

Discussion

# Quality Systems. A Thermodynamics-Related Interpretive Model

Stefano A. Lollai 

Istituto Zooprofilattico Sperimentale della Sardegna “G. Pegreffi”, Sassari 07100, Italy;  
stefano.lollai@izs-sardegna.it

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**Abstract:** In the present paper, a Quality Systems Theory is presented. Certifiable Quality Systems are treated and interpreted in accordance with a Thermodynamics-based approach. Analysis is also conducted on the relationship between Quality Management Systems (QMSs) and systems theories. A measure of entropy is proposed for QMSs, including a virtual document entropy and an entropy linked to processes and organisation. QMSs are also interpreted in light of Cybernetics, and interrelations between Information Theory and quality are also highlighted. A measure for the information content of quality documents is proposed. Such parameters can be used as adequacy indices for QMSs. From the discussed approach, suggestions for organising QMSs are also derived. Further interpretive thermodynamic-based criteria for QMSs are also proposed. The work represents the first attempt to treat quality organisational systems according to a thermodynamics-related approach. At this stage, no data are available to compare statements in the paper.

**Keywords:** quality; general system theory; thermodynamics; entropy; cybernetics; information theory; management

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## 1. Introduction

Quality is the “degree to which a set of inherent characteristics of an object fulfils requirements” and a Quality Management System (QMS) is an organisation that operates according to quality. These definitions are from the ISO 9000 standard, the cornerstone in the field of quality [1].

Moreover, according to this standard, a quality system is defined as a “set of interrelated or interacting elements”, which presupposes an organisation, namely “people which has its own functions with responsibilities, authorities and relationships to achieve its objectives”, in order to perform processes, the mutually interacting of activities which, managed as a whole, allow the organisation to reach its intended results with effectiveness and efficiency [1].

Quality, as expressed by standards, supposes a well-ordered structure, and the maintenance of order presupposes the expenditure of work, as imposed by Thermodynamics. Nevertheless, it is rather strange that a thermodynamically-based interpretation is still lacking for quality systems since it is believed that quality spontaneously descends from an “instinctive drive for precision, beauty and perfection” among human operators [2].

It is well known that quality does cut losses in production, but only a few authors have investigated the cost of quality in itself [3]. The author thinks that this aspect has not received adequate consideration, and a response to the key question posed by Rasberry as to “whether quality systems are so abstract that they escape thermodynamic principles” is thus required [4].

Moreover ambits belonging to the more general quality domain such as total quality management have been examined in the light of systems theories, a group of thermodynamics-related-theories, but the same did not occur for organisations based on “certifiable” quality, as described in standards [5]. In such a field, an interpretive analysis based on systems theories is still lacking, despite QMSs falling

into conventional definitions of system, being “sets of elements standing in interaction”, according to von Bertalanffy, or “integrated set(s) of elements ( . . . ), that accomplish a defined objective”, or even a “combination of assembled and interconnected elements . . . which have a defined goal” [6–8].

Additionally the lack of theoretical foundations for quality has been reported [9]. To the writer’s knowledge, in fact, not many publications exist on this topic and recently works have attempted a theoretical approach on (total) quality management systems based on a broad range of frameworks, e.g., based on a constructivist and pragmatic framework [10].

The aim of the present paper is to provide quality systems with a broad, thermodynamics-related theoretical background. After a first interpretive step aimed to frame quality in the proper system model, quality assumptions are discussed according to Thermodynamics and related disciplines, such as Cybernetics and Information Theory. Ways to evaluate the entropy and information of organisations, processes, and documents are proposed. The paper also attempts further the interpretive suggestions for QMSs.

Aware of the risk of “jumping onto the bandwagon”, for (maybe) overusing the terms entropy and information in inappropriate contexts, as Shannon feared, this reasoning is conducted as closely as possible to the original meaning of such terms [11].

To the author’s knowledge, the present work represents the first attempt to treat QM organisational systems according to a Thermodynamics-related approach. At this stage, no analogue data are available to compare statements in the paper.

## 2. Quality

Certifiable quality is a means of attesting to the attitude of an organisation in providing a service or products matching the requirements of a given (international) standard. The three standards of the ISO 9000 family (ISO 9000, ISO 9001, and ISO 9004) represent the keystone of certifiable quality [1,12]. They provide a reference guide for companies that intend to organise a quality system or service.

ISO 9001 specifies the requirements against which a QMS can be certified. The standards of specific certifiable fields are generally written in line with the ISO 9001 scheme and updated accordingly, e.g., ISO/IEC 17025 in the field of testing and calibration laboratories and ISO 15189 for medical laboratories [12–14]. A third-party certification (or accreditation) body is required to attest that the organisation meets the requirements of the standard.

According to ISO 9001, quality is based upon seven quality management principles (QMPs), the basic beliefs of the theory, which are: (i) customer focus, which drives the company to pay great attention to the needs of customers and other interested parties, a crucial element for the organisation’s adequacy (customers and interested parties represent its environment); (ii) leadership, necessary to ensure unity of purpose as well as quality policy and objectives; (iii) engagement of people in order to promote shared participation; (iv) process approach since “managing interrelated processes as a system contributes to the organisation’s effectiveness and efficiency in achieving its intended results”; (v) improvement, which is important, not only to maintain high levels of performance, but also to adapt to changes in internal and external conditions; (vi) evidence-based decision making since decisions should be based on the analysis of data and information; and (vii) relationship management since, for sustained success, an organisation manages its relationships with the exterior (e.g., interested parties and suppliers). QMPs intertwine with all areas covered by the specification.

The standard (especially the most recent 2015 version) draws particular attention to the fact that the organisation should understand its external and internal context [12]. External context can be defined as the complex interaction of influences arising from social, legal, and economic aspects, government regulations, competitors, and evolutions in technology. The organisation is required to “understand the needs and expectations of interested parties” (identifiable in e.g., customers, suppliers, corporate partners, regulatory bodies, etc.). In accordance, organisations periodically review all important (internal and mainly external) issues.

The way to determine the context is not clarified, but devices to perform such a requirement do belong to classical management and could consist in competitor and SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis, market research, and economic reports.

The scope of a quality management system should thus be consistent with the organisation's context (the needs of customers). A process-based management system is required [12].

Leadership ensures that resources, quality policy, and objectives are established and are consistent with the strategic direction undertaken. This section also deals with customer focus, which is the effort addressed to customers' needs, thus representing the point towards which business activities are focused. It is a crucial element for an organisation's survival (customers represent the environment to which companies have to be attuned) [12].

A quality policy is a strategic document issued to disclose an organisation's directive and purpose with respect to quality [12]. According to ISO 9001, it is a written document to be communicated to and applied within the whole organisation [12]. Moreover, for reasons of clarity and organisational order, roles are to be assigned and responsibilities allocated, communicated, and understood within the organisation [12]. An organisational chart is the best way to comply with this prescription.

Planning in QMSs is an accomplishment fundamentally based on risk analysis. Once identified, risks and opportunities are properly addressed, thus planning mainly consists of preventive action conducted in a systemic way, with the aim of avoiding resorting to ad hoc corrections of undesired effects already in action. It should obviously be developed and balanced according to the organisation's context and objectives in order to find the best way to achieve the intended results [12].

Clearly defined quality objectives consistent with quality policy are thus to be established [12].

