« Nuclear energy, nuclear technologies, and radiological protection »	ISO/TC 85
Date: **2014-06-13**	Doc. Number: **N 1325** *(replace N 1223)*

Assistant: *Patricia RUIZ* *Direct line: + 33 (0)1 41 62 85 11* *patricia.ruiz@afnor.org*	***Your contact:*** *Guilhem CUNY* *Direct line : + 33 (0)1 41 62 84 94* *guilhem.cuny@afnor.org*

Approved Business Plan 2014

FOLLOW UP	For information
SOURCE	ISO/TC 85 Secretary
NOTE	

ISO/TC 85 approved Business Plan
Date: 12/06/2014
Supersedes N 1223

Content:

ISO/TC 85
Nuclear energy, nuclear technologies, and radiological protection

Executive summary

The objectives of ISO/TC 85 are to improve efficiency, safety and radiological protection for all nuclear activities, nuclear technologies and applications of ionising radiation, and sustain the present globalization of the markets with new international standards.

ISO TC 85 objectives are the production of industrial standards addressing the needs of nuclear energy, nuclear technologies, and radiological protection, including:

- Measurement of ionising radiations and of radioactive or nuclear materials;
- Measurement or calculation of safety or performance related parameters;
- Material and equipment specifications, including standard dimension interfaces;
- System specifications;
- Management and conformity assessment.

The scope of ISO/TC 85 is the standardization in the field of peaceful applications of nuclear energy, nuclear technologies and in the field of the protection of individuals and the environment against all sources of ionising radiations.

It includes mainly:

- Nuclear fuel cycle;
- Nuclear power reactors;
- Radiological protection for all nuclear technologies and applications of ionising radiations.

Nuclear Power Plants(NPP) continue to play an important role in the global energy mix. Some 435 NPP produce 12% of the world electricity production, and some 150 are shutdown. The years before the tragic accident in Fukushima in March 2011 had shown a global trend for new plants and for the life cycle or power extension of existing plants. The present situation is complex: some countries have decided to phase out nuclear energy or to postpone their new-build programs, some have launched important programs for safety reviews and improvement of existing or planned plants, and some countries have large new-build programs on the way. During the 2011-2013 three years period, 19 NPP have been shut-down, 8 new NPP have been connected to the grid, and 21 new construction have begun.

The global market in the field of nuclear clean up is growing significantly as facilities from the earlier era of the nuclear industry are being decommissioned, nuclear waste being processed for long term storage and disposal.

Besides nuclear energy, nuclear technologies deal also with medical activities (diagnosis and radiotherapy), industrial activities (irradiation services, measurements, analysis and non destructive testing using radioactive sources, as well as production of the sources needed by industrial and medical activities), research activities (laboratories and research reactors) and activities and situations related to natural radiation sources.

All these aspects of the use of nuclear energy or ionising radiations support the need for standards on a global scale.

ISO TC 85 standards can cover all aspects of a facility or equipment life cycle (design, construction, operation, decommissioning) according to the needs expressed by participating members (P members).

ISO TC 85 priorities for the on-going years are the following:

- Develop and sustain international participation for the production and maintenance of ISO standards in the nuclear and radiological protection fields.
- Lead an ISO process for the harmonization of national standards; the strategic objective of this process is the promotion of best industrial practices at an international level through ISO standards.
- Participate in the international response to the Fukushima accident, including the support to the IAEA revision of its safety series, and the production of ISO standards related to the management of extreme events in nuclear facilities and their environment.
- Drive an ISO initiative to adapt existing ISO standards to the specific needs of the nuclear industry with respect to conformity assessment, and management sytem certification.

ISO TC 85 encourages an effective and active participation of experts from all P members and from international organizations in liaison with the technical committee or its subcommities.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure, which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organisations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable, which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by e.g. ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF ISO/TC 85

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of ISO/TC 85, and they may significantly influence how the relevant standards development processes are conducted and successively address:

- Nuclear energy;
- Other nuclear technologies and applications of ionising radiations;
- Industry structure and standardization;
- Regulatory and specific context of the nuclear activities.

2.1.1 Nuclear energy

The market environment of nuclear energy has changed:

- New demands for energy connected to the development of the economy of fast growing countries (China, India, Brazil, etc.…);
- Increased perception of the climate change risks (global warming and its consequences) due to gas emissions with greenhouse effect, among which an important part comes from fossil fuels (coal, oil, natural gas);
- Increase in prices of oil and natural gas and volatility of enery prices facing uncertainties about the availability of future resources; development of new gaz resources in some countries;
- Deregulation of the electricity market in many countries;
- Dependency on the provision of fossil energy supplies from a small number of countries generates geopolitical risks;
- Reactions to the 2011 Fukushima accident.

In this context, nuclear power, which produces at present 13 % of the world's electrical energy demands (25 % for the countries of the OECD), shows important advantages, but it also has its own handicaps:

- It requires controlling nuclear safety and security, which imposes an important national infrastructure (legally, regulatory, technical) among which robustness, continuity and sustainability shall be insured, before launching any electronuclear program. Indeed, in such a program, the responsibility of a country is bound for at least a century;
- It requires at the same time controlling of the issues of non proliferation, and the guarantee of access to the resources (enriched uranium and nuclear fuel), of technology transfers, and of spent fuel management;
- It requires public acceptance, worried by the environmental protection, security and safety issues: this requires thinking the future development of the nuclear energy by taking into account the principles of transparency and sustainable development;
- Fukushima accident has strongly reinforced the need for harmonization of national regulations, standards and practices at a very high level of safety and radiological protection.

