Recap of Quality Management Systems Workshop

NRL
Science of Quality

SEALAB
SOUTH-EAST ASIA LAB NETWORK

Previous Workshop

- Held between 26 May & 04 June 2021
- 5 x half days
- Attended by nominated representatives from 5 Hospitals:
  - Battambang Provincial Hospital Laboratory
  - Kampong Chhang Provincial Hospital Laboratory
  - Kampong Cham Referral Hospital Laboratory
  - Takeo Provincial Hospital Laboratory
  - Cambodia-China Friendship Preah Kossamak Hospital

Reminder

Laboratory obligations:

- **Provide a quality* service to customers**
  - Carry out tests that are:
    - Accurate & reproducible
    - Reliable & consistent
    - Traceable
  - Provide results on time

*** Quality – "General standard of excellence"**
(Oxford Dictionary)

BUT things go wrong

Laboratory testing is often complex:

- Equipment

  and

- Materials (reagents etc)

  used in

- Processes

  by

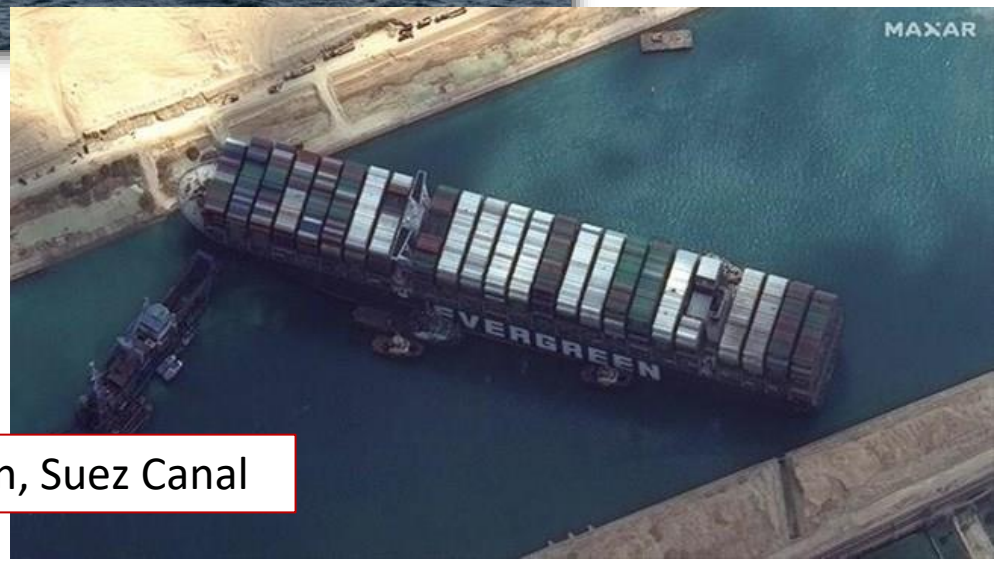
- People

Problems & errors can occur anywhere

Things go wrong

Costa Concordia

Challenger shuttle



Evergiven, Suez Canal

Chernobyl Reactors

Minimising the risk

- The **risks** of errors, problems, mistakes can be prevented or minimised by implementing a **quality management system (QMS)**

QMS = Risk Management strategy

What is a QMS?

A QMS:

What

- is an **organised** & **systematic approach** to planning, management & technical activities

Why

- is designed to achieve **customer satisfaction** & meet **specific requirements**

How

- helps you to **identify** & **control** all **variables** & **failure points** in planning, management & technical activities (manage risks)

Variables, failures, controls?

Variables & failure points?

- People
- Processes
- Equipment
- Materials
- Facilities
- etc

QMS activities that provide controls:

- Organisation, personnel & training
- Documentation control & records
- Procurement, specifications
- Monitoring – staff, equipment, materials
- Appropriate workflow & environment

Scope of a QMS

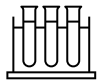
A QMS:

- applies to ALL **activities** that can affect the **quality of the end result**

- also includes a requirement for **review** & **continuous improvement**

Laboratory QMS

- A laboratory QMS ensures that:



- **Results** are accurate, consistent, traceable, reproducible, reliable & timely

