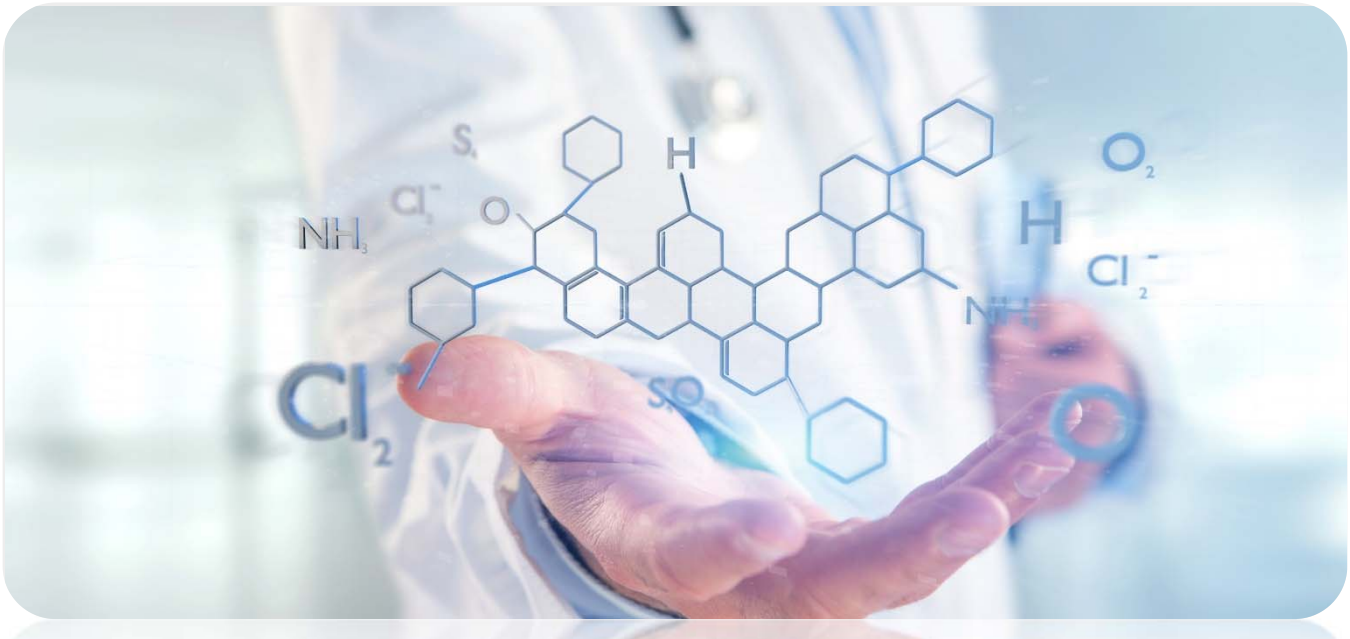
CRIOGES

BIOSEGURIDAD SANITARIA POR FRIO



Patented system for effective combined protection against biological and chemical risks

Scientific Technical Document

CRIOGES®

CRIOGES: SCIENTIFIC SUPPORT FOR HOSPITAL IMPLEMENTATION

The **CRIOGES** patented system is the most effective and suitable measure to comply with the health principles regarding the protection of the health personnel in order to reduce to a minimum the risks of contracting professional diseases. This is regulated by numerous regulations, which once the **CRIOGES** Biosafety System is implemented, leads to its wide compliance. Below, we highlight the most important ones:

- W.H.O (Word Health Organization)

Safe management of waste from health care activities

Second Edition

Published by: Yves Chartier, Jorge Emmanuel, Ute Pieper, Annette , Prüss, Philip Rushbrook, Ruth Stringer, William Townend, Susan Wilburn and Raki Zghondi

https://www.who.int/water_sanitation_health/publications/wastemanag/en/

Attached is an extract where CRIOGES cancels and complies with these W.H.O. parameters

- INSTITUTO DE SALUD CARLOS III. Ministry of Health

"Good practice guide for professional workers exposed to cytostatic agents"