Currently the international market shows:

- A increasing demand exceeding uranium production capacity, leading to the necessity of opening new mining sites, with remaining uncertainties on planification;
- A strong uncertainty concerning the future international organisation of fuel cycle: enrichment, supply of nuclear fuel, management of the spent fuel. There will be a need for strictly controlled national or international programs (for safety, security and guaranty of resources reasons), and a need for a global and competitive international market of fuel services;
- A strong demand of nuclear power production capacity in fast growing countries, leading to new orders of reactors, and to new programs to increase capacity, increase life cycle, or to increase the availability rate of the reactors in operation;

- A growing divergence between countries who want to phase out nuclear energy (or avoid introducing it) and countries who consider it as a key base of their existing or planned energy mix;
- A strong demand of radioactivity monitoring of the environment and food production will induce an increase of the number of radioactivity measurements performed as well as an improvement of radionuclide detection limits for environmental monitoring.

Simultaneously, programs are developing on decommissioning and demolition of first generation reactors and remediation of nuclear sites, as well as waste and spent fuel management facilities:

- The waste management issue moves forward in two directions. Ultimate waste disposal facilities (surface, subsurface, deep storage) are gradually developed in some countries, according to requirements based on the hazard of each type of waste. Interim storage or waste processing facilities are also built for spent fuel and other long-lived waste management, or will have to be built, in parallel to the long process leading to operational disposal facilities. Some of the related services are presently or might become international;
- Some countries consider the interest of a sustainable use of the nuclear energy. It requires the development of fast neutrons reactors and the implementation of a policy of spent fuel recycling. The IFNEC[1] and GIF[2] international initiatives include this option.

2.1.2 Other nuclear technologies and applications of ionising radiations

Ionising radiation and nuclear facilities are used in three important fields of activity, different from nuclear energy:

- The medical field, including diagnosis (PET facilities are in strong development) or medical care (radiotherapy);
- Industrial applications or activities (industrial radiography, industrial irradiation, production of sources, use of accelerators and X-ray generators for industrial and medical activities, and safe and secure management of out of service sources);
- Research activities (research reactors and research laboratories, accelerators, cyclotrons, etc.);
- Natural radiation sources may also have to be considered (NORM industries, exposition of aircrew to cosmic rays, radon).

Research reactors constitute a complex family, because of their multiple functions:

- They allow the qualification of the fuel and structure materials of NPR and RR in normal or accidental situation;
- They contribute to the training of the engineers and the technicians running the NPR and RR;
- They supply irradiation services: production of radioisotopes for the nuclear medicine and for the manufacture of sealed sources, etc.;
- They can supply neutron beams, which are specific means of study of the material, additional to other sources of radiations such as cyclotrons;
- They are, as prototypes, an indispensable step of the development of the future generations of reactors (prototypes of fast neutrons or high temperature reactors, ITER[3] project dedicated to the feasibility study of fusion reactors);

[1] IFNEC: International Framework for Nuclear Energy Cooperation

[2] GIF: Generation IV International Forum

[3] ITER: International Thermonuclear Experimental Reactor

- They might play a useful role in the process of technology and competence transfer and the process of creation of nuclear infrastructures in developing countries intending to launch a nuclear energy program.

The main elements of the environment of these activities are:

- A need to harmonise and promote standards supporting professionals to access to more and more sophisticated technologies (notably for new comers and new generations of professionals);
- Huge evolutions of the medical activities worldwide, both in volume and in kind (new technologies and procedures), with in parallel an increasing concern for the radiation protection of the patients. The priorities are to make progress in the radiation safety in radiotherapy but also in diagnostic and interventional radiology as well as nuclear medicine, and to optimise doses delivered to patients in these medical applications (ALARA principle);
- A strong international concern for security and safety reasons is on the control of the disused sources left unemployed;
- A need to improve the various situations of the world RR: dismantling or refurbishing of old research reactors, improving the use of research reactors, maintaining continued production of short lived radioisotopes for nuclear medicine;
- A new evolution with the internationalisation of some research nuclear programs and activities (GIF, IAEA INPRO[4] project, ITER project, international participations to the French RJH[5] project, etc.).

2.1.3. Industry structure and standardization

The number of operators, companies or interested parties is very variable depending on the different industry fields, as well as the international opening of markets. These aspects are very important because the need for international standards is all the greater with more open international markets, meaning a greater number of stakeholders from different countries. Nevertheless, international standards may also be needed with the objective of sharing best practices, to improve efficiency, safety and radiological protection.

2.1.3.a. Small number of stakeholders

The uranium business, the conversion and enrichment services, and the reprocessing services are activities where a very small number of companies are in competition on a global market.

The same situation exists for the supply of high activity sealed sources and for the supply of the high technology equipments for the nuclear medicine (medical imaging, radiotherapy, cyclotrons).

The power reactors market is in transition to become a competitive global market, with a very small number of vendors, but the interaction with policies of preservation or creation of a national technology in some countries creates a complex situation.

2.1.3.b. Large number of stakeholders

The operation of the nuclear facilities (uranium mines, operating of NPP and RR, operation of irradiation facilities for the industry, hospitals using ionising radiation in medicine) are national activities and involve a very large number of stakeholders on the world's scale.

[4] INPRO: International Project: Innovative Nuclear and Fuel Cycles

[5] RJH: Réacteur Jules Horowitz

On the one side, it is hoped that the use of radiation in medicine and subsequently the number of stakeholders will increase, as the benefits for patients are enormous.

On the other side, the deregulation policies of the electricity markets leads to international groupings, which could lead eventually to a reduced number of international operators of nuclear sites, in complement and often in association with a more important number of strictly national operators.

Equipments and material supplies for power or research reactors are a market in fast transition from national to a global market. This market has a very variable number of stakeholders according to each type of products or equipments.

As regards support services dedicated to the nuclear facilities (maintenance, security and safety or environmental monitoring, radiation protection studies, waste or spent fuel conditioning or transit storage services, transport services, decommissioning and demolition services), we can also expect a progressive evolution of existing national service companies to move towards an internationalisation of some of their services. Some among these services might also interest other nuclear activities and applications of ionising radiations.

Last but not least, transport activities of radioactive or nuclear material are largely developed on an international basis: this includes fuel cycle and sealed sources. Consequently, international standards for transport are of paramount importance.

2.1.4. Regulatory and specific context of the nuclear activities

2.1.4.a. Every country is completely responsible for the nuclear safety, security and radiological protection of its citizens on its domestic territory.

