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How User-Friendly and Effective Are Your Written Standards?

As a compliance officer, do you often wonder if your written standards are missing the mark? Some questions you might ask yourself are...

Do

- employees at your organization regularly **refer to** and use your written standards?
- people **understand** your organization's written standards?
- your organization's written standards **reinforce the company's values or guiding principles and a culture** of compliance?

Written standards are a **foundational element** of an effective compliance program that instruct employees, contractors, and government agencies on the organization's **standard parameters** around the performance of the business' activities, designed to mitigate existing risk. They represent the company's interpretation of the law.

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However, often times compliance departments find that written standards may fail to achieve the intended outcome and are not as effective in practice.

> The Department of Health and Human Services Office of Inspector General (OIG) released its "General Compliance Program Guidance" (GCPG) in November of 2023, and this document was part of an effort by the OIG to "**produce useful, informative resources**" to the health care industry.
> The updated document has a very different look and feel than the prior version.
> These formatting changes can be interpreted as a signal from the government on what more effective written standards may look like.
> This document highlights **10** questions to consider when developing useful, informative, and effective written standards.

Why 10?

> **10** grabs attention.
> **10** stands out.
> **10** highlights the important questions.
> **10** is easy to read.
> **10** can create hype.
> **10** is visually appealing.
> **10** can simplify a complicated subject.

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Are Your Written Standards Formatted for Understanding?

As evidenced by the design overhaul of the GCPG from a multiple-column, small font document to an easy-to-read document with sections highlighting tips and key takeaways, the format and design of your written standards can impact the understanding and **user-friendliness** of the document.

Codes of Conduct and some compliance manuals have started to evolve in our industry, but many written standards have remained in the older formats.

Do your written standards include design features similar to the examples below to enhance the user-friendliness of the document?
- ☐ Call out boxes
- ☐ Multiple font colors
- ☐ Images
- ☐ Large fonts and white space
- ☐ Links or mouseover ability

TIP:
What is challenging as a reader = what to avoid as a writer

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Do Your Written Standards Increase a Reader's Risk IQ?

One way to incorporate a **culture** of compliance via written standards is to use them to increase the risk IQ of the reader.

This can be done through meaningful explanations of the risk, so a reader can remember a principle that can be applied in situations in which the guidance document does not specifically cover.

Most readers of written standards are not experts on laws and/ or compliance. Therefore, a meaningful explanation of risk should go beyond the referencing of applicable laws or the listing of potential risks.

"

The compliance program should also require that all the entity's policies and procedures incorporate a culture of compliance into its day-to-day operations.

General Compliance Program Guidance

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# Do Your Written Standards Explain the Actual **Purpose** of the Document?

Often times the purpose section only states the scope of the document (e.g., this document covers your organization's standards for an activity) but does not go on to explain to a reader the actual purpose of the document in a meaningful way.

The purpose should relate to the **context** provided, as well as the **management of the explained risk**.

TIP:

Documents should be written so that an external (sometimes adversarial) party picking up the document can clearly understand the scope, defined terms, version history, etc.

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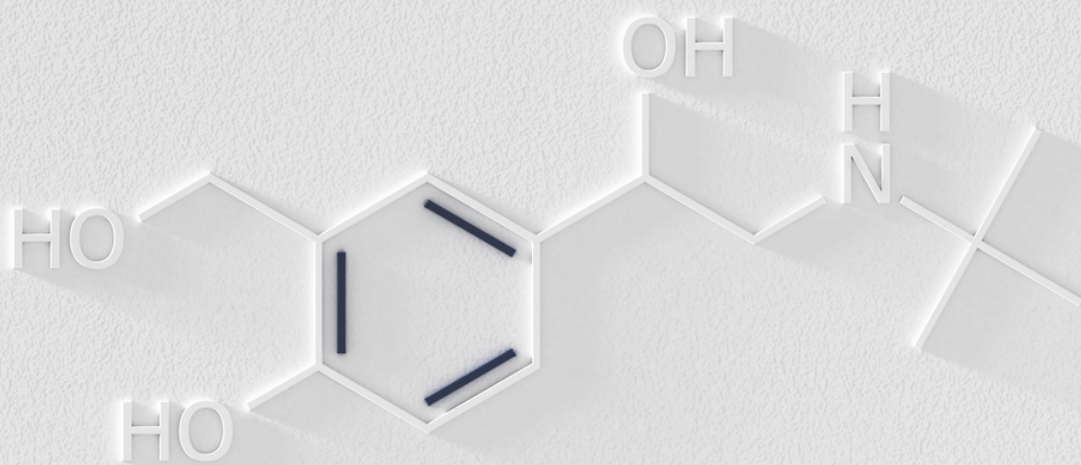
How Easily Can Readers Find the Answer to a Specific Question?

