



*NAVIGATING REGULATOR EXPECTATIONS FOR
MANAGEMENT SYSTEMS SERIES*

Help Guide 2: Right Size Your Assurance

Assurance Program Development and
Implementation

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Overview

Based on our experience working with clients and regulators, there are certain areas across industry that cause confusion relating to management systems. *Through this 3-part series, we will outline the three most common deficiencies we have seen, and offer insight on opportunities for improvement.*

Deficiency 2: Assurance Program Development and Implementation

Audit and inspection programs in practice are often either poorly defined or poorly planned, developed and implemented. **Companies scramble to conduct audits on an as-needed or as-required by regulatory bodies, rather than using their assurance activities as a proactive and integral tool within the management system itself.**

Additionally, the outputs from audits and inspections, such as corrective actions, are often not well documented and/or do not include the proper follow-up to verify implementation or confirm effectiveness of addressing the identified issue.

These deficiencies in assurance programs occur mainly because assurance is looked at as the responsibility of particular roles at a specific point in time, rather than as everyone's responsibility on an ongoing basis. In addition, **risk-based assurance is often overlooked** in favour of regulation-driven assurance, which can be a big miss for proactive identification, management and improvement of deficiencies.

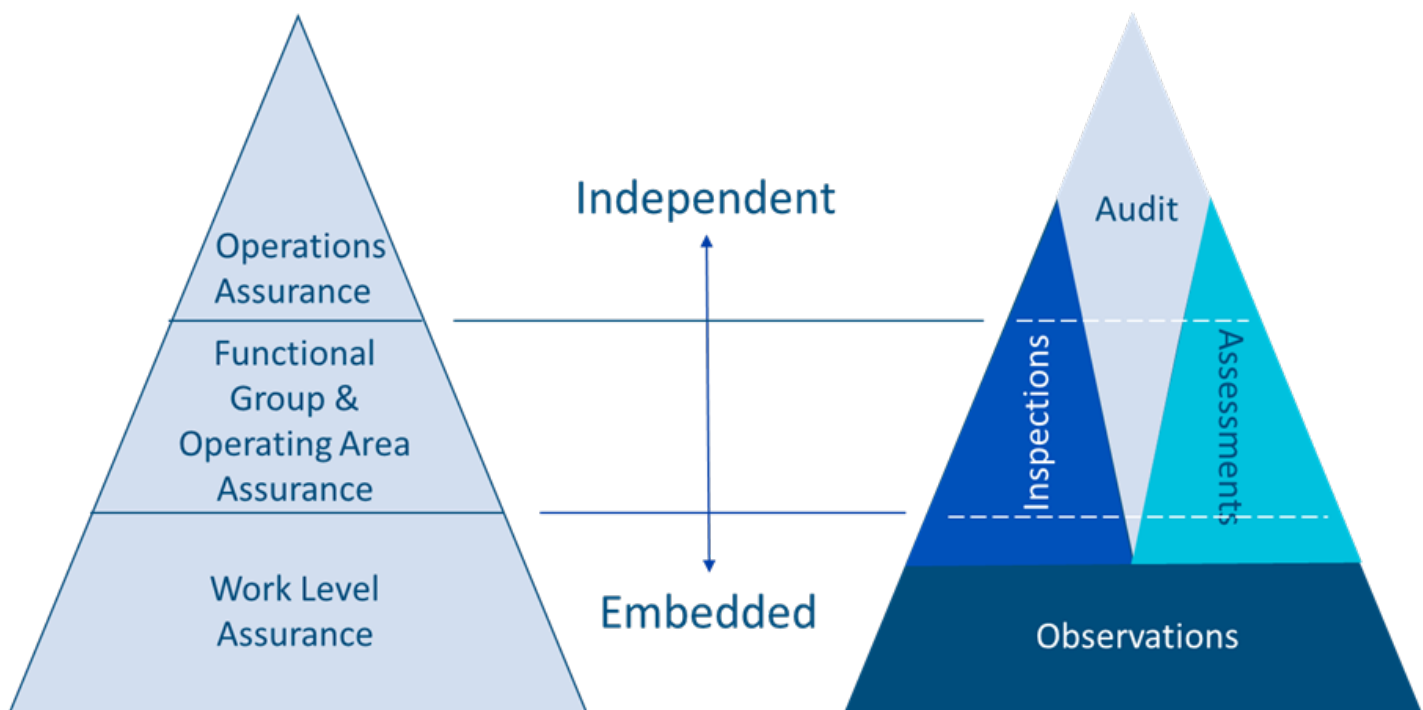
This FREE Help Guide will provide answers to common questions, such as:

