Human Errors Investigation and Prevention Awareness in the QC Laboratory

Carolina (Puerto Rico) - August 2016

Presented by Business Excellence Consulting Inc
Passion for Quality

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Agenda:

- Human Error – some statistics
- Human error and human factor
- Psychology and classification of human error
- Human factors
- How organizations deals with human errors
- How to investigate human error
- Root cause related to human performance
- Human error and retraining
- Working from memory
- Multitasking and human error
- How to reduce the probability of human errors
Details Are Important

An Injustice Has Been Done:
Jail Time for an Error

Eric Cropp is an Ohio hospital pharmacist who was involved in a tragic medication error that cost the life of a beautiful little girl named Emily Jerry. For that, he was punished by a criminal court: 6 months in jail, 6 months’ home confinement with an electronic sensor locked to his ankle, 3 years probation, 400 hours of community service, a fine of $5,000, and payment of court costs. Eric made a human error that could have been made by anyone in healthcare, given the inherent weaknesses in our manual systems: he failed to recognize that a pharmacy technician he was supervising had made a chemotherapy solution with far too much sodium chloride in it. The final solution was supposed to contain 0.9% sodium chloride, but it contained more than 20%.

I have never met Eric, but I am familiar with many of the underlying conditions that contributed to the error. Some details have been provided in the local and national news media; however, I also have reviewed records stemming from Ohio State Board of Pharmacy hearings. I have heard firsthand accounts from low. When Eric Cropp came to work on the day of the event, he learned that the pharmacy computer system was down. His assistant in the preparation area for intravenous (IV) solutions was a pharmacy technician who, according to press reports, was also planning her wedding on the day of the event and, thus, distracted while working. With the pharmacy computer system down, a backlog of physician orders had developed, increasing time pressures for Eric. A nurse had called requesting Emily’s chemotherapy solution immediately, which ultimately may not have been warranted. This added more pressure to Eric’s workload. According to a witness at the state board hearing, the chemotherapy was not needed until much later that afternoon. Testimony at the board hearing also uncovered that Eric was working short-staffed that day and had no time for normal work breaks. The technician started to prepare the chemotherapy. We do not know exactly what caused the sodium chloride overdose in this case. However, when preparing IV chemotherapy, some phar-

Eric made a human error that could have been made by anyone in healthcare, given the inherent weaknesses in our manual systems.

um chloride 23.4% a “high alert” drug, calling for special storage, handling, and check systems—procedures that may not have been in place in Eric’s hospital. Communication failures between technicians and pharmacists, IV compounding-related failures, inadequate documentation of the exact products and amounts of additives, and other system issues have contributed to other fatal errors. We have also seen compounding errors and subsequent failed double-checks due to adverse performance-shaping factors such as poor lighting, clutter, noise, and interruptions. As noted above, in this particular case, news reports suggest that Eric felt
Human Errors

Muere bebé al ser olvidado en el carro del centro comercial de Barceloneta

Reason for Recall
The products have a wrong expiration date on their labeling, 5 years instead of 2 years.

Some Product Recall

**REASON**
Incorrect Expiration Date; product incorrectly labeled as "80/08" rather than correctly as "08/08".

**REASON**
Incorrect Expiration Date; product incorrectly labeled as “07/2104" instead of correctly as "07/2014".
Why Are We Here?

- HPLC vial misplaced
  - Why?
- Incorrect Empower vial sequence preparation
  - Why?
- Wrong sample analyzed
  - Why?
- Wrong sample identification
  - Why?
- Wrong sample ID scanned
  - Why?
- Buffer sample run was created incorrectly
  - Why?
- Wrong reagent used
  - Why?
- Sample pulling time not documented
  - Why?
Behind Lab Door
Behind Lab Doors... You can see

You can see...

- Someone not following basic safety rules
  - Gloves, lab coat, etc
- Flasks/tubes without proper identification
- Samples from different stages or different products side by side
- Mixing problems
- etc
Human Errors?

