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Modeling of Compliance Processes with Specified Criteria in Complex Dynamic Systems

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Abstract

The urgency of research and modeling of complex systems lies in the fact that it is necessary to effectively manage such systems, to predict their development, to use corrective and preventive actions, to eliminate undesirable phenomena. It is necessary to ensure that the system parameters meet the specified requirements and criteria [1],[2],[3],[4]. The complexity of research and modeling of such systems is as follows:

- Increase in the number of components and links in the system
- Complication of internal random relationships
- Existence of stochastic processes
- Changes in the requirements for compliance of key indicators with specified criteria.

The considered class of complex systems is encountered in practice in a number of industries in which strict requirements are imposed on the parameters of the system, to their estimates. For example, to indicators of the quality of products (aircraft construction, management of complex equipment, production of food and drugs, health). For such systems, the problem of identifying deviations, estimating the indices of individual parameters for the objects of the system and methods of applying corrective actions for their elimination is urgent. Topical for the class of systems under consideration are the problems of self-regulation and self-development.

Keywords: Dynamic network systems, Deviations and inconsistencies, Dynamic evaluation criteria, Weight coefficients of groups of criteria, Corrective and preventive actions (CAPA, Corrective and Preventive Action).

1. Introduction

The main problem in the development and implementation of various methods for estimating parameters when deviations and inconsistencies are detected in complex systems is the duration and laboriousness of the corresponding processes. Without developed technological tools, it is not always possible to quickly analyze a large number of dynamic estimates and make the right timely decision.

In Fig. 1, for the considered class of complex systems, a diagram of interacting processes for estimating parameters and monitoring their compliance with the established criteria is shown.

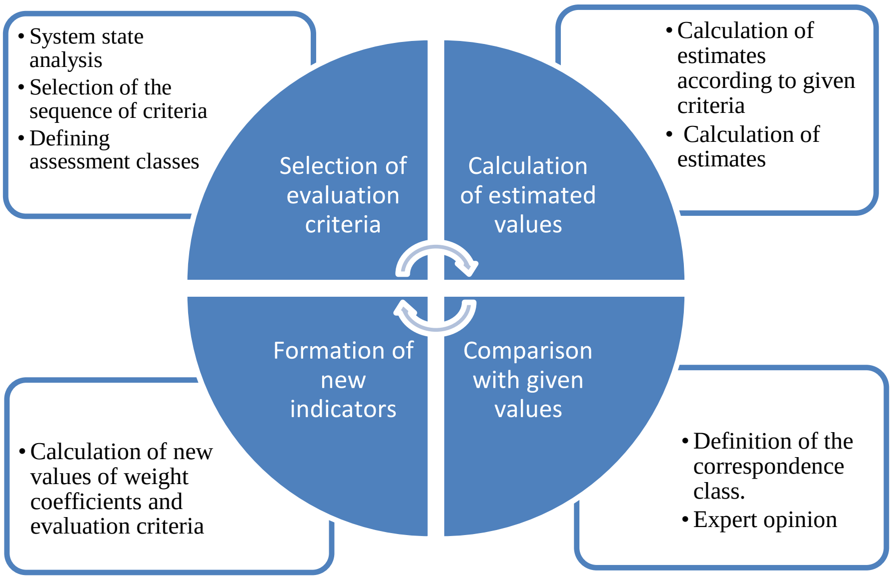

Fig. 1. Sequence of control and analysis of key parameters.

The main topic of this article is the study of the automation of the procedure for performing parameter estimation in dynamic complex systems when nonconformities are detected for making decisions about carrying out the necessary studies, obtaining estimates and performing corrective and preventive actions (CAPA) in order to eliminate the detected inconsistencies.

2. Mathematical Model for Estimating Parameters in Complex Systems

First, we introduce the following notation in the language of set theory:
$S = \{s_1, s_2 \dots, s_n\}$ - a finite set of components of the system to be evaluated,
$G = \{G_1, G_2 \dots, G_m\}$ - a finite set of groups of criteria in which each element G_i is in turn a set the elements of which are a collection of certain similar (with the same characteristic parameters) criteria , i.e., $G_1 = \{g_{11}, g_{12}, \dots\}$, $G_1 = \{g_{21}, g_{22}, \dots\}$, … $G_i = \{g_{i1}, g_{i2}, \dots\}$- there are sets of different groups of criteria. To each G_i we assign a certain weighting coefficient $\lambda(G_i) \in \lambda$, where $\lambda(G_i) = (0 \div 1)$.