The primary purpose of written standards is to serve as resources for employees to find the answers to their questions. Therefore, the useability of the document matters.

What features do you include in your written standards that would help a reader find the answer to a specific question?
- ☐ Naming convention
- ☐ Ability to search within a document
- ☐ Links
- ☐ Table of Contents (at the beginning and/ or throughout)
- ☐ Clear headings

TIP:

Include links back to the original link. Meaning, if a link is clicked to bring a reader somewhere, ensure there is a link back to the original place in the document. It can be much more user-friendly than having to scroll back.

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Example Scenario

How can employees find out whether they can provide flowers to a longtime customer whose spouse recently passed away?

Accessibility

Would the employee know where to find the relevant policies? How easy would it be for them to figure out which documents to look in?

Navigation Between Documents

If the initial document opened did not provide the answer but a related document may, how easy would it be to access that document?

Searchability

How easily and quickly could an employee search within a document for a specific topic? Could they search for flowers or gifts?

Formatted for Understanding

Besides searching, how easy is it for an employee to find specific topics within a document? Are there headings?

Understandability

If the document would consider the giving of flowers a gift, is that defined? Is it easy to find the definition? Is the document written in a manner for employees (e.g., reading level) for easy understanding?

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How Easily Can Readers Find Supporting or Overarching Documents?

Most written standards relate to and/ or reference other documents. How easy is it for a reader to navigate between the documents?

- ☐ Are reference documents listed?
- ☐ Are those documents linked?
- ☐ Do linked documents open up in the same browser or do they open in a new tab or window?
- ☐ Can you easily get back to the original document?

⚠️ **It is important to plan for how external links will be updated as written standards are added or updated overtime.**

TIP:
Linking to a location (e.g., an intranet page) where written standards will be stored or linked can remove the need to update individual links in documents.

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Are Your Written Standards Accessible?

A great written standard is not worth much if people cannot find or easily access the document.

- ☐ Where are the documents stored?
- ☐ Is it intuitive to find a document?
- ☐ Is there only a single-sign on?
- ☐ Can they be accessed and readable on mobile devices?
- ☐ Do you have to know the written standard number to easily find it?

Q: **Is an intranet needed for the storage of written standards?**

A: No. An intranet with a compliance-specific page can be great, but is not essential for the storage of written standards. You can still work cross functionally to find a way to **store** and **share** written standards broadly in an easy to access **centralized** location.

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Are Your Written Standards
Understandable?

In order for a written standard to be useful, readers have to be able to understand it. Two ways to ensure this are clearly defining terms and considering the appropriate reading level.

1. Defined Terms: Defined terms are often important for understanding the content of the document. Document authors should consider: How easy is it to find the meaning of a defined term? Are readers scrolling to a definitions section or opening a glossary? Are definitions consistent across documents?

2. Reading Level: At what reading level are your written standards written? Are the documents full of legalese, jargon and/ or three-letter acronyms? Where appropriate, are documents translated into other languages?

TIP:

The Editor in Microsoft Apps can inform you of the reading level of your document.

