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Risk Analysis: A generalized Hazop methodology state-of-the-art, applications, and perspective in the process industry

Análise de Risco: estado da arte da metodologia Hazop generalizada, aplicações e perspectivas na indústria de processos

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ABSTRACT

Introduction: The Hazard and Operability Study is considered a feasible tool to assess risks, where complex technologies, require new strategies to guarantee efficiency, safety, and quality of products. **Objective:** To perform a Hazop publications review, to establish the state of the art, current procedures and perspectives in the pharmaceutical industry. **Method:** Hazop methodology and improvements to satisfy actual needs were structured. Subsequently, its application and integration with other risk tools, and experts systems, were analyzed to define the current approach and future perspectives. **Results:** The review allowed the understanding where models, simulations and specialized software offered adequate support to assess risk in current complex processes. In addition, an efficient definition of causes and consequences depends of expert systems, where simulations acquire experience through the creation of databases, reducing the need of specific process knowledge, which is a typical limitation of the conventional Hazop methodology. **Conclusions:** A review of the Hazop state-of-the-art highlighted the importance to assess risks within the process industry. However, the use of new technologies designed to meet regulatory affairs to guarantee safety and quality principles would require the ongoing improvement of the Hazop methodology, restricting the dependence of specialists, and increasing the use of expert systems.

KEYWORDS: Hazop; Risk Assessment; Process Hazard Analysis; Deviation; Hazard

RESUMO

Introdução: O Estudo de Perigos e Operabilidade (Hazop) é considerado uma ferramenta para avaliação de riscos, na qual tecnologias complexas exigem novas estratégias para garantir a eficiência, a segurança e a qualidade dos produtos. **Objetivo:** Realizar uma revisão de publicações do Hazop, para estabelecer o estado da arte, os procedimentos e as suas perspectivas na indústria farmacêutica. **Método:** O procedimento Hazop e suas adequações para satisfazer as necessidades atuais foram estruturados. Posteriormente, aplicações e integração com outras ferramentas de risco e sistemas expertos foram analisadas para definir a abordagem atual e perspectivas futuras. **Resultados:** A revisão permitiu a compreensão de que modelos, simulações e *software* especializado oferecem suporte para avaliar riscos em processos complexos. Adicionalmente, a correta definição de causas e consequências depende do uso de sistemas expertos, cujas simulações adquirem experiência através da criação de bancos de dados, reduzindo a necessidade de conhecimento específico do processo, que é uma limitação da metodologia Hazop convencional. **Conclusões:** A revisão do estado da arte do Hazop destacou a importância de avaliar riscos dentro da indústria de processos. No entanto, novas tecnologias utilizadas para atender quesitos regulatórios de segurança e qualidade precisam da melhoria contínua da metodologia Hazop, reduzindo a dependência de especialista por meio do uso de sistemas especializados.

PALAVRAS-CHAVE: Hazop; Avaliação de Risco; Análise de Perigo do Processo; Desvio; Perigo

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INTRODUCTION

The fact that the pharmaceutical industry follows one of the highest standards of regulations at national and international levels, because of the impact its products have on human health, is well known. In this case, regulations are used to guarantee the prevention, diagnosis, treatment or cure of a disease, so, levels of safety and efficacy are crucial for obtaining an optimal result under the appropriate treatment scheme[1]. Thus, the pharmaceutical industry has been a major player in the traditional industry, in order to successfully meet the new requirements, with a decisive factor being the promotion of regulatory agencies towards the adoption of new technologies and production methodologies. Analysis and control aimed at reducing the possible negative impact of a nonconforming product on the health of the patient or final user. Considering that health surveillance is the science and activities related to the detection, evaluation, understanding and prevention of adverse events or any other problem related to drugs from the production process to its commercialization, it allows the determination of the safety profile of the drugs being marketed. In this way, adverse reactions, inappropriate uses, therapeutic failures and undetected complications during the drug research stage and production process can be detected. There are several methodologies with the potential to be used in order to guarantee quality of products[2], however, regarding to production process, it is necessary do establish a potential tool that could lead to a feasible process risk analysis. Over the last decade, the process industry has been considerably aided by the use of complex technology, which is responsible for the transformation of raw materials into products. Nevertheless, it is a fact that technological improvement is usually related to unexpected failures, which were not considered during risk assessment in previous or similar processes. In addition, such failures could be ignored and underestimated due to the lack of knowledge or by the incipient application of risk analysis methodologies[3]. Thus, risk management specialists agree that to prevent failures in manufacturing processes is demanding to reduce and eliminate (when it is possible) factors leading to failures. Consequently, the identification and address of failures during the conception and design of projects has become a mission for risk specialists[4]. Defining hazards as the result of the unexpected interaction of components, or operation methods in exceptional conditions, only the integration of specialists' knowledge involved in the project, will guarantee that undesired events in new plant will be avoided[5]. The implementation of control measures is also a common strategy used to guarantee that a process will operate as desired, even if the conjunction of circumstances could lead to failures[6]. This is the main reason they are applying professional experience to analyze particular aspects of a project to assess failures in early stages of projects more frequently[7]. The promotion of effective prevention actions in the design of industrial process facilities follows the application and constant monitoring of international regulations, where international and local standards and Good Engineering Practices (GEP) can be powerful allies. As the structure of these regulatory issues is supported by technical knowledge and wide experience of deeply involved professionals from the process industry[8]. However, the application of such standards is not an easy task to carry out, because only process engineers and managers involved directly in the process or similar facilities can understand the scope and fundament of such regulations and the impact on their processes when applied[9].

Therefore, this is how the hazard and operability studies (Hazop) provides to the group of specialists a structured procedure to develop a risk analysis systematically and comprehensively[10]. Hazop methodology can be defined as a structured and systematic process analysis, which can be applied in early stages of the project such as conception and basic steps until operational and post-operation stages. This methodology is widely used in the process industry to identify and assess failures that may lead to potential hazards for the personnel and equipment involved in the process, as well as to failures that prevent an efficient operation or are responsible for abnormal operations.

