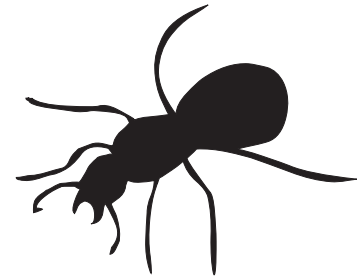


Y2K – What Should You Do Now?

By Kitty Dodd

Although it is very late in the Y2K Readiness process, now is the time to identify and prioritize your non-compliant issues, and act to mitigate these risks. Using the Risk Management and Contingency Planning approaches presented in this article will support this goal.



With the critical dates related to the Y2K bug rapidly approaching, I'm sure your organization has come a long way in establishing its own Year 2000 compliance. Having addressed your own products, you shifted your attention to ensuring the Y2K compliance of all your business partners.

With that shift, you became aware that the Y2K problem complexity is considerably greater than originally expected. This complexity is primarily due to the number of interdependencies among products, processes, multiple sites (your own and those of your suppliers), the IT infrastructure of your company and these same systems for all other companies worldwide that

your company deals with, e.g. utilities, airlines, freight forwarders, post office, payroll services, etc. And sadly, we now realize that innumerable organizations have either started their Y2K programs extremely late or have not yet even started.

Whatever progress we make in our own Y2K conversion activities, the insecurity level concerning what is to be completed will remain extremely high. There is no way of eliminating this insecurity. What we can do with less than 200 days before the Year 2000, is to reduce the overall negative impact for our companies through Risk Management and Contingency Planning.

Risk-prevention: Action taken to reduce the probability of a failure occurring (e.g., testing, system upgrading, etc.). Express probability in percentage of likelihood of occurrence (1– 100%).

Risk-mitigation: Actions taken to reduce the effect of failures (e.g., temporarily reducing activity levels or business volume, changing operational processes, seeking a second source for a part; adding inventory from suppliers not Y2K compliant, etc.).

A mitigation strategy is essential for the most critical products, suppliers, processes and IT infrastructure. It may also include organized shutdown of critical processes and services by end of December 1999 and controlled, phased power-up by early January 2000. Express probability in percentage of likelihood of occurrence, (1–100%). This exercise will prioritize the risks for your company.

A suggested worksheet for the Management of Risk is shown on the following page.

After you have either prevented or mitigated all critical risks to your business that is possible, the next step is to develop your Y2K Contingency Plan. A good contingency plan is a comprehensive document which guides the company to give adequate emergency response to perform interim operation and to fully recover as quickly and cost effectively as possible in the event of an unanticipated Y2K crisis.

Risk Management

Risk Management is executed by a cross-functional Risk Management Team comprising the Y2K Team and the respective experts in the products, processes, suppliers, IT infrastructure, etc. The objective of Risk Management is to identify and assess the major risks to the business.

Suggested Risk Management steps are:

① Identify and inventory all technical, business, financial and legal risks as well as their causes. Suggested company-wide risk categories are:

- Current Products
- Unreleased Products
- Internal IT Infrastructure
- Production Tools and Equipment
- Facility issues
- Suppliers/Service Providers.

② Quantify the impact of each risk. Suggested impact levels are:

- A. Risk will shut down production/development for greater than two weeks.
- B. Risk will negatively affect production/project schedule but can be managed with some loss of productivity and throughput.
- C. Systems do not meet Y2K readiness criteria but activity can be performed manually with minimum disruption to the company.
- D. No effect on the company anticipated.

③ Define preventive and mitigating measures:

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The 90-page Directory costs just \$14.00, including shipping. If you would like a copy, fax us at 408-522-3212 or e-mail us at sales@gmplabeling.com. Be sure to include your ship-to address, and either bill-to address with your P.O. number, or your credit card number.

Y2K – What should you do now?

Suggested Contingency Planning steps are:

1. Describe the risk scenarios based on realistic combinations of the risks described in the risk analysis.
2. Develop a Y2K Crisis Management Team composed of managers, process experts and Y2K officers.
3. Define the priority of mission critical processes and systems. Identify which can be deferred, for how long, and the sequence in which a recovery has to be performed.
4. Identify a strategy towards customers. Which customers will receive preferred support – based on what? What is the minimum acceptable service level to be established? Are there special processes and conditions for Y2K issues?
5. Describe the management of suppliers; identify alternative suppliers and service providers. Develop agreements with suppliers and service providers about preferred and speedy supply. Identify alternative means of transportation for material and manpower with regard to long distance travel.
6. Set up a contingency detection and communication approach to activate the plans in a timely manner that meets the needs of the business. Consider setting up a Call Center with Help Desk and online services.

Year 2000 Risk Categories	Risk Impact: A, B, C, D	Risk Assessment prior to Risk Prevention or Risk Mitigation (%)	Risk Assessment after Risk Prevention or Risk Mitigation (%)
Current Products			
Unreleased Products			
Internal IT Infrastructure			
Production Tools and Equipment			
Facility Issues			
Suppliers/Service Providers			

7. Maintain documentation of preparatory steps taken. Document what has been done, backups, spare parts, tools, means of transport and communications, agreements, workarounds, etc.

