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ORIGINAL ARTICLE

# Application of Failure Mode and Effect Analysis (FMEA) for Risk Assessment in Marine Laboratories

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## ABSTRACT

**back ground:** Safety awareness and the prevention of hazards are necessary to continue improving the quality of laboratory activities, and today this has been recognized by scientific and industrial communities. Therefore, this study was conducted to determine the risk factors and potential hazards and to provide practical solutions in the marine laboratories of the Iranian Fisheries and Shrimp Research Institute (IFSRI).

**Method:** Safety hazards of eight laboratories were evaluated during this intervention study using the Failure Mode and Effects Analysis (FMEA) technique. In the first phase, a team of HSE safety experts, by preparing and completing safety questionnaire forms, assessed the current condition of the safety indicators and danger points of the laboratories. Based on Risk Severity, Occurrence, and Detection, the Risk Priority Number (RPN) was calculated and prioritized, and accordingly, corrective measures were proposed. After implementing corrective measures, the safety questionnaire was completed again, and the aforementioned safety criteria, such as RPN, of the studied laboratories were calculated and analyzed again.

**Results:** Thirty-five hazard points were identified in the laboratories. The range of risk priority numbers varied from RPN = 12 for the Plankton Laboratory to RPN = 210 for the Marine Microbiology and Marine Pollutants laboratories. After control measures, the risk number of the Marine Microbiology Laboratory was reduced to 180 and Marine Pollutants to 120 ($P < 0.05$).

**Conclusion:** The results showed that the FMEA technique is appropriate for identifying risk factors and reducing the risk in marine laboratories. It is an efficient and effective way to assess and classify risks and to provide control strategies to eliminate or reduce risk in research environments.

**KEYWORDS:** *Risk assessment, Marine laboratory, Safety, FMEA*

## INTRODUCTION

In today's world, occupational health and workplace safety constitute an important field in science. Laboratories are among the workplaces with relatively higher rates of hazards and incidents. These hazards stem from chemical, biological, and physical sources and may lead to explosions, cuts, tears, allergies, eye injuries upon contact with chemicals, fire, cancer, and infections transmitted to humans by microorganisms such as bacteria, fungi, and parasites, as well as poisoning or death by gas inhalation (Adamopoulos and Syrou, 2022). According to statistics published by the International Labor Organization, more than

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2 million people die from workplace incidents and associated diseases each year, of whom approximately 350,000 deaths are caused by fatal on-the-job injuries. The scale of economic losses induced by job incidents is virtually immeasurable. According to statistics from the United States, England, and Norway, rough estimations indicate billions of dollars in losses per year. Should such an incident lead to disability or death, it not only causes psychological harm to the personnel and their families but is also recognized as a social harm (Takala, 2002).

On this basis, many organizations have reviewed the health and safety issues of laboratory work (Keith, 2000). As of the writing of this article, more than 70 techniques have been proposed for the qualitative and quantitative assessment of workplace hazards and safety worldwide. These techniques are typically utilized to identify, control, and mitigate the consequences of hazards. The majority of existing techniques are suitable for hazard identification, with their results being well-suited for managerial purposes and decision-making regarding the control and mitigation of consequences. Each industry may use specific techniques depending on its needs.

A major task for any industrial health, safety, and environment (HSE) system is to evaluate different hazard assessment techniques and select the most appropriate one for that particular industry or organization. In general, the chosen method of risk assessment and the depth of such assessments can serve as indicators of the capabilities of the implemented HSE management system in the corresponding industry. Various techniques have been proposed for hazard identification and assessment. Examples of such techniques include Management Oversight and Risk Tree (MORT), Energy Trace & Barrier Analysis (ETBA), Preliminary Hazard Analysis (PHA), Hazard and Operability Analysis (HAZOP), Operational & Support Hazard Analysis (O&SHA), and the ELMERI technique (Malakoutikhah et al., 2019).