“People make errors, which leads to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong.

The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems continue.”

Don Norman
Some Statistics of Human Errors

- >80% of process deviations and non-conformities
- 99% of accidental losses in process industries begin with a human error
- 1.5 million Americans are injured every year by drugs errors in
  - Hospitals
  - Nursing homes
  - Doctor’s office
  - (Patients’ own medication mixups are not included)
- On average, every hospitalized patients is subject to (at least) one medication error per day
Some Statistics of Human Errors (cont)

- 8% of men are color blinded while only 1/200 women have the condition
- 80% of medical product recalls due to incorrect expiration date or incorrect lot/batch number are caused by a transposition of digits
- The rate of error/mistakes for most procedure-based task is 1/100
- Average workers are interrupted every 11 minutes and then spend almost 1/3 of their day recovering from these distractions
Some Statistics of Human Errors (cont)

- Seventeen (17) hours of work without a break is the same as being legally drunk.
- Worst period for human errors: 3 am–5 am.
- About 15% of human errors are due to acquired habits.
- Human error accounts for 90% of road accidents.
There are two main types of human failure: errors and violations. Controls will be more effective if the types are identified and addressed separately.

Reducing human error involves far more than taking disciplinary action against an individual.

There are a range of measures which are more effective controls including design of the job and equipment, procedures, and training.
Key Messages

◆ Everyone can make errors no matter how well trained and motivated they are. Sometimes we are ‘set up’ by the system to fail. The challenge is to develop error-tolerant systems and to prevent errors from occurring.

◆ Paying attention to individual attitudes and motivations and design features of the job will help to reduce violations.
Key Points to Consider

- Human errors are not root causes
- Human errors are symptoms or consequences of deeper causes
- Refrain to use human error (or procedure not followed or similar) as root cause and retraining (refresher, awareness, counseling, orientation, etc.) as corrective action
Reason’s Swiss Cheese Model
Human Errors and Human Factors: James Reason’s bottom line

- Fallibility is part of the human condition
- We can’t change the human condition
- We can change the conditions under which people work
- Human beings will always make errors
- Naming, blaming and shaming have no remedial value
Things Happen

Human Factors

Human Error

Poka-Yoke

Defect

Non-conforming or Adulterated product
US FDA cGMP §211.160
Laboratory General Requirements

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.
Main Opportunities

- Instruments must be qualified and fit for purpose [§211.160(b), §211.63]
- Software must be validated [§211.63]
- Any calculations used must be verified [§211.68(b)]
- Data generated in an analysis must be backed up [§211.68(b)]
- Reagents and reference solutions are prepared and documented correctly [§211.194(c)]
- Methods used must be documented and approved [§211.160(a)]
- Methods must be verified under actual conditions of use [§211.194(a)(2)]
- Data generated and transformed must meet the criterion of scientific soundness [§211.160(a)]
- Test data must be accurate and complete and follow procedures [§211.194(a)]
- Data and the reportable value must be checked by a second individual to ensure accuracy, completeness and conformance with procedures [§211.194(a)(8)]
Laboratory error should be relatively rare. Frequent errors suggest a problem that might be due to inadequate training of analysts, poorly maintained or improperly calibrated equipment, or careless work.

Whenever laboratory error is identified, the firm should determine the source of that error and take corrective action to prevent recurrence. To ensure full compliance with the CGMP regulations, the manufacturer also should maintain adequate documentation of the corrective action.
Data Integrity and Human Error

Data needs to meet ALCOA elements of quality

– **Attributable** – data are identified with a specific subject and a specific observer and recorder. *(Password, audit trail and e-signature)*

– **Legible** – data are readable and understandable by humans *(reports, tables, and listings)*

– **Contemporaneous** - data are recorded at the time they are generated or observed. *(Time stamps and time-limited entry)*

