# BUSINESS PLAN

## CEN/TC 430
## NUCLEAR ENERGY, NUCLEAR TECHNOLOGIES, AND RADIOLOGICAL PROTECTION

## EXECUTIVE SUMMARY

CEN/TC 430 deals with 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.

The purpose of the CEN/TC 430 is:

- to select and endorse without modifications ISO/TC 85 & SCs existing standards, and
- to sustain the development of forthcoming standards within ISO/TC 85 & SCs

answering to European needs at the CEN level.

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of CEN/TC 430, 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;
- Existing organisations producing European or International nuclear standards and use of those standards in Europe;
- Regulatory and specific context of the nuclear activities.

Standardization technical committees in nuclear energy already exist at the international level in ISO. They are supported by the European countries involved in nuclear energy standardization.

The European endorsement of the ISO standards in nuclear energy, nuclear technology and radiological protection (ISO/TC 85 and SCs and ISO/TC 147/SC 3[1]) is relevant in and acceptable for Europe. The promotion of the participation of European experts in the international committees and subcommittees is encouraged accordingly.

This led to the conclusion that at the moment there is no need for “home grown” European standard in the field of nuclear energy in Europe. The establishment of a light European structure using of the Vienna agreement for the endorsement of ISO standards at the European level on a case by case basis without modification is accepted.

CEN/TC 430 already endorsed about 50 standards of ISO/TC 85 and will continue to review and follow the work program of ISO/TC 85.

[1] ISO/TC 147/SC 3 standards are endorsed at European level through CEN/TC 230

CEN/TC 430 will propose to endorse without modification through Vienna Agreement some existing standards of ISO/TC 85 and its SCs which are already published, with a priority to standards already used in some CEN countries.

# 1 BUSINESS ENVIRONMENT OF THE CEN/TC

## 1.1 Description of the Business Environment

Nuclear has a key role to play in solving European energy problems.

Whereas historically Nuclear Power Plants were operating in baseload, the growing implementation of internitent energy sources (wind, solar) and the priority given to such sources in certain countries in recent years tend to oblige Nuclear to adapt and to absorb variable electrical grid conditions.

After the March 2011 Fukushima events, national regulators and the EU initiated a process of safety and risk assessments of NPPs (the so-called stress tests). At the same time some European countries decided to shutdown or plan to phaseout their old nuclear power reactors or took the path of disengagement from nuclear energy. This means that the number of nuclear installations in decommissioning will increase in the near future as well as the waste management needs.

The need for standardization, and preferably international, has increased over the years. The infrastructure of the current nuclear power plants is different today compared to the situation when they were designed, constructed and began to operate. There are significantly fewer manufacturers and suppliers, both nationally, regionally and internationally, which are specifically focusing on components and equipment for nuclear activities. It is often difficult and costly for manufacturers and suppliers to enter into the nuclear market since the global scene is relatively small, safety requirements may vary from country to country and quality requirements are usually stricter than in many other industry sectors in the society. This means that manufacturers and suppliers have a strong interest in standardized designs, products and solutions. The same applies to nuclear power licensees who try to buy products and services since standardization allows a better control of the nuclear product supply chain.

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 activities, 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[2] industries, exposition of aircrew to cosmic rays, radon).

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

[2] Naturally Occurring Radioactive Materials

- 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);

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, 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 concern for security and safety reasons is on the control of the disused sources left unemployed; many sealed radioactive sources are used or disused (DSRS) in Europe, and many were exported from Europe to many countries all over the world; return of DSRS to the supplier or to the country of origin are not considered as import of radioactive waste, according to IAEA recommendations as well as EU directives;
- A need to improve the various situations of the 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.): European countries are strongly involved in these fora.

### 1.1.1 International environment

In ISO, the technical committees related to the nuclear sector are ISO/TC 85 (nuclear energy, nuclear technologies, and radiological protection) and ISO/TC 147/SC 3 (water quality – Radioactivity measurements).

