

# IMPLEMENTING ISO9001:2008 QUALITY MANAGEMENT SYSTEM TO MINIMIZE THE RISK OF MEDICAL EVENT

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**IAEA**

*60 Years*

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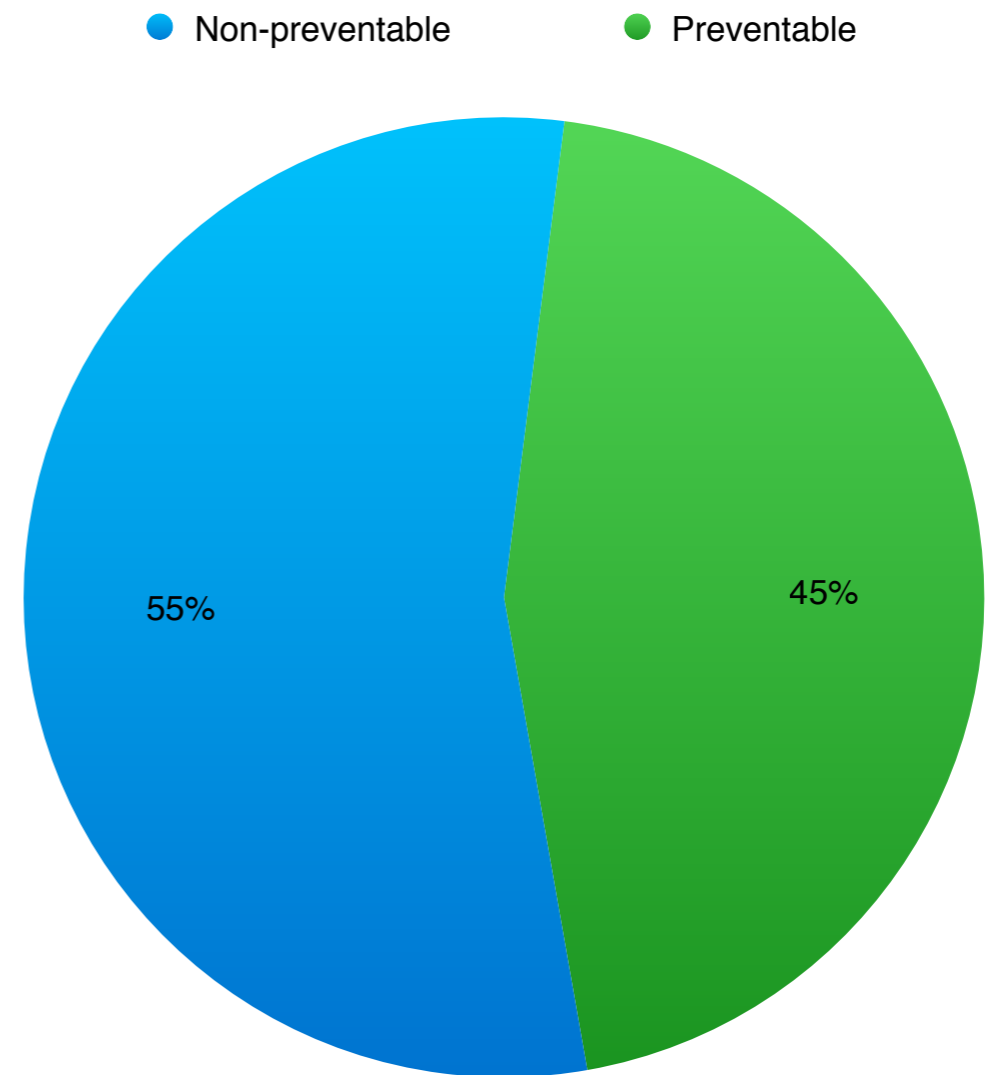