We define a binary function F that can take the value 0 or 1 and is defined on the set G_i,

$$F(G_i) = N' \in N \text{ , where } N'_i = \{0,1\}. \qquad (1)$$

We also introduce a set of standard estimates in the form of ordered subsets of natural numbers

$$K = \{K_{1,} K_{2,\dots} K_z\}, \qquad (2)$$

where $K_z \subset \text{N}$ & $(K_1 \cap K_2 \cap \dots \cap K_z = \{\emptyset\}$&$(K_1 \cup K_2 \cup \dots \cup K_z != \{\emptyset\}$.
The elements of each subset K_z is the ordered sequence of natural numbers $\{m_1, m_2 \dots, m_n\}$ from the set of N, where $m_j = m_i + 1, j = i + 1$. K_i will be called the i-th correspondence class.
For each element s we have a chain of averaged values for each group G_i:

$$F(s_m, G_i) = (f(g_{i1}, s_m) + (f(g_{i2}, s_m) \dots + (f(g_{il}, s_m)), \qquad (3)$$

We define for sm an integral estimate with allowance for the weight coefficients λ,

$$I(s_m) = \sum_{i=1}^{k}(F(s_m, G_i)\lambda_i) \ , \quad (4)$$

where $m = \{0, 1, \dots n\}$ – the number of components in the system,

$k = \{0, 1, \dots z\}$ – the number of set elements K (2).

Finally, we get a couple of expressions that describe the procedure for obtaining a quantitative assessment and monitoring compliance with specified criteria:

$$\begin{cases} I(s_m) = \sum_{i=1}^{k}(F(s_m, G_i)\lambda_i) \\ Q(I(s_m)) = K' \subset K_i \end{cases} \quad (5)$$

The problem is to determine for the integral estimate $I(s_m)$ belonging to one of the classes of correspondences K_i .

For each s_n element, it is necessary to execute the sequence of the following 5 procedures:

1) Generating a value chain $F(G_{i1}), F(G_2), \dots F(G_i)$, (1) where i – the number of criteria groups
2) Calculation of the average values for each group, taking into account the weighting factors: $F(s_m, G_1)\lambda_1$, $(s_m, G_2)\lambda_2$,... $F(s_m, G_i)\lambda_i$,
   where $F(s_m, G_i)$ – the mean value according to expression (3)
3) Calculation of the integral sum $I(s_m)$, according to expression (4)
4) The definition of K_i (i=1,2…z) for which $I(s_m) \in K_i$, i.e., the definition of the group that includes the given integral sum $I(s_m)$ (5)
5) Generation of actions (expert opinion) according to the estimation of $I(s_m)$ and the corresponding group K_i

A practical example (pharmaceutical production)

Consider the foregoing with the example of evaluating and selecting a supplier of ingredients and packaging materials in a pharmaceutical company. The task is to obtain in a timely manner a possible objective integral evaluation with subsequent periodic reassessment that would help to make the right decision when choosing a supplier.

The production of pharmaceuticals by pharmaceutical enterprises is a chain of interrelated processes - from the choice of the supplier and the organization of the supply of ingredients to the production, packaging and supply of medicines to the consumer. All these processes must meet the quality requirements, according to the GMP standard. Ingredients and packaging materials are the most important components of modern medicines and their manufacturers have to be cautious in choosing suppliers.

Among the most important aspects of supplier selection for manufacturers are the following:

- information about the supplier, its reputation and position in the market, the availability of quality certificates, financial statements, customer references and other available information, negative processes related to quality violations, deviations from specified parameters, etc.
- Conditions for providing a guarantee for the delivered products, responsibility for the quality of the products supplied, readiness to assist in eliminating inconsistencies and compensating losses that arose, for example, during transportation
- Terms of payment, product cost, cost and delivery time, quality and timeliness of registration of documentation for product registration and customs operations
- Estimating the total cost of the cost of purchasing the ingredients, taking into account transportation costs, tax duties, the cost of excise taxes, registration certificates, insurance premiums and other payments

- Types of packages of supplied ingredients and materials in terms of ease of transportation, storage and packaging
- Compliance of the declared quality indicators with their actual estimated values during the period of interaction between the customer and the supplier
- Estimation of profitability of production taking into account expenses for ingredients and packaging materials.

