

Fall 2015

Exposure Monitoring in Developing Countries

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Montana Tech of the University of Montana

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Exposure Monitoring in Developing Countries

by

Luis Collado

A report submitted in partial fulfillment of the
requirements for the degree of

Master of Science

Industrial Hygiene Distance Learning / Professional Track

Montana Tech of the University of Montana

2015

Abstract

Formaldehyde is widely used in the healthcare industry. Formaldehyde is used as a disinfectant and sterilant. In addition, formaldehyde/formalin is used as fixative/ preservative of anatomical specimens in pathology departments. Individuals may experience adverse effects following short term exposure above 0.1ppm. Following a laboratory study in the early 1980s, the U.S. Environmental Protection Agency (EPA) classified formaldehyde as a human carcinogen in 1987.

Although the healthcare industry in the United States made major advancement in the safe use of formaldehyde/formalin since the implementation of the Occupational Health and Safety Administration (OSHA) Formaldehyde standard, other developing countries are still struggling with the proper storage, handling and disposal of formaldehyde.

As part of a Joint Commission International (JCI) accreditation assessment team, a baseline industrial hygiene exposure assessment took place in the Dominican Republic's Hospital General de la Plaza de la Salud. This assessment included conducting personal exposure and area monitoring. In addition, an instantaneous monitoring device was use to detect any fluctuations/ Short Term Exposure Limit (STEL) conditions.

Even though the data listed is limited, it was concluded that a significant level of overexposure to formaldehyde is expected during unplanned leaks from sterilizing equipment and the segregation of specimens from formalin in the morgue area.

Keywords:

Dominican Republic, Formaldehyde, Formalin, Hospital, Healthcare, Exposure Monitoring, Developing Countries

Dedication

I wish to thank my mother, Miledy Moscoso, who as a single mother of four continues to make our wellbeing and safety a priority in her life. Her loving and caring for others way, amongst the many great attributes, sparked my interest in the occupational hygiene field. Her current medical condition (Parkinson's) has added to the many reasons I plan to contribute to our profession, including identifying unknown factors, including potential environmental factors. By doing so, I hope it would one day lead to a cure to her medical condition.

Acknowledgements

I would like to acknowledge the assistance provided by both, Baptist Health South Florida and the administration group from Hospital General de la Plaza de la Salud. In addition, I would like to acknowledge the guidance provided by the faculty in the Safety, Health & Industrial Hygiene Department in Montana Tech.

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1. Background

As the science and art devoted to the anticipation, recognition, evaluation, and control of workplace conditions that may cause workers' injury or illness, industrial hygiene was first recognized as early as the fourth century BC. Industrial hygienists use environmental monitoring and analytical methods to detect the extent of worker exposure and employ engineering, work practice controls, and other methods to control potential health hazards (Anna 2011).

As with all professions, the early years of occupational hygiene were full of challenges and countless improvement opportunities. In 1713, the father of occupational medicine, Bernardino Ramazzini, published the first complete dissertation on occupational diseases, *De Morbis Artificum Diatriba*. Although at the time his recommendations were seen as revolutionary in the advancement of health and safety for industrial workers, they lacked specifics and support from organizations and legislative bodies, which play a key role in providing the necessary resources and enforcement to a sound occupational hygiene program. Unfortunately, no significant additions were made for the following 100 years (Anna 2011).

1.1. The U.S. Experience

The United States provided many improvements in the further development of the profession; however the U.S. experience was no different, as it took trial and error for the practice to be finally recognized in the early 1900s. With the passing of the Metal and Nonmetallic Mines Safety Act of 1966, the Federal Coal Mine Safety and Health Act of 1969, and the Occupational Safety and Health Act of 1970 (OSHAct), the U.S. Congress made a major commitment to the advancement of health and safety in the workplace. Today,

all employers are required to implement some or all of these elements into their workplace safety program (Anna 2011).

1.2. The Occupational Safety and Health Act of 1970 (OSHAct)

The OSH Act of 1970 sets occupational safety and health requirements within the workplace. This includes the employer determining the extent of potential employee exposure and making the necessary changes to mitigate those hazards. These hazards include potential air contaminants, and harmful chemicals. In order to reduce the extent and severity of work related injuries, one must establish a management program. (OSHA 1970). OSHA developed and published the voluntary “Safety and Health Program Management Guidelines,” which identify four critical elements to the development of a successful safety and health management program: management commitment and employee involvement, worksite analysis, hazard prevention and control, and safety and health training (OSHA 1990).

