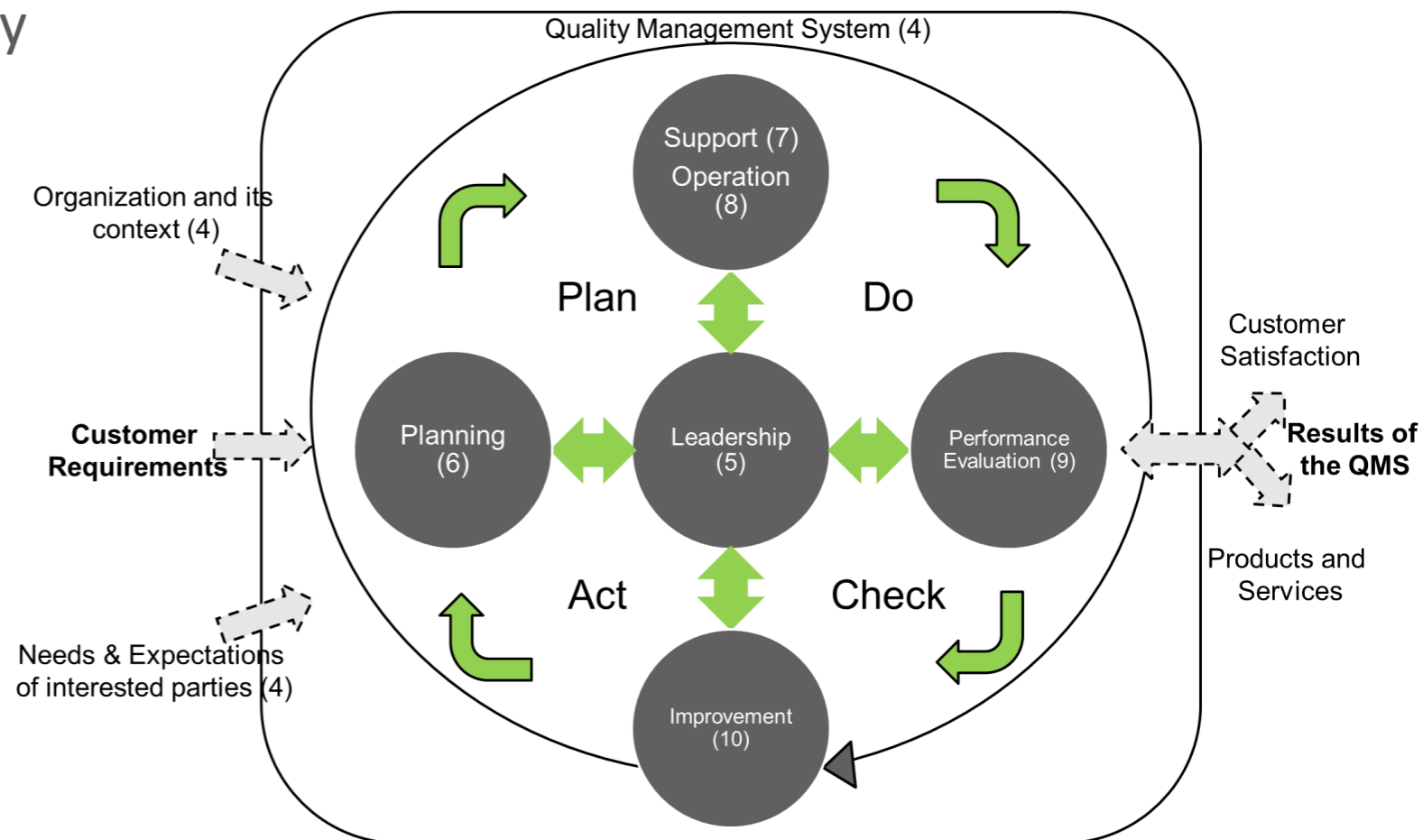




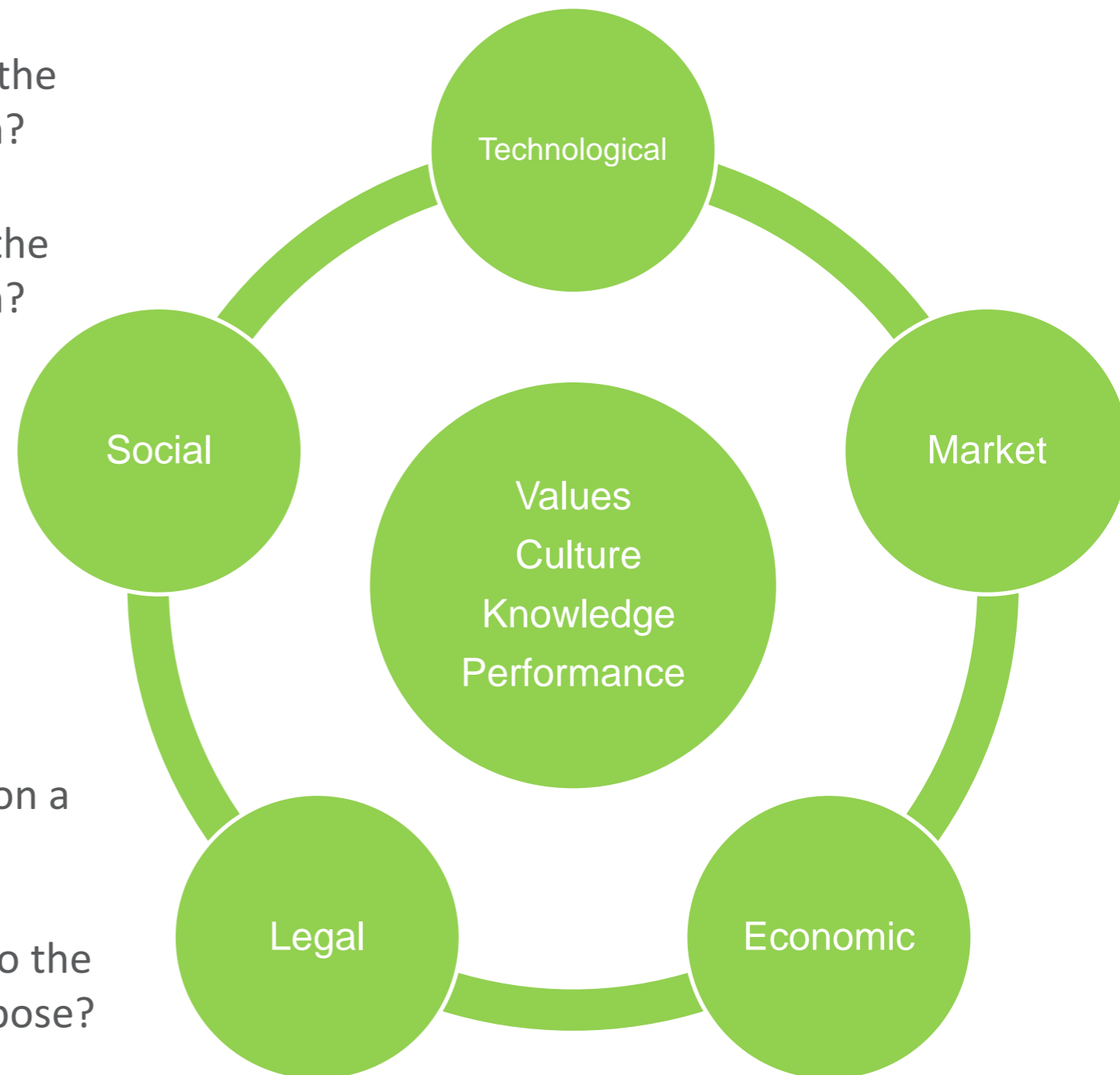
Transitioning from ISO 9001:2008 to ISO 9001:2015

- Review the new standard
- Identify what gaps exist within your current system (if any)
- **Engage leadership & plan actions to address these gaps**
- Implement changes where necessary



4.1 Understanding the organisation and its context

- What are the external issues that are relevant to the organisation and the quality management system?
- What are the internal issues that are relevant to the organisation and the quality management system?
- These issues should be monitored and reviewed on a regular basis
- Document the issues and their potential impact to the business i.e. what risks or opportunities do they pose?



