Effective Quality Management Systems Workshop

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House Keeping

- 4 Hours Duration with 15 Minutes Break in between
- 2 hours Presentation – Followed by Debate & Discussions
- No Smoking
- No Mobiles
- Emergency Situations
- No Photographs – *only at the end*
- No Certificates Issued

Background & Forward

- Education
- Work Experience
- Professional Memberships
- Management Systems Experience
- Why this Workshop?
- Listen very carefully and think
- **You do not have to agree,** *but use logic in putting your point forward------*

Topics Covered

- Effective understanding of concepts of "Quality" & "Quality Management Systems"
- Role, structure, and purposes of ISO standards
- Difference between Quality Management Systems & ISO 9001 standard
- Effective practices of quality management systems implementation
- Misunderstandings of what quality management systems are about
- Impact of "Certification" and "Accreditation" mal-practices

0. Breaking the Mould!!

What do you think about following statements? Do you Agree or Not?

"Quality" is not about Organisations Performance

"Quality" is simply about complying with procedures

"Quality" is only relevant for manufacturing companies

"Quality" is about *only* meeting ISO 9001 requirements

"Quality" can be achieved by one person or one department and without the active engagement and involvement of Top / Senior management

"Quality" is the same for every organisation

"Quality" is simply about achieving Certification

"Quality" is only relevant for profit-making organisations

"Quality" is just about creating documentation

What is "Quality"?

- Different people had viewed "quality" differently.
  - Meeting specifications?
  - Fitness for purpose?
  - Creating documentation?
  - Conforming to set documentation (procedures)?
  - Achieving certification against ISO 9001 standard?
  - What do you think??
- Concept of "Quality" existed for many years.
- Developed over time especially over last 100 years.
- Need to standardise understanding of the concept.

What is "Quality" really about?

- **Quality is not *just* about:**
  - Creating documentation
  - Following procedures
  - Receiving certificates

- **Quality is *definitely* about:**
  - Effective & efficient outcomes (outputs)
  - Stakeholders satisfaction
  - Safe operations & products
  - Minimising waste, errors & rework

1. Development of concept of *Quality*

Evolution of Concept of Quality

2000's-Now

1980's-1990's

1950's-1970's

1920's-1950's

1900's-1920's

TQM

Quality Control

Quality Assurance

Quality Management Systems

Inspections

Meeting Specifications
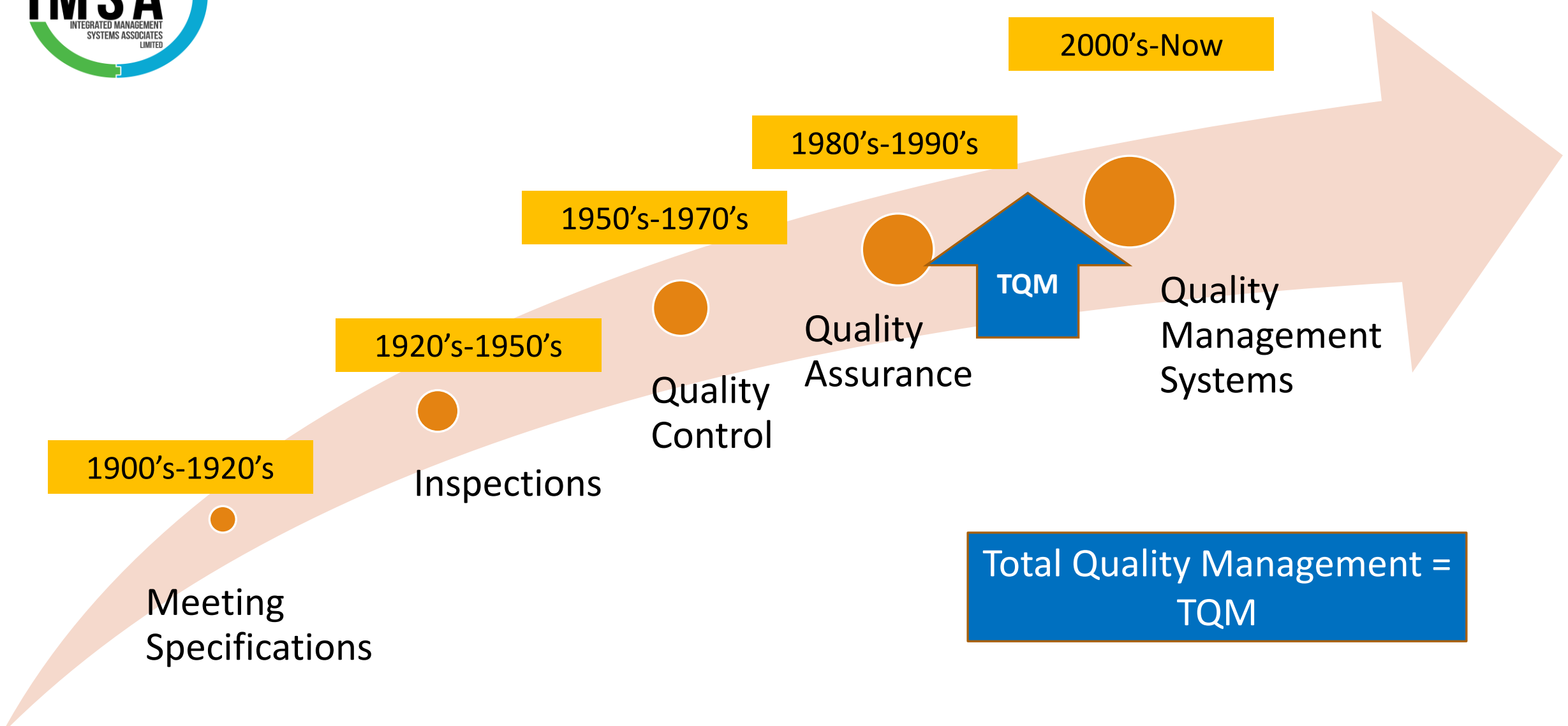
Total Quality Management = TQM

Quality Control
"Part of **quality management** focused on fulfilling quality requirements."

Quality Assurance
"Part of **quality management** focused on providing confidence that the quality requirements will be fulfilled."

Quality Management
"Coordinated activities to direct and control an organisation with regard to quality."

Quality Management

Quality
Degree to which a set of inherent <u>characteristics</u> fulfils <u>requirements</u>.

Characteristic
Distinguishing feature.

Requirement
Need or other expectation that is stated, generally implied or obligatory.

Customer / Stakeholders

Organisation

2. What is a Quality Management System?

Management Systems Concepts
(ISO 9000:2015)

System
Set of <u>interrelated</u> or <u>interacting</u> elements (**processes**)

Management System

Set of interrelated or interacting elements of an organisation to establish <u>policies</u> and <u>objectives</u> and <u>processes</u> to <u>achieve</u> those objectives

XXX* Management System
Part of management system with regard to XXX
* *where XXX could be Quality, Environmental, Occupational Health & Safety,* **Process Safety**, Energy *and even better "**Integrated**".*

Quality Management Principles (Foundations)
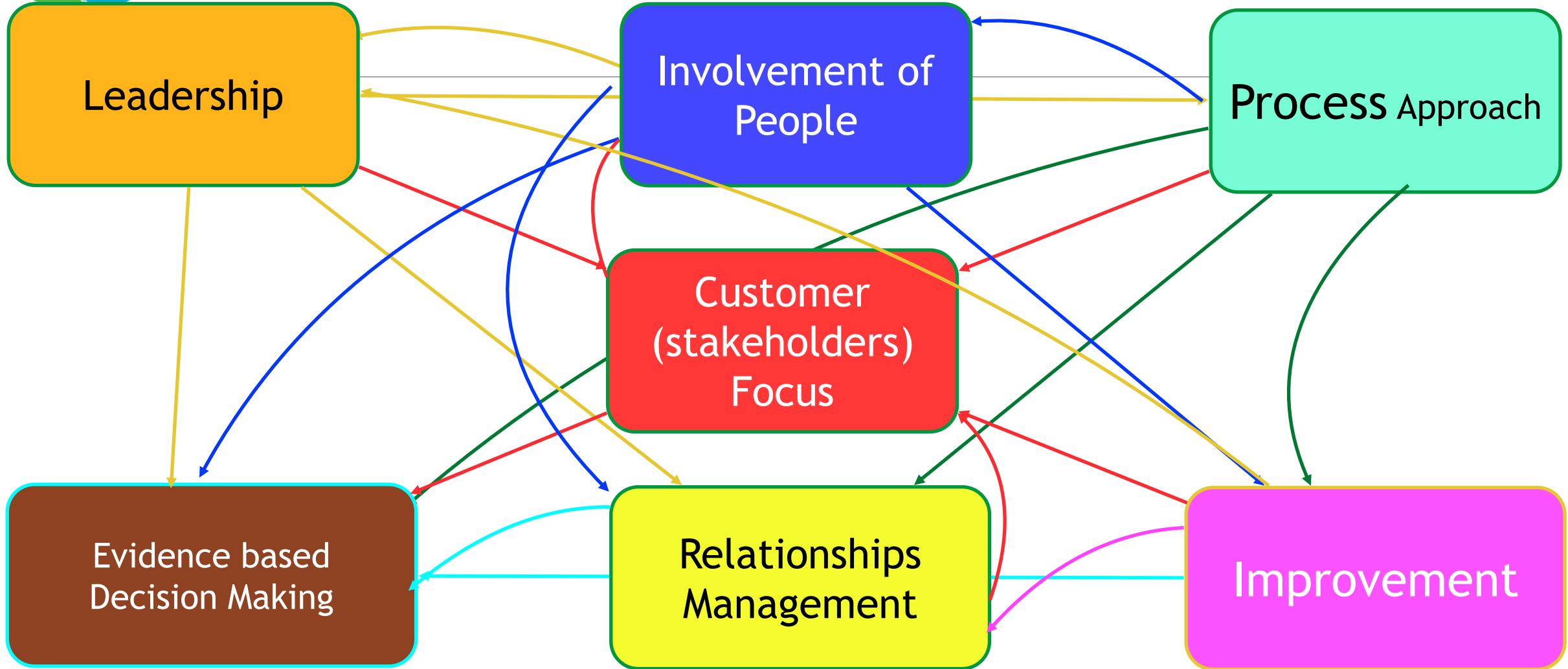
- A quality management system should be dynamic; evolving over time through concept of continual improvement.

- Every organisation has its own operational activities; these need to be planned and managed in a systemic way.

- Developing quality management systems enables organisation to focus on activities that really add value to it and its stakeholders.

- Such a system provides framework for planning, executing, monitoring, reviewing and improving performance.

What is a standard?

"Document, established by **consensus** and approved by a recognized body, that provides, for common and repeated use, information, requirements, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context."

- ISO International Standards designed to help ensure products and services are safe, reliable and of required "quality".
- Should be considered as strategic tools to reduce costs by minimizing waste.
- Should enable access to new markets and facilitate free and fair global trade.

Standards should be seen as providing a "Model" to follow or a starting point to arrive at what is needed.

ISO 9001 ⟶ *effective* **Quality Management System**

انظمة الادارة مقابل مواصفات انظمة الادارة

ISO 9000

ISO 9001

ISO 9002

ISO 9004

العديد من مواصفات الايزو ذات العلاقة

| مواصفات الايزو متطلبات و ارشادات | متطلبات الاطراف المهتمة -احتياجات و **توقعات** | المتطلبات التنظيمية و القانونية | متطلبات خصوصية الاعمال |

Context of the Organisation

المواصفات هي ذات طبيعة عامة بينما نظام الادارة هو مخصص للمنظمة المعنية

ليس فقط متطلبات المواصفة

نظام ادارة الجودة (QMS)

اهداف نظام ادارة الجودة هي ارضاء الاطراف المهتمة و تحقيق الاهداف الاستراتيجية للمنظمة المعنية

ما هي المواصفة **باللغة العربية**
المواصفة هي ببساطة نهج متفق عليه ;و ليس من الضروري جيد!
ولا تشتمل كل مواصفة على متطلبات **معلومات ا و متطلبات ا و ارشادات**

نظام ادارة الجودة ≠ المواصفات
نظام ادارة الجودة = المواصفات++++

ان نظام ادارة الجودة ليس مقتصرا على نظام التوثيق

ISO 9000:2015
Quality Management Systems - Fundamentals and Vocabulary

ISO 9001:2015
Quality Management Systems – Requirements (shall)

ISO/TS 9002: 2016
Quality Management Systems – Guidelines (should) for the application of ISO 9001:2015