Especially and graphically on page 58 **CRIOGES** is referred to as the best solution

- Legislation on Occupational Risks

See attached documentation

CRIOGES SYSTEM AS A METHOD TO COMPLY WITH HAZARDOUS WASTE MANAGEMENT IN HEALTH CARE FACILITIES: EXTRACT

INTRODUCTION:

The latest edition published by W.H.O. on the risks and consequences to humans of hospital hazardous waste clearly defines the guidelines to be followed by the centres with regard to the procedure and measures to be observed in order to reduce the risks to human health as much as possible. In this document, the W.H.O. has stated in many studies that inadequate management of hazardous waste within health centres produces irreversible consequences for human health, especially for workers.

The adoption of the **CRIOGES** system is a definitive solution to cancel out these risks to people in health centres.

W.H.O. CONCLUSIONS

- **Emissions from hazardous waste (biohazardous and cytotoxic) are introduced to humans through inhalation, among other ways 3.1.3**
- **The emissions produced by hazardous waste during its segregation phase enter through the respiratory tract. There are numerous studies and cases where malformations, abortions and mutations have been observed and demonstrated, especially in studies from the USA and Canada (2004) 3.3.3**
- **Mutagenic toxic compounds from waste have been found in workers' urine**
- **Waste should be segregated or dumped as close as possible to the place of generation 7.2**
- **The segregation of hazardous waste should be avoided or minimized by attempting to sort at source as optimally as possible 7.1**

CONSEQUENCES OF THE USE OF THE CRIOGES SYSTEM

- **The CRIOGES system cancels out the emissions of hazardous waste in health centres to zero. (SGS TECNOS & PRL study)**
- **The CRIOGES system reduces to a minimum the environmental pollution, either chemical or biological, creating biosafety spaces.**

- **Prevents accidental spills and accessibility to content (punctures)**
- **Allows to segregate to the closest place of waste generation**
- **It allows an optimal classification and minimization of hazardous waste at the source.**

CRIOGES

World Health Organization

FINAL CONCLUSION

With the CRIOGES system it is possible to comply with the precepts of the W.H.O. in its whole since it cancels the risks that the dangerous waste produces to the people inside the centres.

The system is simple and easy to implement since it not only eliminates the risks to people, but also contributes to improve the environment since it reduces the amount of waste, plastics and emissions to the planet.

Madrid, febrero de 2014

GUÍA DE BUENAS PRÁCTICAS PARA TRABAJADORES PROFESIONALMENTE EXPUESTOS A AGENTES CITOSTÁTICOS

Monografías

ammtas
GOBIERNO DE ESPAÑA
MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD
Instituto de Salud Carlos III
Escuela Nacional de Medicina del Trabajo

Fig. 10. Contenedores específicos para residuos citostáticos

	**Son Contenedores tipo Biocompact, específicos para residuos citostáticos (Clase VI), fabricados en polipropileno de alta densidad, de cuerpo azul y tapa negra. Diferentes tamaños: 30, 50 y 60 L.** • Se recomienda mantener sobrepuesta la tapa de estos contenedores. • Cuando se hayan ocupado las 2/3 partes de su capacidad, deberán cerrarse herméticamente.
	**Contenedores Biocompact de 10, 5 y 3 L, específicos para objetos punzantes y cortantes de citostáticos:** • **Desechar jeringa y aguja SIN SEPARAR** e introducir en el **contenedor de residuos citotóxicos cortopunzantes**. • Cuando en este contenedor se hayan ocupado las 2/3 partes de su capacidad, deberá cerrarse, e introducirse, a su vez, en un contenedor de residuos citotóxicos.
	***Adaptación de sistema de termosellado a los c tenedores de citostáticos:*** • *Mejora la seguridad, empaquetándolos residu peligrosos* en bolsas termoselladas, evitando el riesgo de aerosolización. Estas bolsas no contaminan en el proceso de incineración.
	***Bioseguridad Sanitaria por Frío para Residuo citotóxico:*** • *Mejora la seguridad e higiene empaquetándolos residuos peligrosos* en frío, evitando el riesgo de aerosolización y olor consiguiendo una optimización en el consumo de envases homologados.

