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Appropriateness Criteria for Choosing Proper Risk Assessment Model of Nanomaterial Manufacturing Processes

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The importance of risk identification and assessment of manufacturing processes is well known and it is doubled for unknown products and technologies such as nanotechnology. Whensoever a new technology is offered there are major concerns regarding its potential risks and hazards. So many methods like CHECK LIST, FMEA (Failure modes and effect analysis) and FTA (fault tree analysis) have been yet proposed for risk assessment in the industries, each, in turn, is effective in particular cases. The question is now what kind of technical, social and organizational parameters should be considered through selecting proper model for nanotechnology risk assessment. Study ahead, aims at determining the role of parameters involved in selecting appropriate risk assessment model of nanomaterial manufacturing processes. Accordingly, by examination of all features of common risk assessment methods listed in ISO31000 as well as the opinions of expertise, a pattern was recommended for choosing proper risk assessment model in nanomaterial manufacturing processes. The statistic society was all the active manufacturers of nanomaterials participated at The Third International Festival and Exhibition on Nanotechnology held on November 28, 2010 in Iran. The obtained results indicated that due to the small size of production units of nanomaterials and lack of being organized in such production units, the research hypothesis was rejected for the statistic society. Therewith, presenting an identification model for proper risk assessment methods of nanomaterials manufacturing process were considered meaningless regarding to the current circumstance.

Key Words: Nanomaterial, Manufacturing processes, Nanotechnology, Check list, Failure modes and effect analysis, Fault tree analysis.

INTRODUCTION

Considering nanotechnology is a novel knowledge, much attention has recently been focused on it[1,2]. This technology is a new approach in all disciplines and has ability to produce new materials and tools by manipulating matters at atomic and molecular levels[3-7]. Nowadays, application fields of this technology are expended to all sciences and it has found interdisciplinary popularity[8]. The range of nanotechnology applications in sciences like medicine[9,10], biotechnology[11,12], materials[13,14], physics[15,16], chemistry[17,18] and electronics[19,20] reaches to such an extent that the achievements can be taken into account of major scientific and technological revolutions. On the other hand, after each remarkable scientific and technological revolution, human has ever encountered unpredictable incidents and events[21]. In many of these events, the cause of incident is lack of attention to safety, health and environmental risks in early stages of science development[22]. Unknown technologies as well as impacts and aftershocks resulting from application of these technologies have always been a subject expressed through statistics of incidents and diseases caused by these technologies throughout time. It somehow reveals the safety or unsafety of the novel technology. Beside, efforts devoted by scientists and expertise in the areas of control risks associated with new technologies can theoretically prove them in case of being safe and green[23]. However, lack of understanding of risks associated with new technologies is followed by concerns about their social acceptance. In the field of nanotechnology and usage of nanoproducts, frequent efforts and investments have been made to identify risks associated with the technology[24,25]. Thereby, the basic attempt is made to facilitate the public acceptance of community regarding nanotechnology. Deep influence of nanotechnology in various industries has led governments, unions and associations around the world, which are responsible for safety and health affairs to define several projects in this field[2]. They do their best to extract general standards related to nanomaterials and get approval of the competent authorities, although organizations such as ISO have formed committees in this regard. However, one of the essential steps of standardization is risk identification and assessment. On the other hand, risks related to production of nanomaterials are classified in two main areas of production and consumption. These risks mainly include the risks of toxicology, fire, explosion, economic, *etc*. As far as the process of nanomaterials production requires attention to specific technical and organizational criteria it is possible to involve such factors to present a model for risk identification and assessment. By proper selection of risk identification and assessment method can be appropriately identified and assessed risks derived from nanomaterials production or consumption[24]. It is important to note that if the assessment indicates high risk of the product or process, more investment in the field of laboratory researches as well as standard development is justified.

Although most researchers have done studies on the advantages and disadvantages of each technique independently, but due to reasons like usability few models such as PHA, FMEA, HAZOP and FTA are commonly used in risk assessment of industries. Finally, it should be determined that in each of the activities of producing nanomaterials (with its associated risks) which of the risk identification and assessment models listed in ISO 31000 should be proposed.

EXPERIMENTAL

Research workflow: In the first phase of this research study, the common methods of producing nanomaterials were initially studied. Afterwards, features, advantages and disadvantages of these methods were extracted. The features were investigated within the questionnaire *via* phrases; production types, advantages and disadvantages of production method and factors affecting reaction. After completing the questionnaire and submit it to the target statistic society consisting of all the active manufacturers of nanomaterials participated at The Third International Festival and Exhibition on Nanotechnology (November 28, 2010, Iran), reliability and validity of questions content presented in the questionnaire were analyzed. Therewith, a number of questions were edited regarding the results of this analysis.

