



**IAEA**

International Atomic Energy Agency  
*Atoms for Peace and Development*

# ASSESSMENT OF OCCUPATIONAL EXPOSURE DUE TO INTERNAL RADIATION SOURCES

## UNIT 11

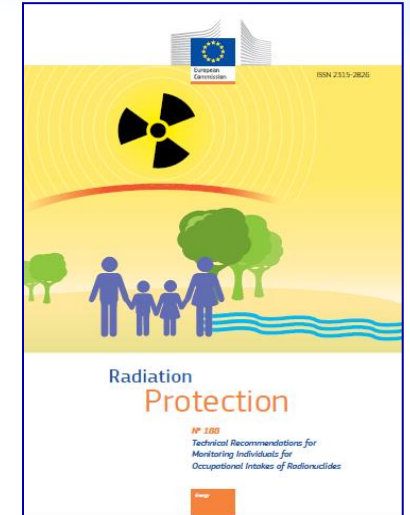
## QUALITY ASSURANCE.

## DOSE RECORDING AND REPORTING

## CONTENTS OF LECTURE

- **QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)**
- **ACCREDITATION/CERTIFICATION OF LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**
- **PARTICIPATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES IN NATIONAL AND INTERNATIONAL INTERCOMPARISONS**
- **DOSE RECORDING AND REPORTING**

EC RP 188



([ec.europa.eu/energy/sites/en/files/rp\\_188.pdf](http://ec.europa.eu/energy/sites/en/files/rp_188.pdf))

Technical recommendations for monitoring individuals for occupational intakes of radionuclides

# QUALITY ASSURANCE. DOSE RECORDING

## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

- ✓ Results of dose assessments from bioassay monitoring data provide valuable information for radiological protection units responsible for the management of events involving risks of intakes of radionuclides at the workplace
  
- ✓ **Individual monitoring programmes** allow fulfilling the objectives as follows:
  - Regulatory: compliance with dose limits (committed effective dose limits and/or equivalent dose limit to the skin and to the lens of the eye);
  - Health: evaluation of the related risk;
  - Optimisation principle (formerly ALARA, "As Low as Reasonably Achievable");
  - Information to exposed workers on the exposure conditions associated with their work.

# QUALITY ASSURANCE. DOSE RECORDING

- **QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)**
  - ✓ **To ensure the quality of the Internal Dosimetry Service (IDS)** over an extended period of time and **to guarantee the reliability of monitoring data and dose assessments** due to intakes of radionuclides, an appropriate **quality assurance programme** should be established, based on solid scientific principles and method validation, including uncertainty study and participation in national and international intercomparisons.
  - ✓ QA includes **quality control**: all those actions by which the adequacy of tools and procedures is assessed against established requirements.
    - The requirements for a **documented in-house measurement and dose assessment QA plan** that guarantees compliance with operational requirements should be stated in accepted written criteria.

# QUALITY ASSURANCE. DOSE RECORDING

- **QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)**

- ✓ The implementation of the recommendations presented in the **ISO standards** on
  - Internal dosimetry
  - quality management
  - general requirements for testing and calibration laboratoriesshould allow the competence of in vivo and in vitro monitoring laboratories and of services and qualified experts responsible for the evaluation of intakes and committed effective doses to be demonstrated.
- ✓ **Reviews or audits** should be conducted periodically, and also when one of the following conditions prevail:
  - when significant changes are made to parts of the assessment procedures, such as staff or management reorganisation or procedural revision;
  - to validate the implementation of previously identified corrective actions.