The task is to obtain in a timely manner a possible objective integral evaluation with subsequent periodic reassessment that would help to make the right decision when choosing a supplier [5].

There are many vendor classification systems. Such systems depend entirely on the competence and qualifications of relevant specialists in the pharmaceutical, food and other industries. Each company needs to create its own acceptable classification system.

One of the classification options for the pharmaceutical industry is presented in Table 1. [5]. Consider the application of the proposed algorithm for this classification option.

Table 1: Vendor classification method.

N	Topic (group of criteria)	Criteria (gij)	Values F(Gi) (0,1)	Values λi (0-1)
1.	Quality level (G_1)	• Compliance with the specification parameters (g_{11}) • Compliance with quality system requirements (g_{12}) • Availability of certificates of conformity (g_{13}) • Access to the product dossier (g_{14}) • Product Stability (g_{15}) • Quality index by product series (g_{16})	$f(g_{11})$ $f(g_{12})$ $f(g_{13})$ $f(g_{14})$ $f(g_{15})$ $f(g_{16})$	1
2.	Production level (G_2)	• Availability of full production cycle (g_{21}) • Competence of the staff (g_{22}) • Level and potential of development (g_{23})	$f(g_{21})$ $f(g_{22})$ $f(g_{23})$	0.8
3.	Logistics (G_3)	• Types and dimensions of packaging (g_{31}) • Offered service (g_{32}) • Periodicity of delivery (g_{33}) • Transport condition (g_{34}) • Geographical location (g_{35}) • Reliability of delivery (g_{36})	$f(g_{31})$ $f(g_{32})$ $f(g_{33})$ $f(g_{34})$ $f(g_{35})$ $f(g_{36})$	0.7
4.	Marketing (G_4)	• Contract pric (g_{41}) • Terms of payment (g_{42}) • Proposed assortment today (g_{43}) • The claimed asortment of tomorrow (g_{44}) • Image and reputation (g_{45}) • Customer Orientation (g_{46})	$f(g_{41})$ $f(g_{42})$ $f(g_{43})$ $f(g_{44})$ $f(g_{45})$ $f(g_{46})$	0.3

It is also necessary to specify several characteristic groups with given ranges of numbers that define the group to which the supplier in question can enter. For example,

Table 2: Characteristic groups and their metrics.

Group	**Metric (Value Range)**	**Characteristic**
K_1	<5	Does not meet the specified criteria
K_2	5-8	Requires revision
K_3	8-10	Partially matched
K_4	10-14.4	Totally coincides

Then it is necessary to calculate the average value for all four groups of criteria:
1. $Av.(G_1) = (f(g_{11}) + f(g_{12}) + f(g_{13}) + f(g_{14}) + f(g_{15}) + f(g_{16}))/6$
2. $Av.(G_2) = (f(g_{21}) + f(g_{22}) + f(g_{23}))/3$
3. $Av.(G_3) = (f(g_{31}) + f(g_{32}) + f(g_{33}) + f(g_{34}) + f(g_{35}) + f(g_{36}))/6$
4. $Av.(G_4) = (f(g_{41}) + f(g_{42}) + f(g_{43}) + f(g_{44}) + f(g_{45}) + f(g_{46}))/6$

Further taking into account the given weight coefficients for each group of criteria, it is necessary to calculate the integral estimate according to a pair of expressions (5) :

$$Int. = Av.(G_1) * 1 + Av.(G_2) * 0.8 + Av.(G_3) * 0.7 + Av.(G_4) * 0.3$$

Now it is necessary to check which group from the given set $K = \{K_1, K_2, K_3, K_4$ contains the obtained estimate to take appropriate action:

- $Int. \in K_1$ -> the supplier does not meet the specified criteria
- $Int. \in K_2$ -> data on the supplier need to be revised, it may be required to request additional materials
- $Int. \in K_3$ -> the supplier partially meets the specified criteria
- $Int. \in K_4$ -> the supplier fully meets the specified criteria

Let's pay attention to two basic singularities of similar systems of estimations:

a. The risk of obtaining inaccurate data due to subjectivity in the development of a system of criteria and the designation of weighting factors. As noted above, you often have to rely on the professionalism of the staff involved in developing the criteria and the vendor evaluation system.

b. When certain events occur, verification is required not at all but at certain criteria, i.e., the choice of the evaluation criteria system is dynamic.