The brief history of the hazard and operability study

A group of engineers in the ICI's division of Heavy Organic Chemicals was in charge to develop a preliminary version of the Hazop (HAZard and OPerability) methodology in the mid-1960s[11]. However, it was not until 1974 when the Flixborough disaster in North Lincolnshire, England caused by an explosion at a chemical plant close to the village, in which 28 people died, and at least 36 were injured, ushered the use of risk prevention techniques[12]. Then, a safety course offered by the Institution of Chemical Engineers (IChemE) at the Teesside Polytechnic (now Teesside University), included simple Hazop procedure to support and possibly determine failures that led to the Flixborough incident. As a result, the very first publication considering the Hazop study appeared in the same year[13], and finally the Chemical Industries Association published a first Hazop guide in 1977. Until then, the term Hazop was not used in formal publications.

The major supporter of the Hazop methodology was Trevor Kletz[14]. To perform his work Kletz took advantage of the IChemE course notes (revised and updated) and structured a standard Hazop methodology, which has been used up to recent days.

Thus, the concept which states that the Hazop methodology is a basic technique to identify risks that may occur to the personnel, equipment, the environment and/or the objectives of the organization began to gain strength[15]. Thereby, the technical background that characterized the hazard and operability studies had become an expected part of chemical engineering degree courses in countries like the United Kingdom and the United States of America[16]. Moreover, although this method was initially developed to analyze chemical process systems, later spread to practically any knowledge area.

Application of the Hazop methodology

The Multidisciplinary Team

The execution of an accurate Hazop study requires several technical documents and specific process information. After the data collection, a multidisciplinary team has the responsibility to analyze and design operation documents, such as Piping and Instrumentation Diagrams (P&ID), Process Flow Diagrams (PFD), material flow diagrams, and operating manuals (among others) describing the system under study[17].

Depending on the scope and depth of analysis, a basic multidisciplinary Hazop study team must consider: a) a study leader, responsible for defining the extent of the analysis, define Hazop specialist team, plan and lead the Hazop meetings. b) Project manager, responsible for the design of an Hazop schedule, book meetings, analyze documents and elaborate the Hazop report, follow actions, and monitoring control measurements. c) Process engineer, process specialist in charge of the process under study; d) instrument engineer; e) operation or commissioning engineer. Therefore, the multidisciplinary team should have the specific knowledge of the process and be able to perform identification of potential deviations. This group should also be able to define causes and consequences for all possible deviations from a normal operation that could arise in a unit of the plant and propose actions aiming to reduce the impact of deviations[18]. This is the main reason the multidisciplinary team must have extensive knowledge of design, operation, and maintenance in process plant[19].

The Hazop procedure

After analyzing technical data, the multidisciplinary team should establish the *"primary guide words"* better known as process parameters. In addition, the experience of past events in similar systems is required to justify the identification of *"secondary guide words"* or deviations, and their effect on the system under study[20,21]. After the identification of risks, severity and probability of events, indexes allow to calculate the level of risk of each deviation. An example of a matrix of the most common process parameters and their deviation is shown in Table 1.

Once the identification of unacceptable consequences or risks is completed, a list of recommendations and actions may be required to improve the process or avoid hazards[22]. In Figure 1, the traditional process of the Hazop study considering the relationship between process information and risks identification is shown[23]. Authors followed this process to support the identification of deviations in critical elements to establish priority points for qualification in a facility for recombinant biomass production. The definition of critical points for qualification was performed in response to regulatory requirements created by Brazilian regulatory agencies[24].

As mentioned, the correct application of the Hazop methodology requires a dedicated multidisciplinary team and the discussion meetings usually are a time-consuming process. According to this, a structured procedure must be followed to maintain focus and objectivity along the study. Ericson[23] recommended an easy procedure to follow in order to apply the Hazop methodology:

Table 1. Example matrix of parameters and guide words as the most common deviations.

Parameter	Guide Words						
	More	Less	None	Reverse	Part of	As well as	Other than
Flow	·	·	·	·	·	·	·
Temperature	·	·					
Pressure	·	·	·	·			
Liquid level	·	·	·				
Volume	·	·	·		·		
Mixing	·	·	·				
Composition							·
Reaction	·	·	·	·			·
pH	·	·					

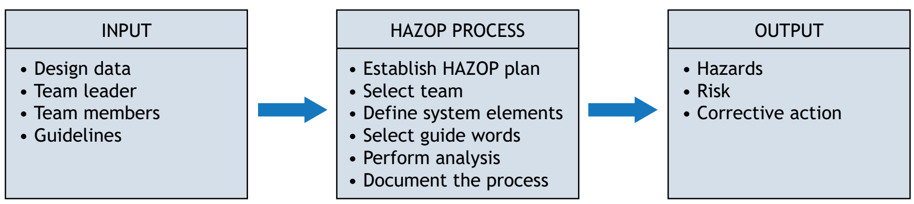

Figure 1. Risk identification procedure using the Hazop methodology.

a. *System Definition*. The first step is to define scope and boundaries of the system.

b. *Planning*. Establish objectives of the Hazop analysis; establish worksheets, schedule, *et caetera*. Divide the system into smaller units for analysis. Items to analyze must be defined.

c. *Multidisciplinary team actions*. Identify a team leader and establish responsibilities for all members. Each member must be a specialist in a technical area related to the process.

d. *Acquire information*. All technical information related to the process or unit must be collected and used for the analysis (P&ID, PFD, manuals, technical descriptions, *et caetera*).

e. *Hazop execution*. Identify items to be evaluated, identify parameters, define a guide word (deviation), establish causes, effects, and recommendations.

f. *Responsibilities*. Assign responsibility to implement actions to reduce risk levels.

g. *Monitoring*. Review the Hazop proposed measures to ensure that actions are implemented.

h. *Document*. Make records of the Hazop process to be used in further analysis.

Finally, the Hazop report should be done, including each of the elements of the methodology, describing the analysis performed by the multidisciplinary team. In Table 2 standard model of the Hazop report is shown.

METHOD

The Hazop methodology in the last decade

Procedure of search and analysis of publications focusing on the methodology

Science Direct is an important bibliographic database of multidisciplinary content from the Elsevier group, providing articles from more than 2,500 scientific journals, and articles from over 11,000 books. In January 2010, more than 9.5 million documents of high scientific quality were accounted, and recently, it was estimated that there are more than 15 million documents, highlighting topics such as Physical Sciences and Engineering, Life Sciences, Health Sciences, Social Sciences and Humanities, among others. Document search is a very powerful and sophisticated tool, which allows to retrieve a large amount of relevant information depending on the terms used in the search. Based on the scope and multidisciplinary of the platform, we restrict the material used for our research considering exclusive articles of Science Direct. In this way, to perform this work, we first define what would be the *keywords* that we would use as input in the search engine. The consensus of the group concluded that we should use in addition to the main word (Hazop), words related directly to "Processes" "New Trends", "Applications", "Procedures", "Health Science", "Pharmaceutical Industry", and "Biotechnology". Finally, the Science Direct system has the ability to filter results considering the relevancy and date of publication. It is important to emphasize that only articles and publications were considered in which the main research topic is the Hazop methodology. As it was observed that several publication mentioned this tool as one of the possible methodologies that could be used, without deepening in its potential application or improvement.