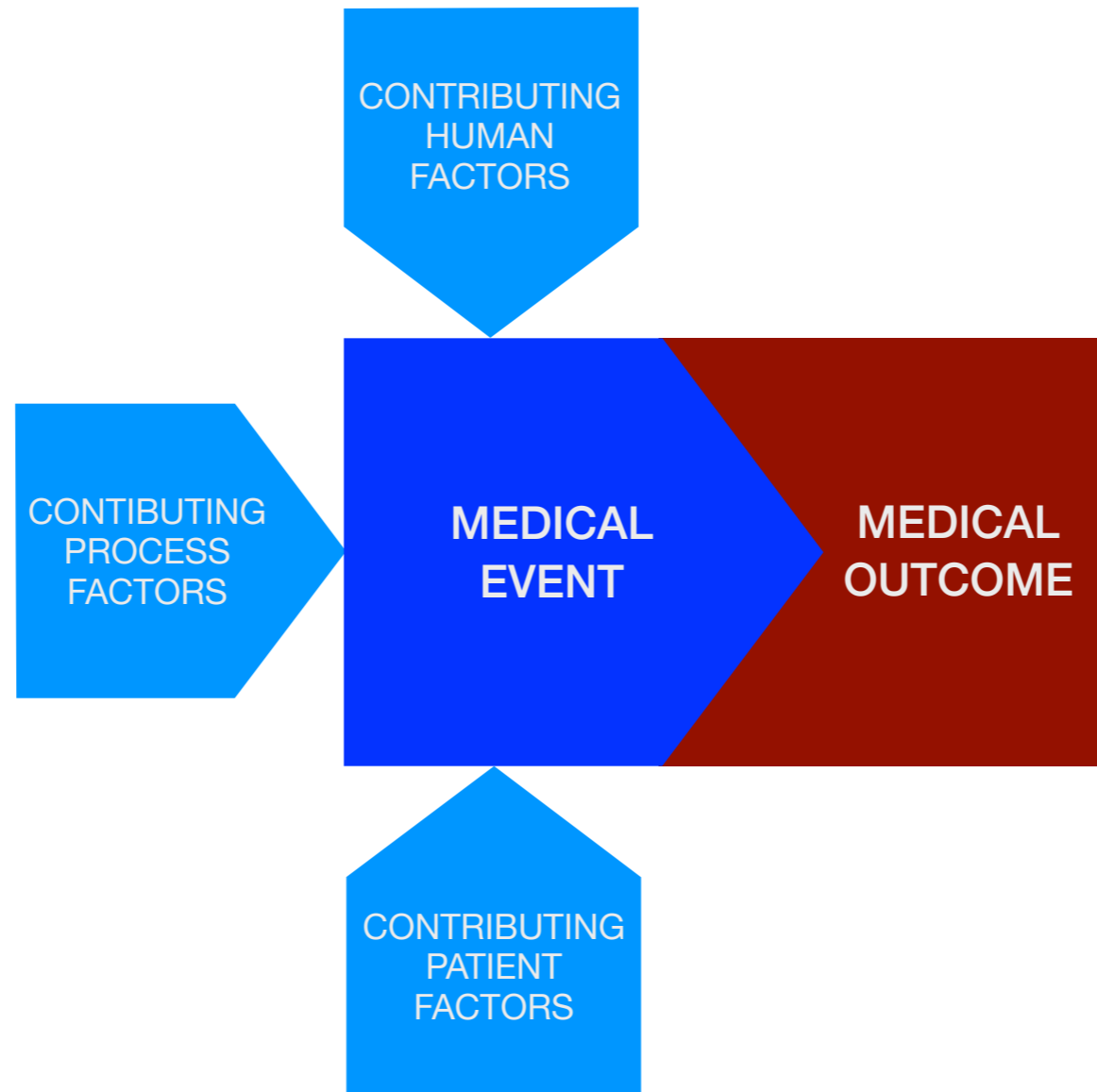


1 + 1 = 2

To err is human but we shouldn't accept it...