3. Model with Dynamic Definition of Control Criteria

In order to take into account the above-mentioned peculiarities of the class of systems under consideration, we introduce an additional set of states $C\{c_1, c_2 \dots\}$ and the set of mappings

$$W = \{w_1, w_2 \dots, w_n\} \text{ , where } w_i(C \to G_1, i = (1,2, \dots n) \text{),} \quad (6)$$

for which to a certain ci there corresponds a chain of the following subsets $(G'_1 \subset G_1) \cap (G'_2 \subset G_2) \cap (G'_3 \subset G_3) \cap \dots \cap (G'_i \subset G_i)$, it is possible $G_i = \{\emptyset\}$ for anyone $(i = 1,2, \dots n)$. By the states ci we mean the appearance in the system of some deviations (inconsistencies), in the result of which it is required to test by groups of criteria according to (expressions 3,4,5).

In practice, this may be, for example - the inconsistency of the equipment's indicators with the specified permissible values or the breakdown of individual components, which may suspend some stages of the production process, etc.

In this case, the problem (item "a") can be formulated as follows: determine the state of the system ci, choose the corresponding subsets of the criteria $G'_1, G'_2 \dots$ and apply the above algorithm for a given chain of criteria.

To determine the weighting coefficients (subsection "b"), we present the following procedure. Suppose for a certain period N production processes were performed, during which, $M(c_i)$ times the deviation of c_i from the set values was observed. At the same time, testing with the given criterion showed k times the discrepancy, i.e., $f(g_{ij})$ takes the value "0" (see expression 1), then $M(c_i)/N$ - will be the probability of occurrence of the event c_m.
And $k(c_i, g_{ij)}/M(c_i)$ is the probability of occurrence of the discrepancy by the criterion g_{ij} at the occurrence of the event c_i.

The total probability of non-compliance with the g_{ij} criterion during the N production processes will be:

$$P(c_i, g_{ij)} = \frac{M(c_i)}{N} * \frac{K(c_i, g_{ij})}{M(c_i)}. \tag{6}$$

In this case, the value of the weighting coefficient for the given criteria g_{ij} from G'_i at occurrence of the events ci can be calculated as follows:

$$\lambda'_i(c_i) = \sum_{j=1}^{m} \frac{P(g_{ij}, c_i)}{m}, \tag{7}$$

where $j = (1 \div m)$, m- the number of criteria in a group G_i.
Similarly, calculating for the criteria of the group G_i when other events $c_j \in C$ occur, for which the condition $w_i(C \to G_i)$ is satisfied, we obtain the final value of the weight coefficient for the group G_i:

$$\lambda_i = sum(\lambda'_i(c_{1i}) + \lambda'_i(c_{2i}) + \dots + \lambda'_i(c_{mi}). \tag{8}$$

In this case, the expressions (5) describing the model of quantitative estimation and control of compliance with the given criteria for s_m will take the following form:

$$I(s_m) = \sum_{i=1}^{k} (F(s_m, G_i)\lambda_i),$$

$$Q(I(s_m)) = K' \subset K_i,$$

$$\lambda_i = sum(\lambda'_i(c_{1i}) + \lambda'_i(c_{2i}) + \dots + \lambda'_i(c_{mi}),$$

$$\lambda'_i(c_i) = \sum_{j=1}^{m} \frac{P(g_{ij}, c_i)}{m}.$$

The corresponding procedure can be specified in the form of the following 6 steps:

1. Analysis of the state of the system and dynamic generation of the chain of criteria $(G_1' \subset G_1) \cap (G_2' \subset G_2) \cap (G_3' \subset G_3) \cap ... \cap (G_i' \subset G_i)$, where “i” is the number of groups of evaluation criteria defined for a given state.
2. Calculation of the average values for each group, taking into account the weighting factors:
$F_1(s_m, G_1) * \lambda_1, F_2(s_m, G_2) * \lambda_2 \ldots F_i(s_m, G_i) * \lambda_i$, where $F_i(s_m, G_i)$ – the mean value according to expression (1).
3. Calculation of the sum $I(s_m)$ according to expression (2).
4. Definition K_i, for which $I(s_m) \in K_i$, where i =1,2,3,4,5, 6, ie., the definition of the group that includes this integral sum $I(s_n)$.
5. Generation of actions (expert opinion) according to the estimation of $I(s_m)$ and the corresponding group K_i.
6. Formation of new probabilistic values for determining the chain of evaluation criteria and their weight coefficients.

