SC3 UNICEN “NUCLEAR POWER PLANTS”

Quality Management System

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QUALITY MANAGEMENT SYSTEM

WG 2

TOPIC	Coordinator	Parties Involved	Meetings
Quality Management System	Pietro Amadei	ANSALDO - TECHINT – THYSSENKRUPP –AICQ – ICIM –ROSETTI MARINO – IBF GROUP –ENEL –ISPRA – SOCIETA' DELLE FUCINE – TENARIS –MANGIAROTTI - ENEA –EON –SOGIN – ITALCONSUL –FOMAS GROUP –MELONI –ANIMA – BUREAU VERITAS –TUV-PROGETTI EUROPA-ACCREDIA-RINA-STF-OMECOS-ELETTRAENERGIA-DNV	9 .06.09 (Sogin) 20.07.09 (Sogin) 5.10.09 (UNI MI) 14.01.2010 (Sogin) 19.03.2010 (Faggiolati Macerata) 2.07.2010 (FOMAS GROUP MI)

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Scope of WG 2

The purpose of the document **UNI/ TR 11510** - "***Nuclear power plants - Particular requirements for the application of the standard UNI EN ISO 9001:2008 in the nuclear field***" is to provide companies wishing to operate in the nuclear field, a support tool for integrating the management system with additional requirements and recommendations required by international law and by the Nuclear Regulator

However, recent initiatives of the international committees ISO / TC 85 "Nuclear Technology" and CEN / TC 430 on the subject of reconciliation between the IAEA and the ISO on Management Systems, makes actual the guide issued by UNI, which may constitute a useful reference for subsequent analysis and study in ISO and CEN. To signal that a possible guide approved by CEN would be binding for the countries of the European Union

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Field of application

In the Italian context, the norm today is a direct application in the **decommissioning** of nuclear facilities and **radioactive waste management**

The document is applicable to Quality Management Systems of Organizations operating in the nuclear field, at different levels of the production chain (operators, suppliers, sub-suppliers), particularly with regard products and/ or services relevant to nuclear safety.

Grading application of each requirement is based on "**Graded Approach**" of IAEA and, with respect to supplier, is specified by the customer during qualifying process and in the contract.

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Scopo of UNI/TR 11510

The standard integrates the requirements of ISO 9001:2008 with specific **requirements** or **recommendations** contained in the guides management systems for Quality produced in the nuclear field by the International Atomic Energy Agency (**IAEA**), which constitute the international reference, taking into account the requirements Western European Nuclear Regulators Association (**WENRA**). In addition, the document comes from the need to define how to combine the international guides with the recommendations defined by the Italian Nuclear Regulator through the Technical Guidelines of the National Committee for Nuclear Energy (**CNEN**), yet to date reference. In preparing the document has taken into account the comparison with other management systems standards applied in the nuclear sector, the American Society of Mechanical Engineers (**ASME**)

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STANDARD REFERENCES

- **IAEA** Safety Standards Series **GS-R-3** – The management system for facilities and activities. Vienna, 2006
- **IAEA** Safety Standards – Safety Guide **GS-G-3.1** – Application of the management system for facilities and activities. Vienna, 2006
- **IAEA** Safety Standards - Safety Guide **GS-G-3.5** – The management system for nuclear installations. Vienna, 2009
- **ASME NQA-1-1994** Edition - Quality Assurance Requirements for Nuclear Facility Application
- **TECHNICAL GUIDES CNEN** (late 70s beginning 80s)
- **WENRA REQUIREMENTS,** 2008

Appendix A to UNI/TR 11510 there is a correlation table **ISO 9001** – **IAEA** - **ASME**, indicated with the requirements/ recommendations integrative than those of ISO 9001.

QUALITY MANAGEMENT SYSTEM

In line with current international standards (ISO 9001:2008) the **IAEA GS R3** consider the management system a tool of management to handle the processes in a controlled manner and ensure the improvement of all aspects of quality, environmental, security, economic, ethical, ..., both the product and the system. This means adopting a system that puts a common factor of policies and objectives arising from the above requirements, in order to avoid conflicts and to ensure that nuclear safety is not compromised.

