Evaluation of Medical Engineered Plastics Processing Risk

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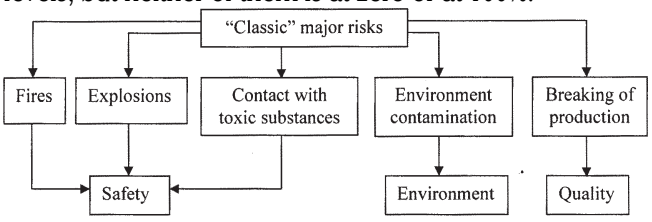
In the medical field of plastics is and will be most useful. Their processing involves engineering concepts which assumes the most diverse risks. But there are conditions, depending on the identification between offer and demand of such services. They come as effects of the concrete availability of resources of all types, of caring facilities, comparing with the demand based on the need for health. In this context the analysis due to risk engineering is appropriate in the management accomplishments of the processors, respectively as it can be used at national and international levels, having effects on the efficiency of the usage of al the involved resources.

Keywords: industrial system, risk engineering, plastic materials

Plastics processing involves complex processes with many factors influence at all stages of the work cycle. In every phase of the processing operation, there is a level of risk [8, 9, 10]. By its definition, risk implies the approach through probability, having economic connotations as well. The health system is familiar with such approaches. The notion is linked to an uncertain but possible event, its origin being an uncertainty. It can be linked to economic, social, political activities, but also in the human relationships or in those between man and nature. In comparison to the ,,classical" activities that are being currently developed, one can identify the appearance of new sources derived from more and more active industrial activities which "supply events" as secondary effects. (fig.1) [1, 2].

The idea of possible loss of any type is involved, a loss caused by the evolution of some factors – called risk factors – that come against all expectations. But different from uncertainty, due to management engineering, there is the possibility that risk should be quantified through the mathematical concepts of probability. Consequently, risk and uncertainty meet at the same time in the involvement levels, but neither of them is at zero or at 100%.



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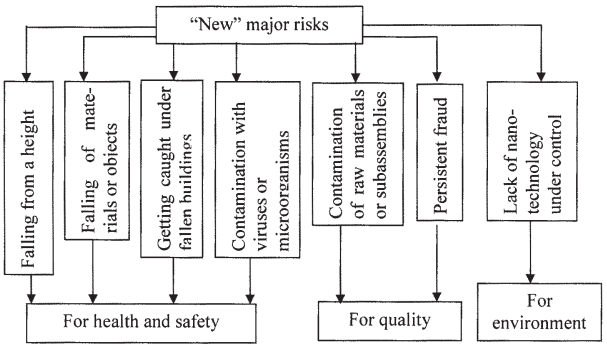

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Fig.1. Major risks in economic activities

In the management activity in associated medical plastics processing an essential element is represented by the engine engineering techniques in the management of decision taking. Any decision problem implies a loss function which quantifies the loss associated to any consequence of the adopted actions and any state of fact. Loss is often expressed in money terms, but there may be other ways of quantifying it. The risk function can also be determined as the environment or the expected value of loss, a definition implying probability functions. In the engineering context of the management problem of risk, one uses the Monte Carlo simulation in order to evaluate the risk associated to the events of the analyzed system in uncertainty conditions [3, 4].

Generally speaking, simulation techniques imply achieving a statistic-mathematical model. Such a simulation model must describe the functioning in terms of individual events of the analyzed system components.

One of the domains in which risk can have very important influences and especially serious consequences is the management quality system. In this context, one should take into account the pair *quality –cost* because both reaching and maintaining an appropriate quality level and the degradation of quality can generate high costs in different ways.

Approaching it through risk engineering of a plastics processing medical system must be accepted as a cyclical process, taking place on the whole period and it implies covering five work stages in order to optimize the potential success:

-planning;
-identification;
-analysis (quantity and quality);
-establishing the approach strategies;
-monitoring and evaluating.

The concepts imply simulations for the evaluation of the program stage costs or the technical performances (e.g. the usage of a new constructive approach) or the planned performances (e.g. the getting and the usage of resources that can influence the project).