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Risk Management in Programmable Electronic Medical Devices

Part 1 of 2

By Gary Seeger

Incorporation of an appropriate and effective risk management program into the design and development of programmable electronic medical devices has become mandatory for medical device manufacturers wishing to market new software-driven devices in the European market.

Under the European CE approval process for medical devices, software programmable medical systems must now comply with the risk management requirements of IEC 601-1-4. IEC 601-1-4 is a collateral safety standard that complements the general safety standard IEC 601-1 and requires that a process be followed and that a record of that

process be produced to support the safety of medical electrical equipment incorporating programmable electronic subsystems. The standard is addressed to certification bodies, manufacturers, and writers of particular standards. The standard covers requirement specification; architecture; detailed design and implementation including software development; modification; verification and validation; and marking and accompanying documents. Aspects not covered by the standard are hardware manufacturing; software replication; installation and commissioning; operation and maintenance; and decommissioning.

In this newsletter issue, I cover the more general IEC 601-1-4 requirements for programmable medical systems including Documentation, the Risk Management Plan, the Development Life Cycle, and the Risk Management Process.

In the next newsletter issue, I will cover the complementary requirements of Personnel Qualification, Requirement Specification, Architecture, Design and Implementation, Verification, Validation, Modification, Assessment, and FDA Congruence.

Documentation

Documents produced under this standard are referred to as the Risk Management File and are maintained as quality records in accordance with 6.3 of ISO 9000-3. The Risk Management File is approved, issued, and changed in accordance with a formal configuration management system as described in 6.2 of ISO 9000-3. A Risk Management Summary is developed throughout the development life cycle as part of the risk management file in accordance with a risk management plan. The risk management summary contains the following items:

- Identified hazards and their initiating causes.
- Estimation of risk.
- Reference to the safety measures, including their required safety integrity, used to eliminate or control the risk of the hazard.
- Evaluation of effectiveness of risk control.
- Reference to verification.

Risk Management Plan

A manufacturer must prepare a Risk Management Plan. The Risk Management Plan for many companies is typically included in the formal design control procedures. The Risk Management Plan should include the following items:

- Scope of the plan defining the project or product and the development life-cycle phases for which the plan is applicable.
- The development life cycle to be applied, including a verification plan and a validation plan.
- Management responsibilities in accordance with 4.1 of ISO 9001.
- Risk management process.
- Requirements for reviews.

Development Life Cycle

A Development Life Cycle must be defined for the development of a programmable electrical medical system. The Development Life Cycle for many companies is typically included in the formal design control procedures. As such, the Development Life Cycle is divided into phases and tasks including the following items:

- A well defined input, output, and activity for each phase of the Development Life Cycle.
- Integral processes for Risk Management.
- Documentation requirements.
- Risk Management activities as appropriate throughout the Development Life Cycle.

Risk Management Process

The Risk Management Process used must contain the elements of Risk Analysis and Risk Control.

Risk Analysis: Hazard identification must be carried out as defined in the Risk Management Plan. Hazards must be identified for all reasonably foreseeable circumstances, including normal use and incorrect use. Hazards include those to patients, operators, service personnel, bystanders, and the environment.

Initiating factors that are considered include human factors, hardware faults, software faults, integration errors, and environmental conditions. Hazard identification methods (fault tree analysis, failure modes and effects analysis, etc.) appropriate to the Development Life Cycle are used and documented in the Risk Management File. The results of the application of the hazard identification methods are documented in the Risk Management File.

Each identified hazard and its initiating causes is recorded in the Risk Management Summary.

A manufacturer *must* prepare a Risk Management Plan

Risk Estimation: The risk for each identified hazard must be estimated. The estimation of the risk must be based upon an estimation of the likelihood of each hazard and/or the severity of the consequences of each hazard.

The severity level categorization method and the likelihood estimation method (qualitative or quantitative) must be recorded in the Risk Management File. The estimated risk must be recorded against each identified hazard in the Risk Management Summary.

Risk Control: Risk must be controlled such that the estimated risk of each identified hazard is made acceptable. A risk is acceptable if the risk is less than or equal to the maximum tolerable risk and the risk is made as low as reasonably practicable.

Methods of risk control must reduce the likelihood of the hazard or reduce the severity of the hazard or both. Risk control methods are directed at the cause of the hazard or by introducing measures which operate when the cause of the hazard is present, or both.

The priorities of risk control are inherent safe design, protective measures including alarms, and adequate user information on the residual risk. The requirements to control the risk must be documented in the Risk Management Summary directly or as a cross-reference. An evaluation of the effectiveness of the risk controls must be recorded in the Risk Management Summary.

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Stellartech Research Corporation designs, develops, and manufactures electronic and disposable medical devices under contract to both start-up and mature medical device companies.

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