In this regard **WENRA** indicates as mandatory (rif.to *Reactor Safety Reference Levels January 2008 - Issue C "Management System")* for the licensee to the establishment of an "**Integrated Management System**" corporate including requirements relating to health and safety, environmental, security, quality and cost.

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STANDARDS IN NUCLEAR FIELD – INTEGRATED MANAGEMENT SYSTEM

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Conventional

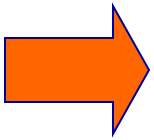
Nuclear

ISO 9001

mandatory for public contracts depending on the amount of work

ISO 14001

at the request of the contracting owner, only in "appropriate cases"



IAEA GS-R-3

BS OHSAS 18001

required by D.Lgs. 81/08 as extenuating circumstance of the offenses referred to in D.Lgs. 231/2001

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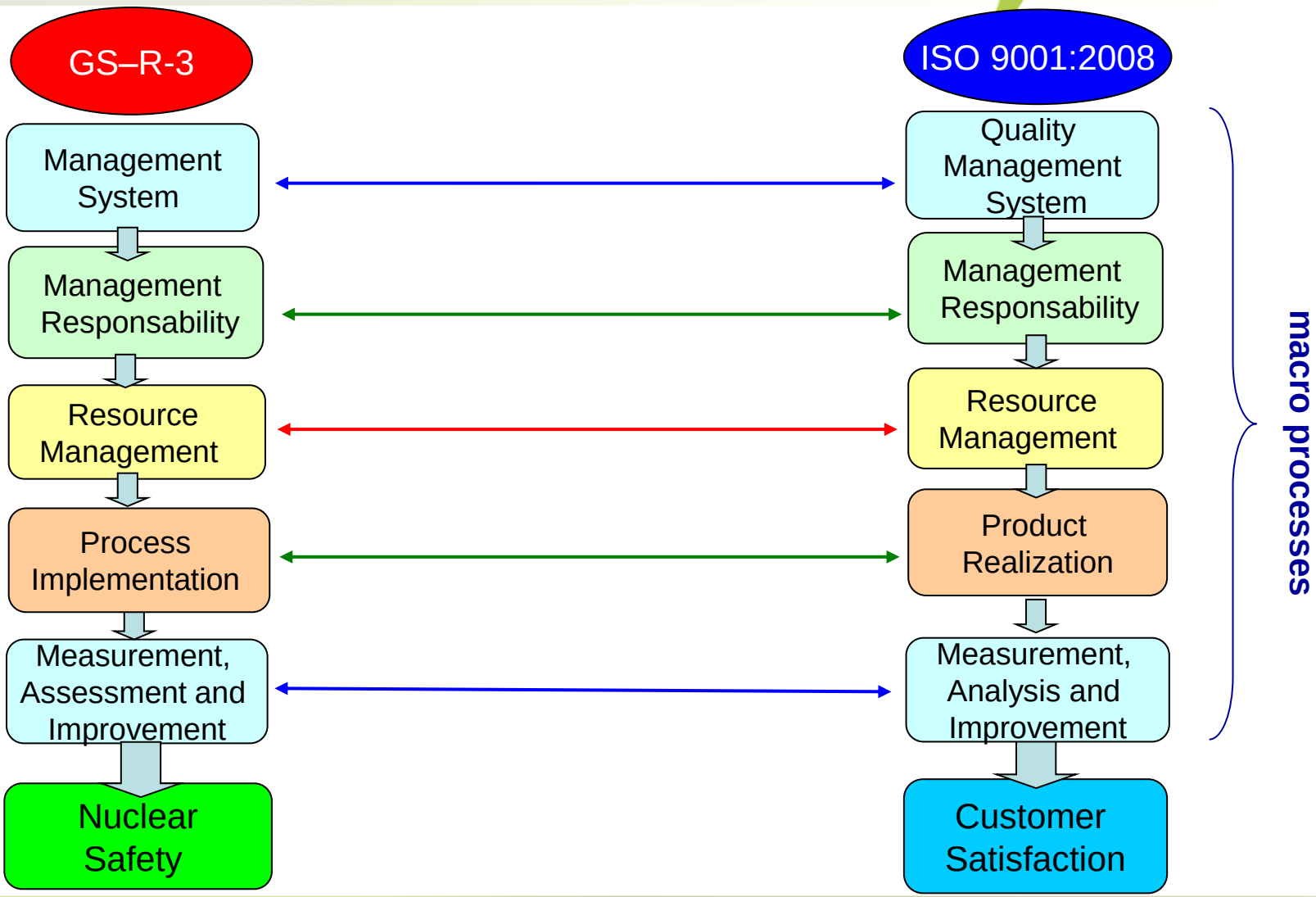
Comparison ISO 9001:2008 and IAEA GS-R-3



