazione ISPESL, 1996.
- ISPESL, Gruppo di Lavoro Tecnico dell'Osservatorio della Sicurezza (D.Lgs. 626/94), "Linee Guida per la Valutazione del rischio, D.Lgs. 626/94 nella P.M.I.; Fogli di Informazione ISPESL, numero monografico 1995.
- 11. F. Benvenuti, A. Di Mambro, R. Lombardi, S. Giambattistelli, "ISPESL Linee Guida per la Valutazione del rischio, D.Lgs. 626/94: applicazione agli Uffici Amministrativi ed ai Laboratori di ricerca, controllo e didattica"; Allegato al n° 4 dei Fogli di Informazione ISPESL, 1995.
- 12. Fernanda Perdelli , Gianluca Ottria , Maria Luisa Cristina , Roberto Lombardi , Marina Sartini , Anna Maria Spagnolo Evaluation of environmental contamination by glutaraldehyde in an outpatient facility for digestive endoscopy in an Italian hospital. International Journal of Environmental Health Research. Volume 18, 2008 Issue 1 Pages 73-78 , 29 Jan 2008.