IAEA
International Atomic Energy Agency
Atoms for Peace and Development

Assessment of Occupational Exposure due to External Radiation Sources

Quality management system

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Set-up of an individual monitoring service

Individual Monitoring Service (IMS)

- Individual monitoring is carried out by an IMS

- Objectives of an IMS:
  - Supply customers with appropriate dose determination techniques :
    - With a high degree of reliability
    - With adequate accuracy
    - At an acceptable cost
  - Provide results within a reasonable timescale
  - Store the results in a secure dose record keeping system

Elements of an IMS

- Uniquely identified s for use by the customers
- Processing equipment to evaluate the s
- An administrative system which includes a database containing details of customers
- A secure dose record keeping system suitable for preserving and updating records for individual users
- Means for ensuring traceability of calibration

IMS Basic Organisational Structure

- Routine dosimetry
- Administration and finances
- Calibration section
- Record keeping
- Quality Management System (including QC)
- If possible a capability for investigation, development and research
- Mailing center
- Workshop
- Customer relations section

- Some parts can be outsourced: calibration, workshop,….

Customer Related Issues

- Several operational issues need to be resolved and agreed with the “customer”
  - Issuing and returning periods
  - Where to wear and how to handle s
  - System of identification of s and wearers
  - Dose record keeping
  - Reporting of results
  - Accessibility, privacy (GDPR for EU!)
  - Background radiation
  - Storage of s at customer
  - How to order, change and cancel subscriptions
  - Information needed from the customer for records
  - Prices

Customer related issues

- Methods for exchanging s
- Handling of lost s
- Amount of time to be allowed to make an order (or cancellation)
- Immediate reporting in case of unusually high doses
- Emergency processing
- Technical, scientific, legal advice and/or assistance (when and how to deal with authorities)

Dose management system and record keeping

Dose management systems

- Database main purpose:
  - To enable full access to the data related to the undertakings, monitored workers and measured doses
- Developed to manage most of the administrative features necessary to keep the service running
  - E.g. allocation of s, visualization of readouts, the production of mailing lists, labels, etc.
- In general, it is required by law that databases used for the handling of personal and classified information should be registered and the access of the worker to his personal data should be ensured
- In some countries the stored data is considered classified and confidential information and may require special precautions (like GDPR in EU countries)

Dose management systems

- Every monitoring period, the databases are updated
  - Upload of dose measurements
  - Update of accumulated dose
- If the worker is monitored for external and internal exposures the sum of the contributions should be compared with the annual dose limits
  - The results may be provided by two different monitoring services
- Workers can be exposed in different workplaces, possibly monitored by different monitoring services
  - Mostly taken care of by introducing national dose registry database

Setting up a Dose Management System

- Except when small numbers are involved, computer based systems offer a great advantage over manual processing
- Complete software packages are available
- However:
  - Difficult to include different national legal requirements
  - Difficult to include differences in local procedures
  - Difficult to take into account all different types of s
- Setting up own dose management system can have advantages
  - Is expensive and long term commitment

Employer identification elements

- Necessary elements are dependent on national legislation
- Examples:
  - Name, employer code number, contact data, address, …
- Category of establishment
  - Often required
  - Examples: industry, nuclear fuel, research, medical applications, safety and prevention, transport, non destructive testing…
  - Within these categories, there are several practices

Record system elements to identify the worker

- Necessary elements are dependent on national legislation
- Examples:
  - Name, unique identification number, employer, site, dates of start and finish, …
- Category of worker occupational category
  - Often required, can be described in national legislation
  - Examples: medical diagnostic radiology, unsealed sources, nuclear medicine, sealed sources, nuclear reactors, …..

Dose report

- The report may be divided into:
  - Clear identification of the monitoring service, undertaking, monitoring period and report title
  - Identification of monitored workers mentioning: name, number
  - Measurement method, calibration traceability, detection limit, recording level
  - Dose data: period, measured doses ($H_p(10)$, $H_p(0.07)$,…), accumulated dose (e.g. annual, 5-year accumulated dose, 12 months dose,…)
- The report should be signed by the person responsible of the monitoring service

Dose report: uncertainty

- ISO/IEC 17025 states that the uncertainty of the measurement should be evaluated and reported
- There is freedom how it should be communicated
  - Include the uncertainty of the dose results in the dose report
  - Produce a leaflet or, report where specific information relating to the measurement procedure and their characteristics (limitations) including the uncertainty, is shown

Supporting documentation should be maintained

- Information on the s used
- Raw data (before calculation, like glow curves,…)
- Working procedures and practices
- Quality assurance results
- Quality control data such as background trends and estimates of LLD
- Equipment calibration procedures and records
- Traceability of standard sources

A gap in the dose record?