CRIOGES SYSTEM

Fuentes: Consenur y KRZ©

Transporte interno de residuos citostáticos: El personal involucrado debe recibir instrucciones sobre procedimientos para el transporte seguro y manejo de derrames. Condiciones generales:

— Debe evitarse cualquier riesgo para pacientes, personal y público.

— Los envases se trasladarán cerrados, por circuitos distintos a los pacientes y público, siempre que sea posible.

STUDY OF EMISSIONS FROM HAZARDOUS WASTE SITES AT VALL HEBRON HOSPITAL. BARCELONA

Study carried out by the international accredited company SGS, which verified how, without the **CRIOGES** system, packaging with hazardous waste produces a constant harmful emission.

With the **CRIOGES** system implemented, SGS was able to verify that the emission is zero. Besides, **CRIOGES** system has a photocatalysis purification system that continuously sanitizes 35 cubic meters/hour for each Biosecurity Station.

SGS

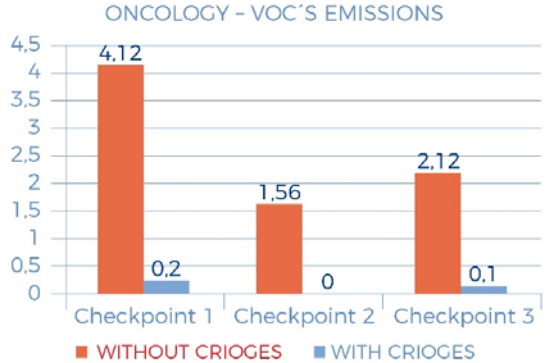
WHEN YOU NEED TO BE SURE

TRADITIONAL MANAGEMENT

The different spilling points of hazardous waste produce a permanent focal point of pollutant emissions to the health centre.

Vall d'Hebron

ONCOLOGY WITHOUT CRIOGES		
EMISSIONS	VOC´S	BIOLOGICAL AGENTS
CHECKPOINT 1	4,12 mg	1320 ufc/m3
CHECKPOINT 2	1,56 mg	350 ufc/m3
CHECKPOINT 3	2,12 mg	480 ufc/m3

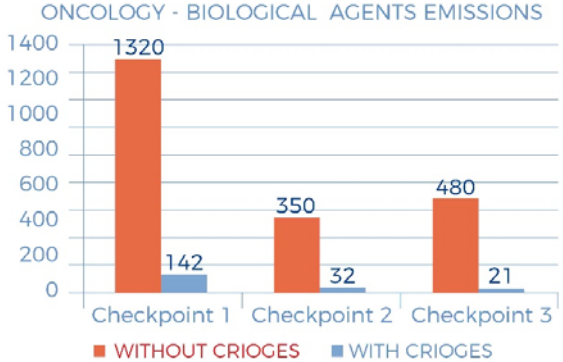


CRIOGES ADVANCED MANAGEMENT

With the CRIOGES system, the emissions coming from the different spilling points of hazardous waste are cancelled. This is the key for a whole decontamination.

Vall d'Hebron

ONCOLOGY WITH CRIOGES		
EMISSIONS	VOC´S	BIOLOGICAL AGENTS
CHECKPOINT 1	0,2 mg	142 ufc/m3
CHECKPOINT 2	O mg	32 ufc/m3
CHECKPOINT 3	0,1 mg	21 ufc/m3



CRIOGES®

Before and after comparison with the use of the CRIOGES system in several hospitals in Spain

