Quality management systems from the perspective of organization of complex systems

Alba N. Zaretzky

Dosimetría de Radiaciones Ionizantes, Comisión Nacional de Energía Atómica, Presb. Juan González y Aragón 15, (B1802AYA) Ezeiza, Prov. de Buenos Aires, Argentina

Received 6 April 2007; received in revised form 13 October 2007; accepted 26 December 2007

Abstract

The aim of this model is to analyse quality management systems from the standpoint of the organization of complex systems introduced by Robert Rosen. The concept that an organized system, under certain conditions, can be modelled as a living system introduces unsuspected tools to analyse its behaviour. The model is oriented towards the understanding of the implications of modifications introduced in laboratories working with a quality organization following the ISO/IEC 17025 standard.

This standard establishes management and technical requirements concerning the documental organization, control of the management and technical records, personnel, equipments, test or calibration methods, etc. The objective of the quality system implementation is to assure the quality of the product, the special consideration being the customer’s satisfaction with all aspects of the service the laboratory offers.

The improper use of the quality system tools has an impact on the laboratory activity. The perception of this fact can be negligible at the moment it happens. The model allows us to realize that this alteration always has a negative impact on the customer and it specially affects the continuous improvement that the laboratory must implement.

© 2008 Elsevier Ltd. All rights reserved.

Keywords: Relational theory; (M, R) systems; Quality management systems; ISO/IEC 17025 standard

1. Introduction

This paper combines the almost 30 years of research I have done on Relational Biology (Zaretzky [14]) and my present work, since 1999, as quality manager of a calibration lab and auditor for the Accreditation Body of Argentina for testing and calibration laboratories working according to the ISO/IEC 17025 Standard: “General Requirements for the competence of testing and calibration laboratories”. I started to think on the quality system as a general organized system for which Robert Rosen’s conception seemed to be especially adequate.

Rosen [7,8,12] worked on the organization of living systems in the context of Relational Biology, which considers qualitative interactions in systems. The term was first used by Nicholas Rashevsky [2–6]. In Rosen’s book “Life Itself” [12], he discusses the ideas introduced by Rashevsky about the concept of Organization. He quotes the words with which Rashevsky inaugurated his investigations into Relational Biology: “We must look for a principle which
connects the different physical phenomena involved and expresses the biological unity of the organism and the organic world as a whole”. As Rosen points out in his book, we must look for a principle that governs the way in which physical phenomena are organized, a principle that governs the organization of phenomena, rather than the phenomena themselves. So, organization is precisely what Relational Biology is about. It concerns with qualitative interactions because, in the sense of Nicholas Rashevsky, each functional property in Biology occurs for every level of organization independently of the subjacent physico-chemical machinery. When we want to know how a system works, and not only biological systems, we need to describe the relationships among its parts. The way to do that must be simple and should not depend on the great variability existing among “individuals”. The first approximation to the description must then be done through qualitative relations.

Rosen starts defining the concept of function. If there is a system that is heterogeneous, that is, one part looks different or behaves different from another part and one of these parts is removed or changed, what would be the effect on the behaviour of the system? He says that any discrepancy between both behaviours defines the function of the removed or changed part. Any part of a system that can be assigned a function in this sense is then a component of the system. This idea of component provides a unit of organization. Any system is then organized to the extent that it can be analysed into or built out of constituent components. Rosen says that the characteristic relationships between such constituent components, and between the components and the system as a whole comprise a new and different approach to science itself, which he called “the relational theory of systems”.

In fact, a component must be endowed with the following properties: (i) it must possess enough “identity” to be considered a thing in itself and (ii) there must be enough room for it to acquire properties from larger systems to which it may belong.

Rosen worked in Biology with \((M, R)\) systems, that is metabolism — repair systems. I will introduce the concept and formalism in order to make clear its generalization to other systems. An antecedent of this different use can be seen in Hong [1], but Rosen himself emphasized that the arguments were valid for general systems, though his main interest was Biology.

