

# Towards a New Definition of Quality: the Italian Case

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**Abstract— All the world is at the core of such technological and, above all, social changes as to require today a revision of the definition of Quality. What do we expect of Quality? Quoting a famous movie: “Same as you. Love, acceptance, a solid return on investment”.**

**Index Terms—Quality definition, Ethics of Quality, Italian Quality Management System.**

## I. INTRODUCTION

*“Degree to which a set of intrinsic characteristics fulfill requirements”.*

This is today's technical definition of Quality, based on technical regulations recognized worldwide. Yet, all the world is at the core of such technological and, above all, social changes as to require today a revision of this definition that I would dare any general manager of any certified organization to remember and, most of all, fully appreciate, especially in this period.

To give these words substance and try to map out a *roadmap* towards a new definition of Quality, We would like to use two classic methods of logical reasoning – reasoning by absurdities and reasoning by queries.

Let us start from the “absurdities”.

“Quality is fundamental” (i.e. it is a complex tool to accomplish organizational targets). “Quality is useless” (i.e. Quality is “a piece of paper”). Both statements – that so obviously contradict each other – are often uttered by consultants and certification-accreditation authorities (especially the former), or by company officers (in general the latter).

Again: complying with technical rules and laws – a mandatory requirement – is not enough to ensure Quality to shareholders, employees, clients, suppliers, the community in general. This is not only due to the fact that the meaning of Quality includes compliance with rules; but also to the fact that technical rules and laws are subject to clear limitations (the technical norm about Quality too) – an actual demonstration is the “*common law*” approach adopted in Anglo-Saxon countries – 5,000 laws vs. Italian 60,000.

Let me move on to the “queries”.

Is the current definition of Quality clear, understandable

and generally known, if not by its literal meaning, at least by its objectives? I do not think so.

What is the problem, then? The current definition of Quality is not only ambiguous and cryptic – also an illegal or immoral organization could fully meet such a definition [1]. Most of all, it tries to tackle fundamental issues though too contingent subjects to the extraordinarily pervasive and transversal character of Quality.

Second query: what do we expect of Quality? Quoting a famous movie: “*Same as you. Love, acceptance, a solid return on investment*”.

That is, given the importance of the term “quality” in everybody's life, we expect Quality to give simple but fundamental answers, that will not be bypassed by words and procedures.

Prof. Amartya Sen, Nobel Prize in Economy, says that to the richness meaning, which is obviously a market must, it has to be added even the meaning of happiness. And happiness is something rather different from wellness.

A man is richer than another when he is more happy and he has got a superior quality of life.

Quality of life becomes an algebraic variable in economic calculations [2. 3].

Hence, in order to draw some early conclusions, We believe that Quality, as a magnitude and a technical subject, must be defined in order to allow for an easier and widespread understanding, also of the ordinary citizen.

We believe that the practical implementation of Quality requires technical capabilities and communication skills (we live in a world that, rather than being global, appears to be interconnected).

We also believe that Quality must give unescapable answers that go way beyond sheer compliance with technical rules and laws. We are talking about values, principles, cleverness and not slyness, about intellectual rather than material honesty. To give an answer that is always relevant, I would like to quote the former Italian Republic President Luigi Einaudi (1954):

*“..... thousands, millions of people work, produce and save money, despite anything we can invent to harass them, hinder them, discourage them. It is a natural calling that pushes them; not just their thirst for money. The taste, the pride of seeing their company flourish, become successful, inspire confidence in larger and larger clientele, expand plants, decorate offices, are an equally powerful driver of success as gain.*

*Were it not so, one would not be able to explain why some businessmen put all their energy and invest all their capital to often gain way lower profits than they could definitely and*

Manuscript received August 5, 2010.

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*easily make from other businesses."*

## II. QUALITY AND ITS EVOLUTION

Quality originates with the need for standardisation in the first mass produced products, especially in the production of automobiles ["The automobile has changed the world, by Womack, Roose, Jones, Rizzoli], for which goods are produced on a large scale and in an economic and remunerative manner, inevitably requiring the adoption of methods to create procedures in productive processes and to organise and manage these processes. The cultural background of these methods lies in "Systems Engineering" (which has become more intricate today with Management Engineering), namely in the study of Complexity and Techniques of Operational Research for the description, simplification and optimisation of complexity for productive purposes.