- **Personnel** are trained, competent & safe

- **Processes** & procedures are documented

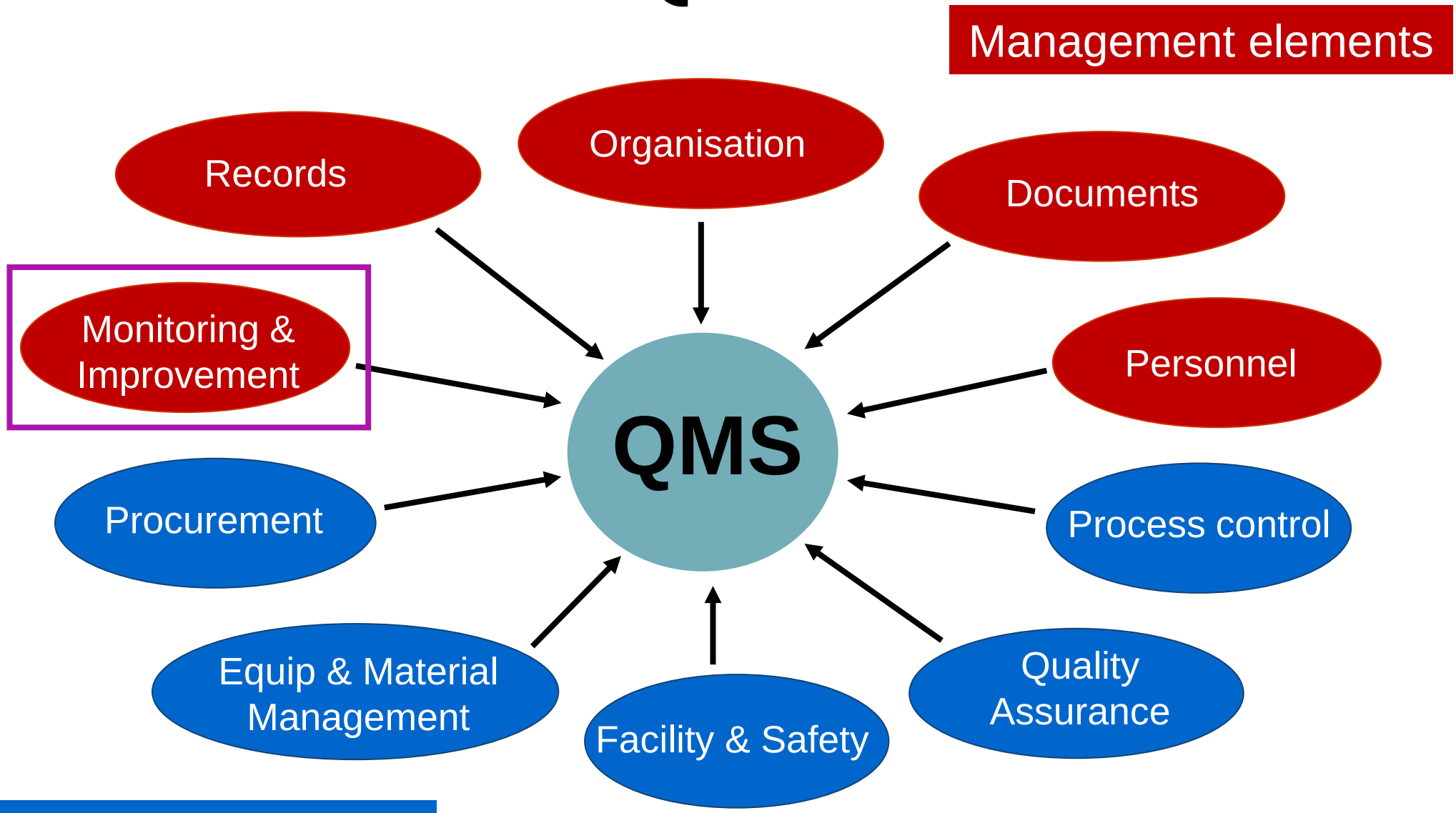
- **Records** are retained

- **Clients** are satisfied

- **Systems** continually improve

- **Costs** are kept low

Elements of a QMS



What activities are in a QMS?

Frequently asked questions:

- What processes should we include in a QMS?
- Are there any instructions?

We can use a STANDARD

Standards

Sets the benchmark for quality

- What is a standard?

"A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that **materials, products, processes & services** are fit for their purpose."

(International Standards Organization)

ISO International Organization for Standardization

NRL Science of Quality

Standards

- **Different standards for different organisations**
  - National, international, internal, external
  - Often voluntary, but can be mandatory

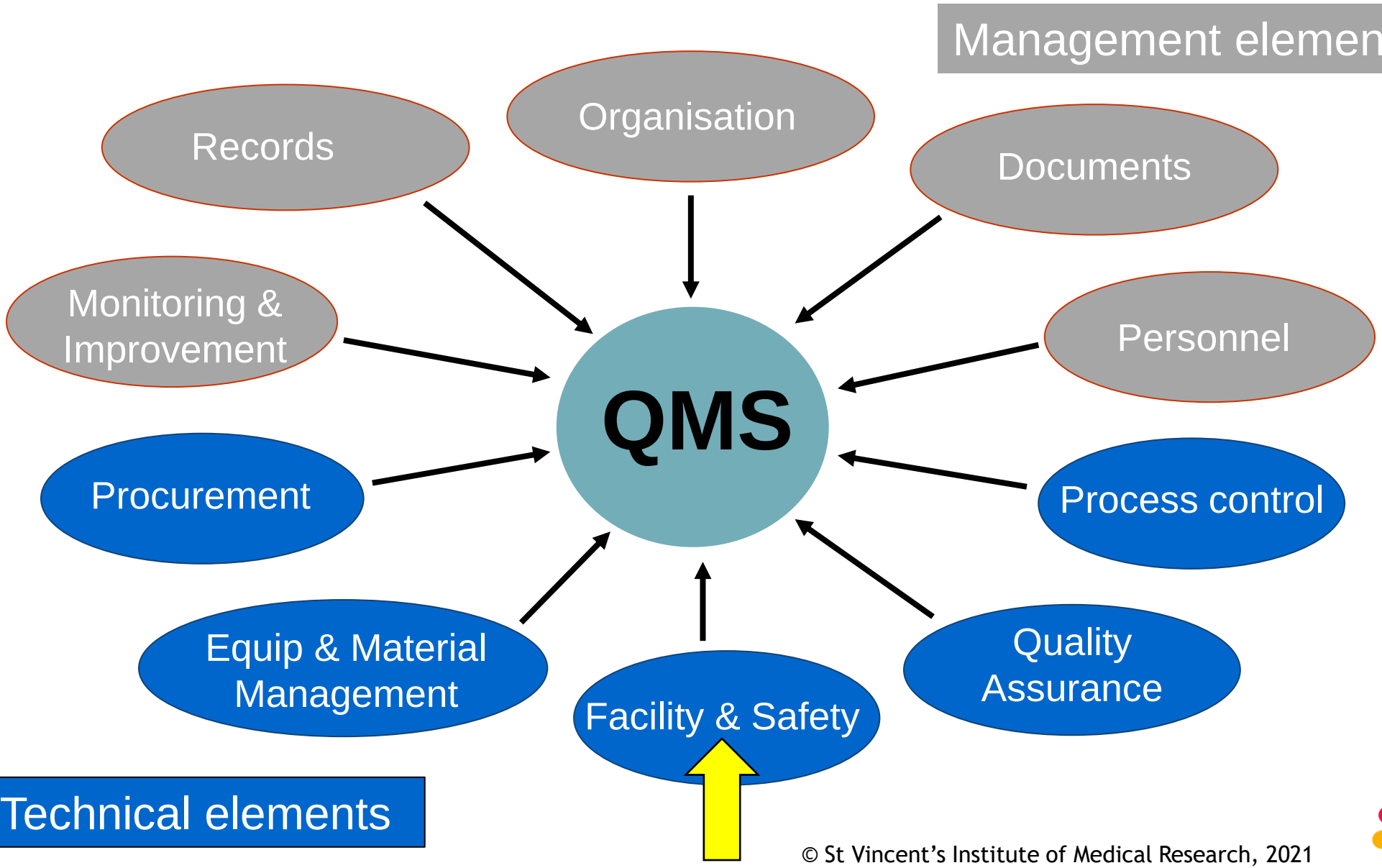
Voluntary
- Testing & calibration labs – ISO 17025:2005
- Quality management systems – ISO 9001:2015
- Medical laboratories – ISO 15189:2012

Mandatory
- Blood components – AABB, Council of Europe, GMP
- Fractionated plasma products – European Pharmacopoeia

Certification versus Accreditation

- **Certification** – the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements.
- **Accreditation** – the formal recognition by an independent body, that the organisation operates according to international standards, & has the competence to work to specific standards.