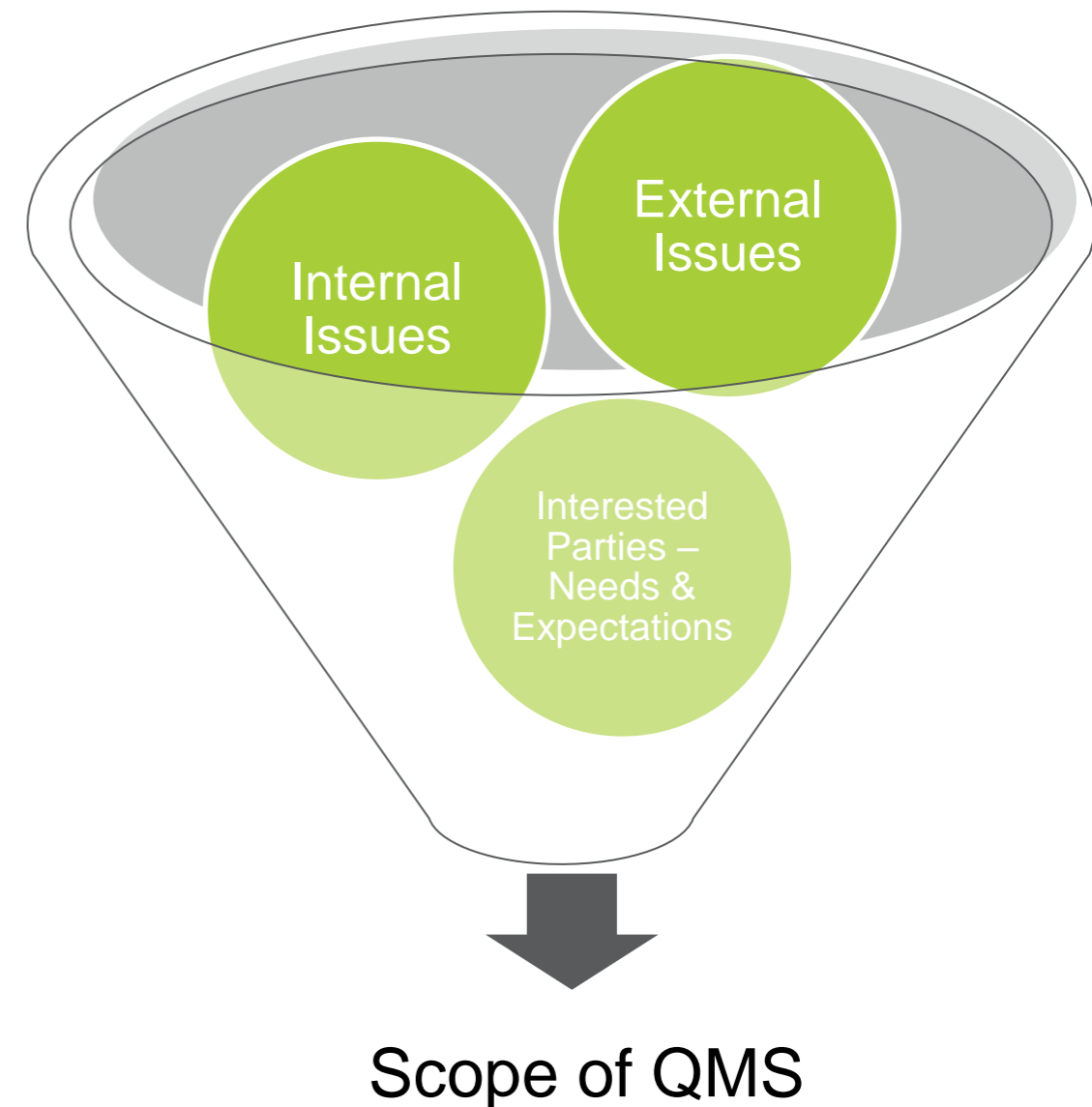
4.2 Understanding the needs & expectations of interested parties

- Identify who the interested parties are that are relevant to the Quality Management System
- What are their requirements, needs & expectations?
- Interested parties and their needs & expectations need to be identified and reviewed regularly as they may be dynamic and change over time
- Document these as part of brainstorming sessions / management meetings

Interested Party	Needs & Expectations
Customers	Quality, Price, Delivery
Regulatory Bodies	Compliance to requirements
Employees	Good Work Environment, Job Security, Career Development
Management	Business Growth, performance etc.