Later, during the Second World War, requirements for Quality increased with the development of technical and productive systems that were particularly critical. This refers, in particular, to new armaments systems (V1 and V2 rockets), war missions of an aeronautical nature, commercial aeronautical passenger transportation and the development of high-risk industries (Chemicals, Nuclear, etc.). During this phase of history, Quality was largely superimposed over needs for Safety, which had also been introduced in operational plans at the time and was not a matter of culture and regulation. "Superimposed" Quality and Safety entailed the development of Dependability, namely mathematical and statistical regulation on the basis of Maintenance, whose "entry" into the world of technical culture took place even later.

After the Second World War the Japanese became the champions of Quality and Dependability and the primary scholars in these fields: thanks to these sciences, the Japanese succeeded in re-launching their national industry, which is a historical touchstone. The most important example of this is Toyota (Toiodà), the automobile industry where a) models of trustworthiness [a term that synthesizes all the measurable properties of Dependability), b) Total Quality Management (TQM – often erroneously translated as "Total Quality", which is better understood as "Integrated Quality in Production"), c) models of maintenance management and product guarantee and d) Just in Time (JIT) or production without warehouse stock, which is understood as the most intelligent and luminous example of innovation in production methodologies, were first experimented. In fact, thanks to these sciences, Japan has become one of the great economic powers of the world. The Japanese were the first to give Customers the product they expected, guaranteeing it for periods of time that were unthinkable for Western producers until just a few years ago.

Between the Sixties and Nineties, Quality developed increasingly in the Western world as well, on the strength of the enormous growth of the world aeronautics industry (Boeing, McDonnell Douglas, Agusta, etc.) in the first place and, in the second place, in concomitance with the extraordinary development in the world of Services and

Public Services in particular, including Health [4, 5, 6].

Services, which must be understood as intangible products (distributed through ad hoc systems of production), developed enormously in Western economies, and had already become completely prevalent in the Eighties, in terms of value, with respect to manufacturing, which tended to be located geographically in regions that had developed more recently, where labour was less costly (this process of transfer is still underway and explains some of the reasons of the current crisis) [7].

Services, and public services of a strategic nature in particular (including Health), pose very strong requirements for standardisation, on the strength of their intangible nature. In the absence of standards of reference and, therefore, of quality, in fact, the distribution of services is increasingly subject to improvisation, to a much greater extent than tangible production. The result, in this case, contradicts the premise that is determining growth in the world of Services – namely the satisfaction of users. It is not by chance that so-called customer satisfaction coincides with the meanings (and normative definitions) that tended to be attributed to Quality in the second half of the Nineties. Public service cards (which have been legally obligatory for several years now) were created to respond to specific rights of citizens: to have accounting of services and the level of strategic services distributed by the Public Administration.

Lately, the mechanisms of Evaluation and Self-Evaluation, which are preparatory and indispensable to Quality, have also become an instrument of economic rationalisation in the public sector, as appears to be evident with respect to the most recent legislative initiatives in many countries.

## III. QUALITY AND RESPONSIBILITY

Identifying responsibilities towards third parties in Quality matters, relative to the operation of any organisational or productive system is a complex problem, because events of this nature are generally due to a chain of events and circumstances, in which several people take action more or less simultaneously.

Like the solution for any complex problem, it is therefore indispensable to identify: a) the limits, which permit us to reduce the complexity of the problem; b) the models of evaluation, which permit use to arrive at homogeneous behaviour for the persons who implement productive processes.

This problem becomes particularly delicate - there is risk that it will become indeterminate, namely that there would be no definitive solutions, in case of services because of their intangible nature, which makes it difficult to conduct investigations on them, unless less "traditional" methods are followed.

This is particularly true when we speak of services with a high content of technology, such as maintenance services and, in particular, health services or the management of maintenance of health structures, which, moreover, have a high social impact [8].