Among these techniques, Failure Modes and Effects Analysis (FMEA) emerged in the 1950s in response to the growing importance of safety issues and the prevention of foreseeable incidents in the aerospace industry. Later, this technique was adopted to enhance safety in processes within the chemical industry. FMEA is based on the principle of primordial prevention and works by identifying potential sources of error. In this methodology, the causes of errors and hazards are ranked and analyzed using the Risk Priority Number (RPN), which is a combined measure of severity, occurrence probability, and detectability (Haimes, 2009; Kazemi et al., 2019).

Depending on available financial resources and economic conditions, technological limitations, human factors, managerial strategies and policies, and background risks (e.g., hidden risks), the admissible level of risk may differ from one individual or organization to another. In a study conducted at the University of Tehran, the effect of implementing an Integrated Management System (IMS) on safety performance indicators was investigated using risk assessment via the FMEA technique in a factory in Yazd, Iran. The results showed that implementation of the IMS could significantly affect the safety risk assessment indicators identified through FMEA, thereby improving the overall safety level of the studied factory (Fallah Madvari et al., 2018).

The Iranian Fisheries and Shrimp Research Institute (IFSRI) possesses more than five decades of research experience in marine studies and aquatic farming, especially shrimp. In line with its organizational mission and to achieve its predefined objectives, IFSRI has been equipped with independent specialty laboratories in marine microbiology, pathology, molecular genetics, marine physio-chemistry, marine contaminants, plankton studies, benthos and sedimentology, and aquatics bioassay. The most important activities undertaken in these laboratories include microbial analyses of water, sediment, and aquatic samples; preparation of pathology slides; molecular assays; analysis of nutrients and contaminants; characterization of planktonic colonies and benthos; and investigation of particle size distribution in sediments. The molecular genetics, plankton studies, and pathology laboratories of IFSRI have been certified under ISO/IEC 17025, with the relevant requirements further implemented in other laboratories of the institute (Samani, 1389).

According to the first revision of the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC 17025 – Rev.1), which is a noncompulsory specialty standard code elaborating on the quality management system of testing and calibrating laboratories, the subject of safety and hazard assessment in testing laboratories is not thoroughly covered and is rather minimally addressed (Standard ISO/IEC, 2007). Since the health and safety of laboratory personnel are of paramount importance, systematic protection and safety have become a necessity in the laboratories of the IFSRI. On this basis, the present research was conducted to identify and assess hazards in the laboratories of the IFSRI using the FMEA method, in order to mitigate the risk of such hazards and quantify the level of risk before and after corrective measures.

## MATERIALS AND METHODS

This research involved an interventional study conducted at eight laboratories: Pathology, Marine Pollutants, Plankton Studies, Sedimentology & Benthic Analysis, Aquatics Bioassay, Molecular Genetics, Marine Physical Chemistry, and Marine Microbiology. The study was carried out during 2014 (prior to implementing the control measures) and 2015 (after implementing the control measures).

## ASSESSMENT PROCESS WITH FMEA TECHNIQUE

*1. Building a team for risk analysis*

Firstly, a team of experienced technical managers of the laboratories and the HSE consultant was built.

*2. Collecting the process-related information and identifying potential hazards*

Through visits to the studied laboratories, the team considered all activities, processes, potential risk factors, environmental hazards, equipment-related hazards, material-associated hazards, human-related risks, and other risk factors. They further analyzed the various states of each hazard, resulting in an HSE checklist of 35 equipment-related, workplace-related, and physical hazards, along with associated test methods and human factors for each laboratory (Table 1). For each hazard on the HSE list, the presence, absence, or applicability to each laboratory was then evaluated.

*3. Risk analysis*

At this step, three components of risk assessment, including severity, occurrence probability, and detectability, were calculated by forming a 10-state matrix with a 1 – 10 scale (Tables 2 – 4) (Mccollin, 1999; Liu *et al.*, 2013).