National regulations can thus introduce specific requirements, which have strong implications in the national codes and standards and may create obstacle to the creation of a global and efficient international market.

However, harmonization factors exist:

- Upstream of the national regulations, international organisations (UNSCEAR[6], WHO[7], ICRP[8], ICRU[9] issue recommendations and IAEA issues safety standards which, without having a binding character, give a common reference to national regulations. The OECD/NEA does not produce standards, but produce studies and evaluations which provide review of the state-of-art and make common points of view possible;
- In the context of new reactors programs, safety authorities launched several initiatives to harmonize as much as possible and as far as useful as possible the regulations, 0codes and standards: MDEP initiative, and the WENRA initiative in the European frame;
- Concerning future reactors, the required new technologies are prepared within the framework of international cooperation (GIF, INPRO project from IAEA, ITER project on nuclear fusion): that will create an opportunity in favour of the development of international standards.

[6] UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation

[7] WHO: World Health Organization

[8] ICRP: International Commission on Radiological Protection

[9] ICRU: International Commission on Radiation Unit

2.1.4.b. Public acceptance and transparency, commitment of stakeholders

The development of the production and the use of ISO standards should contribute to provide public confidence, which is a vital necessity for the future development of nuclear energy and other nuclear activities:

- The transparency of the ISO process offers the public the opportunity to act as a stakeholder or an interested party;
- The ISO process offers the guarantee of an international consensus.

2.1.4.c. Complementary to national responsibilities, the production and use of nuclear materials is submitted to an international system of control or safeguards.

It is based on the NPT[10], which organization is entrusted to the IAEA, and also relies on regional support such as the EURATOM[11] in Europe.

The objective is dual: on the one hand, to check that nuclear materials stay strictly under states control and on the other hand, to verify that no state launches an illicit nuclear program.

2.1.4.d. New international developments

ISO/TC 85 has to consider in its work recent and essential international publications:

- IAEA Safety fundamentals (SF 1);
- IAEA Safety requirements (GSR) and associated guides;
- ISO/CASCO toolbox on conformity assessment standards;
- ISO handbook on "The integrated use of management system standards;
- ISO/IEC Guide 99:2007 – International vocabulary of metrology – Basic and general concepts and associated terms (VIM 2007);
- ICRP 103 "Recommendations of the ICRP";
- WHO Handbook on indoor radon. A public health perspective.

2.2 Quantitative indicators of the environment business:

2.2.1 Nuclear energy world statistics (source: IAEA PRIS and RRDB) concerning NPR and RR

These figures illustrate the foreseen importance of construction, lifetime extension, power increase, decommissioning and demolition programs. Some 440 nuclear power plants in operation produce 13% of the world electricity production (25% in OECD countries)

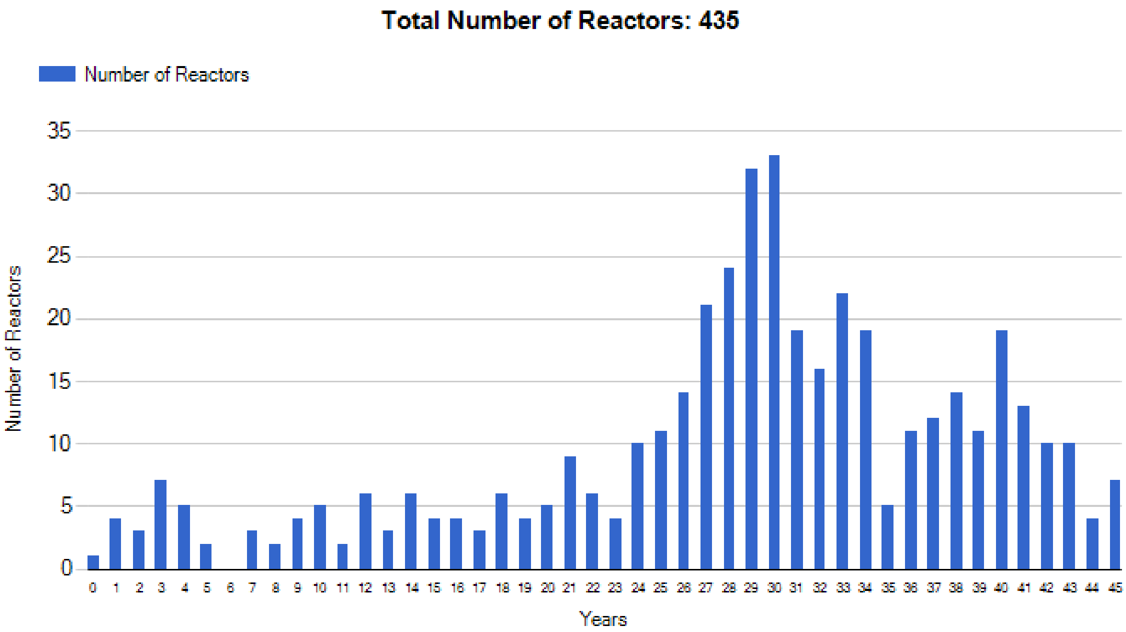
Number of reactors	Under construction	In operation	Shut down
NPR	72	435	151
RR	6	246	163

[10] NPT:Non proliferation Treaty

[11] EURATOM: European Atomic Energy Community

Nuclear energy production (some 2500 TBq from 2001 to 2012) has recently decreased for several reasons, including refurbishment operations in relation with impact of the Fukushima accident. Nevertheless, nuclear energy production is expected to rise in the future, and to reach 3000/5000 TWh by 2030.