Anyway, in general the following questions need to be answered:

1. In a specific situation that takes place during the process of producing and distributing products and services, particularly in the case of absence or lack of objective material or experimental data, what instruments are available to identify responsibilities for Quality? Can the instruments be additional to or alternative to more traditional diagnostics or laboratory instruments, and will they provide objective results more readily?

2. Will any particular difficulties be encountered in using *ad hoc* instruments of evaluation, with respect to laboratory instruments, which are more traditional and usual?

3. What degree of dependability will instruments conceived to evaluate the services provide?

The following limits, or stable points can be established in order to facilitate interpretation of the problem of responsibility in Quality: a) norms of law; b) technical norms; c) the environment of production (or internal); d) technical resources; e) human resources; f) the external environment and g) the organisation.

The **norms of law** have undergone important evolution in the last 50 years. Especially following the acknowledgement of International norms, we have gone from strongly “prescriptive” laws, designed to prescribe punctual behaviour to implement, to laws having a more “liberal” orientation, but which are also very stringent in attributing responsibility and which are designed to require the identification of definite organisations, adequately designed in general architecture, and the quantification of resources to be dedicated, in order to keep any defective processes (and results of processes) under control.

**Technical norms**, the so-called rule of the art, or the best behaviour to implement in design and management of industrial projects, which do not require to burden of proof of the appropriateness of the solution adopted (principle of presumption of conformity). Through the work of institutions that emanate technical norms (in Italy UNI and CEI), it has also been possible to prevent the concept of probability of a damaging event, as well as the quantification of its importance, or the concept of risk, whose evaluation is obligatory today, in all productive situations (work environment, products, plants and machinery, industries and work sites). Then as a failure is – even legally speaking - a “statistic event” we can say that a defective product or process can be avoided a priori following specific methodologies. An appropriate organisation must be created, on the other hand, within the ambit of which there are well defined responsibilities that cannot be delegated, managed according to a logic of continuous improvement in relation to technological progress and knowledge (so-called continuous improvement). An organisation of this type and the consequent procedures that regulate its operation in the sense indicated, is called a “system of management” and is susceptible to self-evaluation and periodical external evaluation, for the purpose of certification, or formal recognition by an independent institution, which is appropriately adequate with respect to the technical norms on quality (ISO 9001).

The **environment** (internal) where an organisation of production operates has an influence on people that goes

beyond what we normally believe, in connection with the possibility of a defect in the processing of products taking place. Several aspects must be taken into consideration, which may indirectly facilitate the occurrence of a chain of events leading to a defect, or directly determine phenomena of exposure to damage.

The following principle aspects must be taken into consideration: the conditions of illumination, noise, the microclimate and the quality of the air.

The **technical resources** consist of machinery, equipment and devices used in the environment of production. These resources must be in conformity with specific sectorial norms, on the basis of the most recent norms, demonstrating that essential requirements of safety have been respected, which are generally established in these directives and are implemented on the practical level by the manufacturers. The safety of the technical resources is established through the application of the so-called “principle of the integration of safety”, or through the successive integration of various technical aspects, until a level of safety is reached that may be considered acceptable by the manufacturer. The aspects to be integrated are: the safe design of technical resources; protective devices; instructions for use and maintenance; any supplementary precautions deemed appropriate; personal protective clothing and equipment; training; the working procedures and methods of work.

The importance of **human resources** for purposes of Quality and Safety has been particularly stressed by research in recent years. Investigations of a historical statistical type, in fact, in addition to several evaluations of a sociological nature, have demonstrated the central nature of human resources in the organisation of production. Although environments of production may be perfectly adequate from a material point of view, in fact, according to this research (and also according to common sense, to be honest) this does not exclude the possibility of a so-called human error. In fact, the statistics demonstrate precisely how frequent this occurrence is. Not only the studies and research conducted by Weaver and Shannon in this sense, as early as the 40’s and 50’s, are extremely interesting, but so are recent experiments conducted in the field of aeronautics in order to implement veritable systems of error management, whose implementation in more or less evolved sectors, nevertheless, requires a radical change of mentality on the part of employers and workers themselves. It is necessary for these two categories, in fact, to implement an authentic collaboration in pursuing the common objective of the concrete valorisation of historical experience, to achieve quality and safety in working situations. All too often, on the contrary, we witness a situation of opposition that has its origin in historical and social circumstances that have little or nothing to do with the objective of quality and safety.

