

## HERCA: Heads of the European Radiological protection Competent Authorities

### Regulatory framework and inspections in Spain

HERCA WGMA Inspector Workshop 2015  
Brussels

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Nuclear Safety Council (CSN)  
SPAIN



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## HERCA WGMA Inspector Workshop 2015

### 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

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### SPANISH AUTONOMOUS REGIONS



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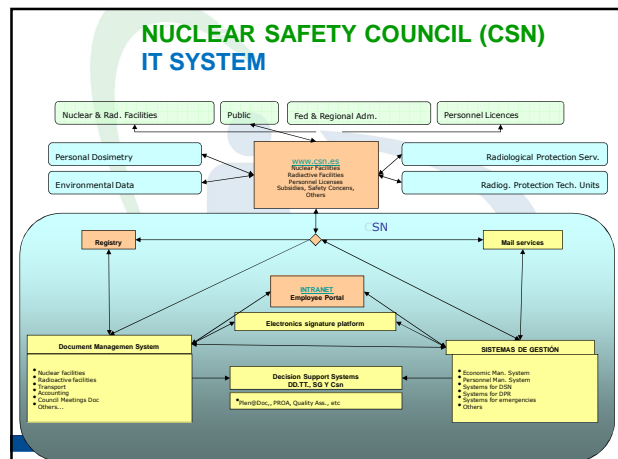
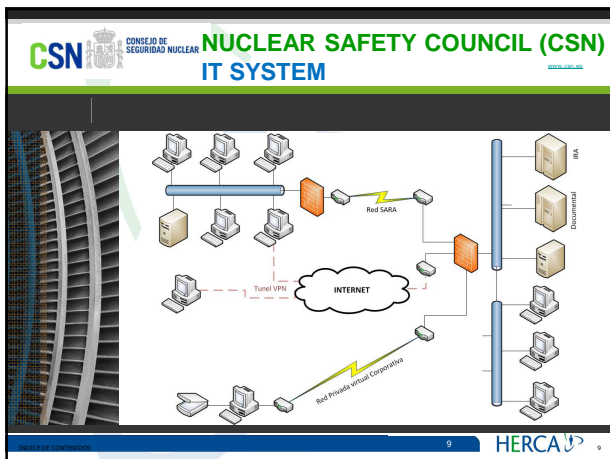
### NUCLEAR SAFETY COUNCIL (CSN)

#### 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. **Not competence on patient**

## HERCA WGMA Inspector Workshop 2015 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.



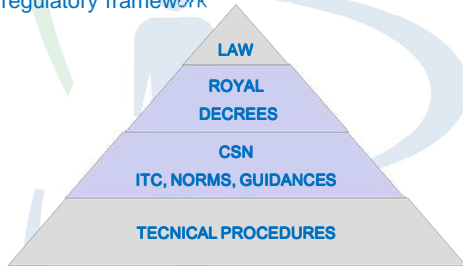
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## HERCA WGMA Inspector Workshop 2015 REGULATORY FRAMEWORK

CSN activities are supported by a pyramidal regulatory framework



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## HERCA WGMA Inspector Workshop 2015 REGULATORY FRAMEWORK

- ✓ Nuclear Energy Law 25/64
- ✓ Nuclear Safety Council Law 15/80 y 33/2007
- 2nd Article: Inspection*
- ✓ 1999 Royal Decree on Nuclear and Radioactive Installations
- Title IV (Inspection, Obligations, Records)*
- ✓ 783/2001 Royal Decree Radiation Protection (Euratom Directive 96/29)
- Title VIII (Organization, scope, obligations)*
- ✓ R. D. 1085/2009 Medical X ray Installations
- ✓ R.D 1976/1999 "Quality control criteria"



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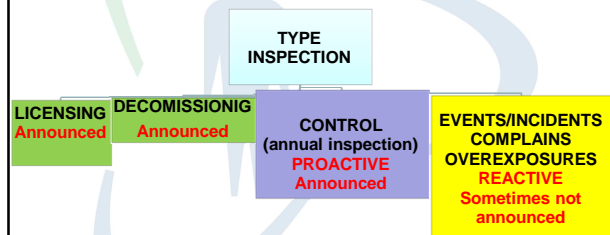
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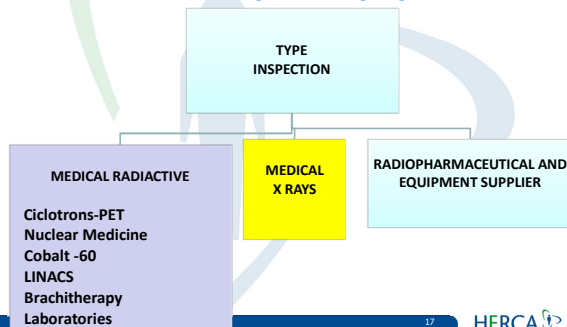
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## HERCA WGMA Inspector Workshop 2015 MEDICAL INSPECTIONS PROGRAM TYPE OF MEDICAL INSPECTIONS BY PURPOSE



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## HERCA WGMA Inspector Workshop 2015 MEDICAL INSPECTIONS PROGRAM TYPE OF MEDICAL INSPECTIONS BY MEDICAL PRACTICE



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## HERCA WGMA Inspector Workshop 2015 MEDICAL INSPECTIONS RADIODIAGNOSTIC UNITS

- ✓ **Specific Normative**, (R. D.1085/2009 Medical X Ray Installations and R.D 1976/1999 "Quality control criteria")
- ✓ **Classification by type** (grade risk approach)
  - 1) CT, intervencionism radiology, mammography, surgic 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 RPTU\***
  - 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

\*Radiological protection services/RP technical units

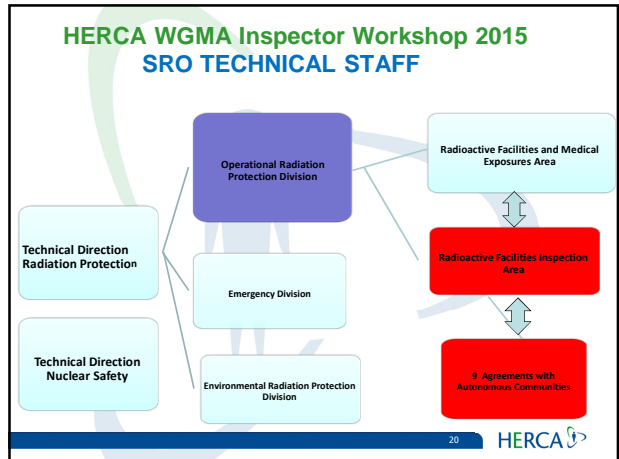
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### HERCA WGMA Inspector Workshop 2015 MEDICAL INSPECTIONS RADIO DIAGNOSTIC UNITS CSN CONTROL

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

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

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### HERCA WGMA Inspector Workshop 2015 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

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### HERCA WGMA Inspector Workshop 2015 INSPECTION PROCESS

- ✓ 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

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