PROCESS FOR MANAGING PRODUCT SAFETY RECALLS

I. Introduction and Overview

This document describes the process for addressing product safety issues and the _____ ("Company") Legal and safety compliance organizations' roles and responsibilities.

When Company receives a report of a product defect or non-compliance with a regulatory standard or other compliance obligation, the defect or non-compliance must be assessed immediately to determine the appropriate course of action. If the non-compliance or defect could result in bodily injury or death, immediate investigation and action is required to prevent harm. Under some circumstances government agencies must be notified immediately. For example, the US Consumer Product Safety Commission (CPSC) requires immediate notice.

Damage to property, our customers' business and Company's reputation may also create serious exposure to the company. There may be non-safety related regulatory notice and action requirements if a product defect or non-compliance is discovered. There are other organizations in Company which deal with particular compliance issues and exposures. For example, Company's Product Security Incident Response Team (PSIRT) addresses software threats and vulnerabilities. Much of the process discussed in this document may be useful to address non-safety related potential exposures, particularly the discussion related to the internal investigations. Quick action to address these potential exposures and to alert the appropriate internal organization will also be required if these non-safety issues could create a substantial exposure to Company.

When a product non-compliance or defect is discovered that could result in bodily injury or death the Safety Response Team ("SRT") must be notified immediately. The SRT will assess the potential risk, notify the appropriate internal organizations and engage the appropriate Company executive. The executive, typically the Business Unit Vice President, will work with the SRT to convene a core virtual team to make an initial assessment of the issue and determine whether (1) a notice to the CPSC (and other regulatory authorities) is required and (2) a product recall is necessary. Once these determinations are made, the executive will appoint a Recall Coordinator. The Recall Coordinator will create a cross-functional team and Expanded Virtual Team to develop the corrective action, logistics, and communications plans.

II. Incoming Incidents

Information concerning a product defect or non-compliance can come from a variety of sources. Compliance team members, product engineers, marketing team members, customers, legal team members and others may identify a product defect or non-compliance. **Regardless of the source of the report, the incident must be reported to the SRT Team Leader immediately**. The SRT is part of the Corporate Compliance organization in CA. SRT members are on constant alert by pager at work or at home, and also monitor the "**product-safety**" alias to which product safety issues may be reported. This team is composed of a team leader and at least one back-up person.

When customers report a product safety issue to the TAC, the TAC personnel are trained to alert the "**product-safety**" alias if the report has any of the following key-words: "safety, halon, burn, spark, melt, short, smoke or fire". If the customer reports a potential safety issue the TAC personnel are also instructed to obtain additional information from the customer. A list of questions that the TAC personnel should ask is at Appendix A. This list of questions is useful to elicit the facts and understand the context of a potential product safety issue.

The SRT is responsible for coordinating all incoming product safety related cases. The SRT's primary functions and responsibilities include:

1. Coordinating, resolving and escalating product safety issues
2. Assigning the initial hazard classification
3. Escalating product safety issues to the Virtual Team and/or the Crisis Management Team
4. Training TAC personnel
5. Working with the Recall Coordinator to manage a product safety recall

III. Hazard Assessment & Escalation

When the SRT receives information related to a potential safety issue the SRT will alert the appropriate BU safety engineer. The SRT will make an initial analysis of the safety hazard classification based on the information received, and discussions with TAC, BU and customer personnel, as necessary.

The severity of the incident is initially classified by the SRT leader and assigned to one of the three hazard categories below.

Class III hazard- there is an issue reported, but no injury or fire. In most cases, the issue does not need escalation beyond TAC. This class of hazard is processed through the regular Engineering Failure Analysis **(EFA)** process, together with the SRT and TAC. Where a safety analysis is deemed necessary in addition to an engineering failure analysis, a safety analysis report is written to close out the issue. This report is archived in EDCS.

Class II hazard- there is a significant risk of bodily injury or fire. The SRT leader immediately convenes the Virtual Team.