The **external environment** is represented by all of the environmental conditions which, although they are not directly involved in the productive activity, could interact unfavourably with internal conditions (a hospital, albeit perfectly functional, could be subject to a serious interruption of several – or all – of its functions due to inadequate electrical power, for example).

Concerning the importance of adequate **labour**

**organisations** what has been said above is reiterated. The contents and objectives of individual roles must be carefully defined.

This also applies to the workload of individual resources and the distribution, qualification and periodical training of resources, times and methods of work, etc. It is desirable to achieve a high level of standardisation through the establishment of formal procedures to be implemented in the performance of duties: substantially, it is not desirable that work be performed on the basis of extemporaneous knowledge or information, or in relation to individual resources. Once again, the implementation of an appropriate system of management by the productive organisation, which should be certified, is an important factor of support for the purpose of safety.

In the presence of the aforementioned limits, which are listed and briefly introduced, we therefore ask which models of evaluation may be adopted to achieve the objective of identifying responsibilities for Quality in organisations, which are complex due to the technology employed and delicate because of their role and the present time.

Strong acceptance of responsibility by producers of products and services, which excludes any possibility to elude responsibility, is therefore an important factor of growth.

Companies, their technical referents and all parties involved in the management and distribution must be free and unafraid to accept their responsibilities for the products and services offered with clarity, through correct technical planning.

In fact, this ability may be a competitive factor whose importance has been greatly underestimated, which could make a company preferable to another and could justify a higher price for services, albeit in a market that tends towards liberalisation and globalisation and, therefore, in a situation of growing competition.

The mechanism of putting the blame on others, in fact, is not acceptable even on the part of the purchaser, who, on the basis of penal norms, cannot and must not found his choices only on the lowest price offered. On the contrary, it is necessary for the purchaser to select his supplier with care and to supervise the efficiency of his work with the same diligence. Just referring to the more intrinsic value of the norm, we are able to realize a Quality focused mechanism, so that it assumes the central role that it deserves for the development of the modern world.

Let us remember that it is a world that illustrious experts define as increasingly “flat” – namely, a world in which the barriers and borderlines that have for years been an important “protection” for local companies from international competition are increasingly disappearing. But mainly we consider our new world an interconnected one, through more and more advanced and economical transportation and communication technologies.

For responsibility in the distribution of products and services to be effectively accepted and protected in the event of controversies of any kind, which has been declared to be an important factor of competitiveness, it is indispensable, however, to state how responsibility can be objectively evaluated or identified and measured. In fact, while in the

case of material products and characteristics the identification of responsibility (due to defective products, poor quality, etc.) is relatively easy or in any case can be arrived at through more well-known and traditional systems, in the case of services and Quality, which are intangible, it is necessary to refer to less widespread techniques. Such are the techniques of analysis and evaluation of organisational systems and the activities they perform.

The evaluation, which literally means to attribute a judgement or a value to something – is the result of a systematic activity of inspection. The word inspection is quite neglected and forgotten, despite the fact that there is a norm (EN 17020) that explains in detail that the activity of inspection is designed to examine a project, product, service or even a person, in order to make a professional judgement. In a field of activity that is not based on the use of instruments that provide a numerical and objective response, but professional judgements, this evidently involves some difficulties and, probably, a certain degree of delay in the spread of techniques of evaluation.

Inspection is an investigative type of activity that involves extremely specific technical and behavioural competence, because it is absolutely indispensable for the inspection to avoid being conditioned by the personal situations of the inspector.

Of course, this means that behavioural techniques must be adopted and, therefore, that the inspection cannot be improvised.

By way of example, it is worth mentioning the experience of the U.S. institution that deals with investigations on accidents that take place in the transportation system, the National Transportation Safety Board (NTSB), which is an important example of an investigative-inspection institution in the technical field, especially since it deals primarily with probable accidents that have not yet occurred.