- If a dose assessment is not available for a period when a radiation worker should have been monitored, such as when,
  - a has been damaged or lost
  - a recorded dose that, on investigation, is declared invalid
- The record keeping system should allow the introduction of doses estimated or assessed by an authorized person
- These doses may need to be flagged so that they can be distinguished from official dose measurements

National dose registry

- Every Member State should create and maintain a national dose register
  - Storage of dose values received by workers monitored in the country
  - For time intervals longer than the worker's working life and the life-time of the undertaking or dosimetry service
- The national dose register (NDR) should:
  - a) store dose values reported by approved dosimetry service or by undertaking
  - b) perform statistical analysis to characterize occupational exposure
  - c) define work activities (for example, nuclear, medicine, industry, or natural)
  - d) regularly publish occupational exposure reports
  - e) provide and/or issue radiation passbooks
- Access to the classified information should be only for radiation protection purposes
- Back-up procedures and security needed

Record keeping is used to:

- Demonstrate compliance with legal regulations
- Assist in work planning (worker allocation)
- Demonstrate the effectiveness of ALARA
- Provide data for analysis of dose distribution
- Evaluate exposure trends
- Develop effective monitoring procedures and programmes
- Provide data for medical and/or legal purposes
- Provide data for epidemiological studies
- May be used in litigation or for other medical or legal reasons

Dose reports may be open to:

- Employer (radiation safety officer/management)
- Radiation worker
- Local safety inspector
- Medical officer
- National legal authorities/inspectorates

The employer should:

- Provide workers access to information in their own exposure records
- Provide access to the exposure records for the supervisor of the health surveillance programme, the Regulatory Authority and the relevant employer
- Facilitate the provision of copies of workers' exposure records to new employers
- When employment stops, make arrangements for retention of exposure records by the Regulatory Authority, or a State registry, etc, as appropriate
- Maintain the appropriate confidentiality of records

When a worker asks for his/her record

- Usually through his employer
- If possible through national dose registry
- A simplified version of the full dose record is appropriate
- On termination of employment, a summary of the dose record may be given to the worker
- Covers the period of last employment and dose information transferred from previous employment

Record retention

- Exposure records for each worker shall be preserved:
  - During the worker's working life
  - Afterwards at least until the worker attains or would have attained the age of 75 years
  - For not less than 30 years after the termination of the work involving occupational exposure

Quality management system

What is Quality?

- A high standard or level
- Degree of excellence
- Distinguishing feature
- Faculty, skill, accomplishment
- Satisfaction of a customer's needs or requirements

- Quality is "totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs"

What is Quality Assurance

- Quality Assurance - planned and systematic actions necessary to provide adequate confidence that a dosimetry product or service will satisfy given requirements for quality

- Technical specifications may not in themselves guarantee that a customer's requirements will be consistently met, if there happen to be any deficiencies in the specifications or in the organizational system to design and produce the service

What is Quality Control?

- Quality Control - The operational techniques and activities that are used to fulfil requirements for quality

- Examples of QC:
  - Routine (i.e. daily) use of irradiated control dosimeters,
  - Various statistical analyses used to verify continued system performance.

Accreditation – Independent assessment

- It is important to establish independent methods to assess the quality of external dosimetry services
- Accreditation is a formal recognition that an organization is competent to carry out specific activities
- Accreditation is conducted through on-site audits, as well as periodic irradiation of s sets for comparison
- Accreditation programmes address the full range of laboratory quality assurance components

Audits

- The objective of audits is to enhance the effectiveness and efficiency of the dosimetry service
- Audits should be conducted by:
  - People who are technically competent
  - Do not have any direct responsibility for those activities
    - Auditors may be staff from other work areas within the organization, or independent experts from other organizations
- Audits and reviews should be performed in accordance with written procedures and checklists

General considerations of a Quality Management System

- Monitoring service providers require a documented management system for their facilities

- Grading of management system requirements
  - Controls on products and services should be based on their influence in affecting quality
  - Small organizations should ensure adequate resources to fulfil critical functions

A Quality System includes several elements

- Appropriate management support
- Development, implementation and management of QA/QC system
- Clear documentation of quality methods, procedures and test results
- Quality awareness and training of personnel
- Proof or certification of QA from equipment suppliers
- Acceptance and testing of new materials
- Appropriate maintenance and testing of equipment, materials and processes
- Calibration, and verification of the calibration facilities
- Reliable testing of the system performance
- Periodic performance testing of the system

Quality Management System (QMS)