RESULTS AND DISCUSSION

A Hazop retrospective

Since it was created in the mid-1970s, the Hazop methodology has been widely employed in the process industry as a reliable tool for risk assessment. That is why a large number of published papers describing case studies and referring to this methodology have been issued. Swann and Preston[25] described the historical evolution of the Hazop methodology. In their work is presented the use of this methodology since the late 1960's until 1995, being the first paper making this type of research. However, it was not the only work mentioning the historical evolution of publications referring to the Hazop methodology. As a second example, Marhavilas et al.[26] conducted a research on risk analysis and assessment methodologies during a decade, starting in early 2000 until the end of 2009. Finally, Dunjó et al.[27] conducted one of the most intensive research of publications where the Hazop methodology was applied within the process industry since it was conceived (the 1960's) until early 2009.

Table 2. Hazop report layout for risk characterization.

Report No.										
Company				Process		Related Equipment			Date:	
Multidisciplinary team				Process Objective						
Node No.										
ID	Parameter	Deviation	Causes	Controls	Effects	Severity	Frequency	Risk Level	Actions	Responsible
1										
2										
.										
.										
n										

Hazop methodology applications in the last decade

At the end of 2016, an idea of carrying out a review of publications of the Hazop methodology in the last ten years was conceived, aiming to establish its state-of-the-art and perspectives within the process industry. For this reason, the period considered in this work included the decade between 2005 and 2015.

As can be observed in Table 3, 55 articles describing the Hazop methodology as a risk assessment tool were published for this period. Although the number of publications has remained constant through the years, the number of publications increased substantially in the year 2012. A possible explanation of such increase is the use of computer tools and development of simulation models performed by risk specialists aiming to simplify its application and reduce time and resources for its execution. Therefore, it is possible to notice that most of the Hazop publications refer to modeling and simulations that were designed to make easier the process of implementation of the methodology by data processing and automated decision-making. Completing the retrospective of the last decade, in the same Table, the knowledge areas responsible for generating more papers about this subject are shown. It is possible to notice that chemical engineering, computer science, engineering, energy and environmental areas published more papers about the Hazop methodology than the other technological areas[28]. This is not surprising, once this methodology is commonly described as a technique used to detect unsafe situations in industrial plants originated by deviations in equipment and abnormal process operations. Finally, in the same Table are displayed possible applications in not engineering related areas, like business and education, where the use of the methodology helped the identification of deviations, measure risk impacts and promote control actions to reduce the adverse effects of events.

The application of Hazop methodology in industrial processes has not changed its procedure significantly over the years, because most of the Hazop methodology applications aimed to assess risks in critical systems, or when is needed to analyze systems looking for a continuous improvement.

As an example, Hashemi-Tilehnoee et al.[29] identified deviations and proposed measures to reduce risks in a reactor cooling following the traditional methodology procedure. In a similar case, Jose et al.[30] applied the methodology and identified deviations and possible effects during the operational staff performance in an electrical discharge machining process. Added to this, their proposed new approach, which is integrating human and equipment risk evaluation, made possible to preserve the integrity of a system through risk analysis. Johnson[31] suggested in his work that risk

Table 3. Journal publications of Hazop methodology as a subject of study from 2005 to 2015.

2005	Papers	2011	Papers
Process Safety and Environmental Protection	4	*Education for Chemical Engineers*	1
2006		*Process Safety and Environmental Protection*	2
Computer Aided Chemical Engineering	1	*Journal of Loss Prevention in the Process Industries*	1
Journal of Loss Prevention in the Process Industries	1	*Fuel Cells Bulletin*	1
2007		2012	
Computer Aided Chemical Engineering	1	*Computer Aided Chemical Engineering*	4
Tsinghua Science & Technology	1	*Procedia Engineering*	4
Journal of Loss Prevention in the Process Industries	1	*Journal of Loss Prevention in the Process Industries*	2
2008		*Process Safety and Environmental Protection*	2
Computer Aided Chemical Engineering	2	*Computers & Chemical Engineering*	1
2009		*Reliability Engineering & System Safety*	1
Process Safety and Environmental Protection	1	2013	
Computer Aided Chemical Engineering	1	*Computer Aided Chemical Engineering*	1
Computers & Chemical Engineering	1	*Process Safety and Environmental Protection*	1
Journal of Loss Prevention in the Process Industries	1	*International Journal of Hydrogen Energy*	1
Systems Engineering - Theory & Practice	1	*Journal of Loss Prevention in the Process Industries*	2
2010		*Fusion Engineering and Design*	1
Computer Aided Chemical Engineering	1	2014	
Journal of Hazardous Materials	1	*Reliability Engineering & System Safety*	1
Computers & Chemical Engineering	1	*Journal of Natural Gas Science and Engineering*	1
Annals of Nuclear Energy	1	2015	
Process Safety and Environmental Protection	1	*Procedia Earth and Planetary Science*	1
Journal of Loss Prevention in the Process Industries	1	*Journal of Loss Prevention in the Process Industries*	4
		Engineering Applications of Artificial Intelligence	1

reduction could be easily achieved if the impact and frequency parameters are established considering the particular order of magnitude. Through its proposal, a better-assessed risks and the reduction to an acceptable level to attend regulatory requirements was achieved. Mohammadfam et al.[32] presented another case where the application of the hazard and operability study in a fatty acid unit of an oil company allowed assessing environmental health and safety hazards. As a result of their work, authors established a fast and efficiently procedure to identify deviations and promote the implementation of mitigation measures.

