International Conference
Nuclear Energy for New Europe 2002
Kranjska Gora, Slovenia, September 9-12, 2002
www.drustvo-js.si/gora2002

NUCLEAR SAFETY AND QUALITY SYSTEMS

Hrvoje Kunaj, Enco Tireli
INETEC - Institut za nuklearnu tehnologiju d.o.o.
Koturaška 51, 1000 Zagreb, Croatia
hrvoje.kunaj@inetec.hr

ABSTRACT

According to ISO 8402:1994 [1] Quality is totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

According to ISO 9000:2000 [3] Quality is degree to which a set of inherent characteristics fulfils the requirements.

The use of nuclear technology for peaceful purposes has been closely related with nuclear safety from its very introduction. Commercial success of the nuclear technology application has been from its beginning, vitally connected with nuclear safety of power plants on one side, as well as protection of the environment on the other side. Nuclear safety has become an issue by having in advance to respond by proper answers to all kinds of questions and to any scenario, having just one word in a philosophy of the approach "**Quality**".

Out of all official definitions of the term "**QUALITY**" in different manuals, standards and laws, probably the simplest aphorism will remain; **that the quality by itself is nothing, but all the rest in human activities is absolutely nothing if the quality is not present**.

What kind of "**nothing**" could remain after missing even the minimum of the required quality in the work of the nuclear power plants (NPP), mankind regretfully had a chance to experience in the relatively short history of nuclear technology application. Even application of nuclear technology in peaceful purposes carries in itself such a level of risk and danger that is not comparable to any technology or other kind of human activity. However, benefit enabled by this technology is such a challenge that nobody rational will deny the option. The question that will remain open for a long time is ..... how?

Future development of, not only nuclear technology, but also all the other supporting technologies, will contribute decreasing of the risk danger and increasing nuclear safety. At the same time, human factor will remain the weakest link in nuclear safety of such facilities. Therefore in the future, human factor will have the most important role in nuclear safety, even than when regarded just in the form of **"the best intention"** cooperation. Inversion of this postulate in the form of "**global terrorism**", in which nuclear facilities became extremely challenging objects of attack, regretfully is today present danger, that we all fight against, while just some of us knowing how, and just a few are successful. By leaving "**global terrorism**" aside for the moment, it has to be admitted that the mistakes caused by human factor out of "**the best intention**" are quite respectable enemy, that is not easy to be put under control, or at least decreased to the acceptable minimum.

Eternal fight between "**good**" and "**evil**" has been played throughout history with different luck. From tribal gurus up to religious procedures, establishing moral and ethic principles, good customs and tradition, well written state laws and regulations, public media and public opinion judgment, always throughout history the term of mistake and failure has

been tried to be decreased to the least possible measure.

So it is with the "**quality systems** ", as the newest weapon in this chain of fights between "**good**" and "**evil**", that basically have the same goal – try do decrease the appearance of the mistake to the least possible measure. Differences in quality systems, are the result of differences in the determined goals such as; satisfaction of customer, resulting safety (nuclear, traffic, health), environment protection, biological equilibrium or harmonizing criteria in laboratory and certification (in education, measurement, quality of products) etc.

States, through which now days man realizes social needs in the form of existential requirements and upgrade possibilities, strive to provide employment to insure minimum of existence, but to give opportunity for creating new values. States as organized systems support realization of such goals through laws, regulations, while all the systems of successful organization are assembled together in the **cross of responsibilities** with the following form:

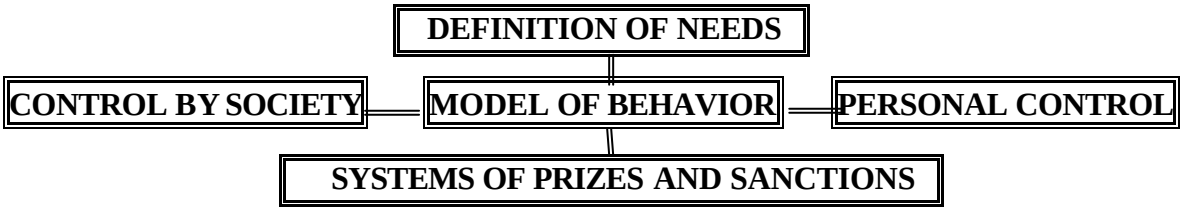

Figure 1: Presentation of quality model in general form

Next figure 2. shows schematic representation of functioning quality system with selection of goals and way of regulations application with respect of strategic decisions.