- When establishing a QMS attention should be paid to the following matters:
  - Top management commitment is vital if the system is to be introduced successfully
  - Ensure there are good internal communication channels and processes within the dosimetry service. Clearly lay out a well communicated plan of activities
  - Involve all the staff in the implementation of the QMS and the processes that comprise the dosimetry service
  - Give some thought to process interaction. It is important that staff within the dosimetry service do not work in isolation but work as a team for the benefit of the customers and the dosimetry service
  - Do not ignore the impact that introducing a QMS will have on the customers and suppliers. Communicate with them to gain insight as to how they view the service and how they feel improvements could be made

Quality Management System (QMS)

- Reviewing:
  - The results of QMS should be reviewed at appropriate intervals
  - When the system is new the intervals will be short but can be longer once the QMS becomes mature
  - Reviewing perceived customer satisfaction is a key metric
  - Management review is important: check if the results meet the objectives and whether the process criteria have been met
- Improving:
  - Dealing with the challenges of the dosimetry service
  - Challenges may be actual issues (such as being late with a delivery) or be about “near misses” (such as almost forgetting to make a delivery)
  - Other examples are issues with suppliers or issues that have arisen with the processes (non-conforming work)

Monitoring of the management system

- Data derived from monitoring can be used to determine trends, customer satisfaction and reduce non-conformances
- The process of performance measurement, analysis and improvement includes:
  - Ongoing monitoring of effectiveness
  - Analysis of customer satisfaction, equipment performance, measurement throughput etc
  - Proactive prevention of non-conformance, to improve and optimize services
  - Reactive action following self-assessment, complaints or outcomes of audits

Documentation of methods, procedures and test results

- Methods used and procedures set up to control the various processes within the service, should be well documented
- This is also important for inspection of the service by official authorities as part of an approval system
- Quality Handbook
  - Covers all aspects of the quality system in a concise and practical way
  - Description of the management system
  - Working documents and job descriptions
  - Additional technical documents and data
- Appropriate parts of the documentation should be made available to staff members
- It may even be useful to display operational instructions "on the spot"

Quality Management System (QMS)

- By establishing a QMS, the implementation of standards can be achieved more easily
- QMS helps organizations to improve customer satisfaction levels, internal efficiency and employee involvement
- QMS described in:
- **ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories**
- Latest version: 2017

Quality Management System according ISO 17025

- In EN ISO/IEC17025:2005 topics covered under the heading of management requirements include:
  - General demands: impartiality and confidentiality
  - Requirements for means:
    - Staff
    - Facilities and environmental conditions
    - Equipment
    - Traceability
    - Subcontractors

Quality Management System according ISO 17025

- Requirements for the process
  - Handling of requests, offers, contracts
  - Selection, verification and validation of methods
  - Sampling
  - Handling of test objects
  - Technical registrations
  - Uncertainties
  - Quality control
  - Reporting
  - Complaints
  - Deviations
  - Data and information management

Responsibility and authority for the management system

- A person should be designated as the quality system manager, authorised to:
  - Develop and manage the system, compliant with standards, harmonize procedures, review operations, address non-compliances and raise staff awareness
  - Communicate quality issues to regulatory and accreditation bodies
  - Communicate with management
  - Be the focal point for non-compliance and improvement
  - Stop work, if performed inadequately
  - Conduct reviews of the system

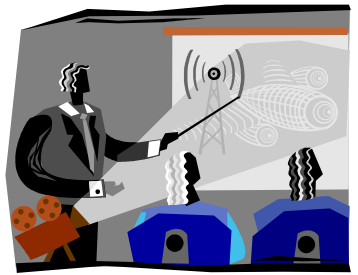
Process implementation

- Provision of resources
  - Staff, equipment and supplies, information, facilities, services, workplace and finance
- Human resources
  - Human resources should be adequate to meet predetermined requirements
  - Staffing levels, education, training, experience, qualifications and performance review

Dosimetry staff needs to be properly trained

- Basic philosophy and strategy of individual monitoring
- Principles and methods used
- Detailed procedures
- Technicalities and potential problems of the processes
- Laboratories should have deputies for key personnel

- Training is a basic QA requirement



Staff training should include:

- Basic philosophy and strategy of external dose assessment
- Principles and details of the methods used
- Technical details and potential problems of the processes in which they are involved
- Recognition and reporting of problems that arise
- Relationship of their work with other parts of the process
- Trouble shooting
- Knowledge of the overall quality system and its objectives
- Their particular responsibility within the quality system

Infrastructure and working environment

- Infrastructure should be adequate
  - For calibration and testing laboratories the regulatory body may impose requirements

- Process for control of monitoring and measuring devices should ensure results are accurate
  - Process should confirm devices are suitable, tested, calibrated, functional and protected

Test and calibration of equipment

- Adequate equipment should be available
  - Periodic calibration
  - Functional tests between calibrations
  - Maintenance by manufacturer and recorded
  - Checks on outgoing and incoming equipment
  - Calculations using software checked and validated
  - Calibration services should have standards traceable to the SI system
  - Store calibration procedures and certificates

