Ciemat Individual Monitoring Service experience: from approval to accreditation

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Outline

1. General Information of Ciemat External Dosimetry Service (EDS)
2. Technical characteristics of Ciemat EDS
3. Approval requirements in Spain
4. Ciemat EDS accreditation experience
5. Accreditation of IMSs in Spain
6. Summary

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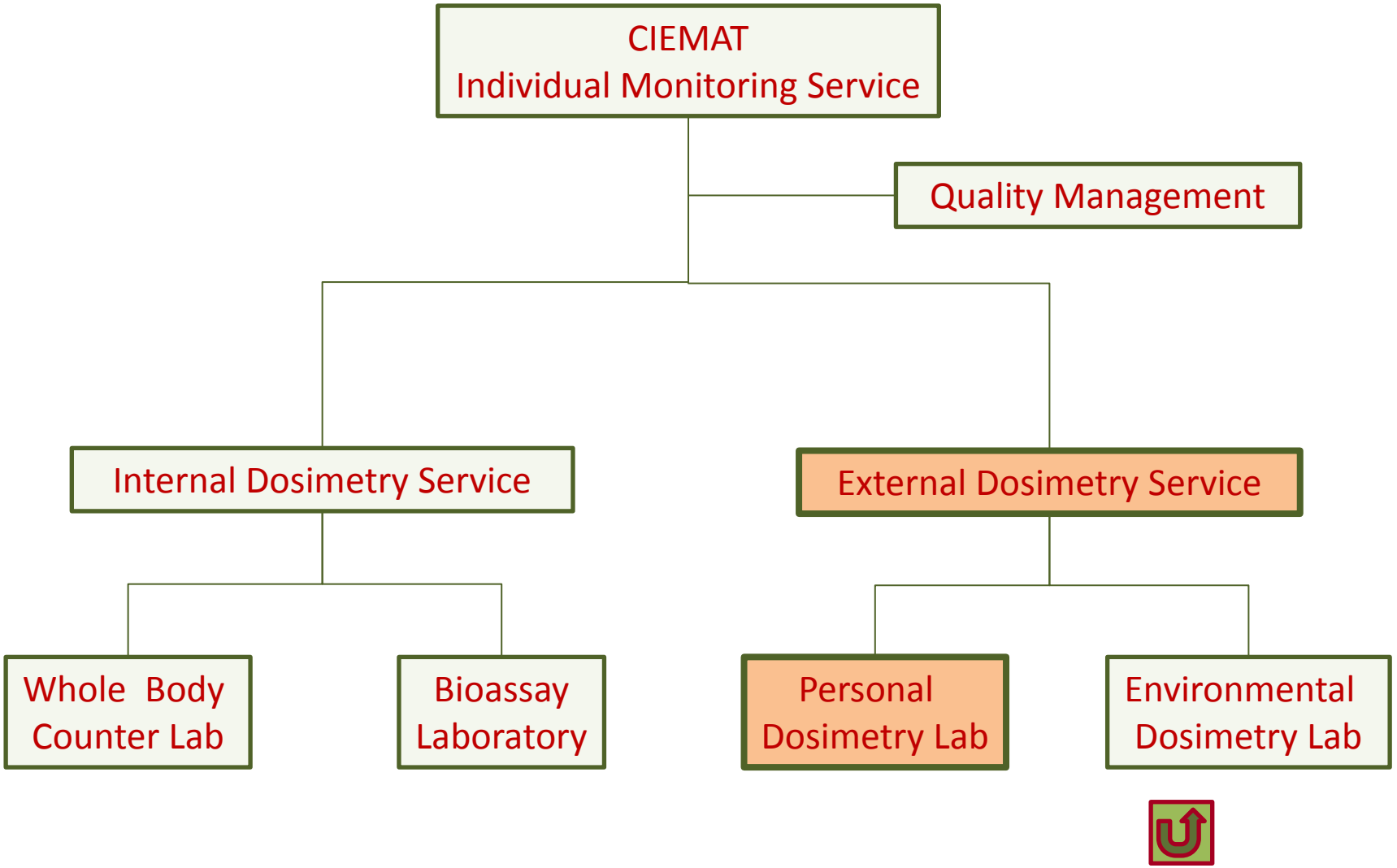
Ciemat EDS: General Information



Ciemat EDS: General Information

- ✓ Significant dates
  - ✓ 1959: First dose records (JEN)
  - ✓ 1984: CSN approval – Film dosimetry
  - ✓ 1992: CSN approval - TL dosimetry
  - ✓ 2012: Accreditation by ENAC - TL personal and environmental dosimetry

