

**Management systems and conformity
assessment**

ISO/TC 85/WG 4

Date:

2014-03-25

Doc. Number:

N 003

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

Draft minutes of the ISO/TC 85/WG 4

1st Meeting

2014-03-04

C OMMENTARIES

- **Location** : AREVA
1, Place Jean Millier

92400 COURBEVOIE
FRANCE
- **Convenor** : Mr Francis Muguet
francis.muguet@areva.com

F OLLOW UP

For information

S OURCE

ISO/TC 85 Secretariat

1	Opening of the meeting and roll call of the delegates	(10:30)
2	Adoption of the agenda	Doc N 1285
3	Standardisation environment of ISO/TC 85/WG 4 1.1. Presentation of the ISO Standardization System 1.2. ISO/TC 85 Presentation	
4	"Livelihood" presentation	
5	<i>Additional topic : contents of the document UNI / TR 11510 "Nuclear installations - Particular requirements for the application of ISO 9001:2008 in the nuclear field"</i>	
6	Review of the technical comments received during the ballot PWI 19443 "NUCLEAR SAFETY AND QUALITY MANAGEMENT SYSTEM – REQUIREMENTS"	Doc N 1280
7	Organization/Programme of work	
8	Requirements concerning a subsequent meeting (Moscow, June 2 to 6 2014)	
9	Any other business	
10	Date and venue of the next meeting	
11	Approval of the decisions	
12	Closure of the meeting	(16:30)

1. Opening of the meeting and roll call of the delegates (10:30)

Francis Muguet (Convenor of ISO/TC 85/WG 4 – *Management systems and conformity assessment*) opened the meeting at 10:30 and welcomed the participants (11 participants) and thanked them for participating to this first CEN/TC 430 Meeting.

5 countries were represented : France / Germany / Italy / Japan / Russian Federation

See the attendance list (*Annex 1*).

2. Adoption of the agenda

The Italian delegation expressed its wishes to make a short presentation about the contents of the document **UNI / TR 11510** "*Nuclear installations - Particular requirements for the application of ISO 9001:2008 in the nuclear field*" during today's meeting. This additional topic is detailed under item 5.

The agenda was approved unanimously.

3. Standardisation environment of ISO/TC 85/WG 4

Since it was the first meeting of a new Working Group, Guilhem Cuny, ISO/TC 85 Secretary, presented to the attendees the standardization system at the international, European and national levels, the ISO's mission, the development process of ISO standards, and made also a presentation of ISO/TC 85 *Nuclear energy, nuclear technologies, and radiological protection*, explaining the role of ISO/TC 85/WG 4 in this ecosystem.

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

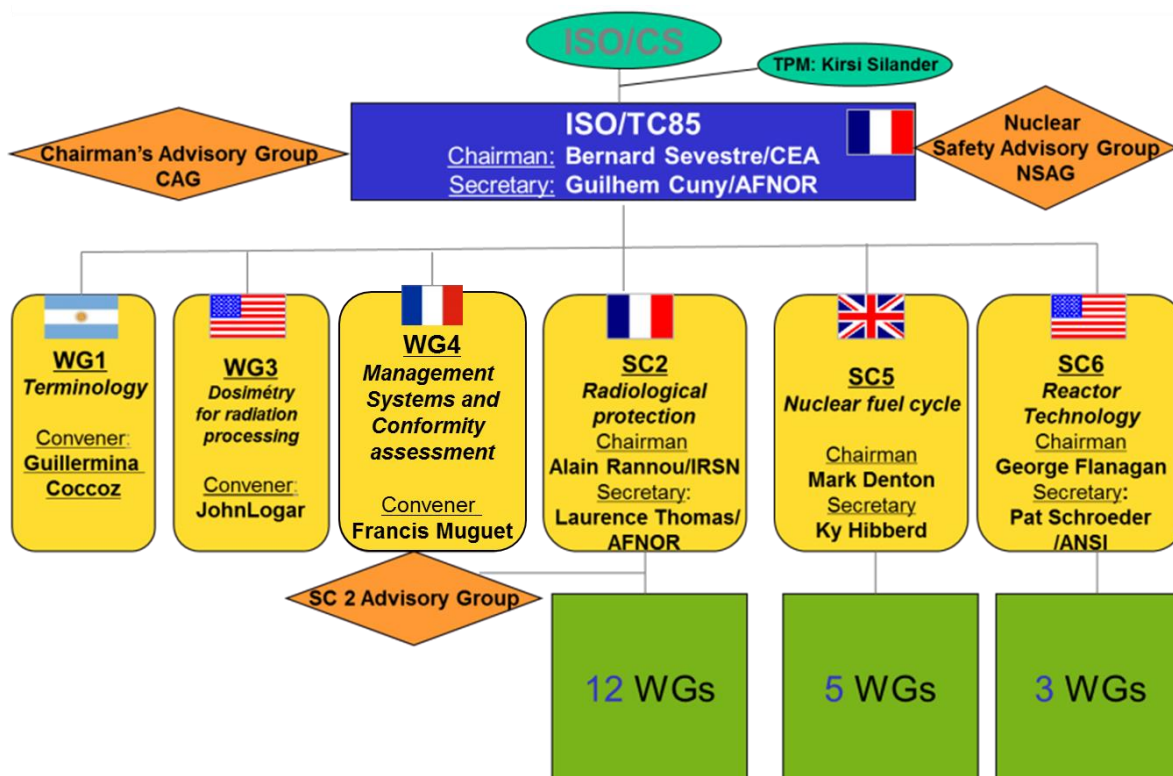
ISO TC 85 objectives are the production of industrial standards addressing the needs of nuclear energy, nuclear technologies, and radiological protection, including:

- Measurement of ionizing radiations and of radioactive or nuclear materials
- Measurement or calculation of parameters important for safety or performance
- Material and equipment specifications, including standard dimension interfaces
- System specifications
- Management and conformity assessment

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

This Technical Committee and its Subcommittees have already published 178 standards.