1.3. National Institute for Occupational Safety and Health (NIOSH)

In addition to the creation of OSHA, another significant part of the OSHAct was the creation of NIOSH. NIOSH was founded to help ensure safe and healthful working conditions by providing information, education, research, and training. One of NIOSH’s greatest contributions was the publication of the NIOSH Pocket Guide. The Pocket Guide provides general industrial hygiene information for several chemicals or substance groupings that are found in the workplace. Data is illustrated in tabular form to provide a clear, expedient source of information about monitoring practices (NIOSH 1990).

Table 1-Major Historical Events in IH	
1,000,000 BC	Australopithecus used stones as tools and weapons. Flint knappers suffered cuts and eye injuries; bison hunters contracted anthrax.
370 BC	Hippocrates dealt with the health of citizens, not workers, but did identify lead poisoning in miners and metallurgists.
Middle Ages	No documented contributions
1500	Paracelsus described respiratory diseases among miners with an excellent description of mercury poisoning. Remembered as the father of toxicology. “All substances are poisons . . . the right dose differentiates a poison and a remedy.”
1713	Bernardino Ramazzini, “father of occupational medicine.” Published <i>De Morbis Artificum</i> , (<i>Disease of Workers</i>) and examined occupational diseases and “cautions.” He introduced the questions, “of what trade are you?”
1830	Charles Thackrah authored the first book on occupational diseases to be published in England. His views on disease and prevention helped stimulate factory and health legislation. Medical inspection and compensation were established in 1897.
1900s	Dr. Alice Hamilton investigated many dangerous occupations and had tremendous influence on early regulation of occupational hazards in the United States. In 1919 she became the first woman faculty member at Harvard University and wrote <i>Exploring the Dangerous Trades</i> .
1930s	American Industrial Hygiene Association organized. American Standards Association and ACGIH prepared first list (maximum allowable concentrations) of standards for chemical exposures in industry.
1960-Present	Metal and Nonmetallic Mine Safety Act, Coal Mine Health and Safety Act, Occupational Safety and Health Act, efforts to significantly amend OSHAct

1.4. The Dominican Republic Experience

Known for its main industries; agriculture and mining, the economy has recently moved into a period of domination from the service industry. Although founded in 1929, the country’s Ministry of Labor has only made minor improvements since, primarily in passing legislation,

but continues to face many challenges in enforcing and providing employers with an effective roadmap, through program management and education, to achieving full compliance.

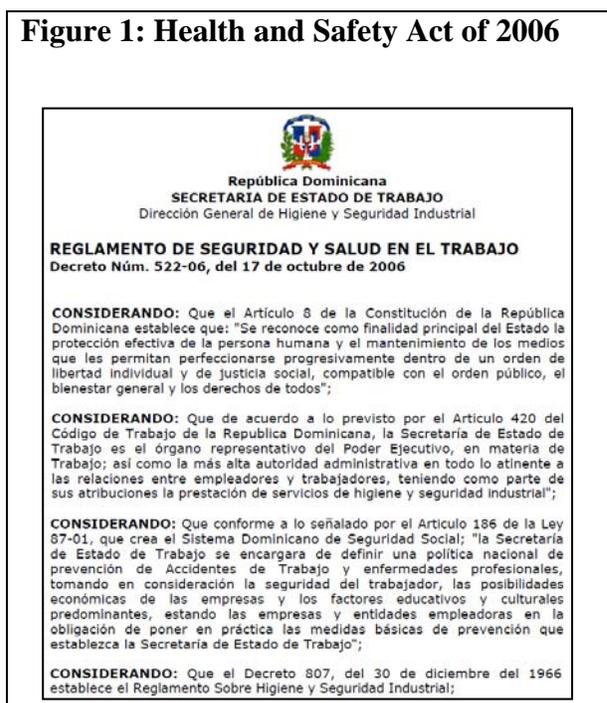
Similar to the U.S. Occupational Safety and Health Act (OSHAct) of 1970, the Dominican Republic's landmark *Reglamento de Seguridad y Salud en el Trabajo, Decreto 522-06* (Health and Safety in the Workplace Act of 2006), set out to make major improvements within the workplace. This Act regulates some hazards within the workplace and requires employers to establish risk prevention initiatives, to include program management, in order to prevent illnesses and accidents within the workplace.