Hazop methodology use in early stages of projects (conceptual and basic design preferably) could bring the opportunity to avoid risks and propose response actions in cases where only low levels of risk can be accepted or when economic resources are restricted. It is the case of Hu et al.[33] in which a multi-component systems analysis was used to identify risks. This strategy made possible to conclude that failures in preventive maintenance procedures for critical elements in a multi-component system were easily detected, simplifying the promotion of measures to reduce risks in the equipment involved. The frequency control of events is another common approach to assessing risks. Duisings et al.[34] performed a risk analysis in port plugs of a Hot Cell Facility to identify the weak points of the current maintenance procedures. The specialist group also established design and operational recommendations aiming to prevent risks by reducing the possibility to occur. In an Hazop analysis within the infrastructure of an oil production facility, Pérez-Marín and Rodríguez-Toral[35] showed the general criteria to accept risks for the oil and gas industry in Mexico. Authors also demonstrated that risk behavior is usually ranked in acceptable levels, increasing, in this case, the reliability of the system. They also concluded that the best way to establish risk prevention measures is by analyzing it according to a qualitative methodology. Silvainita et al.[36] also applied the conventional Hazop methodology as a preliminary strategy to investigate the risk-based on decision making of mooring systems. They concluded that after assessing risks, it was possible to identify critical risks and easily propose measures to prevent deviations in order to guarantee the safety of floating structures commonly used in oil and gas industries. The initiative to use the Hazop methodology in a failure analysis of a thermal process of H_2 production facility in silica membrane reactor via methanol steam reforming presented by Ghasemzadeh et al.[37], made possible to determine critical elements of the process. This analysis also allowed perceiving the need to install control devices at key points in the equipment, aiming to increase the detection of failures. Kriaa et al.[38] used the methodology as support to identify critical security related deviations from the intended behavior in digital control systems, maintaining confidentiality, integrity, availability, and authenticity. For Necci et al.[39] the application of an Hazop study was essential to identify the risk of undesirable events in nearby industrial facilities. They also were able to promote actions if such events lead to a "*domino effect*" that could have a negative influence on more than a single process facility.

Considering that risk, specialists commonly agree that the use of more than a single risk assessment tool could lead to a better risk identification and in most cases PHA tools are complementary. In addition, it is possible to notice a rising number of researchers comparing the effectiveness of methodologies. According to the last fact, Rebelato et al.[40] developed a comparative study of the Hazop methodology and the Failure mode and effects analysis (FMEA). The comparison of both methodologies helped to define the most reliable tool in a bioethanol production facility. The team also analyzed the technical benefits of both methodologies, concluding that the Hazop methodology was more efficient to detect technical deviations than the FMEA method.

For most specialists, Hazop methodology is the most feasible tool for identifying risks in chemical facilities. Nonetheless, Baybutt[41] performed a review of the Hazop methodology, establishing the weaknesses of this method that usually risk specialists ignore. Among the major failures, the dependency of profound and specific knowledge about the process that is required by the personnel involved in Hazop studies makes almost impossible the probability to create a multidisciplinary group to assess risks using the Hazop methodology in several and different processes. Kidam et al.[42] also defined the difficulties to apply the methodology in projects during the preliminary design phase. They concluded that initially, the main obstacle to overcome is the lack of technical information about the process that is considered the base to perform Hazop studies.

Therefore, they recommended gathering any available information about similar processes, like documents and recorded data before applying an Hazop methodology. They also remark that the absence of process flow diagrams (which are usually generated only at the basic engineering and detailed engineering phases) are an impediment to applying this methodology in a traditional way. Because the common procedure is based on technical descriptions and recommendations should normally be implemented before the project components started to be built.

Improving the Hazop methodology procedure

The principal advantage of using the Hazop methodology in the design stage of projects is the opportunity to apply risk reduction measures without generating considerable costs for the company. It could be achieved by proposing and implementing measures to reduce impacts on the system before the execution stage (construction), however, risk analysis can also perform an important role during commissioning steps[43]. The process industry has focused lately on the task of establishing parameter selection criteria to guarantee useful definition of the Hazop nodes.

The strategy of select nodes based on their functionality is the new approach that could attend to this premise.

In recent studies, Rossing et al.[44] analyzed the functionality of key elements of a Vapor Recompression Distillation Pilot Plant. The node identification was performed through the analysis of pipe and instrument diagrams (P&ID) in which the specialist team defined four main functional nodes. In another analysis, Wu et al.[45] proved that multilevel flow models (MFM) lead to a fast identification of nodes in a liquid residues treatment plant. According to Mingda et al.[46], this approach was also reliable to analyze system components separately in a dehydration system of Oldfield United station. As a result, it was easy to perform a structured and accurate node identification model, making easier the deviation analysis process.

The Boonthum et al.[47] proposal, establishes a structural model using a matrix from heat and mass balances to define the relationship among all the variables of a system. The creation of this model simplified the identification of existing deviations and the identification of potential risks that were not considered beforehand in previous risk analysis. In highly complex systems like bioreactors used in the biomass generation to produce pharmaceutical supplies, the identification of nodes can be challenging, because of the high number of components that comprise it. O Herrera et al.[24] applied the concept of functional nodes, which a group of process elements used to perform the same final function or objective like pH control, heating, cooling, etc., in the fermentation line used for recombinant biomass production. These elements were grouped as a single node and subsequently analyzed aiming to reduce the required time for risk assessment. The result of this process leads to the conclusion that most of the deviations identified in the system were caused by external factors. In this pharmaceutical facility, the supply of utilities and raw materials that do not meet the required parameters of operation is the primary source of deviations. On the contrary, the high automation of the system allowed taking corrective actions almost immediately in case the deviations may appear and even to take actions to prevent events when abnormal parameter behavior is detected. However, for Sauk et al.[48], determining the optimal order of identification of nodes can be a difficult task because of the lack of experience or when a logical sequence of analysis is not followed. In their work, they used the matrix process flow behavior to determine the sequence of nodes selection and treatment. Finally, they conclude that a linear and continuous flow throughout the process should be followed; this will ensure the management of documents and understanding of the relationship between the critical elements of the system.

Integration of Hazop and Process Hazard Analysis tools

The Hazop methodology is essentially a qualitative method, which is commonly complemented by other Process Hazard Analysis (PHA) tools. Quantitative Risk Assessment (QRA) has been used in the chemical industry to support decision-making to set arrangements and promote mitigation measures to treat risks related to chemical processes, transportation and storage of dangerous substances[49].