TIP:

Unclear documents are often a result of the writer lacking sufficient knowledge of how the business operates. Be sure to include relevant stakeholders in the development process.

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Do Your Written Standards Provide Clear, Unambiguous Guidance?

Written standards can provide clear, unambiguous guidance in a variety of ways including:

Do's and Don'ts Lists

Do	**Don't**
✓ Use lists	✗ Hide important messages in large paragraphs or long sentences
✓ Clearly articulate guidance	
✓ Provide resources to answer questions	✗ Provide unclear or ambiguous guidance

Checklists

☐ A checklist can be useful resource for an employee to use when conducting an activity.

☐ Checklists can serve both as a guidance document and a source of documentation.

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Do Your Written standards Clarify Past Issues and/ or FAQs?

One sign of an effective compliance program is when results of monitoring and investigations influence written standards.

Sharing Insights

Using call out boxes and/ or FAQs can be a great way to enhance written standards with specific scenarios or topics that require further understanding. Doing so can also draw attention to key points to emphasize important shared learnings.

An **FAQ** can also be a good way to go through a realistic situation a reader may face and provide clear guidance on what to do in such a situation. Furthermore, FAQs can be leveraged as discussion topics during trainings.

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Do You Know Who is Using Your Written Standards and How Often?

To help identify if written standards are being used/accessed, besides surveying employees about the effectiveness of written standards, organizations can track various data points to learn about the effectiveness of their documents. What information can you collect? And what insights can be learned?

For example, what does it mean if …

documents are only opened once a year?
- ☐ People only need to reference the documents once a year for a given activity?
- ☐ The documents are so well written that there is no need to regularly look at the document?
- ☐ Are employees saving versions locally on their own device?

a certain department regularly opens a document?
- ☐ Something is unclear to that department in a document?
- ☐ There was a training or new activity that led to more people opening a document?

⚠️ **What metrics do you have access to to gain insights about your written standards?**

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Frequently Asked Questions

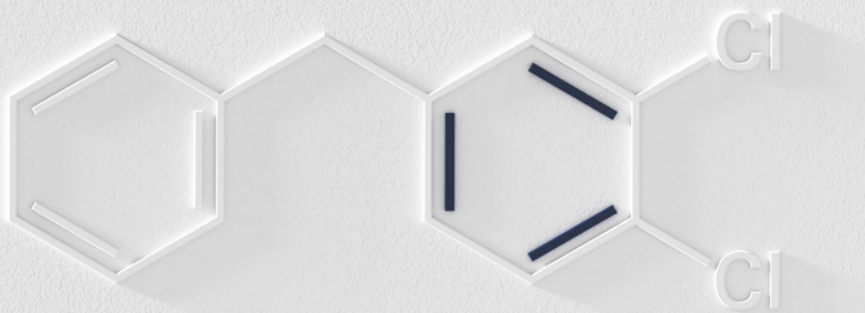**How can Epsilon Life Sciences help?**

Our professionals have expertise in assisting organizations in developing risk-based policies and procedures based on company-specific needs and industry best practices.

Does Epsilon Life Sciences assess compliance programs, including written standards?

Our team regularly conducts reviews of compliance program effectiveness for a variety of organizations (e.g., small pre-commercial, big pharma, medical device). Assessments often include an analysis of the organizations written standards and recommendations for continuous improvement.

How can my team learn to write more effectively?

We conduct trainings with the purpose of providing tools and tips to write clear, concise, and relevant written standards.

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Audrey Koi
akoi@epsilonlifesciences.com
412.592.1532

Steven Klimberg, JD, MBA
sklimberg@epsilonlifesciences.com
609.923.8764

Liz Prinzi, MPP
lprinzi@epsilonlifesciences.com
718.404.8267

Matthew Chandler, JD
mchandler@epsilonlifesciences.com
804.223.6933

Saul B. Helman, MD, MBA, BS
shelman@epsilonlifesciences.com
317.294.1228