1.5. Health and Safety in the Workplace Act of 2006

On October 17, 2006, the Dominican Congress passed its version of the OSHAct; *Reglamento de Seguridad y Salud en el Trabajo (Decreto 522-06)*. The main objective of this landmark mandate is to establish and maintain safe working conditions within the workplace, which will ultimately result in the prevention of injuries and illnesses. Under the Ministry of Labor, the Secretary of Labor's Hygiene and Safety Department is tasked with the responsibility to oversee the evaluation and investigation of potential risk within the workplace and with promoting preventive programs within the workplace. This includes working with employers to create and maintain a successful health and safety program.

Under section 3.2.4 of this Act, a "*tabla indicativa y No Exhaustiva De Valores Limite*"

Figure 1: Health and Safety Act of 2006



or TLV-TWA table is included. This table includes TWA limits for over 82 hazardous substances. Noteworthy, this TLV table does not include any IDLH, TLV-C or TLV STEL requirements. In addition, this table or the Act does not establish any Action Level (AL) values for these hazardous substances. Of equal or greater significance, the table leaves out some of the internationally known carcinogens, such as formaldehyde/formalin.

2. Formaldehyde

According to OSHA, formaldehyde describes various mixtures. The term “formalin” is used to describe a saturated solution of formaldehyde. Formalin is typically 37% formaldehyde by weight (40% by volume) and 6-13% methanol by volume in water. Formaldehyde is often found in water-based solutions. The gas is colorless, strong-smelling,. Formaldehyde is also widely used in particle boards, household products, glues, fiberboard, and plywood. It is also used as an industrial fungicide, disinfectant and germicide.

2.1. Routes of Exposure

Formaldehyde can be inhaled as a gas or vapor or absorbed through the skin as a liquid. Those with highest risk are healthcare professionals, medical lab technicians, mortuary workers as well as teachers and students who handle biological specimens preserved with formaldehyde or formalin (OSHA 2011).

2.2. Harmful Effects

As a sensitizing agent, formaldehyde can cause immune system response upon initial exposure. Airborne exposure above 0.1 ppm can cause irritation of the respiratory tract. Although the short-term health effects of formaldehyde exposure are well known, less is known about its potential long-term health effects. In 1987, the U.S. Environmental Protection Agency (EPA) classified formaldehyde as a probable human carcinogen under

conditions of unusually high or prolonged exposure. In 2011, the National Toxicology Program, an interagency program of the Department of Health and Human Services, named formaldehyde as a known human carcinogen in its 12th Report on Carcinogens. A number of studies involving workers exposed to formaldehyde have recently been completed. One recent study, conducted by the U.S. National Cancer Institute (NCI), looked at workers in industries with the potential for occupational formaldehyde exposure and estimated each worker's exposure to the chemical while at work. The results showed an increased risk of death due to leukemia, particularly myeloid leukemia, among workers exposed to formaldehyde (OSHA 2011).

2.3. Exposure Limits

The OSHA Formaldehyde standard, 29 CFR 1910.1048 provides the following exposure limits:

- The permissible exposure limit (PEL) for formaldehyde in the workplace is 0.75 ppm measured as an 8-hour time-weighted average (TWA).
- PEL in the form of a short-term exposure limit (STEL) of 2 ppm (15-minute period).
- The action level (AL)– which is the standard's trigger for increased industrial hygiene monitoring and initiation of worker medical surveillance –is 0.5 ppm when calculated as an 8-hour TWA.

In addition, the following recommended exposure limits are recognized:

- Ceiling limits: 0.3 ppm (ACGIH), 0.1 ppm- 15 minutes (NIOSH)
- NIOSH's Recommended Exposure Level (REL) of 0.016 ppm (TWA)

2.4. Formalin use in the Healthcare Industry

The safe use of formaldehyde is essential since the chemical has many uses in addition to preserving bodies in the morgue. Formaldehyde is widely used in the healthcare industry; as a fixative/ preservative of anatomical specimens. The overall goal of tissue fixation is to preserve cells and tissue components in a “life-like state” and prepare them for the thinning and staining sections. Fixation can be accomplished by chemical or physical means. The most commonly used fixative agent is formalin. Formalin is used with the “quick fix” method. Over the years alternative fixatives have been studied, such as Bouin and Hollande, and newer products such as GreenFix, UPM and CyMol. A study published in The European Journal of Histochemistry compared these fixatives. Each had their advantages and disadvantages; none provided right combination of satisfactory qualities to replace formalin. The point of that study, however, was to evaluate whether any of those reagents could replace formalin in terms of test validation. The focus was not safe use or ease of disposal.