***Table 1.*** HSE checklist of laboratories

| NO | Potentially effective factors in creating risk |
|---|---|
| 1 | Safety hood |
| 2 | Guidelines for the protection and safety of employees |
| 3 | Sterilization and disinfection instructions |
| 4 | Waste disposal instructions |
| 5 | Separation of waste |
| 6 | Instructions on how to wash glassware |
| 7 | Safety instructions for working with centrifuges |
| 8 | Proper storage of hazardous materials in the laboratory |
| 9 | Optimum safety of dangerous tools |
| 10 | Electromagnetic radiation |
| 11 | Fire hazard |
| 12 | Fire extinguisher cylinders |
| 13 | Fire alarm detectors |
| 14 | Automatic fire extinguishing systems |
| 15 | People trained in the field of fire |
| 16 | MSDS sheets |
| 17 | Safety posters and warning signs |
| 18 | First aid box |
| 19 | Emergency exit ways |
| 20 | Personal protective equipment |
| 21 | Emergency shower |
| 22 | Eyewash machine |
| 23 | Passing labor safety training courses in the laboratory |
| 24 | Registration and reporting of dangerous incidents |
| 25 | General ventilation |
| 26 | Calibration of the equipment used |
| 27 | Good condition of warehouse safety |
| 28 | Proper arrangement of chemicals in the warehouse |
| 29 | Risk of falling objects |
| 30 | Good state of general cleanliness |
| 31 | Appropriate lighting for the laboratory |
| 32 | Autoclave safety condition |
| 33 | Gas hose safety devices |
| 34 | Good workplace discipline |
| 35 | Vaccination of personnel |

***Table 2.*** Severity Ranking (S)

| Ranking | Effect | Process FEMA Severity |
|---|---|---|
| 10 | Hazardous- no warning | May danger machine or operator without warning |
| 9 | Hazardous- warning | May danger machine or operator with warning |
| 8 | Very High | Major disruption in operations (100% scarp) |
| 7 | High | Minor disruption in operations (may require sorting and some scrap) |
| 6 | Moderate | Minor disruption in operations (no sorting but some scrap) |
| 5 | Low | Minor disruption in operations (portion may require rework) |
| 4 | Very Low | Minor disruption in operations (some sorting and portion may require rework) |
| 3 | Minor | Minor disruption (some rework but little effect on production rate) |
| 2 | Very Minor | Minor disruption (minimal effect on production rate) |
| 1 | None | No effect |

***Table 3.*** Occurrence Rankings (O)

| Ranking | Effect | Failures Rates |
|---|---|---|
| 10 | Extremely high-The risk is almost unavoidable | >1 in 2 |
| 9 | | 1 in 3 |
| 8 | Very high- Recurring risks | 1 in 8 |
| 7 | | 1 in 20 |
| 6 | Marginal- Case risks | 1 in 80 |
| 5 | | 1 in 400 |
| 4 | | 1 in 2000 |
| 3 | Low | 1 in 15000 |
| 2 | | 1 in 150000 |
| 1 | Remote | <15000000 |

***Table 4.*** Detecting Ranking (D)

| Ranking | Design FEMA Detection | Process FEMA Detection |
|---|---|---|
| 10 | Absolute uncertainty | Control cannot detect potential cause and subsequent failure mode |
| 9 | Very remote | Very remote chance the control will detect potential cause and subsequent failure mode |
| 8 | Remote | Remote chance the control will detect potential cause and subsequent failure mode |
| 7 | Very low | Very low chance the control will detect potential cause and subsequent failure mode |
| 6 | Low | Low chance the control will detect potential cause and subsequent failure mode |
| 5 | Moderate | Moderate chance the control will detect potential cause and subsequent failure mode |
| 4 | Moderately high | Moderately High chance the control will detect potential cause and subsequent failure mode |
| 3 | High | High chance the control will detect potential cause and subsequent failure mode |
| 2 | Very high | Very high chance the control will detect potential cause and subsequent failure mode |
| 1 | Almost certain | Control will detect potential cause and subsequent failure mode |

*4- Calculate the Risk Number and Risk Priority Number*

At this stage, the Risk Number (RN) and Risk Priority Number (RPN) of each laboratory were calculated according to the following formulas: The Risk Number is the product of two values—Severity (S) and Occurrence (O)—and ranges from 1 to 100.