- Reactors life extension is a strong trend, and life extension is often coupled with power update;
- Operators work hard to improve reactors availability;
- New reactors (72) are under construction, mainly in China, Russia and India.
- 149 reactors are permanently shutdown, mainly in USA, UK and Germany



2.2.2 Uranium statistics

With such a perspective for nuclear energy production, new uranium prospection and mining will be needed:

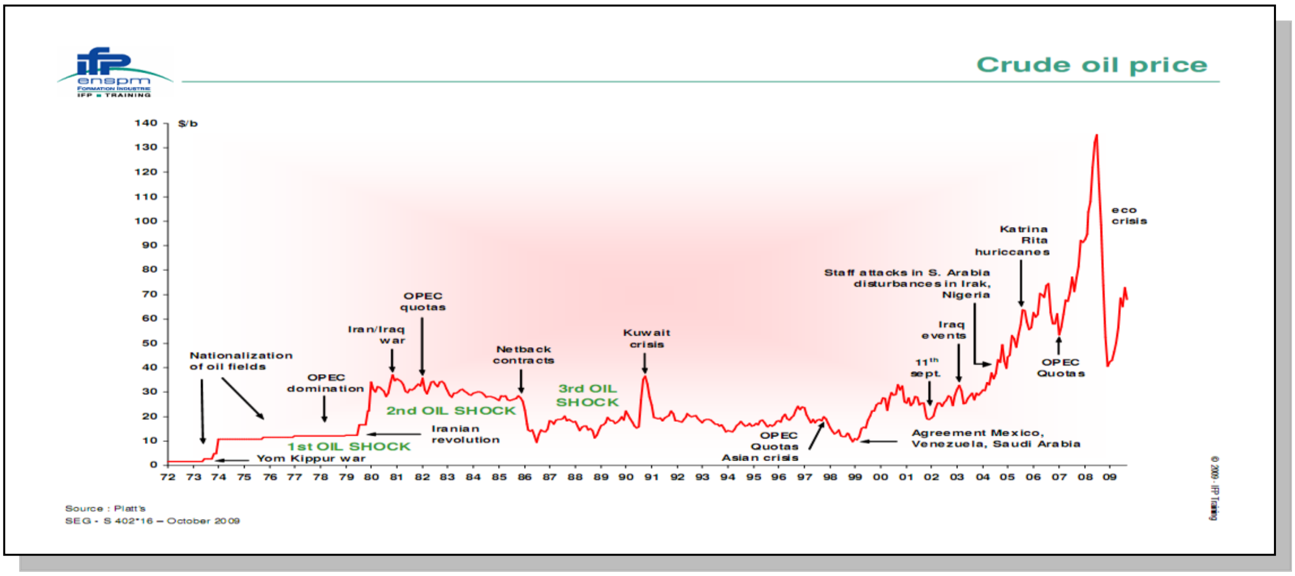
- According to OECD/IAEA “Redbook” (a new edition (2013) of the redbook is under preparation and will soon be published), the annual needs are 66.000 tU and the annual production is presently 40.000 tU;
- The difference is procured by excess inventories, down blending of highly enriched uranium, and re-enrichment of depleted uranium and spent fuel reprocessed uranium;
- The uranium resource is adequate to meet the projected future requirements of 90/120.000 tU in 2030.

The challenge is to develop mines and increase production in a timely fashion to bring these resources to the market.

2.2.3 Economic and climate crisis

The present economic crisis creates a great uncertainity in energy prices and financing capacities of many stakeholders.

The following curve (origin: IFP) shows the volatility of recent crude oil price.



Copenhagen international conference (2009) has given a clear objective (reduce global emission so as to hold the increase of global temperature below 2° Celsius) but no clear technical or legal roadmap to achieve it.

2.2.4 Nuclear activities and applications of ionising radiations (source: French ASN statistics ; AIPES statistics)

Lacking of international statistics, the present business plan includes French statistics with the objective of giving an order of magnitude of the world figures, which could be 10 to 20 times higher, and illustrate the importance of medical activities, and the great variety of the applications of ionising radiation. For some medical activities, AIPES statistics are provided.

Medical activities	Dental radiology	33000	EG
	Medical radiology	16000	EG
	Scanners	800	EG
	Nuclear medicine and radiotherapy	400	US, EG, SS
	Blood irradiation	30	SS
Industrial and research activities sources	Analysis	3200	EG
	Measurements and calibration	2000	SS,EG
	Research	1000	US
	Non destructive testing	300	SS, EG
EG: electric X generators, SS: sealed sources, US: unsealed sources (statistics for France; no available world statistics)			

As concerns medical procedures using unsealed shortlived radionuclides, AIPES estimates the world following statistics: 35 million procedures / year including

28 million procedures using Tc 99m
2 million procedures using F 18 (FDG)

Nuclear medicine needs high quantities of short lived radioisotopes. This requires a worldwide network of reactors (research reactors and/or dedicated reactors) and specialized laboratories. Most reactors presently used are near their end of life.

New reactors or adaptation of existing research reactors will be necessary. At the same time, there is a strong security demand to move from HEU to LEU technologies for the production of fission product radionuclides.

3 BENEFITS EXPECTED FROM THE WORK OF ISO and ISO/TC 85

3.1. Contributions of the ISO system

Beyond ISO/TC 85, ISO publishes a collection of standards of general interest that are useful for the nuclear industry activities and applications of ionising radiations. The present document is focused on ISO/TC85 standards: all information related to other ISO productions is available on the ISO website.

3.2. Current or foreseen ISO/TC 85 specific contribution:

ISO TC 85 objectives are the production of industrial standards responding to the needs of nuclear energy and nuclear technology, including:

- Measurement of radiations and radioactive or nuclear materials;
- Measurement or calculation of safety or performance related parameters;
- Material specifications, including standard dimension interfaces;
- System specifications;
- Management and conformity assessment.

ISO TC 85 standards can cover all aspects of any facility or equipment life cycle (design, construction, operation, decommissioning) according to the needs expressed by P members.

ISO TC 85 priorities for the on-going years are the following:

- Develop and sustain international participation for the production and maintenance of ISO standards in the nuclear and radiological protection fields.
- Lead an ISO process for the harmonization of national standards and the promotion of best industrial practices at an international level through ISO standards.
- Participate in the international response to the Fukushima accident, including the support to the IAEA revision of its safety series, and production of ISO standards related to the management of extreme events in nuclear facilities and their environment.
- Drive an ISO initiative to adapt existing ISO standards to the specific needs of the nuclear industry with respect to conformity assessment, and management system certification.