Despite its known health hazards, formalin is a key component of the histopathology and pathology laboratory (Gatta 2012). As a critical step in the preparation of histological sections, formalin plays a key role in preventing tissue deprivation after removal from the body. Tissue specimens are removed from the patient. Afterwards, the tissue is transported in a container containing formalin to the pathology laboratory. Due to issues of cost, re-validation and the need to evaluate long-term effects of alternate fixatives on tissue preservation, it is unlikely that total elimination of formalin is likely or even possible.

3. Hospital General de la Plaza de la Salud

Located in the nation's capital, Santo Domingo, Hospital General de la Plaza de la Salud (HGPS) is one of Dominican Republic's largest teaching medical institutions. The hospital opened its doors in 1996. As a teaching hospital, HGPS specializes in family and community medicine, medical emergency and disasters, and rehabilitation medicine.

Since its opening, the facility has not undergone any major upgrades to its infrastructure or its environment. In 2014, the institution obtained the services of Baptist Health International (BHI) for consultation and hopes to improve the quality and safety of its

environment of care. Ultimately, the institution plans to achieve Joint Commission International (JCI) accreditation by 2017. This accreditation process includes making major improvements in quality and safety, to include proper handling of hazardous materials.

Figure 2: Hospital de la Plaza de la Salud



3.1. Formaldehyde/Formalin use in HGPS

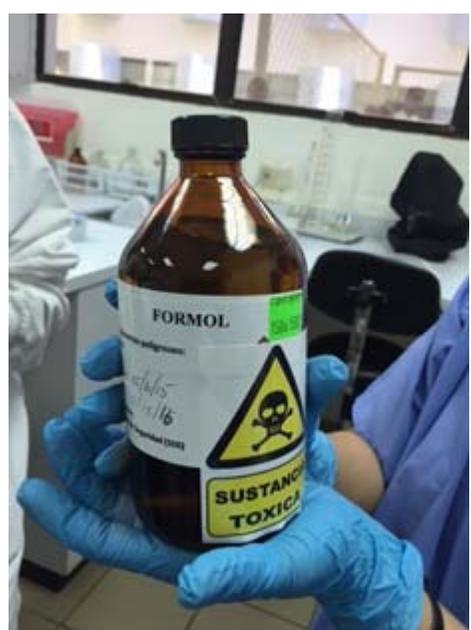
As part of BHI's consultation, an industrial hygiene assessment was conducted in September 2015. This assessment included reviewing the current usage, storage and disposal of hazardous materials, to include formaldehyde/formalin. Currently, the pathology department (to include the morgue area), the laboratory, and the sterilization department all use formaldehyde. At the time of this assessment, the pathology department was still using formaldehyde and diluting it into formalin. This practice is highly discouraged in advanced countries, as it's widely known to increase the potential

of exposure via inhalation. The sterilization department was still using a formaldehyde sterilizer.

Figure 3: Sterilizer (Sterilization Dept)



Figure 4: Formalin container (Lab Dept)



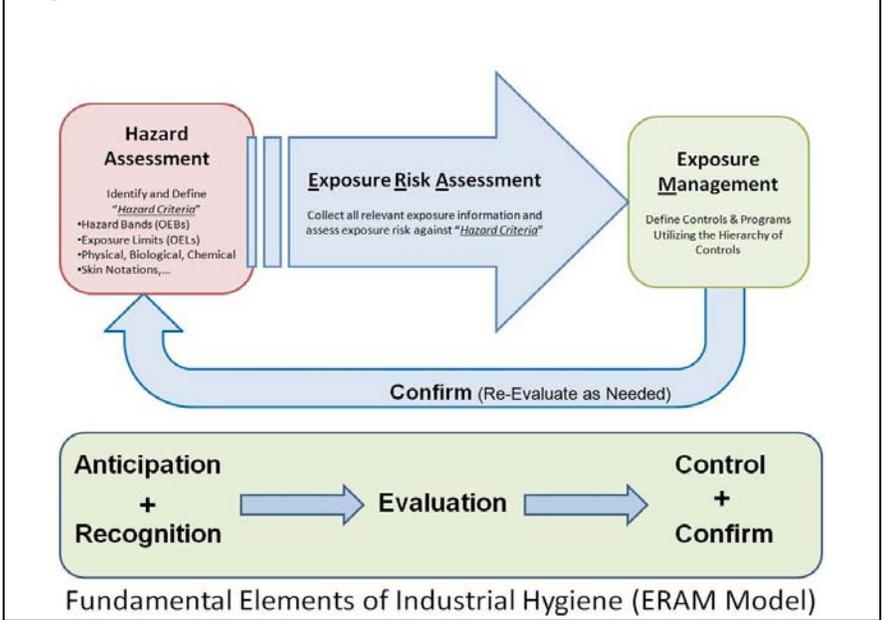
3.2. Hazard Assessment (HGPS)

In order to properly identify and define each potential hazard, a robust literature review took place, to include any applicable OEL/REL.