Recently, a large number of researchers use risk management methodologies as support to increase the reliability of Hazop studies. Johnson[31] proved the benefits of using Hazard and Operability Studies, Layer of Protection Analyses (LOPA) and Safety Integrity Level (SIL). The main objective of this integration was to sort risk scenarios through the estimation of the risk's order of magnitude, making easier to apply risk reduction measures. Liu et al.[50] also executed a similar work highlighting the importance of using Hazop, SIL LOPA to establish risk acceptance limits for life extension management in oil platform systems. In the study led by Giardina and Morale[51], the integration of FMECA and Hazop methodologies, avoided the omission of failures in a regasification plant. It was achieved by establishing failure modes and identifying hazards through analyzing causes and effects of deviations in process parameters following the normal application procedure. Mohammadfam and Zarei[52] established the risk study for a hydrogen production plant using a combination of Hazop and a Preliminary Risk Analysis (PRA) as qualitative methods.

After that, a Quantitative Risk Assessment (QRA) tool was used to quantify risk, thus increasing the depth and coverage of the analysis. It is a fact that the Hazop methodology could be complemented not only with conventional PHA procedures. Specialized techniques can be used in conjunction with the operability studies to increase the robustness of security programs designed to protect people, facilities, and the environment. It is the case of Process Safety Engineering (PSE) and Fire Protection Engineering (FPE) tools proposed by Chen et al.[53]. Both techniques were used to increase the number of elements to be considered during risk identification to ensure safety and take advantage of the benefits of these programs when integrated with conventional risk assessment techniques.

New trends of application of Hazop studies using modeling, simulations, and computer aided tools

Recently, a new strategy has been used in the process industries to implement successfully the Hazop analysis methodology, however, it is necessary to comply with the following premises.

1. Firstly, the Installation must be properly designed, in relation to the experience, knowledge of the processes involved, and the application of the regulatory standards and codes.

2. On the other hand, the materials of construction must be adequate and the construction and assembly have been carried out correctly (installations in operation).

In the first case, new processes are historically dependent of experience; this issue has been considered as the greatest limitation of the methodology. Thus, this is the reason why computer systems are currently widely used, aiming to avoid the dependence and subjectivity of experience on the part of the specialists.

For this reason, a recent approach to Hazop methodology included the use of computer simulations better known as expert systems. According to Sharvia and Papadopoulos[54], the traditional application of Hazops becomes a challenge because of the higher complexity of modern systems and the potential human error of manual processes. That is why the use of computational systems provides a faithful support for decision making through the "*learning*" of data generated from simulations in case studies.

As mentioned by Chung et al.[55] the amount of data generated in the engineering and routine operation stage of projects could be extensive, in this way, it is mandatory to have automated tools to analyze and process efficiently the large amount of information. In response to this demand, the authors state that the HAZID software is a feasible tool that allows identification of risks through the qualitative analysis of the main and/or more critical units that are represented in diagrams P&ID. Subsequently the HAZID software is able to correlate causes and consequences of potential failures between units that comprise the entire system or process[56]. The need to develop contingency plans for responding to failures in a sulfur recovery unit was the motivation for Alaei et al.[57] to use the Hazop methodology. In order to achieve this, they used expert systems to facilitate the analysis process and help in determining measures that may be taken by the personnel involved in the operation to prevent incidents and reduce the impact of these deviations. The development of computer system simulation applied to Hazop studies has been present in the last years. For example, Švandová et al.[58] demonstrated that tools initially designed for the model and to simulate chemical reactors allowed to establish a new methodology for identifying hazards when integrating to models and hazard and operability studies. The conversion model of hydrolysis of propylene oxide into mono propylene glycol helped to conclude that the integration of simulations and risk assessment tools granted a fast identification of deviations and possible consequences. The model also led to establishing actions to reduce the impact and frequency of undesired events.

From the early 2000s commercial software for performing Hazop like the HAST software has been used for risk management in production plants[59], including several "*intelligent*" Hazop software developed to aid Hazop analysis such as the PHASUITE. Zhao et al.[60] performed an analysis in a pharmaceutical process using this intelligent software as a case study. As a result, this software could identify dangerous situations that could be easily avoided when corrective actions are applied. Moreover, the integration of mathematical modeling into the Hazop study may potentially lead to the detection of unexpected aleatory deviations. Nevertheless, they concluded that in particular situations the extreme amount of information could be extensive, causing losing of objectivity and could be responsible for the lack of corresponding knowledge to promote measures needed to face undesirable deviations. They also established that too much information could lead to the promotion of non-viable solutions, or even worse, to propose too many options to reduce risks, turning the process of eliminating risks a difficult task to realize.

Eizenberg et al.[61] in a similar work established a model to perform Hazop analysis in a semi-batch reactor where an exothermic reaction takes place. The model was exported to popular mathematical simulators like MATLAB, and abnormal conditions (previously identified) were used as data in an Hazop procedure. Labovský et al.[62] used the same modeling concept to establish a mathematical model in a tubular reactor design for ethylene oxide production. They also developed a computer algorithm called DYNHAZ to identify hazards in similar production systems. In a further research, Labovský et al.[63] applied the same algorithm to perform a steady-state analysis and perform a detail safety analysis for a relatively complex process. A methyl tertiary-butyl ether (MTBE) production unit was chosen as a case study to demonstrate this methodology, due to the complexity and extensity of the Hazop analysis.

The development and use of specialized software designed to simplify risk analysis in complex installations are a new trend that is being followed by risk specialists. Zhao et al.[64] designed a specific expert system called Petrohazop, which can help automate "non-routine" Hazop analysis due to the software capacity of learning. Therefore, Hazop analysis can be continuously improved through experience stored in databases. As an example, Cui et al.[65] developed an intelligent software called HASILT, by integrating the Hazop, LOPA, Safety Requirements Specification (SRS) and SIL techniques. In this case, this integration not only allows to make easier the execution of risk assessment studies, the software also facilitates the promotion of potential solutions based in the experience gained in similar events. Another common tool for hazard identification is the ExpHazop[66], this expert system was designed to identify hazards and suggesting mitigation measures in a process facilities. This software is well known because its friendly interface, enhanced graphical user interface, methods to identify a study nodes, dynamic knowledge-base, failure propagation algorithm, report generation, etc. All these features make this expert system one of the most used support tools for Hazop analysis.

