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Journal of Atlantic Research and Technology

Professional hazards assessment at the Materials, Nanotechnology and Environment Laboratory (MNEL) using the Failure Mode Effects and Criticality Analysis (FMECA) method.

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ARTICLE INFO

Article history:
Received 25th January, 2024
Received in revised form 26th March, 2024
Accepted 27th March, 2024
Available online 1st April, 2024

Keywords:
Materials
Environment
Bioactive substances
biological activities
Nanotechnology

ABSTRACT

The Materials Nanotechnology and Environment Laboratory (MNEL) is a scientific workplace in phytochemistry responsible for extracting and valorizing researching bioactive substances around medicinal plants by researchers and chemical analysis for their scientific work (determination of chemical and biological activities, dosage of bioactive compounds, chemical synthesis, etc.). This work environment is considered to be a high-risk one, considering that it has a lot to do with being exposed to all kinds of chemicals and reagents, thus it is crucial to identify and control these risks. In this study, we tried to investigate and manage these risks by applying the risk management method FMECA (Failure mode effects and criticality analysis), in which we analyze qualitatively the whole process in order to determine the failure modes, the causes, and their effects, and in the same time rate criticality based on the parameters of frequency of occurrence, severity, and detection so we can have a quantitative analysis of each of the failure modes.

1. Introduction

The analysis carried out at the Materials, Nanotechnology and Environment Laboratory (MNEL) are subjected to a potential risk starting from the stages of sampling (pre-analytical phase) until the return of the results to the prescriber (analytical station phase).The risks faced by researchers can result from the contact with chemicals and poison substances, as well as workplace accidents and/or the development of specific diseases known as occupational diseases. An occupational risk is defined as a harm that may be caused to workers' health by the inherent property or capacity of a work equipment, substance or method [1]. One of the risks in the toxicology and pharmacology laboratories (LTP) are those resulting from chemical exposure (corrosion, allergy, cancer, etc.), which represent a serious problem in the occupational environment [2]. Upper and lower respiratory tract exposure to solvents in absence of appropriate preventive safety and control measures is potentially the most significant workplace risk faced at the Laboratory. Additionally, Laboratory workers are exposed to a multitude of risks related to the materials they use and the methods they apply during their work.

The usual activities of the Nanotechnology Materials and Environment Laboratory (MNEL) involve not only the handling of toxic substances, but the utilization of chemical reagents and biological samples. Risk management in the MNEL must be considered as a major field of interest, which aims not only to coordinate or federate regulated health vigilances, but also to implement a global policy of prevention and risk reduction in order to ensure the health safety of the laboratory users [3]. In this regard, the hazard assessment within the MNEL for the handling of drugs and poisons allows to control, as a corrective and preventive measure, the risks of non-conformity that can affect negatively the quality of the chemical activities.

The aim of this investigation is to apply the FMEA tool (Failure Mode, Effects and Criticality Analysis) to improve chemical operations in the laboratory and to raise awareness, directly and indirectly, of the "risk culture". Indeed, the specific objectives of this work are to:
Conduct an inventory, identify hazards, identify potential workplace exposures, suggest an occupational hazard

management plan for the Laboratory and establish a preventive and corrective action plan.

The AFNOR ("French Standards Association") defines risk as any event of which the realization is uncertain and the occurrence is capable to affect the objectives of a project. [4]. This is the frequency of occurrence of a defined problem, within a specific population, and in a dangerous environment, for a specific period of time. Hence, an occupational hazard is identified as a hazard whose intrinsic property or ability of a particular equipment, substance, or work method may adversely affect the health of workers [5].Laboratory risks may vary depending on various elements, including the type of the laboratory, the methods used, the materials employed and the number of workers. Three major types of risks exist in the laboratory : chemical risks, physical risks and biological risks.

Chemical risks: Chemical handling is part of the daily work routine for many chemical laboratory workers, yet the hazards and dangers are still the same. So many organic and inorganic chemicals are skin and eye corrosive and potentially toxic. The identification of the hazards caused by the chemicals allows us to distinguish between explosive, corrosive, oxidizing, flammable, noxious, toxic for reproduction and environmentally hazardous substances [6].

Physical risks: Physical risks are usually defined as those generated by occupational exposure to energy sources. These include risks related to the work environment (heat, noise, vibrations and lighting) and radiation (ultraviolet, infrared, ionizing and electromagnetic radiation).

Biological risks: Bacteria, viruses, parasites and fungi used in the laboratory may result a significant number of biological hazards. All of these materials have the potential to deliver dangerous diseases or allergens that can put the laboratory team at risk [7].