ISO/TC 85 prepares standards 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. ISO/TC85 comprises 3 sub committees: SC 2 (Radiological protection), SC 5 (Nuclear installations, processes and technologies) and SC 6 (Reactor technology) and 3 working

[3] ITER : International Thermonuclear Expertimental Reactor

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

[5] RJH : Jules Horowitz Reactor

groups: WG 1 (Terminology), WG 3 (Dosimetry for radiation processing) and WG 4 (Management systems and conformity assessment).

ISO/TC 85/SC 2 (radiological protection) prepares standards in the field of the protection of individuals (workers, patients, members of the public) and the environment against all sources of ionising radiations in planned, existing or emergency exposure situations linked to nuclear activities, medical activities, industrial activities, research activities and natural radiation sources.

ISO/TC 85/SC 5 (Nuclear installations, processes and technologies) prepares standards in the field of fuel cycle, waste management and decommissioning activities (e.g. characterisation (waste, fuel, MOX pellets…), standardization related to criticality safety, transport).

ISO/TC 85/SC 6 (Reactor technology) prepares standards about analysis and measurements dedicated to the safe and efficient siting, design, operation and decommissioning of nuclear power reactors, standards concerning the safe and efficient operation of research reactors and the irradiation services from research reactors, standards including reliability data for nuclear power reactors and research reactors, and data related to nuclear power reactor long term operation.

The ISO/TC 85, ISO/TC 85/SC 2, ISO/TC 85/SC 5 and ISO/TC 85/SC 6 portfolios comprise respectively 27, 66, 65 and 6 published standards. More information on this committee, its sub committees and the documents they published can be found on the ISO website: http://www.iso.org/iso/iso_technical_committee?commid=50266

ISO/TC 147 prepares standards in the field of water quality, including the definition of terms, sampling of waters, measurement and reporting of water characteristics; the topic of limits of acceptability of water quality is out of scope. ISO/TC147/SC3 covers radiological methods. In the past, SC3 had been closed due to a lack of interest of the participating members, but in 2011 SC3 was reactivated to deal with the formerly standardised methods on radiological investigation and their updating to the state of the art. The necessity for new standards in this field is acknowledged and 9 projects of standard development are currently ongoing.

The ISO/TC 147/ SC3 portfolio comprises 24 published standards; more information on this subcommittee and the documents it published can be found on the ISO website: http://www.iso.org/iso/iso_technical_committee?commid=52932. ISO/TC 147/SC 3 standards are endorsed at European level through CEN/TC 230

### 1.1.2 European environment

Point (b) of Article 2 of the **Euratom Treaty** provides for the establishment of uniform safety standards to protect the health of workers and the general public. Article 30 of the Euratom Treaty defines “basic standards” for the protection of the health of workers and the general public against the dangers arising from ionising radiations in normal and emergency situations.

In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of the Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The Directives have been revised several times. The latest Council Directive 2013/59/Euratom was published on 5 December 2013 which repealed earlier Directives (Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom).

**WENRA** (Western European Nuclear Regulator Association) started its activities in 1999. This association is a network of chief nuclear safety regulators of the countries with nuclear installations

within the EU and Switzerland and observers of other interested countries. The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to review nuclear safety in applicant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues.

After establishing WENRA, two working groups were launched to harmonise safety approaches between countries in Europe - Reactor Harmonisation Working Group (RHWG) and Working Group on Waste and Decommissioning (WGWD). The aim was to continuously improve safety and to reduce unnecessary differences between the countries.

**HERCA** (Heads of the European Radiological protection Competent Authorities) was created in 2007. HERCA is a voluntary association in which the Heads of Radiation Protection Authorities work together in order to identify common issues and propose practical solutions for these issues. HERCA is working on topics generally covered by provisions of the EURATOM Treaty. The programme of work of HERCA is based on common interest in significant regulatory issues. HERCA brings together 49 radiation protection Authorities from 31 European countries.

**EURADOS** (European Radiation Dosimetry Group) is a non-profit association for promoting research and development and European cooperation in the field of the dosimetry of ionizing radiation. It is a network of more than 50 European institutions (Voting Members) and 250 scientists (Associate Members). **The activities of this newtwork encompass** coordination of working groups which promote technical development and its implementation in routine work and which contribute to compatibility within Europe and conformance with international practices, as well as organization of scientific meetings and training activities and organization of intercomparisons and benchmark studies.

