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# Don't Be Haunted By Your Words!

By Nancy Singer and Joseph Pickett

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*In this article, Ms. Singer and Mr. Pickett offer advice to both government and industry officials on writing clear and concise reports that won't come back to haunt them in the future.*

## **How to Avoid Mistakes in Documents That Destroy Your Credibility and Lead to Legal Trouble**

If you think about it, an electronic document is like a diamond. It is very precious, and it lasts forever.

This is especially true in the field of food and health care products. These products are necessities. The people and entities regulating and manufacturing food, drugs and medical devices are highly visible. That visibility is often a plus, but when things go wrong, it can be a minus.

For FDA-ers, you and your documents are under the intense scrutiny of:

- Defense lawyers.
- Office of the Inspector General (OIG).
- Congress.
- Trade associations.
- The media.

Food, pharmaceutical and device firms, you too are under intense scrutiny. The groups that are closely watching you and your writings include:

- The competition.
- Federal prosecutors.
- State prosecutors.
- Plaintiffs' lawyers.
- The media.

Basically, if food or health care products cause harm, the public will blame the product manufacturers and the government—whose job it is to oversee the manufacturing of these products.

So, it is vital to use care when you write emails, reports, and other documents. The consequences of carelessness may not come immediately. But, six years later, during an oversight hearing or in a trial, you could have members of Congress, prosecutors, or the media saying, "Can you *believe* they wrote that?"

## For FDA – Lack of Specificity or Evidence in EIR Statements

The *Investigations Operations Manual* (IOM) is the primary source regarding FDA's policy and procedures for field investigators and inspectors. The foreword to the IOM states: "...Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations."

Section 5.10.4 of the IOM says that the narrative report in the Establishment Inspection Report (EIR): "...should be factual, objective, and free of unsupported conclusions. Be concise and descriptive while covering the necessary aspects of the inspection." "

Sounds simple, right?

However, when we reviewed several EIRs, we found statements such as:

### Example 1:

*"The firm calibrates all of its manufacturing equipment every six months."*

This is problematic. Why? First of all, it is vague. But there is a deeper problem. In essence, the investigator has just *endorsed* an unsubstantiated claim of the company. If that company's devices don't work because the equipment manufacturing the device was not properly calibrated, the investigator could have some unpleasant questions to answer.

Here is a better way to convey the same information:

*"I reviewed the firm's SOP, which states that the Director of Calibration will calibrate all of the manufacturing equipment every six months. (See Exhibit 1). I reviewed the firm's calibration documentation for the calendar year 2010, and the records reflect that all of the equipment identified in the SOP has been calibrated according to the schedule."*

This statement provides clear, concise facts about the SOP. It also makes clear that the investigator verified the company's *records* rather than the company's *actions*.

### Example 2:

Another EIR example states: *"The production rooms are cleaned daily."*

A member of Congress would have a lot of fun with this one. Imagine yourself on the receiving end of this question: "If the production rooms are cleaned daily, Mr. Investigator, how can you explain the existence of rodents in the production facility?" Once again, the investigator is setting himself or herself up as the defender of the company's actions.

Here is a better and more accurate way to state this: *“The SOP on sanitation states that the production rooms are cleaned daily.”*

**Example 3:**

A third vague example from an EIR states: *“The firm uses Yost Pest Control Services, and the firm has not had problems with pests.”*

How nice of you to take the company’s side, Ms. Investigator!

Let’s try that again: *“I reviewed the firm’s pest control reports from Yost Pest Control Services for 2010, which are attached in Exhibit 1. Of the ten reports reviewed, I did not see any reports of rodent activity.”*

**For FDA – Know When to Use Active and Passive Voice.**

Section 5.10.4 of the IOM on Narrative Report elements states: “Generally, [EIRs]...should be written in the first person using the active voice.”

The FDA Intranet states “Readers prefer active voice sentences, and we should try to use the active voice in most of our business writing... Active voice identifies the action and who is performing it. Unfortunately, much of government writing is in the passive voice....[it] becomes a habit; one we should all work to change.”

To eliminate the passive voice, EIR statements should include answers to the following:

- Who?
- What?
- Where?
- When?
- Why?
- How?

Challenge the significance of each observation by asking, “So what?”

In passive voice, the subject is acted upon. Statements usually are wordy, contain the verb “to be,” and can hide the actor. We want the document to clearly identify the actor. There should be no confusion down the road as to who did what.