The health state of employees is determined by the access to health and to health services. But efficiency at all levels depends strictly on the level of education and involvement of the demanders. Access to health depends a lot on external to the health system: genetic, environment,

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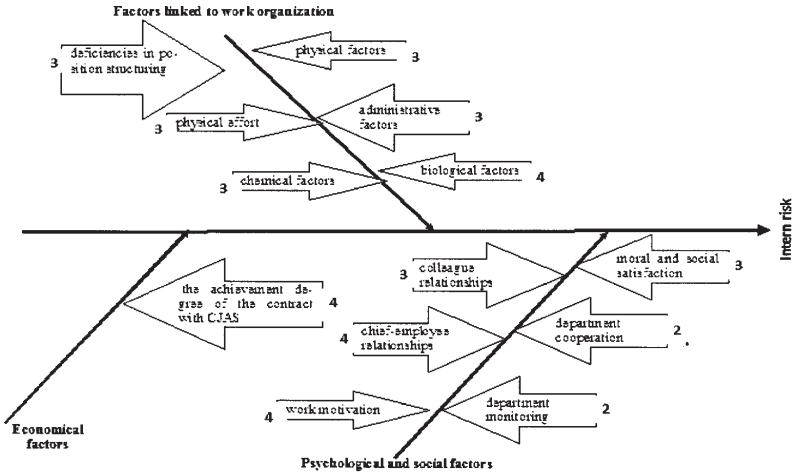

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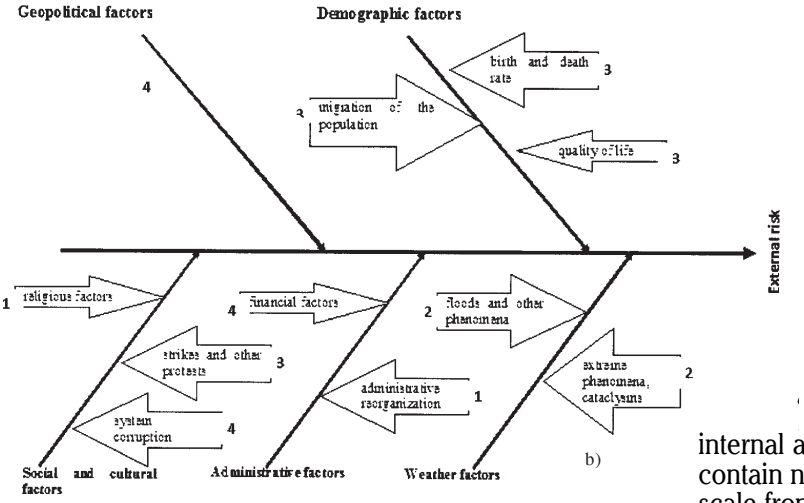

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Fig. 2. Factors linked to internal (a) and external risk (b)

economical development, social and cultural. The differences in the access to caring come from at least four causes: ethnic or racial; economical, including the direct costs supported by the population (co-payment, costs linked to treatment and hospitalization) and the indirect ones (transport costs, waiting tines); inadequate geographical positioning of assistance facilities; unequal quality of the same services [5, 6].

Consequently, the undergoing process is extremely actual and has as main purpose the analysis through risk engineering of the factors contributing to the management performances of medical plastics processing, applied at a national and an international level, having effects on the optimization of the usage of all the involved resources.

Risk categories specific for the domain

Taking into account that every activity is subjected to risk, one can say that the development of any activity is a continuous risk assuming. In order to know the specific risks, a classification is very useful when approaching the theme. Depending on the nature of the source generating them, one can distinguish between :

-pure risk;
-business risk;
-project risk;
-operational risk;
-technological risk;
-political risk.

These risk categories are not exclusive, they can be found in practical activities in combined forms. In the engineering domain, risk sources come both from the interior and the exterior of the functional system, defining internal and external sources (fig.2) The following plans contain numbers associated to increased risk levels on a scale from 1 to 5. Their meaning is presented in detail in the rest of the paper.

External sources are the result of events outside the system. They cannot be controlled because they do not depend on the concrete functioning of the system. E,g.: laws, normativs, decrees of the general or professional coordinating organisms, competition.

Internal sources represent the result of events inside the system. They can be controlled. One can see the usage risks of the technological equipment, risks coming from the human resource activities, work or risks associated to organization management.

Risks of a industrial processing system

In a industrial system, the risk generating factors are influenced, can be defined:

Factors depending on work organization are prevented in detail in table 1

Psychological and social factors, through:

-colleague relationships;
-hierarchical relationships;
-work motivation;
-moral satisfaction of one's work.