ISO 9001 Clause 7 requires adequate resources to ensure that objectives and essential elements of quality (establishment, implementation, and improvement of the system) are provided, viz. people, infrastructure, and environment for operations [12].

Moreover, the organisation should be aware of the knowledge (information) necessary for carrying out its processes and, maybe more importantly, the organisation should consider how to acquire and improve any necessary additional knowledge to enhance competence. Knowledge thus consists of information gained from experience (internal knowledge) or imported from the exterior (e.g., methods, standards, technology) [12].

Documented information, viz. instructions and registrations, is to be maintained. Some standards specifically prescribe a "Quality manual" and procedures (e.g., ISO/IEC 17025, ISO 15189) [13,14].

It is important to underline that the latest version of ISO 9001 has replaced the previous terms "documents" and "records", focusing on the single term of "information".

Operation, dealt with in Clause 8, represents the core of the organisation's activity. It can be stated that the whole of the surrounding system governs this section. It foresees adequate process and controlling criteria. The organisation should, in fact, design, implement and control processes, as well as establish criteria for their acceptance. Feedback should be acquired from the customer in relation to products and services provided.

To be in tune with the standard requires that the company ensure the conformity of externally provided processes, products, and services, mainly if they are intended for incorporation into the organisation's own domain. The organisation must also apply criteria for the selection and monitoring of external providers [12].

The evaluation of performance is actuated by monitoring customer satisfaction as well as the outputs of internal activities aimed at satisfying it, then through internal audits and management review [12].

Planned audits, together with non-conformity managements (see [12]), are one of the most important control mechanisms adopted to maintain the set requirements. Management review is a high level integrated control, according to which top management, at planned intervals, reviews the whole system. It is conducted by analysing the most important indices of adequacy, e.g., information on performance, feedback on customer satisfaction and from interested parties, the management of

non-conforming events, audit results, improvement, etc. Outputs are decisions intended to realign system performance with the previously set strategic direction.

Improvement is mandatory for QMSs. It consists of any actions necessary to enhance customer satisfaction. It can be realised in a continuous way but also by breakthrough changes, innovation, and re-organisation.

Management of non-conforming events is a crucial control mechanism. It generally presupposes an immediate correction but also the identification of the causes of deviation in order to avoid recurrence. Organisations should review the effectiveness of any corrective action taken to realign the process [12].

It is important to highlight that many clauses require the organisation to maintain documented information on activities, regarding planning, design, and registrations as a sort of virtual system mirroring the organisation.

### 3. Quality and Systems Theories

The systemic approach was a significant theoretical framework, which arose during the 1900s, and still represents an important pattern of thought. It deeply impregnated the overall cultural environment, including Philosophy, after Smuts, in his holistic theory of 1926, recognised wholeness as the correct approach to interpreting phenomena [15].

Such a background influenced many scientific fields, among which are Biology (e.g., organisms, ecosystems), Chemistry and Physics (thermodynamic systems), Information Theory (information systems), Cybernetics (neural networks), Economics (market systems), and Psychology (Gestalt theory). System theories in the scientific area emerged, in fact, through the influence of the advancing knowledge in Biology, Economics, and Engineering at the beginning of the Twentieth Century and in contrast to the dominant mechanistic approach. In 1968, the Austrian biologist von Bertalanffy harmonised the emerging ideas and conceived General System Theory (GST), a meta-theory mainly devoted to comprehending the “whole(s) consisting of interacting components” [6]. GST encompasses a variety of disciplines under a unique wide-ranging framework and a system-based approach [6,16].

A fundamental element in system theories is that of hierarchic order. Systems are organised in levels of increasing complexity both in structures and functions (or processes). At each level of complexity, systems can show emerging properties, new features not existing at a lower level [17]. This is a crucial aspect of the systemic approach that contrasts with the Cartesian paradigm, which dominated Science until the nineteenth century, according to which all behaviour can be fully understood by studying the properties of its parts.

In order to highlight isomorphism among disciplines, GST promotes the development of system models to show the intrinsic unity of science. The preeminent aim of GST is, in fact, to “investigate the isomorphy of concepts, laws, and models in various fields, and to help in useful transfers from one field to another . . . ” [6]. From the introductory depiction given above a question arises: what kind of system do QMSs belong to ?

A deeper incursion into system theory is thus required in order to better characterise QMSs. Depending on their features, systems can be classified in many ways. According to their interactions with the environment, systems can be defined as (i) isolated systems, with no communication with the exterior; (ii) closed systems, exchanging only energy; and (iii) open systems, exchanging both energy and matter [18]. Even if organisations are sometimes characterised as closed systems in conventional approaches (assuming that the behaviour of an organisation mainly depends on its internal elements), it is useful to correctly recognise QMSs as open systems due to their essential need to exchange matter, energy, and information with the exterior [16].

Miller, in his seminal work “Living Systems”, distinguished three main types of systems: conceptual, or symbolic, abstracted or mathematical, and concrete or physical [19,20].

Accordingly, two kinds of levels are recognisable in QMSs; a physical one and a conceptual one, the latter made up of system documents, which formally describe and set the rules for the former, which consists of the material elements of the organisation.

It is also important for a proper characterisation to refer to the hierarchical vision devised by Boulding in his 1956 “General Systems Theory”, which ranked systems in nine groups of increasing complexity: (i) the level of static structure or “level of frameworks”; (ii) simple dynamic systems interpretable by the laws of Mechanics or “the level of clockworks”; (iii) control mechanisms or cybernetic systems, which are feedback regulated and exemplified by the homeostasis of viable systems, i.e., “the level of thermostat”; (iv) open or self-maintaining systems such as the “level of the cell”; (v) genetic-societal level, e.g., plants, characterised by the division of labour between differentiated cells; (vi) animals, which are mobile with self-awareness and teleological behaviour; (vii) human level, with self-consciousness; (viii) social organizations, expressing “human life and society in all its complexity and richness” e.g., art, music and poetry; and (ix) transcendental systems [16]. It is assumed here that QMSs have a similarity with the third type of system, since they are feedback regulated, and also, to a certain extent, with the fifth and sixth levels.

However, a “new wave of system thinking emerged” when the scientific community became aware of certain behaviors due to “organized complexity” in natural or artificial systems [21]. Speculations regarding the complexity of chaotic events and the nonlinear behaviours of systems led, in fact, to the advent of Complexity Theory, a new interdisciplinary approach, which emerged out of GST [22]. From this perspective, among others, Holland, in his 1962 work entitled “Outline for a Logical Theory of Adaptive Systems”, proposed the Adaptive System model, which later entered the field of management and was thus considered an effective (and practiced) tool for interpreting organisations [23].

Complex Adaptive Systems (CASs) are systems with a large number of interacting components, capable of adapting and learning, which are sometimes hierarchically organized. Typical examples of CASs include ecosystems, flock of birds, markets, cities, and social groups. CASs are able to self-organise themselves as a coherent form without any steering element devoted to driving self-organisation or controlling the system [24].

CASs presuppose resonance (i.e., shared reverberation and harmony between system elements), accreting nodes (i.e., the rapidly expanding “coalescences” of elements, e.g., ideas), pattern formation (i.e., interpretive schemes of situations that are dynamically evolving), and mutual catalytic behaviour between system elements. Such dynamic interactions and behaviours are able and fit to produce “emerging properties” and complex outcomes such as innovation [24].

