Why do we need to manage for safety and liability avoidance?

- Customers are asking for it.
- It’s good for business.
- Potential product liability without it.
- Required for sale to Europe.
- Regulators require it.
- Nothing remains the same
Managing future risks

- Changes in technology
- Changes in consumer attitudes toward risk
- Changes in the law
Changing technology

- Computer hardware
- Medical devices
- Machine control systems
- Software
Changing social attitudes

Just A Little Current Can Kill

<table>
<thead>
<tr>
<th>millamps*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>30</td>
</tr>
<tr>
<td>40</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>7.5-watt Christmas tree light</td>
</tr>
<tr>
<td>12-watt electric shaver</td>
</tr>
<tr>
<td>100-watt bulb</td>
</tr>
<tr>
<td>1000-watt hair dryer</td>
</tr>
</tbody>
</table>

* A millamp is 1/1000th of an ampere, a measure of electrical current

**A GFCI is a Ground Fault Circuit Interrupter, a device which protects against serious shock.
Genetically modified food

- Corn genetically engineered to be insect resistant
- Reduction in use of pesticides
- Public concern for genetic effects on humans
- Millions of people affected
Mobile phones

- Ease of communication
- Concern for health effects
- Effects on driver accident rates
- Inconsistent scientific studies
- Emission testing
- “Hands-free” use laws
Internet

- Communication
- Information
- Viruses
- Changing law of the internet
How do we find out what is broken?

- The product safety audit.
- How did the company do?
- How can the company improve?
What to look for

- Company policy
- Organization
- Design and compliance engineering
- Manufacturing and quality control
- Marketing and sales
- Customer and field service
- Communication
Planning, organization and control

- Management commitment to the program
- A safety team involving all departments in the company
- A system for measurement, corrective action and status reporting
Planning, organization and control (cont’d)

- A system for finding and handling safety problems
- Safety awareness and training
Risk analysis

- During product design and development, is a “Risk Analysis” of the product undertaken?
- Are products which contain unreasonable risks modified?
Risk management

- Product Limits (Foreseeable Use)
- Hazard Identification
- Risk Estimation
  - Risk Evaluation (Technical, Legal, Social)
  - Probability
  - Severity
- Risk Reduction
  - Monitor Technical, Legal and Social
Product limits

- Analyze the product limits and functions to identify potential hazards
- Foresee possible operations and uses of product
- Foresee who will use or be in the vicinity of the product
Product life cycle

- Installation
- Use
- Service
- Maintenance and repair
- Disposal
Hazard identification

- Identify each type of hazard
- Identify each hazard scenario – how can the hazard cause injury to a person
# Acceptable risk level matrix

<table>
<thead>
<tr>
<th>Hazard Likelihood</th>
<th>Hazard Effect Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Frequent</td>
<td>I. Catastrophic</td>
</tr>
<tr>
<td>B. Probable</td>
<td>II. Critical</td>
</tr>
<tr>
<td>C. Occasional</td>
<td>II. Marginal</td>
</tr>
<tr>
<td>D. Remote</td>
<td>IV. Negligible</td>
</tr>
<tr>
<td>E. Improbable</td>
<td></td>
</tr>
</tbody>
</table>

- **Hazard Likelihood**
  - A. Frequent
  - B. Probable
  - C. Occasional
  - D. Remote
  - E. Improbable

- **Hazard Effect Category**
  - I. Catastrophic
  - II. Critical
  - II. Marginal
  - IV. Negligible

- **Unacceptable Risk**
The hierarchy of countermeasures

- Design For Minimum Risk (Most Preferred)
- Incorporate Safety Devices
- Provide Warning Devices
- Develop Procedures, Manuals, Warnings, and Training (Least Preferred)
Research, analysis and testing during design and development

Throughout design and development, is research, analysis and testing conducted?

Is compliance with the safety requirements verified?
Design and engineering change procedures

- Policy defining engineering change procedures?
- Formal procedure for dealing with suppliers and subcontractors?
- Sign-off by the product safety coordinator?
Manufacturing and quality control

- Supplier selection and control
- Receiving inspection
- In-process control
- Finished product inspection
- Storage, handling and shipping
How are products sold and distributed?