Nano-materials production methods applied in initial design of the questionnaire are named in the followings:

• Nanoparticle processing in fluids using chemical methods (sol-gel, hydrothermal, sonochemistry, electrochemical deposition, combustion synthesis, *etc*.).

• Nanoparticle processing in gases [physical vapour synthesis (PVS), chemical vapour synthesis (CVS)].

• Nanoparticle processing using mechanical methods.

All the questions in the questionnaire were given an identification code from ‘a’ to ‘n4’ to be analyzed after being exerted in SPSS software. These codes are used to examine the research hypotheses.

Validity calculation of the questionnaire: One of the methods applied for calculating reliability of questionnaires is Cronbach's α coefficient. It is commonly used to measure the internal consistency or reliability of a merriment tool like questionnaire. In such tools the answer of each question can obtain different numerical values. Cronbach's a is defined in the following:

$$\alpha = \frac{K}{K-1}\left(1 - \frac{\sum_{i=1}^{K} \sigma_{Y_i}^2}{\sigma_X^2}\right)$$

where; K is the number of components (K-items or testlets), σ_X^2 the variance of the observed total test scores and $\sigma_{Y_i}^2$ the variance of component i for the current sample of persons.

Determining appropriateness criteria: In order to determine the appropriateness criteria for choosing a proper risk assessment model in nanomaterial manufacturing processes, Delphi method was applied. For this purpose, all information related to the considered manufacturers (*i.e.* the ones who took part at The Third International Festival and Exhibition on Nanotechnology, 2010, Iran) were initially gathered. After primary analyses of the responses, the questionnaire was edited and sent back to the Delphi panelists' mail box. It is worth noting that given the number of nanomaterials manufacturers does not exceed 20 active units in the considered statistic society; intermediate manufacturers (nanomaterials consumers as production food) and researches were invited as well. With frequent follow-up, 37 questionnaires were completed. To analyze the responses, SPSS Software was applied. After distributing the questionnaires at Nanotechnology Exhibition and gathering them, a database of manufacturers and researchers of nanotechnology consisting of 70 electric mails was prepared to be used in further processes of the research. It is noteworthy that literature reviews were quite useful for initial designing of the questionnaires. After tree rounds of Delphi, a consensus was obtained amongst the panel members and the repetition of rounds was terminated.

Proposed pattern for risk identification and assessment: Along with completing the questionnaire, the study of risk identification and assessment methods was initiated. Accordingly, all methods of risk identification and assessment were listed considering ISO31000. Based on this standard and other scientific source, all factors affecting on selection of each method were extracted. Subsequently, the role of each factor in selection of risk identification and assessment method was specified using Delphi method and applying safety and risk assessment expertise. The listed parameters were finalized based on the expertise's opinion in the field of safety science (Table-1). It should be mentioned that T-test was used to examine the research hypotheses.

RESULTS AND DISCUSSION

The results obtained from Delphi Method revealed that the consensus amongst the panel members was obtained after tree rounds; thereby there was no need for further repetition of rounds. Accordingly, after tree rounds of Delphi, the questionnaire was fixed and submitted to the expertise in the form of proposed pattern for risk identification and assessment (PPRIA).

Quantitative analysis of statistical findings in order to use in proposed pattern for risk identification and assessment: For quantitative analysis of statistical findings, responses to each criterion were classified into two types of responses agreed or disagreed. Consequently, responses like 'meaningless', 'completely disagreed', 'disagreed', 'absolutely does not apply' and 'does not apply' were classified as opposite responses

TABLE-1
TECHNICAL PARAMETERS AFFECTING ON CHOOSING PROPER RISK ASSESSMENT MODEL OF NANOMATERIAL MANUFACTURING PROCESSES

Technical criteria	Dependency of risk identification techniques on accurate technical data and maps.
	Capability of risk identification techniques in identification and classification of hardware failure.
	Capability of risk identification techniques in identification and classification of process deviations.
	Appropriateness of risk identification techniques in identification of system tolerability in failures and faults.
	Capability of risk identification techniques in identification of performance of control methods, risk control and recommendations for appropriate control measures.
	Appropriateness of risk identification techniques for industries and complicated processes.
	Dependency rate of method on high experienced technical expertise.
	Capability of risk identification in integration of risks caused by human and hardware in system.