Evaluation must obviously permit the expression of a judgement, which must therefore be strongly objective, either in linguistic or quantitative, numerical terms.

The judgement must be “objective” because it is based on facts and is “systematic” – namely, it must be possible to repeat the evaluation, just as one would repeat a measurement made with a traditional instrument; in the same manner, the evaluation must also be repeatable, without the fear of arriving at different results, and must permit the achievement of homogeneous results, which can be compared.

There are many situations of evaluation that are common knowledge for everyone: for example, there are university examinations; when you go through an examination, you are subject to evaluation by an expert teacher – whom it is hope is also expert in making evaluations – who assigns his professional judgement – on the basis of what the person subject to examination tells him.

Additionally, medical evaluations can also have a juridical – legal importance (this is the case of cognitive evaluations). So it is indispensable to ask whether these evaluations are conducted with criteria that ensure objectivity, systematic and homogeneous evaluations, since the life of persons may be at risk due to similar procedures.

To confer credibility to the result of an evaluation, it must be taken into account that there is a probability that the

person subject to evaluation could pass an examination, even if he or she is not in possession of the necessary pre-requisites. There are precise statistical properties in this connection, which permit us to evaluate and therefore keep the errors committed under control.

Another important aspect to take into consideration is the type of evaluation. Since an evaluation is made that leads to the formation of a professional judgement, in fact, it is necessary to take into account that professional judgements are typically characterised by what is technically called a “fuzzy” evaluation; the degree of nuance goes beyond the greater or lesser certainty that we attribute to this evaluation. Again in this case, there are mathematical techniques like fuzzy logic and others that assist us in keeping the judgement of evaluation under control and expressing it in as appropriate a manner as possible.

In order to perform production activities, or the complex system of activities, implemented to attain certain levels of quality and dependability of products, it is indispensable to have an adequate organisation and adequate technical resources, which can be made subject to quantitative evaluation through the previously cited regulation of quality.

This orientation is a first important step forward, because a purpose is attributed to quality evaluation or to quality certification that has not heretofore been commonly ascribed to it (where quality is understood as “the degree to which a set of characteristics of a product satisfies requirements”): both for reasons that are not of a technical type (it is easier to attribute a general efficiency-related meaning to quality, or even a merely commercial meaning) and for reasons of a technical nature (quality evaluations are based on statistical samplings and therefore do not take into consideration all aspects of an organisation).

Nevertheless, it is felt that if quality certification is managed by truly expert personnel and is supported by the innumerable instruments and algorithms of evaluation that technical literature has made available, it may be an effective instrument to express an evaluation of the level of adequacy of an organisation and its processes (and of course it cannot be neglected that the logic of evaluation and certification have always been largely employed in the more complex and critical chains of production on the level of management, sometimes on the basis of precise regulations: Aeronautics, defence, the nuclear industry, the chemical industry, the automobile industry, etc.).

The certainty that an organisational system is adequate (or is not adequate) still does not allow us to express a judgement with a sufficient degree of accuracy, which could possibly be “defective”. That is to say that it is necessary to be in the possession of additional instruments of analysis, which permit us to identify the so-called connection of cause and effect between an undesirable event and the responsibility of the party distributing the defective products and services.

Again in this case, techniques of systems analysis are available that may assist us; albeit they are innovative for the purpose of identifying responsibility, they are widely used in extremely evolved and complex technical fields.

Two techniques of analysis are cited that may be utilised in series: the so-called FMECA (“Failure Mode, Effects, and Criticality Analysis”) and Pareto Analysis (which is a

technique “borrowed” from economic-managerial disciplines) [9].

Once the organisational system of a potentially responsible distributor of a defective service is evaluated, it is possible to identify, classify and quantify all of the anomalies that the organisational system may perpetrate through its processes, through application of the FMECA system and, above all, to associate with each of these anomalies an appropriate risk index (generally based on the probability of occurrence of the anomaly, the seriousness of the consequence of the anomaly and the “detectability” of the anomaly) and to classify it in relation to the specific defect that is being investigated.

