

**Dangerous Documents:
Avoiding Land Mines in Your Records and Emails
Contact: Nancy Singer – nancy@compliance-alliance.com**

1. Name
2. Title
3. City, State

Documents are like diamonds.
They are very precious.
And they last forever.

Fact, Lay Opinion, and Expert Opinion

A fact is something that can be demonstrated by empirical evidence.

For example:

- The firm has 11 standard operating procedures.
- The name of the firm is Bates, Inc.

An opinion is what someone thinks. It can be recognized by a subjective judgment (adjective).

For example:

- The phone call was perfect. .
- The company is doing a great job complying with the requirements.

Lay opinion - one given by an ordinary person of reasonable intelligence.

Expert opinion - one given by a person who, because of training or experience, is qualified to provide an opinion.

Directions: In a series of polls, you will indicate whether the statement is a fact, lay opinion, expert opinion, fact and lay opinion, or fact and expert opinion.

1. The location for FDA's headquarters is listed on FDA's website.

- Fact
- Lay opinion
- Expert opinion
- Fact and lay opinion
- Fact and expert opinion

2. Mary Smith (age 5) thinks it is going to snow in Maine on August 10 because it hasn't snowed in a long time.

- Fact
- Lay opinion
- Expert opinion
- Fact and lay opinion
- Fact and expert opinion

3. Dr. Frank Charles, a noted cardiologist, believed that the Tap drug would be the best drug to treat Mike Tate's heart condition.

- Fact
- Lay opinion
- Expert opinion
- Fact and lay opinion
- Fact and expert opinion

4. The minutes state, "The Dr. Bill Jones, head of Harvard's Cancer Center, believed that one of the symptoms of cancer is a loss of appetite."
- Fact
 - Lay opinion
 - Expert opinion
 - Fact and lay opinion
 - Fact and expert opinion
5. The Post-it note, written by Susie Smith (the Administrative Assistant to the Division Director), says, "The investigator is new and may not understand the issue."
- Fact
 - Lay opinion
 - Expert opinion
 - Fact and lay opinion
 - Fact and expert opinion

Angry Email

Jack,

I just came back from re-inspecting the ABC company, and that plant was a disaster! I can't believe that you didn't cite the company for their insufficient software validation, their inadequate complaint handling procedures, and their ineffective supplier audits. To have missed those obvious discrepancies demonstrates to me that you were either asleep, on something, or on the take. Get with the job or quit. YOU ARE AN EMBARRASSMENT TO THE AGENCY!!!

Harry

Instructions - Breakout Room 1: Angry Email

- Divide into breakout rooms.
- The person whose last name is closest to "A" in the alphabet is the "Chair".
- Each breakout room has a different number.
- 1 minutes to get organized.
- 4 minutes to discuss the question.
- 1 minute warning before the time is up.
- After the breakout room closes, the "Chair" can report on the group's decision, or he/she can select another person.

Questions (Jack and Harry are Peers)

1. Why might Harry have written this email?
2. List the problems in Harry's email.
3. Explain how the press or the OIG could interpret the email.
4. Should Jack reply to Harry's email?
5. What should Jack do?
6. If management gets involved, what should they do?

To find out which Breakout Room you are in and which question you need to answer, look for the following sign:



Inflammatory Words

Below is a list of inflammatory words. In the space provided, substitute a softer WORD or PHRASE that will communicate the idea in a less inflammatory way.

1. Crisis _____
2. Emergency _____
3. Story _____
4. Excuse _____
5. Shortcut _____
6. Attack _____
7. Catastrophic _____

Breaking It Down Personal Email

Since everything written on the organization's computers belongs to the organization, the organization should audit emails and other electronic documents, and reprimand people for inappropriate statements. Discuss in your breakout room if you agree or disagree with this statement.

- Divide into breakout rooms.
- The person whose last name is closest to Z in the alphabet is the chair.
- 1 minute to get organized.
- 3 minutes to answer questions.
- 1 minute warning before time is up.
- After the breakout room closes, the "Chair" can report out the group's decision or he/she can select another person to report.

Points to Remember

1. Documents last forever.
2. You should not have an expectation of privacy when using the organization's computer.
3. People read your documents with their own agendas.
4. If you have responsibility and authority for an issue, express your opinion.
5. If you don't have responsibility and authority for the issue, write the facts to the decision maker.
6. Discuss controversial subjects in a meeting.
7. Use the phone or communicate in person when you don't need a written record.
8. Refrain from writing inappropriate Post-it notes.
9. Refrain from writing emails when you are angry.
10. Refrain from writing personal emails on the organization's computer.
11. Only provide copies of emails to people who need to know about an issue.
12. Avoid inflammatory words.
13. Don't forward long email chains. People don't want to read them, and they may include inappropriate information.

Actions to Take to Avoid Dangerous Documents

1. _____
2. _____
3. _____