QMS technical elements



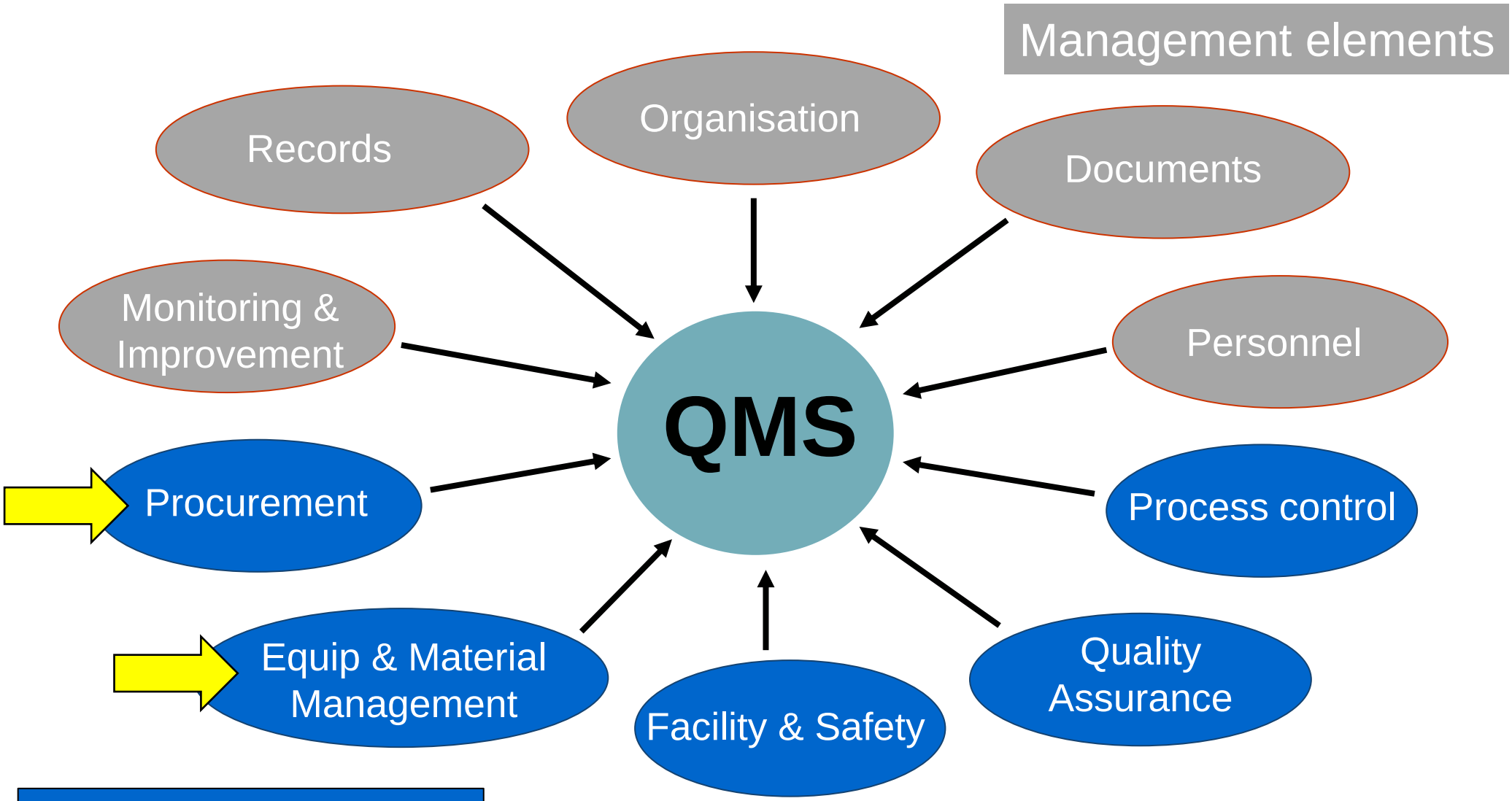
Facilities & safety

Requirements defined in ISO 15189

- Laboratories should:
  - be well designed - adequate working & storage space to permit a good, safe workflow
  - be maintained & cleaned regularly
  - have environments that meet the requirements of the activities conducted (temperature, humidity)
  - be supported by reliable services (electricity etc)
  - follow safety standards & requirements

Reduces the risk of errors, contamination & safety issues

QMS technical elements



Procurement

Requirements defined in ISO 15189

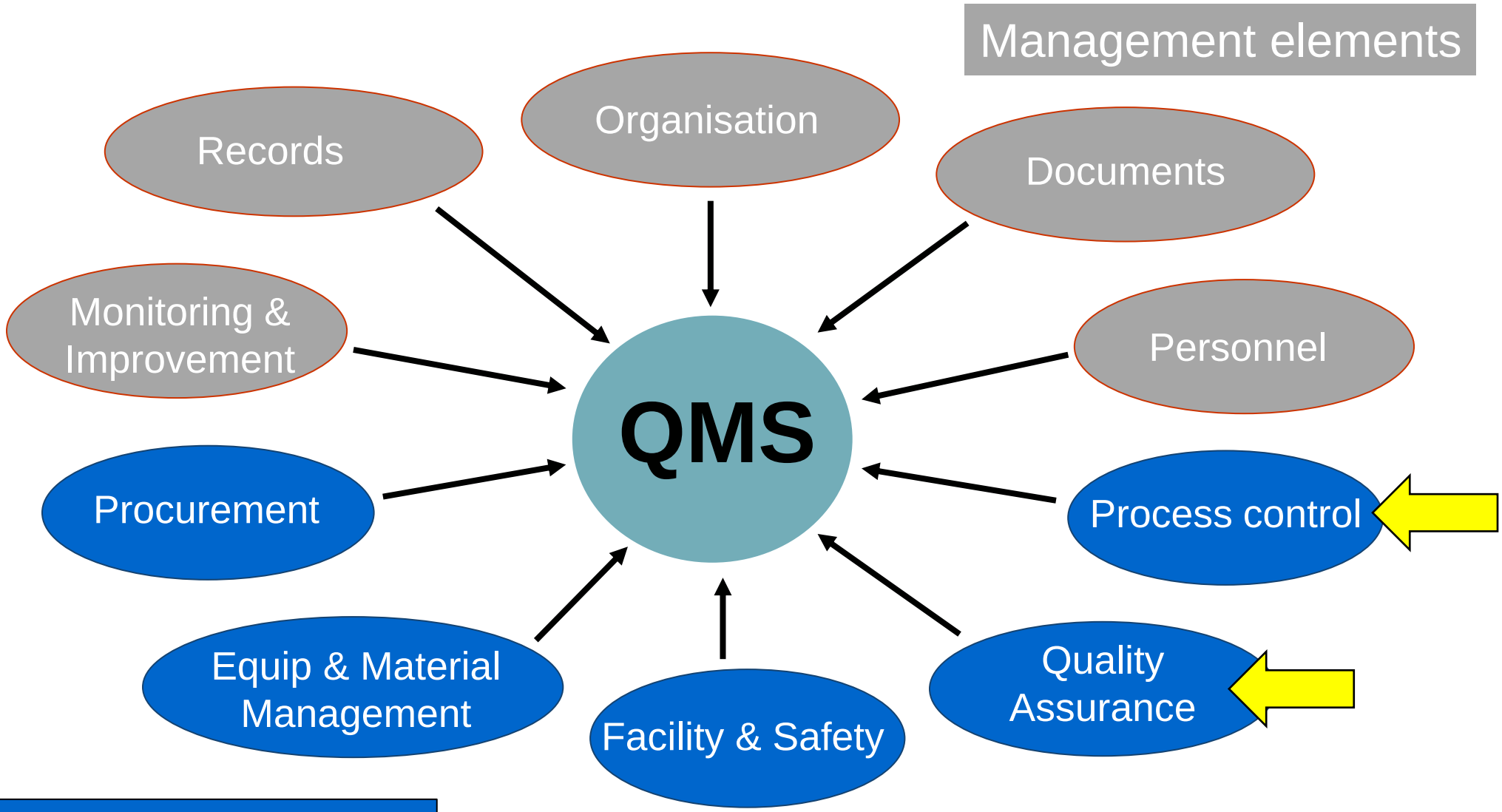
- A documented procurement process for critical services, materials & equipment is a QMS requirement:
  - Tenders, contracts
  - Preferred suppliers
  - Specifications for the services, materials & equipment
  - Monitoring of supplier performance
  - Inventory / stock control