Moreover, as Zamenopoulos and Alexion [13] say, Rosen’s concern was not only Biology. That is more evident in relation with his theory of anticipatory systems. For example, they say, “Rosen’s examination of anticipatory systems [11] with its associated premises has not only been an inspiration for the study of biological worlds, but also for the scientific enquiry, understanding, modelling and control of complex systems in general”. And they add “For him (Rosen) the idea of building and employing predictive models was also a fundamental aspect of science in general, perceived as a means to construct homologies between modes of social and biological organization and sustain a general theory of planning, policy generation and decision making”.

The paper of Hong Li highly clarifies the relevance of the relational model that he applies to enterprise development. It is an important antecedent for the present paper.

The metabolic system \(M\) was conceived as a system consisting of components, which have inputs and outputs. A component transforms a set of input materials into a set of output materials.

The simplest such system may be seen in Fig. 1.

Here \(M_a\) is the component and \(\rho_1\) and \(\rho_2\) are the input and output of \(M_a\), respectively.

Naturally, some outputs of one component may be inputs of other components, giving block diagrams as the one in Fig. 2.

In real living systems, the components \(M_i\) have a finite life, and there must be a subsystem \(R_i\), where \(R_i\) repairs \(M_i\). Then the subsystems \(R_i\) have components and input and output materials, with the particularity that the output of \(R_i\) is the component \(M_i\).

The block diagrams were reformulated in terms of abstract block diagrams, which allowed the study of the former ones with the formalism of the theory of categories Rosen [8–10].

The Category Theory is a mathematical theory. A category has objects and morphisms between them. There must be an identity morphism for every object; morphisms may be composed and the composition must be associative.
In an abstract block diagram, inputs and outputs of a component are the objects of the category and the components are represented by the arrows (morphisms). The abstract block diagram corresponding to Fig. 2 may be seen in Fig. 3.

Formally, in the category of \((M, R)\) systems, if \(A\) and \(B\) represent the set of inputs and outputs to a component, then the metabolic activity is represented by \(f \in H(A, B)\), with \(H(A, B)\) the set of arrows connecting \(A\) with \(B\).

In the Aristotelian language, \(a \in A\) corresponds to the material cause and \(f(a)\) is the effect; \(f\) corresponds then to the efficient cause of the effect. \(f(a)\) is not the final cause because the final cause of an effect depends on what is entailed by the effect. But there is no organization without finality. So, the question, “why \(f(a)\)?” has two different and correct answers: because \(a \in A\) and because \(f\). This means that the reason for having the effect \(f(a)\) is because we have the material to get it (\(a\)) and we have the way to get it (\(f\)).

So, we can say that, in the category, \(f : A \rightarrow B\) means that for any element \(a\) in its domain \(A\), \(a\) entail \(f(a)\). That is to say, \(a \Rightarrow f(a)\), or better, \(f \Rightarrow (a \Rightarrow f(a))\). It means that the mapping \(f\) and the specific argument \(a\) on which it acts, are each required to entail the image \(f(a)\).

As Rosen says, the images \(f(a)\) have yet no function, because they have nothing to entail and \(f\) itself and its arguments have only function, but they are themselves unentailed. By embedding a component in a larger abstract block diagram, the images \(f(a)\) can be endowed with something to entail. In that way, the images \(f(a)\) are endowed with particular functions, while other components in the diagram acquire new functions with respect to \(f\) itself. This augmented abstract block diagram is the following

\[
A \xrightarrow{f} B \xrightarrow{\phi_f} H(A, B).
\]
Fig. 4. The red (grey) arrows represent material causation. The black arrows represent efficient causation. $B$ is the result of an efficient cause ($f$) acting on a material cause ($A$) in order to produce the effect ($B$). But $B$ is also the material cause for the efficient cause ($\phi$).