HEALTHCARE FACILITIES	CONCENTRATION OF VOC´s PRIOR TO THE CRIOGES SYSTEM	POST CRIOGES VOC ´s CONCENTRATION	% DECREASE OF VOC's	CONCENTRATION OF MICROORGANISMS PRIOR TO THE CRIOGES SYSTEM	CONCENTRATION OF MICROORGANISMS AFTER THE CRIOGES SYSTEM	% OF MICROORGANISM REDUCTION
SERMAS	2,18ppm	0,71ppm	-89,9	64,4	6	-90,68
VALENCIA SALUT	1,59ppm	0,22ppm	-98,61	327,85	49,22	-84,7
IB-SALUT	0,157ppm	0,046	-71,7	96*	43	-55,2
SERVEI CATALA DE SALUT	0,33ppm	0,71ppm	-89,9	N/D	N/D	N/D
CANTABRIA SALUD	0,40ppm	0,24ppm	-76,4	89,8	18	-79,95
SERGAS	0,4ppm	0,24ppm	-76,4	N/D	N/D	N/D
SERMAS	3,2 ppm	0,60ppm	-81,25	N/D	N/D	N/D

*** Contrast measurements made with a difference of less than 24h.**
The longer the time between measurements the greater the % decrease in AMA and MLA.

These same or similar rates are produced in more than 200 hospitals with the CRIOGES system implemented.

Source of measurements: SGS WHEN YOU NEED TO BE SURE AISL MEDICIONES

CRIOGES®

SERVIZO GALEGO de SAÚDE

In 2016, Chop generated more than 11,000 kilos of cytotoxic waste -

For a year now, the Complexo Hospitalario Universitario de Pontevedra (Chop) has had an innovative health biosafety system for special or cytotoxic waste from **CRIOGES**

https://www.lavozdegalicia.es/noticia/pontevedra/2017/06/22/chop-genero-2016-once-mil-kilos-residuos-citotoxicos/0003_201706P22C4993.htm

SaludMadrid

Hospital General Universitario Gregorio Marañón

Comunidad de Madrid

FROM YESTERDAY TO TODAY IN THE NURSING CARE OF PATIENTS UNDERGOING DEBULKING AND HYPEC

Hospital Gregorio Marañon

The Hospital General Univesitario Gregorio Marañón uses and recommends class VI waste containers, refrigerated at temperatures below 4ºC. CRIOGES

http://seoq.org/docs/files2015/congreso/heras-escobbar-carmen.pdf

CRIOGES®

MEDICINA y SEGURIDAD del trabajo
INTERNET

Control del Formaldehído, Xileno y Compuestos Orgánicos Volátiles mediante el Sistema Integral de Friocongelación y Fotocatalización.

Mileida Andreina Peñalver Paolini, Luis Carlos Mazón Cuadrado, Pilar Berrocal Fernández...

MATERIAL Y METODOS

Se realizaron 26 mediciones ambientales en Anatomía Patologica del Hospital Universitario de Fuenlabrada, en area de laboratorio (20 mediciones) y sala detallado (6 mediciones), de COVs, Xileno y de Formaldehído; las tomas se hicieron en dos fechas distintas, en febrero del año 2017 (primeras tomas: T1) y en marzo del mismo año (segundas tomas: T2), posterior a la instalación de los purificadores y sistemas de frio congelación.

Por último se compararón los resultados de las mediciones de Formaldehído en la sala detallada, con los datos de 7 hospitales del mismo nivel de la Comunidad de Madrid, realizando 2 mediciones (Pre: T1y Post: T2) en cada hospital.

Figura 1. Esquemas de punto de muestreo. Zona de Laboratorio.

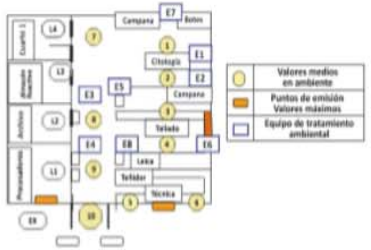
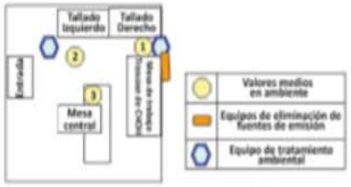


Figura 2. Esquemas de punto de muestreo. Zona de Sala de Tallado.