The Pareto analysis then permits us to draw a relationship between the number of anomalies encountered and the risk index and thus to verify the occurrence of anomalies, not only from the statistical point of view (as might be expected, since we are speaking of the number of anomalies), but also from the point of view of the analysis of the causes and effects (the risk index, in fact, is understood to be oriented towards the specific defects being investigated).

Definitively, when defects are detected in a material product and the cause and party responsible are sought, a material analysis is made on the product (with destructive and non-destructive analysis of the materials, verification of calculations, etc.) and the probability is evaluated that a certain defect could be traceable to one of the causes analysed.

In the presence of a defective service (like Quality management and certification is), a similar analysis is performed, with the exception that instead of the microscope and other laboratory machinery, systemic techniques of analysis are utilised to verify the cause of the defect and to verify the calculations, again in this case, but this time oriented towards the design of the service.

The analysis of the organisational system, in light of quality regulations, moreover, is deemed to be an important element of knowledge as a starting point in both the cases of the material product and the service, even if it does not generally allow us to establish the connection between cause and effect that an evaluating organism may need to seek.

There is no difficulty in performing these evaluations of a technical logical-systemic nature, except for the “intangibility”, which definitely requires us to fact something less common.

Finally, the level of dependability may be high, providing it is taken into account that the need to achieve often specific objective results, and therefore a great deal of even interdisciplinary competence is required in the activity of evaluation. An evaluation entrusted to a single evaluator in a delicate situation may be inappropriate and misleading; it is indispensable, in some cases to have collective bodies of evaluation.

As confirmation of the fact that these techniques are highly credible, it may be stated that they are enjoying widespread and growing diffusion in public administration, including the university.

The design of the quality services, therefore, it is of fundamental importance as Quality evaluations have to be objective, systematic and homogeneous, that is to say that they must be performed by competent experts and within an

absolutely rigorous ethic based protocol of rules and praxis.

Quality services imply the consideration of consultants, certification bodies and, mainly, of the standardization and accreditation bodies which staying at their role are able to deeply influence al the quality system in a country like Italy.

#### IV. THE ITALIAN CASE

Speaking of the Italian productive and quality system – and of their compliance with the rigorous ethic based protocol before mentioned - may lead us to put downs pages and pages without an end.

We therefore mention specific situations that appear in contrast with the needing of a national quality system which main focus should be the improvement of industrial companies and the growth of economy.

The main national Italian body for technical rules is today chaired by an entrepreneur who has executive roles in construction companies, in waste treatment companies and in certification bodies.

The Italian accreditation body, that is to say the organization which controls the certification bodies is the only one agency adopted by the Italian Government for such a role.

Such an accreditation body is chaired by an entrepreneur in various different fields: agriculture, banking, consultancy, certification, facility management.

The technical committee for the accreditations is chaired by the general manager of an important consultancy company.

The members of the committees to whom address eventual compliances, even if the statute says that they must be independent, are really nominated by the management of accreditation body.

The prices that the accreditation body applies to the certification bodies are widely dishomogeneous. Basing on a number of simulations in which different dimension certification organizations are compared, infact, it appears that the incidence of the accreditation cost varies very widely considering it in front of each certification, each contract and the return of the certification body (Table 1).

Last but not least, nowadays the technical normative organizations are partners of the Italian accreditation body that is the only one adopted by the Italian Government, while all these organizations are private ones.

Table 1 – Accreditation costs for certification bodies with a return < 1 MEuro (I) compared with accreditation costs for certification bodies with a return > 10MEuro (II).

Certification body type	cost incidence over each certification		cost incidence over each contract		cost incidence over return	
	I	II	I	II	I	II
Accreditation costs	31,6	3,76	75,3	4,58	5,9	0,36

#### V. CONCLUSION

In conclusion, the Italian case in our opinion underlines concretely the urgency of a new technical definition of Quality even considering the authentic revolution in act from the communication point of view, made possible by the low cost of Internet.

It is our opinion that the new definition of quality should be more friendly, less cryptic and at the same time it should explicitly involve as main focus the ethic behaviors of all the actors, well beside the simple respect of technical and legal normatives.

Only in this way Quality may recover the lost credibility in the last few years and, more important, become a truly and effective tool to ride the social-economical developments.

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