Now $f(a)$ has something to entail for each argument $a$.

Then, $a \in A$, $f(a) = b$, $\phi_f(b) = f$. This means that the output of $\phi_f$ is the component $f$. That is to say $\phi_f \Rightarrow (f(a) \Rightarrow f)$ or, which is the same, $\phi_f(f(a)) = f$. Now $\phi$ is an efficient causation of the effect $f$ which was called the “metabolic function”. $\phi$ is called the “repair function”.

But now $\phi$ is unentailed and the question why $\phi$? cannot be answered within the system. Then a new function is needed so that $\phi$ can be entailed. This new function is called the “replication function”.

Rosen found that in these systems, a mapping $\beta$ exists such that $\beta (f) = \phi_f$, completing a cycle given by:

$$A \xrightarrow{f} B \xrightarrow{\phi_f} H(A, B) \xrightarrow{\beta} H[B, H(A, B)].$$

Then, which is the efficient cause of $f$? According to the cycle previously described, it is $\phi$. Then $\phi$ is an efficient cause of the effect $f$. And “why $\phi$?” Because $\beta(f) = \phi$. So, the entire “why” questions have an answer within the system.

Then, the former cycle may be redesigned in the way shown in Fig. 4, which gives a new idea about what it represents.

As it was said before, in biological terms, $f$ is the metabolic component, $\phi$ is the repair component and $\beta$ is the replication component.

Then, the following definition is given by Rosen [12]: a material system is an organism if, and only if, it is closed to efficient causation. That is, if $f$ is any component of such a system, the question “why $f$?” has an answer within the system.

Taking this definition into consideration, the diagram of Fig. 4 is the relational model of an organism.

Hong Li points out that “if we want our organizations to be able to adequately answer the question “why $f$?” we will need to find this new model to make our organizations and our program life cycles inherently and organizationally adaptive, self-learning and self-evolving, just like any biological organism is capable of doing through the internal abilities they have acquired during millions of years of evolution”.

2. The quality system as an organism

The ISO/IEC 17025 standard is an international standard applicable to all organizations performing tests and/or calibrations. It has management requirements about the organization of the lab; its quality system; document control; review of requests, tenders and contracts; subcontracting of tests and calibrations; purchasing services and supplies; service to the customer; complaints; control of nonconforming testing and/or calibration work; corrective actions; preventive actions; improvement; control of records; internal audits and management reviews. The technical requirements are about the personnel; accommodation and environmental conditions; test and calibration methods and method validation; equipment; measuring traceability; sampling; handling of test and calibration items; assurance of the quality of test and calibration results and reporting the results.

So, to have implemented a quality system according to this standard means to have the corresponding documentation, equipment, trained personnel, adequate accommodations, validated laboratory methods, etc., which means that not only the processes are organized according to the requirements but also the technical competence of the lab must be strictly controlled to guarantee a good product and the customer’s satisfaction.

Let us start the model assigning to the elements appearing in Fig. 4 a meaning in the system implemented by the lab.

$A$ is a set of elements $A = \{a_1, a_2, \ldots, a_n\}$. It represents the material inputs to the system: equipment, operators, test material, etc.
Fig. 5. Abstract block diagram representing a part of a particular process.

$f$ represents the quality system designed in order to fulfill the requirements of the ISO/IEC 17025 standard. It says *how* things must be done. It represents the *formal cause*. It is composed by the general procedures, operative procedures, working instructions, etc., which are put together and as they are the skeleton of the quality system, they constitute the efficient cause of the effect.

It must be remembered that when it is said $A \xrightarrow{f} B$ we are representing the set $H(A, B)$ where there are $a_i \in A$, $f_j \in H(A, B)$ and the products $b_k$, the effect of the $f_j$ acting on the $a_i$. Then the $f_j$ (working instructions, for example) tell us how to use the elements $a_i$ (an equipment, an operator) in order to get a part of the calibration or the test being held.