# QUALITY ASSURANCE. DOSE RECORDING



## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

✓ ISO standards provide an effective basis for a QA programme:

- **ISO 17025:2017** - General requirements for the competence of testing and calibration laboratories
- **ISO 28218:2010** - Performance criteria for radiobioassay
- **ISO 20553:2017** - Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material *to be revised according to ICRP OIR (Occupational Intakes of Radionuclides) Parts 1-5 publications*
- **ISO 27048:2011** - Dose assessment for the monitoring of workers for internal radiation exposure
- **ISO 16638-1:2015** - Monitoring and internal dosimetry for specific materials -- Part 1: Inhalation of uranium compounds
- **ISO 16638-2:2019** - Monitoring and internal dosimetry for specific materials -- Part 2: Ingestion of uranium compounds
- **ISO 16637:2016** - Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources
- **ISO 20031:2020**: Monitoring and dosimetry for internal exposures due to wound contamination with radionuclides

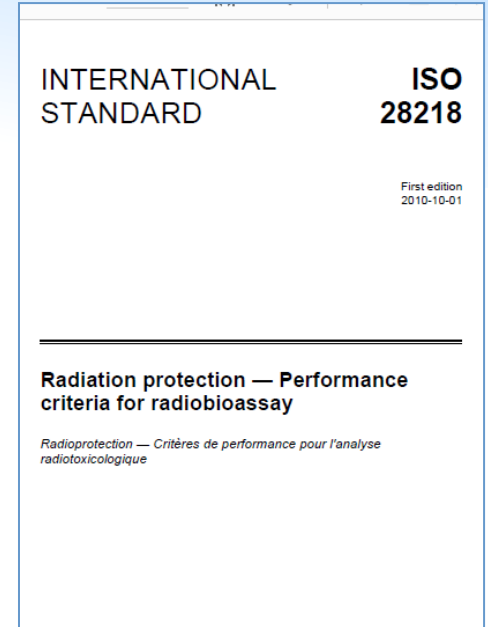
# QUALITY ASSURANCE. DOSE RECORDING

## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

Management and performance criteria of Internal Dosimetry Laboratories (IDLs) should follow the ISO 28218:2010 principles. Topics to be addressed:

### ✓ QA Plan

- Organisational structure, management and operational responsibilities;
- Qualification and training of laboratory staff;
- Instructions and procedures;
- Document control;
- Identification and control of material and samples (chain of custody);
- Inspection and testing of material and equipment;
- Control and maintenance of calibration standards;
- Validation of methods, procedures and software (e.g. commercial codes for spectra analysis or dose assessment);
- Documentation of detection limit and QC results (accuracy and repeatability tests);
- Periodic performance evaluations including proficiency activity measurements and/or dose assessment tests;
- Corrective actions.



# QUALITY ASSURANCE. DOSE RECORDING

## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

### ✓ QC Plan

- Performance checks of instrumentation, calibration and procedures for *in vivo*, *in vitro* and workplace monitoring;
- Verification of detection limit determinations;
- Performance checks on *in vitro* radiobioassay procedures regarding biological samples;
- Computational checks;
- Use of reference radioactive materials for equipment calibrations (traceable radionuclide reference standards);
- Intra-laboratory analysis;
- Participation in inter-laboratory intercomparison programmes;
- Evaluation of conformance to the performance criteria of ISO standards on internal dosimetry;
- Evaluation of quality control data.



## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC) – INTERNAL DOSIMETRY

### ✓ Dose Assessment

The assessment of internal doses is a **step-by-step procedure** where the **traceability of the results should be ensured** from the start of the process (workplace characterisation and design of individual monitoring programmes) to the end (assessment of E(50), recording and reporting):

### 1.- Characterisation of exposure conditions in the workplace

Essential information provided in detail by

- the Radiation Protection Officer (RPO) or
  - the Radiation Protection Expert (RPE), or
  - by the customer after consulting an RPE
- on topics including:
- radionuclides (type of radiation, energy, half-life, biokinetics),
  - chemical composition and
  - particle size (AMAD) of materials to which workers may be exposed.

# QUALITY ASSURANCE. DOSE RECORDING

- **QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)**

- ✓ **Dose Assessment** the traceability of the results should be ensured:

## 2. Design of monitoring programmes

The application of **ISO 20553** is recommended for the monitoring of workers exposed to a risk of internal contamination in the facility, using the information on characterization of exposure conditions.

Human and economic resources as well as national regulations should also be taken into consideration.