$RN = S \times O$

The risk priority number is the multiplication of three numbers: severity (S), occurrence (O), and probability of detection (D).

$RPN = S \times O \times D$

*5. Hazard prioritization*

At this step, all hazards were prioritized based on their Risk Priority Number (RPN), with higher-priority analyses assigned to risks with higher RPNs. Accordingly, corrective measures were prioritized, as

***Table 5.*** Classification of risk number*

| O/S | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | N | N | N | N | N | N | N | N | C | C |
| 2 | N | N | N | N | N | N | 10 | 8 | C | C |
| 3 | N | N | N | N | 10 | 7 | 6 | 5 | C | C |
| 4 | N | N | N | 8 | 6 | 5 | 4 | 4 | C | C |
| 5 | N | N | 10 | 6 | 5 | 4 | 3 | 3 | C | C |
| 6 | N | N | 7 | 5 | 4 | 3 | 3 | 2 | C | C |
| 7 | N | 10 | 6 | 4 | 3 | 3 | 2 | 2 | C | C |
| 8 | N | 8 | 5 | 4 | 3 | 2 | 2 | 2 | C | C |
| 9 | N | 7 | 5 | 3 | 3 | 2 | 2 | 1 | C | C |
| 10 | N | 6 | 4 | 3 | 2 | 2 | 1 | 1 | C | C |

S = Severity, O = Occurrence, N = Corrective measures is not required, C = Corrective measures is required (if the risk detection probability is equal to or greater than the number in the table)

***Table 6.*** Ranking of control measures to reduce or eliminate risks

| Risk rank | Control measures |
|---|---|
| Low | It can be ignored |
| Moderate | Maintain existing control measures |
| High | In the future, control measures should be implemented. |
| Very High | Control measures should be implemented as soon as possible. |

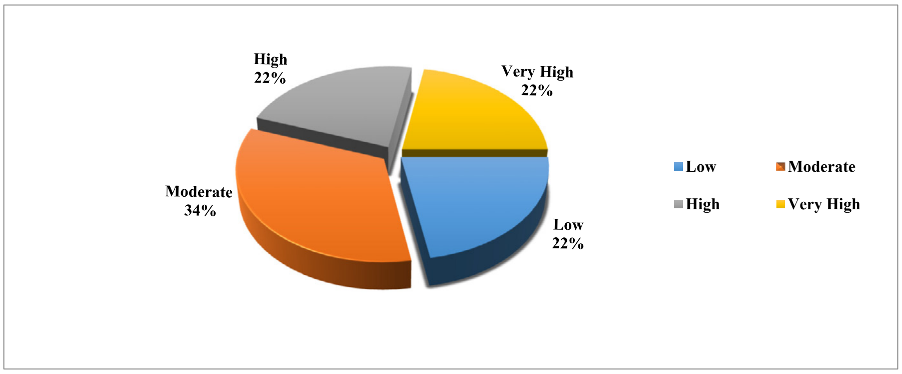


***Figure 1.*** Distribution of the risk ratings of the ISRC laboratories before the control measures

reported in Table 5 [10].

*6. Proposing controlling and corrective measures*

The corrective measures listed in Table 6 were proposed to the managers of the IFSRI and technical associates at various laboratories in an effort to eliminate the root causes of risks, mitigate the severity of consequences, increase the detectability of hazards, and enhance employees' satisfaction with safety conditions (Liu et al., 2013).