ISO 9004:2018
Quality Management Systems – Quality of an Organisation – Guidance (should) to achieve sustained success
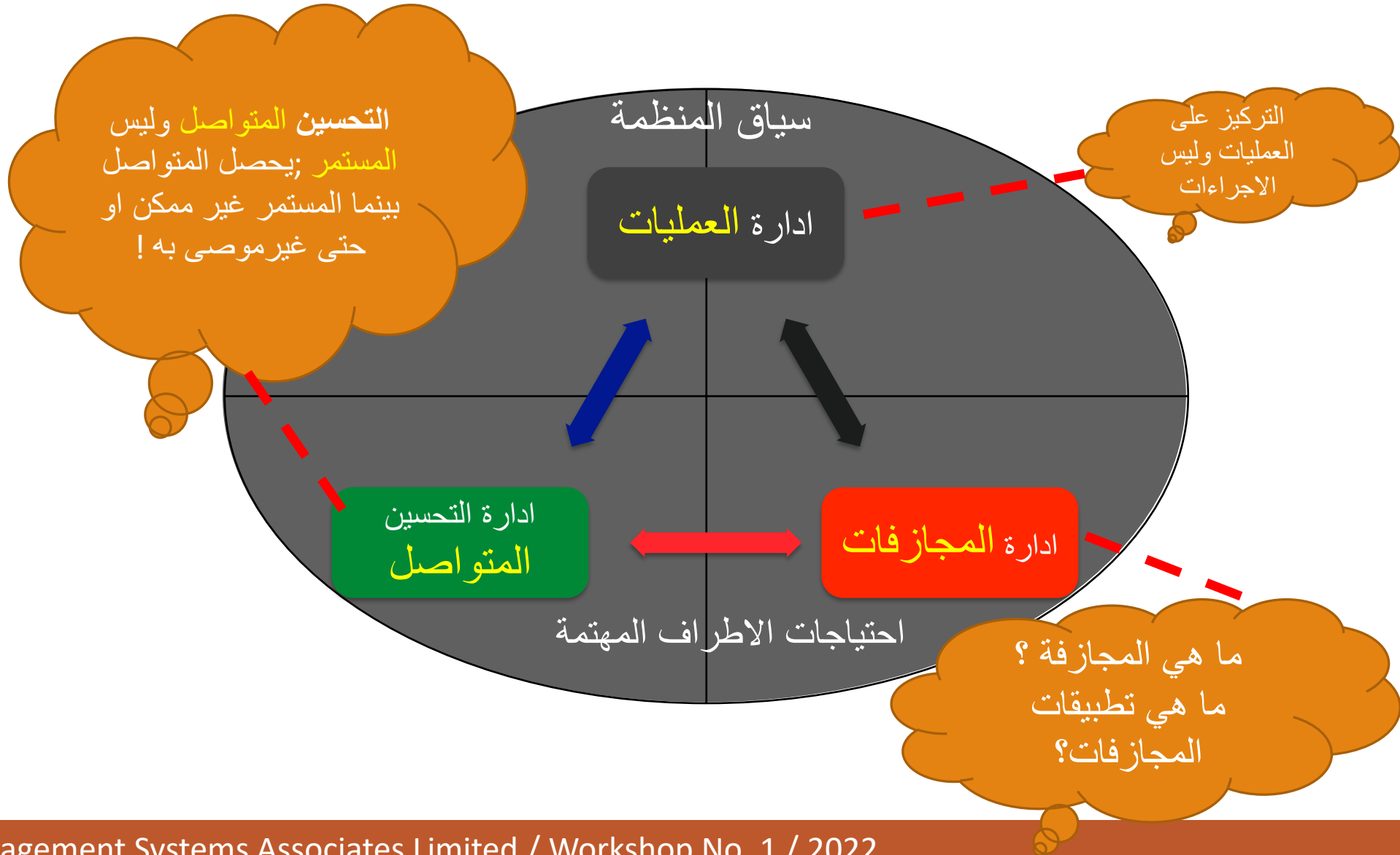
I hope you can appreciate the difference between the two approaches.
Which approach generates better results?

Procedure Approach

Process Approach

Input requirements

Process linkage across departments

Effective and efficient outputs
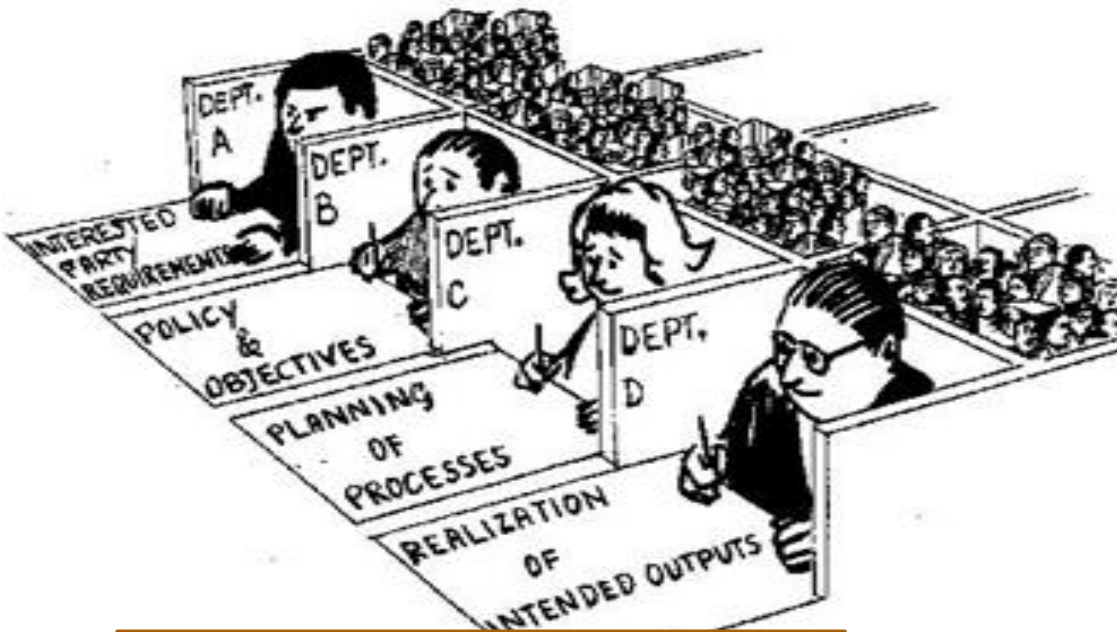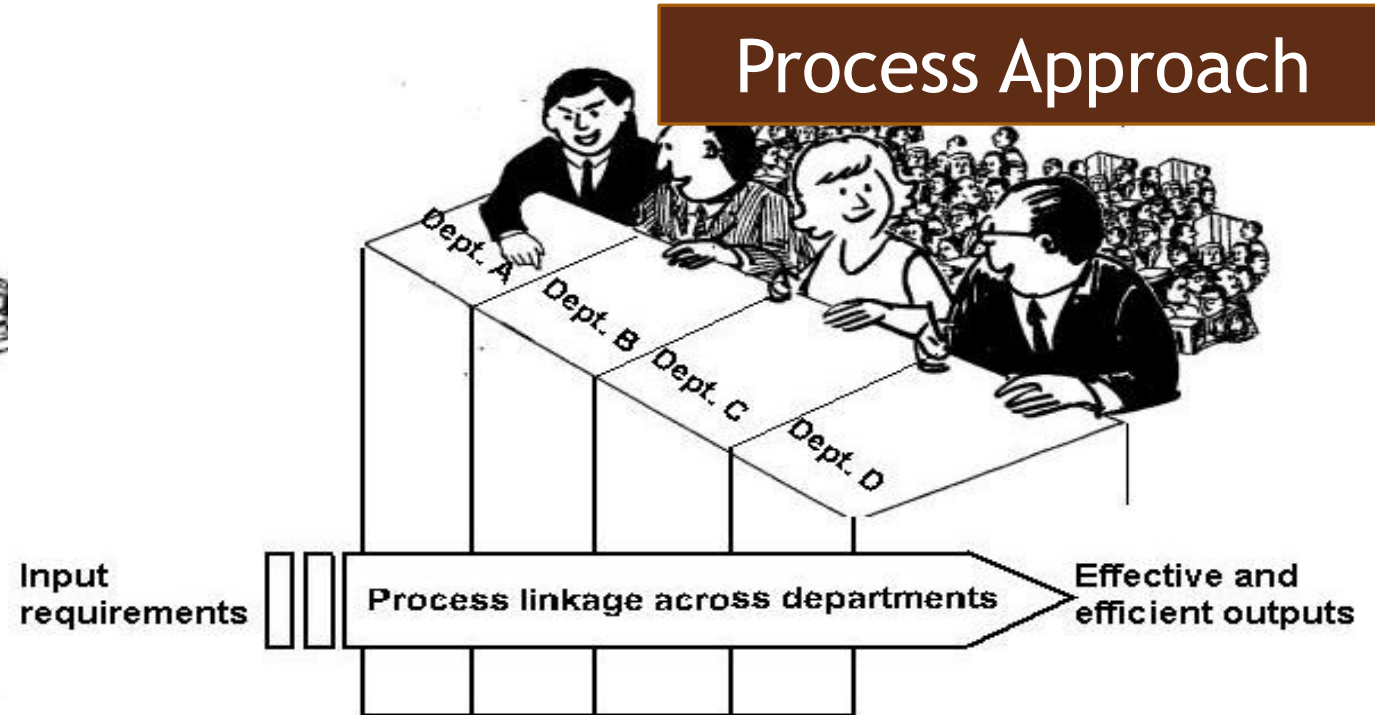
Quality Management System

Organisations Strategic Objectives

Interested Parities (Customers) Requirements

Process A

Process B

Process C

Process D

Process E

Process F

Challenge – Managing Interfaces between Processes
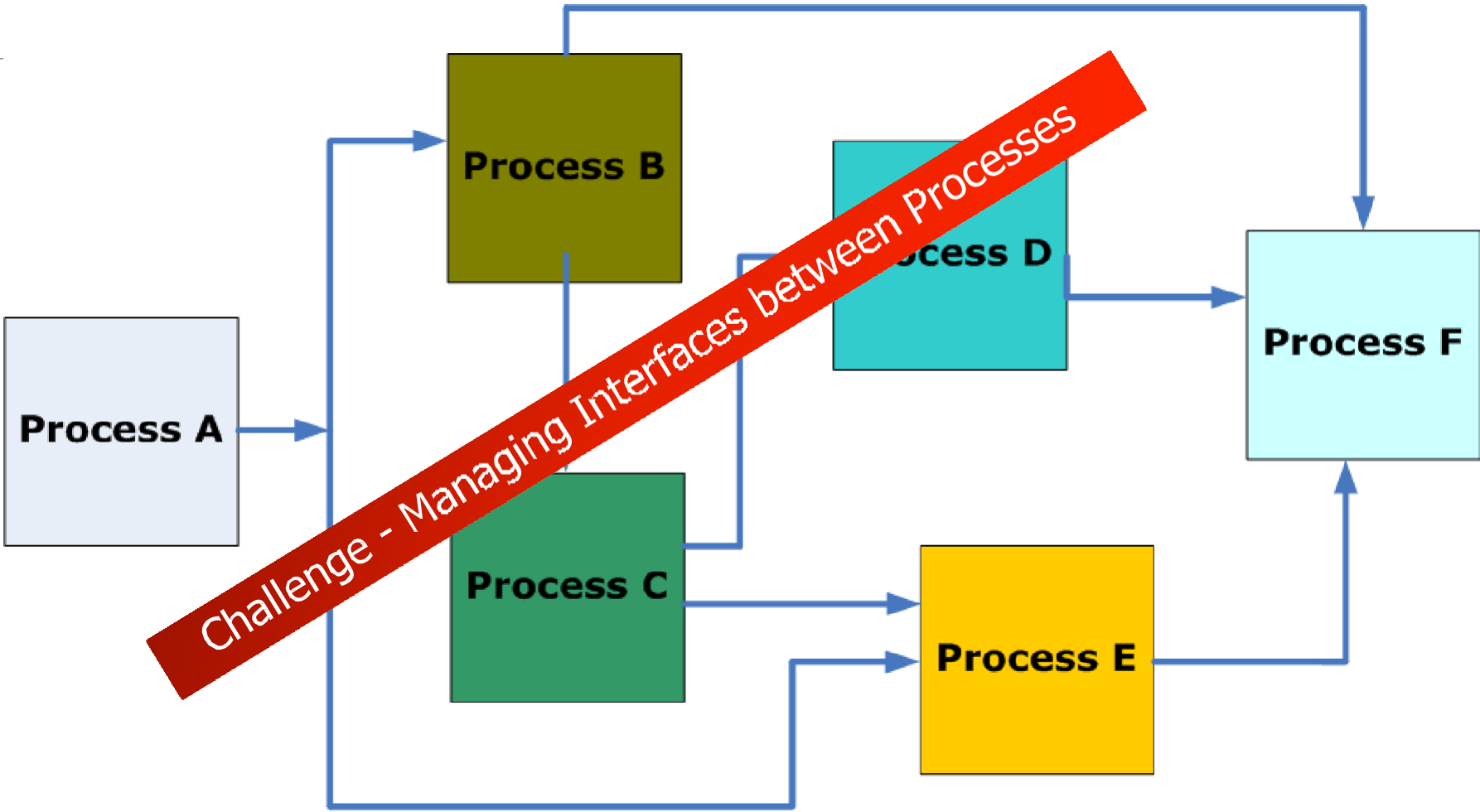
Interested Parities (Customers) Satisfaction