Handling of items

- Testing and calibration items should be handled carefully
- Procedures should address:
  - Identification and labelling of incoming test and calibration items
  - Reporting of abnormalities
  - Instructions for handling, storage and transport and required environmental conditions
  - Instructions on return of items or approved disposal
- Unique labeling which identifies the and the person concerned throughout the process from sampling to the recording of the measurement results
- Chain of custody of all samples to preclude loss, contamination, tampering or incorrect analysis

Contamination control

- Contamination and extraneous radiation sources must be prevented from entering the dosimetry laboratory
- Equipment and supplies entering the dosimetry laboratory should be minimized
- Attention should be given to external contamination or extraneous radiation sources brought in by visitors

Quality Control procedures

- Should be carried out at appropriate intervals
- Should cover the following:
  - Documentation of the required performance criteria
  - Identification of the person responsible for operation and maintenance of equipment
  - Performance checks of measurement systems
  - Traceable instrument calibration
  - Participation in interlaboratory-comparison programs
  - Computational checks
  - Periodic review of procedures, specifications and operating records
  - Observation of operations and evaluation of quality control data

Reporting of results

- Results should be reported accurately, comprehensively meeting customer needs
- The layout of reports should consider
  - Requirements of regulatory bodies
  - Requirements of relevant standards
  - Organizational rules on reporting
- Data from subcontractors should be identified
- A procedure should be in place for changing reports

Control of records

- Retain records of original information for audit trail
- Information should allow identification of uncertainties and conduct of repeat tests
- Record identity of persons sampling, testing and checking results
- Records may include: forms, worksheets, workbooks, check lists, control graphs… etc
- Mistakes in records should be crossed out, correct values entered and initialled. If electronic record, equivalent measures to be taken

Customer satisfaction

- Customers are the most important stakeholder
- A contract for a service should include:
  - Customer needs
  - Related regulatory requirements
  - Resources required
  - Customer communication needs
- Feedback should be collected and evaluated

Complaints

- Registration:
  - All complaints need to be registered
  - Only after that an analysis will be done if the complaint is valid
  - After registration, the responsible of the group is notified
  - All correspondence and documentation of the complaints is archived
- Causal analysis
  - If needed a correction is done immediately
  - Causal analysis will show which corrective and preventive actions are needed
  - If the complaint is not valid, the customer will be informed why
  - If the complaint can not be fixed immediately, the customer will be informed about this

Complaints

- Correction, corrective measures, preventive measures
  - A correction towards the customer needs to be done as fast as possible
  - Corrective measures take away the cause of the complaint and prevent that the same complaint will happen again
  - Preventive measures will remove the cause from future unwanted situations related to the complaint
- Closing a complaint
  - The QA coordinator can close the complaint after checking that all measures are taken

Non-conformances and corrective actions

- Non-conformances could include
  - Incorrectly entered raw data
  - Application of incorrect algorithms
  - Incorrect calibration data or factors
  - Measurements with instruments out of their range
  - Incorrect output data
  - Incorrectly performed sampling or sample treatment
- Impact of non-conformances on safety should be assessed and management notified
- A policy/procedure for resolution of complaints is required
  - Implemented following a complaint, customer feedback or a non-conformance. Records to be maintained
- Preventative (prospective) action may follow a corrective (retrospective) action

Management system review

- Management review should include
  - Persons involved
  - Factors considered
  - Decisions reached
  - Actions planned, persons responsible and timescales
  - Review and approval of the report
- Results incorporated into laboratory planning system include goals, objectives and action plans for the year
- Management should ensure actions are carried out

Approval of dosimetry services

Approval of dosimetry services

- The regulatory body is responsible for the authorization or approval of service providers for individual monitoring
- The purpose of approval is to recognize and verify that a dosimetry service provider is technically competent, able to generate technically valid results and has adequate administrative, technical and management systems
- Accreditation of the management system in accordance with a relevant international standard such as ISO/IEC 17025 could be one of the steps to the approval

Approval of dosimetry services

- An approval process can in general be summarized as follows:
  - Documentation: a report containing information about the dosimetry system is examined by the authority
  - Type test results, dosimetry procedures, calibration traceability, management, organisation, personnel, equipment quality control and procedures…
  - Quality system: quality system certification or accreditation according to either ISO 9000 series or EN ISO/IEC 17025
  - Traceability to national standards
  - Irradiation performance test: external irradiation performance test at unknown doses in unknown situations
  - Inspection of the laboratory: on-site assessment by dosimetry experts who evaluate such areas as staff (including training), equipment, facilities, calibration and dosimetry procedures
  - Approval performance tests should be carried out at regular intervals. Such tests can be organized by the authorities, or participation in international external intercomparisons can be obliged