Ciemat EDS: General Information

- ✓ Ciemat EDS staff
  - ✓ 4 technicians
  - ✓ 4 laboratory assistants
- ✓ Ciemat EDS Dependences
  - ✓ Laboratory for dosimeters reception and preparation
  - ✓ Laboratory for dosimeters readout
  - ✓ External and Environmental Dosimetry Laboratory (Irradiators)
- ✓ Exposed workers monitored monthly in the Ciemat IMS
  - ✓ Whole body dosimeter : ~ 1000 Exposed Workers
  - ✓ Extremity dosimeter: ~ 140 Exposed Workers
    - Medicine 24%
    - Industry 1%
    - Research 32%
    - Government 18%
    - Waste manag. 25%

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Ciemat EDS: Technical characteristics:

- ✓ Dosimeters and hangers

TLD System	Panasonic: Whole body UD-802 Hanger UD-874 Extremitu dosimeter: UD-807	
	TL MATERIAL	FILTRATION
E1	$^{n}Li_2\ ^{n}B_4O_7$: Cu	14 mg · cm^{-2} (Plastic)
E2	$^{n}Li_2\ ^{n}B_4O_7$: Cu	300 mg · cm^{-2} (Plastic)
E3	$CaSO_4$: Tm	300 mg · cm^{-2} (Plastic)
E4	$CaSO_4$: Tm	1000 mg · cm^{-2} (Plastic+ Pb)
RING	$^{7}Li_2\ ^{11}B_4O_7$: Cu	20 mg · cm^{-2} (Plastic)

Ciemat EDS: Technical characteristics:

- ✓ Panasonic UD-710 and UD-716 readers

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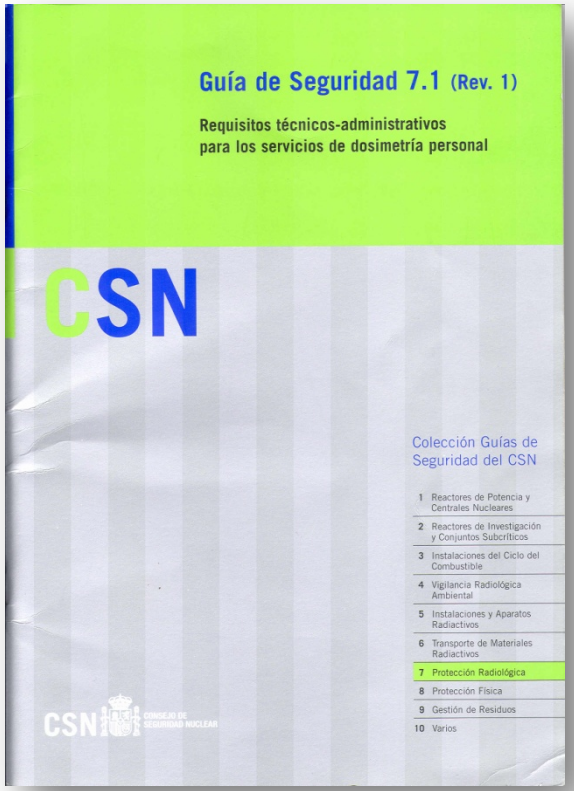
Approval Requirements in Spain:

- ✓ Spanish Regulatory Body:
  Nuclear Safety Council (CSN)

CSN Safety Guidance nº 7.1 (Rev.1):

"Technical and Administrative Requirements for Individual Monitoring Services" (2006)



- ✓ Official dosimetry:
  Thermoluminescence dosemeters (TLD)

Approval Requirements in Spain:

- ✓ Personnel Requirements
  - ✓ Minimum: Technical Manager(Degree in Science)
    Technicians (Vocational Education &Training)
    Administrative staff
  - ✓ Enough to cover holidays and sick leave
  - ✓ Qualification and training in RP and dosimetry
  - ✓ Program for continuous education and training

- ✓ Equipment Requirements
  - ✓ Dosemeters and hangers > $H_p(10)$ & $H_p(0.07)$
  - ✓ Readers > automatic operation
  - ✓ Environmental laboratory conditions > readout and storage
  - ✓ TLD annealing Ovens > controlled heating profile
  - ✓ Dosemeter irradiation facilities > annual verification
  - ✓ Contamination monitor > periodic calibration/verification

Approval Requirements in Spain:

- ✓ Technical procedures
  - ✓ Education, organization and responsibilities of staff
  - ✓ Equipment: operation, verification and maintenance
  - ✓ Dosemeter management procedure: homogeneity, delivery, use
    - ✓ Monthly periodicity, recording level: 0,1 mSv/month
  - ✓ Periodic calibration and verification of readers
    - ✓ Annual calibration, monthly verification
  - ✓ Dosemeters readout, dose assessment and reporting
    - ✓ Natural background subtraction
  - ✓ Treatment of deviations
    - ✓ Notional dose: $H_p(10)$=2mSv/month - $H_p(0,07)$=40 mSv/month
  - ✓ Dosimetry management application and database
  - ✓ Dose record keeping
- ✓ Initial characterization of dosimetry system
  - ✓ According IEC 1066:1991(*) for whole body dosemeters
  - ✓ According ISO 12794:2000 for extremity dosemeters