Despite having a few shared aspects, some key features of CASs are not mirrored in QMSs.

The following features are apparently associated with them: interaction with internal and mainly external context as well as feedback reactions; hierarchy and self-organisation; and the import and storage of information of external origin [16].

However a number of important distinctions can be highlighted. In QMSs, interaction with the external context is a methodically conducted activity, and commensured reactions are not sudden or spontaneous [12]. Preventative planning, made on a rational basis against possible future adverse conditions, is required [12]. Process-based operations are prescribed, and processes are accurately designed [12]. Also the self-organisation of QMSs is quite different from the analogue feature of CASs. In QMSs, it does not arise spontaneously from the interaction of elements but from pre-defined criteria. In fact, although alternative and less bureaucratic approaches could be adopted, it is usually a planned disposition defined by a chart. Moreover, in QMSs, the correction of the route is a periodic and scheduled activity and, more importantly, is decided by a singular steering entity (the top-management), whereas there is no central driving unit in a complex system [12,24]. A scheduled reciprocal control (internal audits) exists, and control conducted by third party bodies also affects system decisions [12].

From the discussed considerations, QMSs seem quite different from CASs. Additionally they closely recall the basic premises summarised by Boulding for “classic” GST, according to which order,

regularity, and non-randomness are preferable to lack of order and orderliness in making the world good, interesting, and attractive to systems theorists [16].

For the reasons discussed above, in the present paper it is proposed to treat QMSs under a theoretical framework close to “classical” Thermodynamics and Cybernetics.

#### 4. Quality and Thermodynamics

Thermodynamics is the branch of physics concerned with energy transformation. It states that energy is conserved but also tends ‘to degrade’ itself as heat, a form of energy linked to chaotic molecular motion and relatively unemployable to produce useful work.

A thermodynamic system is a physical system, the transformations of which are subject to the laws of thermodynamics, namely, conservation and degradation of energy, describable by thermodynamic state variables, chiefly internal energy and entropy.

The internal energy  $U$  is a quantity normally associated with the system’s energy potential or capability to perform useful work. In physical systems, it is the amount of energy contained within the system, it depends on matter/energy content such as volume and mole numbers, and it can be expressed by the following relation:

$$\Delta U = L + Q \quad (1)$$

where  $Q$  indicates heat (thermal energy) and  $L$  denotes the mechanical work performed by or over the system.

Heat can produce work by means of its natural flow from a higher to a lower temperature, but, since the temperature scale has a lower limit, heat becomes progressively less effective in producing useful work.

The concept of entropy (from  $\epsilon\nu\tau\rho\pi\acute{\iota}\alpha$ , the Greek word for transformation) was introduced in the middle of Nineteenth Century by the German physicist Clausius, with the aim of giving a measure of the relative unavailability of thermal energy to produce useful work, a statement that goes by the name of the Second Principle of Thermodynamics [25].

In physical systems, entropy ( $S$ ) is related to heat ( $Q$ ) and temperature ( $T$ ):

$$S = \frac{\Delta Q}{T} \quad (2)$$

According to the Second Principle, the relation (1) can be transformed into:

$$\Delta U = T\Delta S + \Delta L \quad (3)$$

where  $T\Delta S$  (temperature  $\times$  entropy) is equal to  $Q$ , the energy not fully employable to produce useful work.

Essentially, given  $U$ , the more the entropy, the less the energy available for the system to perform useful work. Boltzmann in 1877, in a statistically-based interpretation of Thermodynamics, directly linked entropy to the number of molecular configurations of  $W$  (the thermodynamic weight) of the system [26]:

$$S = K \ln W \quad (4)$$

with  $K$  as a suitable constant. In physical systems  $K$  is the Boltzmann constant, defined in Joule/Temperature in Kelvin degrees. According to Boltzmann’s theory, the greater the number of possible  $W$  configurations of the system particles, the higher the entropy so that, at the equilibrium, when the system is thermally homogeneous, the number of indistinguishable states is at a maximum along with its entropy. Therefore, according to the statistical interpretation of the Second Principle, natural processes spontaneously tend toward a state of equilibrium and homogeneity, characterised by maximum molecular disorder and maximum entropy. Entropy thus represents the physical index of disorder, expressing also the missing information about a system [27].

Rasberry underlined that the relationship between quality and thermodynamics has not yet been sufficiently investigated [4]. The lack of attention paid to the costs necessary for maintaining quality standards sounds like a confirmation of this assumption.

Only costs of “missing quality” have in fact been analysed to any degree [28], whereas only a few authors such as Feigenbaum have recognised the costs of quality itself, albeit limiting their attention to the “right” amount of quality to be performed to avoid economic losses [3]. Indeed quality does presuppose efforts being maintained and, in agreement with Jha et al., at least the following are to be mentioned to provide some examples: “personnel training and qualification; controlling the product design; controlling documentation; controlling purchasing; product identification and traceability at all stages of production; controlling and defining production and process; defining and controlling inspection, measuring and test equipment; validating processes; product acceptance; controlling non-conforming products; instituting corrective and preventive action when errors occur; labelling and packaging controls; handling, storage, distribution and installation; records; servicing and quality assurance techniques; ( . . . ) management practices, manufacturing practices, operation practices and strategy to build the quality into the product” [29]. Not to mention the amount of records required to ensure traceability. Moreover, the higher the degree of quality desired, the greater the effort. In spite of this, quality direct costs have never been analysed from a thermodynamic perspective.

On the contrary, and surprisingly, a thermodynamic approach has been effectively adopted in fields equally far from Physics, like Social Sciences. An analogue of internal energy, in fact, was conceived by the sociologist Bailey in the Population, Space, Technology, Organization, and Information (P.S.T.O.I.) model, which defined the “level of living” of a society by assigning it the dimension of an energy, it being dependant on “the number of calories available for the entire society” and functionally linked to P.S.T.O.I. (knowledge) [30]. Similarly Boulding devised “psychic capital” as the total amount of psychic energy of an organisation [31].

In QMSs, the analogue of internal “exploitable” energy  $U$  could be sought in the system’s elements that express the QMS’s capacity for producing valuable work. Ishikawa’s  $M$ ’s rule of quality theory could help us to identify the most appropriate, i.e., Manpower ( $Mp$ ), Machines ( $Ma$ ), and Materials ( $Mt$ ), and thus express the quantity  $U$  as a function of these concurring variables [12,32]:

$$U = f(Mp, Ma, Mt) \quad (5)$$

where Manpower,  $Mp$ , (probably the most important factor in “classical” quality theory) is constituted by the physical and brain work of operators, machines and technology ( $Ma$ ) by the tools and equipments employed, and Materials ( $Mt$ ) by the stuff involved in the production process.

The term entropy has been used in various disciplines, albeit under various meanings. It has also been used in Management to express a general concept of uncertainty or disorder or the number of unfavourable events in a project. To the best of the author’s knowledge, it has never been used in “classic” Quality as expressed by standards. In this paper, entropy is treated in a way as close as possible to its physical meaning and is proposed as index measuring the degree of disorder in an organisation [8,33].

This is not such an implausible assumption if we consider that the idea of physical entropy, as a disorder index, has already been extended from Physics to other disciplines, including Information theory, Biology, and Economics, in light of Brillouin’s statement, according to which “we must be prepared to discuss the extension of entropy to . . . all forms of intelligent thinking” [27].