Managing equipment & material

- **Equipment:**
  - Qualification & validation
  - Equipment ID register
  - Procedures for operation
  - Maintenance, service & calibration
  - Repair – requalification needed?
  - Monitoring – QC, EQAS etc
  - Investigation & reporting of adverse performance
  - Decommission when removed from service
- **Material:**
  - Validation, incoming inspection
  - Critical Material List
  - Procedures for use
  - Handling & storage (quarantine/rejected)
  - Inventory management
  - Monitoring – QC, EQAS etc
  - Investigation & reporting of defects or adverse performance
  - Label & quarantine when removed from use

Reduces the risks of using unsuitable equipment & material, & unreliable performance

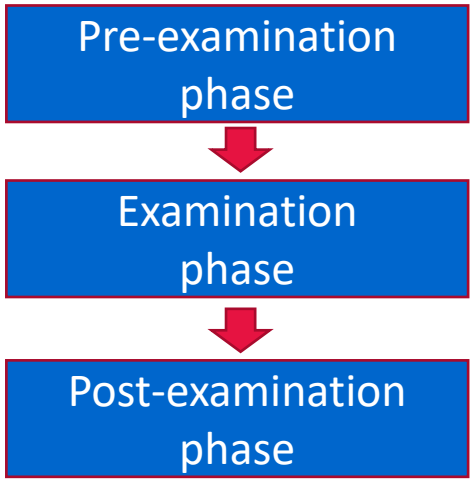
QMS technical elements



Process control & QA

Requirements defined in ISO 15189

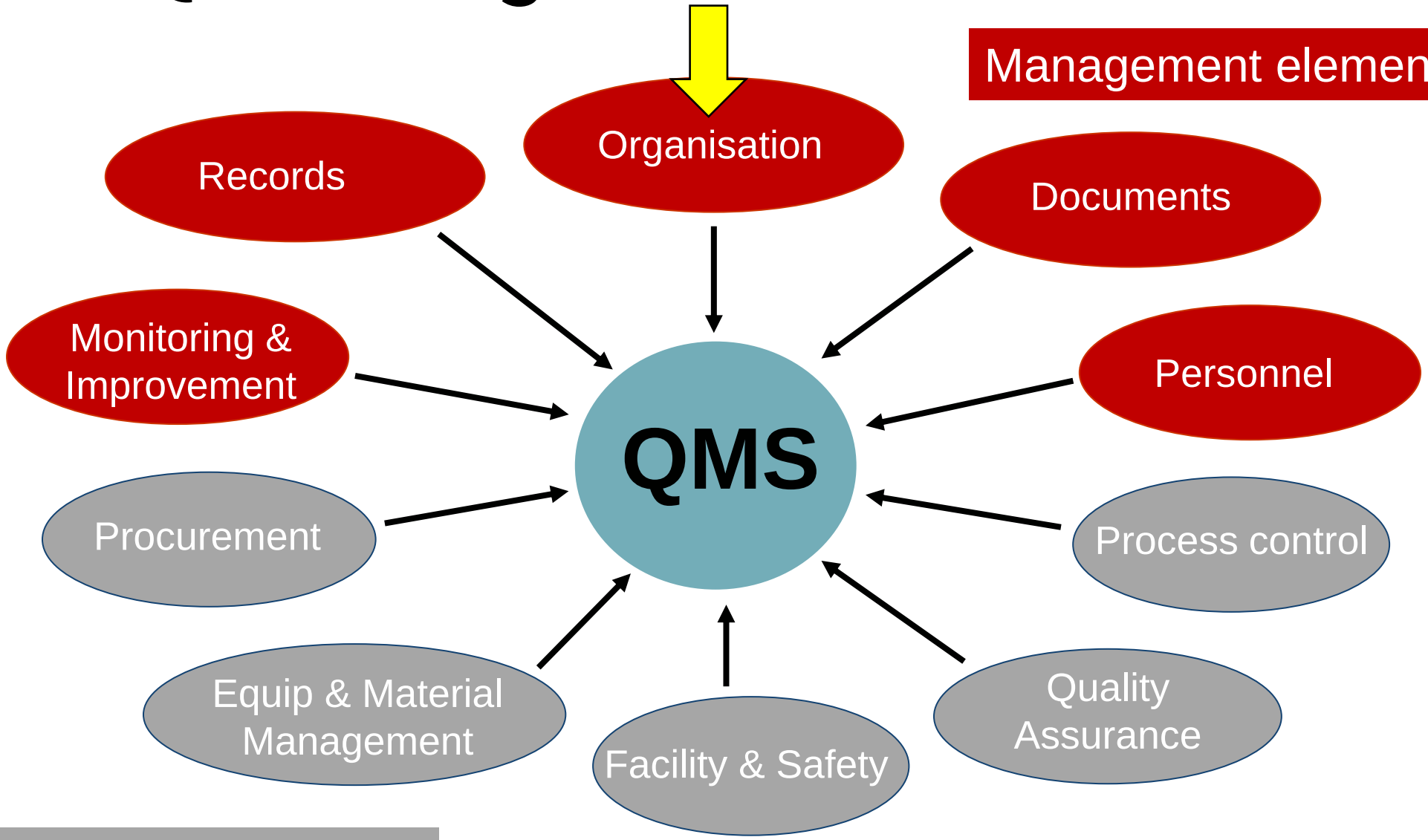
- Process control:
  - Validation of test methods used
  - Traceability
  - Critical control points



- Quality assurance:
  - External Quality Assessment Schemes (EQAS)
  - Quality Control programs (QC)
  - Accuracy & precision of test results

Reduces the risks of out of control processes or failing to identify trends & drifts

QMS management elements



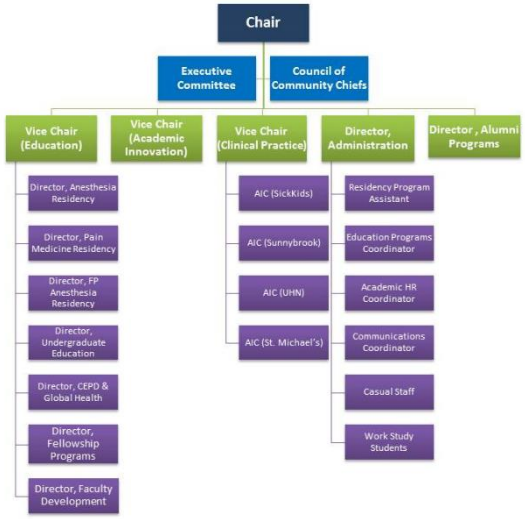
Organisation

Requirements defined in ISO 15189

- Commitment to the QMS – starts with top management's vision for quality:
- Quality Policy:
  - Statement of commitment to quality
- Quality Manual:
  - "Road map" describing the QMS
- Planning & implementation:
  - Clear objectives for quality
  - QMS implementation plan for agreed standard