Process Risk Profile
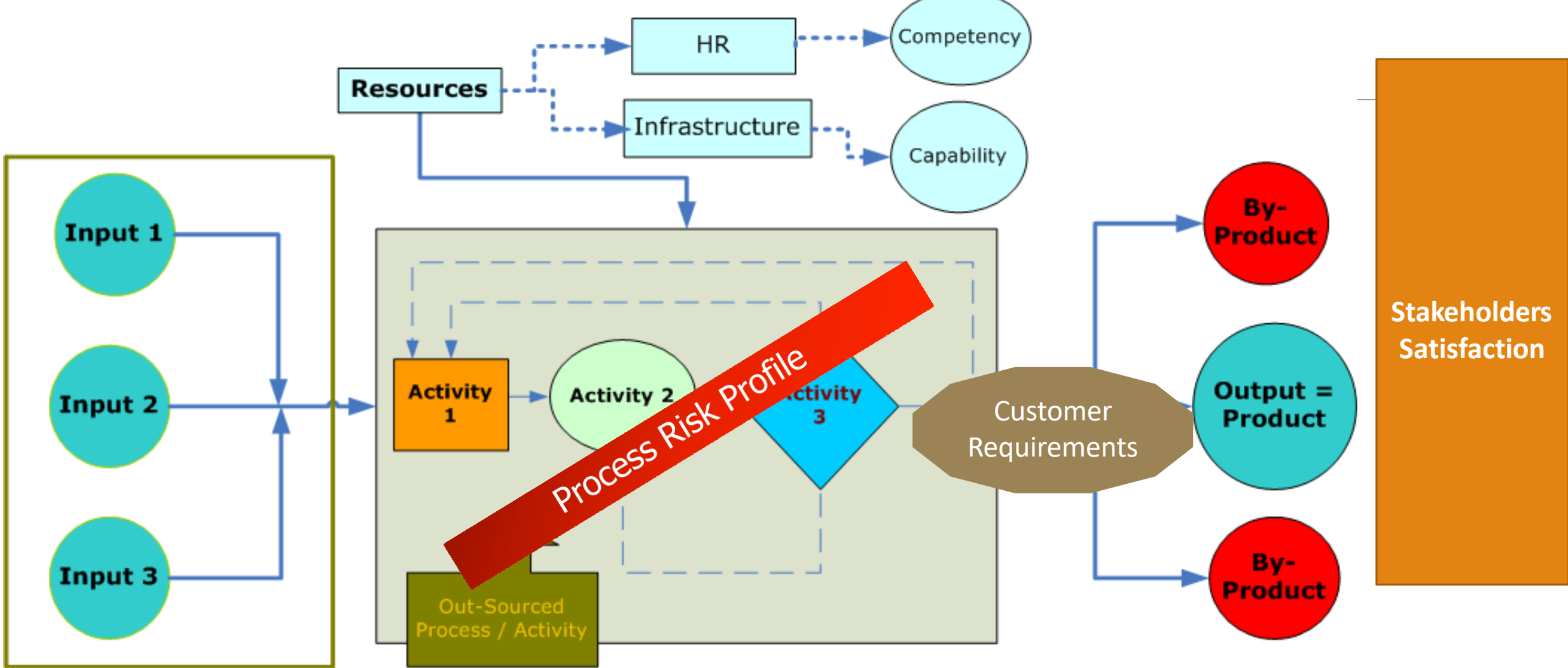
Risk

- Risk is the effect of uncertainty (negative or positive)

- Process risk profile is description of any set of risks associated with the process & its outputs

- Risk source is an element which alone or in combination, tangible or intangible, has the intrinsic potential to give rise to risk

- Risk could be of different nature (quality, process & product safety, occupational health & safety, environmental, security, etc)

Risk Management Process
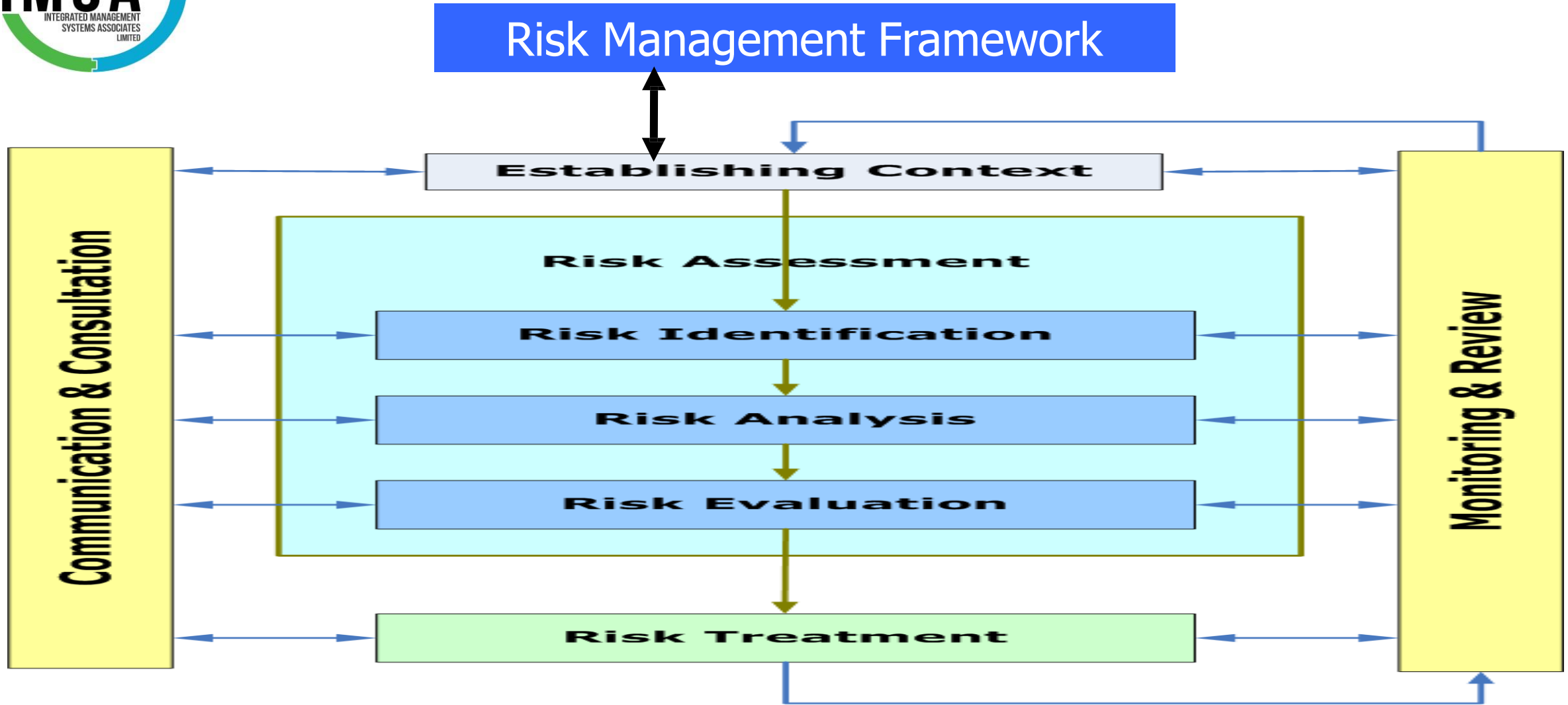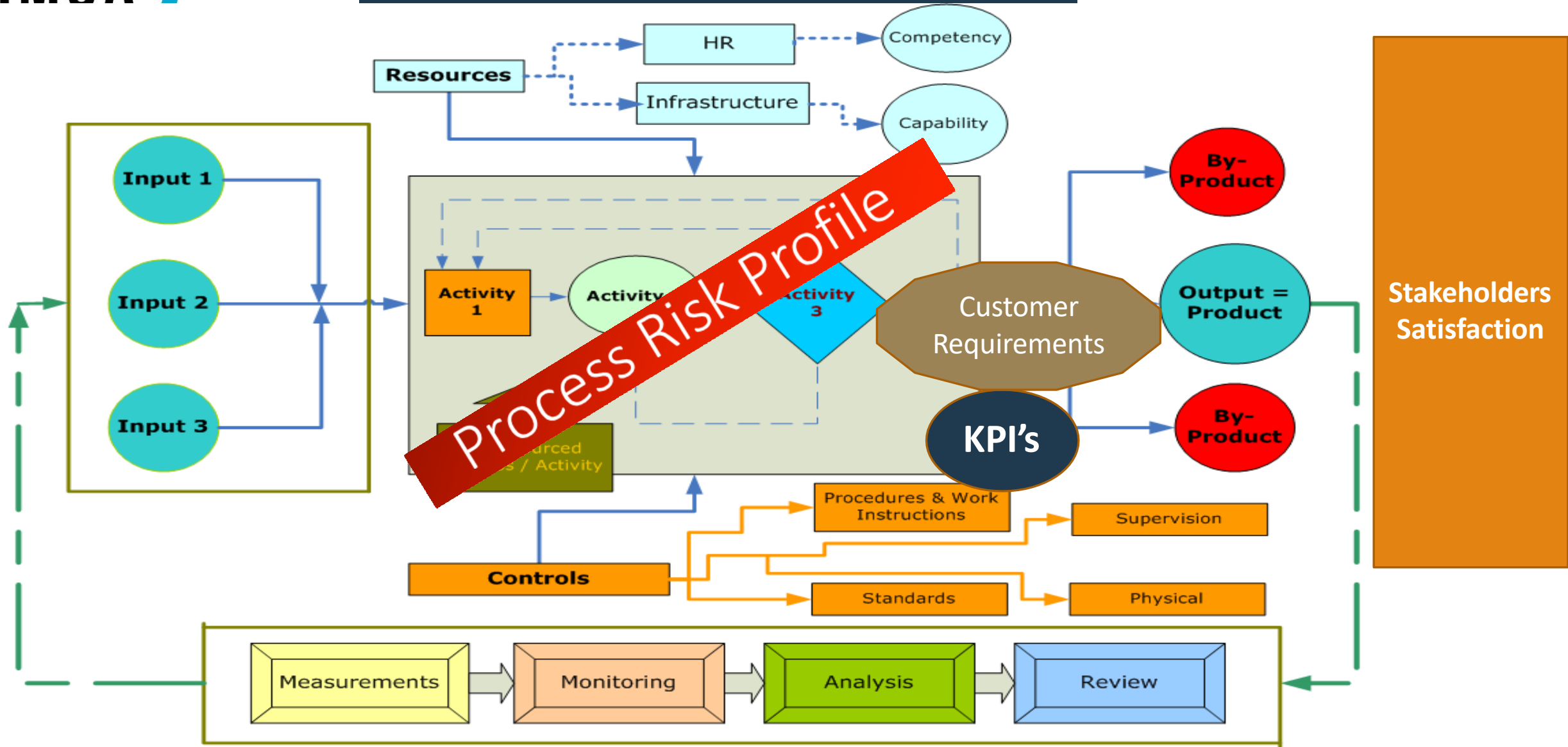
Continual Improvement

Improvement can be realised through the PDCA Cycle

Plan	set objectives and define processes necessary to deliver required outcomes
Do	implement and manage processes planned
Check (Verify)	measure and monitor processes performance against set objectives
Act	take actions to improve processes performance and generated outcomes

Correction

"Action to eliminate a <u>detected nonconformity</u>."

Corrective Action

"Action to eliminate the <u>cause</u> of a nonconformity and to prevent recurrence."

Preventive Action

"Action to eliminate the <u>cause</u> of a <u>potential</u> nonconformity or other potential undesirable situation."

3. What is a "Standard"? Who is ISO and What is their Role?

Management Systems Standards
Annex SL – Key Issues

- MSS Types

- Unified Terms & Definitions

- High Level Structure (HLS)

- Concept of "Organisation Context"

- Concept of Interested Parties (Stakeholders)

- Concept of "Process Approach"

- Incorporation of the "Concept of Risk"

- Improvement coupled with conformance

- Documented Information

Annex SL

Quality Management Systems (ISO 9001)

Asset Management Systems (ISO 55001)

Food Safety Management Systems (ISO 22000)

Environmental Management Systems (ISO 14001)

Energy Management Systems (ISO 50001)

Occupational Health & Safety Management Systems (ISO 45001)