– **Original** – data are recorded for the first time. *(Source data)*

– **Accurate** – data are correct *(Calculations, algorithms, analyses)*
FDA Inspection – Data Integrity

Specifically,

A) During our inspection of the QC analytical laboratory on 01/05/14, we observed one analyst back-date the working standard issuance and destruction logbook for (b)(4) USP/EP batch # (b)(4) and # (b)(4). This analyst was observed to sign and date the record “04-JAN-2014.” We immediately questioned this analyst regarding the reason for back-dating this record, who responded that he had only entered “2014,” despite our visual observation of him entering a signature and full date entry a few moments earlier.
Definitions

**Mistake**

The execution of a prohibited action, the failure to correctly perform a required action or the misinterpretation of information essential to the correct execution of an action.

**Mistake proofing**

The use of process or design features to prevent manufacture of non-conforming product.
Errors and Violations

Human failures can be divided into two broad categories, errors and violations:

• A human *error* is an action or decision that was not intended, that involved a deviation from an accepted standard, and that led to an undesirable outcome.

  A laboratory technician working with two tests simultaneously uses the wrong sample for one of the tests

• A *violation* is a deliberate deviation from a rule or procedure.

  A production operator filled out a cleaning record without performing the task
Type of Human Failures

Human Failure

Errors

- Skill-based errors
  - Slips of actions
  - Lapses of memory

Mistakes

- Ruled-based mistakes
- Knowledge-based mistakes

Violations

- Routine
- Situational
- Exceptional
# Memory Slips and Lapses

Table 3.9 Slips and lapses of memory.

<table>
<thead>
<tr>
<th>Slips (commission or execution errors)</th>
<th>Lapses (omission errors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating the wrong switch control or valve</td>
<td>Equipment identification not recorded in the batch record</td>
</tr>
<tr>
<td>Misordering a sequence of steps</td>
<td>Omission of information that must be recorded</td>
</tr>
<tr>
<td>Transposing digits when printing a lot number or expiration dates</td>
<td>Omitting a step or series of steps from a task</td>
</tr>
<tr>
<td>Product mixups (incorrect label, incorrect product, both incorrect)</td>
<td></td>
</tr>
<tr>
<td>Failure to detect incorrect expiration date, incorrect lot number, incorrect size, or other defect during an inspection</td>
<td></td>
</tr>
</tbody>
</table>
Attention, Memory and Human Errors

- Human errors are not a uniform collection of unwanted acts.
- Attention plays a significant role in all categories of human errors. Slips, lapses, and mistakes are all more common when situational factors divert our attention.
- Factors like fatigue, sleep loss, alcohol, drugs and illness, workload, stress, work pressure, multitasks, boredom, frustration, fear, anxiety, and anger.
Latent Failures
(Human Factor Precursors)

- Latent failures are made by people whose tasks are removed in time and space from operational activities (designers, decision makers and managers).

- Latent failures are typically failures in management systems (design, implementation or monitoring).
Examples of human factors behind latent failures are:

- Poor design of plant and equipment
- Inadequate procedures and work instructions
- Ineffective training
- Inadequate supervision
- Inadequate staff and resources
- Ineffective communications
- Uncertainties in roles and responsibilities.
Latent Human Errors
# Other Categories of Human Errors

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning Gap</td>
<td>don’t know ⇒ lack skill or knowledge, or insufficient understanding of consequence</td>
</tr>
<tr>
<td>Memory Gap</td>
<td>know but don’t remember ⇒ unable to use skill or knowledge at time/situation req’d</td>
</tr>
<tr>
<td>Inconsistency</td>
<td>“know” but variability in method/standard ⇒ inconsistent performance/results</td>
</tr>
<tr>
<td>Application</td>
<td>know but applied incorrect action/info ⇒ slips, wrong outcomes, transcription errors</td>
</tr>
<tr>
<td>Omission</td>
<td>know but missed a step/action/info/”difference” ⇒ missing info or step, used wrong item</td>
</tr>
<tr>
<td>Decision</td>
<td>wrong decision given situation/info ⇒ inappropriate decisions and/or behavior</td>
</tr>
</tbody>
</table>

**Why?**

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*BUSINESS EXCELLENCE CONSULTING*
Common Sense?
Nursing Errors?

