

Experiences with focus on the medical sector from the IAEA IRRS mission to Spain

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01 | THE INITIAL SCENE



• RP of workers and members of the public

- Introduced in Spain as early as 1964 (Nuclear Energy ACT). EU BSS first transposed to national regulations in 1987.
- Regulation & control: CSN (as of 1980)

• RP of Patients

- First introduced in 1986 (General Health ACT) following EURATOM Directive 1984/466 on medical exposures.
- Regulation & control : Health Authorities.

• Two separated fields

- Workers + public <> patients
- CSN <> Health Authorities.

02 | RP of Patients. Regulatory development



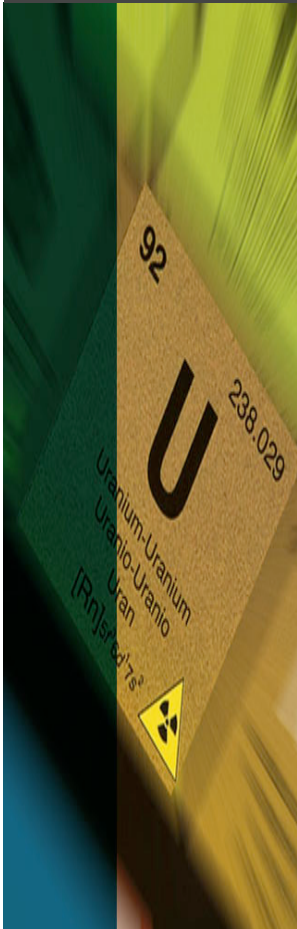
- Decree on fundamentals measures for patients RP.1990.
- **EU Directive 1997/43/EURATOM. Medical Exposures, Revised**
- Decree on quality control in Nuclear Medicine. 1997.
- Decree to create Radio-physics as a health professional speciality. 1997.
- Decree on quality control on Radiotherapy. 1998.
- Decree on quality control in radio-diagnostics. 1999 (**previous 1995**).
- Decree on justification of medical exposures. 2001.
- All released by Health Ministry. CSN informed all these regulations and took part in working groups for drafting many of them.

03

Interfaces RP Workers + Public/ Patients. Operation

- Personnel qualification and training.
 - Radio-physicst. Recognised by Education + Health authorities.
 - RP Expert. Recognised by CSN. **Head of RP services.**
 - RP Supervisor. Recognised by CSN. **In Charge of RP at operating RT NM facilities.**
 - RX Diagnostic facilities
 - Director . Recognised by CSN. **In Charge of RP.**
 - Additional training required by health authorities for interventional radiology .

- Requirements from both Health authorities and CSN related to
 - Quality control | radiation equipment and sources.
 - Commissioning & periodic testing



04

Interfaces RP Workers + Public/ Patients. Organisation 1



- Required by health authorities
 - Radiotherapy facilities to have internal radio-physicist team.
 - Nuclear medicine and X ray Diagnostic, radio-physicist support external/internal
- Required by CSN
 - Hospitals with RT+NM+X-ray must have internal radiation protection Service.
- In practice big hospitals create Radiation Protection + Health Physics Services to provide support on Patients, Workers and Public radiation protection.
- Heads of RP Services required to be recognised as Radio-physicist .
- In public health system RP + HP services provide support and expertise to small health centres (mainly X-ray) according to distribution by Health Authorities .

05

Interfaces RP Workers + Public/ Patients. Organisation 2



- Private health: radiation protection and radio-physics support to small centres provided by Radiation protection technical Units, authorised by CSN and required to have recognised radio-physicists in its staff.
- As of January 2002 management and operation of the health system no longer in charge of government but in charge of (up to 17) regional health authorities, included organisation for Radiation Protection and Radio-physics.
- Harmonisation and co-ordination through interregional high level Commission. Specific working group on Radiation Protection and Radio-physics created.

06 |

Interfaces RP Workers + Public/ Patients. Regulatory Surveillance

- Workers and m. public radiation protection in Charge of CSN.

Authorisation, Inspection, Control and Enforcement related to the whole radiation protection program.

- Patients Radiation Protection in charge of Regional Health Authorities.

Review, Audit and enforcement related to general requirements, justification and quality control programs.

- X-Ray facilities. Copy of quality control program must be sent to CSN. Joint document to hold both radiation protection and quality control programs allowed.
- Comforters RP, I-131 patient release, Health workers RP training.....