- Are advertising and sales claims reviewed?
- Are warranties reviewed?
- Are terms and conditions reviewed?
- Are hazard warnings on the product and in the manuals reviewed?
Hazard alerts: signal words

- **Danger**
  - Used to indicate a situation which, if not avoided, will result in death or severe injury.

- **Warning**
  - Used to indicate a situation which, if not avoided, could result in death or severe injury.

- **Caution (with safety alert symbol)**
  - Used to indicate a situation which, if not avoided, could result in minor or moderate injury.

- **Caution (without safety alert symbol)**
  - Used to indicate a situation which, if not avoided, could result in property damage.
Hazard alerts

Symbol: Hazard Description

Safety Alert Symbol and Signal Word

Text: Hazard ID, Consequence, Avoidance

(c) Lewis Bass International, Inc.
2005
Warnings in manuals and procedures

- Adequate safety information in the manuals and procedures?
- Is there a safety section?
- Are the warnings explained?
Service

How are products repaired and maintained?
How does the company communicate?

- Regulators
- Customers
  - On-product warnings
  - Website
  - Safety letters
  - Recall notices
  - Customer hotline
- Product safety team
Incident reporting, investigation and analysis

- Policies and procedures developed?
- Legal counsel involved?
- Incidents investigated?
- Failure analyses performed?
- Corrective action analysis undertaken?
Recall preparedness

- Recall procedure?
- Employee’s trained in the procedure?
- Recall coordinator designated?
How effectively can the company defend itself and its products?

- Team approach with defense counsel
- Lessons learned from litigation
- Recommendations for improvement
Summary

- Avoiding product liability is a management issue
- There are lessons to be learned from litigation
- Managing for safety and liability avoidance requires teamwork
- “Due Diligence” in managing for product liability avoidance involves risk analysis
LEW BASS applies his engineering experience to the analysis of the liability associated with products, facilities and the environment. He holds a B.S. in Mechanical Engineering, an M.S. in Industrial and Systems Engineering, and a J.D. in Law.

Mr. Bass has reviewed the safety of hundreds of products and factories. He has testified in court regarding risk assessment, warnings and safe design involving a wide variety of products.

Mr. Bass has taught many courses in safety, risk analysis and liability prevention. Mr. Bass is the author of "Products Liability: Design and Manufacturing Defects 2nd Edition", (Thompson West) and the Editor of “Managing for Products Liability Avoidance 3rd Edition (2004),” (Commerce Clearing House). He is a frequent speaker at professional seminars and conferences.

Mr. Bass is a member of the American Society for Quality, American Society of Safety Engineers, National Fire Protection Association, Semiconductor Safety Association, Regulatory Affairs Professionals Society (RAPS), DRI and the ABA.
LBI Clients

- Alcoa Aluminum
- IBM
- Motorola
- Emerson Electric
- Zurich Insurance Co.
- Delphi
- Chubb Insurance Company
- Alza
- Ethicon Endo-Surgery
- Intel
- Bernzomatic (Rubbermaid)
- Applied Materials
- Canon
- Hitachi

(c) Lewis Bass International, Inc.
2005
For over 26 years, we have provided Legal and Safety Engineering Consulting to large and small companies around the world. We work with companies in the construction, food processing, medical device, semiconductor equipment, consumer products and other industries.

We evaluate products for potential hazards and liability. Based on risk analyses, we provide recommendations for safety program improvements, safe product design, labels and manuals. We provide clients with recommendations for warning content, placement and methods of communication to reduce liability and accidents and increase profits.
Total Product Safety Services

- Product Safety and Liability Avoidance
- Product Risk Analysis, Warnings and Manuals
- Regulatory Compliance
  - Compliance and consultation
  - Recall decision-making
- Product Safety Training
  - Safe product design
  - Warnings and instruction manuals
  - Electrical and mechanical safety
  - Guards and interlocks
  - Ergonomics