At MNEL, the purpose of the FMECA method is to minimize the criticality of operations associated with analyses. This is done by evaluating the potential failure mode that has an impact on the quality of the results of the analyses and consequently on the care of the patients and personnel. The SH GTA 04 guide of April 4, 2015 highlights the FMECA method for risk control. The guide describes the potential hazards as ones that may provide erroneous, overdue and imprecise results or those accompanied by inappropriate interpretation which may impact the results. Identifying the risks, estimating them according to the FMEA ratings (gravity, frequency, delectability) and prioritizing them are required in the method validation files. The objective is to manage and control the risks by implementing appropriate actions [8].

2. Materials and Methods

2.1. Location and Study Period:

The study was conducted in MNEL during six months, from June 2021 to December 2021.

2.2. Type of study:

The study based, as planned, on the observation of the personnel (researchers) activity, service structures and the working environment analysis.

2.3. Laboratory structure:

The laboratory is a research unit in analytical phytochemistry whose mission is to extract the polar (polyphenols, flavonoids, tannins, saponins, etc.) and non-polar (fatty acids, sterols, tocopherols, etc.) components of medicinal and aromatic plants, to analyze and dose their bioactive molecules and their chemical and biological activity.

2.4. Population studied:

The study involved the entire laboratory staff, for a total of 26 people, including: chemists (professors and PhD students), laboratory assistants, service agents, and cleaning and collection personnel.

2.5. Data collecting:

The method is an observation based one; considered as a reflection step which is carried out by observing the laboratory personnel during their activities, each one according to his/her profile as well as the places and equipment's.

2.6. Determining the causes and modes of failure:

To identify these, we applied the FMEA method, which produces and arranges the ideas or hypotheses about the possible causes of problems in a process. This analytical process summarizes a wide range of data by demonstrating the relationship and the connections between an event and its cause or possible cause.

2.7. Criticality Index Determination:

Once the rating indices for the different scales have been determined, the Criticality is determined using the following formula:

$$C = F \times G \times D$$

C: Criticality; F: Frequency; G: Gravity and D: Detectability

A decision-making matrix has been elaborated by the workgroup in order to define the levels of risk depending on the level of criticality. In the present paper, the criticality will be marked Ci, which is the criticality index with "i" corresponding to the failure mode number that will be seen more in the rest of the study.

2.8. Risk management plan proposal and re-evaluation of the criticality level following the corrective action:

The corrective recommendation actions were carried out in two phases: A first one in which all the suggestions for enhancement were formulated without delay or considering the context. Then, these different enhancement options were examined by the supervisor of the laboratory in order to match them with the actual context of the MNEL. After evaluation of the criticality levels, all hazards that are in the 3rd criticality class will need corrective actions immediately, and these will be presented in the rest of the work.

3. Results and discussion

Within the analytical process of tracking and observing the risks by applying the FMEA method in MNEL during a period of 6 months, we identified a total number of 26 risks. Among these risks, 7 were identified in the pre-analytical phase during sampling, labeling and transport conditions, and they will be treated according to the plan adopted for this method (table 1).

Therefore, within the analytical phase, 17 risks have been identified in the following stages (table 2):

A. Preparation of samples for extractions and analyses;
B. Extraction;
C. Analysis.

Concerning the post-analytical phase, since we work in a research laboratory that does not have commitments with other organizations or individuals to provide the results of our analyses, we have only three risks that are frequent in this phase (table 3):

We can clearly see that the analytical phase has the majority of risks with a percentage of 68.38% followed by the pre-analytical phase with 26.92% and the post-analytical phase occupies the last position with a percentage of 7.69% (Fig.1).

The analytical phase contains 17 risks out of 26 in total, most of them exceed the level of acceptable criticality, so in order to reduce or eliminate the criticality of these risks, it is necessary to make a total reorganization of our laboratory, from receiving and storing chemicals to recording results and writing our scientific papers, with the need to improve working conditions within the laboratory, by creating logs to record all chemicals and materials arrived at the laboratory (solvent, chemicals reagents, equipment…) including the date and the name of the student or professor assigned to them, in addition to determining the working hours and persons authorized to access the laboratory.

In order to avoid health risks for doctoral students, there must be an internal law for the laboratory that prohibits working without wearing masks, gloves and gowns, as well as noting the date and time of access to the laboratory with the need to create several channels to ventilate the laboratory and install at least two fume hoods for manipulations with acids and products that generate toxic gases. On the other hand, we need to construct a team dedicated to the maintenance and the supervision of the laboratory equipment regularly, and to avoid contamination of our product during the analytical phase, we must ensure that we create, validate and respect a cleaning protocol for the equipment used.

We note that all these actions will be applied in our laboratory to reduce the criticality of the major risks in the different phases and afterwards we will repeat this study to see the impact of our changes on the criticality of risks and the productivity of our team.

Table 1: Pre-Analytic Risk Assessment.