Dennis Quaid twins recovering from medical overdose
Thu Nov 22, 2007 4:26am EST

LOS ANGELES (Reuters) - The two-week-old twins of actor Dennis Quaid were recovering in a Los Angeles hospital on Wednesday after mistakenly being given a massive overdose of a blood thinning drug.

Cedars-Sinai Medical Center, one of the United States' leading hospitals, apologized on Wednesday for what it called the "preventable error" that led to the twins and another unidentified child being given 10,000 units of the anticoagulant Heparin, instead of the normal 10 units given to babies.

The Quaid twins, Thomas Boone and Zoe Grace, were born via a surrogate mother on November 8.
**EVENT**

**Oxygen tubing erroneously connected to a needleless IV port**

**POTENTIAL FOR HARM**

High

**CASE STUDY**

- A patient’s oxygen tubing became disconnected from his nebulizer and was accidentally reattached to his IV tubing Y-site by a staff member who was completing a double shift.

- The patient died from an air embolism, even though the connection was broken within seconds.

**WARNING:** Photographs depict oxygen tubing erroneously connected to a needleless IV port. Do not do this!!

**THE JOINT COMMISSION SAFETY TIP**

Identify and manage conditions and practices that may contribute to healthcare worker fatigue, and take appropriate action.
Foley catheter erroneously connected to NG tube

**POTENTIAL FOR HARM**
Low

**CASE STUDY**
- A patient was found with her Foley catheter disconnected from its drainage bag. One end of the catheter was still in her bladder and the other end was connected to her nasogastric (NG) tube.
- Urine was noted to be flowing into her NG tube.
- The NG tube was connected to suction and more than 300 mL of urine drained.
- The patient’s vital signs were stable and her laboratory results were within normal limits.

**THE JOINT COMMISSION SAFETY TIP**
Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions.
SUCCESS STORY!

These photos show that PAS pump tubing is now NOT CAPABLE of connecting to IV vascular access devices.

EVENT

Pulsatile anti-embolism stocking erroneously connected to IV heparin lock

POTENTIAL FOR HARM
High

CASE STUDY

- A patient admitted for stroke had a pulsatile anti-embolism stocking (PAS) on the left lower extremity and an IV heparin lock in the right ankle.
- The patient was alert and oriented on admission but shortly after was found unresponsive and cyanotic.
- The PAS pump tubing was found connected to the IV heparin lock in the patient's right ankle.
- The patient died of a massive air embolus.

THE JOINT COMMISSION SAFETY TIP

Manufacturers should implement "designed incompatibility" as appropriate, to prevent dangerous misconnections of tubes and catheters.
Catastrophic Errors

“Although it allegedly calls for Isordil, the pharmacist filled it as Plendil. The jury's $450,000 judgment, finding both the cardiologist and pharmacist negligent, is believed to be the first of its kind nationwide to focus solely on bad handwriting.” – American Medical News, 1999
Some Product Recall
667,000 packages recalled

swallow one whole tablet with water every 24 hours
do not exceed one tablet in 24 hours
do not divide, crush, chew or dissolve the tablet
the tablet does not completely dissolve and may be seen in the stool (this is normal)
Every group of people develops a ‘culture’: shared attitudes, beliefs and ways of behaving. In an organization with a good compliance and quality culture, everyone puts those elements high on the list.