Below is a structural and functional diagram of an information system (software) that implements interrelated processes of evaluation and control of the parameters of the class of complex systems under consideration.

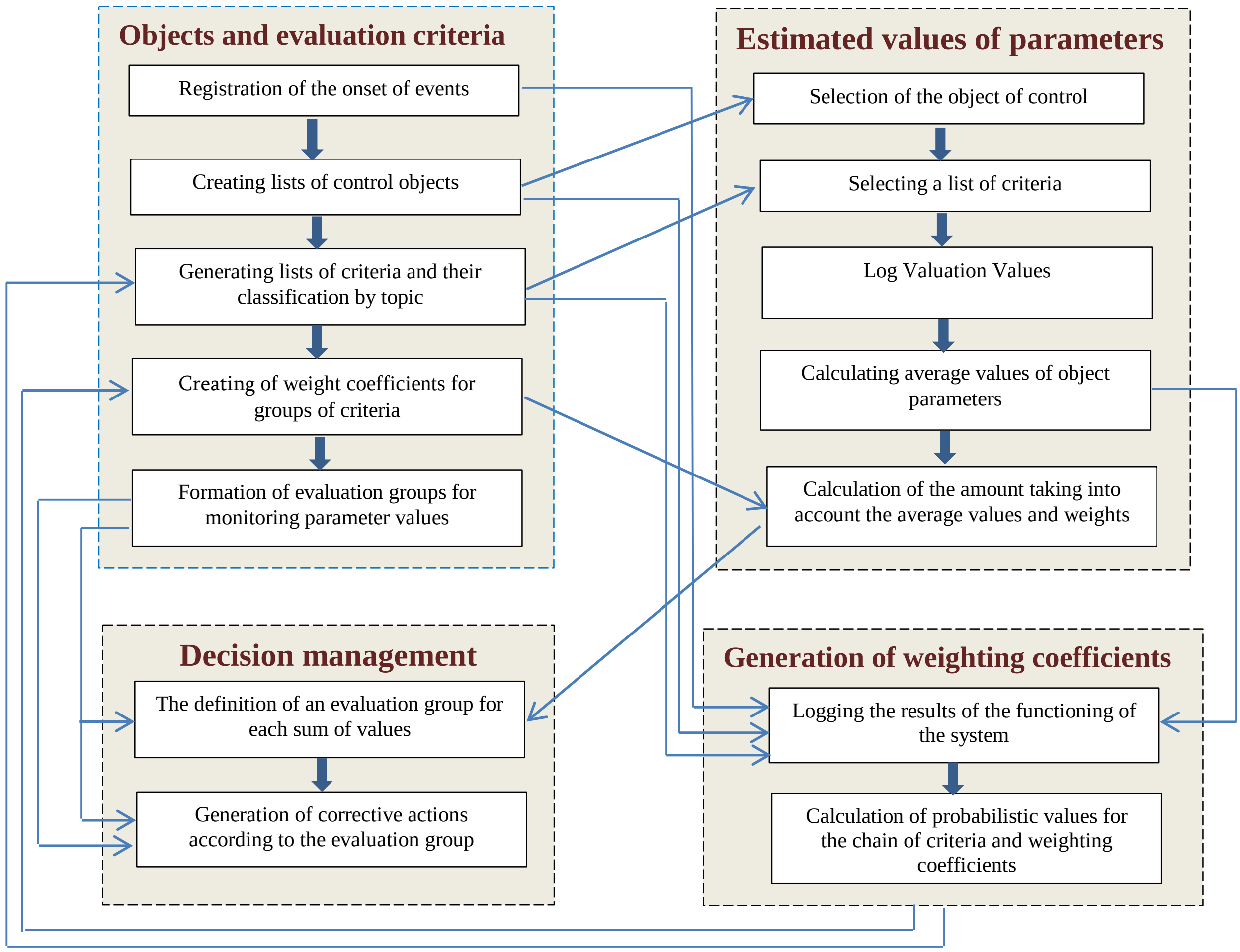

Fig. 2. Functional Components of the Information System.