Taking into account their consequences, industrial system risks can be of 5 types:

Catastrophe (level 5) is associated to at least one of the consequences:

-needs an external agent to investigate,
-causes serious damage to image of the company,
-negative presentation on long term and on large areas
-legal actions with serious spending or civil actions implying fees of over 1 million euros

A.1. Deficiencies in the position structuring	A.2. Physical effort	A.3. Physical factors	A.4. Chemical factors, associated to substances	A.5. Biological factors
-spreading tasks, - correlation of competence with given tasks	- manipulation şi transport of employees and materials , -work positions: damaging positi-on; frequency of repeating movement.	- presence ionic radiations, - presence of non-ionic radiations, -noise, -illuminated -microclimate	-dezinfectant, -antiseptic, -laboratory reactive substances, -medicine, - anesthetic gas, - latex	- viruses, - bacteria, - fungi, - parasites

Table 1
FACTORS DEPENDING ON WORK ORGANIZATION

-more dead and injured persons
-serious damage to the environment
-stopping on long term (months) of basic activities
-destruction or annihilation on a long term of infrastructure, systems and resources having a direct impact on activities
-financial loss uncovered by the insurance system (more than 5 million euros)

Major (level 4) is associated to at least one of the consequences:
-extended negative media presentation
-legal actions with serious spending or civil actions involving fees of over 5.000 euros
-one dead and / or more injured persons
-stopping of basic activities on short term
-financial loss uncovered by the insurance system (between 2.5 – 5 million euros)

Medium (level 3) is associated to at least one of the consequences:
-negative media presentation
-critical cases needing treatment in another hospital
-significant disruption (days) of basic activities
-uncovered financial loss by the insurance system (between 500.000 and 2.5 million euros)

Minor (level 2) is associated to at least one of the consequences:
-limited negative media presentation
-critical cases needing treatment inside the unit
-short term disruption (days) of basic activities
-long term disruption (weeks) of correlated activities
-uncovered financial loss by the insurance system (between 50.000 and 500.000 euros)

Insignificant (level 1) is associated to at least one of the consequences:
-improbable to have a negative impact on the public image of the unit
-absence of critical cases or their quick transformation into medium or small seriousness
-minimum impact on activities
-minimum financial loss (under 50.000 euros)

Taking into account the probability to happen, there are 5 risk levels:
- almost certain (level 5) – a risk which is very likely to happen several times in the next year.;
- probable (level 4) – a risk which is likely to happen more than once in the next 12 months;
- possible (level 3) – a risk which is going to happen at a certain moment in the next 2-5 years;
- improbable (level 2) – a risk which is going to happen at a certain moment, but it is unlikely;
- rare (level 1) – a risk which can happen, but is extremely unlikely, once every 10 years.

Taking into account the already mentioned, one can make the risk matrix (consequences – probability), table 2, thus structured so that every risk level, linked to the previous table, for a system / health unit, must be done as prevention and annihilation activities through different methods.

In order to have a critical level of risk, the action must be performed immediately the risk is discovered. The intended activity or task generating such a risk must be discontinued. Measures must be taken to reduce the level of risk in a reasonable way, using the hierarchy of risk control.

In order to have a high level of risk, the action must be performed the same day the risk is discovered. The risk generating activity may continue if the following conditions are fulfilled: risk level has need reasonably reduced, using

Consequence						
	5	Medium	High	Critical	Critical	Critical
	4	Low	Medium	High	Critical	Critical
	3	Low	Low	Medium	High	Critical
	2	Very low	Low	Low	Medium	High
	1	Very low	Very low	Low	Low	Medium
		1	2	3	4	5
		Probability				

Table 2
THE RISK MATRIX

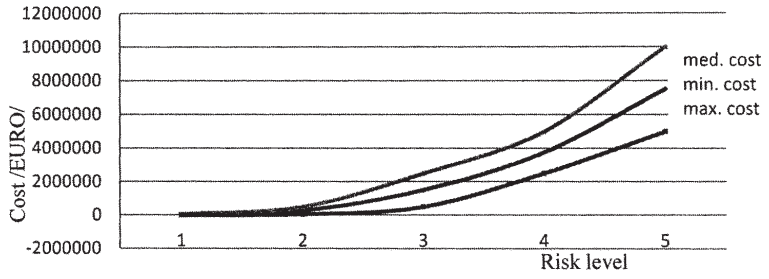

Fig. 3
The cost dependence on the risk levels

Strong points	Weak points
-the existence of competent specialists	-different degrees of technical competence for persons having the same payment level
- the existence of an important percentage of young staff members capable to form themselves according	- deficiencies in assuming responsibility -local old-fashioned infrastructure
-the staff and the equipment, investments and recent or undergoing arrangements	-limited funding, sometimes insufficient
-capacity to work prolonged hours	-low motivation caused by the incapacity to differentiate between persons with a different output
-a staff formed in different domains (both the base one and in associated or complementary domains), a fact which increases the capacity to solve some complex problems	-an institutional environment which does not encourage team work -the incapacity to monitor the way of task fulfillment both at an individual and at a department level -the lack of continuity in giving tasks -the lack of a career plan for the employees and of a coherent politics about the training and the attraction of staff -a large number of coordinated / subordinated institutions -the lack of an integrated informational system