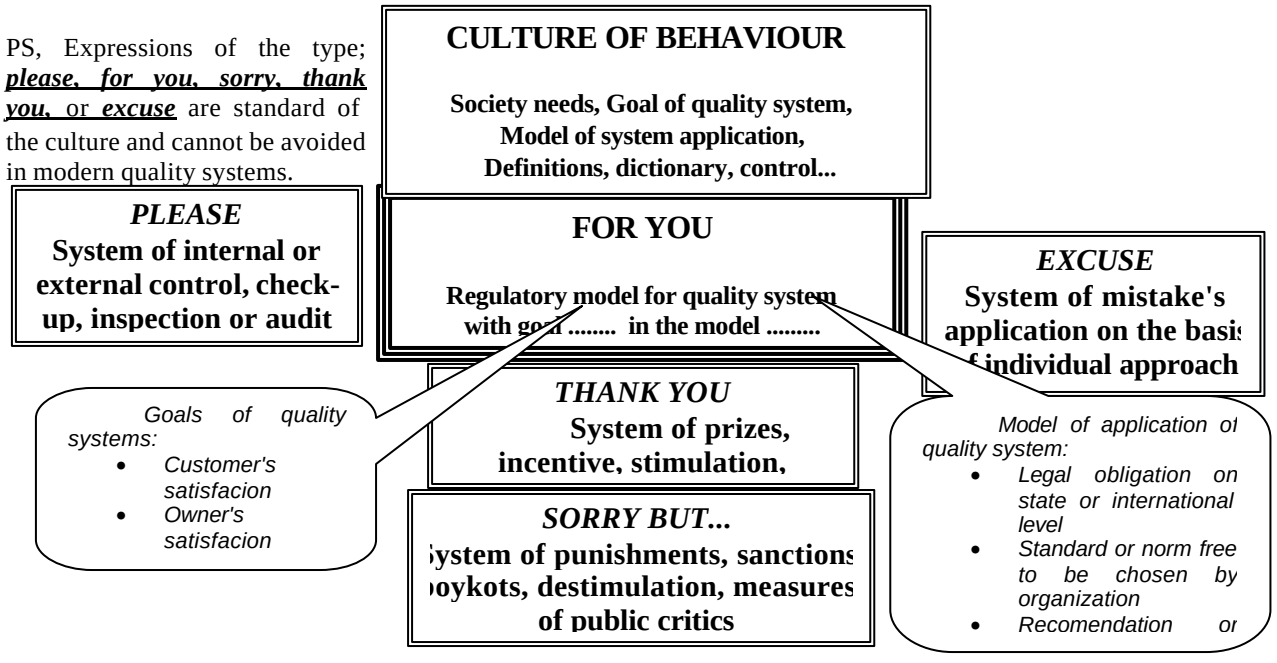

Figure 2: Schematic representation of functioning quality system in general form

1 INTRODUCTION

Now days regulative from the field of complete quality system is originated out of three basic principles, being the same as to modern approach to quality is based on, regardless of to which field of economy or with what purpose is applied:

1. "Plan in documented form what and how you will control"
2. "Control as you have planned"
3. "Document as you have been controlled"

When we discuss about the approach to the today's quality systems applied in just for the needs of nuclear power plants and insuring nuclear safety, it is necessary to take in the account some elements from the history and tradition of the west European civilization.