This Technical Committee is structured as follows :



The whole presentation is provided as [Annex 2](#)

4. "Livelihood" presentation

Guilhem Cuny made a short "live" presentation of the Livelihood system and pointed out the benefits for the experts to use such a system. Guilhem Cuny emphasized that a good cooperation between TC 85, its Sub Committees and Working groups requires experts to be registered in ISO Global Directory.

Experts have to be registered in each structure they are interested in.

If not registered :

Please contact your National Standardization Body (NSB) to be registered in the Global Directory. Your contact in your country is indicated under part 3 - Participating (P) countries and Observing (O) countries of the document "Scope, Structure and Contact" in [Annex 3](#).

An additional presentation of the Livelihood is given in [Annex 4](#).

5. Presentation of the document UNI / TR 11510

The presentation is available as *Annex 5*.

UNI / TR 11510 "*Nuclear installations - Particular requirements for the application of ISO 9001:2008 in the nuclear field*" had been produced by the WG "Quality Management", set in the sub-Commission UNI SC3 "Nuclear Plants" of the UNI Commission "Nuclear Technology and Radiation Protection", coordinated by Mr Pietro Amadei and with the active participation of many members of the Italian industry and other interested parties (ENEA, ISPRA, ACCREDIA, certification bodies, laboratories, ANIMA).

In view of a possible return to nuclear, the Commission UNI "Nuclear Technology and Radiation Protection", with the active participation of Sogin SpA and many members of the Italian industry and other interested parties (ENEA; ISPRA ACCREDIA, certification bodies, laboratories, SOUL), had launched initiatives of regulatory update with several working groups, one of which is "Quality Management System" has produced the UNI / TR 11510 - "nuclear installations - Particular requirements for the application of ISO 9001:2008 in the nuclear field", with particular reference to the IAEA standards.

Sogin is a state-owned company responsible for the environmental cleanup of nuclear sites and the Italian radioactive waste management including those produced by industrial activities, research and nuclear medicine.

The Nuclear Regulator considers that the requirements and recommendations contained in the standards IAEA (International Atomic Energy Agency) are acceptable for nuclear power plants and that provide adequate guidance to meet the requirements of the TG No. 8 (CNEN - Technical Guide No. 22, 23, 24, 25, etc..).

The decision to consider an additional element, which requirement (mandatory for the organization) or recommendation comes from the comparison of ISO 9001:2008 with the IAEA Safety Standards GS-R-3 and related Safety Guides GS-G-3.1 and GS-G-3.5, and with the ASME III NQA1, while ensuring consistency with the ISO 9001 and compliance with the mandatory standards, also taking account of the Technical Guidelines imposed by the Safety Regulator and requirements WENRA.

In the field of conventional means to meet the requirements of ISO 9001, ISO 14001, OHSAS 18001, the application of which is required by law (Public Contracts Code, Legislative Decree no. 231/2001, Legislative Decree 81/08, ...)

6. Review of the technical comments received during the ballot PWI 19443 "NUCLEAR SAFETY AND QUALITY MANAGEMENT SYSTEM – REQUIREMENTS"

The ballot regarding the Pre Work Item PWI 19443 "Nuclear Safety and Quality Management System - Requirements" ended on November 2013 with positive criteria. This ballot was intended to allow the creation of the new WG 4 "Management system and conformity assessment" (the former ISO/TC 85 Ad Hoc Group). This new WG 4 will 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. The first project undertaken by WG 4 is the New Project NP 19443 on the basis of an existing document, NSQ-100. (see doc N002 on the WG4 Livelink:

<http://isotc.iso.org/livelink/livelink?func=ll&objid=16344254&objaction=ndocslst>)

Some comments were issued by Germany, Iran, Russian Federation and Sweden, with this first ballot.

The comments were examined at the present meeting and observations of the secretariat are available as *Annex 6* (and also doc N 1292 on TC 85 Livelink).

7. Organization/Programme of work

The organization of the WG and the programme of work were discussed at the present meeting and the following steps were approved:

- Issue a new document by the middle of May (before the Moscow plenary meeting on 2 to 6 June 2014) taking into account the comments discussed today.
- During the plenary meeting, consider whether the project goes directly to CD level.
- At the end of the plenary meeting, schedule other meetings of WG 4
- Redefine the scope of NP 19443 “Quality management systems -- Specific requirements for the application of ISO 9001 and IAEA GS-R requirements by organizations in the Supply Chain of the Nuclear Energy sector”
- Discussions on accreditation and certification (back to CASCO meeting)

8. Requirements concerning a subsequent meeting (Moscow, June 2 to 6 2014)

The next meeting of ISO/TC 85/WG 4 is schedule on June 3 and 4, 2014, from 9:00 to 16:00 during the Moscow Plenary Meeting. More information about this event: see [Annex 7](#).

9. Any other business

None

10. Date and venue of the next meeting

See under item 8.

11. Approval of the decisions

See under item 7.

12. Closure of the meeting (16:45)