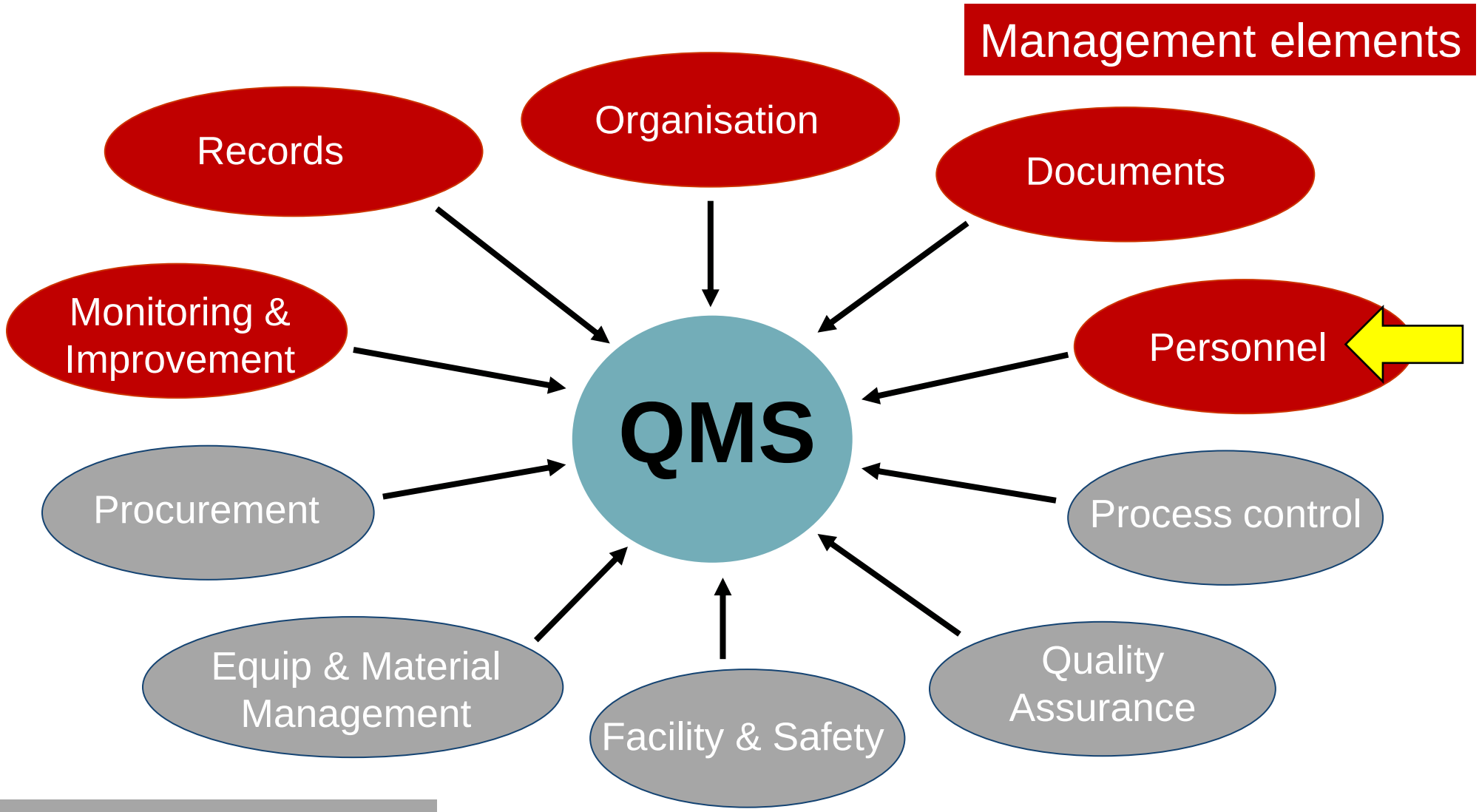
Organisation

- Organisational structure – needs to clearly define:
  - responsibilities
  - authorities
  - reporting lines
- Quality Manager appointed – appropriate authorities for QMS
- Effective communication lines



Reduces the risk of staff not knowing their roles & responsibilities, not performing their required tasks

QMS management elements



Personnel

Requirements defined in ISO 15189

- Establishing & maintaining an effective QMS relies upon people
- For this reason there should be sufficient, trained & competent personnel to carry out all tasks according to documented procedures

Personnel

Each staff member needs :

- to be appropriately qualified for his/her position → RECRUITMENT
- to know what his/her responsibilities are
- to know who is their supervisor