**Routine monitoring programme:** establishing appropriate **measurement techniques and monitoring intervals** that guarantee the detection of E(50) at the Recording Level (RL= 1 mSvy<sup>-1</sup>), taking into account the availability and sensitivity of the measurement methods.

# QUALITY ASSURANCE. DOSE RECORDING

## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

✓ Dose Assessment - traceability of results ensured:

### 3. Individual monitoring of workers

- *In vivo* and/or *in vitro* measurements should be carried out according to the specified monitoring programme.
- Monitoring data should be obtained by internal dosimetry laboratories using well-validated methods according to the principles described by ISO 28218:2010, taking into account the QA/QC plans of the laboratory which should themselves be in coherence with ISO/IEC 17025:2017.
- Uncertainties on measurements should be provided together with the monitoring data



# QUALITY ASSURANCE. DOSE RECORDING

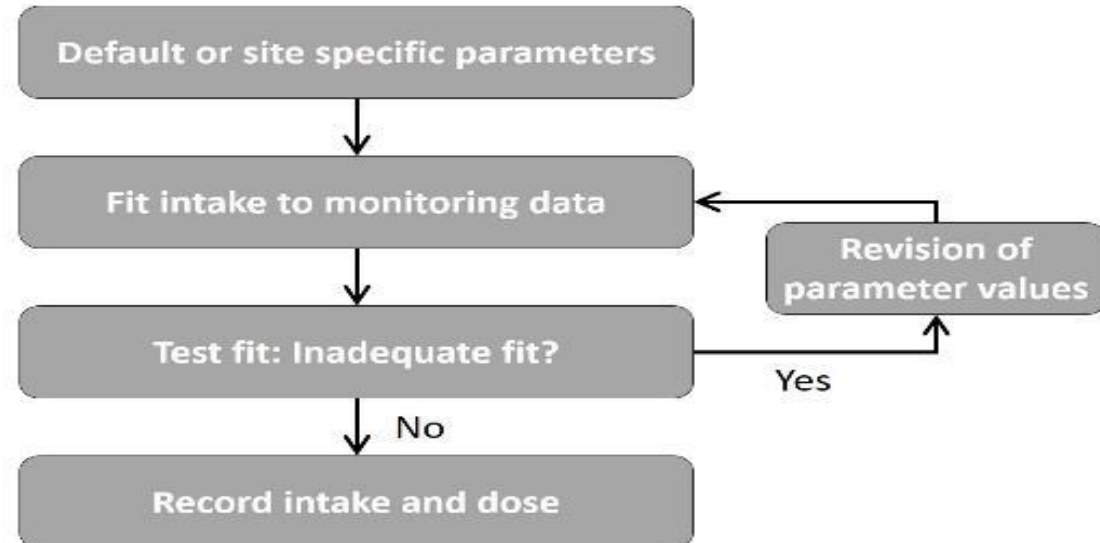
## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

- ✓ Dose Assessment the traceability of the results should be ensured

### 4.- Assessment of intake and dose

- The interpretation of monitoring data should be carried out taking into account ICRP recommendations, models, data and tools, and structured approaches e.g. as described in ISO 27048:2011 or IDEAS Guidelines
- Interpretation of monitoring data for the calculation of intake  $I$  and dose  $E(50)$ :

**step-by-step procedure:**

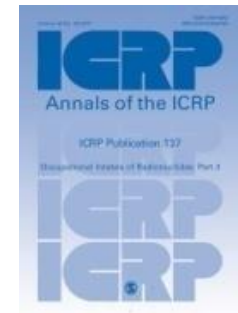


# QUALITY ASSURANCE. DOSE RECORDING

## • QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC)

### ✓ Dose Assessment the traceability of the results should be ensured

- If **computer codes** are applied for the calculation of doses and/or intakes:
  - Compliance with ICRP reference biokinetic and dosimetric models should be demonstrated in addition to
  - Compliance with the requirements of those procedures described in ISO 27048:2011 that the codes address.
- Available commercial (validated) software should be used with the authorisation of the national competent authority. Examples of commercial software include: TAURUS, IDEA-Plus and CADORmed consistent with ICRP/OIR Models and dose coefficients



# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ The aim is to **guarantee technical competence** for
  - (1) **monitoring** of radionuclides incorporated in the body and
  - (2) **evaluation of Committed Effective Dose  $E(50)$  mSv.**
- ✓ Major challenges: Uncertainty analysis, traceability of calibration sources, validation of methods, appropriate evaluation of the sensitivity of detection and to avoid the potential subjectivity in the dose assessment



# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ Implementation of a **Quality Management System (QMS)**, accredited or certified, according to international standards: important way of achieving continuous improvement of an organisation.
- ✓ **ISO 9001:2015** Standard developed for quality management
- ✓ **ISO/IEC 17025:2017** Standard developed for demonstration of the technical competence of testing laboratories.
- ✓ **ISO 15189:2012** specifically addresses clinical testing laboratories.

These standards are continually updated by ISO, and future revisions should be taken into account by the IDS.

# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ Taking into account the scope of its activities, its risk assessment system and its management system, a laboratory may decide on:
  - **Certification** of its activities: ISO 9001:2015 scheme is necessary
  - **Accreditation:** an ISO/IEC 17025:2017 scheme, or an ISO 15189:2012 scheme, is necessary.

Requirements of the national regulatory body and the competent certifying or accrediting authority should be taken into account.



# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ The quality management system should be documented in a **quality manual**.
- ✓ A quality policy and management procedures and Technical procedures need to be developed, in accordance with ISO 9001:2015 and/or ISO/IEC 17025:2017 specifications.
- ✓ Procedures should include plans for training of personnel, for control of equipment, for validation of methods, and for quality control (including participation in intercomparison exercises).
- ✓ **Methods applied by the IDS should be validated**, for example by successful participation in intercomparison exercises.
- ✓ The implementation of the system should be demonstrated with appropriate evidence (e.g. by keeping records of QA/QC tests performed).

# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ **ISO Standards on Quality Systems**

- **ISO/IEC 17025:2017** - General Requirements for the Competence of Testing and Calibration Laboratories. This standard is a generic reference guide, applicable to all laboratories regardless of the scope of testing or calibration activities, including:
  - **Management Requirements** - related to the operation and effectiveness of the **quality management** system within the laboratory.
  - **Technical Requirements** - includes factors which determines the correctness and **reliability of the results** obtained by the methods performed in laboratory.

It demonstrates that a laboratory operates a system of effective quality management and continuous improvement, is technically competent and able to generate technically valid results.

# QUALITY ASSURANCE. DOSE RECORDING

- **ACCREDITATION/CERTIFICATION OF INTERNAL DOSIMETRY LABORATORIES AND SERVICES ACCORDING TO ISO/IEC STANDARDS**

- ✓ **ISO Standards on Quality Systems**

- **ISO 15189:2012, Medical Laboratories - Requirements for Quality and Competence**

- This standard is based on ISO/IEC 17025:2017 and ISO 9001:2015, and specifies requirements for **competence and quality that are specific to medical laboratories.**
- The results of a clinical laboratory have implications for the **health of patients**, aspects not covered by ISO/IEC 17025:2017
- ISO 15189:2012 provides guidance and services to the patient and physician, and aims to improve working conditions and biosafety.
- It covers the entire analytical process, giving importance to biological and analytical variability and instrumental analysis techniques to meet medical requirements and diagnostic utility.