This phase includes making basic characterization thru anticipation and recognition.

Using the ERAM Model, this assessment was followed

Figure 5: Fundamental Elements of IH (ERAM Model)



by an Exposure Risk Assessment.

3.3. Exposure Risk Assessment (HGPS)

In order to determine exposure profiles, the effectiveness of current controls, and address recent employee concerns, personal exposure and area monitoring took place.

To carefully select and effectively use resources, an overall plan for sampling, that includes the type or number of samples, was necessary. Therefore, the NIOSH Sampling Strategy was used to make the following determinations:

- Chemical(s) are potentially released into the workplace based on processes
- Written determination of employees above the AL for formaldehyde/formalin
- Need to measure exposure of maximum risk employees who may be above the AL
- Determine if exposure is above PEL/AL/STEL

Some of the objectives of this exposure assessment is to define similar exposure groups (SEGs), their exposure profile, judge acceptability of the profile for each SEG, and ultimately determine if current controls, to include engineering and personal protective equipment, are adequately protecting workers.

3.4. Establishing SEGs (HGPS)

In order to properly establish similar exposure groups (SEGs), the following variables were considered during sampling:

- Location,
- Type of process/procedure,
- Materials,

- Environmental variables
- Specific agent(s)
- Engineering & administrative controls

3.5. Environmental Sampling (HGPS)

Using NIOSH's sample determination chart and sampling method, the following determinations were made:

- Selected a full-period, continuous sampling (using passive badges)
- Evaluate potential fluctuations/STEL monitoring by using an instantaneous photoionization detector (PID) device (ppbRae 3000)
- Employees were randomly selected in the Pathology Department, Clinical Laboratory Department, and Surgical Services (includes Sterilization area)
- In addition to monitoring for formalin/formaldehyde, the following substances were also included in this IH assessment:
 - Xylene (Pathology Dept)
 - Alcohols (Pathology Dept and Laboratory Dept)
 - Waste anesthetic gases (Surgical services)

Figure 6: Fume hood (Pathology)



- o Kem Medical was used as third party laboratory for analysis of passive monitoring badges.

Figure 7: Passive monitors (Surgical Services staff)



4.0. Results (HGPS)

Table 2- IH Monitoring Results (Pathology)-Results are all TWA

Area/ Employee	Badge #	Vapor	Results-PPM	ppbRAE-
			(exposure concentration)	PPM Reading
Histology	XG9011	Xylene	0.77	<42
	AL5185	Alcohol	23.81(I)	<40(I)
Histology Tech	XH0381	Xylene	19.6	NT*
	AL5183	Alcohol	206.96 (I)	NT*
Pathologist	XH0383	Xylene	7.65	NT*
	FH3554	Formaldehyde	ND*	NT*
Admin (Pathology)	XH0382	Xylene	8.19	NT*
	AL5184	Alcohol	15.66	NT*
	FH3572	Formaldehyde	ND*	NT*
Morgue Tech	FH3561	Formaldehyde	0.10	4
	AL5186	Alcohol	ND*	NT*
Blank	FH3568	Formaldehyde	ND*	N/A
	XH0384	Xylene	ND*	N/A
	AL5187	Alcohol	ND*	N/A

ND*(Not detectable) NT* (Not tested)

Table 3- IH Monitoring Results (Clinical Laboratory)-Results all in TWA

Chemistry	Area/ Employee	Badge #	Vapor	Results-PPM (exposure concentration)	ppbRAE- PPM Reading
	Chemistry	Biochem Tech	AL5190	Alcohol	ND*
Area		AL5189	ND*		<10
Hallway		AL5188	ND*		<10
Urinalysis	Urinalysis Tech	FH3560	Formaldehyde	ND*	NT*
	Area	FH3562		ND*	<.001
	Hallway	FH3555		ND*	<.001
Blank	FH3569		Formaldehyde	ND*	N/A
	AL5179		Alcohol	ND*	N/A

Table 4- IH Monitoring Results (Surgical Services)