ISO/TC 85 will have to make a substantive contribution to the harmonization work of national codes and standards, for which the international community expresses a strong need.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC 85

4.1 Countries/ISO member's bodies that are P and O members of the ISO committee

Please find all information on the AFNOR Livelink website in public information (doc N 1177)
http://ecom.afnor.org/livelink-fr/livelink.exe?func=ll&objid=374739&objaction=ndocslist

or on ISO/TC 85 Website as follows:
http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm

4.2 Analysis of the participation

Over the past few years, the participation in ISO/TC 85 subcommittees and working groups has been growing.

ISO/TC 85 encourages effective and active participation of all P members:

- Proposition and vote on NWIPs and PWIs
- Designation of relevant experts
- Development of co-convenership in all TC 85 working groups

ISO/TC 85 encourages participation of experts from relevant organisations in liaison

5 OBJECTIVES OF ISO/TC 85 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1. Defined objectives of ISO/TC 85

ISO TC 85 (as well as SC2, SC5 and SC6) priorities for the on-going years are the following:

- Develop and sustain international participation for the production and maintenance of ISO standards in the field of nuclear activities and nuclear technologies including all applications of ionising radiations.
- Lead an ISO process for the harmonization of national standards and the promotion of best practices at an international level through ISO standards.
- Participate in the international response to the Fukushima accident, including the support to the IAEA revision of its safety series, and production of ISO standards related to the management of extreme events in nuclear facilities and their environment.
- Drive an ISO initiative to adapt existing ISO standards to the specific needs of the nuclear industry with respect to conformity assessment and management.

5.1.1. TC 85 Working Groups

- **WG1: Terminology**

  The scope of ISO/TC 85/WG 1 is to develop, maintain and promote standards in the field of TC/85 WGs and SCs. The development of these standards is based on the documents produced by ISO/TC37 “Terminology and other language and content resources”.

  The objective of ISO/TC 85/WG 1 is to review the vocabularies used by different TC85 subcommittees and working groups and draft standards containing updated, commonly used terminological data not only in ISO but in other organizations such as IAEA.

  WG1 experts need the cooperation of experts from TC85 subcommittees and working groups to produce high quality vocabulary standards covering the different sub subject fields of this important area of human activities.

  WG1 experts are also engaged in cooperating with TC85 experts to help them to overcome language and terminological concerns in order to ensure that communication in the nuclear energy domain is effective and that difficulties in understanding are minimized].

- **WG3: Dosimetry for radiation processing**

  The scope of ISO/TC 85/WG 3 is to develop, maintain and promote standards on practices and methods for use of dosimetry in ionizing radiation processing applications including medical products, pharmaceuticals, foods, polymers, and other consumer products.

  During a five-year period between 1999 and 2004, ISO and ASTM conducted and successfully ran a Pilot Project “Radiation Processing Dosimetry Standards” in which 25 published ASTM dosimetry standards were transformed into ISO/ASTM standards. This pilot project was accepted under ISO Council resolution 26/1999 for a group of standards that had been used in the global marketplace and for which there is no counterpart in ISO.

Detailed procedures were developed by ASTM Subcommittee E10.01 and ISO/TC 85/WG 3 whereby the ISO/ASTM standards were periodically reviewed and maintained by ASTM with unrestricted participation and input from ISO. In 2006, the maintenance procedure was updated and approved by ISO/TC 85 during its plenary meeting in Ottawa in 2006.

Over the past years, ASTM has developed and published five additional radiation processing dosimetry standards which are intimately related to the set of 25 ISO/ASTM standards, but which were not identified in the original Pilot Project. In an effort to harmonize this situation, a new procedure has been discussed and approved in Orlando in 2008 to introduce these additional closely related ASTM radiation processing dosimetry standards to the existing set.

The new and simplified maintenance procedures for ISO/ASTM radiation processing dosimetry standards have been distributed to TC 85 members on January 2013. This is document N 1248.

- **WG 4: Management systems and conformity assessment**

The scope of ISO/TC 85/WG 4 is to develop, maintain and promote standards with respect to management systems for the nuclear industry, who produces equipments, systems and services for nuclear operators and for NPP or NR vendors, there is a need for enhanced requirements with respect to ISO 9000/17000 series with the main objective of conformity assessment guaranties in coherence with the safety importance / classification.

Excluded : Management standards for operations of nuclear installations, matters dealt with by IAEA.

An ad-hoc group on management systems and conformity assessment was initiated during the Orlando 2008 plenary meeting. This group had undertaken an analysis of the nuclear energy industry practices and needs in the field of management standards, and conformity assessment standards. Conclusions and propositions following JEJU 2010 plenary meeting have been largely communicated to stakeholders for feedback.

Main conclusions and results from feedback were the following:

On the one hand, nuclear operators are encouraged to develop and maintain an integrated management system; integration process can be helped by the use of IAEA GS-R-3 and associated guides and the existing ISO Handbook; certification process of the management system should be improved to include the option of global ISO 9001 + ISO 14001 + GS-R-3 certification. This may need additional requirements to ISO 17000 series.

On the other hand, nuclear operators and nuclear vendors need enhanced conformity assessment guarantees for the procurement of products and services; additional requirements to ISO 9000 and ISO 17000 series are needed.
Following the conclusions of the ad-hoc group, a set of specific management and conformity assessment standards will be proposed :

- Additional requirements to ISO 17000 series for certification and conformity assessment responding to the nuclear industry’s needs.

- Additional requirements to ISO 9001 for the suppliers of products and services to nuclear operators or nuclear vendors, with the objective of improved conformity assessment.

On December 2013, the *Ad hoc Group* became ISO/TC 85/WG 4.

5.1.2. TC85/SC2 Radiological protection

Terms of reference for the SC 2 activities regard standardization in the field of the protection of individuals (workers, patients, members of the public) and the environment against all sources of ionizing radiations in planned, existing or emergency exposure situations linked to nuclear activities, medical activities, industrial activities, research activities and natural radiation sources. It includes notably standardization for the design and use of equipment/systems/sources, metrology of radiation, dosimetry and related protocols, monitoring and measurement methods for the environment, control of goods and materials that may contain radioactive substances.