# QUALITY ASSURANCE. DOSE RECORDING

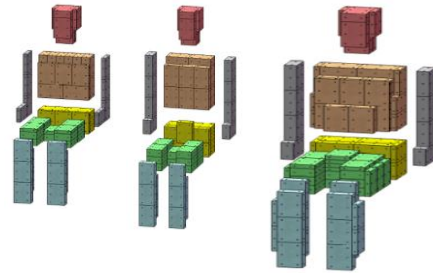
- **PARTICIPATION OF INTERNAL DOSIMETRY LABORATORIES/SERVICES IN NATIONAL AND INTERNATIONAL INTERCOMPARISONS ON MONITORING AND DOSE ASSESSMENT**
  - ✓ Participation in national and international intercomparisons: **essential part of QA and QC programmes** and an important step towards the accreditation of laboratories according to ISO/IEC 17025
  - ✓ Laboratories performing internal **dose assessments** should participate in national or international **inter-laboratory comparisons (“intercomparisons”)**.
    - These exercises allow participants to compare the results of dose assessments made under clearly defined conditions with reference values and with the results of other laboratories.
    - Intercomparisons of the results of interpretations of monitoring data from case studies are useful in improving reliability and harmonisation at national and international level

# QUALITY ASSURANCE. DOSE RECORDING

## • PARTICIPATION IN NATIONAL AND INTERNATIONAL INTERCOMPARISONS

✓ IRSN in vivo Intercomparison, annual organization, 3 programs:

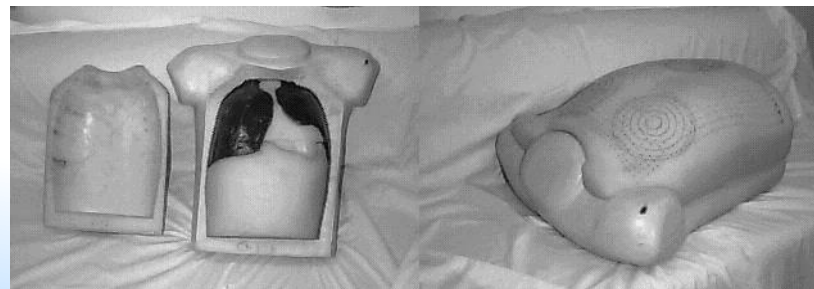
(1) Gamma emitters in total body



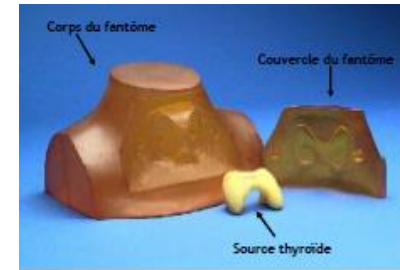
IRSN Brick Phantoms: Female (50 kg),  
Standard Man (70 kg) and Big Man (90 kg)