**Example 1:**

In passive voice, the subject is acted upon, and the actor is indistinct.

*Passive: “Six records were reviewed and discrepancies were found in each record.”*

In active voice, the subject performs the action.

*Active: "I reviewed six records and found discrepancies in each record."*

**Example 2:**

*Passive: "The Form FDA 483 was annotated by the firm."*

**Not good.** This statement does not answer who, what, or when. The FDA wants to know the facts if something should happen at the firm.

*Active: "At the end of the inspection, the firm's Vice President of Quality Assurance, Joe Yakes, annotated each of the items on the Form FDA 483."*

Result: If the firm does not follow up on the corrective items, the FDA knows whom to contact.

**Example 3:**

*Passive: "A list of all batches of SAP drugs manufactured since the last inspection was provided."*

*Active: "At my request, Mr. Bates provided a list of all batches of SAP drugs manufactured from January 2010 through June 2010, which is attached as Exhibit 4."*

However, sometimes the passive voice is acceptable, such as when the actor is:

- Unknown: The office was built in 2006.
- Unimportant: The Toal Company's response to the Form FDA 483 was mailed on June 10, 2010.
- Better left unsaid (tact): Your form was written incorrectly.

**Here are some other examples of when passive voice is acceptable.**

*"The previous inspection was classified as VAI."*

*"No Form FDA 483 was issued."*

*"The inspection of this Class II device manufacturer was conducted on Nov. 23, 2010."*

**For Industry – Problems with Passive Voice**

To create accurate historical records, industry officials should use the active voice in official documents. Think about trying to reconstruct an incident five years later when a problem arises. By that time, many of the employees who were involved may have left the firm. The documents should state who did what and when they did it.

Section 5.3.6.2 of the IOM states that in order to establish relationships between violative conditions and responsible individuals, the following types of information would be useful:

- What orders were issued? (When, by whom, to whom, and on whose authority and instructions)?
- What follow-up was done to see if orders were carried out (when, by whom, on whose authority and instructions)?
- Who decided corrections were or were not complete and satisfactory?"

Let's apply this to typical corrective and preventive action (CAPA) documentation. The company should state:

- What has happened.
- Why it happened.
- What specific people did about it.
- Why the solutions were effective.
- How the company made sure it would not happen again.

However, the company often uses passive voice in the CAPA report to tell what happened without revealing the responsible parties. Those documents contain no blame, no accountability, and little useful information.

**Examples:**

*"Complaints were received."*

*"The investigation took place."*

*"The corrective action was taken."*

These vague statements can result in the reader of the document (perhaps an FDA-er or an attorney) not understanding the root cause of the failure, as well as the compliance story.

Again, we need to make sure that future readers can easily understand the accurate story if all those involved in the company incident are gone.

**For Industry – Avoid Sloppy Writing.**

Let's also look at the industry side. Company employees are often guilty of other types of poor writing that can cause trouble.

**Example 1:**

This is an example of a statement from an industry document:

*"The purpose of this study was to ensure that the coating material #234 will not affect the leak and tear resistance of the latex gloves."*

The problem here is that the company employee has injected bias into the statement. The employee should rewrite this to be completely neutral:

*“The purpose of the study was to determine whether or not the coating material #234 will affect the leak and tear resistance of the latex gloves.”*

**Example 2:**

*“The raw data can be found in Appendix 1. The official data for this study can be found in the mechanical test report.”*

What is the difference between raw data and official data? Why not just say “data”?

**Example 3:**

*“This report tested the accuracy of the glucose monitor readings.”*

This statement, if read literally, does not make sense. Reports don’t test the accuracy of anything. Reports give readers the findings.

*“This report includes the results from testing the accuracy of the glucose monitor readings.”*

**Conclusion**

The federal government has been trying for years to encourage the use of plain, clear language in government documents. In 1998, President Clinton directed agencies to write all documents in concise language. The Office of Management and Budget also formed a group called the Plain Language Action and Information Network ([www.PlainLanguage.gov](http://www.PlainLanguage.gov)). Vice President Gore even created the “No Gobbledygook” award, which the FDA won on four occasions!

The government wants all of us to use clear language, so that we can keep food and healthcare products safe and reliable. By following these tips, both the FDA and industry can produce clearer and more concise documents in the future.