<u>Excluded</u>: Radiological protection instrumentation matters dealt with by IEC/SC45B and Water quality - Radiological methods dealt with by ISO/TC147/SC3.

The scopes of SC 2/WGs are as follow :

TC 85/SC 2/WG 2 Reference radiations fields
To develop, maintain and promote standards covering the definition of reference radiation fields for type-testing and calibrating of radiation protection dosemeters in terms of the operational quantities for external exposure for individual and area dosimetry. The types of radiation include photons, beta particles and neutrons. The standards also include the dosimetry methods and the procedures for calibrating and determining the response of dosemeters.

TC 85/SC 2/WG 11 Sealed sources
To develop, maintain and promote standards covering sealed radioactive sources and associated devices. It deals with the following radiological protection aspects:

– Classification and determination of mechanical and shielding requirements to assure the integrity of sources and devices in normal use and accident situations.

– Leakage test methods to assure radioactive source integrity

– Labelling and identification.

<u>Excluded :</u> specifications of chemical or radiological properties of radioactive material and packaging for transportation or safety and security aspects.

TC 85/SC 2/WG 13 Monitoring and dosimetry for internal exposure
To develop, maintain, promote and harmonize standards addressing the monitoring and dosimetry of internal exposures from radionuclides. The aim of WG13 focuses on the definition and implementation of the monitoring programs for acute or chronic exposures, the reference protocols for in vivo and in vitro individual measurements, theirs performances, detection limits, sensitivity, accuracy, precision and confidence limits. The group also focuses on interpretation of bioassay data in terms of intake or internal dose assessment, considering a possible decorporation therapy, using the most appropriate biokinetic and dosimetric models and the estimation of overall uncertainties, quality assurance, quality controls and performance testing programs.

TC 85/SC 2/WG 14 Air control and monitoring
To develop, maintain and promote standards addressing the measurements of airborne radionuclides in nuclear facilities or other facilities producing or handling radionuclides. Sampling strategies, sampling and measuring instrumentation, maintenance and documentation are recommended according to the relevant protection goal defined for workers, general public and the environment by the international radioprotection community.

TC 85/SC 2/WG 17 Radioactivity measurements
To develop, maintain and promote standards covering test methods for radioactivity measurement needed for the monitoring of the environment for regulatory purposes, research, etc.

Standards cover basic aspects of radioactivity measurements (statistics, characteristics limits, calibration, etc.), laboratory test methods, in situ measurements and on-line measurements, of natural and artificial radionuclides as well as global parameters (gross alpha or beta activity assessment).

The test methods include nuclear measurement techniques and mass spectrometry taking into account inter alia ISO 17025.

Excluded : Radioactivity measurements of water covered by ISO/TC147/SC3 "Water quality – Radioactivity measurements".

TC 85/SC 2/WG 18 Biological dosimetry
To develop, maintain and promote standards covering all technics/methodologies or practices aimed at providing an estimation of a radiation dose or a risk due to the exposure of human beings to ionizing radiations by means of a biological indicator/marker from human tissues (blood, tooth enamel, etc.).

TC 85/SC 2/WG 19 Individual monitoring of external radiation
To develop, maintain and promote standards covering measurement techniques and methods used for the monitoring of individual exposures due to external radiation of any type (photons, beta, neutrons). Concerning measurement techniques, standards aim at defining tests and requirements to insure that a dosimetry system is adapted to its use. Regarding methods, standards aim at defining requirements and making recommendations on the methodologies applied to determine the need for monitoring worker exposure, and subsequently to choose the right dosimetry systems and to use them in practice.

TC 85/SC 2/WG 20 Illicit trafficking in radioactive material - Dormant

TC 85/SC 2/WG 21 Dosimetry for exposures to cosmic radiation in civilian aircraft
To develop, maintain and promote standards addressing the conceptual basis as well as methods and procedures for the determination of ambient dose equivalent for the evaluation of exposure to cosmic radiation in civilian aircraft and for the calibration of instruments used for this purpose. It also includes requirements for the qualification of codes used for dose assessment for aircrew members.

TC 85/SC 2/WG 22 Dosimetry and related protocols in medical applications of ionizing radiation
To develop, maintain and promote standards addressing diagnostic and therapeutic medical procedures using sources of ionizing radiation either external or internal and sealed or unsealed. It includes estimation of patient dosimetry and patient activity, calibration of

imaging devices, measurement protocols, and quality control. Standardization of medical procedures is excluded.

It deals also with radiological protection aspects associated with the use of radio-pharmaceuticals (waste management, protection of family and conforters).

Excluded : the standardization of medical procedures

TC 85/SC 2/WG 23 Shielding and confinement systems for protection against ionizing radiation
To develop, maintain and promote standards addressing the protection of workers, patients, the environment and members of the public with regards to ionizing radiations through the development of standards related to shielding provisions against external exposure risks or related to confinement systems (static containment, dynamic confinement systems) against the risks of spread of hazardous materials.

The design, construction, commissioning, operation, maintenance and dismantling of the systems involved in the control of these risks are part of this scope, as well as the associated calculations performed for these systems.

The dynamic confinement systems include, but are not limited to : the ventilation systems, the filtration systems, their components and their materials.

TC 85/SC 2/WG 24 Remote handling devices for nuclear applications
To develop, maintain and promote standards addressing systems enabling distant manual work in nuclear installations. It encompasses both mechanical or electromechanical devices and computer-controlled systems. These systems are composed of an effector working in the exposed zone (slave) as well as an interface manipulated by the operator and a transmission enabling the operator to remotely handle objects.

5.1.3 TC85/SC5: Nuclear fuel cycle

Terms of reference for the SC 5 activities regard standardization in the field of nuclear fuel cycle and nuclear technologies.

Fuel cycle includes analytical methodologies and nuclear criticality safety.