Information Security Management Systems (ISO 27001)
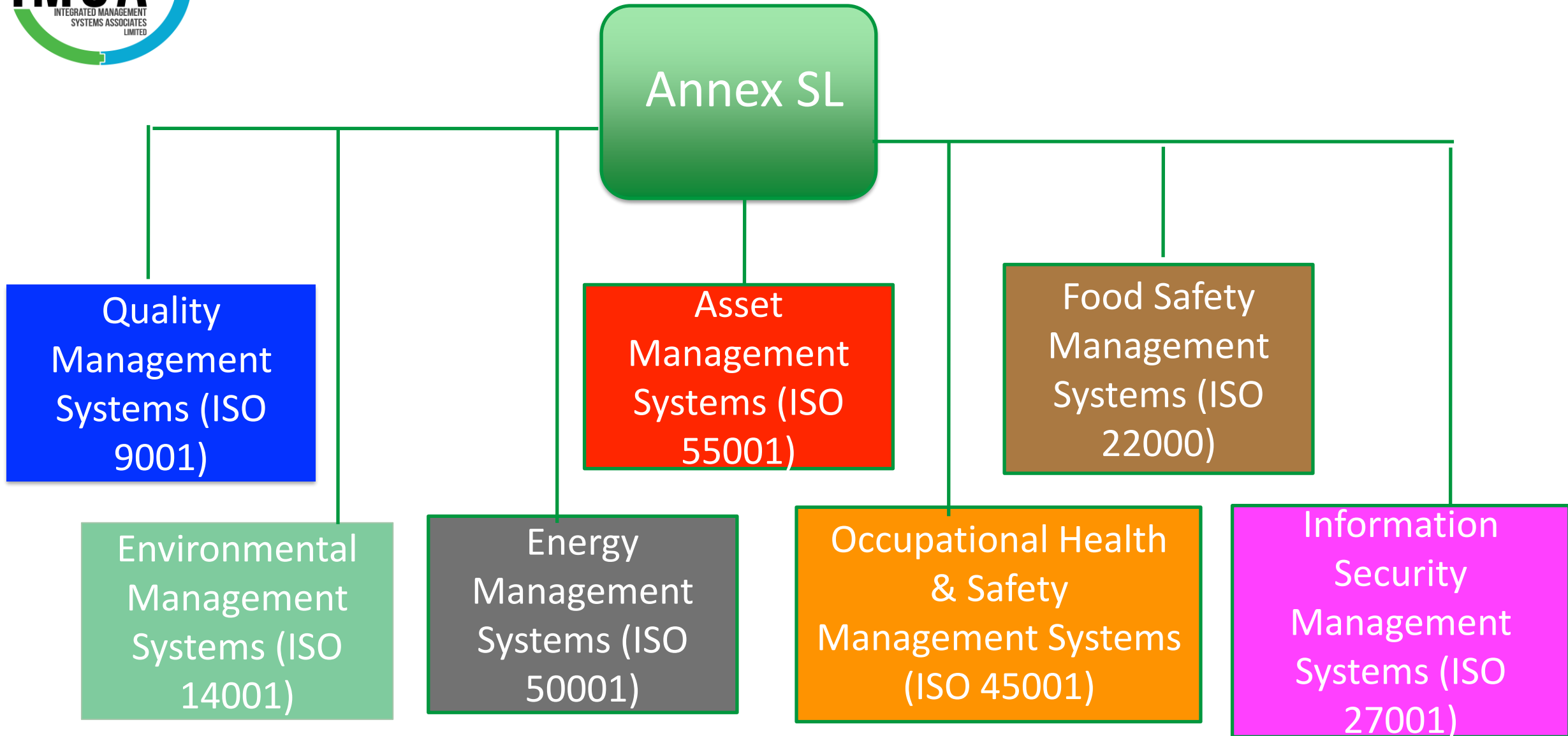
HLS *(all MSS)* – Generic –Sector specific Quality Management Systems Standards: Why?

Key Concerns
Lack of Context
Simply Documentation
Empahasis on Achieving
Certification

Oil & Gas, Petrochemical Quality Management Systems (ISO 29001:2020)

High Level Structure

Quality Management Systems (ISO 9001)

Nuclear Energy Quality Management Systems (ISO 19443: 2018)

Railways Industry Quality Management Systems ISO/TS 22163: 2017)

Aviation, Space & Defence Quality Management Systems (BS/EN 9100:2016)

Key Requirements

Annex SL Management Systems High Level Structure

Key Element

4. Context of the Organisation
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the XXX management system
- 4.4 XXX management system and its processes

5. Leadership
- 5.1 Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 XXX objectives and planning to achieve them

7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operations
- 8.1 Operational planning and control

9. Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement
- 10.1 Nonconformity and corrective action
- 10.2 Continual improvement

Quality Management System standard (ISO 9001)

4. Context of the Organisation
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system management system
- 4.4 Quality management system and its processes

5. Leadership
- 5.1 Leadership and commitment and commitment
- 5.2 Quality Policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operations
- 8.1 Operational planning and control
- 8.2 Requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided processes, products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconforming outputs

9. Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement
- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

Purpose

- A framework to protect the environment and respond to changing environmental conditions in balance with socio-economic needs.

- Designed to provide a tool to achieve intended environmental outcomes

Environmental Management Systems Standards (ISO 14001)

Enable Sustainable Development to deliver:

- Protecting the environment by preventing or mitigating adverse environmental impacts

- Mitigating potential adverse effect of environmental conditions on the organisation

- Assisting the organisation in the fulfilment of compliance obligations

- Enhancing environmental performance

- Using life cycle perspective that can prevent impacts from being unintentionally shifted elsewhere the lifecycle

- Achieving operational and financial benefits that can result from implementing environmentally sound alternatives that strengthen organisation's market position

- Communicating environmental information to interested parties

Environmental Management System (ISO 14001)

4. Context of the Organisation
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining scope of the environmental management system
- 4.4 Environmental management system and its processes

5. Leadership
- 5.1 Leadership and commitment
- 5.2 Environmental Policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 Environmental objectives and planning to achieve them

7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operations
- 8.1 Operational planning and control
- 8.2 Emergency preparedness and response

9. Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement
- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

ISO 9000:2015

Quality Management Systems - Fundamentals and Vocabulary

ISO 14001:2015

Environmental Management Systems – Requirements with guidance for use

ISO 14004:2016

Environmental Management Systems – General guidelines on implementation

ISO 14064-1:2006

Greenhouse gases - Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals

ISO 14064-2:2006

Greenhouse gases - Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements

ISO 14064-3:2006

Greenhouse gases - Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions

Purpose

- Provide framework for managing OH&S risks
- Prevent work-related injury and ill health to workers
- Provide safe and heathy workplaces
- Eliminate hazards and minimise risks by taking effective preventive and protective measures.
- Meeting Objectives
- Fulfil legal requirements
- Continual improvement

Occupational Health & Safety Management Systems (ISO 45001)

4. Context of the Organisation
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the OH&S management system
- 4.4 OH&S management system and its processes

5. Leadership
- 5.1 Leadership and commitment
- 5.2 OH&S Policy
- 5.3 Organizational roles, responsibilities and authorities
- 5.4 Participation and consultation

6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 OH&S objectives and planning to achieve them

7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operations
- 8.1 Operational planning and control
- 8.2 Management of Change
- 8.3 Outsourcing
- 8.4 Procurement
- 8.5 Contractors
- 8.6 Emergency preparedness and response

9. Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement
- 10.1 Incident, nonconformity and corrective action
- 10.2 Continual improvement

ISO 9000:2015

Quality Management Systems - Fundamentals and Vocabulary

ISO 45001:2018

Occupational Health and Safety Management Systems - Requirements with guidance for use

ISO 45004:???

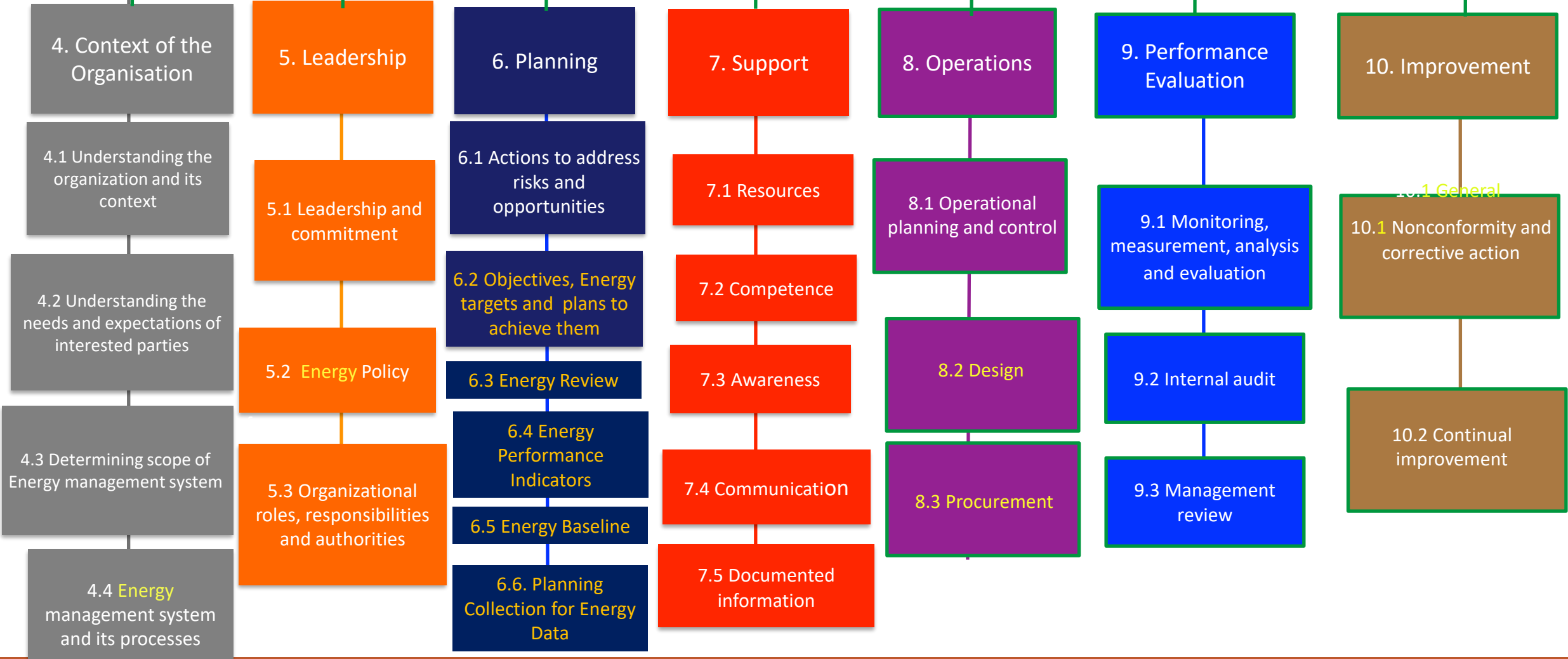Occupational Heath and Safety Management Systems – General guidelines on implementation

Purpose

- Establish systems and processes necessary to continually improve energy performance, including energy efficiency, energy use and energy consumption

- Includes an energy policy, objectives, energy targets and action plans related to its energy efficiency, energy use, and energy consumption

- Meeting applicable legal requirements and other requirements.

- Enables an organization to set and achieve objectives and energy targets, to take actions as needed to improve its energy performance, and to demonstrate the conformity of its system

Energy Management System (ISO 50001)

4. Context of the Organisation
- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining scope of Energy management system
- 4.4 Energy management system and its processes

5. Leadership
- 5.1 Leadership and commitment
- 5.2 Energy Policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 Objectives, Energy targets and plans to achieve them
- 6.3 Energy Review
- 6.4 Energy Performance Indicators
- 6.5 Energy Baseline
- 6.6. Planning Collection for Energy Data

7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operations
- 8.1 Operational planning and control
- 8.2 Design
- 8.3 Procurement

9. Performance Evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement
- 10.1 General
- 10.1 Nonconformity and corrective action
- 10.2 Continual improvement

Type A MSS

MSS providing **requirements** (shall's) – ISO 9001, ISO 14001 , ISO 45001, ISO 50001

Examples
- ➢Management system requirements standards (generic).
- ➢Management system (including sector-specific) requirements standards.

Type B MSS – ISO 9002, ISO 9004, ISO 14004, ISO 45002

MSS providing **guidelines** (should's)

Examples
- ➢Guidance on the use of management system requirements standards.
- ➢Guidance on the establishment of a management system.
- ➢Guidance on improvement / enhancement of a management system.

ISO Management Systems Standards Structure
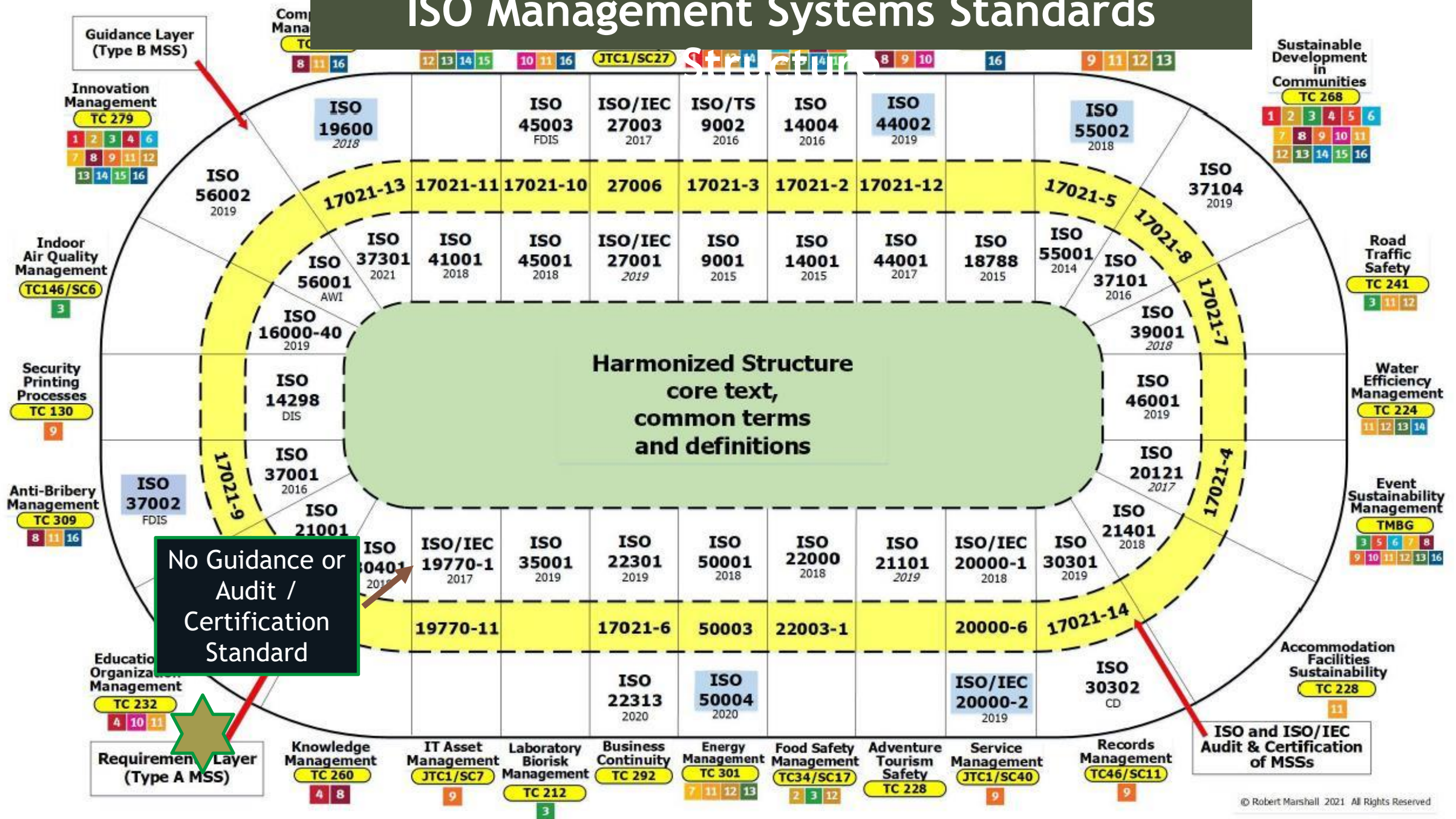
4. Context of an Organisation – What is it & Why?