In another case, Wang et al.[67] designed and tested a computer program called HELPHAZOP in a processing system for residuum hydrotreating. This software works with databases of incidents, considerations, risk parameters, *et caetera*, and serves as a guide to reducing human errors originated by the lack of experience about the process. The creation of databases from process parameters and treatment procedures has become usual within the process industry. Databases are stored in computer systems and made available to guide in the resolution of abnormal situations. It was shown in the work by Wang et al.[68], in a plant producing ethylene glycol.

A new structured approach to Hazop modeling and simulation is the signed direct graph (SDG) theory. This theory provides algorithms and methods that can be applied directly to the chemical process[69,70]. The SDG analysis can validate models and is a basis for the development of software simulation environment to make possible the automation of validation activities[71,72,73].

Trying to find all the possible logical paths in the SDG model Lü and Wang[74] used signed directed graphs (SDG). The SDG models integrated to Hazop methodologies, made possible to determine more certain deviations and consequences, saving time, human resources, and expenses than the conventional Hazop. Wang et al.[75] also used SDG and proved the effectiveness to identify the most likely operating mistakes that may cause process variable deviations in a polyvinyl chloride (PVC) plant. Kwamura et al.[76] proposed an intelligent Hazop support system that integrates a Dynamic Flow Diagram (DFD). After performing a simulation, the resulting information could be used in conjunction with specialized software to identify risks in real-time during operation. The model also can propose feasible solutions to prevent damage to infrastructure, procedures and all personnel involved in the process.

According to Adhitya et al.[77], Dynamic Simulations previously defined by Haug[78], were used to identify deviations in different supply chain parameters. Dynamic Simulations were also applied to identify possible causes, consequences, safeguards, and mitigating actions using a systematic framework for risk management. The simultaneous hazard analysis in multi-node systems with different failure modes could be a time-consuming task if there were no models to simplify this process. Hu et al.[79] established the fact that it is possible to solve practical safety-related problems in the industry. Such problems included a significant information loss and the difficulty of safety system decision-making during the traditional computer-aid Hazop analysis by the fuzzy information fusion theory[80]. However, it was noticed that the resulting model must be modified practically in each phase of the system lifecycle; this process resulted in more time and resources to conduct studies every time that was necessary to apply adjustments. As mentioned above, the methodology Hazop analyzes P&ID diagrams to define deviations in plants design with the only intention to detect failures in a system before it has been constructed. Cui et al.[81] developed specialized software for Hazop analysis, and they also propose the integration with SMART Plant software to assist in troubleshooting during a plant design, as well as reducing the effort and time required for this analysis. It is a fact that the use of computer simulators, not only will decrease the implementation of the Hazop methodology, it can also be a valuable tool for fast decision-making. Jeerawongsuntorn et al.[82] proposed the implementation of an automatic Hazop analysis integrated into a human-machine interface (HMI). The purpose of this analysis was to monitor a biodiesel production system and reducing the response time to implement actions to reduce frequency and impact of risks. It was concluded that undesirable situations could lead to a complete lack of effectiveness of the analysis as stated by Wang and Gao[83]. Nevertheless, they propose with success a new database construction method based on Hazop analysis, which could guide the operator to act fast when facing deviations and to prevent potential damages within the system.

Bayesian networks (BNs), also known as belief networks (or Bayes nets for short), belong to the family of probabilistic graphical models (GMs). These graphical structures are used to represent knowledge about a variable domain. In particular, each node in the graph represents a random variable, while the edges between the nodes represent probabilistic dependencies among the corresponding random variables[84]. These conditional dependencies in the graph are often estimated by using known statistical and computational methods. Hence, BNs combine principle from graph theory, probability theory, computer science, and statistics[85].

Operational risks include a variety of types of failures which quantification is not easy because the lack of data is a fundamental feature[86]. Making risks databases is an essential requirement in process risk assessment. These databases consist of detailed functional procedures and equipment characteristics. However, in specific cases, due to their low availability, it will be necessary to access external information sources of validation or deviation data. Unfortunately, the opinion of experts and subjective probability definitions are commonly the only source of such information. Nonetheless, a Bayesian approach is capable to process and validate such information due its capacity to analyze accumulated data and consequently improve its quality[87]. Thus, Bayesian Networks are being used as a method to calculate probabilities of events[88] and as a tool for decision making in expert systems during implementation of the Hazop methodology.

BN also support decision-making in situations where it is necessary to evaluate gains and costs versus risks[89]. Hu et al.[90] presented a model that uses the integration of the Hazop methodology and a dynamic Bayesian network. This model was developed aiming to aid in quantification of deviation level through the relationship analysis between parameters in complex processes.

Limitations of expert systems to support Hazop studies

Although the expert systems provide the necessary support to facilitate the process of applying the Hazop methodology, these tools present some limitations that must be considered during their use to challenge the results[91,92].

Sense: An Expert System lacks common sense, which is essential to specify based in knowledge, each and every one of the conditions and circumstances of the context and environment. For the Hazop methodology, even the most simple decision based on common sense, is not considered by the system, since the interpretation of acquired data along the time creates data bases, without applying criteria for specific cases.

Natural language: Just as a human uses a language in order to maintain communication with another individual, an Expert System uses a programming language, which prevents the possibility of informal conversation. Thus, users most conform to the system language, leading to limitations to state ideas, causes, consequences and particular expressions.

Provision for learning: The ability of a person to learn from mistakes is relatively high and rapid. Designing an Expert System that offers these conditions is very complex.

Ability to prioritize: For human experts, it is not very difficult to differentiate between the relevant topics of an issue from the irrelevant ones, which for an Expert System is not so trivial, and requires complex databases of events, and usually demands upgrades of the programing to achieve this objective.

Sensory aptitude: An Expert System, unlike a human being, is not able to perceive any of the five senses, which limits its capacity of perception.

Nevertheless, each day, new technologies are being developed, and in a near future it is expected that a decision making will be feasible for expert systems.

An Hazop methodology perspective

As seen above, the use of models and simulations will be the base for risk identification and it will provide a guide for decision-making in risk management. However, although it is well known that computer systems will give support to risk specialists and perhaps such systems will reduce the need for an extensive multidisciplinary team in a long term; what are the immediate future and potential uses of the Hazop methodology?