(*)IEC 62387:2012: replaces IEC 61066, IEC 62387-1 and covers scope of ISO 12794

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Ciemat EDS accreditation experience:

- ✓ Steps
  - ✓ 2008: Decision, diagnostic and planning
    - ✓ Planning structure and scope
    - ✓ Contact with other accredited labs
    - ✓ Quality Manager appointment
    - ✓ Diagnostic audit
    - ✓ Acquisition of IT tool for management system
  - ✓ 2009 -2010: Documentation and Implementation
  - ✓ 2011 - 2012: Application for accreditation, ENAC audit, Accreditation Certificate

Ciemat EDS accreditation experience:

2008

- ✓ Decision, initial diagnostic and planning (1)
  - ✓ Planning structure and scope
    - ✓ Individual Monitoring Service:
      - ✓ External Dosimetry: Personal and Environmental Dos. Labs
      - ✓ Internal Dosimetry: Whole Body Counter and Bioassay Labs
    - ✓ Scope:
      - ✓ Hp(10), Hp (0,07) and H*(10)
      - ✓ E(50)
  - ✓ Contact with other accredited labs
    - ✓ IAEA, ITN
  - ✓ Appointment of the Quality Manager and the Group of Quality
    - ✓ Monthly follow-up meetings

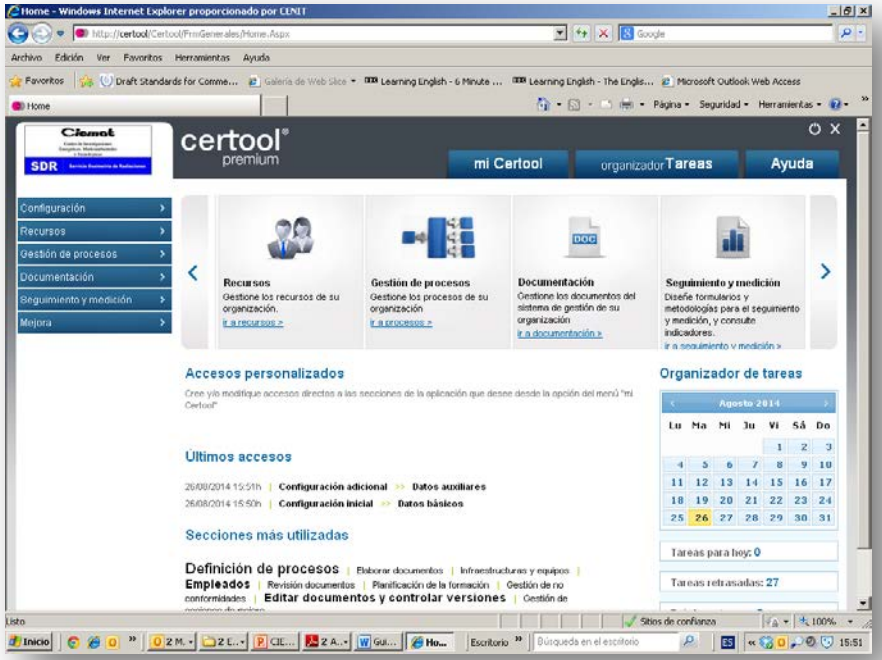
- ✓ Decision, initial diagnostic and planning (2)
  - ✓ Contract with a consulting company – Diagnostic audit
    - ✓ Starting point: 10 technical procedures, some of them not revised since 1992!!!
    - ✓ 38!! auditor's recommendations:
      - ✓ Management requirements:
        - ✓ Quality manual
        - ✓ Document control
        - ✓ Control of records
      - ✓ Technical requirements:
        - ✓ Equipment
        - ✓ Validation and uncertainty
        - ✓ Reporting the results

2008

- ✓ Decision, initial diagnostic and planning (3)
  - ✓ New IT tool for the management system: CERTOOL

    Certool is a client / server web application designed and updated by AENOR (Spanish Association for Standardisation and Certification) for the effective management of systems.

2008



Ciemat EDS accreditation experience:

- ✓ Decision, initial diagnostic and planning (4)
  - ✓ New IT tool for the management system: CERTOOL

2008

- Personnel and Training
- Purchasing and supplies
- Customers, contracts
- Infrastructures, equipment
- Audits
- Process Management
- Management reviews
- Document Management and Control of Records
- Managing nonconformities, corrective and preventive actions

✓ Documentation and implementation (1)

✓ 4. Management requirements

2009-2010

- ✓ Six new procedures and new edition of Quality Manual
  - ✓ 4.1 Organization
  - ✓ 4.2 Management system (Quality Manual)
  - ✓ 4.3 Document control
  - ✓ 4.4 – 4.8 Customers, suppliers, complaints
  - ✓ 4.9 – 4.12 Nonconfomities, Improvement, Corrective and Preventive actions
  - ✓ 4.13 Control of records
  - ✓ 4.14 Internal audits
  - ✓ 4.15 Management review

- ✓ More than 50 !! new records – Evidences are needed!