So, the abstract block diagram of Fig. 5 could mean the following:

Suppose a ionisation dosimeter is being calibrated. In order to do that, the ionisation chamber, as part of the dosimeter, must be positioned very carefully in order to receive an irradiation during a fixed lapse and under very well controlled environmental conditions: temperature, humidity and pressure. In order to do this, the operator $A_1$ using the micrometer $A_2$ and the thermometer $A_3$, according to the working instructions $f_{11}$ and $f_{12}$ produces the correct placement of the ionisation chamber ($B_1$) and the value of the temperature correction ($B_2$), both elements being part of the calibration process of the radiation dosimeter.

The $f_{ij}$ are representing the quality system being implemented (efficient cause) and the implicit formal cause is conformed by the documents of the system.

It must be remembered that, in the categorical language, each component $M_a$ of the system is represented by an arrow $f_a$.

$$f_a = (f_{a1}, f_{a2}, \ldots, f_{an}).$$

This means that $M_a$ has $n$ outputs. The domain (dom) of each $f_{ai}$ is:

$$\text{dom}(f_{a1}) = \text{dom}(f_{a2}) = \cdots = \text{dom}(f_{an}) = A$$

with $A = A_1 \times A_2 \times \cdots \times A_m$, $A$ being the input of $M_a$ consisting of the simultaneous input of $A_1, A_2, \ldots, A_m$. The codomain (codom) of each $f_{ai}$ is an object $B'_{ai}$ representing an output of the component $f_a$.

What is obtained in $B$? The product, the service, the test or the calibration or parts of it. Then the question “why $b = f(a)$?” answered by “because of $a$ and because of $f$ ” means that we obtain our product not only because we have the materials (equipment, samples, operators, accommodations) but also because of $f$, the quality system being implemented.

But, which is the role of $\phi$ in the model? It is the efficient cause of the effect $f$.

It is connected with the customer: $\phi_f \Rightarrow (f(a) \Rightarrow f)$ means that “the customer and the product of the test or calibration each are required to entail the quality system”. Each part exists because the other parts exist.

Then, when we say that $\phi(b) = f$, it is because the customer feeds the quality system with the complaints, the positive or negative feedback, questions, suggestions, any other communication from the customer to the lab, which is something the 17025 standard strongly requires taking into account, and, specially important, asking for the service again after a certain time or, even more important, never coming again and asking for the same service from another lab. The customer takes the product the lab is giving, and after processing it, in its widest sense, reacts with some or all the former alternatives and then feeds the system the lab has implemented, considering the management aspects and the technical aspects as well.
The system has environmental inputs and outputs. The environmental inputs are conformed by what the system uses coming from outside. In this context these elements are, for example, the calibration of the laboratory’s own equipment, proficiency tests, audits, etc. The environmental outputs of the system are of different kinds. Some of them are “real” environmental outputs, like elements which are discarded, or personnel leaving the lab. But many of these environmental outputs are the inputs of the “repair” system, in the language of \((M, R)\) systems. They are considered environmental outputs of \(M\) because they are not inputs to other components of \(M\). But they are inputs to the repair components: the calibrated equipment or the test results for the customer; the calibration certificates or test information; phone calls to the customers; opinion polls, etc. It is through \(\phi\) that the quality system \((f)\) receives, directly or indirectly, its regeneration. The finality of the system is the service and its user. This system must be fed by them and, eventually, inducing a modification on it. The system has its own mechanisms of modification, but they are at the end induced by the improvement of the service, that is to say, by the customer’s demands and satisfaction.

Now we come back to the question “how are the \(\phi_i\) produced?” That was the question which Rosen made about the repair components \(R_i\) for the metabolism — repair systems in cells. And the answer came through the sequence

\[
A \xrightarrow{f} B \xrightarrow{\phi_i} H(A, B) \xrightarrow{\beta} H[B, H(A, B)]
\]

where \(\beta(f) = \phi\). In this model, the meaning assigned to \(\beta\) is that it represents the continuous improvement, which is the soul of the ISO 17025 standard. It is the continuous improvement operating on the quality system which will induce the customers to feed the system in a better way and will keep it functioning.