*7. Calculating the RPN and risk priorities following the controlling and corrective measures*

Following the implementation of the corrective measures by the technical associates at the laboratories, the HSE checklist was recompleted, and severity, occurrence probability, and detectability of different hazards, along with the RPN (risk number) and percent reduction of the RPN, were calculated through the following equation. This enabled us to statistically analyze the change in the RPNs upon implementing the controlling measures via the paired-sample t-test, as compared to those before implementing such measures.

$$\frac{\text{Initial RPN} - \text{Final RPN}}{\text{Initial RPN}} = \text{Reduction of RPN (\%)}$$

## RESULTS

According to the findings, prior to implementing the controlling measures, the highest RPN was attained by the laboratories of Marine Microbiology and Marine Pollutants (RPN = 210), followed by the Marine Physical Chemistry Laboratory (RPN = 150), and then Molecular Genetics (Extraction), Sedimentology & Benthos Studies, Pathology, Molecular Genetics

***Table 7.*** Risk priority number and risk rating of laboratories before and after control measures

| No | Laboratory name | RPN | | Risk rank | |
|---|---|---|---|---|---|
| | | After control measures | Before control measures | After control measures | Before control measures |
| 1 | Pathology | 18 | 45 | Low | Moderate |
| 2 | Marine pollutants | 120 | 210 | Moderate | Very High |
| 3 | Plankton studies | 8 | 12 | Low | Low |
| 4 | Sedimentolgy & Benthos | 48 | 72 | Moderate | Moderate |
| 5 | Aquatics biometry | 8 | 12 | Low | Low |
| 6 | Molecular genetics (extraction) | 48 | 120 | Moderate | High |
| 7 | Molecular genetics (electrophoresis) | 8 | 28 | Low | Low |
| 8 | Marine physical chemistry | 80 | 150 | Moderate | High |
| 9 | Marine Microbiology | 150 | 210 | High | Very High |

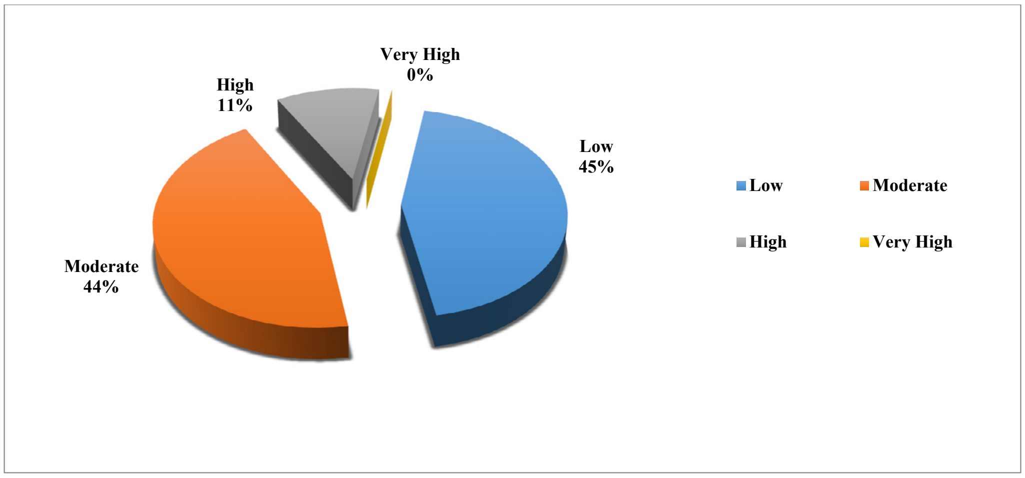


***Figure 2.*** Distribution of the risk ratings of the ISRC laboratories after the control measures

(Electrophoresis), Plankton Studies, and Aquatics Bioassay Laboratories (Fig. 1 and Table 7). Following the implementation of the controlling measures, the RPNs of the Microbiology and Pollutants Laboratories dropped to 180 and 120, respectively, while the Physical Chemistry Laboratory ended up with a reduced RPN of 80. Molecular Genetics (Extraction) and Sedimentology/Benthos Studies Laboratories exhibited an RPN of 48, the Pathology Laboratory showed an RPN of 18, and Molecular Genetics (Electrophoresis), Plankton Studies, and Aquatics Bioassay Laboratories were found to exhibit RPNs as low as 8. Before the controlling measures, only 22% of the laboratories had low risk ratings, while implementation of the controlling measures increased the share of low-risk laboratories to 45% (Fig. 1, 2 and Table 7). The RPN showed significantly different values before and after implementing the controlling measures ($p < 0.05$).