Thus, also for QMSs, entropy may be linked to system randomness. For this purpose, it is useful to adopt the distinction made by Brillouin between bound (or physical) and free (or virtual) entropy [27]. A distinction linked to the two kinds of (sub)system already introduced.

It is proposed here that the physical entropy of a QMS is given by the following contributions: a bound entropy  $S_b$ , an entropy linked to machines ( $S_{ma}$ ), and an entropy linked to materials ( $S_{mt}$ ):

$$S = f(S_b, S_{ma}, S_{mt}) \quad (6)$$

Bound entropy  $S_b$  deserves some extra comments. It includes an organisational component, linked to the multiplicity of the physical system, which can be expressed by an adaptation of the Boltzmann Equation (4). In order to explain how to evaluate it, let us start from an organigram, a diagram showing the relation between the constitutive units of an organisation. The way of calculating the entropy of an electrical diagram proposed by Brillouin is a good starting point [27]. Let us suppose that a QMS organizational chart contains  $N$  constitutive units. For the sake of simplicity, each unit can be connected to any other, giving  $W$  different possible binary configurations:

$$W = N^2 \quad (7)$$

The entropy of the chart is:

$$S = K \ln N^2 \quad (8)$$

For the sake of simplicity, it is assumed that all possible  $W$  states are equally probable. Let us assign the value of 75 (J/T) to the constant  $K$  (the reason is explained below). If we assume, as is reasonable, that the units are 10 (e.g., with one operator each), we obtain:

$$S = 75 \ln 100 = 345.39 \quad (9)$$

This represents the entropy value of the organisation if the units are coupled in dual aggregates. Let us suppose now that coherent aggregates of units are created, e.g., that the organigram consists of ten bigger units. The entropy is reduced to:

$$S = 75 \ln 10 = 172.69 \quad (10)$$

because of the decrease of the thermodynamic weight.

The first arrangement of the chart (with all the possible associations in two units) simulates, in fact, a random aggregation, a condition of high disorder. Organisationally speaking, it means that too many interactions among units correspond to a disordered state, and it means also that, in a QMS, the application of a matrix-type organisation with multiple interactions per unit should be carefully evaluated, if only for thermodynamic reasons.

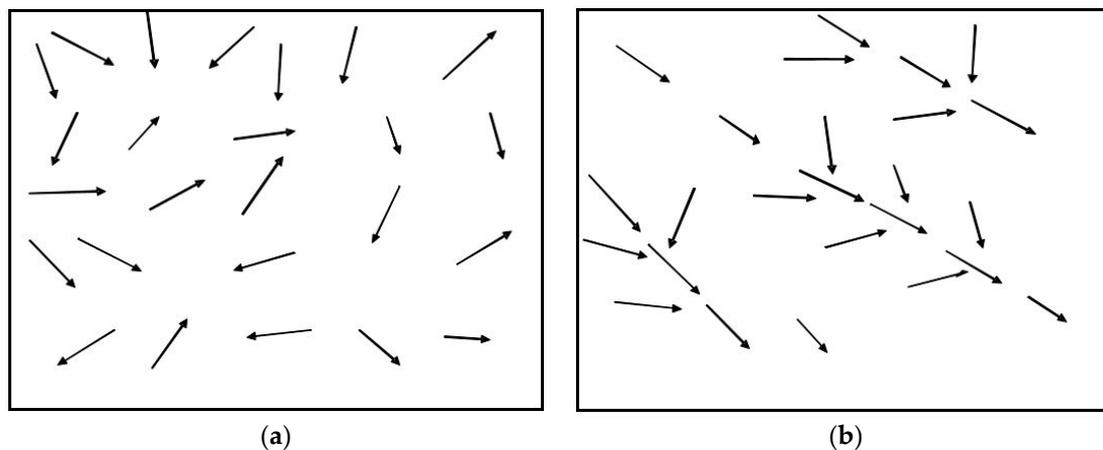
Additional situations might increase the level of uncertainty. Let us move away again from system structure: it should correspond to the description planned in the documents. However, discrepancies can occur between the planned and the real system, e.g., if an inaccurate realisation has been made. As a result, the physical configuration may not exactly match the planned one, and badly-implemented configurations may subsist (as if the system “wobbles” around the set position) thus raising the “thermodynamic weight”.

It is easier to exemplify this assumption for a single process (e.g., in the analytical field covered by ISO/IEC 17025 and ISO 15189 standards) [13,14]. Let us suppose that a (clearly defined) procedure is inappropriately performed a few times with significantly different outputs. Each  $W$  output represents one of the possible ‘configurations’ assumed by the process. The entropy of the process is thus calculated accordingly. The same approach can be used to define the entropy of instruments or materials.

Let us see now the way in which process (bound) entropy can be reduced. Quality organisations have to achieve self-imposed objectives, which require process cohesiveness and alignment [12]. The way to reduce entropy starts with the setting of common quality goals, towards which efforts have to converge. The establishment of quality policy and leadership according to ISO 9001 can reinforce such a mechanism [12].

Organisation quality objectives thus act like a “magnet” or a “thermodynamic attractor”, polarising efforts and processes [34]. After having identified the desired direction to undertake, the organisation thus ensures that every effort operates coherently with purposeful and productive

labour [35]. The number of system configurations is thus reduced along with entropy, which is forced to a lower level in conjunction with a higher level of process organisation (Figure 1).



**Figure 1.** In this figure are represented (a) a non-aligned processes of a system (represented by vectors) and (b) the same system processes after alignment and the reduction of the number of configurations,  $W$ . (from Box [34], adapted).

As a consequence, in order to raise the level of order, every system component should be accurately managed and aligned and the roles and responsibilities clearly assigned [12]. System operators have to counteract the spontaneous descent into disorder sanctioned by the Second Principle. Without shared goals and the alignment of processes, in fact, the state of the system may be imagined to be in a disorderly condition, which can be effectively depicted by a Brownian state, in which elements move independently and chaotically. Acting as an “entropy-reducing machine”, a QMS operator lowers the “thermodynamic weight” of the system [35].

In a striking image, operators can be effectively compared to the imaginary sorting “demon” devised by Maxwell in his famous thought experiment, namely, the hypothetical being capable of reconstituting the system’s internal order by separating molecules according to their speed, maybe violating the Second Principle [36]. However, unfortunately, such a job is energy demanding, and even intellectual work is not beyond the Second Law. Energy, in fact, is expended to acquire and update information, as Szilard showed for intelligent beings and Landauer strengthened for computing processes [37,38]. Energy-demanding control mechanisms are required to align and focalise processes towards predefined targets, so a thermodynamic cost is to be paid for order.

Additionally, if we consider, along with Juran, that “even a small company could have over a billion things to be controlled” we can realize how important the energy requirement in order to force entropy down is [2]. Even if not inspired by strictly physical considerations, a similar concept was also thought up by Deming, who recognized that “Left to themselves . . . components become selfish . . . and thus destroy the system” [39].

Human work, as supposed also by Rasberry, is the best candidate to provide an indication of the amount of energy required to counteract the entropy burden in a QMS [4].