Now the circle is complete:

(i) The material elements (equipment, personnel, among other things) by means of the tools the quality system provides, end in a product, with all the elements formerly described.
(ii) The customers receive the product and make use of it.
(iii) The customer processes the product and, directly or indirectly, reacts in a way that feeds the system producing a reaction in the lab, inducing (or deciding not to do it) modifications in the system in order to improve the service.
(iv) Continuous improvement is a never-ending activity in order to improve the capacity of fulfilling the requirements. The requirements are represented by the \(f’\)s (quality system).

With all these elements we may claim that the extended system conformed by the material elements, the quality system organization, the customers and the continuous improvement activity may be modelled by a graph as the one in Fig. 4. Following Rosen [12], “any material system possessing such a graph as a relational model (i.e., which realizes that graph) is accordingly an organism”.

### 3. Mathematical consequences — organizational consequences

Now the laboratory with its quality system, its service and its customers may be seen as a living organism. As there is a mathematical representation for this kind of organization and behaviour, we will use these mathematical tools to evaluate in a formal way how the system acts and reacts.

It is clear that a relational system may have many equivalent abstract block diagrams. In our system this means that, with the natural restrictions on some technical aspects connected with the service, there are many ways to design the quality management system.

One of the situations these systems suffer from is the sometimes extremely huge quantity of documentation that is developed to fulfill the requirements of the standard. The problem is that much of the information is redundant because it appears in more than one document. Very often, changes in one activity produce a documental modification. If the information appears in more than one document it might be corrected in one and not in other documents having the same information, producing a contradiction in the system. This kind of contradiction may produce important nonconformities. It may be that some members of the personnel are following some instructions and other members are following other instructions. If the contradiction is a technical one, its influence may be severely affecting the results.

Before a quality system is installed at a laboratory, the technical work is usually done in a proper way. This is the main argument of people working at this kind of laboratories who are resistant to the implementation of a formal system. What the implementation of this formal system produces is (1) that the inputs \(A_i\) previous to the implementation of the quality system are similar but not the same as after it: for example, the equipment is generally
not systematically calibrated and the calibration laboratories which are suppliers of the calibration of the lab equipment are not qualified as they are after the implementation of this kind of system; the labs do not participate regularly in intercomparisons; the personnel may be well trained but usually they are not encouraged to increase their skills on different subjects; the records may be taken carefully but usually they are not completely traceable in order to check or repeat any test or calibration that has been done at the lab; the calibration certificates or test information are seriously made but it may be that some important information is lacking; uncertainty of measure may be calculated but usually not so carefully as when there is a specific demand on having it properly calculated, etc. (2) The lack of a documental system \( f \) generally induces the personnel, specially people with a big experience, to make changes during the process or to use some elements \( A_i \) which are not completely or properly controlled. The effects of these changes are very difficult to discover, unless it is too late or the problem is big enough. As it has been said, to work with a system in which the original choice of components is too coarse produces redundancies which may lead the system to impose contradictory directives to its users. Then the ideal situation would be to arrive to a system organized in the most simple way, which Rosen has demonstrated is possible to obtain. With the model that has been posed it may be proved that it is possible (Rosen [7]). This is done through the use of the category theory and the determination of canonical forms for abstract block diagrams.

Let us now revise the construction of the mapping \( \beta \), which we have interpreted as the continuous improvement in the system.

\( \beta \) appears in the mathematical formalization as the inverse of \( \hat{b} : H[B, H(A, B)] \to H(A, B) \), considering that each element \( b \in B \) is itself a processor, acting as a mapping \( \hat{b}(\phi_f) = f \). So, in order that \( \beta \) can exist, \( \hat{b} \) must be 1–1. In this case \( \beta(f) = \phi_f \).