Class I hazard- there is a risk of death, serious bodily injury or major damage to property by fire. The SRT leader alerts the VP of Customer Advocacy (CA) and the Company Crisis Communications Team Leader. Senior management chain of Corporate Compliance, the VP/GM of the BU, and Company Legal are also contacted. Under some circumstances a Virtual Team may be convened. The supporting Legal team member should also alert the General Counsel, who will alert, among others, the Company Crisis Communication Team Leader.

IV. The Company Virtual Team Case Investigation and Analysis

The Vice President and General Manger of the BU that owns the product with the potential safety issue is responsible for making the decisions regarding product safety. The Core Virtual Team is a small internal team whose function is to assess the situation, and assist the BU VP/GM in making the decision whether (1) notification to safety regulatory agencies is required and (2) a safety recall is necessary.

The Core Virtual Team typically consists of representatives from the following functions:

BU VP/GM
BU Safety Compliance
BU Product Manager
BU Product Engineering Manager
BU PR
Legal (Licensing and Litigation)
SRT Leader

The Core Virtual Team must immediately determine whether the product defect or non-compliance could create a substantial risk of injury to the public. The investigation should be done at the direction of Legal Counsel and should be subject to the Attorney-Client Privilege. The investigation should be conducted quickly and should focus on obtaining the facts necessary to enable the BU Vice President to make the notice and recall decisions. Under the CPSC rules, for example, Company must report the issue within 24 hours after obtaining information that the defect or non-compliance could create a substantial risk of injury to the public.

Under some circumstances, a safety defect or non-compliance may not be subject to government regulatory jurisdiction; however, notice to customers and a product recall may still be warranted. For example, the CPSC jurisdiction is "consumer" safety. While the definition of consumer is quite broad (including schools, homes, hospitals) Company products may not be "consumer products" for purposes of CPSC jurisdiction. Regulatory agencies outside of the United States may have different policies. If the team and the BU VP/GM conclude that notice and a recall are not necessary or if the product is not "consumer product", it may be prudent to get an opinion from independent legal and safety experts since internal decisions to not take action may be subject to future scrutiny by government agencies or other third parties. In the past, Company has utilized consultant services such as outside counsel, CPSC specialists, and third party test labs such as UL.

The Core Virtual team's investigation should focus immediately on the following issues.

1. What is the probability and severity of the actual or potential injury that may result from the defect or non-compliance?
2. Is the product deployed where the actual or potential injury may affect the public, or will it affect a relatively limited number of people?
3. Is the product deployed in homes, schools or hospitals?
4. Should Company stop manufacturing or distributing the product?

5. If the safety issue is not subject to the government jurisdiction, is a non-public product safety recall warranted?
6. Are advice and second opinions from independent experts prudent?
7. Is there sufficient, accurate and detailed information to make an informed and factually based decision? If not, what additional information is required?

A working internal investigation topic checklist is attached as Appendix B. In conducting the investigation, it is important to train Company employees to report the facts necessary to make the notice and recall decisions. Emotional or unsubstantiated opinions and conclusions are counterproductive.

If the BU VP/GM and the virtual team conclude that the defect or non-compliance is not a safety issue and is a product reliability issue, the team should expeditiously determine the appropriate course of action since customers may still be damaged and Company may still face potential exposure.

V. Recall and Corrective Action Plan Development and Execution

If the BU VP/GM determines that notice to government safety authorities and a product recall is necessary, the BU VP/GM shall designate a Recall Coordinator. The Recall Coordinator should work with the SRT to understand the product safety recall procedures. The appropriate CA Serviceability Design Engineer (SDE) can provide considerable assistance to the Recall Coordinator, since the SDEs are expert at customer communication and cross-functional problem resolution. The Recall Coordinator must have the authority to involve appropriate organizations in implementing a product recall. The Recall Coordinator is also responsible for coordinating all communications concerning the possible safety recall, including internal disclosures of information, as well as any public disclosures.