From the beginning of the civilization mistake was immanent to every form of human activity (it is human to error and everybody that works makes mistakes). Every society had basically be goal to establish such a system of values that will sin and mistakes bring to the least possible measure. From the early times of Christianity it was regarded that the sin has been originated from the four basic forms of human activities, or as traditionally prayed "***I* sinned a lot** ... by **thought, word, act and failure.** Even today's modern quality systems try to introduce strict "**control**" in all the phases of the creation process.

1. **Thought** - has been leading idea in every process of human activity, therefore in all the quality systems accepted now days it is required to be expressed; "**Plan in documented form what and how you will control".**
2. **Word** - enables and realizes communication but the word is not a proof if not written and checked, so any quality system requires "**Document how you have controlled".**
3. **Act** - can be honored then and only then, when it is a result of formerly thought prepared in form of plan, and not a result of occasional events. That is why every quality system requires control of all the phases of the process "**Control as you have planned".**
4. **Failure** - is a form of human activity that is the most difficult to be proved. Excuses of the type; that was not object of the contract, that was not in accordance with the law, that was not written, that was not my job, I am not in charge for such procedures, I cannot remember, I haven't seen anything,… are constant form of excuses when someone denies guilt**.**

Quality systems also have the most difficulties in the "**failure**" area. Proofing somebody's right that one hasn't seen anything, or that it hasn't been his duty, it was not part of the contract or it was not my obligations, is very difficult task but also the task when proofed, it would be very difficult to sanction in accordance with any law.

However, importance of nuclear safety does not accept justification of the type "**failure**" and excuses stated above. That is why it is good to see how four basic forms of "**mistake**" in human activities are presented in different quality systems, especially how they are implemented into regulative dedicated to insure nuclear safety.

2 BASIC PRINCIPLES OF QUALITY ASSURANCE

As already mentioned, quality control regulations, including ISO Norms, originated from three basic principles on which modern approach towards quality was based regardless of the branch of the economy was applied or what was the purpose, **Plan in documented form, Control as you planned, and Document as you control** (see 2. Introduction).

The approaches in developing quality systems prescribed by formerly mentioned standards had been very similar, and in some cases even identical, what enabled quick transition to the requirements of ISO Standards. In today's society market competition and economic parameters control quality level for the vast majority of products, being at the same time acceptable for the customer (competitive) and cost-effective for the producer (profitable). Such principles developed system of norms about quality with primary goal to protect customer and press producer not only on full responsibility for the product, but also to the full transparency of internal production, organization, personnel policy and management of the company. In today's quality systems some requirements are implemented that up to thirty years ago seemed senseless, but recently became basics for development of quality, as:

- Definition of Quality Policy approved by management and implemented into organization
- Clearly established system of internal organization recognizable for any associate,
- Decision-making on the basis of analysis, discussion and objective evidences,
- Defined relationships of rights and duties for every participant in working process,
- Transparency of communications and information system,
- Recognition of working process and process orientation in management,
- Documenting of all working procedures
- Planning of activities and control of activities in written form,
- Review, revision and approval of documentation as well as documentation keeping system,
- Constant internal control of processes and supervision of working processes and activities (audits),
- Constant indoctrination of all personnel (from workers to management),
- Constant supervision, control and check-ups of measuring equipment in organization,
- Documenting of results, analysis, grading and measures for improvement of processes,
- Collection of return information about product value, comparison to competition,
- Documenting of noticed errors,
- Conducting of measures for elimination of mistakes and obligatory preventive actions.

It should be pointed out that ISO 9000 system of norms just as majority of other norms for quality was not meant to be law, nor was obligatory related to technical, juristic or other legal requirements. As for now quality norms were meant just as norms that should be: welcome by media, voluntarily accepted in organization, stimulated in business environment, regarded trustworthily from customers but **left without possibility for sanctions**.

That was acceptable approach for keeping customer satisfied with quality, however for the needs of nuclear safety that approach would be even unserious. In order to quality assurance system make effective in certain society, it was not sufficient enough to wait for the market to make distinction between the **good** and the **bad products**. Nuclear safety required support of legally controlled quality systems that has to be obligatory, however all the others associated activities were taking part in the process of the quality system, from control, sanctions, reporting of mistakes and stimulations, had to be legally determined.

