

THE QUALITY ASSURANCE



PODCAST

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EPISODE 3

**POLICIES WITH PURPOSE:
SOPs THAT PROVE PERFORMANCE**



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IN THIS EPISODE

- The core purpose and function of standard operating procedures (SOPs).
- Identifying the correct authors to draft internal procedures.
- The essential components every SOP must contain.
- Creating tangible evidence through measurable deliverables and templates.



“

If you want a cake to turn out
the same everytime,

you need to follow a
recipe.

An SOP is a recipe.

JEANETTE STEWART

CEO & Co-Founder, PRN



WHAT IS AN SOP?

- acts as step-by-step processes outlining exactly how to perform specific tasks
- support regulatory requirements by demonstrating to inspectors, auditors, and clients how an organization executes expected activities

WHO SHOULD WRITE THE SOP?

- authored and reviewed by the team members who actively perform the specific tasks (e.g., those conducting monitoring visits, processing safety cases)
- having individuals write procedures when they **do not** actually perform the activities or understand the logistics is a **disaster waiting to happen.**





That is a disaster waiting to happen.
Because what happens is
**team members who are actually
doing it are doing it the way they
think they should be doing it,
not the way it's defined in the SOP,** which
opens you up to scrutiny during an
inspection or an audit.

ASHLEY HEHR

Quality Assurance Expert





WHAT ARE THE COMPONENTS OF A STANDARD OPERATING PROCEDURE (SOP)?

EPISODE 3 - POLICIES WITH PURPOSE: SOPs that Prove Performance

COMPONENTS OF AN SOP

TITLE

Clearly explains the document's exact subject (e.g., Interim Monitoring Visit).

PURPOSE

Outlines the specific reason the document exists to provide absolute clarity.

SCOPE

Defines the boundaries, including what is applicable and what is excluded.

COMPONENTS OF AN SOP

ROLES & RESPONSIBILITIES

Pinpoints exactly who within a department is responsible for specific actions, moving beyond broad departmental labels.

REFERENCE

Cross-references other applicable SOPs, forms, and templates.

PROCEDURE

The core recipe that must be clear, concise, logically structured, and feature realistic timelines.

HOW DO TEAMS PROVIDE TANGIBLE EVIDENCE THAT AN SOP IS BEING FOLLOWED?

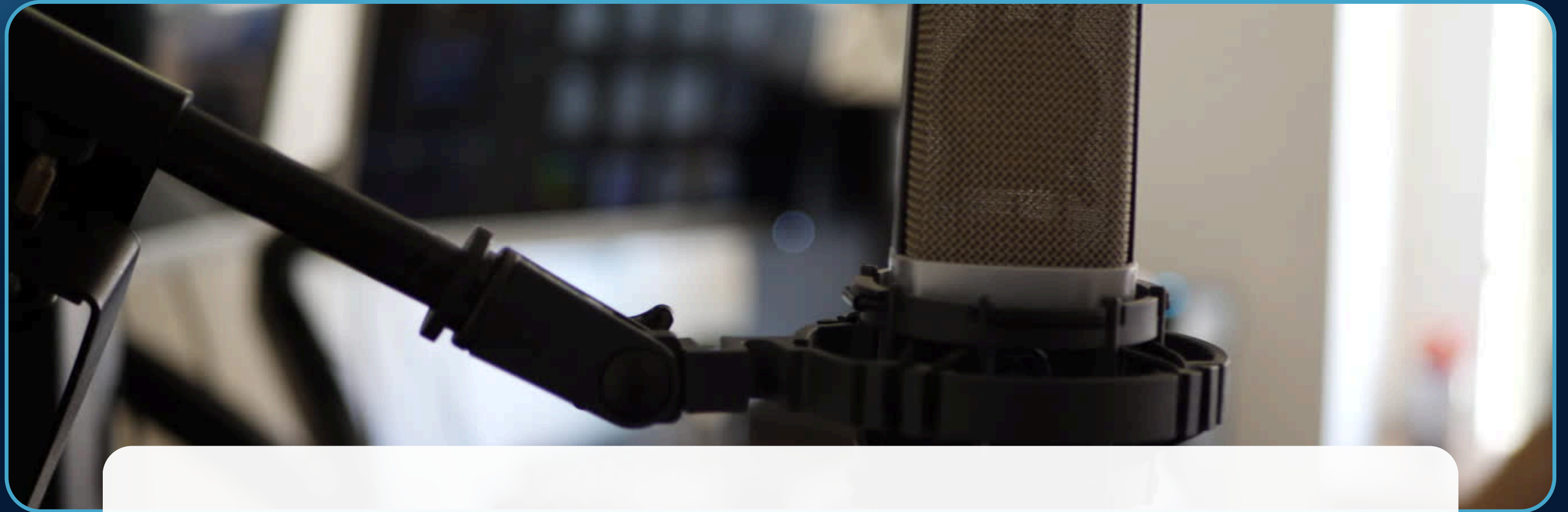
- Procedures must result in measurable deliverables, not just passive statements of intent.
- Instead of stating "ensure vendor is qualified," an SOP must define the exact actions and documents required to prove qualification.
- Procedures should use active voice and simple commands rather than passive suggestions.
- Standardized forms and templates keep data collection concise, and they should feature text fields for necessary extra information rather than limiting responses to strict yes/no checkboxes.

**NEED HELP WITH QUALITY SOPs?
WE'RE HERE TO HELP!**



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