Medical errors cost \$37 billion/year  
Deaths due to medical error 44000/year





Systemic approach to error prevention is needed

# MEDICAL EVENTS IN PROSTATIC BRACHYTHERAPY

- Errors are events in your practice that make you conclude: “that was a thread to patient well-being and should not happen. I don’t want it to happen again”
- Such an event affects or could affect the quality of the care you give your patients
- Errors may be large or small, administrative or clinical, or actions taken or not taken
- Errors may or may not have discernable effects
- Errors are anything that you identify as something wrong, to be avoided in the future

Makeham MAB, Stromer S, Bridges-Webb C et al. Patient safety events reported in general practice: a taxonomy. *Qual Saf Health Care*. 2008;17:53-57.



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## ACMUI endorses ASTRO–recommended definition of medical event

*Rockville, Md., February 13, 2012*

At ASTRO's urging, on February 7 the Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Use of Isotopes (ACMUI) reconsidered its proposed **definition of medical event** for permanent implant brachytherapy and instead endorsed a definition that more closely resembles an ASTRO–recommended definition. The new definition tracks closely with the definition that **ASTRO offered in April 2011**, and it follows a November 30, 2011, ASTRO request for ACMUI to revise an earlier definition that ASTRO believed was overly complex. Both ACMUI's new definition and ASTRO's definition rely on determining medical events based on activity, rather than dose. In addition, the ACMUI definition allows for the authorized user to complete the written directive before the patient has been released from the authorized user's control and to include all details of the procedure, including any unusual aspects of the procedure. The NRC is working on changes to the rule governing the use of medical isotopes, including the definition of medical event. A draft rule is expected by the end of 2012, with a final rule in December 2014. For more information, please contact [Cindy Tomlinson](#).

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*Content last updated 2/20/2012*

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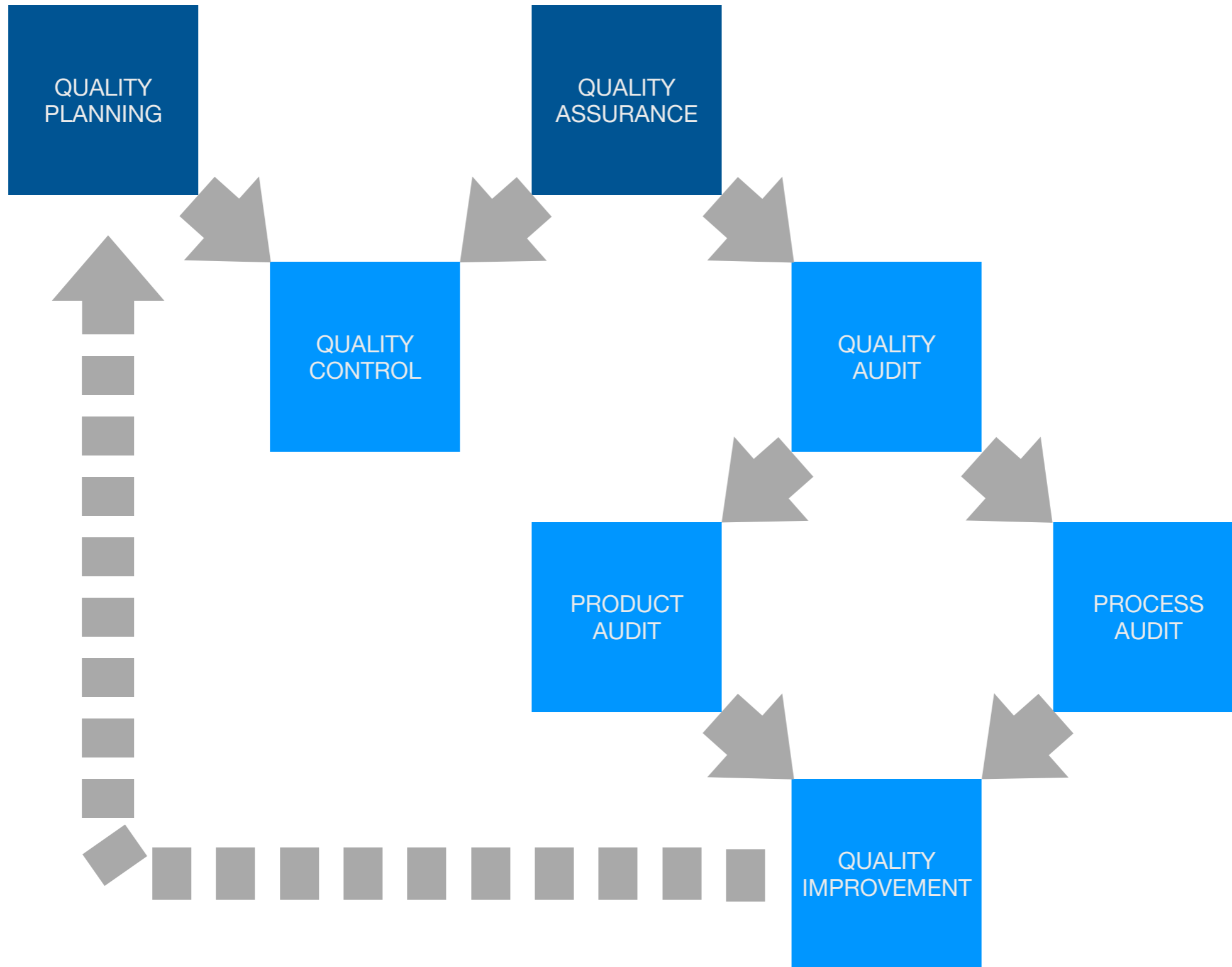