3 DIVISIONS IN THE APPROACH AND PURPOSE OF QUALITY SYSTEM

Even now days regardless of broadly spread intention for internationalization of quality assurance norms, there has been easily noticeable division of norms on legally obligatory with **determined sanctions**, and **voluntarily obligatory** without legal sanctions. The terms of

quality have been closely connected with the basic goal that has to be fulfilled and narrow area of application that certain quality systems had to satisfy. All the attempts to define norms with general purpose for all branches of the economy, and work of non-profitable institutions, do not give satisfactory results up till now. Appearance of now specific quality systems should be expected in the future for specific branches of human activities.

1. Principle of QA for profitable organizations with the purpose of maximum **customer protection** found wide application in international norm from series **ISO 9000** acceptable for the most of economy. Now days ISO represented integration of positive engineering practice in the period before the first issue in 1987 until today.
2. With development of **ecological consciousness** in the last period another similar appeared in the series of the norms ISO 14000, that was meant for pressing the economy to take into account not only customer's requirements, but **environmental protection requirements** (voluntary for the time). Advantage of this norm in relation to ISO 9000 was the obligation to recognize legal aspect – the law (for environment protection), while there was no auditor's obligation in accordance with ISO 9000 to know the law or process of the law.
3. New norm **ISO 17025** is similar to norm **EN 45000**, with the attempt to equalize non-profitable area of works in the society with respect to quality with in the activities like: harmonizing education of personnel for the inspection and accreditation institution, work of laboratories and measurement institutions, work of inspection institutions, etc. The goal of those standards is not customer's satisfaction, but **equalization of certification criteria,** and **ensuring of the application of the law** in laboratories and institutions enforced by the state. EN norm has required winning accreditation from the side of **state regulatory bodies**.
4. **Car industry** has developed under influence of the "big three" (GM, Ford, Chrysler) chain of norms **QS 9000**, similar to ISO 9000, but with some additional chapters specific for car industry (traffic safety, buyer's requirements, constant improvement, etc.). The power of one branch of economy became so dominant, that one internationally recognized quality system had to be changed for leading auto industry in the world.
5. **In nuclear industry**, USA regulations in quality has achieved the greatest recognition up till now. Even though it has been developed as national regulations, in time it became widespread in more countries of the world in the same form, or with little modifications for the same purposes, safety control of NPP. Key advantage of those regulations was that the obligation has been defined to apply it under requirements of code **10-CFR-50 App.B** with the goal to **insure nuclear safety**. Disobeying the regulations was sanctioned through direct authority of **the state body, NRC**. Nuclear safety has been set above the **customer's requirements, contractual obligations, business secrets or other legal regulations.**
6. **Reporting of defects regarding nuclear safety** has been separated into code **10-CFR-50** in order to prevent that any activity that might endanger nuclear safety could be hidden behind the law. Individual has been given absolute right and duty in reporting mistake **concurrent with personal moral and ethical principles**.

It could be seen that there was big difference in the approach to quality system, so there are no regulations that are absolutely powerful or generally accepted. Divisions are going to exist on **legally prescribed** and **voluntarily obligated**. Further divisions are going to exist regarding basic satisfaction of the goal like; customer satisfied, ecology requirements, safety requirements (nuclear, traffic), independent certification procedure and laboratory activities.

4 NUCLEAR TECHNOLOGY AND QUALITY SYSTEMS

Development of nuclear technology was impossible from the very beginning without precisely determined rules during construction, production and organization of NPPs. In the history of mankind there could not be found an example where application on of a new technology would bring possibility of human error with unforeseen consequences for inhabitants and environment as nuclear technology.

That was the reason why successful use of nuclear technology was vitally connected to development of quality systems. Looking back now at 40 years in application of the NPP, it could be pointed out that successful application of nuclear technology is proportional to level of development of quality system in the environment. Countries users of NPPs as a rule, together with technology, bought the regulations. Lack of such a practice, or inadequate application of national standards lead to heavy consequences for the operation of such objects.