### 1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators, extracted from Communication COM (2017) 237 final 'Nuclear Illustrative Programme', describes the business environment in order to provide adequate information to support actions of the CEN /TC 430:

Nuclear energy is part of the energy mix of half of the EU Member States. In those countries that choose to use it, nuclear has a role to play in ensuring the security of electricity supply. In this context, the Energy Union Strategy and the European Energy Security Strategy stressed that Member States need to apply the highest standards of safety, security, waste management and non-proliferation as well as diversify nuclear fuel supplies. Doing so will help achieve the objectives of the 2030 climate and energy framework.

The EU is currently one of the three major economies that generate more than half of their electricity from low-carbon energy sources (about 58%).

There are 129 nuclear power reactors in operation in 14 Member States, with a total capacity of 120 GWe and an average age close to 30 years. New build projects are envisaged in 10 Member States, with six reactors already under construction in Finland, France, Slovakia and United Kingdom. Other projects in Finland, Hungary and the United Kingdom, are under licensing process, while projects in other Member States (Bulgaria, the Czech Republic, Lithuania, Poland and Romania) are at a preparatory stage. The United Kingdom has recently announced its intention to close all coal-fired power plants by 2025 and to fill the capacity gap mainly with new gas and nuclear power plants.

The EU nuclear industry has developed into a global technology leader in all nuclear industry segments and directly employs between 400 000 and 500 000 people, while creating around 400 000 additional jobs. Such leadership can be an important asset worldwide. Nuclear related investment needs in the global market are estimated at around EUR 3 trillion by 2050, with the majority expected in Asia. The number of countries operating nuclear power reactors and the global nuclear installed capacity are expected to increase by 2040. China's nuclear installed capacity alone is projected to increase by 125 GWe, a value higher than the current capacity of the EU (120 GWe), the United States (104 GWe) and Russia (25 GWe). The Commission predicts a decline in nuclear generation capacity at EU level up to 2025, taking into account the decisions of some Member States to phase out nuclear energy or to reduce its share in their energy mix. This trend would be reversed by 2030 as new reactors are predicted to be connected to the grid and the lifetime of others will be extended. Nuclear capacity would increase slightly and remain stable at between 95 and 105 GWe by 2050. Since electricity demand is expected to increase over the same period, the share of nuclear electricity in the EU would fall from its current level of 27% to around 20%.

## 2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 430 => to be discussed at next revision

Following the Euratom Treaty signed in 1957, nuclear safety of Nuclear Power Plants (NPPs) was situated outside the European competences. Till the end of the 90s, the European Standardization System was de facto aligned on that legal situation and no European standards (ENs) were published.

From 2000 onwards, the situation started changing. WENRA (Western European Nuclear Regulator Association) started its activities and published in 2007 its Safety Reference Levels (SRLs) for

operating plants. Following the debate triggered by the publication of the SRLs for operating plants, the CENELEC Technical Board decided in 2007 to activate two CENELEC Technical Committees to produce ENs in the domains of Instrumentation and control of nuclear facilities and of Radiation protection instrumentation. The EU adopted in Council Directive 2009/71/EURATOM establishing a Community framework for the nuclear safety of nuclear installations and the Council Directive 2011/70/ EURATOM establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste which complemented the existing legal body on radiation protection. An amendment to the nuclear safety directive considering the lessons learned from the Fukushima Dai-ichi accident was issued in 2014.

In 2012 in order to examine the need for European standards in the field of nuclear energy a survey took place, where 12 European countries participated, on which national territories 112 nuclear power reactors are operated. So 138 nuclear power reactors being operated in Europe, the results of the analysis of those answers are representative of 81% of nuclear power reactors operated in Europe. The questionnaire was not returned by Spain and Czech Republic which both have operating nuclear power plants.

Following the analysis of the nuclear energy standardization framework, the report expresses a clear preference for technical standardization activities to take place at the international level, but also recommends that a justified selection of those international standards should become European standards in order to contribute to the harmonisation of nuclear safety and radiological protection in Europe.

Standardization technical committees in nuclear energy already exist at the international level in ISO. They are supported by the European countries involved in nuclear energy standardization. The promotion of the participation of European experts in the international committees and subcommittees is encouraged accordingly.