Context of the Organization *(Annex SL & ISO 9000:2015)*
"combination of internal and external issues (*factors*) that can have an effect on an *organization's* approach to developing and achieving its *objectives*"
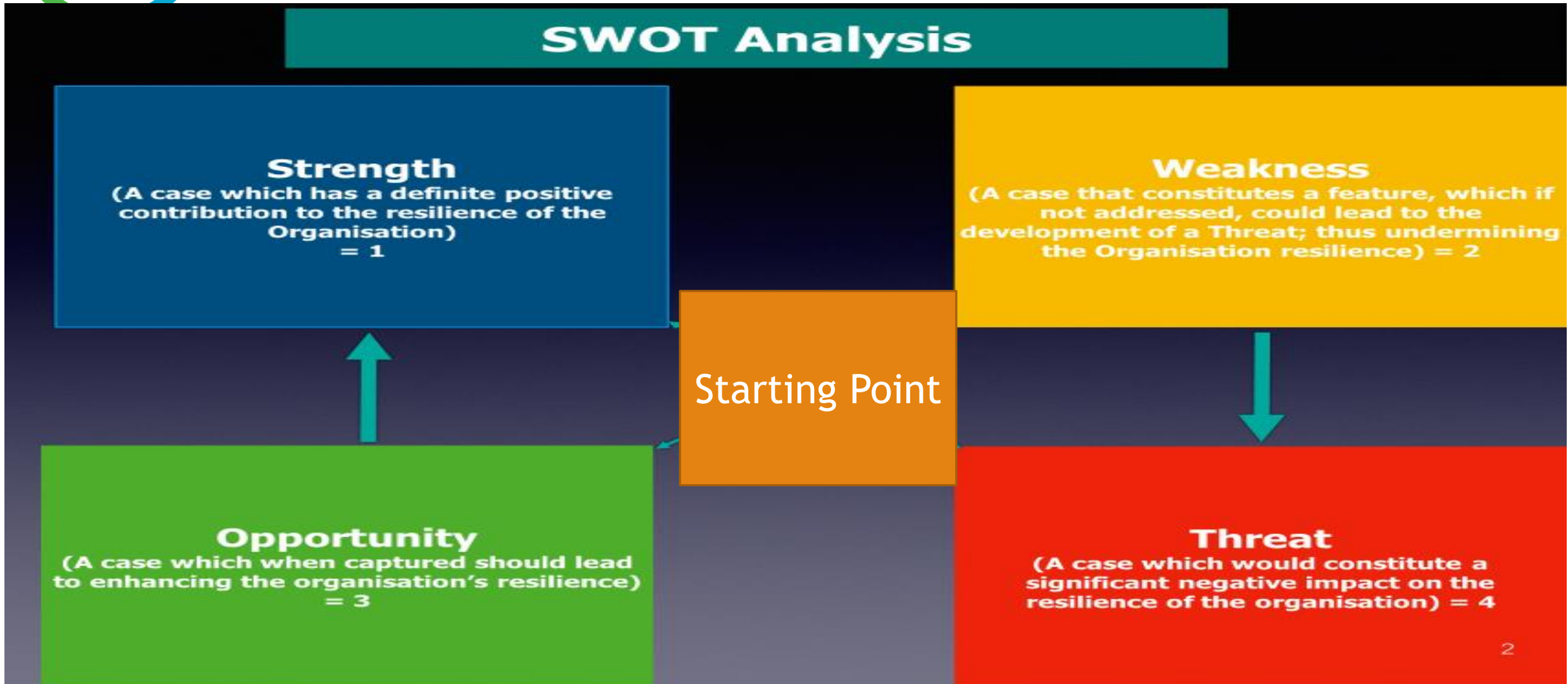
Also referred to as Business Environment / Culture of the Organisation.
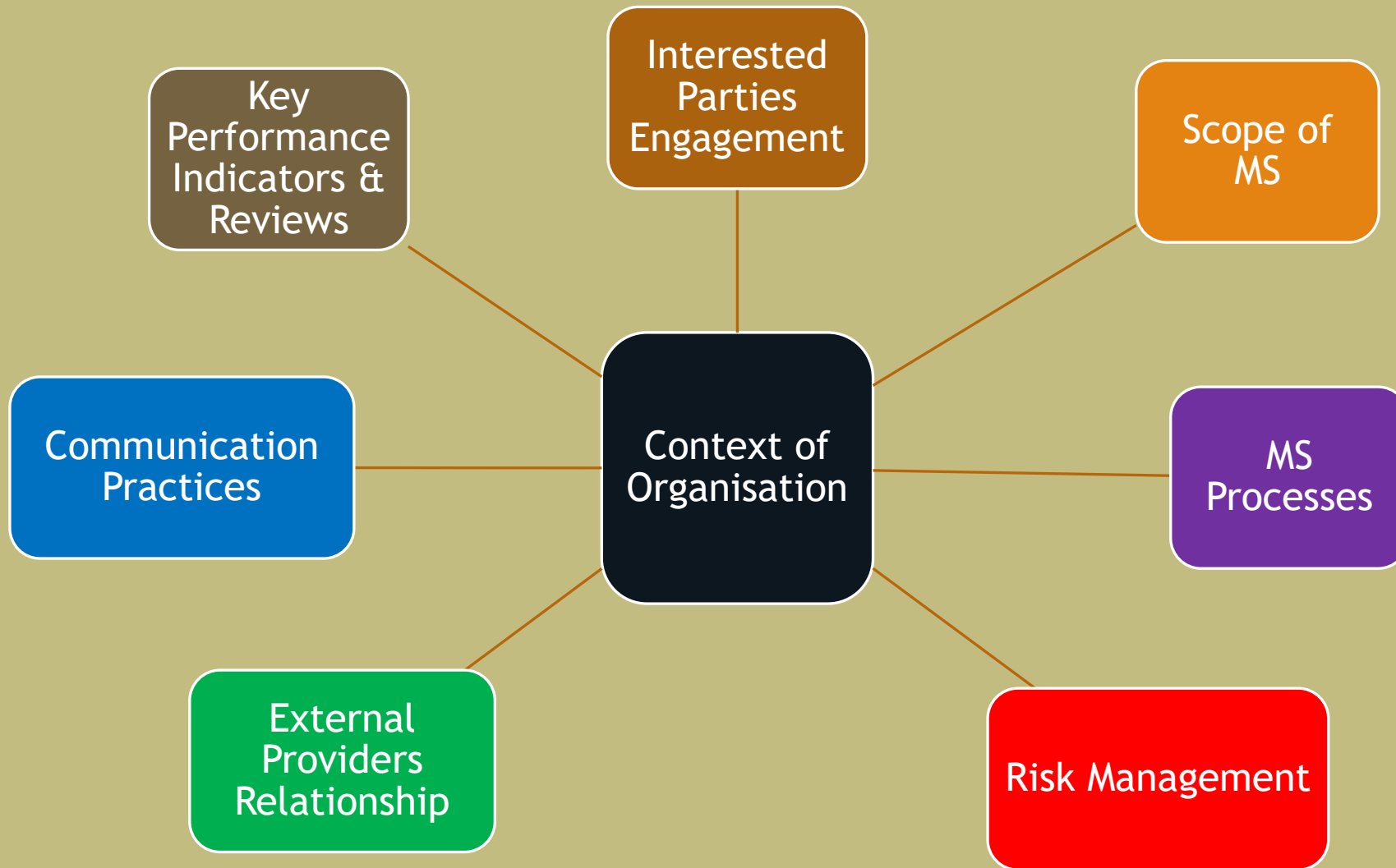
PESTLE Technique

Factor	External	Internal
Political		
Economic		
Social		
Technological		
Legal		
Environmental		
Others		

SWOT Analysis

Strength
(A case which has a definite positive contribution to the resilience of the Organisation)
= 1

Weakness
(A case that constitutes a feature, which if not addressed, could lead to the development of a Threat; thus undermining the Organisation resilience) = 2

Starting Point

Opportunity
(A case which when captured should lead to enhancing the organisation's resilience)
= 3

Threat
(A case which would constitute a significant negative impact on the resilience of the organisation) = 4

2

Context of Organisation Influences

Influence of "Context" on KPI's
(Power Station)

Performance Aspect / Element	Country A	Country B
Power Generation Planning	15.0%	15.0%
Maintenance Planning & Implementation	15.0%	20.0%
Production Performance	35.0%	40.0%
Power Outages (Planned & Unplanned)	25.0%	5.0%
Incidents Management	5.0%	10.0%
Resources Management	5.0%	10.0%
Total	100.0%	100.0%

Iraq

UK
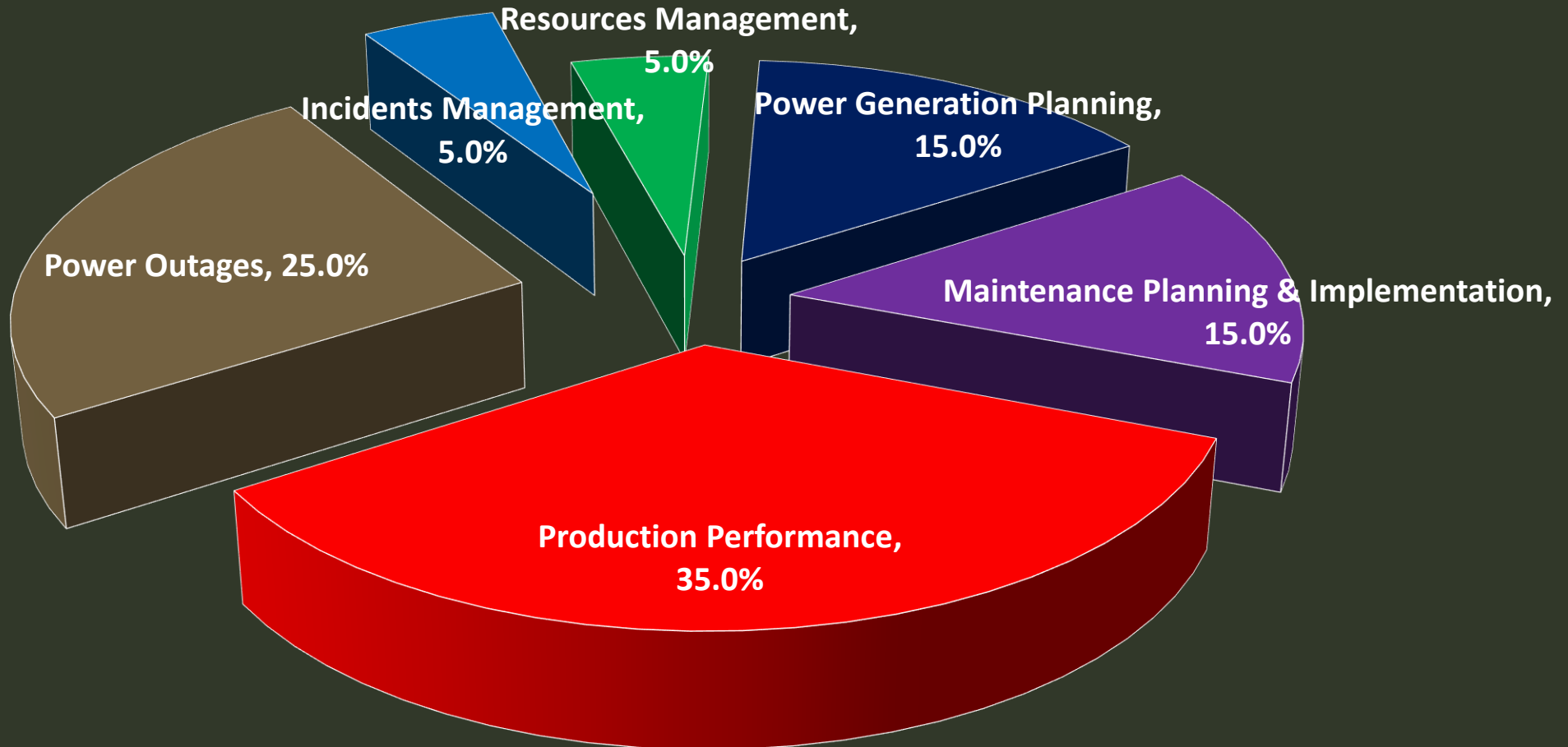
5. Role of Top Management

Who is Top Management?

