

Certification and Approval of French Medical Biology Laboratories (MBL) involved in the monitoring of workers exposed to ionising radiations in the frame of Occupational Health



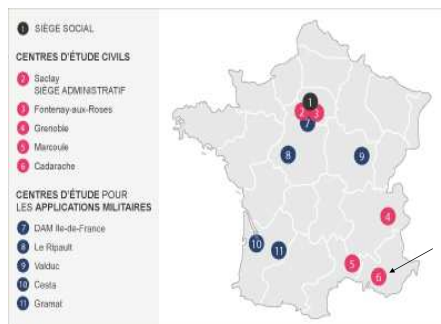
A1024

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15/03/2012

1

French Atomic Energy Commission



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2

Monitoring of workers exposed to ionising radiations



- **External irradiation** - Radionuclides outside of the body
 - Dosimetry by film
 - Criticality accident: MBL analysis
- **External contamination** - Radionuclide on the surface of the skin
 - contamination on skin : MBL analysis
- **Internal contamination** - Radionuclide inside the body
 - Inhalation, ingestion or wound: MBL analysis



Dosimetry is calculated by Occupational Physicians and in conformance with regulatory limits

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3

Analysis performed by MBL



External irradiation: Criticality accident

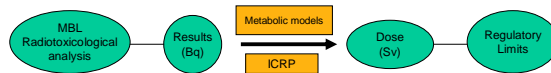
- Measurement of Na^{24} by whole body counting and in blood
- Measurement of P^{32} in the hair and nails

External contamination

- Direct measurement of Gamma-X emitters on the skin

Internal contamination

- Measurement of Alpha - Beta - Gamma emitters in urine and/or in faeces
- Measurement of Gamma-X emitters in the body and/or lungs by whole body counting (Anthroporadiometry)
- Direct measurement of Gamma-X emitters in wounds



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4

Certification of French MBL



In order to be allowed to monitor workers exposed to ionising radiations, the French MBL must meet 3 conditions

1- Accreditation of MBL by COFRAC (Technical part)



Standards of accreditation
ISO CEI 15189 - specific to MBL - radiotoxicology
ISO CEI 17025 - anthroporadiometry

2- Recommendation from the French Radioprotection and Nuclear Safety Institute (IRSN)

3- Approval by the French Nuclear Safety Authority (ASN)

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5

Focus on technical accreditation requirements



Quality Management

- Quality policy
- Management commitment
- System of management
- Program, procedures, instructions
- Control of the documentation
- Customer satisfaction evaluation
- Follow-up of corrective actions...

Technical requirements

- Personnel: skills - training
- Installation and surroundings conditions
- Validation of methods
- Uncertainty estimations
- appropriate equipment and follow-up of performances: calibration - periodic checks...
- Quality of results and of analysis reports



Quality assurance of analysis results

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6

Focus on the IRSN recommendation



- Appropriate materials and methodes
 - Pertinent detection levels
- Results of regulatory proficiency testings
 - Good results in terms of accuracy
- Transmission of all radiotoxicological results to the IRSN national data bank: SISERI

→ **Favorable recommendation from the IRSN**

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7

Focus on the ASN approval



- Notification of accreditation from COFRAC
- Last accreditation evaluation reports
- Notification of favorable advice from IRSN

→ **approval issued by the ASN**

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8

Approval of the MBL



Accreditation by COFRAC

- Objective technical competence to perform radiotoxicological analysis - evaluation every 12-16 months

Recommendation from the IRSN

- Certification that analytical techniques performed are in accordance with the best practices used in detecting pertinent levels of contamination

Approval by the ASN

- Authorization of workers monitoring by MBL

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9

Conclusion



**Regulatory certification of French MBL by
Cofrac - IRSN - ASN**



guarantee



**- Accuracy of measurements performed
- Adequacy of subsequent dosimetric calculations
for workers exposed to ionizing radiations**

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10