**This led to the conclusion that at the moment there is no need for “home grown” European standard in the field of nuclear energy in Europe. The establishment of a light European structure using of the Vienna agreement for the endorsement of ISO standards at the European level on a case by case basis without modification is preferred.**

Besides standardization, the topic of codes for NPP Design and their harmonisation in Europe was raised. The feasibility to have an harmonisation process in Europe is still to be determined.

The dynamics of the European projects (EPR, ITER, generation IV, ESS ...) in Europe is an opportunity to elaborate an European common approach regarding nuclear codification.

CEN/TC 430 will thrive to respond to the needs of all European countries:
- those who use and plan to use Nuclear Energy
- those who have decided to phase out Nuclear Energy
- those who do not use and do not plan to use Nuclear Energy.

To fulfil this objective, CEN/TC 430 scope includes:
- decommissionning and waste management
- nuclear technologies other than energy
- radiological protection

CEN/TC 430 will develop a process for identification of European needs. Two guiding lines will be taken into consideration:

- transboundary issues (concerning products, services and workers)
- promotion of “state of the art” practices (including identification of existing national standards or other documents that are considered a good basis for such a promotion).

## 3 PARTICIPATION IN THE CEN/TC 430

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Considering the intention of managing CEN/TC 430 as a light structure with no specific working groups at CEN level, CEN countries will be asked to choose participants in CEN/TC 430 mainly as “standard policy makers” and to designate experts in ISO/TC 85 and SCs Working Groups. Participation as observers of recognized European or International organizations is also possible under certain conditions. Participants in CEN/TC 430 will be asked to propose a list of organizations with whom CEN/TC 430 should untertain relations (mutual information) or create a formal liaison.

To participate in the activities of CEN/TC 430, please contact the national standards organization in your country.

## 4 OBJECTIVES OF THE CEN/TC 430 AND STRATEGIES FOR THEIR ACHIEVEMENT

### 4.1 Defined objectives of the CEN/TC 430

CEN/TC 430 objectives are the production of industrial standards addressing the needs of nuclear energy, nuclear technologies, and radiological protection, 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;
- Waste management;
- Decommissioning.

CEN/TC 430 will examine proposals from CEN members and reach consensus for initiatives (PWI or NWI) from European countries in ISO/TC 85 and SCs :

- new needs
- existing national standards or documents proposed in ISO/TC 85 harmonisation process

CEN/TC 430 will propose to endorse without modification through Vienna Agreement some existing standards of ISO/TC 85 and its SCs which are already published, with a priority to standards already used in some CEN countries.

CEN/TC 430 will examine proposals from CEN members and reach consensus for providing guidance on how “non nuclear” standards and codes can be used in nuclear energy and technologies.

CEN/TC 430 members are encouraged to identify and develop relationships / connections with representative organizations, mainly in Europe.