→ POSITION DESCRIPTION

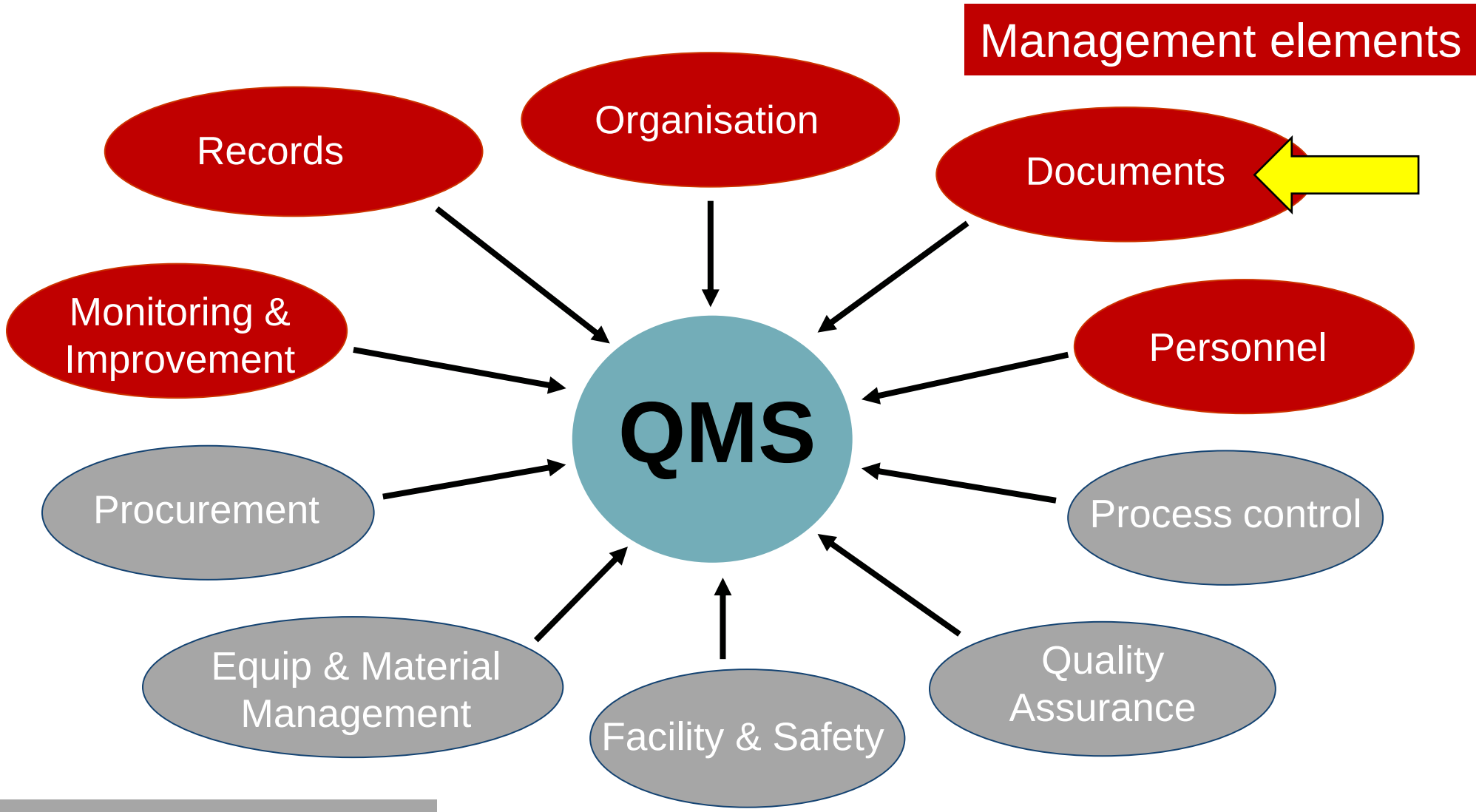
- to be adequately trained → TRAINING PROCEDURES
- to be shown to be competent → COMPETENCY ASSESSMENT
- feedback on performance → PERFORMANCE REVIEW

Personnel

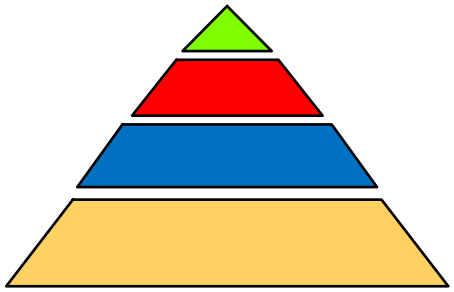
Key responsibilities:

- **Laboratory director:** resource QMS, action plan
- **Laboratory management:** set vision, drive QMS
- **Management:** communication & monitoring
- **Quality Manager:** responsibility & authority for establishing, implementing & maintaining QMS processes

QMS management elements



Documentation



- Importance to a laboratory:

Policies, QM	• Describes commitments
SOP, WI,	• Describes how activities are to be performed
Plans for changes & improvements	• Sets out plans for new activities or changes to activities
Specifications, standards	• Describes requirements that need to be met for equipment, materials, processes & people
Checklists, forms → records	• Provides evidence that quality has been achieved & all requirements met (traceability)

Documentation

Requirements defined in ISO 15189

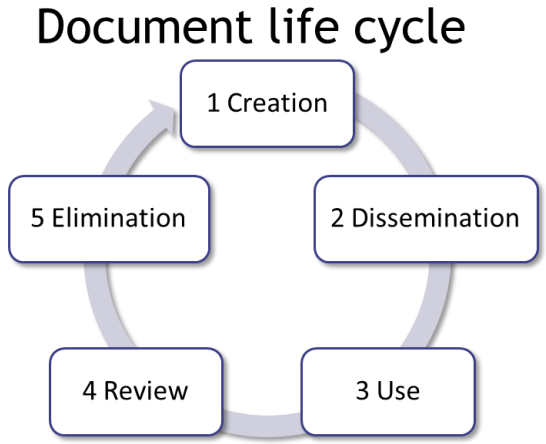
- Quality Manual:
  - Critical document
  - Defines laboratory's commitment to quality
  - Provides a "road map" for the QMS
  - Requirements for a quality manual are set out in ISO 15189
  - Accessible to all staff, & read by all staff

Documentation

- **Procedures, SOPs, WIs:**
  - Critical documents, must be written in a **clear, consistent** way using a **standard format** so that:
    - staff can **easily understand them**
    - they can be used effectively for staff **training**
- **Process mapping useful planning tool for SOPs:**
  - Identifies critical control points
  - identifies gaps & overlaps, redundancy, wastage etc

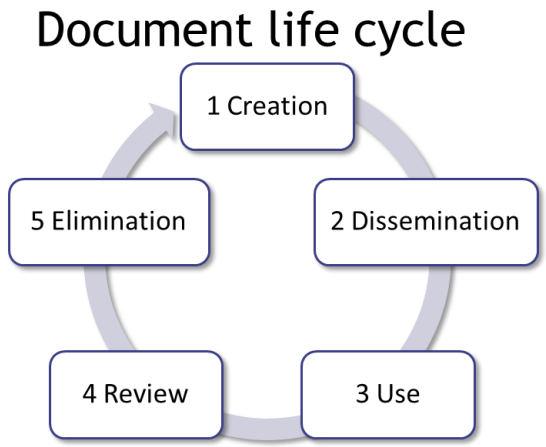
Reduces the risks of staff misunderstanding procedures, poor training & inefficient processes

Documentation



- Document control system sets out rules for managing documents
  - **Creation –**
    - owners, authors, reviewers, approvers
    - standard format, identification & versioning
  - **Dissemination -** (distribution) to relevant areas
  - **Use –** unauthorised copies & amendments
  - **Review –** at set timeframe or when changes occur
  - **Elimination -** (removal) from use when outdated – one master copy archived of each version