IMPLEMENTING  
QUALITY MANAGEMENT SYSTEMS  
IN BRACHYTHERAPY

# A GENERIC QUALITY MANAGEMENT SYSTEM IN BRACHYTHERAPY





ISO Store

ISO Standards

By ICS

By TC

How to use the ISO Catalogue

Standards in action

Management and leadership standards

ISO 26000 - Social responsibility

ISO 31000 - Risk management

Management system basics

ISO 50001 - Energy management

ISO 9000 - Quality management

>> ISO 9000 essentials

Quality management principles

Selection and use

ISO 9001:2008

ISO 9001 for SME's

More ISO 9000 resources

Origins and ISO/TC176

## ISO 9000 essentials



This section concisely describes the essential features of the ISO 9000 family.

The ISO 9000 family of standards represents **an international consensus on good quality management practices**. It consists of standards and guidelines relating to quality management systems and related supporting standards.

ISO 9001:2008 is the standard that provides **a set of standardized requirements for a quality management system**, regardless of what the user organization does, its size, or whether it is in the private, or public sector. It is the only standard in the family against which organizations can be certified – although **certification is not a compulsory requirement** of the standard.

The other standards in the family cover specific aspects such as fundamentals and vocabulary, performance improvements, documentation, training, and **financial and economic aspects**.

### Why an organization should implement ISO 9001:2008

Without satisfied customers, an organization is in peril! To keep customers satisfied, the organization needs to meet their requirements. The ISO 9001:2008 standard provides a **tried and tested framework** for taking a **systematic approach** to managing the organization's processes so that they consistently turn out product that satisfies customers' expectations.

### How the ISO 9001:2008 model works

The requirements for a quality system have been standardized - but many organizations like to think of themselves as unique. So how does ISO 9001:2008 allow for the **diversity** of say, on the one hand, a "Mr. and Mrs." enterprise, and on the other, to a multinational manufacturing company with service components, or a public utility, or a government administration?

### Related information

- [ISO and IAF announce schedule for implementation of accredited certification to ISO 9001:2008](#)
- [ISO 9001:2008 - Introduction and support package](#)
- [More ISO 9000 resources](#)
- [Quality management principles](#)
- [ISO 9001 - What does it mean in the supply chain?](#)
- [ISO 9001:2000 auditing kit](#)
- [More ISO 14000 resources](#)

### ISO 9001 for Small Businesses



Aimed to help SMEs to understand and implement ISO 9001.