### 4.2 Identified strategies to achieve the CEN/TC.s defined objectives.

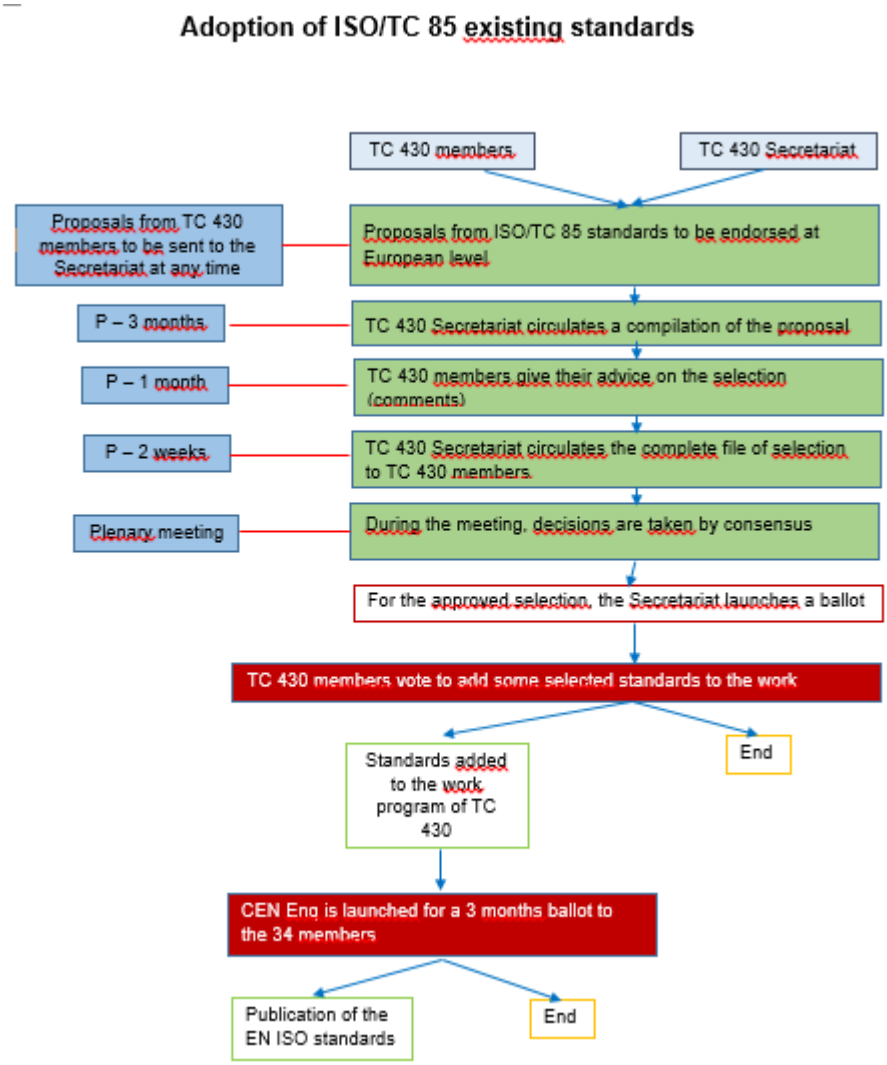
#### 4.2.1 Adoption of ISO/TC 85 existing standards.

CEN/TC 430 will propose to endorse without modification through Vienna Agreement some existing standards of ISO/TC 85 and its SCs which are already published, with a priority to standards already used in some CEN countries.

a) The proposal comes either from CEN/TC 430 Secretariat, either from CEN/TC 430 members. The proposal should be duly justified by using the correct template (see doc N030)
b) The proposal from CEN/TC 430 members can be sent to the Secretariat at any time.
c) 3 months prior to the meeting, the Secretariat makes a compilation of the proposals (including its own proposal) and distributes it to CEN/TC 430 members.
d) TC 430 members are requested to send their advices (comments) on the selection to the Secretariat one month prior to the meeting.
e) Two weeks prior to the meeting, the Secretariat distributes the complete file of selection to TC 430 for discussion at the plenary meeting.
f) During the meeting, finding consensus on the proposed selection will be a priority. Decisions will be taken on each standard selected for potential endorsement process : *Approved* (suitable for CEN endorsement) / *Postponed* (to be discussed again) / *Disapproved* (not suitable to become EN standard).