"person or group of people who **directs** and **controls** an *organization* at the highest level"

ISO 9000:2015

Top management has the power to delegate **Authority** but not **Responsibility**.

- Take accountability for effectiveness of the management system.
- Establish <u>Policy</u> & Objectives (cascading from Strategic to Operational), inline with Context & Strategic Direction.
- Ensure effective integration of management system into business processes and activities.
- Promoting the centrality of Process Management & Risk Management *(not just a documentation regime based on procedures).*
- Ensuring availability of resources (competent human resources & capable infrastructure).
- Effective communication & consultation (two way street).
- Directing & supporting others to engage effectively.
- Promoting concept of continual improvement, through determining root causes & benefiting from lessons learned.

Responsibilities cannot be delegated (Management Representative); however authorities can be.
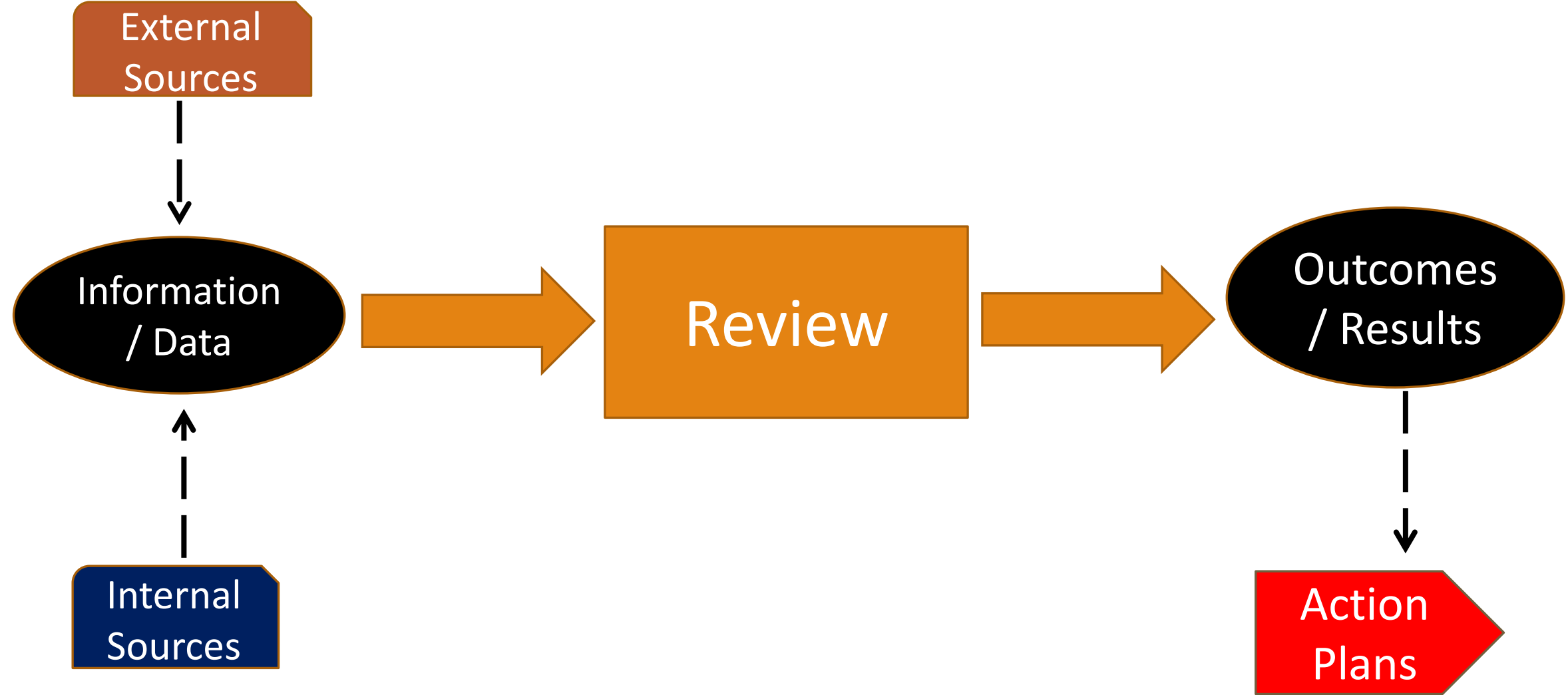
6. Competency – What is it & its Role

Human Resources "Competency"

Competency is defined as "**demonstrated** ability to apply knowledge and skills".

Competency is defined for the "**Role**" not the "**Person**"; *however, we try our best to ensure that the Person designated to occupy the role satisfies and **continue** to satisfy the competency requirements of the allocated role.*

Competency Elements include combination of:
  ➢ Knowledge / Qualification
  ➢ Skill
  ➢ Experience
  ➢ Training

Suitable combination of requirements for Critical Roles, to be determined by the Organisation, taking into account all relevant factors

Management Systems Competency Elements

Each Element is defined specific to the Role. There will be different requirements between processes and within a process.

When deciding Competency Requirements, organisation must take into account Risks associated with the Role, its responsibilities & authorities.

Qualification / Knowledge

Training

Competency
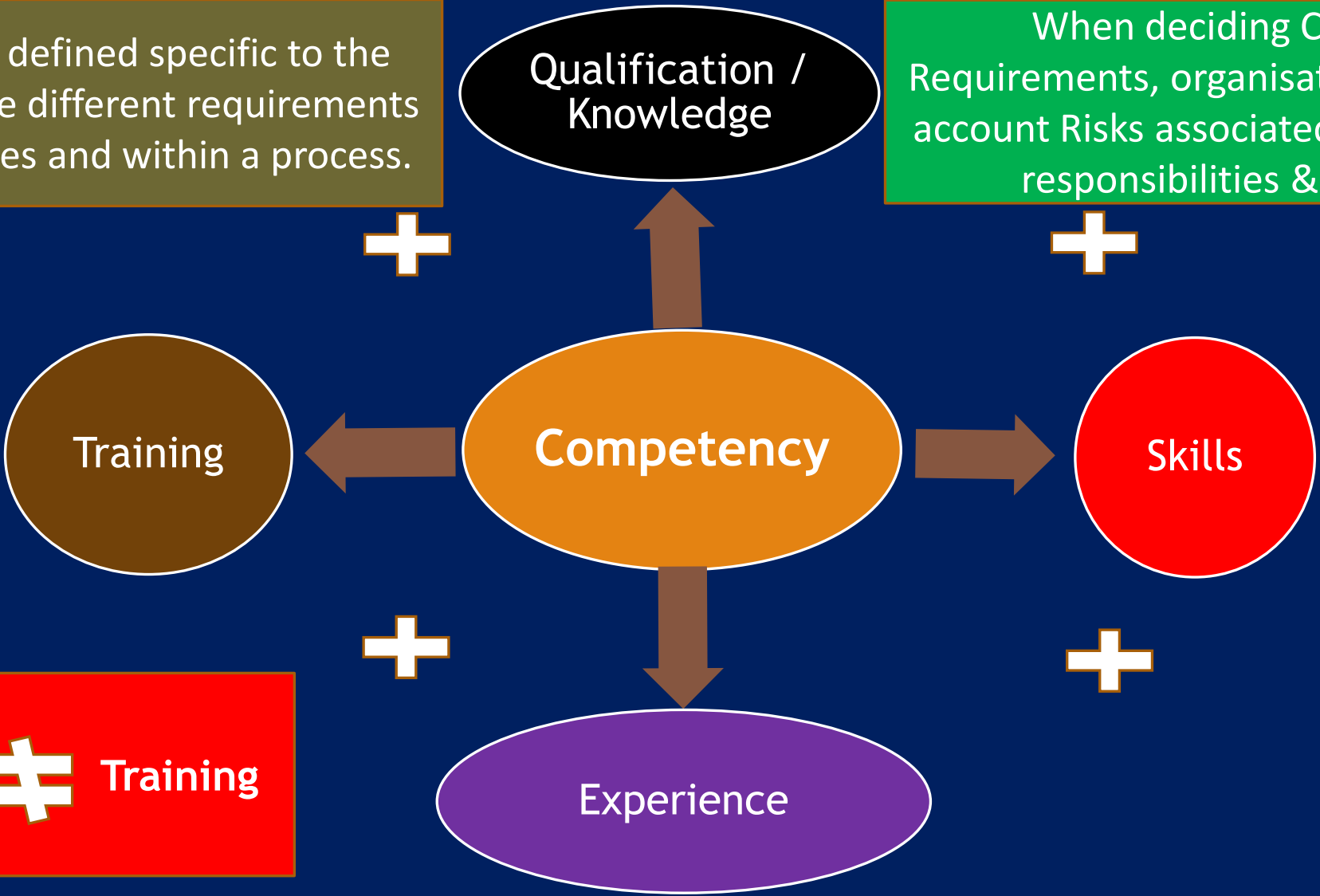
Skills

Experience

Competency ≠ Training

Human Resources Competency Matrix

Role	Education / Knowledge	Skills	Experience	Qualification / Certification / Training
Process Manager				
Deputy Process Manager				
Process Engineer				
Process Supervisor				
Process Technician				
Process Operator				

Each "Critical" Role Needs to have its own Specification with respect to the four elements of Competency, based on Role Responsibilities & Authorities

Establish suitable Criteria for minimum level of Skill

Set minimum years (& type) of experience

Determine the minimum Educational level for the corresponding Role

Decide level of Training and Qualification & Certification, as relevant

Remember all of this is reference to the Critical Roles within Processes, rather than to People. Critical Roles are those affecting the management of Processes (Effectiveness & Efficiency).

Human Resources Competency Management
(Competency Enhancement)

Role	Role Competency Requirement	Role Occupant Competency Level	Required Actions
Process Manager			
Deputy Process Manager			
Process Engineer			
Process Supervisor			
Process Technician			
Process Operator			
Process Operator			

Existing Gap

Determined by assessment, appraisal & monitoring of actual performance; not by simply attending training or gathering certificates.

Suitable Assessment Criteria; "Competent", "partly Competent" & "not Competent"

Agreeing Training and other measures. Effectiveness of such actions need to be demonstrated

Annex SL Management Systems High Level Structure

- **4. Context of the Organization**
  - 4.1 Understanding the organization and its context
  - 4.2 Understanding the needs and expectations of interested parties
  - 4.3 Determining the scope of the XXX management system
  - 4.4 XXX management system and its processes

- **5. Leadership**
  - 5.1 Leadership and commitment
  - 5.2 Policy
  - 5.3 Organizational roles, responsibilities and authorities

- **6. Planning**
  - 6.1 Actions to address risks and opportunities
  - 6.2 XXX objectives and planning to achieve them

- **7. Support Processes**
  - 7.1 Resources
  - 7.2 Competence
  - 7.3 Awareness
  - 7.4 Communication
  - 7.5 Documented information

- **8. Operations Processes**
  - 8.1 Operational planning and control

- **9. Performance Evaluation**
  - 9.1 Monitoring, measurement, analysis and evaluation
  - 9.2 Internal audit
  - 9.3 Management review

- **10. Improvement**
  - 10.1 Nonconformity and corrective action
  - 10.2 Continual improvement

Competency & Not simply Training!!

7. Management Systems Documentation Factors

- Many Users implemented a management system to mean creating a serries of Documented Procedures.
- To them requirements in standards meant creating corresponding documented procedures.
- For example the 1994 version of ISO 9001 had 22 Clauses. So many users simply created 22 documented procedures!!
- ISO 9001 standard never stipulated the above, but Users interpreted it this way.
- A very unhealthy situation which the standard had to deal with somehow?

Management System Documentation HLS (Annex SL)

Documents = A + X

Documented Procedures = B + Y

Records = C + Z

Type	Standard	Organisation
Documents	A	X
Documented Procedure	B	Y
Records	C	Z

Documentation necessary to ensure effective planning, operation & control of organisations processes

BUT

Document: Information and its Supporting Medium

- *Medium can be paper, electronic, sample, etc*

Record: A special type of Document that provides evidence or results of actions

- *A record is a special type of document; every Record is a Document but not every Document is a Record*

- Many Users interpreted that a Management System is simply creating documentation (procedures) and following them

Management Systems Documentation
(as per Annex SL HLS)

- Documented Information *shall be* <u>MAINTAINED</u> = Documents

- Documented Information *shall be* <u>RETAINED</u> = Records

Has been changed to "made available", as many Users misunderstood the convention!!

8. Conformity Assessment & Certification / Accreditation Process

Certification

provision by an independent body of written assurance (a certificate) that the product, service or **system** in question meets specific **requirements**.

Accreditation

formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to **international standards**.

- ISO does not accredit or certificate.
- Certification is not an ISO demand. In other words, management systems can be implemented without need for third party conformity assessment (certification).
- Certification is normally provided by commercial entities, who might be "accredited" or not, based on requirements of ISO 17021 for system certification.
- Accreditation is normally provided by non-commercial entities and are members of entities such as IAF & EA.

To use Commercial "Accreditation Entities" is not good enough, I am afraid, even if they are members of IAF!!!