There is no requirement more important to society than to insure nuclear safety when dealt with nuclear technology. That element has to be clearly defined in all the parts of nuclear regulations that insure quality in nuclear industry. In order that to be realized in efficient manner it is necessary that in nuclear industry:

1. QA system needs to be legally controlled and obligatory for all legal participants and for all the individuals in work and or cooperation with nuclear technology,
2. That there is independent state organ for control of QA in nuclear industry, with the widest appointments and when required above the other systems, determined by the law,
3. That there are legally defined sanctions based on state level or international,
4. To establish a system that will enable every mistake found endangering nuclear safety could be quickly reported to independent state organ for control. Reporting of mistakes has to be right and duty of every individual, regardless of obstacles set by the society. Establishment of such a system enables every individual to acting by the position of moral and ethical principles gets the right and duty to insure nuclear safety.
5. It is therefore important to establish system of stimulations and prizes of the activities that would increase the level of nuclear safety and the quality. That system has to have social importance must be stimulated in moral and material sense for individuals and organizations taking part.

5 BASIC PRINCIPLES OF USA REGULATIONS FOR NUCLEAR SAFETY

USA nuclear safety regulations used for application of quality system in nuclear industry takes into account all the elements stated above from the history and tradition. The fact that failure becomes out of four basic human activities; ***thinking***, ***word, act*** and ***fail*** had to be implemented into regulations to prevent occurrence. Importance of nuclear safety did not accept any justifications or excuses and therefore it is interesting to see how it is presented

1. Basic goal of QA system in application of nuclear technology is safety of nuclear facilities. It **is set above** buyer's requirements, or relationship purchaser-supplier as defined by law.
2. USA regulations define obligation of QA system application with the basic goal to insure nuclear safety through requirements in **the law 10-CFR-50 App.B.** Quality requirements cannot be so detailed; accurate and encircling in obligations like non-obligatory norms or standards. However it has to be pointed out that in some elements requirements of 10-CFR-50 are stiffer and stringed than in compatible standard ISO 9001.
3. Wider application of legal principles set like that is presented in details in **ASME NQA-1&2**. Those standards represent practical resolution of the law requirements by the society

of mechanical engineers. Nuclear technology users are expected to adopt those standards completely, without accreditation on state level.

When quality regulation requirements are compared, it is necessary to make comparison between **ASME/ASME NQA**, with the requirements of **ISO 9001**. It could be concluded that NQA norms are somewhat more stringent in the requirements, but that difference becomes out of detailed description of activities specific for the nuclear industry. In principle both norms are similar, ISO even encompasses some additional activities in organization that NQA does not recognize as important in nuclear industry (Contract review, Maintenance, Statistic).

4. In USA standards NQA-1, there are also **Supplements** that explain intentions of the standards more in details; obligatory **Subparts** that accurately and in more details define specific kind of activity on the equipment, and Nonmandatory **Appendices** that additionally define just certain activities from nuclear technology.

In the ISO 9000 system there are appendixes with similar intention, as supplement to ISO 9004 (Guideline) with nonmandatory goal of more clearly defining of basic ISO norm.

5. In USA regulations control of nuclear safety law obeying is in direct state authority of **NRC**. NRC has very wide authorities in conducting control on federal level, and executive right for sanctions and conducting direct preventive measures of nuclear safety.
6. Nuclear safety requires acting of each individual in accordance with **moral and ethical principles** that have to be set above interests of business secrets, contracts and above law. If any individual judges that the responsible person in the organizational chain of his organization or nuclear industry did not act satisfactory in his opinion, the individual is obliged to report of his notice directly to **NRC**. Tel. no. is part of 10-CFR-21.
7. In nuclear technology obligation for quality systems application has to be part of legal obligation, including the consequences for not following the law as **sanctions and fines**.

This way, USA regulation for nuclear technology has completely implemented **all four forms** of human behavior that could influence nuclear safety or quality in its legal obligation. The cross of responsibility as it is presented on fig.1 & 2, of this article is completely implemented into requirements of nuclear safety quality assurance with direct power as legal obligation.