✓ Documentation and implementation (2)

✓ 5. Technical requirements

2009-2010

- ✓ In depth revision of procedures
- ✓ New documents were required
  - ✓ 5.2 Personnel and training
  - ✓ 5.4 No problem with calibration but new docs for validation (method and data) and uncertainty
  - ✓ 5.5 New procedures were needed for equipments
  - ✓ 5.10 New dose report layout to meet reporting requirements

- ✓ More than 50 !! new records – Evidences are needed!

- ✓ Documentation and implementation (3)
  - ✓ **Implementation of the system**

2010-2011

- ✓ 1st Internal audit (2010)
  - ✓ **7 nonconformities: mostly related to qualification, records and documents control, validation and reporting**
- ✓ 2nd Internal audit (2011)
  - ✓ **2 minor nonconformities: one record incomplete, some information missing in the report**

- ✓ Documentation and implementation (4)
  - ✓ **Implementation of the system**
    - ✓ Biggest efforts:
      - ✓ Documentation to comply with management requirements, personnel and training
      - ✓ Control of documents and records: periodic revision!
      - ✓ Evidences of validation: method, software, records… including excel files!
      - ✓ Uncertainties analysis
      - ✓ Involving the staff to use Certool to maintain the system
      - ✓ New dose report template to meet reporting requirements

Ciemat EDS accreditation experience:

✓ Application for accreditation, ENAC audit, Accreditation Certificate

2011-2012

- ✓ 2011: Apply for accreditation
  - ✓ Technical and management activities more systematic
  - ✓ More objective decision criteria
  - ✓ Internal audits and inspections easier to pass
- ✓ ENAC Audit
  - ✓ 2011 – Technical requirements
  - ✓ 2012 - Management requirements
  - ✓ 1 auditor, 1 tech. expert, 2 days
  - ✓ No nonconformities, only 4 minor deviations
  - ✓ 13/04/2012: Certificate of accreditation

ENAC
Entidad Nacional de Acreditación
Otorga la presente / Grants this
ACREDITACIÓN
144/LE1836
a la entidad técnica / to the technical entity
CENTRO DE INVESTIGACIONES ENERGETICAS, MEDIOAMBIENTALES Y TECNOLOGICAS (CIEMAT)
Servicio de Dosimetría de Radiaciones
Según criterios recogidos en la Norma UNE-EN ISO/IEC 17025, para la realización de ENSAYOS en el ÁREA DE LA PROTECCIÓN RADIOLÓGICA definidos en el ANEXO TÉCNICO adjunto.
According to the criteria in UNE-EN ISO/IEC 17025 for the performance of Test of Radiological Protection as defined in the attached Technical Annex.
Fecha de entrada en vigor / Coming into effect: 13/04/2012
D. Antonio Muñoz Muñoz
Presidente
13 de abril de 2012

Ciemat EDS accreditation experience:

Ciemat EDS accreditation experience:

After 3 years of experience as accredited…

- ✓ From 10 procedures and 5 technical instructions in 2008, to 23 procedures and more than 100 records in 2015!
- ✓ 2 ENAC audits (0 nonconformities), 3 internal audits and 2 CSN inspections
- ✓ Reassessment audit is scheduled for 2016
- ✓ The cost of accreditation is estimated at 2% of income

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IMS accreditation in Spain:

- ✓ 20 approved EDS
- ✓ 6 accredited EDS

Type of dosemeter	Whole body	Extremity	Environmental
CENTRO DE DOSIMETRÍA	X	X	Area
CIEMAT	X	X	X
ENUSA	X		X
C.N. SALUD AMBIENTAL	X		
INFOCITEC	X		
INTE	X		X

- ✓ 1 accreditation only for environmental dosimetry
- ✓ 2 accreditation for internal dosimetry + 1 for Uranium concentration in urine

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Summary

The accreditation is a "healthy" process for an IMS that compels it to a revision in depth of the administrative and technical procedures, the validation of the method, the control of documents and to pass internal and external audits periodically.

- ✓ Pros
  - ✓ Systematization of technical and management activities
  - ✓ Increase in objectivity of decision criteria
  - ✓ Reliability of results are easier to prove to customers and regulators
- ✓ Cons
  - ✓ Maintenance of the quality system requires time and dedication
  - ✓ The frequency of internal and external audits is hard to reconcile with daily work
  - ✓ Increase of costs

Thank you for your attention!