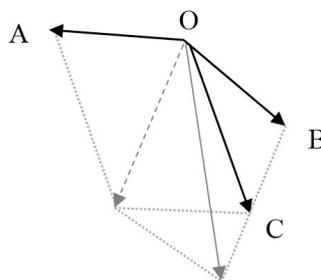
Although the quantification of human labour is deemed somewhat complicated, evaluations have been attempted ever since the nineteenth century social economist Podolinsky predicted the outcome of Thermodynamics in the field of production. He estimated a measure of (almost) 0.5 kWh (thus  $\cong 430$  Kcal or  $\cong 1.8 \times 10^6$  J) as the mechanical energy normally produced daily by a worker [40]. More recently, a power of 75 W per man was assumed for useful work, which is equivalent to 270,000 J per hour and 2,160,000 J per eight-hour day [41]. In a roughly preliminary approach, we can assume, according to Juran, that the maintaining of order imposes a burden of 10% of the workload of the

organisation [2]. Thus the resulting additional energy to counteract entropy burden may be roughly estimated as about  $2.16 \times 10^5$  J per man per working day.

However, empirical and more accurate studies are needed, also because standards in particular fields prescribe a very high level of quality control (e.g., ISO/IEC 17025 in the field of food safety), which involves efforts likely to exceed 10%.

It is interesting to note here that a disorganising effect on processes can occur also when too many diverse activities (i.e., too many non-coordinated targets) are carried out by operators, an event occurring, for example, when operators are involved in multiple and heterogeneous activities.

As properly described by Hackman and Wageman, it is the situation in which operators risk “head(ing) off in the wrong direction ( . . . ) merely because . . . (they) are not entirely clear about what they are supposed to do” [42]. This situation is exemplified in Figure 2, where operator O is shown to receive many diversified targets not consistent with each other, illustrated as diverging vectors.



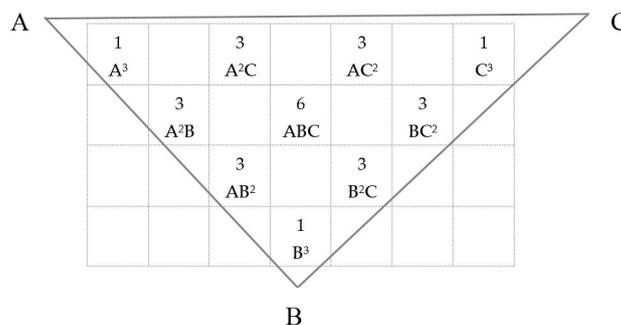
**Figure 2.** Vectors of diverging activities A, B, C produce dispersive effects (and diverse) resultants over operator O.

The operator’s attempt to reach several different goals can be effectively visualized by means of a “random walk”, an Operational Research approach. Let us suppose operator O is moving to reach the unique target point A along one definite path requiring  $n$  steps. The effort of the operator is thus concentrated solely on the one target he has to achieve, with a probability  $P = 1$  of it being reached.

Let us suppose now that  $n$  extra targets are assigned. The operator’s effort is now scattered over several new  $n$  paths quantifiable by the polynomial power function:

$$(a_1 + a_2 + \dots + a_k)^n = \sum \frac{n!}{i_1! \cdot i_2! \cdot \dots \cdot i_k!} a_1^{j_1} \cdot a_2^{j_2} \cdot \dots \cdot a_k^{j_k} \tag{11}$$

with  $j_1 + j_2 + \dots + j_k = n$ . For the sake of simplicity, let us suppose the above-mentioned three targets, A, B, and C, require three steps each to be achieved. The result of the above, Equation (13), is 27 total possible paths, exemplified by the corresponding “section” of the trinomial Pascal tetrahedron (Figure 3).



**Figure 3.** Possible paths required to reach three targets A, B, C of three steps each. Trinomial coefficients represent the number of paths reaching each position.

The probability  $P$  of reaching the target point  $A$  in three steps ( $A^3$ ) is now given by the probability of  $A$  ( $=1$ ) divided by the total number of possible paths (the sum of coefficients), that is, the answer is equal to  $1/27 = 0.037$ , which is a number  $\ll 1$ .

It is important to notice that such a dispersive effect on performance, deriving from a high number of targets, is not contemplated by the ISO standard. Too many targets assigned lead to a disruption of the normal flow of work, rendering it “Brownian” and ineffective. Consequent uncoordinated activity lowers the chance of success, which thus requires a massive amount of extra work to be achieved. Such a condition is an analogue of “thermal motion” or “thermal noise” of physical systems [43]. The number of conflicting activities per operator, in other words, the “degrees of freedom” of “temperature vectors” illustrated above, should be scored to represent the “temperature of the organization”, an indication of the basic disorder of an organisation. This has the effect of raising the value of the term  $T\Delta S$  of Equation (3), i.e., the amount of internal energy relatively unemployable to produce useful work.

Additionally, it is important to note again that the appropriateness of matrix-type organization for QMSs should be carefully considered. An organisation chart in which individuals report to more than one line can easily fall into the conflict delineated above, if the related targets are not carefully weighted.

It is necessary now to give a reason for the value assigned to the constant  $K$ . Such a constant should be dimensional and expressed in  $J/T$ . In physical systems, it represents the kinetic energy of one system element (particle) in defined conditions. In organisational systems, we think it should represent the energy contribution of a single system element (thus an operator), i.e.,  $75 J$  divided by the temperature  $T$  of the organization, as defined above. For the sake of simplicity, we assume  $T = 1$ . However, for the purpose of calculation, it might be enough to just assign a value to entropy, even if conventional, and compare differences rather than absolute quantities.

## 5. Quality and Cybernetics

Cybernetics or Control Theory is a theoretical framework dedicated to governing (and interpreting) systems, both living and artificial, in the framework of communication and self-regulation theory. It was Wiener, in 1948, who laid the foundations for this discipline as a distinct body of knowledge [43]. Cybernetics, along with Thermodynamics, represents the backbone of GST. It has been generalized to cover biological, cognitive, and, as a dynamic model, even socio-economic systems [44]. The British theorist Stafford Beer also included management in the framework of cybernetic theory, assuming Cybernetics to be the science of effective organisation and devising also the Viable System Model (VSM) as a method of interpreting organisations as similar to viable systems [45]. As far as the writer knows, Cybernetics has already been applied to the general field of quality management; however, not in a systemic way in the field of certifiable quality.

The feedback loop is the basic unit of cybernetic control [43]. It consists of an energy-demanding mechanism designed to make sure that the output of a system (or process) always maintains the desired value. It basically consists of three steps; sensing, computation, and actuation, which typically comprises an observer or sensor device, which measures the actual performance of the process and reports to a controller. The latter consists of an umpire (or telltale), which compares the sensed value with the previously set output standard or reference. If a deviation (an error) is detected, the umpire triggers an actuator, which supplies the corrective action to force the system back to the expected reference value (Figure 4) [46].

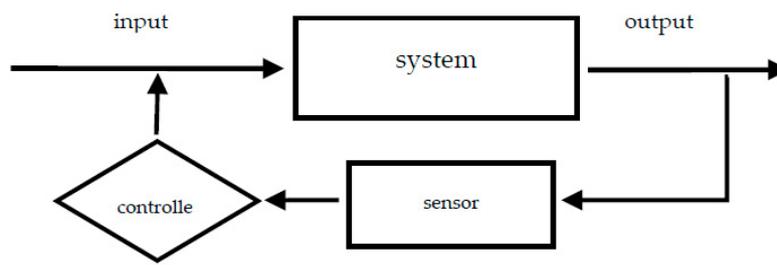


Figure 4. Feedback mechanism scheme.