Risk identification and analysis			Risk assessment				Risk actions
	Process	Risk	F	G	D	C	Action to be implemented
Phase	Identification	Absence of request	1	2	1	2	Additional information to be requested from the sampler
		Date and time of the sample are not visible	2	2	1	4	Confirmation and supplementary information to be requested from the sampler
	Sampling	Insufficient sample quantity	1	3	3	9	Request for an additional sample
		Opened or damaged bottle	1	5	1	5	Request for bottle replacement
		Inadequate Sampling Method	1	3	3	9	Reject the sample / Notify the collector
	Labeling	Date and time of samples not listed	1	2	1	2	Request the information from the sampler
		Two or more requests at the same time with the same identity	1	4	1	4	Request for confirmation and additional information from the sampler

Table 2: Analytic Risk Assessment.

Risk identification and analysis			Risk assessment				Risk actions
Phase	**Process**	**Risk**	**F**	**G**	**D**	**C**	**Actions to be implemented**
The Analytical phase	Preparing	Water cut-off during the washing process of the plants to be extracted	1	3	1	3	Checking the conditions before starting
		Contamination from another plant during the milling process	2	4	3	24	Cleaning the machine after every use
		Loose of the plant powder	2	4	1	8	Repeat the process and pay attention to it
	Extracting	Water cut-off during the extraction process	3	3	4	36	Repeat the process and Check the conditions before start
		Electrical power failure during the extraction process	1	3	1	3	Checking the conditions before starting
		Loss of the organic solvent during the extraction process	3	3	3	27	Repeat the extraction and check the cooling water before starting.
		burnt plant extract	2	3	2	12	Repeat the extraction with a sufficient volume of solvent and a lower temperature
		Loss of extract during concentration with the rotary evaporator	2	4	1	8	Repeat the extraction and turn on the air pump before starting the rotation
		Extract insufficient for analysis	2	2	2	8	Check the plant's bibliographic data before starting the extraction.
	Analyzing	Insufficient volume prepared for analysis	2	3	2	12	Repeat the calculation and prepare an additional volume
		Extract insoluble in the solvent described by the analysis protocol	2	2	2	8	Check the purity of the solvent applied and use the ultrasound to facilitate the dissolution
		Malfunction of the micropipette	2	4	4	32	Regular review of the maintenance and calibration of the micropipette
		Contamination with other extracts	1	5	3	15	Separation between extracts during the analyses
		Inhalation of toxic chemicals	4	4	3	48	Wear a mask and work in a fume hood extractor.
		Burns caused by contact with corrosive agents	1	5	1	5	Wear gloves, close the gown and work in a fume hood extractor.
		Uncalibrated balance	3	3	2	18	Regular review of the maintenance and calibration of the balance.
		Unstable baseline in UV-Visible spectrometer	2	3	1	6	Detector lamp change.

Table 3 : Post-Analytic Risk Assessment.

Risk identification and analysis			Risk assessment				Risk actions
Phase	**Process**	**Risk**	**F**	**G**	**D**	**C**	**Actions to be implemented**
The post-analytical phase	**Recording and interpreting the results**	Record data loss	**1**	**5**	**1**	**5**	Save results in paper version.
		Non-significant results	**1**	**4**	**1**	**4**	Check the data record and/or repeat the analysis if necessary.

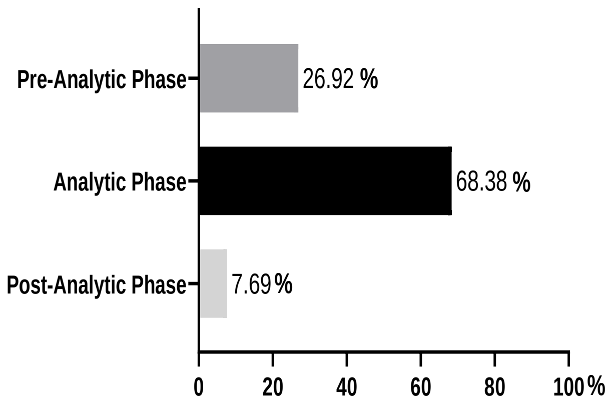

Fig. 1. The criticality percentages of each phase

4. Conclusion

The reliability of the results of chemical analyses implies mastery of the pre-analytical phase which is the first part of the quality circle that begins with the sampling, continues with the execution of the analysis in the laboratory (analytical phase), and ends with the interpretation of the result and the transmission of the result (pre-analytical).

This work has highlighted, using the method, a significant number of risks in the pre-analytical, analytical and post-analytical phase; identification problems, errors related to the prescription sheet, non-compliance with transport and delivery conditions as well as the risk of contamination, etc. This has led to set up a risk management system for the pre-analytical, analytical and post-analytical phase within the, which will contribute to improving quality and safety of patients and staff considered as a major concern.

The risk analysis and assessment allowed to put in place corrective and / or preventive measures based on the use of quality management tools through written control procedures corresponding to the most critical points that were able to identify. Further steps will be taken as the adverse reaction management system is put in place.

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