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Comparison ISO 9001:2008 and IAEA GS-R-3

IAEA GS-R-3

Target

SATISFY THE REQUIREMENTS OF SAFETY OF FACILITIES, PERSONNEL AND STAKEHOLDERS

ISO 9001:2008

Target

FULLY MEET CUSTOMER'S REQUIREMENTS

QUALITY MANAGEMENT SYSTEM

Comparison ISO 9001:2008 and IAEA GS-R-3

THE REQUIREMENTS OF THE IAEA GS-R-3 NOT EXPECTED IN ISO 9001

INTEGRATED MANAGEMENT SYSTEM

This means adopting a system that puts a common factor the policies and objectives arising from the safety, health, quality, environmental, security, economic, ethical, ..., requirements, in order to avoid conflicts and to ensure that nuclear safety is not compromised.

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Comparison ISO 9001:2008 and IAEA GS-R-3

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THE REQUIREMENTS OF THE IAEA GS-R-3 NOT EXPECTED IN ISO 9001

GRADED APPROACH

The graded approach is a means to determine the types and extent of the checks to be carried out on specific parts of the system, services and processes

The graded approach provides for a gradual application of the requirements of the management system in relation to:

- **Criticality and complexity of the product/ activity**
- **Importance of product / activity for safety, health, environmental impact, security, quality and economic impact**
- **Possible consequences of a product faulty or not an activity performed properly**

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Comparison ISO 9001:2008 and IAEA GS-R-3

THE REQUIREMENTS OF THE IAEA GS-R-3 NOT EXPECTED IN ISO 9001

INDEPENDENT VERIFICATION

IN INSPECTION AND TEST

Inspections and tests must be conducted by defining:

- level of independence of personnel conducting the tests and inspections

IN DESIGN

The adequacy of the design, including design tools, data input and output, must be verified by individuals (or groups of individuals) other than those who performed the design or participated to the design activities.

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Comparison ISO 9001:2008 and IAEA GS-R-3

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THE REQUIREMENTS OF THE IAEA GS-R-3 NOT EXPECTED IN ISO 9001

ARCHIVE DOCUMENT AND RECORD

The locals used for archives must preserve documents from damage or destruction caused by natural events (floods, fires, earthquakes, presence of insects, etc.) or adverse environmental conditions (light, temperature and humidity).

When you can not have premises built with the requirements adequate to withstand adverse events (earthquake-resistant buildings equipped with sprinkler system, no pipes inside, equipped with ventilation systems, etc..) is necessary to provide for a duplication of documentation and to the physical separation of the archives, in order to minimize the possibility that the they are exposed simultaneously to the same dangerous event.

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Comparison ISO 9001:2008 and IAEA GS-R-3

THE REQUIREMENTS OF THE IAEA GS-R-3 NOT EXPECTED IN ISO 9001

SAFETY CULTURE

- **Creation, dissemination and improvement of safety culture, at various levels of the organization.**
- **Collection and exchange of information relevant to nuclear safety, both within the organization and with the outside world, national and international (adoption of "best practices") for the purpose of recycling operational experience.**