Opportunities	Threats
-the possibility to use repayable funds in order to renovate, modernize or equip the infrastructure	-the high degree of the migratory phenomenon in the technical system staff towards the EU states, especially of the highly qualified and performing ones -the decrease of the service quality
-industrial activity is a domain with a major social impact, being capable to supply arguments for the adoption of efficient politics and social satisfaction	-the increase of the information level of the employees will lead to higher expectations and also to an increase of the demand for complex technical services, -the industrial system must have mechanisms which should ensure the orienting of the financial resources on the basis of the efficiency principle
-the EU joining implies adopting standards and recommendations, having as final purpose the increase of efficiency and quality	-the freedom to circulate of the people and services gives the possibility to users to get in contact with service suppliers from different countries and to change their expectations
-being an EU member provides new financing possibilities for projects based on European funds	-the development of the private system represents a competitive environment for the industrial system, offering motivating salaries in the domain
-the interest of the local public administration authorities to take over a part of the responsibilities	-the aging of the population and the migration of the young labor force, - increase collateral costs, -the lack of specific studies in the industrial domain at the level of the local administration

Table 3
ESTIMATED DATA ACCORDING TO THE SPECIFICITY OF THE SWOT ANALYSIS IN THE INDUSTRIAL UNIT

the hierarchy of risk control; the risk control instruments must be similar to those established by the current legislation (SR ISO 30010); the risk has been evaluated and validated by a supervising authority; a procedure or an adequate methodology for the safety and work health has been prepared; the supervising authority must approve and evaluate the efficiency of the adopted measures.

In order to have a medium level of risk, the action must be performed the same week the risk has been discovered. The risk generating activity can continue if the following conditions are fulfilled: risk level has been reasonably reduced, using the hierarchy of risk control; the risk has been evaluated and validated by a supervising authority; a procedure or a methodology for the safety and health work has been prepared.

In order to have a low and a very low risk level, the action must be performed the same month the risk has been discovered. Risk is dealt with by applying the local routine procedures which must however contain the hierarchical risk evaluation.

Taking into account the damage (minimum, maximum and medium) linked to any risk category, the situation is presented as a scheme in figure 3.

The risks can be thus classified:

Major risks (system ones) influences the industrial system at a national level, affecting most of the units.

Concurrent risks influence some health units during some periods caused by the structure and the subordination of the main credit sources.

Minor risks determine insignificant changes linked to unexpected elements which can produce effects on a short period of time in a limited area (floods, weather problems, low intensity violence, strikes)

SWOT Analysis

At the level of the industrial system, given the specificity of the SWOT analysis, the estimated data characteristic are presented in table 3.

Conclusions

Human resources are the key-element for the good functioning, the adaptation and the sensitivity of the engineered plastics processing system to ensure the needs of the plastics market. Instead, the lack of balance in the planning, forming and usage of human resources, in the context of limited financial means, can generate unwanted, social and economical phenomena, influencing the wrong usage and the increase of costs.

Another problem is the improvement of specific infrastructure, providing the institution with performing and efficient equipment in what regards the price. Efficient use is associated with the training and the attraction of employes to assume the responsibilities and risks.

In the context of the evaluation of medical engineered plastics processing, the essential problems are the following:

a)the disproportionate allotment between the existing number and the needed one regarding the various specialists,

b)the distribution of professional abilities linked to the professional degree of the specialists and the specific requests of the industrial system,

c)the migration inside and outside the country of highly qualified staff in the national industrial system.

At the same time the problem of the lack of medium qualified employees has become very serious.

All the above mentioned issues are caused by the inadequate payment and the inefficient management of the staff in the system. The insufficient motivation and

benefit system, the inappropriate working conditions, the underdevelopment of the physical infrastructure and the lack of modern equipment make difficult the hiring and the maintaining of the staff in industrial system. The employees mention as causes of their dissatisfaction the absence of a clear definition for the obligations of one's position, the inadequate supervision from the part of managers and the reduced involvement in the decision taking process. All these are serious barriers to improving professionalism in processing plastics.

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