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Managing R&D Records to DOE, NARA, and ISO Standards

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Argonne & ISO

- **Then**

  Summer 2006 UChicago Argonne, LLC, commitment to DOE

  - Obtain certification to ISO 9001 and 14001 standards
  - Develop a stronger customer focus
  - Adopt a cross-organizational, process-based approach to management

- **Now**

  - Argonne has "Laboratory Management System" or LMS ….
    - Multidisciplinary teams define work processes, policies, and procedures that are implemented by line organizations
    - All work falls under one of 17 core processes
  - Lab "passed" pre-audit in March, main ISO audit begins in early May
  - **Records – both scientific and business – are in the spotlight**

ISO standards … according to ISO

- **ISO 9001** addresses “quality management“ –
  what an organization does …
  - To fulfill customers’ quality requirements and applicable regulatory requirements
  - While enhancing customer satisfaction and continually improving its performance in pursuit of these objectives

- **ISO 14001** addresses “environmental management“ –
  what an organization does …
  - To minimize harmful effects on the environment caused by its activities
  - To continually improve its environmental performance

Argonne LMS core processes

- **Strategic planning**
- **Business development**
- **Research, development & engineering (records)**
- **Scientific user facilities**
- **Governance of LMS (records)**
- Contract management
- Project management
- Risk management
- Safety & health
- Environment
- Security
- Financial management
- Asset management
- Human resources
- Procurement
- Information services
- Communications and public affairs

Why a spotlight on records?

- "Objective evidence" that an organization follows its own work processes is central concept underlying ISO quality standards

- In an ISO setting, records are a leading form of objective evidence

- ISO 9001 calls for an organization to have 6 types of procedures:
  - Document control
  - **Records control**
  - Internal audit
  - Control of nonconforming product
  - Corrective action
  - Preventive action

R&D records: ISO vs the feds

- **From ISO perspective**, R&D records ….
  - Prove Argonne followed its own formal processes for R&D management
  - Must be identified, in procedures, as data/documents that employees are required to create and keep
  - Must be "controlled" to be readily retrievable – translates to specifying, on a lab-wide level, the *one-and-only* job role that holds each type of record and the medium and filing method for each type of record
  - Are destroyed on "hard" dates set by Argonne

- **From DOE & NARA perspective**, R&D records ….
  - Capture the knowledge created by Argonne's science
  - Are a resource for historians, future scientists
  - Are not as crisply defined as the typical ISO records
  - Are destroyed long after project ends, after Argonne applies "soft" criteria set by DOE & NARA

Argonne's R&D records under ISO

- **New records management & control procedure**
  defines six work processes that, in combination,
  meet both ISO and DOE/NARA requirements for R&D records:
  - Coordinating records activities within Argonne organizations
  - Identifying and preserving records held by employees
  - Maintaining inventories of records held by employees
  - Managing inactive records
  - Transferring records to a sponsor or regulatory agency
  - Periodically reviewing records from completed R&D projects
- **New research, development & engineering (RD&E) procedure**
  defines a process for managing programmatic work. Includes steps that:
  - Identify, at the outset of a project, records to be created and maintained
  - Assign custodial responsibility for records at the end of a project

Step 1 of Argonne's RD&E procedure

The principal investigator takes these actions:

1.1 Identify funded scope and requirements.

1.2 Assess opportunities and risks.

1.3 Establish plans and controls to accomplish funded scope safely and effectively.

1.4 Plan records creation and management:

- **Identify the types of records that will be generated to document the RDE process and its effectiveness and communicate planned records to the division records coordinator. Subject to a graded approach, records may include some or all of the types of records listed in the Exhibit.**
- **Designate custodian(s) and storage locations for the records during the work activity, in accordance with LMS-PROC-2.**

Procedure step includes this note:

The customer and other stakeholders, including legal or regulatory bodies, impose requirements that must be incorporated into the RDE process. Safety hazards must be addressed in accordance with ESH-21.2.

Steps 2 - 5 of RD&E procedure

- **Step 2:**
  The PI's management reviews the research project management plan and verifies that "the records plan is adequate to provide objective evidence of work performance and effectiveness"

- **Step 3:**
  Principal investigator and RD&E team conduct the work.

- **Step 4**:
  Upon completion of the work, the PI's management reviews the project to determine if plan was followed. Actions include:
  - **Verify required records were established.**
  - **Designate a custodian to retain the records**

- **Step 5:**
  PI's organizational records coordinator updates records inventory

Exhibit to the RD&E procedure: Examples of records generated by RD&E projects

- Administrative records; including documented management reviews and approved plans and controls
- Design documentation; drawings, basic data sheets and data logs
- Computer code documentation and software/hardware requirements
- Preliminary sketches, drawings, specifications, and photographs
- Raw data, including that contained in lab notebooks
- Evaluated or summarized data resulting from study of raw data
- Technical documents, including final publications and technical progress reports, and supporting technical information
- Reports of inventions, disclosures/patents and copyrights
- Procurement, financial, and training records (if deemed necessary to supplement those maintained in the central Argonne business information systems)
- Safety records (if deemed necessary to supplement those maintained by central Argonne safety offices)

Challenges and solutions – now and in the future

- **Challenge**: Federal records schedules don't match up neatly with new types of Argonne records that will document the management of national scientific user facilities. *Solution TBD.*

- **Challenge**: Federal schedules don't explicitly address issues stemming from massive quantities of digital data from experiments and simulations

  Solution: Argonne's RD&E procedure empowers PIs to decide what portion of experimental data to maintain as a record

- **Challenge**: Records rapidly becoming all-digital

  Solution: Argonne is developing repositories for digital records – from data to meeting minutes – on internal drives, while looking at capabilities of Oracle (aka Stellent) records module

Benefits of Argonne's LMS and ISO certification effort

- **LMS approach** made ISO records readiness exercise a lab-wide initiative
  - Impetus for improved management of R&D records emerged from a multidisciplinary LMS team of scientists and engineers, with resulting buy-in from programmatic management
  - Records have the attention of R&D managers, from principal investigators through senior management
- **ISO approach** supports long-term success
  - The highly structured nature of ISO procedures has clarified roles and responsibilities for R&D records management
  - The recurring audits (every 6 months) that accompany ISO certification will maintain a focus on R&D records