Nuclear technologies include technologies other than nuclear energy and technical issues of common interest for reactors and other nuclear installations, such as transport of radioactive materials, radioactive waste management and decommissioning.

Excluded : - specific enabling technologies and techniques for the weapons-grade enrichment of fissionable materials, the enrichment and production of heavy water, and the reprocessing of irradiated nuclear materials;
- sealed sources, radiation processing, mining and topics related to siting of nuclear installations.

The scopes of SC 5/WGs are as follow :

TC 85/SC 5/WG 1 Analytical methodology in the nuclear fuel cycle
To develop, maintain and promote standards for physical and chemical characterization of products such as UF_6, UO_2, $(U,Gd)O_2$ and MOX products, including input and end products of reprocessing plants such as PuO_2 and reprocessed Uranium products.

TC 85/SC 5/WG 4 Transportation of radioactive material

To develop, maintain and promote standards associated with the equipment and procedures used for the transport of all radioactive material, including material from the nuclear fuel cycle, research activities, the industry, and for medical use, in order to improve safety, consistency and efficiency.

TC 85/SC 5/WG 5 Waste characterization

To develop, maintain and promote standards related to characterization and lifecycle management of all types of radioactive wastes.

TC 85/SC 5/WG 8 Nuclear criticality safety

To develop, maintain and promote standards for the protection against the consequences of a criticality accident, preferably by prevention of the accident and for responding to such accidents should they occur.

TC 85/SC 5/WG 13 Decommissioning

To develop, maintain and promote standards related to decommissioning and remediation of nuclear sites and facilities.

5.1.4 TC85/SC6: Reactor technology

Terms of reference for the SC 6 activities regard standardization in the field of nuclear power plants and research reactors.
The scope includes siting, design, construction, operation and decommissioning.

Siting includes all types of nuclear installations and all topics such as flooding, seismic hazards, etc.

Research reactors include a large variety of facilities : production of neutron beams, irradiation of specimens, production of isotopes (especially production for nuclear medicine) and test reactors or prototypes of new technologies.

Excluded : decommissioning is limited to technical topics that are specific to reactors.

The scopes of SC 6/WGs are as follow :

TC 85/SC 6/WG 1 Power reactor analyses and measurements
To develop, maintain and promote standards covering calculation, analysis and measurements in support of physics of power reactor core design and operation.

Such standards will (a) provide criteria for the selection of nuclear data and computational methods; (b) provide appropriate benchmark problem specifications for verification of calculation methods used by reactor core designers; (c) provide criteria for evaluation of accuracy and the range of applicability of data methods; (d) define methods of verification and of estimating uncertainties.

TC 85/SC 6/WG 2 Research and test reactors
To develop, maintain and promote standards for the design, construction, operation, maintenance, utilization, and decommissioning of research and test reactors.

For the forthcoming years, priority will be given to operation, maintenance, utilization including refurbishment issues, dosimetry for research reactors services, and production of isotopes for nuclear medicine.

TC 85/SC 6/WG 3 Power Reactor, Siting, Design, Operation, and Decommissioning
To develop, maintain and promote standards dealing with all topics related with the siting, design, operation and decommissioning of Power reactors.

Operation includes emergency equipments.

Power reactors include non-electrical applications and transportable nuclear reactors.

Excluded : the standardization of ventilation systems (dealt with by SC2) and technical issues of common interest for reactors and other nuclear installations (dealt with by SC5) and topics which are within the scope of work of SC6/WG1

International standards relating to essential technical requirements for GEN IV nuclear power plants (NPPs) are needed prior to commercialization of these systems. This needs to be done cooperatively with the Generation IV International Forum (GIF).

A set of international standards may be needed to support the development and maintenance of international services associated with GEN II and GEN III NPPs with a specific focus on the needs of the countries entering into activities associated with nuclear power generation.

In addition, a set of international standards may be needed, to support siting activities, in parallel with the licensing activities associated with GEN III and GEN IV nuclear power plants.

Accordingly, ISO/TC 85/SC6/WG3 was established to contribute to the international demand for harmonization of codes and standards by inter alia:

- Proposing essential technical requirements through an ISO consensus process; and,
- Proposing a set of international standards with respect to fire safety in NPPs.

In response to the March 11, 2011 event at Fukushima-Dai-ichi, and regulatory responses associated with improving the safety of NPP operation, ISO/TC 85/SC6/WG3 has identified projects related to the protection of NPPs against extreme external natural phenomena hazards and external manmade events.

5.2. Identified strategies to achieve these goals

The strategy of ISO/TC 85 is to produce standards responding to the users' needs and demands, and to promote the dissemination, knowledge and usage of its standards.

To achieve this strategy, ISO/TC 85 has identified the following objectives:

- To improve participation: the systematic use of the ISO global directory by P and O members on one hand, annual reporting from each convenor to the SC and TC level on the other hand, will allow ISO/TC 85 to observe the effectiveness of participation, and allow reaction when needed;
- To improve liaisons: ISO/TC 85 wants to listen to the users needs; to understand these needs and also to avoid duplication or contradiction with other works, ISO/TC 85 will continue to develop an active network of formal and informal liaisons with other international organisations like:
  - Institutional organisations: IAEA, UNSCEAR, WHO, ICRP, OECD/NEA, ICRU, EC, WANO[12], etc;
  - Professional organisations: WNA13, PNC14, ENISS, WANO15, ISSPA16, WNTI17, etc;
  - research organisations: ITER, GIF, etc;
- To improve the promotion of ISO standards: ISO and ISO/TC 85 standards and methods are not sufficiently known. The present business plan, ISO TC 85 website and other ISO existing documentation will have to be used at all levels of ISO organization (chairs, conveners, liaison officers) to develop and improve information of stakeholders (potential participants to standards production and of potential standards users);
- To improve ISO/TC 85 structure: The structure of ISO/TC 85 and its subcommittees must be a living structure; following the needs, working groups or *ad-hoc* groups have to be created, restructured or disbanded. The same is true for subcommittees. The objectives of these evolutions of TC 85 structure will be to develop a better efficiency of the mobilised expertise, (which is a rare resource from the industry) and a better response to the industry needs. These evolutions will offer concrete opportunities for lobbying actions to improve the effective participation of a sufficient number of countries and stakeholders to ISO/TC 85 work. Effective participation of more countries in each new WG will be searched, at the expert level and for convenors appointments as well. The appointment of co-conveners from different countries can be an efficient opportunity for a better international involvement, and will be developed inside TC85 on a systematic basis;
- To maintain a document giving a user friendly access to existing international standards on the ISO/TC85 web site, including access to IAEA and IEC or ICRU standards, to improve promotion, knowledge and use of international standards, and to help experts producing standards to avoid overlapping and contradiction;