TABLE-2
CRITERIA APPLIED FOR PROPOSED PATTERN FOR RISK IDENTIFICATION AND ASSESSMENT

Checklist	Brainstorming	Delphi method	Interviews	Influence Diagram	PHA	HAZOP	WHAT IF	FMEA	The methods of risk identification and assessment
4	3	2	3	2	3	1	2	1	The ability to run fast
4	3	3	4	2	2	1	2	1	Ease of run
2	3	3	2	4	2	4	3	4	Skill level required for the identification and assessment team
1	2	2	2	3	2	4	3	4	The dependence of the method to accurate technical data and maps
3	4	4	3	4	3	4	3	4	The dependence of the method to high experienced technical expertise
4	4	4	4	3	3	2	4	3	Combination capability of the method dependency to the others
1	3	3	2	3	3	3	4	3	Capability in risk identification, assessment and analysis
4	2	2	1	4	3	2	3	2	The overview the method gives of whole system (the capability to identify the dependency of the system components together)
2	1	2	1	4	3	2	3	3	Capability of risk identification in integration of risks caused by human and hardware in system
3	3	3	2	3	2	3	3	3	Comprehensiveness of risk examination (Imagination of all the possible risks and explore unknowns)
2	2	2	2	2	3	2	2	4	Capability of risk identification techniques in identification and classification of hardware failure
2	2	2	2	3	3	4	2	2	Capability of risk identification techniques in identification and classification of process deviations
1	2	2	1	4	2	3	3	4	Appropriateness of risk identification techniques in identification of system tolerability in failures and faults
2	2	2	2	3	2	3	2	3	Capability of risk identification techniques in identification of performance of control methods, risk control and recommendations for appropriate control measures
2	3	2	2	3	2	4	3	3	Appropriateness of method for industries and complex processes
1	2	2	1	2	2	4	3	4	The ability to quantitative analysis of identified risks
2	3	4	1	2	2	4	2	4	The dependence to define exactly the target and scope of assessment
3	4	4	2	1	2	2	3	2	Capability to evaluate work procedures and activities related to system maintenance
3	2	4	3	2	2	2	2	2	Capability to investigate and identify training requirements for staff
2	3	4	4	1	2	2	1	3	Level of motivation and creativity of individuals to participate in run the method as well as discovery
2	3	2	3	4	2	4	2	3	The method application in concept and design phase (possibility to compare projects)
1	2	3	2	4	2	3	2	4	The method application in development and details reform phase
3	2	3	2	2	2	2	2	3	The method application in the production phase
2	1	4	1	3	3	4	2	2	The complexity of the documentation process
2	4	3	4	2	2	2	2	2	Dependence of expertise to the interactions within and outside the organization
1	1	2	2	3	2	3	2	4	The method cost
59	66	73	58	73	61	74	65	77	Total
19	19	15	22	16	34	17	18	18	Total scores for each method
.32	.28	.23	.37	.27	.44	.225	0.27	0.23	Weight percent for each method

while contrary to the mentioned above responses were categorized as agreed responses. Afterward, for each category, disagreed or agreed responses were summed together according to the criterion. The average of agreed or disagreed responses of all questions associated with each criterion was computed separately. At the end, it was revealed that m % of n polled people are agreed or disagreed with the criterion. Now if the obtained average is a number between 1 % -25 %, the score of one is consider ed for the criterion in table of proposed pattern for risk identification and assessment (Table-2). Likewise, for

TABLE-3
EVALUATION OF THE FIRST HYPOTHESIS

First hypothesis	Tested value = 2.5						
	Statistic (t)	Degrees of freedom	Significant level	Test level	Average	Distance estimation for differences in averages	
						Lower	Upper
Technical parameters	-1.252	30	0.220	0.05	2.35	-0.3940	0.0945

TABLE-4
EVALUATION OF THE SECOND HYPOTHESIS

Second hypothesis	Tested value= 2.5						
	Statistic (t)	Degrees of freedom	Significant level	Test level	Average	Distance estimation for differences in averages	
						Lower	Lower
Social parameters	-.235	26	0.816	0.05	2.46	-0.3612	0.2872

TABLE-5
EVALUATION OF THE THIRD HYPOTHESIS

Third hypothesis	Tested value = 2.5						
	Statistic (t)	Degrees of freedom	Significant level	Test level	Average	Distance estimation for differences in averages	
						Lower	Lower
Organizational parameters	-0.889	34	0.380	0.05	2.40	-0.3287	0.1287

the averages between 25-50 %, 50-75 % and higher than 75 % the scores; 2, 3 and 4 are respectively considered. Subsequently, after column summation of the criteria scores, the weight percent of each criterion was calculated.

Evaluation of research hypotheses: T-test analysis was applied to evaluate research hypothesis.

$$H0 : \mu <= 2.5$$
$$H1 : \mu > 2.5$$

First hypothesis: Technical parameters are effective in selection of risk assessment model for nanomaterials.

H0: Technical parameters have no impact on selection of risk assessment model for nanomaterials.

H1: Technical parameters influence on the choice of nanomaterials risk assessment models.