In QMSs a qualitative type of feedback usually operates. Given  $O$ , the output of the system (or process),  $E$ , the expected (or reference) output, and  $R$ , the triggering reaction, the feedback logic may be described by the relation:

$$\forall O \neq E \Rightarrow R \quad (12)$$

as long as the expected value is achieved:

$$O - E \rightarrow 0 \quad (13)$$

QMS methods of control such as the management of non-conforming events and complaints, the monitoring of corrective actions, audits, and management reviews are all examples of processes the control of which is based on feedback, and feedback-based mechanisms incessantly operate in every process according to the continuous improvement strategy actuated by QMSs [12,39].

In a mechanical system, input and output are usually linked by a predictable mathematical relation named the transfer function [46]. In QMSs, since control loops are managed by human operators, the transfer function is logical rather than mathematical. In addition, a single variable type of control system, or SISO (single input-single-output), usually operates.

QMSs must interact with the environment in order to acquire information and thus react via a feedback mechanism to adjust themselves to the changing conditions. Knowledge of the exterior is thus a priority, and QMSs should have proper interacting devices or “transducers”, able to collect stimuli and forward them to a controller. In a QMS, transducers may be represented by questionnaires, customer complaints, or other forms of survey, designed to gather information from the exterior, here represented by customers [12].

When the stimulus is translated into an understandable form, the system itself becomes aware that something has changed and that action is required. The action represents the effector component of the feedback. Its scope is to restore the deviation observed, e.g., via an MOC, a motor output channel in the terms of Stafford-Beer [45].

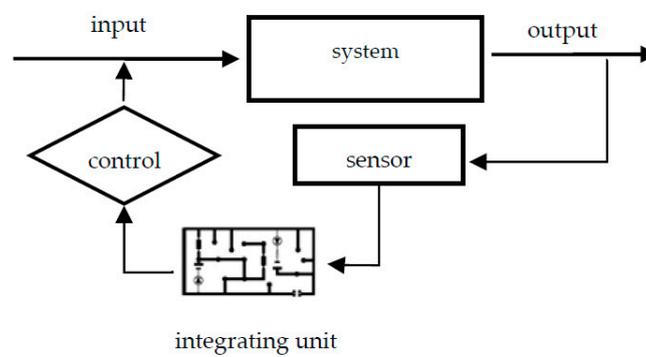
A correctly designed feedback loop requires a preliminary definition of reference output and the selection of sensors and control subjects. The designer of the system sets the standards for control (i.e., the criteria under which the process is to be considered at risk) and the sensing tools. The designer also establishes the action to be undertaken when set standards are not met [47]. In QMSs Shewhart charts are typical sensing tools to control processes, while operators are the decision makers, responsible for the proper corrective action.

The management of deviations (in quality jargon, non-conformity events or NC) represents the most typical case of feedback control in a QMS. When a process goes out of control, a feedback-based corrective reaction is triggered. The way to respond is interpretable according to Stafford Beer’s VSM [45]. Correction can be accomplished in a simple or in an integrated way: the process-controller (the operator) evaluates the deviation and corrects it via direct feedback, simply actuating a sort of “reflex arc”, an option that represents the lowest level of intervention (Figure 4).

Otherwise a higher level of decision may be required when a broader evaluation is necessary [45]. System performance can, in fact, be altered by unpredictable perturbations so that the management of

deviations may require a more articulated feedback loop called “corrective action”. This requires a preliminary investigation (“cause analysis” in ISO/IEC 17025), consisting of a series of activities aimed at ascertaining the origin of the problem in order to apply the appropriate solution. Monitoring of the corrective action is also necessary in order to evaluate the appropriateness of the correction and to be sure that the specific problem does not recur in the future. The cycle closes when the monitoring of changes shows that the right solution has been chosen (Figure 5).

Tacit evidence of a certain unpredictability, or unobservability, in QMSs (intended as difficulty in evaluating the state of the system through indirect observations) is given by the management of corrective actions. Since an underlying model is not always recognisable, the transfer function may be not always predictable. In this case, the controller has to treat the system as a “black box”, adjust the output consequently, and monitor the outcome until the desired value is obtained. Such a monitoring period is imposed by certain standards, e.g., ISO/IEC 17025, and gives evidence of a certain complexity of QMSs, due to their lack of linearity and predictability, albeit being controllable or capable of being forced to maintain a particular state [13,46].



**Figure 5.** Feedback mechanism scheme when a higher level of integration is required.

Preventive actions are another kind of feedback that quality standards, e.g., ISO 9001 and ISO/IEC 17025, foresee with the purpose of correcting slight deviations before they become true errors [12,13]. In cybernetic terms, they can be considered to be feed-forward mechanisms or actions triggered to correct a disturbance before it becomes a manifest error [46]. A future-oriented action is applied in order to set the desired adjustment before the deviation gets out of control so that the information acquired can be used to generate feedback to counteract the deviation. This kind of correction has temporarily to anticipate errors; consequent motor signals must be modulated in advance to render the reaction consistent with the (future) deviation. Usually, an underlying model of the process should aim to avoid the risk of a mis-sized or wrongly timed reply. However, due to the unpredictability of QMSs, a monitoring period is needed to check and commensurate (adapt) the response, as described above for corrective actions. The important section of risk-based analysis, introduced in ISO 9001 2015 in order to preliminarily individuate deviations and put in place preventive controls, is also interpretable as a systemic extension of a feed-forward-type mechanism. However, even in such cases, the effects of the disturbances cannot be accurately predicted and when activated it requires a monitoring period [13].

Management review is another example of a feedback-based mechanism in QMSs [12]. It is a planned activity carried out to align the main indicators of adequacy (i.e., customer satisfaction, non-conformities, audit results, etc.) with the strategic direction scheduled [12,13]. It represents a higher level of decision-making and is probably the only MIMO (multiple input-multiple output) type of control in a QMS. It is useful to describe such a decision-making process according to Stafford-Beer’s theory. A registry of system deviations should be maintained and transmitted to the top management at the right moment. The registry can be identified with the “sensory register” or “sensorium”, a collection of (deviation) data to be transmitted through an afferent channel to the multinode ganglion (the “anastomatic reticulum”), represented by the top management level. Here a complex interaction

between a bundle of inputs and outputs occurs [45]. As a decisional tree, management review proceeds by integration and thus a reduction in the number of inputs received (along with entropy). A “reduction of variety” (in the meaning of Ross Ashby, 1956) is hence actuated, also complying with a necessity already highlighted by Jackson, who stressed that “attention to reducing the variety of the system” is necessary for control [48,49].

Even the “continual improvement”, the never-ending process of the Shewart-Deming wheel (or PDCA cycle), which is crucial to enhancing performance, is a multiple feedback mechanism actuated in four stages [12]. In the initial step, usually referred as the Plan, targets and actions are set, whereas it is during the second step (Do) that activities are carried out. It is at this moment that processes are feedback-aligned and entropy reduced (Figure 2). In the third step (Check), the system compares its performance against the planned results and reacts appropriately to reduce divergence (Act) [12].