- الأنشطة الرئيسية لعملية المصادقة
  - ➤ الأجراءات الادارية
  - ➤ التدقيق
  - ➤ الموافقة / عدم الموافقة
- يختلف مستوى الخدمة في جميع أنحاء العالم وحتى داخل نفس البلد
- تشمل التحديات ما يلي:
  - ➤ النزاهة
  - ➤ جودة الاعتماد و المصداقية (بما في ذلك "المعتمدين" مقابل "غير المعتمدين")
  - ➤ آهلية المدقق
- تم تصميم مواصفة ISO 17021 (باجزائها المختلفة) في شكل "متطلبات" لتكون بمثابة أساس للاعتماد؛ بعيدًا عن كونها مواصفة "مثالية"
- تم تصميم مواصفة ISO 19011 في شكل "إرشادات" "أفضل الممارسات" للتدقيق بعيدًا عن كونها مواصفة "مثالية"
- لا يزال أمامنا العديد من التحديات!!

- كان **المفهوم في الأصل**، هو أنه إذا حصلت المنظمات على شهادة **"المصادقة"**، فيمكن أن نثق في ذلك كدليل على وجود نظام إدارة **قادر على تلبية احتياجات الزبائن**، وليس مجرد تلبية متطلبات المواصفة.

- كان الواقع مختلفًا جدًا. **فشلت العديد من المنظمات** في تحقيق رضا الزبائن لعدة أسباب.

- سرعان ما أدركت المنظمات أن مجرد طلب إثبات "المصادقة" (الشهادة) **لا يكفي!**

- هذا ليس وضعًا صحيًا مما يجب إدراكه والتعامل معه.

- تم وضع نهج **تحسين متعدد الأوجه** ويتم اتباعها.

- في غضون ذلك، ماذا يمكننا أن نفعل **لزيادة مصداقية** نظام الإدارة المعمول به؟
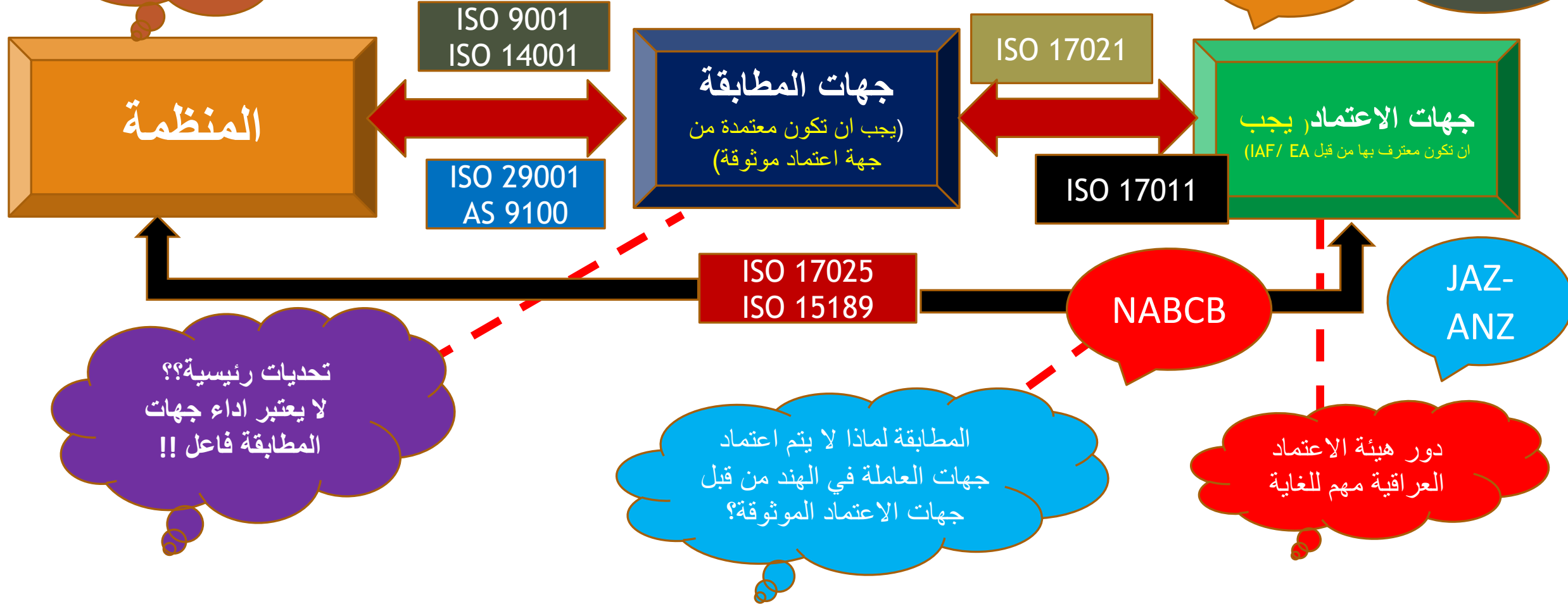
- Perform Gap Analysis, based on
  - ➢ Requirements of the applicable Model (ISO 9001, ISO 14001, ISO 45001, etc) and;
  - ➢ **Requirements** of the organization related to its unique Factors & needs necessary to satisfy its Stakeholders (including Customers)
- Employ a suitable assessment tool to enable assessing the ongoing maturity of the Integrated Management System through the process of continual improvement (PDCA)
- For assessing maturity, a clear criteria need to be defined to enable determining the existence, or otherwise, and also the effectiveness of implemented control points

ممارسات عملية المصادقة في العراق

- هيئات "المصادقة" الدولية، مثل SGS, LLOYDS و"اخرين"، الذين لديهم اعتماد "موثوق" لديهم بعض التواجد المحدود.
- يبدو أن السوق مشغول بشكل أساسي بهيئات "المصادقة" من الهند وتركيا وما إلى ذلك، الذين هناك "شك" في جهة اعتمادهم.
- من هي هيئات الاعتماد الدولية المعترف بها؟
  - ➢ UKAS (المملكة المتحدة)
  - ➢ ANAB (الولايات المتحدة الأمريكية)
  - ➢ JAS-ANZ (أستراليا – نيوزيلندا)
  - ➢ NABCB (الهند)

  شكل من أشكال الاعتراف المتبادل
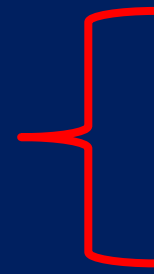
- أعلاه ليست كيانات تجارية (هي غير ربحية) ولديها اعتراف رسمي من نوع ما.
- هناك هيئات اعتماد "تجارية" تعمل في الولايات المتحدة الأمريكية (IAS) و(UAF) يتم استخدامها لاعتماد هيئات المصادقة "الهندية والتركية" العاملة في العراق.

9. Integrated Management Systems

That is not the case. This does not produce an Integrated Management System. It is not simply a matter of bringing together different standards; it is about integrating standards "requitements" into the organisation management System.

Emphasis on Standards and achieving Certification, and not on implementing effective management systems.

ISO 9001 ➕ ISO 14001 ➕ ISO 45001 ➕ ISO 50001 ➕ ISO 55001 ➕ ISO 22000 ➕ ISO 27001 ≠ IMS

Achieving Certification

Integrated Management Systems Logic

Fragmented Management Systems

Integrated Management Systems

Quality Management System

ISO ~~9001~~

Environmental Management System

ISO ~~14001~~

Occupational Health & Safety Management System

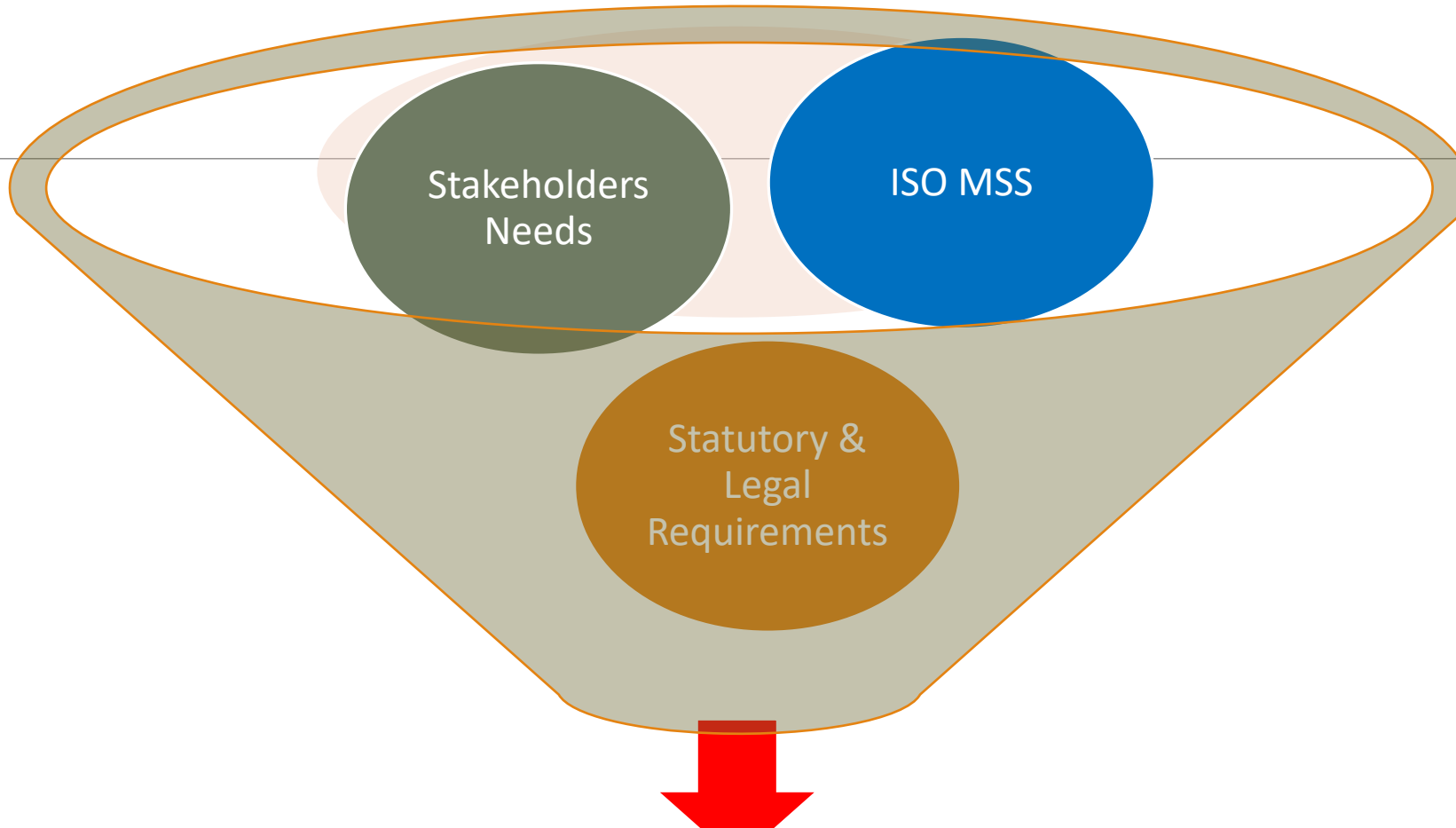ISO ~~45001~~

Integrated Management System

No ISO Standard
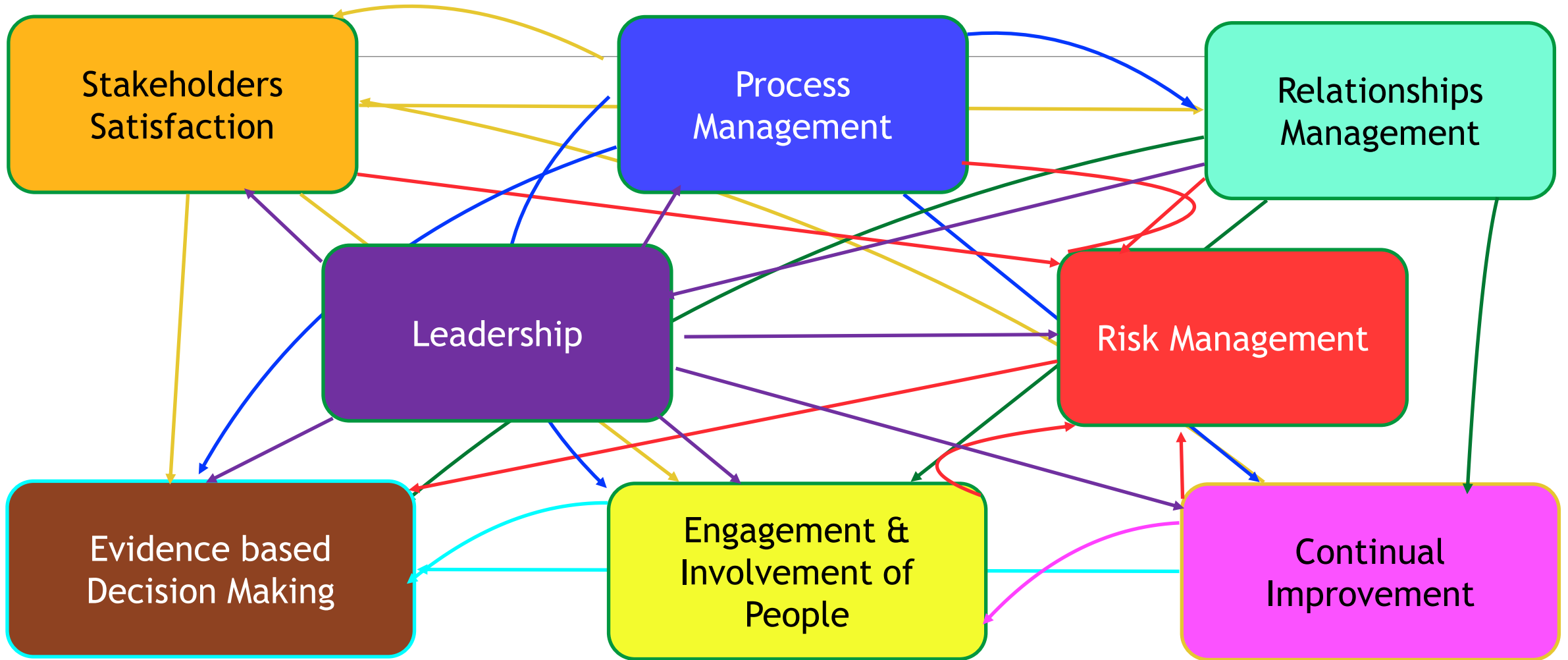
Stakeholders Satisfaction