Everyone shares accurate perceptions of the risks and adopts the same positive attitudes to compliance and quality. This influences the ways in which individuals in the group handle new events and decisions.
Compliance and Quality Culture

Some key aspects of an effective culture include:

- good ways of informing and consulting the workforce
- recognition of the fact that everyone has a role to play
- commitment by top management to involving the workforce
- cooperation between employees
- open two-way communications
- high quality of training.
While most people will notice a written warning, only half will actually read it and only a third will comply with the instructions. This shows that we cannot rely on a warning to produce the response we want.
Adequate Supervision

- Number one element to reduce human errors and violations
- Supervisors on the floor?
Many of the procedures do not follow best practices for controlling human error, and so the written process actually contributes to increased error rates. Many organizations have lengthy procedures (often exceeding one hundred pages) poorly written and organized. For procedures to be effective, they must be used. Procedure inaccuracies preventing their use include:

- Procedures are difficult to use in the work environment
- Procedures are difficult to understand
- Procedure are incorrect or incomplete

Easy to understand?

Second verification for significant/critical steps?
Task Design

- Who does this activity?
- Exactly what tasks/action do they do?
- What tools or equipment are needed?
- What decisions are made?
- What information is needed to do the task?
- Where does this information come from (people/paper/computers/displays)?
- How is the task learned and competence assessed?
Task Design

- How often is the activity carried out?
- Where is the task carried out?
- What is the working environment like (temperature/noise/lighting/etc)?
- Are there time constraints on the task?
- What can go wrong? Where is there potential to make errors?
- How can failures be detected and corrected?
- What compliance and quality consequences can result?
Clear Instructions?

- Mix well.
- Stick together for a few seconds.
- Verify all parameters.
- Mix for approximately one minute.
Human Factors Natural Mappings

Stove A

Stove B
Regulated industries normally do a good job on training, including on-the-job training. However, training systems opportunities include:

– How to troubleshoot the process
– Considering training as the cause of the incident. This is evidenced because most of the time, retraining is the only “corrective action” listed

Provide operators with enough practice on critical tasks
Training as Human Factor

Evidence of training?

But the key question must be...

Was it effective?
Root Cause Categories Related to Training

- Lack of training
  - Training not required
  - Missing training

- Training not effective
  - Content not adequate (task analysis, qualification/certification, OJT)
  - Training method not adequate
  - Language barriers
  - Environment not adequate
  - Instructor not adequate
  - Insufficient practice or hands-on experience
  - Frequency not adequate (insufficient refresher training)
Dealing with Human Errors

Old Way
- Document as human error + retraining
- Human Resources intervention
- Employees are lazy and careless about their jobs

New Way
- In-depth root cause investigations
- Human factors as precursors
- Interview centered on human factors
Identifying human errors

Try to identify all the significant human errors that the person could make. Think about:

◆ What human errors can occur with each task?

◆ What influences are there on performance? Typical influences include: time pressure, design of controls, displays and procedures, training and experience, fatigue, and levels of supervision.

◆ What are the consequences of the identified errors?

◆ Which are the significant errors?

◆ Are there any opportunities for detecting each error and recovering it?
Investigating Human Errors

Why this happened?

Why nobody detected it?
Root Cause Identification for Human Errors

Why this happened?

Human Factors

Incident or Event

Causal Factor

Root Cause

Causal Factor

Root Cause

Corrective and Preventive Actions

Corrective and Preventive Actions

Corrective and Preventive Actions

Barrier Controls
(Poka-Yoke)

Why nobody detected it?
Causal Factor and Root Cause Identification

- **Human Error** is NOT a good root cause
  - ✨ It is a consequence

- Human error as the only identified/documented root cause most of the time

- Human being always make mistakes (machines does not)

- Why did the human make the mistake?