It is a fact that the hazard and operability methodology will continue to be employed in the process industry for a long time. Since it makes easier systems analysis in early stages of design by analyzing deviations in abnormal system behavior, when processing raw materials into products. That is the reason why it will become more common to see new potential areas of application of this methodology, such as, informatics, business, medical educational, and processes that may include process parameters.

Potential application areas, should consider that deviations could also be responsible for affecting not only mechanical devices but also computer systems, regulatory issues, or even those elements involved directly or indirectly in this process as the environment and critical infrastructure[93]. However, as seen in this paper, the fast growing technological evolution of the industrial infrastructure may turn the conventional Hazop methodology obsolete. Applying Hazop procedures could not be feasible when the increase of some components and complexity of possible deviations that may occur during the operation will require the additional effort of those responsible for the risk assessment. Not to mention the highly cost of resources and time needed to perform a risk analysis to identify and apply control measurements. Therefore, now it is common to see that this Hazop methodology is being adapted and is suitable to meet the needs of new processes. Thus, the risk management specialists agree that automating procedures of Hazop application will be in a near future, the only practical approach to deal with highly complex analysis if adopted.

Applications in the pharmaceutical industry

Capacity and complexity of upcoming industrial facilities must be fundamental criteria when risk assessment tools are being used. Industrial risk assessment using the Hazop methodology require a complete understanding of components function and their relationship with the whole system. Nowadays the industrial infrastructure in several sectors needs to be updated, aiming to meet quality requirements. As a special case, it is possible to notice that the pharmaceutical and biopharmaceutical industry are remarkably evolving in recent years. Both industries are responsible for producing health supplies, which in some cases the final product could be the same; however, the technological difference is the production platform.

The conventional pharmaceutical industry commonly use chemical synthesis for generating health products, requiring expensive raw materials to perform processes. Meanwhile, the generation of biotech products (as its name suggests) requires biological platforms, such as bacteria, mammalian or insect cells, and more recently the use of plants to produce therapeutic proteins, bacterial and viral vaccines, etc. However, the biological platform requires improved technological facilities and expensive equipment like bioreactors, when working with genetically modified organisms (GMO).

As consequence of current regulations like the FDA[94,2], required equipment must meet high specifications and complex operational procedures. At this point, the Hazop methodology provides the necessary risk assessment support. Accordingly, the biotechnological systems responsible for material transforming operations into products are built of some components that could be considered as Hazop nodes. In Figure 2 an example of node identification in a stainless steel tank used for bacterial culture dilution is shown.

In this case, the node identification seems to be an easy procedure to follow, however, Figure 3 illustrates the complexity of a bioreactor for bacteria used in the process. In this case, the node identification could represent a challenge for the multidisciplinary team, because each line representing utilities, solutions, media, gas exhaustion, etc., should be considered as a node. It must be considered too that wether the lack of a single element required for the process, or a deviation of the function of consents will have negative impacts on the product or to the system itself.

Thus, the new approach to nodes selection through the functionality may be the answer to reducing the number of components considered as nodes, by component groups with the same function within the process. This strategy will simplify the procedure of identifying, process and treat of deviations, allowing a simultaneous analysis of several variables at the same time as it was demonstrated by O Herrera et al[24].

Also, the multidisciplinary group experience needed in risk analysis that uses this methodology can be reduced if specialized software tool that enables the acquisition of information and generates databases can be used as a basis for decision-making.

CONCLUSIONS

a. The Hazop methodology is one of the most PHA tools used by specialists in risk management. As it was seen in this paper, it will continue to be employed in the process industry for a long time. However, to address new challenges within the current process industry, the methodology has to be improved aiming to attend its implementation in high complex facilities. Upgrades of this methodology will allow its fast adaptation to current or even future process requirements as it was seen in recent publications.

b. This review made possible to notice that most of the consulted authors consider the Hazop methodology a reliable tool to identify deviations in process parameters. Also, its structured approach brings the necessary support to make easier the determination of causes and effects using as a basis the knowledge of a multidisciplinary team or databases from expert systems, however, in all cases the need of specialists will be continued to be necessary due to the limitations of the expert systems (explained above).

c. Hazop studies are designed to promote measures to eliminate risk, and propose controls to reduce the impact of risks when cannot be avoided. However, most of the authors mentioned in this paper, converge on the premise that the identification and characterization of deviation using Hazop methodology databases are not the only information source, and requires a wide and deep experience of those involved in the risk assessment.

d. Current processes are being built using the most recent technology, making systems more complex than they were in the past. That is the main reason why the conventional application of the Hazop methodology cannot meet the requirements of subsequent processes risk assessment. Nevertheless, the new trend that has been followed by Hazop specialists is the design and application of intelligent Hazop studies. The creation of models, simulations, and use of the specialized software will simplify the procedure for dealing with deviations, making the hazard and operability studies a fast and low-cost tool for risk assessment. Although the systems are not infallible, it is expected that in the near future, the need of human experience to support expert systems, will become increasingly less or even unnecessary.