[More information >>](#)

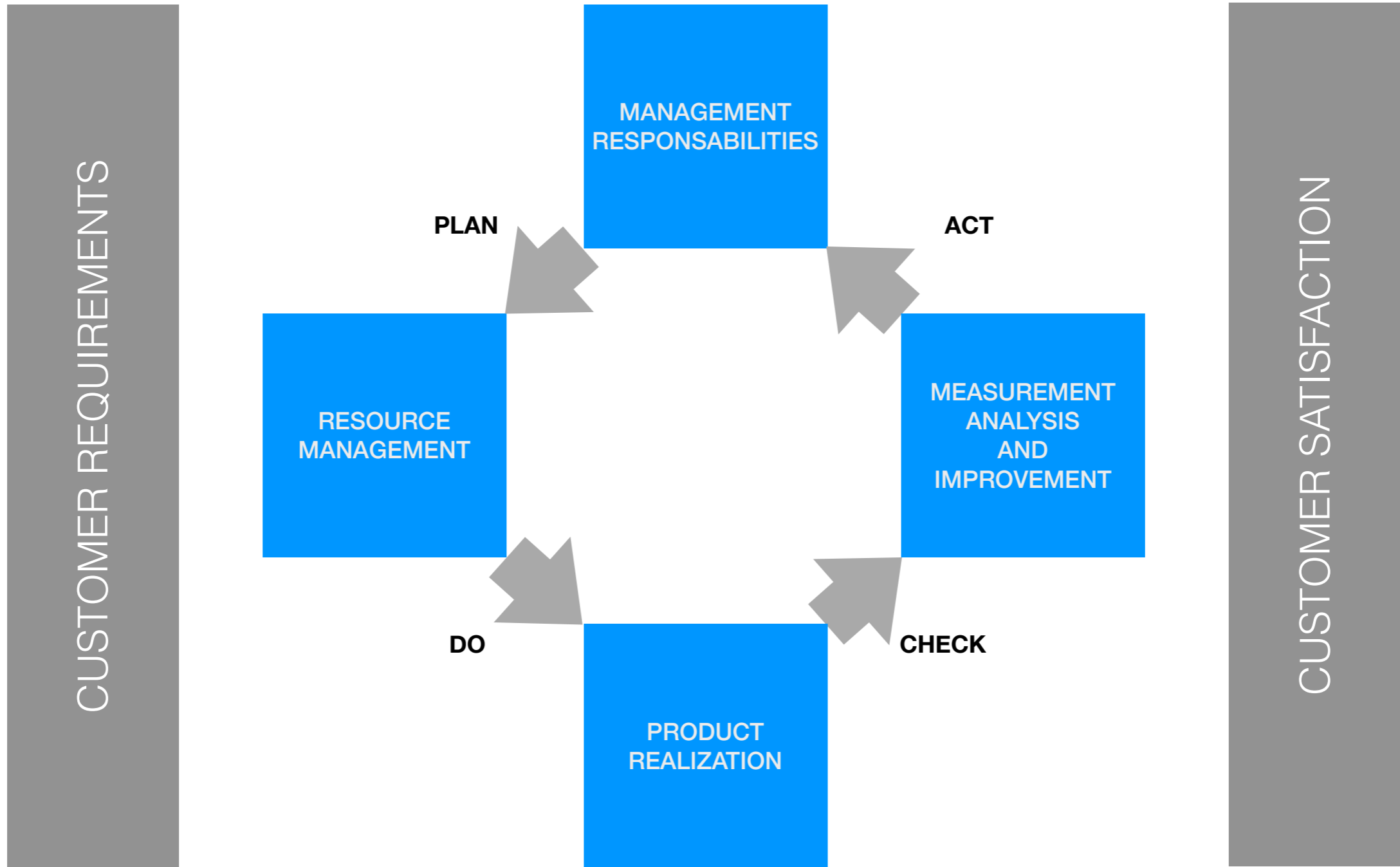
### The integrated use of management system standards



Guidance on how to make integrated use of management system standards

[More information >>](#)

# CONTINUAL IMPROVEMENT (PLAN-DO-CHECK-ACT)



CONCLUSION