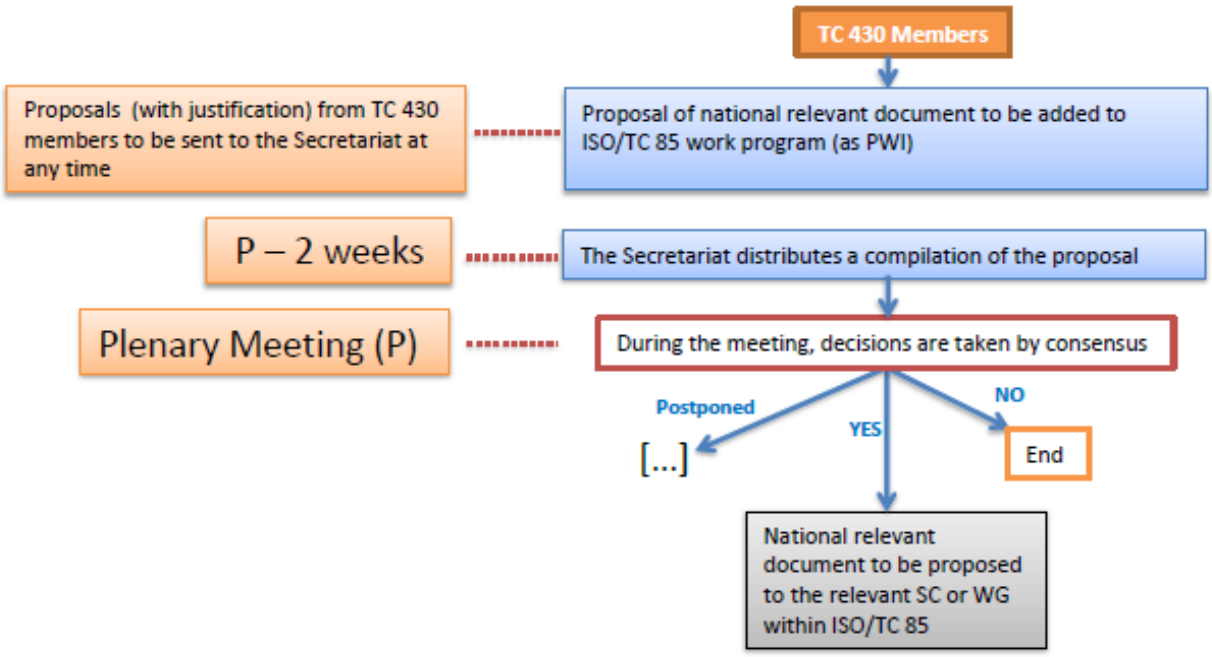
   **Only the vote of TC 430 members attending the meeting will be taken into account. Only the standards which do not encounter a formal disagreement from a member attending the meeting will be approved.**

g) After the meeting, the Secretariat launches a CEN/TC 430 internal ballot during two months for all the "suitable for EN endorsement" standards for approval by CEN/TC 430 community.
h) For the approval, the "suitable for EN endorsement" standards those standardards will be balloted in order to add them as NWIPs to the work program of CEN/TC 430
i) CEN/TC 430 will start the enquiry after the approval for the work program, those standards will be send out for the enquiry to all member of CEN.
j) Upon approval, the selected ISO standards become EN ISO standards.




### 4.2.2 Examination of relevant national standards or other documents proposed for ISO/TC 85 harmonization process

a) The proposal comes from CEN/TC 430 members at any time. The proposal should be duly justified by using the correct template (see **doc N031**)
b) Two weeks prior to the meeting, the Secretariat distributes the proposal of national documents to CEN/TC 430 members, for discussion at the plenary meeting.
c) During the plenary meeting, TC 430 members will present and comment their proposals and the other CEN/TC 430 members should give their position : *approved/ disapproved* to add to the work program of ISO/TC 85 (as a Pre Work Item – PWI) or *postpone* (e.g : delay requested for translation of the document, request of complementary information, etc.)
d) If the relevant national standards are intended to be proposed to ISO/TC 85 work program, CEN/TC 430 members are requested to directly get in touch with the relevant Subcommittee (SC) or Working Group (WG) within ISO/TC 85.




### 4.2.3 Identification of necessary actions/issues for the nuclear use of non-nuclear standards and codes

CEN/TC 430 will examine proposals from CEN members and reach consensus for providing guidance on how “non-nuclear” standards and codes can be used in nuclear energy and technologies.

a) The proposal comes from CEN/TC 430 members at any time.
b) Two weeks prior to the meeting, the Secretariat distributes the proposal to CEN/TC 430 members, for discussion at the plenary meeting.
c) The relevant necessary actions will be examined case by case. The relevant stakeholders responsible of any action will also be identified case by case.

## 5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 430 WORK PROGRAMME

The key factor is participation. To identify relevant European organizations (and invitate these organizations to CEN/TC 430 meetings) or to participate in their own meetings will help CEN/TC 430 to be aware of all stakeholders needs and goals, and improve its own strategy.

Differences in the nuclear policy of CEN members with regard to nuclear energy should not be an obstacle for an active participation in CEN/TC 430.