(3) Lung Counting

Livermore  
Torso  
Phantom



(2) Radioiodine in thyroid



Livermore  
Thyroid  
Phantom

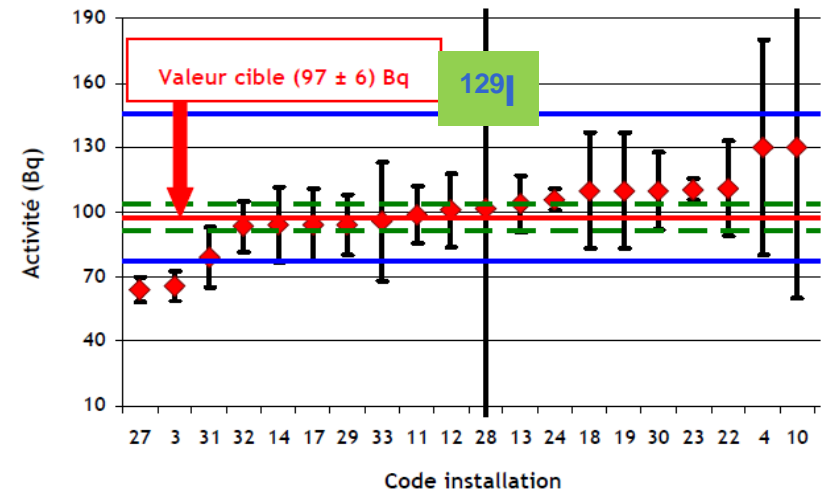


Figure 5 : Présentation graphique des résultats pour la mesure du fantôme 1

# QUALITY ASSURANCE. DOSE RECORDING

- **PARTICIPATION OF INTERNAL DOSIMETRY LABORATORIES/SERVICES IN NATIONAL AND INTERNATIONAL INTERCOMPARISONS ON MONITORING AND DOSE ASSESSMENT**
- ✓ **PROCORAD** ([www.procorad.org](http://www.procorad.org)) is a **European organization of laboratories** dealing with **in vitro measurements of radionuclides in excreta samples**.
  - Organization of **regular intercomparisons** of measurements to promote fruitful scientific and technical exchanges between its members.
  - Laboratories from Europe and from outside Europe are regular participants
  - A scientific meeting is organized each year during the Association's General Assembly, alternately in France and abroad. A technical report is published each year in French and in English.
- ✓ **BfS In vitro and in vivo Intercomparisons in Germany**
- ✓ **ARADOS** (Asian Radiation Dosimetry Group) - **Intercomparisons on in vivo monitoring of radionuclides in Asian countries**
  - ✓ **EIVIC 2021 - WBC Intercomparison in Europe**

# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

- ✓ The strategy and objectives for the monitoring of workers for occupational intakes of radionuclides should be documented.
- ✓ Dose recording and reporting should reflect the objectives of the monitoring programme, including the basis for the interpretation of the individual monitoring data in respect of regulatory requirements.
- ✓ **Records of individual occupational exposure:** any assessed committed effective dose, intake and equivalent dose to the skin .
- ✓ Details of any involvement of the worker in abnormal events
- ✓ To retain records referencing the monitoring methods and biokinetic and dosimetric models used for data analysis and interpretation, because they may be needed for future interpretation of the records of occupational exposure.
- ✓ **Traceability of the measurement results and the dose assessment is essential.**

# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

- ✓ Dose record keeping is a requirement of the 2013 Directive [EC 2014] and applies to all partners involved in internal dose assessment.
- ✓ Apart from demonstrating compliance with legal regulations, dose records may also be used many years later in the event of a claim for compensation or for epidemiological studies
- ✓ ISO 20553:2006: **doses  $E(50) \geq$  the recording level (RL)** (which is set to be no more than 5% of the dose limit, i.e.  $1 \text{ mSv y}^{-1}$  for a dose limit of  $20 \text{ mSv y}^{-1}$ ) **must be recorded.**
- ✓ One year is defined as twelve consecutive months or as one calendar year, depending on national regulations.



# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

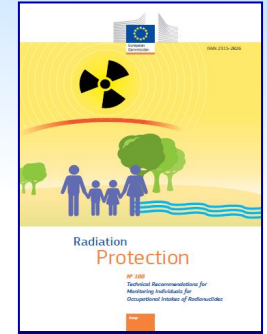
- ✓ Values of total annual internal dose  $<$  RL do not need to be recorded, but "below recording level" should be added to the dose record to show that the individual was subject to routine internal monitoring.
- ✓ Dose values  $<$  RL may need to be recorded, depending upon the frequency of the monitoring and magnitude of the assessed dose.
- ✓ If a cumulative annual dose may reach the RL, then with  $n$  monitoring periods per year, **the effective recording level for each monitoring period would be  $RL/n$ .**

# QUALITY ASSURANCE. DOSE RECORDING

- **DOSE RECORDING AND REPORTING**

- ✓ As a general approach, for a **RL = 1 mSv**:

- if  $E(50) < 0.1$  mSv, no dose value is to be recorded;
    - if  $E(50)$  from a single intake falls in the **range 0.1-1.0 mSv**, it should be included in the annual accumulated  $E(50)$ ;
    - if the annual accumulated  $E(50) \geq 1$  mSv, over a twelve consecutive months period or during the calendar year (depending on national regulations), it should be recorded.



