HERCA: Heads of the European Radiological protection Competent Authorities

Regulatory framework and inspections in Spain

HERCA WGMA Inspector Workshop 2015
Brussels

Marina Sánchez
Nuclear Safety Council (CSN)
SPAIN

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CONTENT

I.- NUCLEAR SAFETY COUNCIL
II.- REGULATORY FRAMEWORK
III.- MEDICAL INSPECTIONS
  ✓ RADIODIAGNOSTIC UNITS
  ✓ TECHNICAL STAFF
  ✓ INSPECTIONS PROCESS

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NUCLEAR SAFETY COUNCIL (CSN)

- Regulatory body in Spain, the sole competent authority in nuclear safety and radiological protection
- It is independent from the Government
  ✓ Accountable only to Parliament
  ✓ Assets and legal status of its own, financed fundamentally by fees.

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NUCLEAR SAFETY COUNCIL (CSN)

COMPOSITION:

- A single body: Board composed by a Chairman and four Commissioners
- Commending of functions to 9 Autonomous Regions (regional offices): inspection/inspection plus evaluation

SPANISH AUTONOMOUS REGIONS
NUCLEAR SAFETY COUNCIL (CSN)

COMPETENCES:
- CSN is responsible for all sectors: nuclear, radioactive (industrial, medical, research, commercials)
- CSN is responsible for ionising radiation exposures: occupational, public, environment
- Collaborate in radiological protection programmes of patients undergoing diagnosis or treatment procedures involving ionising radiations. 

NUCLEAR SAFETY COUNCIL (CSN), ACTIVITIES
- Licensing
  - Facilities: operating, modification and decommissioning authorisations.
  - Activities: transport, commercialization and constructions permissions.
  - Workers: accreditations, degrees, licenses.
- Inspection and Control
  - Safety levels and legal requirements verification
  - Power to suspend operation of facilities or withdraw workers licenses
- Regulations
  - Formulate proposals for regulations
  - 35 Safety Instructions and 64 Safety Guides
- Enforcement actions
  - Formulate proposals for disciplinary proceedings, warnings and fines.

IT SYSTEM
- Nuclear & Radiological Facilities
- Public
- Personal Licences
- Personal Dosimetry
- Environmental Data
- Decision Support Systems
- Subsidies, Safety Concerns
- Systems for DPR

ELECTRONIC OFFICE
- Radiological Protection
- Safety
- Nuclear
- Systems
- Radiation

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REGULATORY FRAMEWORK

CSN activities are supported by a pyramidal regulatory framework:

- **Law**
- **Royal Decrees**
- **CSN ITC, Norms, Guidances**
- **Technical Procedures**

Regulatory Framework:
- Nuclear Energy Law 25/64
- 1999 Royal Decree on Nuclear and Radioactive Installations
  - Title IV (Inspection, Obligations, Records)
  - Title VIII (Organization, scope, obligations)
- R. D. 1085/2009 Medical X ray Installations
- R.D 1976/1999 “Quality control criteria”

REGULATORY FRAMEWORK

**CONTENT**

I.- NUCLEAR SAFETY COUNCIL
II.- REGULATORY FRAMEWORK
III.- MEDICAL INSPECTIONS

- **Radiological Units**
  - Classification by type (grade risk approach)
    1. CT, Interventionism radiology, mammography, surgical and portable equipment
    2. General, veterinary and no intraoral dental installations
    3. Intraoral dental, podiatrist and bone densitometer units
  - Requirement of contract with a RPS or RTPU
  - Entities authorized by CSN
  - Personal: Head and experts in RP (RPE and RPO)
  - Mission: technical advise and conformity certificate
  - CSN can require the availability of a SRP/RTPU

**SURVEYS TYPE OF MEDICAL INSPECTIONS**

- **By Purpose**
  - Licensing: Announced
  - Decommissioning: Announced
  - Control: Announced
  - Proactive (annual inspection)
  - Reactive: Sometimes not announced

**SURVEYS TYPE OF MEDICAL INSPECTIONS**

- **By Medical Practice**
  - Medical Radiative
    - Cyclotrons-PET
    - Nuclear Medicine
    - Cobalt-60
    - LINACs
    - Brachitherapy Laboratories
  - Medical X Rays
  - Radiopharmaceutical and Equipment Supplier

**SURVEYS TYPE OF MEDICAL INSPECTIONS**

- Classification by type (grade risk approach)
  1. CT, Interventionism radiology, mammography, surgical and portable equipment
  2. General, veterinary and no intraoral dental installations
  3. Intraoral dental, podiatrist and bone densitometer units
- Requirement of contract with a RPS or RTPU

**SURVEYS TYPE OF MEDICAL INSPECTIONS**

- Radiological protection services/RP technical units
INSPECTION PROGRAM

TYPE OF INSPECTIONS BY MEDICAL PRACTICES

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MEDICAL INSPECTIONS

RADIODIAGNOSTIC UNITS

CSN CONTROL

1.- DIRECT: INSPECTION OF DIAGNOSTIC INSTALLATIONS
CSN /autonomous inspectors
1% aprox of total (315 in 2014)
Denunces, overexposures, x ray type 1
Risk based aproach programme (anually analysis of results)

2.- INDIRECT: CONTROL OF RPS/RPTU
Anual Reports
Inspections every 2/3 years

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SRO TECHNICAL STAFF

CSN inspectors: Bachelor’s degree, usually in science
Government exam
Training programme
For medical inspections this includes physics, doctors, chemistries, engineering ….(not specifically medical personal)
Continuous training programme:
biennial occupational RP course
not programmed training courses

Inspection performance of medical installations are usually conducted by 1-2 inspectors; preparation at CSN office by a team
The inspections include assessment of
• consistency of practice with licensing conditions
• procedures and protocols
• worker dosimetry
• radiological verifications
• equipment QC and QA programmes
• staff accreditation and training

Thank you!! Any question?