*Toyota has an average of 12 mistake-proofing (poka-yoke) mechanisms per process*
A checklist cannot be the investigation

## 12. INVESTIGATION

### 12a. Analyst

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyst properly trained in technique or similar methodology?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Analyst followed correct test method?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Analyst followed test method as written?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Correct specification / revision followed?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### 12b. Equipment

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct equipment used?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Equipment maintenance is current?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Equipment calibration is current?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Equipment used within its calibrated range?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Analyst trained to operate equipment?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>
How to Investigate Human Errors

- As you do for any other nonconformance or deviation within your quality system.
- We just have a symptom and we need to discover its causal factors (human factors in this case) in order to reach the root cause.
- Do not fingerpoint
  - It is not about blaming an associate for the situation
- Interviewing those humans is the most important method used to investigate the “human errors”
Interviewing, Not Interrogating

- It is a non-threatening format.
- The goal is to gain more information or knowledge about the process.
- The tone is non-accusatory.
- It takes a relatively short time frame to complete (15 minutes to one hour).
- The conversation could be conducted with or without total privacy.
- A formal (in writing) report of the conversation should follow.
**Human Error Investigation Form**

## Human Error Investigation

<table>
<thead>
<tr>
<th><strong>TOPIC</strong></th>
<th><strong>OBJECTIVE EVIDENCE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure Quality and Content</strong></td>
<td></td>
</tr>
<tr>
<td>1) <strong>Is there a formal (written) instruction to</strong></td>
<td></td>
</tr>
<tr>
<td>perform this task?</td>
<td></td>
</tr>
<tr>
<td>2) Were procedures or working instructions</td>
<td></td>
</tr>
<tr>
<td>available in the immediate area where the task was performed?</td>
<td></td>
</tr>
<tr>
<td>3) Did the procedure or working instruction changed recently?</td>
<td></td>
</tr>
<tr>
<td>4) Is the procedure or working instruction clear and well understood by the employee?</td>
<td></td>
</tr>
<tr>
<td>5) Has the procedure or working instruction sufficient level of detail?</td>
<td></td>
</tr>
<tr>
<td>6) Did the procedure or working instruction use specific details rather than a qualitative description (slowly, soon, few, well, and so on)?</td>
<td></td>
</tr>
</tbody>
</table>
## Human Error Investigation Key Points

<table>
<thead>
<tr>
<th>Do</th>
<th>Don’t</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Investigate every human error up to its root cause(s)</td>
<td>• Use human error as root cause</td>
</tr>
<tr>
<td>• Search for precursors of the human error</td>
<td>• Use retraining as the default corrective action for human failures</td>
</tr>
<tr>
<td>• Improve your working instructions and records</td>
<td>• Assume that your employees are lazy and careless about the job</td>
</tr>
<tr>
<td>• Improve your training system</td>
<td></td>
</tr>
<tr>
<td>• Measure the effectiveness of your training efforts</td>
<td></td>
</tr>
</tbody>
</table>
Human Error + Retraining
Working from Memory: Enough Memory?
Human Errors and Memory

- Lack of attention and memory plays a significant role in all categories of human errors. Slips, lapses, and mistakes are all more common when situational factors divert our attention.

- However, in the regulated industries, these factors should be negligible because we are not supposed to rely on our memory to remember how to do things.

- Batch records, device master and device history files exist for one purpose.
Multitasking and Human Errors

- Very important as causal factor for human errors
- You can do two things at once, but you can’t focus effectively on two things at once
- Multitaskers make more mistakes than non-multitaskers
Multitasking and Human Errors

- We lose around 30% of an average workday to multitasking ineffectiveness.
- There is just so much brain capability at any one time. Divide it up as much as you want, but you’ll pay a toll in time and effectiveness.
- Distracted driving is responsible for 16% of all traffic fatalities and half million injuries each year in USA.
Multitasking and Human Errors

An idle phone conversation while driving takes 40% of your focus

The same effect as being drunk
How to Reduce the Probability of Human Errors
Reducing Errors

- Addressing the conditions and reducing the stressors which increase the frequency of errors
- Designing plant and equipment to prevent slips and lapses occurring or to increase the chance of detecting and correcting them
- Making certain that trainings are effective
- Designing jobs to avoid the need for tasks which involve very complex decisions, diagnoses or calculations
Reducing Errors