The average of the technical parameters is less than 2.5 (equal to 2.35). According to the responses valuated in proposed pattern for risk identification and assessment Table-2 (1 = the score '1' is assigned to the answer; "it is completely at odds", 2 = the score '2' is assigned to the answer of "Does not apply", 3= the score '3' is allocated to the answer of "Applies to some extent" and 4= the score '4' is devoted to the answer of "applies completely"), the obtained average reflects the criterion doesn't apply to selection of nanomaterials risk assessment model. T-test results show that as regards sig value is more than 0.05 (0.220) hence, H1 hypothesis is rejected and H0 is confirmed (Table-3). In other words, technical parameters have no impact on selection of nanomaterials risk assessment model.

Second hypothesis: Social parameters are effective in selection of risk assessment model of nanomaterials.

H0: social parameters have no impact on selection of risk assessment model for nanomaterials.

H1: social parameters influence on the choice of nanomaterials risk assessment models.

The average of the social parameters is less than 2.5 (equal to 2.46). According to the responses valuated in Table-2 (1 = it is completely at odds', 2 = Does not apply, 3= Applies to some extent and 4= applies completely), the obtained average reflects the criterion doesn't apply to selection of nanomaterials risk assessment model. T-test results suggested that considering the sig value is beyond 0.05 (0.220) thus, H1 hypothesis is rejected and H0 is confirmed (Table-4). In other words, social parameters have no impact on selection of nanomaterials risk assessment model.

Third hypothesis: Organizational parameters are effective in selection of risk assessment model of nanomaterials.

H0: organizational parameters have no impact on selection of risk assessment model for nanomaterials.

H1: organizational parameters influence on the choice of nanomaterials risk assessment models.

The average of the organizational parameters is less than 2.5 (tantamount to 2.40). Based on the responses valuated in Table-2 (1 = it is completely at odds', 2 = Does not apply, 3 = Applies to some extent and 4= applies completely), the obtained average reveals that the criterion doesn't apply to selection of nanomaterials risk assessment model. T-test results suggested that regarding the sig value which is beyond 0.05 (0.380) therefore, H1 hypothesis is rejected while H0 is confirmed (Table-5). In other words, organizational parameters have no impact on selection of nanomaterials risk assessment model.

Conclusion

Lots of models have been developed regarding the identification and assessment of occupational risks and environmental aspects. The models have long been used in various industries. Through the results of applying these models, risks and consequently the control measures have been prioritized. In other words, the knowledge of safety owes its development to risk assessment techniques. With rapid growth of technology, despite the unknown risks of new technologies, the knowledge of safety must be capable enough to introduce new techniques and procedures to identify and assess potential risks as well as new environmental aspects or enhance or modify the previous methods and techniques. The question now is which model has better performance among such a plenty of models. It is an important issue that should be reviewed with a great deliberation. The findings would be crucial for the industry holders whereas it is not economically justified for organization to identify and assess risks via inappropriate techniques. Misunderstanding of the current situation can bring irreversible disasters.

The present study focuses on presenting comprehensive appropriateness criteria for choosing proper risk assessment model in nanomaterial manufacturing processes. The authors try their best to determine all possible evaluation criteria by strong literature reviews and applying Delphi method. The results obtained from the research ahead can be categorized as follows:

• Technical parameters have no impact on selection of the risk assessment model for nanomaterials, whereas the T-test significance level is greater than 0.05 (0.220).

• Social parameters have no impact on selection of the risk assessment model for nanomaterials due to greater than 0.05 (0.816) significance level of T-test.

Organizational parameters do not have any impact on selection of the risk assessment model for nanomaterials. Because, the T-test significance level is greater than 0.05 (0.380).

As it is evident of findings presented above, the research hypothesis is rejected for the statistic society *i.e.* presenting an identification model for proper risk assessment methods of nano-materials manufacturing process is considered meaningless regarding the current circumstance. The reason could be that most nanomaterial manufacturers are not getting organized as necessary. Given the importance of controlling the risks resulting from nanomaterials, beside, the failures observed based on the research findings on the health, safety and environment aspect among manufacturers of nanomaterials, it is recommended to establish an independent HSE Department at Nano Center of Presidency of the Islamic Republic of Iran-Scientific and Cultural Affairs. The agency will identify and evaluate projects and control health and safety risks to all producers under its coverage. This proposal would be more effective if all the manufacturers could be established in a Nano Manufacturing Complex. It is also necessary to be defined supportive budgets regarding control of health and safety risks among nanomaterial manufacturers. Development a systematic communication between the manufacturers (with each other) and community (public awareness) should be supported by appropriate budget. It is highly recommended that a research group is formed to investigate about presenting a comprehensive model to evaluate the fitness of each risk assessment method regarding various circumstances.

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