Process Management

Relationships Management

Leadership

Risk Management

Evidence based Decision Making

Engagement & Involvement of People

Continual Improvement

Integrated Management Systems (No ISO Standard, but we need a Model)

IMSA — INTEGRATED MANAGEMENT SYSTEMS ASSOCIATES LIMITED

4. Organisational Factors
- 4.1 Organization Context
- 4.2 Needs & expectations of Interested Parties
- 4.3 Scope of Integrated Management System
- 4.4 Management Systems Processes Design & Mapping

5. Leadership
- 5.1 Leadership & Commitment
- 5.2 Vision, Mission, Strategies & Polices
- 5.3 Organisation Structure
- 5.4 Roles, Responsibilities & Authorities
- 5.5 Engagement, Participation & Consultation

6. Planning
- 6.1 Risk Assessment
- 6.2 Risk Treatment
- 6.3 System Objectives Realization Planning
- 6.4 Operational KPI's Planning
- 6.5 Management of Change
- 6.6 Business Continuity Planning

7. Main Processes
- 7.1 Products Determination & Review
- 7.2 Design & Development
- 7.3 Operational Planning & Control
- 7.4 Procurement Process
- 7.5 Contractor Management
- 7.6 Output Control
- 7.7 Emergency Preparedness & Response

8. Supporting Processes
- 8.1 Resources Management
- 8.2 Human Resources Competence
- 8.3 Infrastructure Capability
- 8.4 Communication
- 8.5 Information Management

9. Performance Evaluation
- 9.1 Measurement & Monitoring Activities
- 9.2 External & Internal Feedback
- 9.3 Inspection & Audit
- 9.4 Analysis & Evaluation
- 9.5 Reviews

10. Continual Improvement
- 10.1 Incidents Investigations
- 10.2 Nonconformity Management
- 10.3 Corrective & Preventive Actions
- 10.4 Lessons Learned Capture

Intergated Management Systems Inputs

ISO 9001
ISO 14001
ISO 45001
ISO 50001
ISO 55001
ISO 22301

Many other related ISO Standards

ISO Standards (Requirements & Guidelines)

Stakeholders Requirements (Needs & Expectations)

Statutory & Legal Requirements

Specific Business Requirements

NOT ONLY

Integrated Management Systems (IMS)

Standards are Generic while a Management System is Specific

MS ≠ Standards
MS = Standards+++++

Quality Management System *Policy*
(as per ISO 9001:2015)

Top management shall establish. Implement and maintain a quality policy that:
- a. is appropriate to the purpose and context of the organisation, and supports its strategic direction;
- b. provides a framework for setting quality objectives;
- c. includes a commitment to satisfy applicable requirements;
- d. includes a commitment to continual improvement of the quality management system.

Quality policy shall:
- a. be available and maintained as documented information;
- b. be communicated, understood and applied within the organisation;
- c. be available to relevant interested parties, as appropriate.

Top management shall establish. Implement and maintain an environmental policy that, within defined scope of its environmental management system:

a. is appropriate to the purpose and context of the organisation, including the nature, scale and environmental impacts of its activities, products and services;

b. provides a framework for setting environmental objectives;

c. includes a commitment to the protection of the environment, including prevention of pollution and other specific commitments relevant to the context of the organisation;

d. includes a commitment to fulfil its compliance obligations;

e. includes a commitment to continual improvement of the environmental management system to enhance environmental performance.

Environmental policy shall:

a. be maintained as documented information;

b. be communicated within the organisation;

c. be available to interested parties.

Top management shall establish, implement and maintain OH&S policy that:

a. includes a commitment to provide safe and healthy working conditions for the prevention of work-related injury and ill health and is appropriate to the purpose, size and context of the organisation and to the specific nature of its OH&S risks and OH&S opportunities;

    b. provides a framework for setting OH&S objectives;

    c. includes a commitment to fulfil legal requirements and other requirements;

    d. includes a commitment to eliminate hazards and reduce OH&S risks;

    e. includes a commitment to continual improvement of the OH&S management system;

    f. includes a commitment to consultation and participation of worhers and where they exist, workers' representatives.

OH&S Policy shall:

    a. be available as documented information;

    b. be communicated within the organisation;

    c. be available to interested parties, as appropriate;

    d. be relevant and appropriate management shall establish, implement and maintained.

Top management shall establish. Implement and maintain an integrated management system policy designed to be:

   a. appropriate to the purpose and context of the organisation, and supports its strategic direction, taking into account the full range of its operations and all associated risks;

   b. provides a framework for setting relevant business objectives;

   c. includes a commitment to satisfy relevant statutory and legal requirements;

   d. includes a commitment to manage all relevant risks;

   e. includes a commitment to engage and consult concerned parties and individuals;

   d. includes a commitment to continual improvement of the integrated management system.
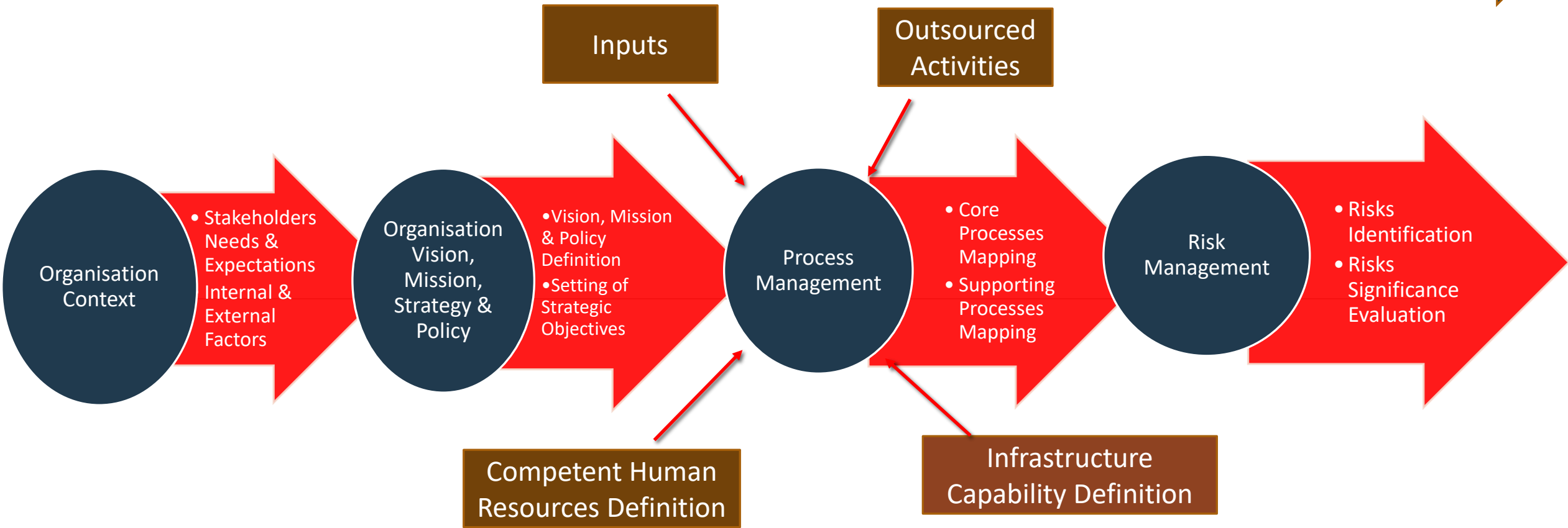
Integrated management policy shall:

a. be available and maintained as documented information and under control;

b. be communicated, understood and applied within and outside the organisation;

c. be available to relevant interested parties.

Integrated Management Systems Implementation Road Map

Information Management (Creating documented Information; such as Documents, Documented Procedures, Specifications, Plans, Records, etc.)

Inputs

Outsourced Activities

Organisation Context

- Stakeholders Needs & Expectations Internal & External Factors

Organisation Vision, Mission, Strategy & Policy

- Vision, Mission & Policy Definition
- Setting of Strategic Objectives

Process Management

- Core Processes Mapping
- Supporting Processes Mapping

Risk Management

- Risks Identification
- Risks Significance Evaluation

Competent Human Resources Definition

Infrastructure Capability Definition
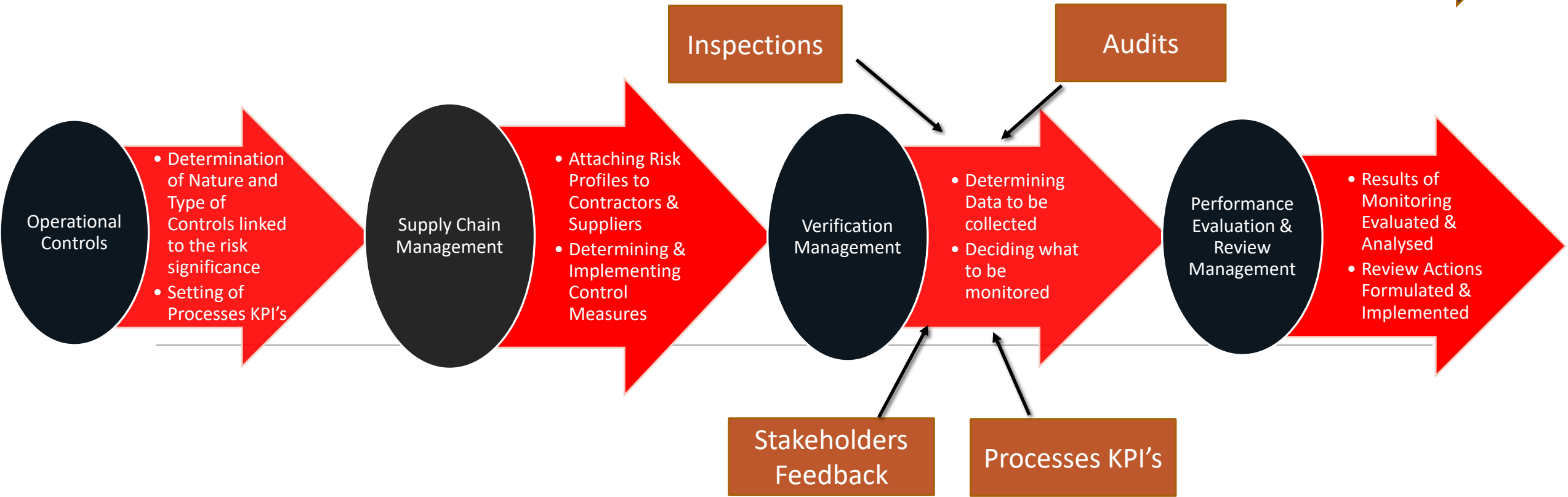
Integrated Management Systems Implementation Road Map

Information Management (Creating documented Information; such as Documents, Documented Procedures, Specifications, Plans, Records, etc.)

Inspections

Audits

Operational Controls
- Determination of Nature and Type of Controls linked to the risk significance
- Setting of Processes KPI's

Supply Chain Management
- Attaching Risk Profiles to Contractors & Suppliers
- Determining & Implementing Control Measures

Verification Management
- Determining Data to be collected
- Deciding what to be monitored

Performance Evaluation & Review Management
- Results of Monitoring Evaluated & Analysed
- Review Actions Formulated & Implemented

Stakeholders Feedback

Processes KPI's

Integrated Management Systems Maturity Assessment

Assessment Criteria = IMS Requirements (ISO MSS Standards ++++++)

Five Maturity Levels (1 to 5)

Policies & Objectives

Information Management

Leadership & Commitment

Reviews & Continual Improvement

Stakeholders Management

Correction, Corrective & Preventive Actions

Organisational Structure

Incidents Investigation

Process Management

Verification & Validation Activiries

Risk Management

Planning & Implementation of Operational Controls

Actual Assessment Score

5.00
4.50
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00

- Important to realise that "Certification" (commercial but independent conformity assessment) always has to be based on ISO Standards
- It follows that Certification Bodies cannot certify an Integrated Management System, due to absence of ISO relevant standard to base it on
- Traditionally, certification is about assessing Organisations against the requirements of a management system standard (such as ISO 9001, ISO 14001, ISO 45001, etc.); *very few certification auditors focus on the management systems requirements*
- Therefore, most certification bodies restrict themselves to providing different standards-based certifications; some also provide an umbrella integrated management system certification (by mentioning more than one standard)
- Major challenges still face certification bodies; *had to react to market needs*
- **But remember that it is not about achieving certification; rather it is about delivering satisfaction to the stakeholders of the organisation**