- Ensuring proper supervision particularly for inexperienced staff, or for tasks where there is a need for independent checking;
- Checking that procedures and instructions are clear, concise, available, and up-to-date;
- Thinking about the different causes of human errors during incident investigations in order to introduce measures to reduce the risk of a repeat incident;
- Monitoring that measures taken to reduce error are effective.
Reducing Violations

- Take steps to increase the chances of violations being detected by routine monitoring
- Make rules and procedures relevant and practical
- Improve design factors that affect the likelihood of corner cutting
- Involve the workforce in drawing up rules to try to increase acceptance.
Design features which increase violations

- Awkward, uncomfortable working posture
- Equipment or software which seems unduly slow to respond
- High noise levels which prevent clear communication
- Frequent false alarms from instrumentation
- Difficult-to-use or uncomfortable personal protective equipment
- Unpleasant environments: dust, fumes, extreme heat or cold
Areas to Focus

**Improve Documents**
- Integrate manufacturing instructions and records
- Improve content (should, will, need, **must**)
- Enhance document format (Imperative tone, graphic elements, clear and comprehensive content)

**Improve Training**
- Reading working instruction is not learning
- Why we must do that?, why this way?
- Measure training effectiveness
Areas to Focus

Improve Manufacturing Processes
- **Do not** operate by memory:
  - Read ➔ Execute ➔ Record
- Mistake-proofing your processes – Barrier Controls
- Attention to multitasking
- Improve the investigation process

Improve the Human (Soft) Side of the Equation
- Make people accountable
- Zero Tolerance vs. defect-free recognition programs
- Enhance Supervision
The Best Recipe…

Read ➔ Execute ➔ Record
## Barrier Control Analysis

<table>
<thead>
<tr>
<th>Physical barriers</th>
<th>Administrative barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Separation among manufacturing or packaging lines</td>
<td>• Training and certifications</td>
</tr>
<tr>
<td>• Emergency power supply</td>
<td>• Clear procedures and policies</td>
</tr>
<tr>
<td>• Dedicated equipment</td>
<td>• Adequate supervision</td>
</tr>
<tr>
<td>• Barcoding</td>
<td>• Adequate load of work</td>
</tr>
<tr>
<td>• Keypad controlling doors</td>
<td>• Use of checklist</td>
</tr>
<tr>
<td>• Software that prevents further input if a field is not completed</td>
<td>• Verification of critical task by a second person</td>
</tr>
<tr>
<td>• Redundant designs</td>
<td></td>
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</tbody>
</table>

*Mistake proofing (poka-yoke) are examples of control barriers*
Obsession with details

One Sunday morning, January 6th, 2008 I was attending religious services when my cell phone vibrated. As discreetly as possible, I checked the phone and noticed that my phone said "Caller ID unknown". I choose to ignore.

After services, as I was walking to my car with my family, I checked my cell phone messages. The message left was from Steve Jobs. “Vic, can you call me at home? I have something urgent to discuss” it said.

Before I even reached my car, I called Steve Jobs back. I was responsible for all mobile applications at Google, and in that role, had regular dealings with Steve. It was one of the perks of the job.

"Hey Steve - this is Vic", I said. "I'm sorry I didn't answer your call earlier. I was in religious services, and the caller ID said unknown, so I didn't pick up".

Steve laughed. He said, "Vic, unless the Caller ID said 'GOD', you should never pick up during services".

I laughed nervously. After all, while it was customary for Steve to call during the week upset about something, it was unusual for him to call me on Sunday and ask me to call his home. I wondered what was so important?

“So Vic, we have an urgent issue, one that I need addressed right away. I've already assigned someone from my team to help you, and I hope you can fix this tomorrow” said Steve.

"I've been looking at the Google logo on the iPhone and I'm not happy with the icon. The second O in Google doesn't have the right yellow gradient. It's just wrong and I'm going to have Greg fix it tomorrow. Is that okay with you?"