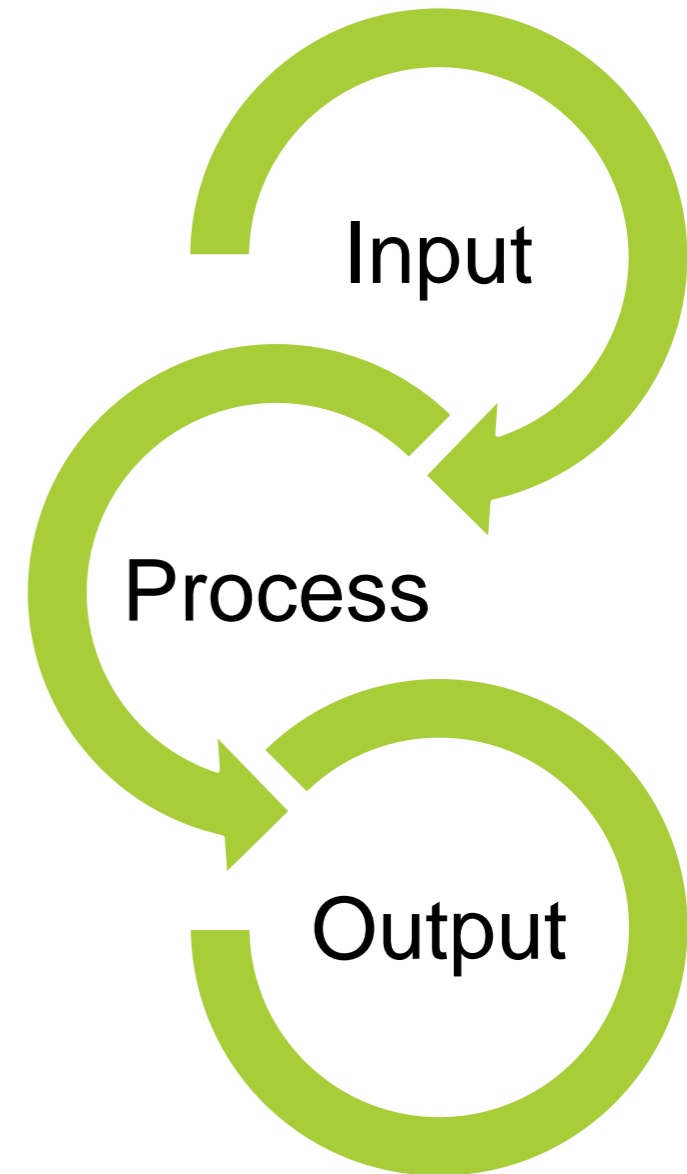
4.3 Determining the scope of the quality management system

- The information gathered in clause 4.1 & 4.2 needs to be considered when determining the scope of your quality management system
- Make reference to evidence of the reviews of the issues identified in clause 4.1 & 4.2 in the scope document
- The scope should state the products / services provided and also list all applicable sites / locations