So, as we said before, in our quality system terminology, the continuous improvement acts on the quality management system \( f \) and produces a process of reaction in the customer.

Let us analyse the fact that this mapping is 1–1. It is a bijection \( f \leftrightarrow \phi_f \).

This means that each \( f_i \) has a reason to exist, which has a final impact on the customer, some of them evident, and some not so. For example, if we have a document which establishes the methodology to ask for a date for the calibration service or to do a test, this document has the objective that the customer can receive the service in a ordered way, optimising the waiting times and in order to know in advance when he will have his instrument out of use because it is being calibrated or he will have the result of a test that he needs for his own customers. The documents about contracts are made, among other things, so that the customer can clearly establish the conditions of the service, the time it will take to do it, the price, etc. The technical documents will have an impact on the calibration or test service itself, each of it with a part of the process of which the customer receives a final product. Having more personnel will produce a quicker service which will allow the customer to be more satisfied and take the decision of asking for the service again or requiring another product the lab is able to produce. It is evident that there is always a transaction between the lab and the customer, formally recorded or imperceptible, between each process within the system and some processes of the customer using the service.

We have to remember that in the block diagram for each component \( M_a \) there exists a component \( R_a \) being represented in the abstract block diagram model by the arrow \( \phi_{f_a} \).

\[
\phi_{f_a} = (\phi_{f_a}^1, \phi_{f_a}^2, \ldots, \phi_{f_a}^n)
\]

with \( n \) the number of outputs of \( M_a \).

\[
\text{dom}(\phi_{f_a}^1) = \text{dom}(\phi_{f_a}^2) = \cdots = \text{dom}(\phi_{f_a}^n) = B
\]

being \( B = \prod B_i^j \), and \( B_i = \text{codom}(f_i) \).

Each \( \phi_{f_i} \) is representing the way in which the elements received from the lab by the customer, as a consequence of the implementation of \( f_i \) and of the inputs \( a \), come back to the lab (processed, transformed), and then, come back to the system.

The question is: what happens when one or more of the quality system tools are not used? That is to say, what happens if some working instructions are not used, or some records are not taken in the way the system requires? What happens if some periodic controls to the equipments are not done when they were planned? This means, in other
words, what happens if one or more \( f_i \) are not being used or they are not used in the strict way they are defined? Then the bijection \( f_i \leftrightarrow \phi_{f_i} \) is not working any more, that is to say \( \hat{b} \) (and \( \beta \)) fail to be bijections.

**First consequence:** \( \beta \) does not exist any more, so the continuous improvement cannot be implemented until the system is repaired.

**Second consequence:** when \( f_j \) disappears, there is no way to produce \( \beta \left(f_j\right) = \phi_{f_j} \). Then:
(a) \( \phi_{f_j} \) is not produced any more or
(b) \( \phi_{f_j} \) is produced in an inadequate way if the system tries to continue operating with the remaining \( f_i \neq f_j \).

Then, if the \( \{f_i\} \) are the required ones, it is impossible that not using the tools of the quality system in the proper way will not have an influence on the customer; and considering that \( \beta \) stops existing, then the modification in the relation with the customer cannot be anything other than a negative one.

### 4. Conclusion

The paper has introduced the concept of living organism in the context of the relational theory of systems to represent a quality system implemented in a test or calibration lab. This representation allowed using mathematical tools developed for the representation of general relational systems. The organization and behaviour of the system were analysed through this representation.

One of the main consequences of the utilization of the model is that though the laboratory may not be able to detect the impact deviations in the system may have on the customer, this impact exists and it is a negative one.

Besides, it gives a justification for the importance of having a quality management system, because through the model introduced in this paper it becomes clear that if changes are not planned in advance, this fact not only affects the activity but all the relationships involving the technical work and the customer.

### References