Energy demanding feedback-based controls are thus crucial for QMSs to escape a disorderly state, a condition which may preclude not only task-oriented activities but also the activation of control mechanisms. High-level noise (disorder), in fact, influences the sensitivity of sensors, as well as the effectiveness of feedback loops, since the higher the disorder, the greater the sensor’s difficulty in identifying abnormal signals [46].

As anticipated above, QMSs can be interpreted according to the broader cybernetic-based VS model; they have to maintain homeostasis, interact with the exterior, be informed on the changing environment, and have information/communication routes [12]. They thus operate like “nervous channels”, having “sensors” to monitor the exterior (e.g., by questionnaire, market data collection, and SWOT analysis), as well as a steering unit capable of self-analysis and decision-making (top manager or brain). All these units respectively mirror the Stafford Beer theorised VS model [12,45]. In the wake of this theoretical consideration, it should be noted that the PDCA cycle, in the latest version of ISO 9001 standard, foresees a preliminary phase of investigation of the external environment (e.g., customer needs) in order for the organisation to be better attuned to the context in which it operates. QMSs can thus be assimilated to “teleological organizations”, which are self-regulated, self-governing, and finalised to reach the self-assigned goals planned [50].

In such a framework, however, one “niche” cannot be strictly planned in terms of the way the system responds to stimuli. QMSs are not, in fact, mechanical systems, and, having to cope with complex perturbations (e.g., changing of the environment, complaints, non-conformity events), they must count on a high grade of variety, where “variety” means the number of possible responses the system is able to implement [49]. Yet QMSs are self-organizing in a peculiar way. If we agree to define “self-organisation” as behaviour deriving from the mutual interaction of system elements, QMSs are not strictly so. As discussed above, they do possess, in fact, a steering element (the top management) and mainly organise themselves according to standards of external origin (e.g., through conformity to a definite standard through accreditation/certification). Due to conscious intention, this property is better definable as “purposiveness”.

For similar reasons QMSs cannot be assimilated to complex adaptive systems. The terms, in fact, usually indicate a system that emerges over time into a coherent form and adapts and organises itself without any singular entity deliberately managing or controlling it [17,23].

## 6. Quality and Information

The organisation shall document that activities are being carried out as planned according to the information contained in quality documents [12] (CL 6). The management of information is therefore crucial for QMSs.

Information, born as a mathematical quantity expressing the probability of the occurrence of a particular sequence of symbols, received a theoretical arrangement by Shannon in his Information Theory in 1948 [51,52].

The information  $I$  contained in an event  $x$  is defined as:

$$I(x) = -\log_b P(x), \quad (14)$$

where  $b$  is an appropriately chosen base of the logarithm and  $P(x)$  is the probability of the event  $x$ .

It is important to highlight that the above Equation is similar to Boltzmann's one for entropy, though the sign is changed. This analogy has provoked many interpretive contributions by several authors, including Wiener and Brillouin, who theorised upon the inverse relationship between information and entropy, which are closely related quantities [27,43]. As for entropy, it is convenient to distinguish bound from free information, the former being linked to the number of complexions of the physical system, whereas the latter is related to its conceptual level, that is, the reliability of documents.

As stated by Rothstein, organisation is a generalisation of the term information and a synonym of order, quantifiable as the "amount of information required to specify an organisation in terms of its unorganised components" [53]. Therefore, "organisation" is considered here to be an acquired energy demanding feature rather than an "inherent" or constitutive property of a system [20,30].

The bound information contained in an organisational structure with  $N$  constitutive units can be calculated as made for entropy in (8):

$$I = -K \ln N^2. \quad (15)$$

Conversely, free information is embodied in system documents, which constitute the conceptual subsystem, the image of the concrete level as it should be actualised. We have already observed that the two system levels must be isomorphic. Documents should, in fact, plan with the greatest accuracy the configuration and processes to be conducted [12]. This means that only one "state of affairs" in the sense of Wittgenstein's assumption, should be deductible from system planning documents [54]. Vagueness in defining structure and processes is, in fact, likely to increase the number of (imaginable) states and thus document entropy. The reason lies in the fact that documents are written in natural language and suffer from a certain degree of ambiguity (or amphiboly in philosophical terms). Ambiguity, "the quality [of words or sentences] of being open to more than one interpretation" is a known shortfall of natural languages [51].

There are several kinds of ambiguity; lexical (due to a word's imprecision), syntactic (when more than one grammatical structure can be given), semantic (where a sentence can be read in more than one way), and pragmatic (when a sentence has several meanings in its context). It depends both on the imprecision of words and grammatical constructions or context [55]. Moreover, lack of precision, as in the sentence "corrective action should be started as soon as possible", may even occur in not totally accurate quality documents. Therefore, in order to decrease the level of uncertainty, it is important firstly to scrutinise QMS documents for ambiguity, "manually" or, better, with the help of dedicated software, capable of identifying and indexing ambiguities [55,56].

A measure of the entropy of the text can thus be conjectured. Let us suppose that, in a document describing a system,  $n$  ambiguous related sentences are detected, each admitting, for the sake of simplicity, only two possible meanings (possible different "states"). Therefore  $n$  sentences admit  $2^n$  meanings; thus, according to Equation (4), the entropy of the document is:

$$S = K \ln 2^n. \quad (16)$$

Since ambiguities depend on the context, it is better to ascertain their number by referring to a corpus of words in the specific field under examination. Equation (4) consequently becomes:

$$S = K \ln(W|C), \quad (17)$$

in which  $W$  is the number of ambiguities, given the context  $C$  [57].

It is important to highlight that planning documents, if ambiguous, are capable of transferring entropy to the physical subsystem, so in QMSs conceptual information may have physical significance

and produce, in perspective, effects upon the concrete level. For this reason, information stored in planning documents must be of the highest grade to avoid the risk of lowering the level of order when “transferred” to the real domain. Therefore, documents should be written by avoiding confusing words, should preferably be long and devoid of synonyms, with a limited number of pronouns, and should be written in a “protocol fashion”, preferably in a sequential and executable way, without circumlocutions or postponed sentences [58]. Such a criterion must represent the best precept in writing quality documents. The underlying theory is that documents must describe the real system as a “state of affairs” [54]. In the wake of the same logical point of view, this has some remarkable consequences. The correspondence between the conceptual level (the documents, the theory) and the concrete level (the real and physical) represents a sort of “degree of truth” with the singular feature that the truth value is here inverted: the content of the document is not evaluated on the basis of correspondence with the observed “states of affairs” but the observed is evaluated on the basis of what is stated in the documents.

In order to reduce ambiguity, an approach near to Carnap and Bar-Hillel’s suggestion for short simple sentences is to be sought [59]. The system state (i.e., the organisation) should be described by state descriptions ( $Z$ ), or “atomic sentences” made up of a noun ( $n$ ), referring to a system object coupled with a predicate  $\pi$ , indicating its property (or role) in the system.

As an example, sentences should therefore be expressed in a way as close as possible to the following form:

$$Ma. Fb. (Mc \supset \bigcap Oc), \quad (18)$$

the meaning of which is that the system element  $a$  has the property  $M$  and the system element  $b$  has the property  $F$ , and if the element  $c$  has the property  $M$ , then it has also the property  $O$ .