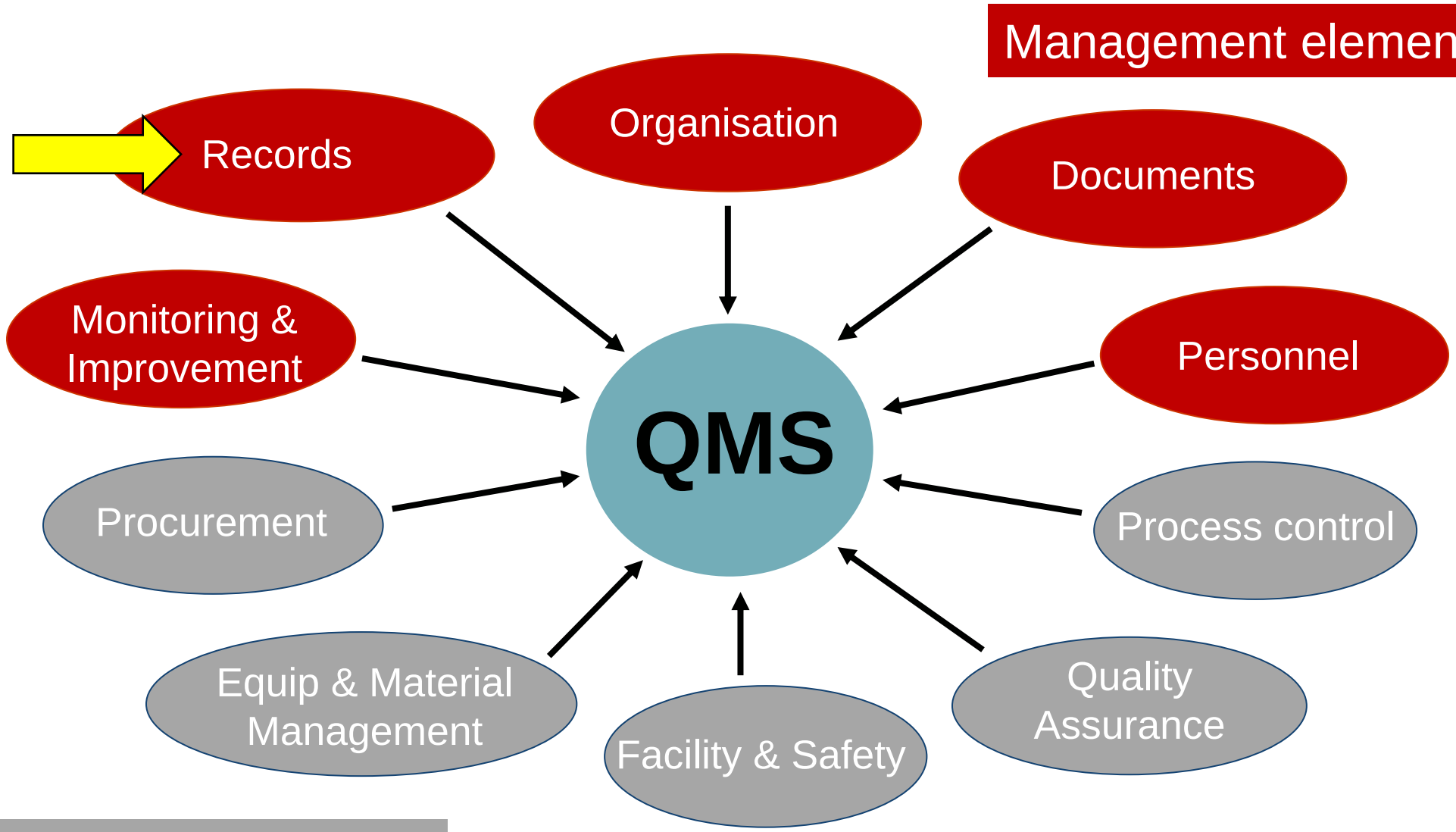
Documentation



- Document control ensures documents are:
  - consistently formatted
  - always up-to-date (current)
  - at the required location
  - not changed unless authorised
  - traceable to which version was being used at which time

Reduces the risk of using outdated, incorrect procedures

QMS management elements



Records

Requirements defined in ISO 15189

- Evidence that
  - QMS is functioning effectively
  - organisational quality requirements have been met
- Provide traceability
- Must be legible (changes made correctly)
- Stored securely
- Define retention time (legal requirement where applicable)

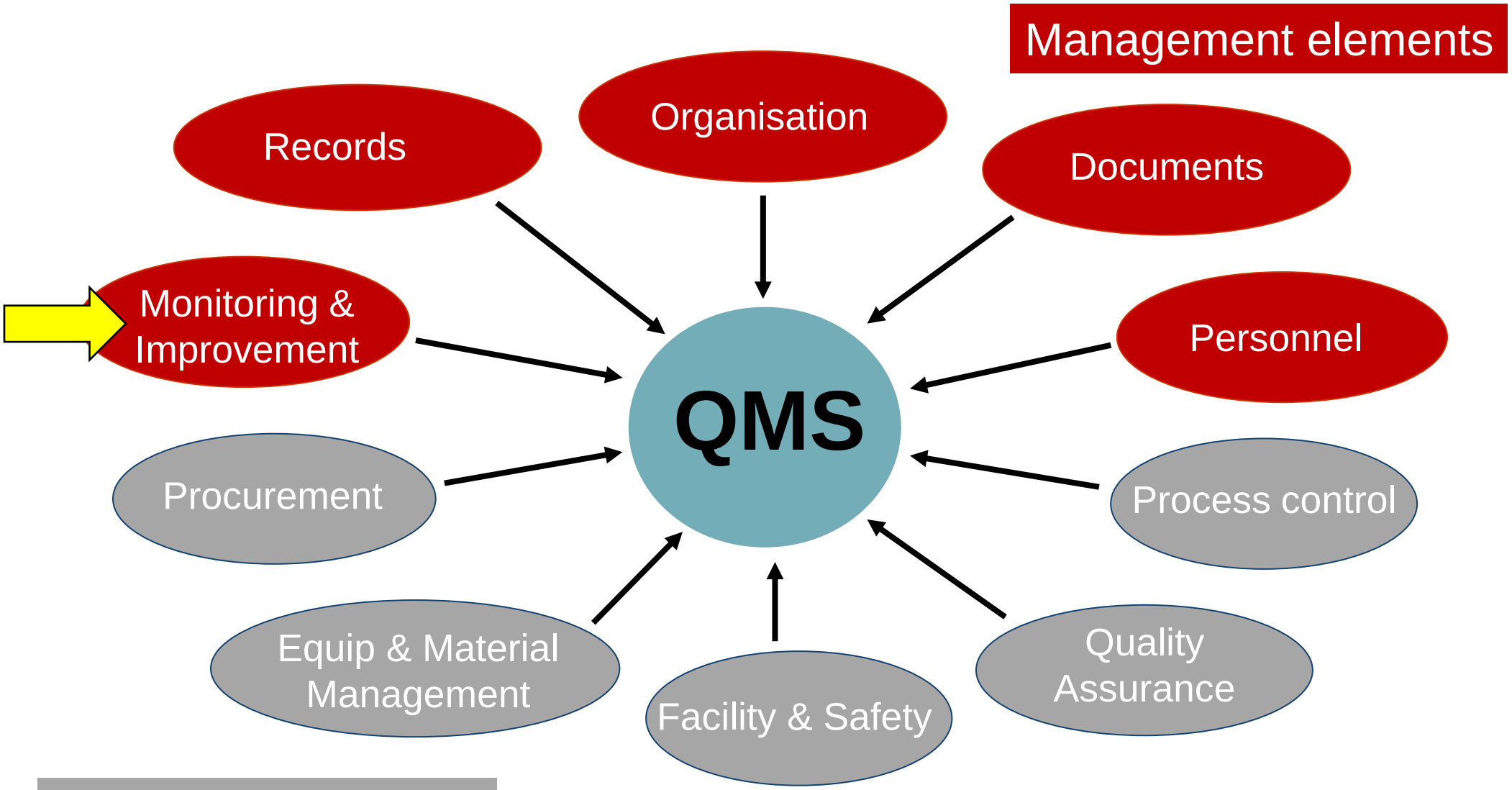
Records

- Investigation of:
  - Problems, errors
  - Transfusion reactions
- Material recalls