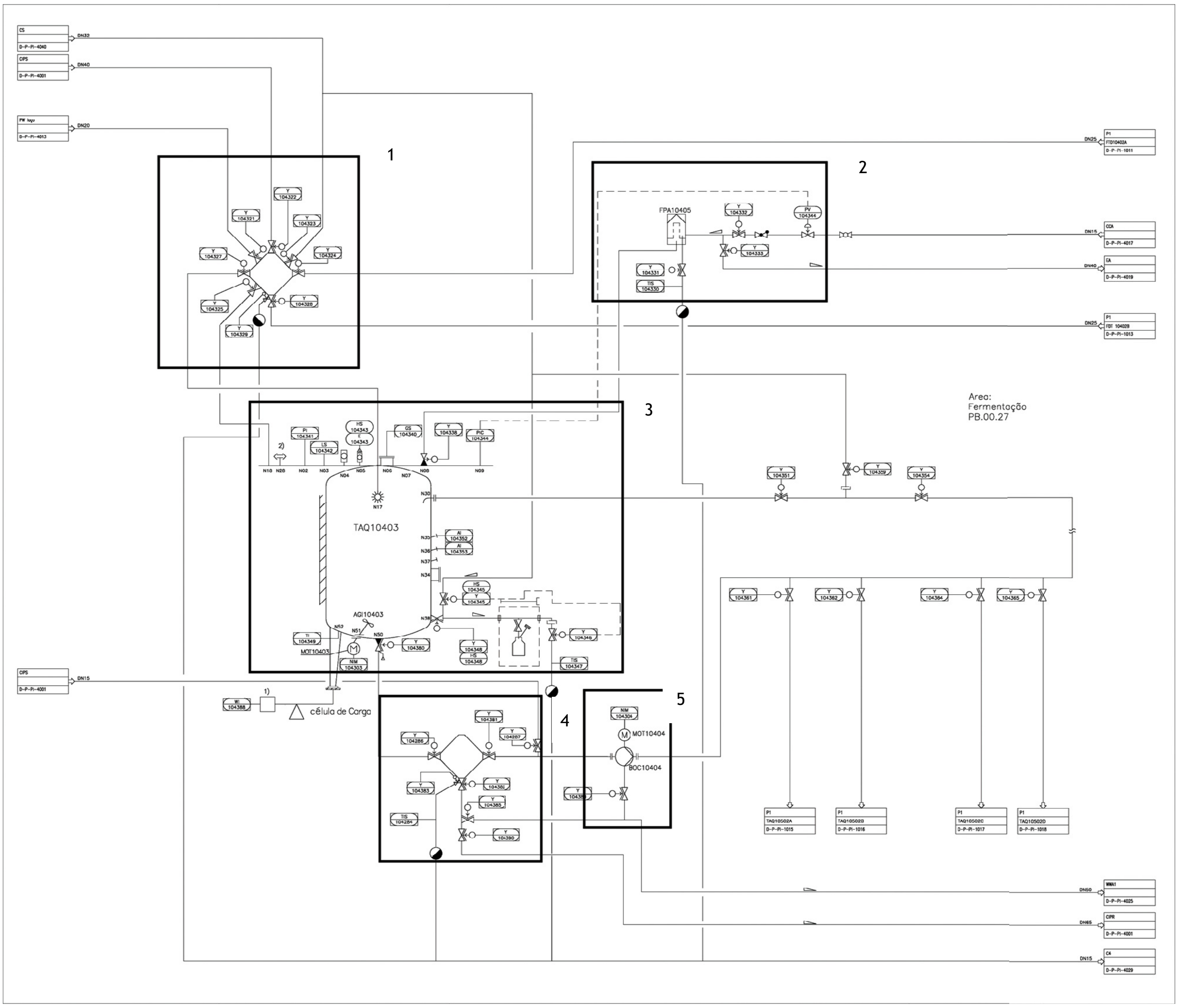

Figure 2. Node identification in bacterial culture dilution tank. M+W, 2014.

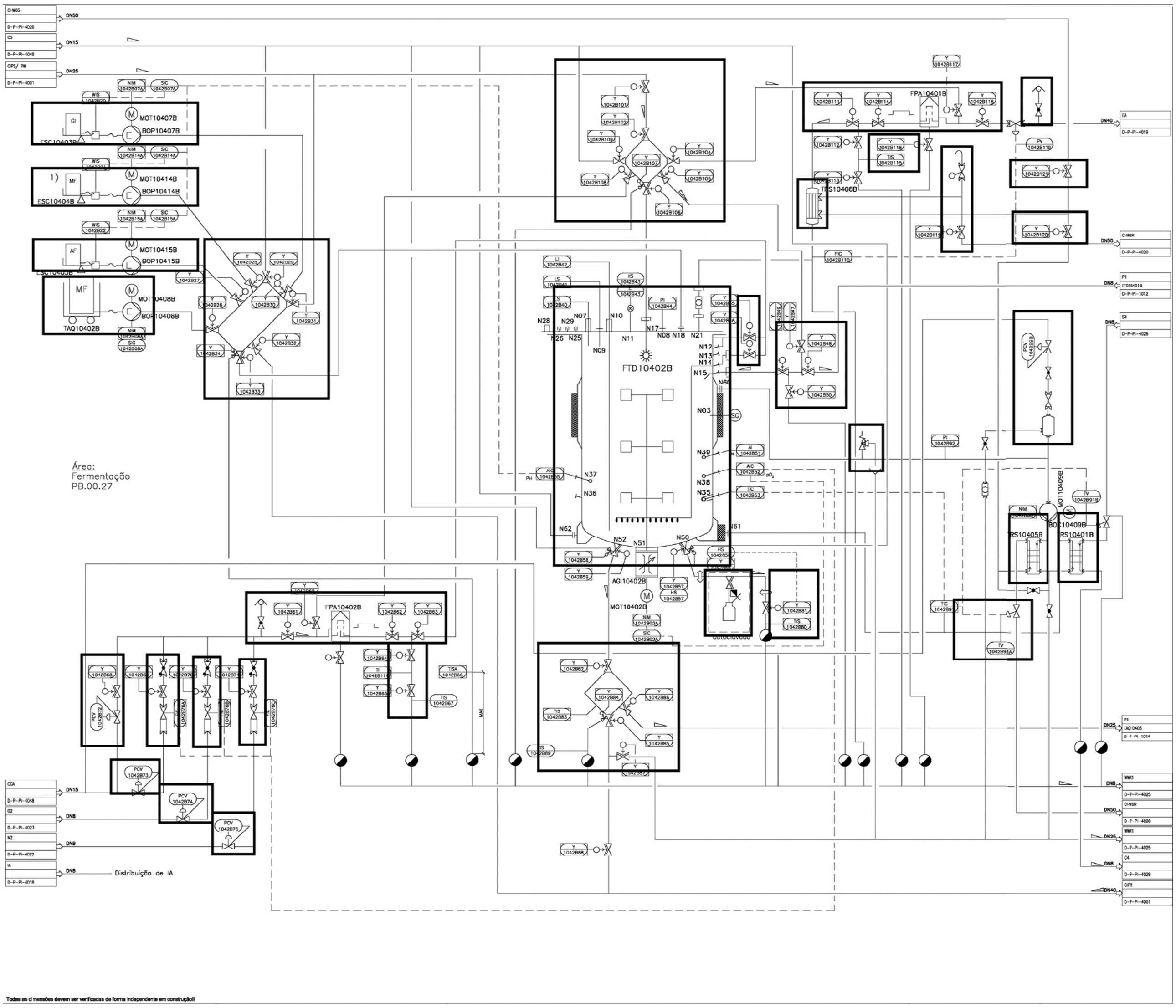

Figure 3. Node identification in complex bioreaction system. GE, 2015.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.