Sterilization Area	Area/ Employee	Badge #	Vapor	Results-PPM (exposure concentration)	ppbRAE- PPM Reading
	Sterilization Area	Dirty Area	FH3556	Formaldehyde	ND*
Dirty Area (Hallway)		FH3565	ND*		<.001
Sterilizer Room		FH3563	ND*		<.001
Sterilization Tech #1		FH3557	ND*		NT*
Sterilization Tech #2		FH3570	ND*		NT*
OR and PACU	Anesthesiologist #1	VB9328	WAGs	ND*	NT*
	Anesthesiologist #2	VB9321		ND*	NT*
	CRNA #1	VB9327		ND*	NT*
	CRNA #2	VB9323		ND*	NT*
	Anesthesia Machine	VB9317		ND*	NT*
	Area	VB9325		ND*	NT*
	Area	VB9320		ND*	NT*
Field Blanks		FH3559	Formaldehyde	ND*	N/A
		VB9322	WAGs	ND*	N/A

Waste Anesthetic Gases (WAGs): Sevoflurane/ desflurane/ isoflurane

5.0. Recommendations (HGPS)

Table 5- U.S. Federal Standards

Vapor	Xylene	Isopropanol(I)	Methanol(M)	Ethanol(E)	Formaldehyde
8 hour TWA	100	400	200	1000	0.75
STEL (15 mins)	150	500	250	N/A	2

WAG Vapor	Ceiling Limit (1 hour)
Sevoflurane	2 ppm
Desflurane	2 ppm
Isoflurane	2 ppm

The following findings and recommendations are based on U.S. Federal exposure standards (Table 5):

- **Discontinue the practice of diluting formaldehyde to formalin.**
- **Discontinue the use of faulty sterilizer (formaldehyde), as leaks have taken place. Otherwise, provide adequate personal protection to staff, to include respiratory protection to be used while the sterilizer using formaldehyde is in use. Currently, staff are provided with half-face air purifying respirators.**
- **Provide adequate hand and skin protection, to include gloves that adequately protect from solvents.**
- **Morgue Tech:**
 - Potentially overexposed to formalin.
 - Therefore, we recommend the following controls:
 - Discontinue the use of N-95 respirators and use NIOSH-approved respirator for formaldehyde/formalin.
 - Do not perform formalin/biological tissue separation task. Dispose of waste as hazardous waste or via separate waste streams under

local exhaust ventilation or provide adequate personal protection, including respiratory protection, to staff performing this task.

- Install local exhaust ventilation or this morgue area should be completely negative to adjacent areas.
- Repeat IH monitoring once above is completed or when process changes.

- **Histology Tech:**

- Potential above normal exposure to isopropanol and potential fire hazard.
- Therefore, we recommend the following controls:
 - Histology tech's task required local exhaust ventilation. This ventilation is to be directly vented outside the building. Current fume hood does NOT vent directly outside. In addition, this hood does not have the necessary filtration for VOCs or flammables. Furthermore, it was indicated that current filters are not replaced.

- Repeat IH monitoring once above is completed or when process changes.



6.0. Conclusion

In conclusion, the Dominican Republic's landmark *Reglamento de Seguridad y Salud en el Trabajo, Decreto 522-06* (Health and Safety in the Workplace Act of 2006), has set out to make major improvements within the workplace. This Act regulates some hazards within the workplace and requires employers to establish risk prevention initiatives, to include program management, in order to prevent illnesses and accidents within the workplace.

Even though this Act makes noticeable advancements, it lacks specific guidelines to protect workers from potential exposure to known carcinogens, such as formaldehyde. As one of the biggest formalin/formaldehyde-using industries healthcare organizations have little to no guidelines on how to properly use, store and ultimately dispose of this

known human carcinogen. The exposure assessment and monitoring performed in one of the country's largest hospital, Hospital General de la Plaza de la Salud, shows the urgent need to include this known human carcinogen in the Act's *Tabla Indicativa y No Exhaustiva de Valores Limite* (ACGIH TLV-TWA). In addition, similar to OSHA's Formaldehyde standard (29 CFR 1910.1048), the Act needs to provide specific guidance on how to properly protect workers.