- How do I embed assurance processes into my management system?
- What are the components of a successful assurance program?

EMBED YOUR ASSURANCE

Assurance programs are best viewed as an integral part of the management system, with responsibilities for assurance embedded directly within each area of the system.

Audit and inspection activities need to be viewed as two tools in an overall program of operational assurance, including assessments and observations. The following diagram shows the **hierarchy of assurance activities**, where **independent vs embedded assurance** takes place, and **the different types of assurance activities** which should be used.

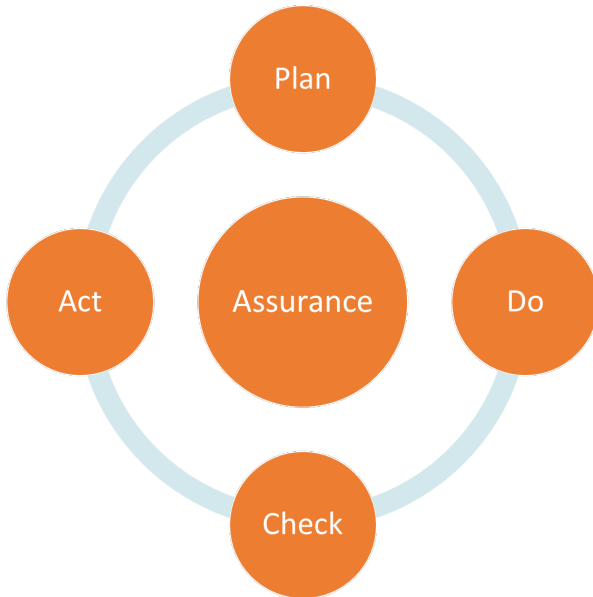


For efficiency and effectiveness, each area (element, sub-element etc.) of the management system should define the assurance activities it is responsible for and make a plan for ongoing execution. Independent assurance (audits) may be the responsibility of a separate group, or independence can be achieved through external contractors or other personnel in the company that are separate from the functions they are auditing.

RIGHT SIZE YOUR ASSURANCE

Plan-Do-Check-Act

Assurance is a critical part of the Plan-Do-Check-Act system inherent in any management system. However, assurance needs to be right-sized for each organization based on the identified risks, hazards and controls currently in place to help ensure suitability of assurance activities for the business.



TIPS FOR SUCCESS

- Successful assurance requires planning and clear identification of responsibility.
- Audits and inspections are not complete until findings are all followed up with actions that are planned, implemented and confirmed as effective.
 - *Note: Many companies simply do not have efficient or effective systems in place to do this well, check the tools you use.*
- Audit and inspections are key activities for confirming goals and objectives are met, and providing input to management.

i PLAN

- Develop long-term and annual assurance plans to enable budget and resource allocation.
- Prioritize assurance activities to address identified risks.

i DO

- Apply appropriate controls to risks and hazards (*example controls: administrative, design, skills and knowledge*).

i CHECK

- Conduct assurance activities such as audits, assessments, inspections and observations on a continual and planned basis.

i ACT

- Identify corrective (and preventative) actions.
- Verify assurance results.
- Conduct a management review.
- Review lessons learned.

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We operate in a highly collaborative way, working side by side with our clients to help them reach their goals and sustain solutions long-term.