---

[12] WANO: World Association of Nuclear Operators

[13] WNA: World Nuclear Association

[14] PNC: Pacific Nuclear Council

[15] WANO: World Association of Nuclear Operators

[16] ISSPA: International source suppliers and producers association

[17] WNTI : World Nuclear Transport Institute

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC 85 WORK PROGRAMME

The key factor is participation. ISO/TC 85 develops and sustains international participation for the production and maintenance of ISO standards in the nuclear field.

Differences in the nuclear policy of P members with regard to nuclear energy should not be an obstacle for an active participation:

- All countries use nuclear technologies other than nuclear energy, and are welcome in TC 85 and TC 85/SC2 working groups;
- Countries which maintain or develop nuclear energy should support TC 85/SC5 and TC 85/SC6 working groups;
- TC 85/SC5 created working groups for the production of standards on waste management and decontamination of nuclear facilities: these groups should respond to the needs of all countries, wherever they want to phase out, to sustain or to develop nuclear energy.

All P members are strongly encouraged to develop their active participation, and all O members are welcome to consider P membership.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC 85

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees**, through hyperlinks to ISO website**: the material on this site will have been reviewed by each chair and secretary.

7.1 Structure of the ISO committee

See beneath

7.2 Current projects of the ISO technical committee and its subcommittees

7.3 Publications of the ISO technical committee and its subcommittees

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work

7.1 Structure of the ISO committee, subcommittees and working groups

ISO/TC 85 Nuclear Energy, nuclear technologies, and radiological protection

- TC 85/CAG Chairman advisory group *AFNOR*
- TC 85/NSAG Nuclear Safety Advisory Group *AFNOR*
- TC 85/WG 1 Terminology *IRAM*
- TC 85/WG 3 Dosimetry for radiation processing *ANSI*
- TC 85/WG 4 Management systems and conformity assessment standards *AFNOR*

TC 85/SC 2 Radiological protection *AFNOR*

TC 85/SC2 SC2 advisory group

TC 85/SC2 working Groups:

- WG 2 Reference radiations fields
- WG 11 Sealed sources
- WG 13 Monitoring and dosimetry for internal exposure
- WG 14 Air control and monitoring
- WG 17 Radioactivity measurements
- WG 18 Biological dosimetry
- WG 19 Individual monitoring of external radiation
- WG 20 *Illicit trafficking in radioactive material* - DORMANT
- WG 21 Dosimetry for exposures to cosmic radiation in civilian aircraft
- WG 22 Dosimetry and related protocols in medical applications of ionizing radiation
- WG 23 Shielding and confinement systems for protection against ionizing radiation
- WG 24 Remote handling devices for nuclear applications

TC 85/SC 5 Nuclear fuel cycle *BSI*

TC 85/SC 5 Working Groups:

- WG 1 Analytical methodology in the nuclear fuel cycle
- WG 4 Transportation of radioactive material
- WG 5 Waste characterization
- WG 8 Nuclear criticality safety
- WG 13 Decommissioning

TC 85/SC 6 Reactor technology *ANSI*

TC 85/SC 6 Working Groups:

- WG 1 Power reactor analysis and measurements
- WG 2 Research and test reactors
- WG 3 Power reactor siting, design, operation, and decommissioning

7.2 Thematic list of ISO/TC 85 Working Groups

Dosimetry/metrology

- Reference radiations fields TC 85/SC 2/WG 2
- Dosimetry for radiation processing TC 85/WG 3
- Monitoring and dosimetry for internal exposure TC 85/SC 2/WG 13
- Biological dosimetry TC 85/SC 2/WG 18
- Individual monitoring of external radiation TC 85/SC 2/WG 19
- Dosimetry for exposures to cosmic radiation in civilian aircraft TC 85/SC 2/WG 21
- Dosimetry and related protocols in medical applications of ionizing radiation TC 85/SC 2/WG 22

Activity or nuclear material measurements

Air control and monitoring TC 85/SC 2/WG 14
Radioactivity measurements TC 85/SC 2/WG 17
Illicit trafficking in radioactive material TC 85/SC 2/WG 20 – DORMANT
Analytical methodology in the nuclear fuel cycle TC 85/SC 5/WG 1

Other measurements

Analytical methodology in the nuclear fuel cycle TC 85/SC 5/WG 1
Power reactor analysis and measurements TC 85/SC 6/WG 1

<u>Specific equipments or facilities</u>

Sealed sources TC 85/SC 2/WG 11

Shielding and confinement systems TC 85/SC 2/WG 23

Remote handling devices TC 85/SC 2/WG 24

Transportation TC 85/SC 5/WG 4

Research reactors TC 85/SC 6/WG 2

Power reactors

Power reactor analysis and measurements TC 85/SC 6/WG 1
Power reactor siting and design TC 85/SC6/WG 3

<u>Quality and safety</u>

Terminology TC 85/SC 5/WG 1

Management systems and conformity assessment TC 85/WG 4

Waste management TC 85/SC 5/WG 5 Waste characterization

Decommissioning TC 85/SC 5/WG 13

Nuclear criticality safety TC 85/SC 5/WG 8

Decay heat TC 85/SC 6/WG 1 Power reactor analysis and measurements

Nuclear Safety Advisory Group, TC 85 / NSAG