6 BASIC PRINCIPLES OF ISO NORMS SERIES 9001:2000

The need for great revision of norms ISO 9001:1994, came on the basis of experiences gathered in the former period of time. According to final analysis of the problems, Technical Committee **TC-176** noticed four problems that create most of the troubles in quality systems:

1. Wrong attitude of the management structure (inappropriate management, decisions based on bad premises, non coordination of activities, lack of preventive actions).
2. Weak resources management (insufficient links between management and base, problems with personnel, weak communication, low level of responsibility towards information.
3. Low level of process management knowledge (low process understanding, bad process control, lack of process measurement, nonresistance of feedback)
4. Weak measurement, lack of analysis, lack of needs for improvements, (insufficient links with customers, lack of comparison with competition, lack of analysis).

To eliminate problems noticed above, main requirements in the new norm ISO 9000:2000 are:

1. Customer is put on the top
2. Total management of the process because mandatory part of quality system,
3. Quality system goals must become means for managing of company policy,
4. Management grading have to deal with measurement of quality system efficiency
5. Activities in organization have to be analyzed through process evaluation,
6. Total requirements for managing of processes (from quality planning to product realization)
7. Type of communication with customer is defined in order to insure customer's satisfaction
8. Methods have to be developed for measuring of customers satisfaction, for collecting and representation of information in order to enable improvement
9. For process measurement, including results of the process for internal improvement, adequate methods have to be applied, including measuring of workers satisfaction
10. Listed process have to be defined, implemented, maintained in the existing quality system of the organization with the goal set for constant improvement.

New system of ISO norms has set the following principles that have to be regarded in application of ISO 9000:2000, although not explicitly mentioned in the norm:

1. **Organization directed towards customer**: Organizations depend on their customers, so for that reason they have to understand future needs of the customer, satisfy their requirements, and exceed their expectations.
2. **Leading role**: Management has to establish unity in organization. Internal environment has to be stimulative for people that are included in the process of realization.
3. **Personnel engagement**: Personnel in all the levels of the organization have to be adequately included in the process, their abilities have to be used for the benefit of the organization.
4. **Process approach**: All the activities in the organization have to be organized like processes.
5. **Systematic approach in managing**: recognition, understanding and managing of the connected processes system with known targets improves efficiency of the organization
6. **Constant improvement**: Constant improvement has to be lasting target
7. **Decisions based on facts**: All decisions have to be based on facts and information that has been measured, analyzed and evaluated
8. **Mutual benefits between the suppliers**: Business partners must have relations that enable creation of new values for both parties.

It can be seen from everything stated that ISO 9000:2000, although without the power of law, sets requirements for quality in more details. Modern approach towards TQM is major step forward having in mind inclusion of all the participants comparing to quality control.

7 FUTURE DEVELOPMENT DIRECTIONS

Development of all the quality norms has been in almost all the cases through four phases regarding approach of increasing quality in order to achieve TQM and "aero errors".

1. (**QC - quality control**) even today represents for most of the people, the term where activities connected to quality finish. The picture of QC-person measuring product, eventually with presentation of test result on sample, is general impression in people's

minds. There stop any other thinking about quality of the product.
2. (**QA-quality assurance**) for many people included into quality, it is relatively unknown set of activities. QA is form of internal organization under lead of independent body (QA department) with purpose to prevent activity that might lead to errors in the process.
3. (**QM-quality management)** is now days the most widely spread term in modern quality systems, where the top management in the company organization is established with purpose to prevent occurrence of the mistake. If the mistake occurs, management will be informed and implement measures that will prevent it.
4. (**TQM-total quality management**) is the final goal of all the quality systems in which every individual, including members of the governing board have the duty and responsibility to act in such a way that will prevent the occurrence of failure.

TQM understands full quality mastering by every participant in the process, not just the personnel involved in process. ISO 9000 norms start to apply the same philosophy that is valid for nuclear safety (10-CFR-21) or the one tending to TQM requirements: **include all individuals into the quality process**.