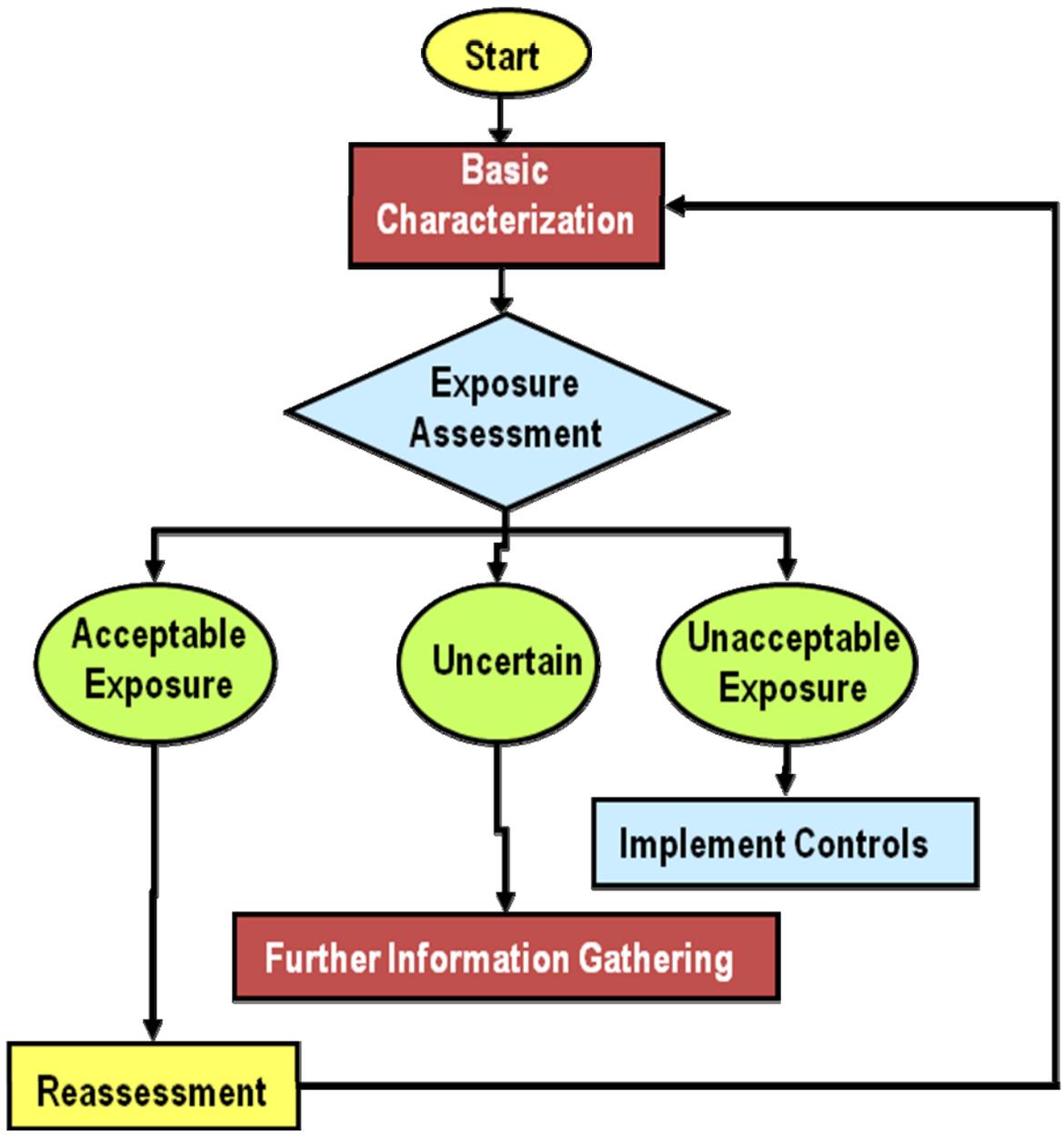
The above was evident by the existing current practices that place employees of Hospital General de la Salud at risk of being overexposed to formalin and other VOCs. In addition, the lack of regulation and guidelines provides a challenge for employees to adequately recognize potential hazards and for employers to know how to properly provide the necessary protection.