RESULTADOS

En la tabla III se presentan los resultados de las mediciones de valores medios en ambiente de **COVs** y **Xileno** en la zona de laboratorio, llevada a cabo en 10 puntos: T1 (Pre), primeras mediciones realizadas el 02/02/2017 y T2 (Post), segundas mediciones realizadas el 02/03/2017), tras la implantación de las medidas de prevencion colectivas.

Tabla III. Valores medidos en ambiente-zona laboratorio, COVs - Xileno.

ZONA (Z1)	COVs - ppm		Xileno - ppm	
Laboratorio	T1	T2	T1	T2
Punto 1	3,5	0,3	1,5	0,1
Punto 2	5,8	0,4	2,5	0,2
Punto 3	2,8	0,8	1,2	0,3
Punto 4	2,8	1,1	1,2	0,5
Punto 5	5,6	0,5	2,4	0,2
Punto 6	2,8	0,8	1,2	0,3
Punto 7	6,3	0,5	2,7	0,2
Punto 8	6,1	0,7	2,6	0,3
Punto 9	9,4	0,9	4	0,4
Punto 10	2,2	1,8	0,9	0,8
	SIN CRIOGES	CON CRIOGES	SIN CRIOGES	CON CRIOGES

CONCLUSIÓN

El estudio a permitido demostrar que el sistema integral de friocongelación y purificación mediante fotocatalización , es una medida tecnicamente complementaría y eficaz que optimiza el control de la exposición Formaldehído, COVs y Xileno; por otro lado, a nivel cualitativo los trabajodores manifestaron mayor confort (no olores no sintomas de irritación aguda).

Figura 1. Esquemas de punto de muestreo. Zona de Laboratorio.

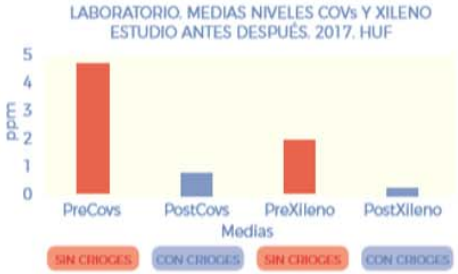


Figura 4. Valores medidos en ambiente-zona laboratorio, Xileno.

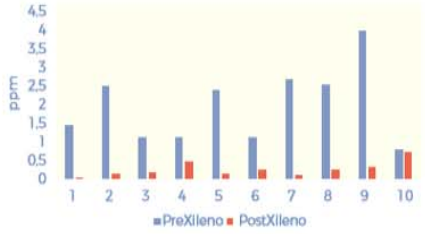
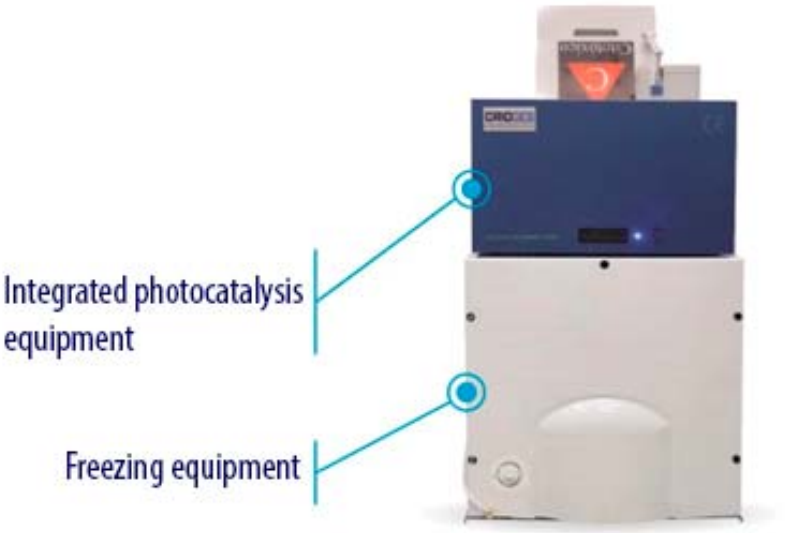


Tabla V. Valores medidos en ambiente-zona sala de Tallado, Formaldehído.