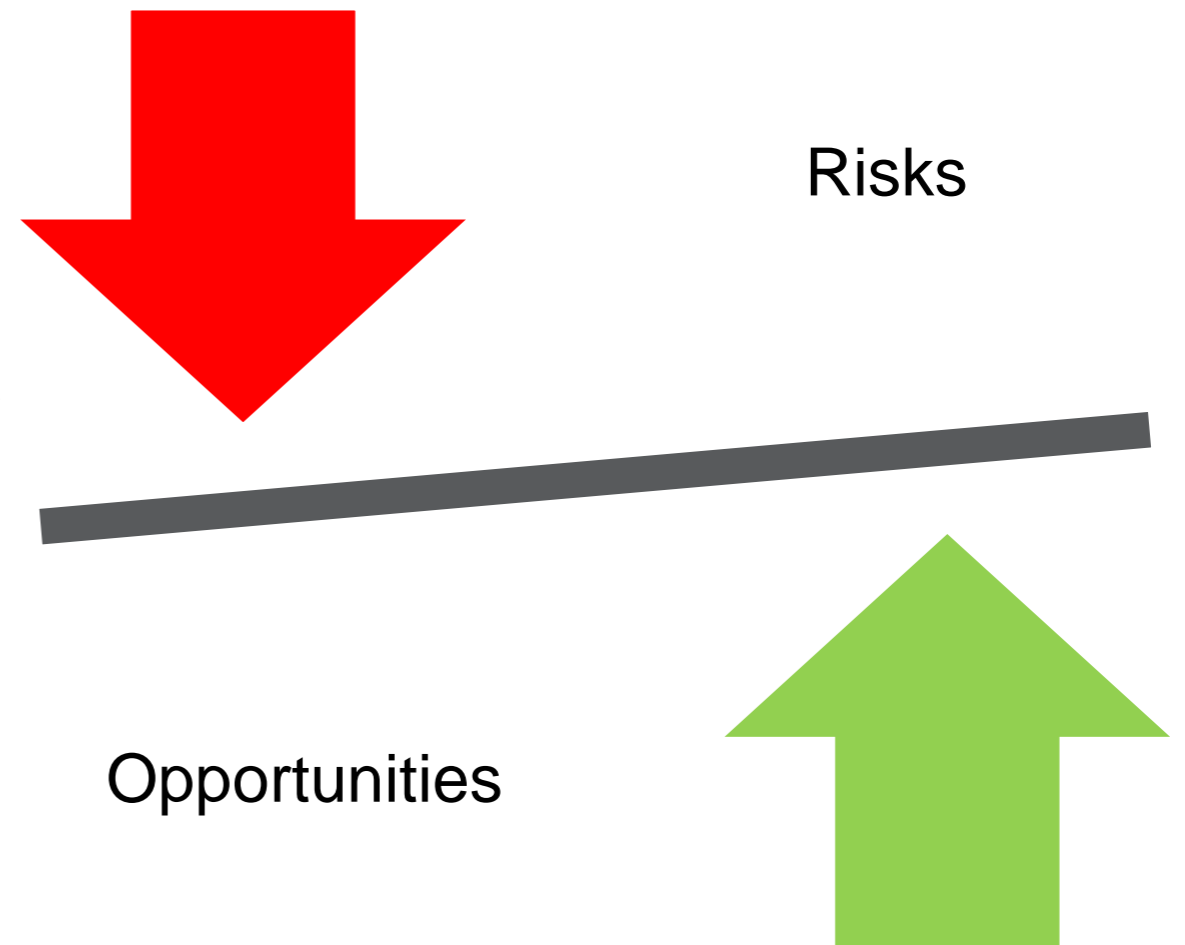


4.4 Quality management system & its processes

- Identify the processes that are relevant to your quality management system
- Determine what the inputs & expected outputs are
- Demonstrate their sequence & interaction
- What resources are required?
- How to monitor and measure the effectiveness of the processes?
- Are there risks & opportunities associated with the processes?
- Can processes be improved?



- Identify risks and opportunities that can impact your business, these may be linked with the issues identified in clause 4.1 & 4.2
- Plan actions to address the risks and opportunities that may impact your business
- Implement actions & monitor the effectiveness of actions taken
- Risk based thinking is not new, it is probably something you already do
- Formal risk management is not specifically required



- There is a greater emphasis on Leadership and Management commitment in ISO 9001:2015
- Engagement of Top Management is essential for a successful transition
- Context, interested parties, assessment of risks & opportunities fits in with the needs of Top Management
- No longer a specific requirement for a Management Representative



- Transitioning to ISO 9001:2015 does not necessarily mean a complete overhaul of your existing quality management system
 - If you are upgrading an already effective system then the changes may be minimal
 - If it works for your business keep it!
 - Many of the changes are not completely new and may be something that you are doing already!
 - If you haven't already started planning the transition, start today!
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