- Traceability:
  - **Who** – name, position, signature/initial, activity, training
  - **When** – date, time
  - **Where** – name of department/location
  - **What** – activity, which step, equipment, materials, lot numbers, critical parameters
  - **How** – SOP, checklists
  - **Outcomes** – QC & results review, checks, further action required

Reduces the risk of being unable to investigate problems, errors etc effectively

QMS management elements



Monitoring

Requirements defined in ISO 15189

- Monitoring is a key **QMS requirement** & a driver for **continuous improvement**:
  - Effectiveness of QMS activities eg:
    - on-time review of documents
    - internal audits on schedule
  - Performance eg:
    - suppliers
    - equipment & materials
    - processes
    - staff performance

How?
- Internal audits
- Management Review
- EQAS & QC
- Customer feedback etc

Against what?
- targets, specifications, quality indicators

Where reviewed?
- at Quality Meetings or as part of Management Review

Improvement

- **Continuous improvement is key requirement of ISO 15189:**

Reactive drivers:

- Investigations of:
  - Errors, process failures
  - Audit nonconformities
  - EQAS or QC failures
  - Complaints
- Corrective & preventive action systems

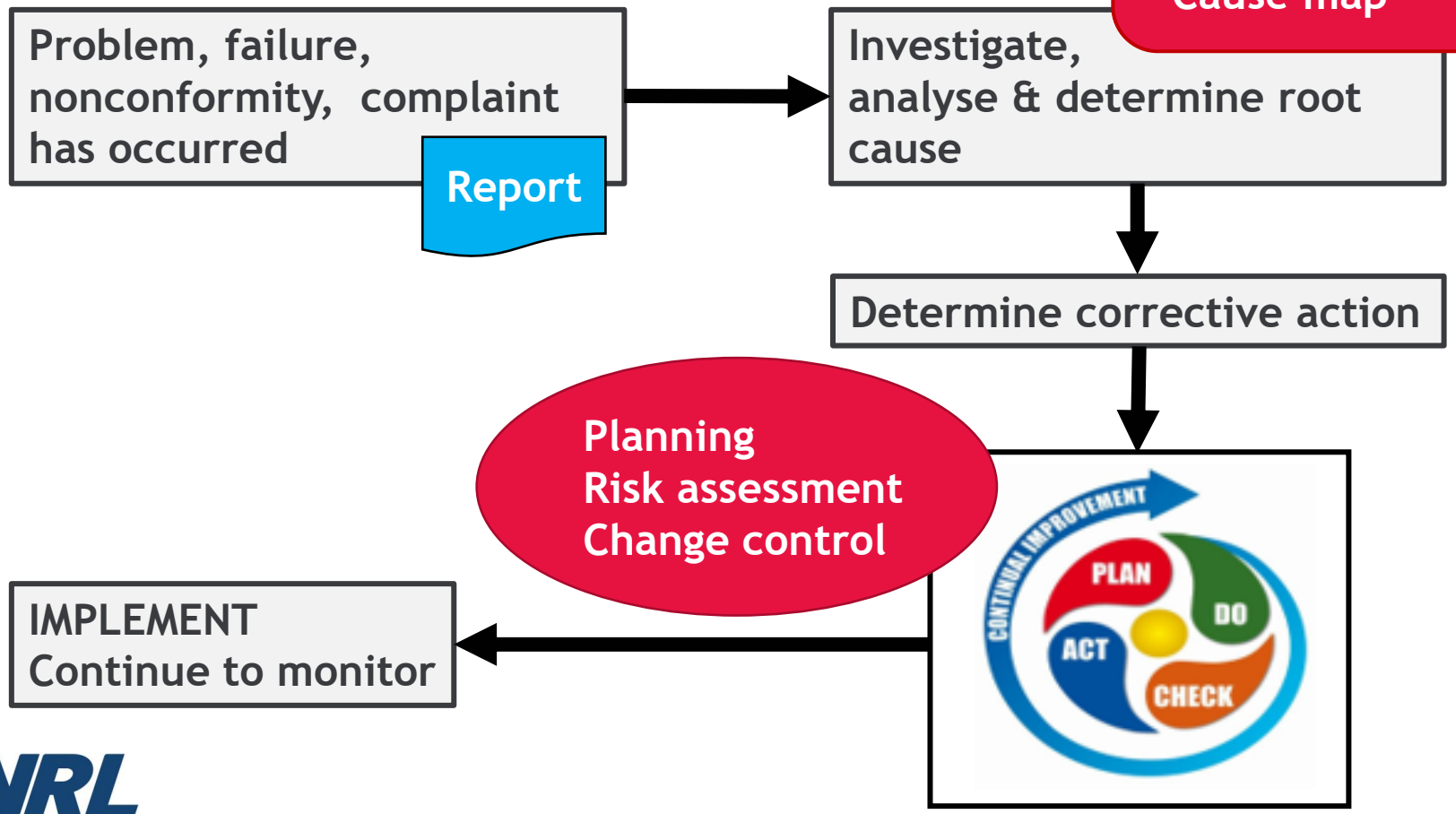
Proactive drivers:

- Performance monitoring
- Internal & external audits
- Customer feedback
- Process mapping
- Dedicated improvement activities

Improvement

- Reactive drivers:

Root Cause Analysis (RCA):
- 5 whys,
- Fishbone,
- Cause map



Improvement

- Proactive drivers:
  - Improvement opportunities identified during:
    - audits or from customer feedback
    - review & analysis of activities
  - Tools for improvement are available:
    - Model for Improvement
    - The 72 change concepts
    - Process mapping with Failure Mode Effect Analysis (FMEA)

Simple & easy to use

Change Control

- QMS implementation
- New processes, new documentation
- Revising processes & documentation
- Improvements

- Result in CHANGES
- Must be controlled
  - Risk assessment
  - Planning
  - Monitoring

Reduces the risks of implementation failures & adverse flow-on impacts

Implementation of QMS

Frequently asked questions:

- How do we implement a QMS? Instructions?
- Where do we start?
  - LQSI: WHO laboratory stepwise implementation tool:
    - LQSI phases
    - LQSI Quality System Essentials
    - LQSI Checklist
    - https://extranet.who.int/lqsi/
  - WHO Laboratory Assessment Tool
  - SMLTA: Strengthening Laboratory Management toward Accreditation
  - WHO LQMS Handbook

Summary of recapped topics

- Definition of a QMS & use as risk management strategy
- Standards & certification vs accreditation
- Elements & scope of a QMS eg ISO 15189
- Monitoring & improvement
- Tools for:
  - Implementing a QMS
  - Continuous improvement (eg process mapping, PDCA)
  - Managing change (PDCA)

THANK YOU!