> **Lord Kelvin** ones made a statement that has become widely present in quality systems as important element of system's improvement: "**If you watch some process and want to influence on it, you have to find possibility to present the result of that process in measured values. If you are not in a position to do that, your knowledge about that process is not appropriately sufficient and inappropriate to control the process**".

Translated into the quality requirements, where constant improvement is required that all processes have to be measured. Only that way we are able to determine in further analyses if the results in organization and management are positive. This might be simple in financial results, production indexes, but in some processes that might create huge problems. Starting right from the process of customer's satisfaction, to the internal audits, according to ISO 9000 it is required that the results have to be presented in measured values (numbers).

In the future success of organization will be based on the results of measurement of five basic system values that will have to be measured and presented in numbers: **Customer's, Owner's, Manager's, Worker's and Community's satisfaction.** Basic balance of all those five elements can be established only then when exact measurement of satisfaction exists for each of those groups. Satisfaction balance is the basic condition for creation of generally acceptable quality system for all forms of human activities.

8 CONCLUSION

Therefore for any quality system to be successful, especially quality assurance system for nuclear safety, it is necessary that quality systems be in the future:

1. Social obligation required by law, (with clear target and application mode),
2. Under constant control of independent state institutions,
3. Possibility for individual to take part on the basis of own moral and ethical principles,
4. Sanctioned in accordance with the law for disregard of rules,
5. Stimulated by the society with prizes, benefits etc.

Regarding nuclear technology requirements it is sure that nuclear safety stays on the top of the structure and in priorities it has to be set high above "customer's requirements", the existing "contractual and legal obligations" or "business secrets". That is the reason why USA

regulations “10-CFR-50 App.B”, with legal support of the rights and duties to report defect “10-CFR-21”, is far more applicable for nuclear safety, compared to norms ISO 9000.

However, there is the fact that for the majority of countries that use nuclear technology, the term of ISO standard is more acceptable due to global economy movements. ISO standard develops very fast, is widely used and the largest number of experts for implementation of quality is educated for the application of ISO standards. Also ISO 9000 norm is a system that in the best way unifies the requirements in transition to TQM. That why ISO system is good basis that can serve for preparation of international law for nuclear safety or as an upgrade to the quality system IAEA 50-C-QA, but taking into account all the previous conditions.

The success of each quality also nuclear safety can be insured only when each individual wins the right and the duty to take part in the quality process. The role of an individual is the key element in keeping nuclear safety, being the reason why in USA regulations that element is additionally defined by the law, as the obligation to report defect 10-CFR-21, what gives to the nuclear safety additional value with respect to the ISO 9000.

It is fact that legal obligations, sanctions and strict control are not enough for success of any project, the same being valid for quality system. Psychology knows very well that only one fifth of communication with child in education or in communication with associates can be based on comments, the rest have to be forms of stimulative behavior by society. The same is valid for implementation of quality system in certain society is not going to achieve results if those requirements are not fulfilled. Nuclear safety system cannot be an exemption.

REFERENCES

[1] EN ISO 8402 “Quality Management and Quality assurance - Vocabulary, Edition 1994

[2] EN ISO 9001 “Quality System – Model for quality assurance in design, development, production, installation and servicing, Edition 1994

[3] EN ISO 9000:2000 “Quality Management System – fundamentals and vocabulary

[4] EN ISO 9001:2000 “Quality Management System – Requirements

[5] 10-CFR-21, “Reporting of Defects and Noncompliance”

[6] 10-CFR-50, Appendix B "Quality Assurance Criteria for Nuclear Power Plants”

[7] ASME NQA-1-1994 Edition, Part I (Basic Requirement and Supplementary Requirements for Nuclear Facilities), and (ANSI/ASME N 45.2 – 1977)

[8] ASME NQA Technical Report 1993: Comparation of ASME NQA-1 and ISO 9001

[9] ASME NQA Technical Report 1993: Comparison Handbook 10-CFR-50 App B / ISO 9001-1994