ZONA	Z2	Formaldehído - ppm	
Sala de Tallado	Punto	T1	T2
Tallado derecho	1	0.37	0.06
Tallado izquierdo	2	0.29	0.07
Ambiente	3	0.39	0.08
		SIN CRIOGES	CON CRIOGES

CRIOGES
BIOSEGURIDAD SANITARIA POR FRIO

IMPLEMENTING THE NETWORK OF CRIOGES STATIONS GUARANTEES A WORKING ENVIRONMENT FREE OF HARMFUL BIOLOGICAL (virus, bacteria, fungi, ...) AND CHEMICAL AGENTS



Autonomous photocatalysis equipment, continuously sanitizes the environment

radius of action: 40 square meters

Radius of action: 14 square meters

CRIOGES®

THE PREVENTION OF OCCUPATIONAL RISKS FOR HEALTH PERSONNEL MUST BE AND IS COMPATIBLE WITH COMPLIANCE WITH ENVIRONMENTAL LEGISLATION ON WASTE AND ALSO REPRESENTS A COST SAVING FOR THE HOSPITAL

The Royal Decree 664/1997, of 12 May on the protection of workers from risks related to exposure to biological agents at work provides in Article 6 for the reduction of risks for healthcare workers by

- Adoption of safe measures for the reception, handling and transport of biological agents within the workplace

- Use of safe means for the collection, storage and disposal of waste by workers, including the use of safe and identifiable containers, after appropriate treatment if necessary

- Use of hygiene measures that prevent or hinder the dispersion of the biological agent outside the workplace.

The Royal Decree 665/1997, of 12 May (BOE 24/V/97) on the protection of workers from the risks related to exposure to carcinogens at work.

Whenever a carcinogen is used, the employer shall apply all the following necessary measures:

a) Limit the amounts of the carcinogen or mutagen in the workplace.

b) To design work processes and technical measures in order to avoid or minimize the formation of carcinogens.

c) Limit the number of workers exposed or likely to be exposed to the hazard to a minimum.

d) Evacuate carcinogens at source, by localised extraction or, where this is not technically possible, by general ventilation, under conditions which do not pose a risk to public health and the environment

e) Use the most appropriate measurement methods, in particular for immediate detection of abnormal exposures due to unforeseen events or accidents.

f) Apply the most appropriate procedures and working methods.

g) Take collective protection measures or, where exposure cannot be avoided by other means, individual protection measures.

The Royal Decree 374/2001 on the protection of workers exposed to chemical agents states in Article 2.2 that exposure to a chemical agent is the presence of a

chemical agent in the workplace which involves contact between the worker and the chemical agent, normally by inhalation or via the skin.

Law 54/2003 Reform of the LPRL Article 5, in relation to Article 16 of the LPRL, refers to the powers of the Health and Safety Committee.

a) To participate in the development, implementation and evaluation of risk prevention plans and programs in the company. To this end, before their implementation and with regard to their impact on risk prevention, the projects on planning, organization of work and introduction of new technologies, organization and development of protection and prevention activities referred to in article 16 of this Law and project and organization of training in preventive matters will be discussed".

Royal Decree 117/2003 of 31 January on the limitation of emissions of volatile organic compounds due to the use of solvents in certain activities.

In addition to these regulatory provisions, there are the Health Surveillance Protocols published by the National Health Commission or the Technical Prevention Notes, which are good practice guides published on the initiative of the National Institute of Safety and Hygiene in the Workplace. Their indications are not obligatory unless they are included in a regulatory provision in force. In order to assess the relevance of the recommendations contained in a particular NTP, it is advisable to take into account its date of publication.