# QUALITY ASSURANCE. DOSE RECORDING



## • DOSE RECORDING AND REPORTING

### ✓ Dose Record Keeping and the Transfer of Data

- Employers and registrants must
  - maintain records of occupational exposure for workers for whom assessment of occupational exposure is required,
  - provide workers with access to records of their own occupational exposure
  - provide the supervisor of the programme for workers' health surveillance with access to those records.
- Competent authority and relevant employer with access to workers' records of occupational exposure must
  - Facilitate provision of copies of workers' exposure records to new employers when workers change employment,
  - make arrangements for the retention of exposure records for former workers by the employer, registrant or undertaking, as appropriate
  - give due care and attention to maintaining the confidentiality of records.
- All dose records from individual monitoring should be transferred to a data system for radiological monitoring which could be implemented either as a network or as a National Dose Register maintained by the competent authority.

# QUALITY ASSURANCE. DOSE RECORDING



## • DOSE RECORDING AND REPORTING

### ✓ Approved Dosimetry Service

- Approved Internal Dosimetry Services (IDS) should be either responsible for, or informed of, the planning of the monitoring programme.
- IDS should be informed of work situations and levels of exposures, then design the monitoring programme in the light of risk assessment and management (or be informed of its design), and finally proceed with monitoring and dose assessment.
- All the information related to exposure conditions, the monitoring programme, and the dose assessment should be recorded.
- Individual monitoring carried out by Approved Dosimetry Services should ensure that any significant intake is detected at an early stage, based on a suitable combination of *in vivo* measurements and *in vitro* analysis. The design should include the basis for the interpretation of the monitoring results and should specify how this meets the objectives of the programme. All data should be recorded.

# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

- ✓ **The worker**

The worker is responsible for correctly following the instructions of all monitoring programmes put in place in the workplace (attending appointments for *in vivo* measurements, complying with the instructions for biological sample collection).

- ✓ **Radiation Protection Expert (RPE)**

- The RPE is an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities.
- RPE must give competent advice on matters relating to occupational exposure and public exposure; and that the advice of the RPE must cover:
  - the classification of workers;
  - workplace and individual monitoring programmes;
  - appropriate methods of personal dosimetry.

# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

- ✓ **Radiation Protection Officer (RPO)**

- The RPO is an individual technically competent in radiation protection matters who is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking.
- The tasks of the RPO may be carried out by a radiation protection unit established within an undertaking or by a RPE. The tasks of the RPO include:
  - supervision of the implementation of workplace monitoring programme
  - maintenance of adequate records of radioactive sources;
  - supervision of the implementation of the personal monitoring programme.
- **RPO provides information on the characterisation of the workplace**, and for the design of individual monitoring programmes in the event of risk of occupational intakes of radionuclides at the workplace. The results of workplace monitoring (air monitoring, swipe tests, monitors, etc.) should be recorded .
- **The RPO and the RPE should have access to the internal dosimetry results of individual monitoring (unless national regulations indicate differently).**

# QUALITY ASSURANCE. DOSE RECORDING



- **DOSE RECORDING AND REPORTING**

- ✓ **Occupational Health Service (OHS)**

- An OHS is responsible for guaranteeing appropriate health conditions and the capacity of the worker, and should have access to the internal dosimetry results of the individual monitoring of workers.
- All medical data should be recorded.
- Approved Dosimetry Services should determine the internal and external dose to exposed workers subject to individual monitoring in order to record the dose, in cooperation with the undertaking and the OHS.
- In some countries, dosimetry data is considered as confidential medical data, and is managed by the OHS.

# QUALITY ASSURANCE. DOSE RECORDING



## • DOSE RECORDING AND REPORTING

### ✓ Content of the Dosimetry Data Records for Individual Monitoring

- The internal dosimetry laboratories and services should maintain records of exposure information, measurement data and dose assessment results.
- Final assessed doses should be passed to the dose record keeping service where they are maintained with the rest of the individual's dose record.

### ✓ Duration of the Dosimetry Data Files of Individual Monitoring

- Dosimetry records should be confidential and should be preserved in a manner approved by the competent authority.
- Dosimetry records shall be retained during the period of the working life of the workers concerned involving exposure to ionizing radiation and afterwards until they have or would have attained the age of 75 years but in any case not less than 30 years after termination of the work involving exposure.



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