4. Conclusion

In this paper we propose a model for estimating the parameters of complex systems and detecting nonconformities (deviations) to a given set of dynamically generated criteria. Based on the described model, a method is proposed for determining corrective and preventive actions to eliminate the detected discrepancies. During the operation of the system, experimental data were obtained, which make it possible to calculate the probabilistic values of the interrelated evaluation criteria and their weight coefficients. The software that implements this method was introduced in pharmaceutical manufacturing companies.

The main result obtained in the course of operation is the prompt elimination of inconsistencies and the reduction of current expenses by 45-50% due to

1) reducing the time for calculating the monitored parameters of the nonconformity detection system and taking decisions on the implementation of CAPA actions
2) reducing the risk of inconsistencies and deviations of the main parameters from the specified criteria.

References

[1] V. A. Ostrejkovsky, *Theory of Systems*, M .: High School, 1997.
[2] B.Ya. Sovetov, *Modeling of Systems*, Moscow: Higher School, 2001.
[3] M. Mesarovic, D. Mako and I. Tahakara, *The Theory of Hierarchical Multi-level Systems*, Moscow: Mir, 1978.
[4] J. Peterson, *Petri Nets Theory and Systems Modeling*, Moscow: Mir, 1984. .
[5] A. V. Aleksandrov, “GMP: evaluation and audit of a pharmaceutical company supplier”, "Industrial Review", vol. 6, no. 11, pp. 42--45, 2008.

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Բարդ դինամիկ համակարգերում համապատասխանության վերահսկման պրոցեսների մոդելավորման մեթոդներ

Ռ. Աղաջանյան

Ամփոփում

Բարդ համակարգերի հետազոտման և մոդելավորման կարևորությունը պայմանավորված է այդ համակարգերի արդյունավետ կառավարման անհրաժեշտությամբ, դրանց զարգացման կանխատեսման և գործունեության մեջ շեղումների վերացման ուղղությամբ։ Համակարգի հիմնական խնդիրն է ապահովել համապատասխանությունը հիմնական ցուցանիշների և տրված չափորոշիչների միջև։ Նման համակարգերի

հետազոտման և մոդելավորման բարդությունը պայմանավորված է մի շարք պատճառներով, որոնց թվում՝

- Համակարգում կոմպոնենտների քանակի ավելացումը
- Մեծ թվով բարդ ներքին ստոխաստիկ կապերի առկայությունը
- Պատահական պրոցեսների առկայությունը
- Հիմնական ցուցանիշների համապատասխանության պահանջների փոփոխություն

Դիտարկվող բարդ համակարգերը հանդիպում են մի շարք ոլորտներում (բարդ տեխնիկայի կառավարում, սննդամթերքի և դեղերի արտադրություն, առողջապահություն), որոնց պարամետրերի նկատմամբ դրված են խիստ պահանջներ, օրինակ՝ արտադրանքի որակի չափանիշների նկատմամբ: Շեղումների հայտնաբերումը, համակարգի պարամետրերի ցուցանիշների գնահատումը և կանխարգելիչ մեթոդների կիրառումը համարվում են արդի նման համակարգերի ուսումնասիրման և մոդելավորման համար:

Метод моделирования процессов контроля соответствия заданным критериям в сложных динамических системах

Р. Агаджанян

Аннотация

Актуальность исследования и моделирования сложных систем обусловлена прежде всего необходимостью эффективного управления подобными системами, прогнозированием их развитием и использованием корректирующих и превентивных действий для устранения нежелательных явлений в их функционировании, обеспечении соответствия параметров системы заданным требованиям и критериям. Сложность исследования и моделирования подобных систем обусловлена рядом причин, среди которых можно выделить следующие:

- увеличение числа компонент и звеньев системы
- наличие большого количества сложных внутренних случайных взаимосвязей
- наличие стохастических процессов
- изменения в требованиях на соответствие ключевых показателей заданным критериям.

Рассматриваемый класс сложных систем встречается на практике в ряде отраслях, в которых предъявляются строгие требования к параметрам системы, их оценкам, например к показателям качества выпускаемой продукции (авиастроение, управление сложным оборудованием, производство пищевых продуктов и медикаментов, здравоохранение). Для подобных систем является актуальной задача выявления отклонений, оценка показателей отдельных параметров для объектов (звеньев) системы и методы применения корректирующих действий для их устранения.