Such a need has already been deemed important and has been developed in other fields, e.g., in the legal field to render laws clearer [60]. Similar efforts have also been attempted in order to reduce sentences in common language to their underlying logical forms [61]. Once a text is converted it is, of course, easier to identify contradictions and inconsistencies. In the field of quality, such an advancement could represent a valid means of further reducing the uncertainty of documents.

A useful elucidation from Brillouin helps us to understand how document entropy can be reduced and information content increased accordingly. Information and entropy, as we know, are opposite quantities, thus free information can be expressed as follows [27]:

$$I = -K \ln W. \quad (19)$$

Uncertainty reduction, as already observed, is linked to the number of imaginable  $W$  states of the system. If  $W_0$  is the initial and  $W_1$  the final configuration number of the system (with  $W_1 < W_0$ ), the initial and final values of free entropy are:

$$S_0 = K \ln W_0, \quad (20)$$

$$S_1 = K \ln W_1. \quad (21)$$

After reducing entropy, the gain of information is:

$$I_0 - I_1 = K \ln W_0 - K \ln W_1, \quad (22)$$

which corresponds to:

$$I_0 - I_1 = S_0 - S_1, \quad (23)$$

$$\Delta I = S_0 - S_1. \quad (24)$$

Thus the entropy is lowered from  $S_0$  to  $S_1$ , and the difference corresponds to the gain of information  $\Delta I$ . Intuitively, the meaning is that the lower the number of system configurations,

the lower the entropy and the higher the information we have on the system. The decrease in entropy is then equal to the increase in information intended as negative entropy, a quantity that could be defined also negentropy [27].

Such an increase in negentropy can also be accomplished by importing information from the exterior, e.g., in the form of standards and knowledge (remember that QMSs, being based on standards, have periodically to introduce external information) [12]. Such behaviour recalls what was formulated for viable systems by Schrödinger in his essay “What is Life”. In a striking image, as well as viable systems, in fact, QMSs have to tackle the “statistical tendency of matter to go over into disorder” by “feed(ing) upon negative entropy” and “continually sucking orderliness from its environment” [62]. High-level information can, in fact, be acquired and stored in documents, then prospectively actualised, or better “translated”, into system structures and processes. In this way, documents represent the “code” for building the system and for regulating its processes (its “metabolism”), alongside VSs, which are able to store and translate the information contained in their DNA. This is an analogy which strengthens the applicability of the VS model to QMSs even more.

The interpretive framework adopted, based on Thermodynamics and Information theory, also helps us to examine some further aspects of quality.

Continual improvement is a recurring activity foreseen in quality standards (e.g., ISO 9001, ISO/IEC 17025, ISO 15189), driven by the PDCA cycle and representing the main mechanism through which QMSs evolve [12,14,39]. However, it has been pointed out that the growth curve that continual improvement describes necessarily tends to a plateau phase in which negligible improvements are obtained despite considerable effort [34]. It means that such progress becomes rather ineffectual in the long run. Due to the law of diminishing results, to keep development active, QMS must resort to “breaking points”, which might consist in the re-engineerings and/or reorganizations of processes. A “manual process” could, for example, be re-engineered by introducing new machinery or by the acquisition of new methods or technology; in other words, by a massive introduction of knowledge. Continual improvement is thus limited by informational and thermodynamic constraints, a consideration that was finally recognised by the 2015 revision of the ISO 9001 standard, which admits that organisations evolve also by breakthrough changes (innovation and re-organisations).

It is interesting to note that such confidence in continual improvement (even if partially modified) shows a similarity between quality and the economic theories that assume a continuous growth model. The criticism that such theories have aroused for ignoring thermodynamic restrictions could also be extended to the above-mentioned quality improvement approach [63]. Moreover, such a similarity strengthens even more the lack of consistent thermodynamics-based assumptions in quality.

Therefore, a steady state cannot be the unique state of QMSs. Such periodic “paradigm shifts” of QMSs is a behaviour that might be assimilated to that foreseen by Kuhn for the advancement of knowledge, an assumption that permits us to include the evolution of quality systems in a wider interpretive framework [64]. Such an assumption is perhaps the basis of the breakthrough change finally accepted by the ISO 9001 standard. Therefore, like Senge’s “learning organisations”, QMSs should be aware that “over the long run, superior performance depends on superior learning” [65].

## 7. Conclusions

The paper tries to provide a broad interpretation of (certifiable) Quality systems. A Thermodynamics-related interpretation of quality is given under the theoretical framework of System Theories and thus Cybernetics and Information Theory.

QMSs are interpretable under the theoretical framework of General System Theory as well as being thermodynamically interpretable.

It is quite inexplicable why the thermodynamic cost of maintaining standards in quality-managed organisations has always been underestimated, as if they were capable of bypassing the Second Law of Thermodynamics. As shown in the paper, the Second Principle overhangs them, and the expenditure of system internal energy is required to counteract entropy increase and maintain system order. It occurs

at the expense of QMSs' capacity to produce valuable work, e.g., by means of manpower and machine potentials. Two different kinds of entropies have been identified; a bound or physical one, linked to system configuration (e.g., organisation chart and processes), and a free or virtual entropy, related to system planning documents. For both, a method of estimation is proposed. The approach adopted emphasizes that QMSs must take into account constraints related to the thermodynamic cost to be applied in keeping the system in order and under control. The paper provides an estimate of the work required to counteract the natural entropy decay of the system.

QMSs are also discussed under the framework of Cybernetics. The main control actions of QMSs such as the management of non-conformity events, complaints, adaptation to external conditions, and self-corrective actions are discussed as feedback, whereas preventive actions and risk-analyses are interpreted as particular or general feed-forward preventive mechanisms, respectively. QMSs showed to be also interpretable via the Viable System Model, being feedback regulated, dynamically attuned with the changing environment, self-organised, and having also the ability to acquire, "memorise", and then "translate" information into internal processes, along with a certain teleological orientation toward self-assigned goals.

As well as entropy, in a QMS, two levels of information are defined. A free/virtual information and a concrete/physical one. The former related to the information content of planning documents, the latter to the organisational structure of the system. Proposals are given for the preparation of system documents in order to enhance their information content. Improvement in QMSs depends mainly on their capacity to acquire, store, and employ new information and knowledge.

Some useful criteria are derived from the approach adopted in order to define the effectiveness of a quality system. Organisational entropy, as well as a parameter named the "thermal index" (representing the system intrinsic disorder), can be useful as a measure of the adequacy of organisations. Thermodynamics-based considerations also provide some evidence on the type of organisation that it is appropriate for a QMS to adopt or not.

From a systemic point of view, QMSs are preferably handled according to "classic" GST rather than Complex adaptive systems because of their "planned" activity, which is required by the standards with which they have to comply; thus their control mechanisms are treatable under the theoretical frame of conventional Thermodynamics and Cybernetics.

Thus QMSs are systems in which new properties emerge with difficulty. Their organisational patterns seem to be unsuitable to promote the rise of new outcomes and innovation.

The need to avoid misleading goals is probably incompatible with the ideas of innovation inherent to the CAS model.

However, it should be noted that some elements of the most recent ISO 9001 standard seek to give QMSs an arrangement closer to the more recent complex system approach. Some aspects, in fact, such as a certain peripheral responsibility in managing processes, breakthrough improvements, and enhancing internal competence as a development factor, seem to be an attempt to embrace more recent approaches based on complexity.

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