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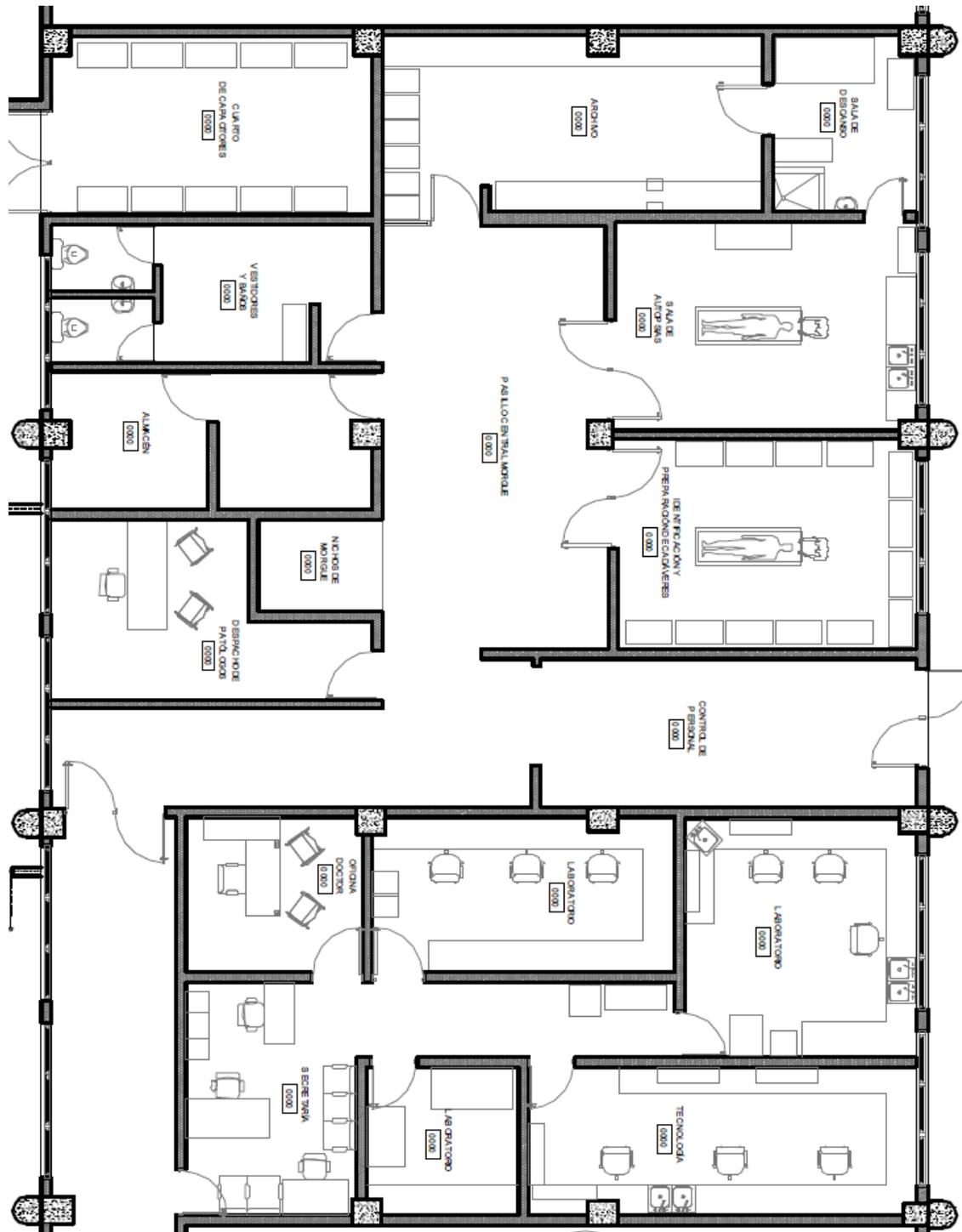
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Appendix A:

Strategy Assessing and Managing Occupational Exposures (3rd edition AIHA)



Pathology Department (HGPS)



Clinical Laboratory Area (HGPS)



Appendix B:

OTM-Comparing to PELS

- **Equation II:1-6C**

- 10,000 PPM = 1%

Since
$$\text{ppm}_{\text{NTP}} = \frac{\text{mg/m}^3 \times (24.45)}{(\text{Mwt})}$$

$$\text{ppm}_{\text{PT}} = (\text{ppm}_{\text{NTP}}) \times \frac{(760)}{P} \frac{(T)}{298}$$

Where:

24.45 = molar volume at 25°C (298°K), 760 mm Hg

Mwt – molecular weight

NTP = Normal Temperature & Pressure, 25°C, 760 mm Hg

PT – Temperature in Kelvin & Pressure at conditions

Laboratory Analysis information:

Methods of analysis:

- Modified OSHA #103 (WAGs)
- Modified OSHA #1400 (Alcohols)
- NIOSH # 2016, OSHA#1007 (Formaldehyde/formalin)
- Modified NIOSH# 1501 (Xylene)

Overall System Accuracy (OSA):

- Isopropanol: +/- 12.28%
- Ethanol: +/- 11.47%
- Methanol: +/- 10.07%

- Xylene: +/- 5.65 %
- WAGs:
 - +/- 7.23% (Sevoflurane)
 - +/- 6.81% (Desflurane)
 - +/- 10.89% (Isoflurane)
- Formaldehyde: +/- 9.40%

Lowest Detectible Limit: 0.02 ppm (for all Vapors)