Exercise 6a
Problem Cause Investigation – Brainstorming

Name: _____   Date: _____

Instructions:

1. Review the background information.
2. Conduct a brainstorming session using the "unstructured", free-wheeling method and generate ideas that include:

   a. Problem areas to improve
   b. Consequences from the problem
   c. Possible causes of the problem
   d. Ways to eliminate causes of the problem

3. Record the ideas on the whiteboard or sections provided below.

Background Information

The CEO of a growing medical device manufacturing company also acts as the Quality Assurance Manager. In the last quarter, three customer audits showed significant findings against the quality management system. As business demands increase the CEO has been struggling to keep up with the Quality System responsibilities along with overall business needs and has not dedicated the effort needed to maintain the system. The CEO recognized it was time to hire a full time QA Manager. A new QA Manager was brought on board and tasked with resolving the issues identified in the customer audits.

The QA Manager reviewed the customer audit reports and noted that findings affected several areas. All the affected areas had issues related to training. The findings related to training are summarized below:

Customer Audits – Training Related Findings	
Customer	**Audit Finding**
A	• Lack of training records for customer service manager and shipping staff for order processing • Assembly personnel not aware of procedures related to their job duties
B	• Lack of training plans for production manager, assembly and welding personnel • Training records for welding staff not to current procedure revision • Reports not available to show status of training
C	• Purchasing personnel not following procedures related to their job duties • Lack of training records for newly hired personnel in clean room and stockroom.

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Background Information – Continued

The QA Manager then reviewed the training procedure. The basic requirements are:

- The department manager and/or supervisor is responsible for training of personnel and assigning qualified personnel to provide the training.
- Training plans and blank records are available in Document Control Department.
- Completed training records and plans are returned to Document Control for storage in personnel files.

The QA Manager then decides to hold a brainstorming session and identifies the problem (or topic) as "reasons why the training program is ineffective". Help the QA Manager by participating in the brainstorming session

Brainstorming Session Steps

Note: Use whiteboard or template provided.

1. Identify the problem.
2. Use the free-wheeling method to launch ideas.
3. Nominate someone to record every idea launched, using the original wording as proposed.
4. ***Do not*** criticize or evaluate the ideas during the session.
5. Allow the flow of ideas to stagnate once, it will usually pick up again. Stop the process when new ideas are only reformulations of previously sated ideas.
6. Evaluate the ideas then combine and sort into groups, either by theme or decreasing potential.

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Brainstorming Template

Problem (or topic):
Ideas
Idea Groups