The Recall Coordinator shall determine what additional resources are necessary to implement the product recall. The Recall Coordinator will form an Expanded Virtual Team, including the following individuals and functions:

BU VP Engineering
BU Marketing and channels representative
BU controller
VP of manufacturing to designate a representative
Logistics
CA (Customer Service, TAC, and Serviceability Design
Finance
Global Supply Management
Risk Management
Other third party advisors
- Outside Legal Counsel
- Outside Safety Consultants (e.g. UL, CPSC Specialists)
- Product vendor representatives
- Contract manufacturer representatives

The Extended Virtual Team must develop, implement and execute a corrective action plan. The following issues should be addressed in formulating the corrective action plan:

1. Is the defect in a component or the entire product defective?
2. Do we need to stop manufacturing, distributing or shipping the product?
3. What is the most effective action: notice, replacement, refund, software patch?
4. Is the corrective action compliance with safety standards and is the compliance documented?
5. Who are the customers?
6. Where are the products located?
7. What is the degree of access to the products (i.e. desktop, wiring closet, central office)
8. What are the replacement costs? Components? Logistics? Third Party?
9. Can the customer do the replacement or rework?
10. Can the replacement or work be done in the field or must the customer return the products?
11. When will the replacement components/products be ready to ship?
12. What actions/precautions should the customer take before the replacement product is available?
13. Do we have enough spare components or replacement products?
14. What is the current product warranty?
15. Will Company be providing an extended warranty?
16. Do any of the customers have support contracts? If so, what is the impact of the recall?
17. Has the BU controller set aside reserves for additional costs (i.e., recall, field installation, extended warranty)?
18. Does Company have sufficient and external resources dedicated to implementing the corrective action plan?

VI. Logistics Plan

The development of a comprehensive logistics plan is a critical component of a successful corrective action plan. A plan should be devised to ship replacement parts or new units to distributors or customers participating in the product recall or otherwise repair units in inventory. Until a production change can be made to incorporate a new model number or date-of-manufacture codes on the product, some means needs to be implemented to differentiate products that have been checked and corrected from recalled products. For a large-scale recall, Company's Customer Service organization may not have the immediate capability to execute the recall logistics and a third-party logistics organization may have to be engaged. The following logistics issues need to be addressed:

1. Returns and stock rotation (US and worldwide)
2. Costs
3. Logistics vendor management

4. Timing for replacements
5. Tracking the return shipment
6. Communicating with the customer
7. Returned product or component disposal
8. Monitoring, tracking, reporting
9. Product quarantine
10. Internal or outsource execution

VII. Communications Plan

Timing, consistency, accuracy, control and coordination are important criteria of a successful communications plan. The Recall Coordinator, working with the appropriate PR team, must develop a communications plan. The Recall Coordinator should carefully coordinate all communications. During the early, investigation phase, internal communications should be controlled and limited to a core group within Company on a need to know basis.

All internal and external communications (i.e. field notices, release notices, safety bulletins, FAQs, internal communications, press releases, and reports to the government) concerning the product safety issue must be reviewed for factual consistency and accuracy. In addition, the following issues need to be addressed:

1. What are the realistic time frames for such communications?
2. How will the message be communicated internally?
3. Who at Company needs to receive such communications?
    a. Legal (Litigation/Licensing & Sales team)
    b. PR/IR
    c. Executive staff

Once the decision has been made to notify government safety authorities, any public communications must be coordinated with the agencies. The CPSC, for example, will not permit any public notice of the recall until the CPSC staff approves the communication.

The Virtual Teams need to be reminded of proper e-mail etiquette. E-mails should be limited to the Virtual team and should be limited to factual subject matter. The Legal team representative shall examine and collect any email that was prepared prior to the creation of the virtual team. The Legal team representative should provide direction concerning the Attorney/Client Work Product privilege.

The Recall Coordinator, PR, Legal should carefully control external communications. Once the corrective action plan has been approved and the regulatory authorities have approved the external communication plan, customer communications can be initiated through the following Company functions:

PR (BU and Corp)
BU Marcom
Sales-account managers and SEs,

Sales-channels
Customer advocacy-Serviceability Design
Customer Advocacy-NSA

VIII. Government Reporting Obligations

Certain government safety organizations require notification of public safety risks. The US CPSC has the most specific reporting requirements. The laws may change so the Legal and Compliance teams should re-examine this issue when faced with a potential recall.