## DISCUSSION

Risk assessment in laboratories of the IFSRI was performed through the FMEA. In this study, implementation of low-cost controlling measures (e.g., codification of four protocols on personnel protection and safety, washing glass-made equipment, sterilization, and waste segregation and disposal; setting up a banner containing material safety datasheets (MSDS); recording and reporting hazardous incidents; purchasing fire extinguishers and first-aid kits; repairing the emergency shower; installing a shared eye-washing machine in the corridor; and retraining principles of job safety in the laboratory) in the laboratories of Pathology, Plankton Studies, Aquatics Bioassay, and Molecular Genetics (Extraction and Electrophoresis) reduced the risk level to such a low level that it was practically negligible. In the laboratories of Physiochemistry, Sedimentology and Benthos Studies, and Marine Contaminants, however, the same course of action lowered the risk level to a moderate level, where the controlling measures should be maintained. In the Microbiology Laboratory, the risk level dropped from very high to high, calling for further controlling actions in the future. Results of this assessment pointed out two groups of imperfections across the entire laboratory system, including

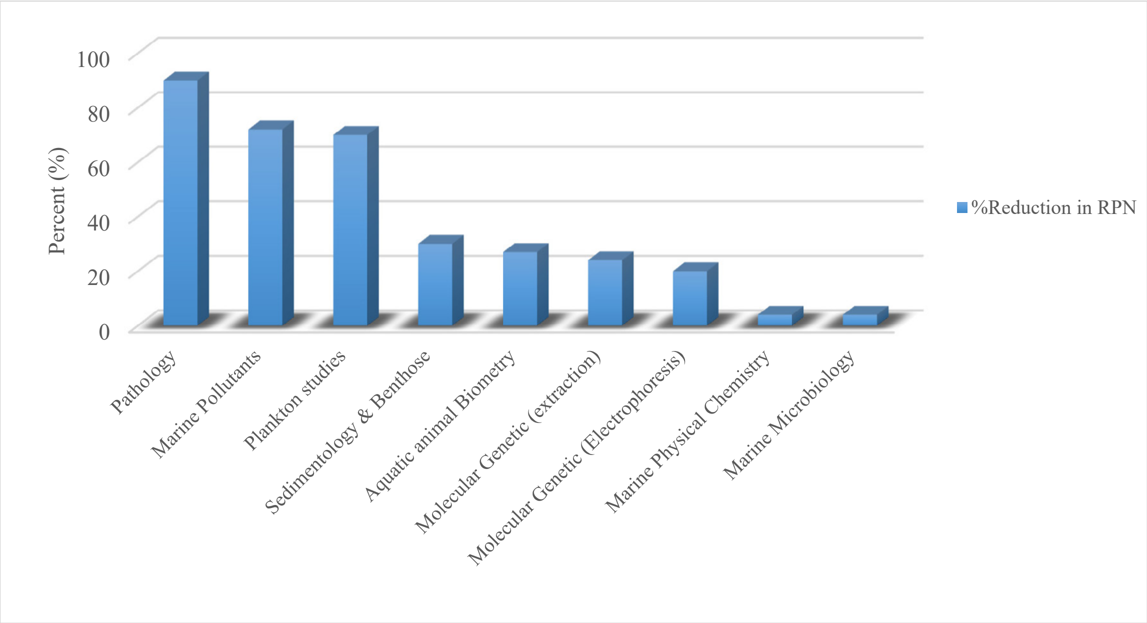


***Figure 3.*** Reduction of risk priority number after corrective measures

structural imperfections caused by financial constraints and organizational imperfections caused by lack of awareness and training among personnel. The following are examples of non-addressed structural imperfections in the system: autonomous fire extinguishing system; a separate room for the autoclave equipped with an ejector plate; piping to transfer the gas capsule to an outdoor space beyond the laboratory facilities; an appropriate warehouse with suitable ventilation and other standard conditions; and a canopy hood for the Sedimentology and Benthos Studies Laboratory. Focusing on human resources, employment of well-trained individuals or training of current employees was planned. Another issue reported by the HSE team in most laboratories was the lack of awareness, forgetfulness, or failure to observe safety requirements by experts, despite their knowledge of the possible hazards.