We highlight the **NTP 432 Formaldehyde in laboratories, 480 Waste Management in laboratories, 572 Exposure to Biological Agents, 576 Integration of Management Systems, 739 Biosafety Inspection, 972 Covs and Photocatalysis, 1051 Exposure to hazardous drugs, 740 Occupational exposure to cytostatics**

In all of the aforementioned regulations concerning occupational risks related to the exposure and handling of health care waste, chemical substances and dangerous medicines, the focus is on the already known risks of skin and mucous membrane irritation due to direct application, as well as on the possibility of health risks for personnel who handle them after chronic exposure and in small quantities to some of these medicines, due to the fact that they produce aerosols, as evidenced by Falk's 79th study on the mutagenic action in the urine of nurses who administered cytostatics. **Pag 11 HEALTH SURVEILLANCE PROTOCOLS SPECIFIC TO CITOSTATIC AGENTS published by the PUBLIC HEALTH COMMISSION INTERRITORIAL COUNCIL OF THE NATIONAL HEALTH SYSTEM**

The routes of penetration of these substances are:

a) Inhalation of aerosols and micro-droplets that are released during the preparation of cytostatic solutions and during their administration, or by the breakage of vials, when purging the system, etc.

b) By direct contact, by penetration of the drug through the skin or mucous membranes.

c) Oral: ingestion of contaminated food, drinks, cigarettes. This is the least frequent route.

d) By parenteral route: by direct introduction of the medicine through punctures or cuts produced by the breakage of blisters

NTP 740 of the Ministry of Health and the National Institute of Safety and Hygiene at Work : Occupational exposure to cytostatics in the health sector

This Technical Note on Prevention updates and extends the previous Technical Note on Occupational Exposure to Cytostatic Compounds (NTP 163), which contained the preventive information available at that time on this type of product. It comments on the main aspects to be considered in the handling of cytostatic compounds in the healthcare environment, both in hospitals and in primary care centres, where, although there is adequate equipment, guidelines and protocols, the expected results are not always achieved.

Although there are numerous action protocols and procedure manuals and in recent years there have been significant improvements in preventive and protective measures, often based on technological innovations, the presence of cytostatics on work surfaces, in the air or in the urine of allegedly exposed persons has been noted.

Presence in working air would be the first direct cause of inhalation exposure.

In the case of cytostatics, it is important to note that the contamination of the external part of the supplied vials is not part of the working procedure, which means that protective measures must be taken from the moment the containers are entered and unloaded in the warehouse [17]; 8) fumes [18] and 9) latex [18].

However, a quantitative assessment is not envisaged for most products used in the hospital environment (especially for medicines or dangerous drugs but also for pesticides) since, among other considerations, there are often no approved sampling and analysis methods or legally defined occupational exposure limit values.

With regard to risk control measures (in addition to the monitoring of the basic universal principles of prevention and reduction of exposure and personal hygiene measures) 1) general ventilation which is different according to the areas of hospital activity; 2) localised extraction where there is a release of products (regardless of whether there are biological safety cabins); 3) correct maintenance of the installations, work equipment and, if necessary, the levels of containment of the different areas or laboratories (especially with regard to biological risk); 4. implementation of good practices through the application of work procedures or instructions; 5. correct storage and labelling of products; 6. availability of product information, including information on how to act in the event of a spillage; 7. appropriate use of work clothing and personal protective equipment; 8. mechanisation or automation of processes involving chemicals; 9. waste management. **(12th International Conference on Occupational Risk Prevention ORP)**

CONCLUSION

Numerous studies, regulations and institutions agree on the need to reduce the risks to health professionals as much as possible. With **CRIOGES**, after more than 10 years of national and international experience and with more than 200 hospitals and laboratories of vanguard, conclude:

CRIOGES is the only system in which dangerous emissions from infectious and cytotoxic waste points are cancelled

CRIOGES is the only system that creates a biosafety ring by ridding the interior space of biological and chemical agent residues in environmental suspension.

Furthermore, and very importantly, **CRIOGES** manages to reduce by 24% plastic containers/bags which contributes to:

- ☐ Produce less plastic
- ☐ Optimising road transport
- ☐ Reducing emissions by destruction

CRIOGES was created to:

- ☐ Reduce emissions
- ☐ Protecting our planet