The CPSC requires a company to provide an initial report to the CPSC within twenty four hours after a company obtains information that reasonably supports the conclusion that a product defect or non-compliance creates a substantial risk of injury to the public. This report may be made orally, but must be confirmed in writing within forty-eight hours of the initial report. According to the CPSC, if a company is uncertain whether the information is reportable, the company may spend a reasonable time investigating the matter. The CPSC will presume that after ten working days, the company has received and considered all information that would have been available to it had a reasonable, expeditious, and diligent investigation been undertaken.

The CPSC requires the following minimum information in the **Initial Report**:

(1) Identification and description of the product.
(2) The name and address of the manufacturer (or importer) or, if the manufacturer or importer is not known, the names and addresses of all known distributors and retailers of the product.
(3) The nature and extent of the possible defect, the failure to comply, or the risk.
(4) The nature and extent of the injury or risk of injury associated with the product.
(5) The name and address of the person informing the Commission.

The CPSC requires a more detailed "**Full Report**" as soon as the information is reasonably available. The requirements of this Full Report are detailed in the CPSC regulations at Appendix C. The most current CPSC regulations should be examined to ensure that the Extended Virtual Team is aware of any new rules since the publication of this document.

There may be other governmental reporting obligations and related issues that arise during the course of the investigation. For example, OSHA, FCC or EU agencies may impose certain reporting obligations. The Legal team member and compliance managers assigned to the Extended Virtual Team are responsible for determining whether there are any other applicable government or standards body reporting obligations. Since each event may be unique, it is difficult to generalize about other regulatory requirements however the Legal team's regulatory affairs group will be able to assist

IX. Chronology-record keeping and Post Action Reviews

The Recall Coordinator and the virtual teams must maintain records of the various reports, analyses and correspondence related to the recall, in the event that there are follow-up

government investigations or potential litigation. The Recall Coordinator and team should establish a process for archiving documents and date related to the recall.

After the recall has been completed and the appropriate close out reports have been filed and approved by the government agencies, the Recall Coordinator shall conduct a post action review on the recall process. The purpose of the post action review is to determine process improvement for the recall process. This review should be done with active involvement of Company Legal and should be conducted subject to the attorney-client privilege.

Appendix A

INITIAL INTAKE FORM

These first series of questions assume that a customer has called with a complaint about a product failure, but it is not clear from the call what happened:

What product?
What happened?
When did this happen?
Where did it happen?
Who was present at the time?
Where is the device now?
What is the serial number of the product?

These are open-ended questions trying to elicit from the caller what the facts are. If the caller uses words that would indicate that there was a safety hazard (fire, smoke, halon, burn, shock, hurt etc.), then the following more focused questions should be asked

Did anyone suffer any injury? If yes, to what extent?
Was there any fire or damage to property?
Did the customer smell anything?
Did the customer shut down the system or did the unit shut itself down?
Did the customer see any smoke, flash, or flame? If yes, please note location.
If the customer saw flames, did the flame exit the enclosure of the equipment? If yes, how long was flame present?
Was there enough smoke, flame or combustion to activate the fire alarm?
Was the site evacuated?
Was the fire department dispatched?
If the power supply failed, did the failure take down the entire system, or just one power supply?
Was the unit running when the failure occurred? Or did the failure occur when the system was turned on or when the power supply was inserted into the system?
Please be specific if using the term “fried” or other vernacular. Did the card or power supply stop working, or was there actual burning?
If a card was damaged, is there visual indication of burning? Please describe in as much detail as possible.

Appendix B

PRODUCT RECALL – WORKING INVESTIGATION OUTLINE

General

1. Review initial in-take form, if any.
2. Was there an actual injury reported? What is the extent of the injury?
3. What is the probability of (future) injury?
4. What is the severity of (future) injury?
5. When did Company first learn of this problem?
6. Where did this initial information come from?
7. Was the initial contact from an internal or external source?
8. Examples of internal sources- "Company product safety alias, BU, Company manufacturing
9. Examples of outside sources- contract manufacturer, customer, distributor, third party test lab
10. Have there been any problems reported in the field, at the Company manufacturer, or internally?