Various techniques have been proposed for assessing the risk of hazards in laboratories and other workplaces. In a descriptive-analytic study on laboratory-associated hazards at Yazd University of Medical Sciences (2010), it was found that the majority of imperfections stemmed from managerial mistakes, followed by inadequate ventilation, lack of adequate heating/cooling systems, absence of safe work protocols, and physical space deficiencies, among other causes (Halvani et al., 2011).

According to a study conducted at the Sun Air Research Institute of Ferdowsi University (Mashhad, Iran), where health and safety hazards were assessed using FMEA, the applicability of this technique for identifying and assessing job-related risks in research-oriented workspaces was confirmed, as it helped the HSE team formulate controlling solutions (Karami, 2020).

In the training–research laboratories of Shahid Beheshti University, researchers' on-the-job exposure to harmful chemicals was subjected to risk assessment. Beginning with the calculation of the initial concentration of all chemicals, the primary risk factors, coupled with the physical and chemical properties of the materials, were used to calculate secondary risks based on the respective tables published by the National Occupational Health and Safety Commission of Australia. Investigations showed that 93% of the occupational exposures were associated with moderate risks, while only 7% of the exposures were of low risk.

The laboratories of the Faculty of Health and Molecular Biology were associated with the highest levels of risk, while the Immunology Laboratory was the safest premise (Malakouti et al., 2010). Mirabelli et al. (2011) assessed the risk of exposure to formalin solution for students and lecturers. They reported that observation of controlling and corrective measures (wearing personal protective equipment, improving the air conditioning system, and repairing the hood conduits) can not only provide practitioners with convenient working conditions but also reduce occupational health problems and prevent particular diseases among students and academic staff at the Anatomy Laboratory (Mirabelli et al., 2011). This suggests that the mentioned values (i.e., RPNs) may differ depending on the methodology used for risk assessment. That is, we might end up with significantly different results for the risk assessment at IFSRI should the laboratories be assessed based on chemicals and their dosages.

In an investigation conducted at a Chinese university in 2009, the authors concluded that the laboratory safety regulations in that country were significantly inadequate, leading to the introduction of new regulations for laboratory safety (Lu et al., 2009; Mao et al., 2009; Yang et al., 2022). Similar to the current work, the Chinese researchers reported a significant reduction in risk levels following the codification of safety protocols and their retraining to laboratory experts in many laboratories. It can be stipulated that even low-cost controlling measures can reduce the level of risk. Another piece of evidence supporting this finding was the significant increase in detectability from very low to very high in the Electrophoresis Laboratory. The main reason behind this improvement was the proper and regulated maintenance of hazardous materials after implementing the controlling measures. As a system ages, it becomes more difficult and costly to implement changes for risk mitigation—this fact underscores the importance of risk prioritization.

## CONCLUSION

One should note that hazards are not always detectable to employees in a laboratory, and negligence of health and safety regulations can lead to serious consequences. A safety policy can be successful when its sequence of initiation, continuation, and implementation is supported by a responsible manager with sufficient authority, whose responsibility begins at the design stage of the laboratory and the startup of the apparatus. In the present research, laboratory hazard assessment was conducted using the FMEA technique as a foundational approach. With the imperfections of the laboratories identified through FMEA, effective corrective and controlling measures can be formulated. Therefore, the FMEA technique can play a significant role in the management of laboratory hazards/ risks.

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