07

CSN Law amendment

- November 2007, CSN creation law amended to include as a new function:

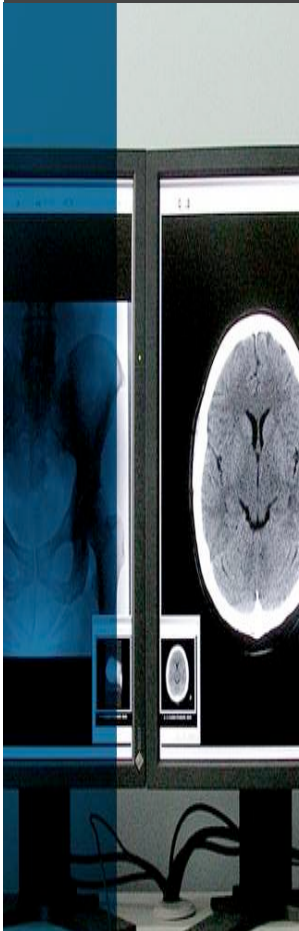
Co-operation with health authorities in patients radiation protection.

- CSN existing resources for medical uses of radiation allocated to also carry out the new function.

- First steps, working group to:

- Document past CSN work on patient radiation protection
- Identify current needs
- Ask the stakeholders about areas where CSN contributions are perceived as more valuable.
- Write an action plan to implement the new function.

- Existing forums for Co-operation between CSN and Radiation Protection and Health Physics professional societies identified as a key element.



08

IAEA IRRS Mission to Spain



- Peer review phase performed January 2008.
- Full scope mission. Patient radiation protection not included in official agenda for review.
- Three international experts to review practices with ionising radiation including medical exposures.
- Plan to develop the new function related to patient radiation protection Reviewed in the frame of the review of implementation of CSN creation law amendment.
- IRRS report statement:

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Follow up to IAEA IRRS Mission to Spain



- Carried out January 2011.
- One international expert to review radiation protection areas.
- Advances in patients radiation protection reviewed:
 - General agreement between CSN and Health Ministry.
 - Project to perform national survey on X-ray medical diagnosis procedures.
 - Support to take part in EU project EPI-CT

10 | Agreement between CSN and Health Ministry



- Signed November 2010
- General frame agreement for co-operation.
- To be developed through specific agreements related to joint tasks and projects to carry out.
- Up to 16 topics for co-operation identified, including:
 - Regulation development
 - Harmonisation of practices in all regions.
 - Maintenance on inventories of facilities
 - Epidemiology
 - Use of New tools for risk analysis
 - Information on accidents, incidents and malfunctions.
 - Patient dosimetry, development of dosimetry information systems.
 - Information and training for professionals and public.
 - Development of infrastructures for calibration and verification
 - Perform cross checks and inter-comparison campaigns.

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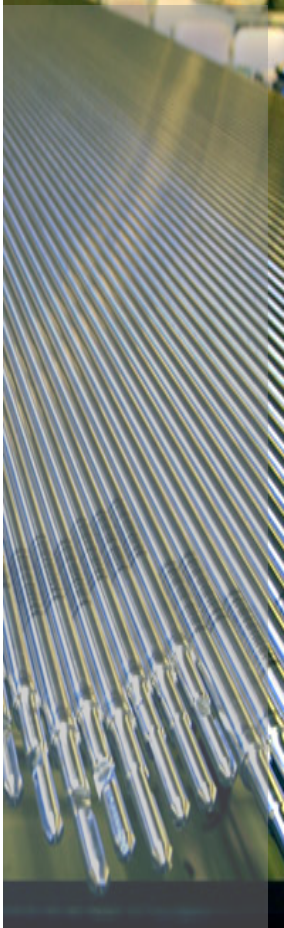
National survey on x-ray diagnostic procedures

- Started 2011, to be completed 2013.
- Co-operative project CSN/Health Ministry/ Málaga University
- Prospection of x-ray diagnostic procedures in 17 regions.
- Methodology proposed in EU RP-154 to be followed.
- Technical advisory Committee anticipated.
- Co-ordination with Spanish participation on EU project Dose Datamed 2.



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Support Spanish contribution to EPI-CT EU project



- Spanish contribution to build an European cohort to estimate health risks exposures to ionising radiation during childhood and adolescence.
- In addition a case control study about leukaemia to be performed on Spanish cohort. Exposures, sensitivity and effects of ionising radiation will be analysed using bio- markers.
- Co-operative project CSN/Health Ministry/ CREAL
- CREAL is acting as a partner at the EU project.
- Activities:
 - Gathering patients info and link to cancer and other diseases registers.
 - Dose reconstruction
 - Data analysis and validation
 - Statistical analysis

14 | Conclusions



- Separated systems for patient/ Worker + Public radiation protection initially established in Spain
- In practice many operational, organisational a regulatory interfaces occurred.
- Co-operation among all organisations and professionals involved allowed for good performance.
- Co-operation enhanced following amendment of CSN Law.
- On going developments for better performance and harmonisation
- IAEA IRRS mission to Spain witnessed that enhancement process and supported it through the advice from international experts.

THANK YOU