Product Issues

1. What is/are the product(s)?
2. Product identification (model numbers, serial numbers, and date codes)
3. Does this impact a particular product(s) or an entire product family(ies)?
4. When did this product first FCS?
5. Has this product been associated with any other product reliability or safety issues?
6. What other BUs or Company organizations are affected by the defect or non-compliance?
7. What is the product warranty?
8. Is this a product from an acquisition?
9. What pre-acquisition records are available?

Manufacturing Issues

1. Who manufactures the component(s) or product for Company?
2. Does the manufacturer have any other reports of defects or non-compliance?
3. What records are available from the manufacturer?
4. Has there been a manufacturing line stop?
5. Have we stopped shipping products?
6. What dates were the products manufactured, imported, distributed, or sold?
7. Are there other reported recalls of the manufacturer's product?

Distribution/Customer Issues

1. Do we know who the customers and end users are? Is there a list? How many can we identify from Company records?
2. What type of customers?
    a. Service Providers
    b. Enterprise Customers
    c. SMBs

d. Home users
e. Consumers
f. Schools/universities
g. Medical institutions
h. Government
i. What are the sales channels? (direct, single-tier, two tier distribution, retail)

Logistics Issues

1. Product location (i.e. factory, stock, depot, resellers, distributors, end user customers)
2. What is the total number of products/units in the field and in distribution?
3. What geographic destinations have the products been shipped to?
4. How many products are in our logistics support centers?

Engineering Analysis

1. What has been the engineering analysis to date?
2. Has root cause been determined?
3. What type of testing of the product has been conducted?
    a. Third party test lab, internal testing? Vendor?
4. What is the number of reported defects?
5. What type of defect? Design defect? Fab defect? Other defect?
6. Has there been a fix developed?
7. What evidence is there that the fix is effective?
8. What is the timeframe to develop and distribute the fix?

Appendix C

CPSC FULL REPORT FORMAT 15 CFR 1115.13 (D)

(1) The name, address, and title of the person submitting the ``full report'' to the Commission.
(2) The name and address of the manufacturer (or importer) of the product and the addresses of the manufacturing plants for that product.
(3) An identification and description of the product(s). Give retail prices, model numbers, serial numbers, and date codes. Describe any identifying marks and their location on the product. Provide a picture or a sample of the product.
(4) A description of the nature of the defect, failure to comply, or risk. If technical drawings, test results, schematics, diagrams, blueprints, or other graphic depictions are available, attach copies.
(5) The nature of the injury or the possible injury associated with the product defect, failure to comply, or risk.
(6) The manner in which and the date when the information about the defect, noncompliance, or risk (e.g., complaints, reported injuries, quality control testing) was obtained. If any complaints related to the safety of the product or any allegations or reports of injuries associated with the product have been received, copies of such complaints or reports (or a summary thereof) shall be attached. Give a chronological account of facts or events leading to the report under section 15(b) of the CPSA, beginning with receipt of the first information which ultimately led to the report. Also included may be an analysis of these facts or events.
(7) The total number of products and units involved.
(8) The dates when products and units were manufactured, imported, distributed, and sold at retail.
(9) The number of products and units in each of the following: in the possession of the manufacturer or importer, in the possession of private labelers, in the possession of distributors, in the possession of retailers, and in the possession of consumers.
(10) An explanation of any changes (e.g., designs, adjustments, and additional parts, quality control, testing) that have been or will be effected to correct the defect, failure to comply, or risk and of the steps that have been or will be taken to prevent similar occurrences in the future together with the timetable for implementing such changes and steps.
(11) Information that has been or will be given to purchasers, including consumers, about the defect, noncompliance, or risk with a description of how this information has been or will be communicated. This shall include copies or drafts of any letters, press releases, warning labels, or other written information that has been or will be given to purchasers, including consumers.
(12) The details of and schedule for any contemplated refund, replacement, or repair actions, including plans for disposing of returned products (e.g., repair, destroy, return to foreign manufacturer).
(13) A detailed explanation and description of the marketing and distribution of the product from the manufacturer (including importer) to the consumer (e.g., use of sales representatives, independent contractors, and/or jobbers; installation of the product, if any, and by whom).
(14) Upon request, the names and addresses of all distributors, retailers, and purchasers, including consumers.
(15) Such further information necessary or appropriate to the functions of the Commission as is requested by the staff.