Medical Device Risk Management

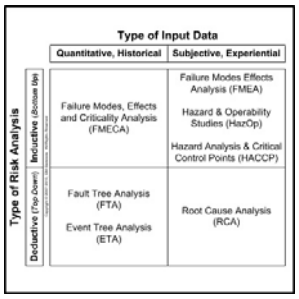
ESTIMATING LEVEL OF EFFORT FOR RISK MANAGEMENT

The US FDA requires that Class 2 & 3 medical devices comply with the Design Control regulation (21 CFR 820.30). Risk management is not only an element of design controls; it is also a good business practice regardless of device classification. Its purpose is to protect stakeholder value. Risk management is also required by international consensus standard ISO 13485:2003. It specifically identifies international consensus standard ISO 14971 ("Application of risk management to medical devices"), which is an FDA-recognized standard. Risk management includes the iterative process consisting of:

- risk identification (is there a potential source of harm?),
- risk assessment (do I really care?),
- risk mitigation (can I adequately reduce the targeted risk?),

The risk management file is documented evidence of proper execution of the risk management process. Please refer to the decision flowchart on the backside of this page.

There are multiple tools available for risk analysis; what tools you decide to use depend upon both the type of data you have available and whether or not you are doing an objective or subjective analysis. Furthermore, a frequent mistake is to assume that just a bottom-up analysis (e.g., FMEA) is both effective and acceptable. This is false! The approach is not compliant with ISO 14971 and only a combined analysis (top-down and bottom-up) will provide comprehensive coverage of single point failures and reveal multi-point failures. Doing only a partial analysis provides the device manufacturer with only marginal benefit, while providing a false sense of confidence.



A complete and correct design risk analysis considers hazards associated with hardware, software, human factors, manufacturing, security, operations (including maintenance) and disposal. A design risk analysis, upon identification of a hazard, estimates the probability of occurrence and the severity of harm; it never includes probability of detection ("detectability"), because the user is unaware of the internal workings of the device and never has the opportunity to modify the design. Including "detectability" in a design risk analysis erroneously underestimates the real risks to both consumer and producer.

In order to estimate the level of effort to conduct (or review) a risk analysis, the following documentation is required:

1. Device description (e.g., intended use, intended operational environment, and high-level block diagram),
2. Complete set of electrical & mechanical schematics and, if used, software flowcharts,
3. Complete set of draft labeling (e.g., device labels, package labels, user manual),
4. Any published adverse events with predicate or similar devices,
5. Any existing device-specific risk management documentation.

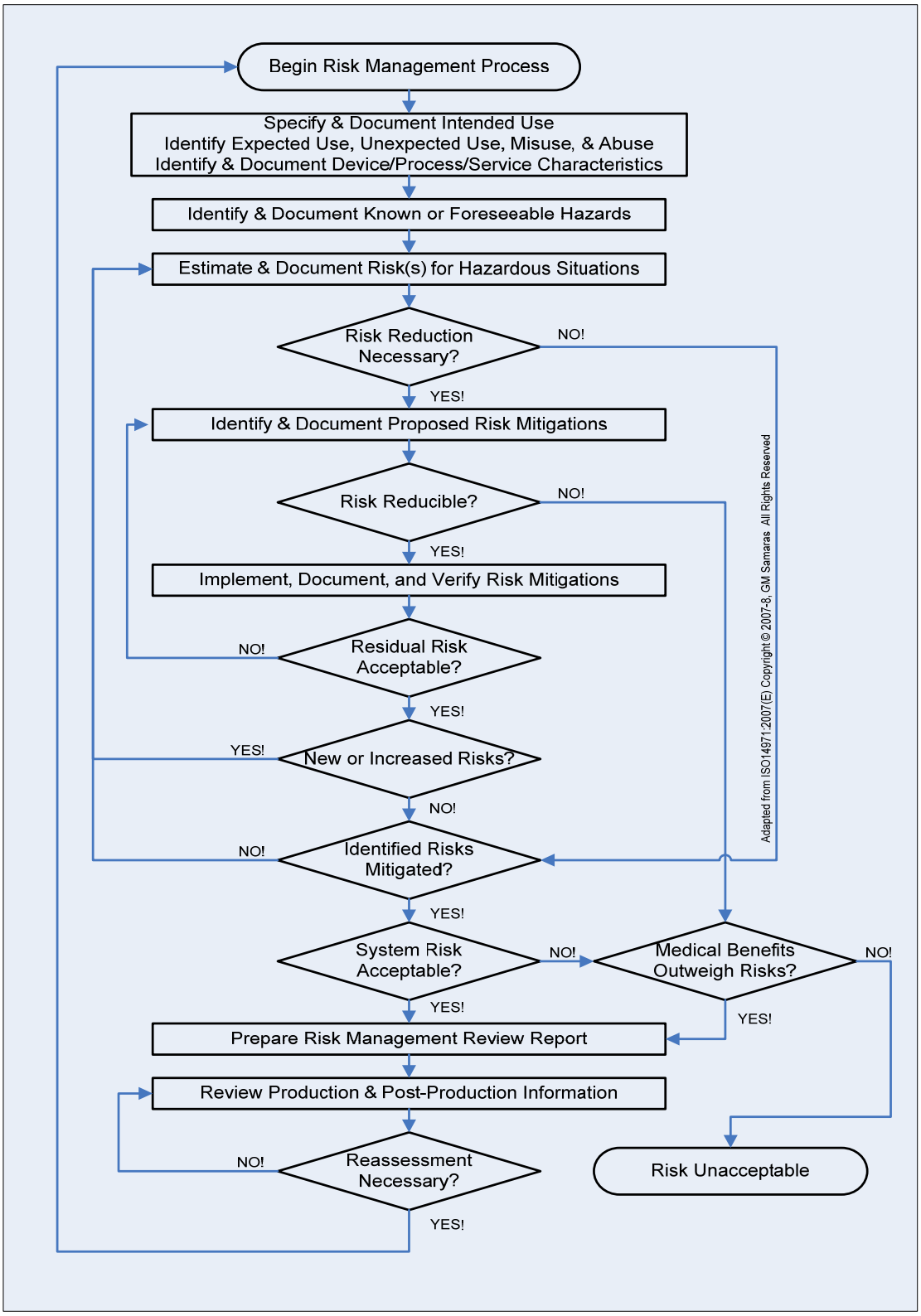
One important result of complete and correct risk management is that the medical device design may have to be changed. This can be very expensive late in the development process or just before regulatory submission. Furthermore, unidentified or unmitigated risks have adverse sequelae for both the device user and the device manufacturer.

The following are a few useful references for medical device risk management; you should familiarize yourself and your development team with these documents PRIOR TO BEGINNING your device development efforts:

1. International Standard ISO 14971:2007. Medical devices – Application of risk management to medical devices. October 1, 2007.
2. Guidance for Industry and FDA Premarket and Design Control Reviewers: Medical Device Use-Safety: Incorporating Human Factors into Risk Management, July 18, 2000
3. Musa, JD. Software Reliability Engineering. New York: McGraw-Hill. 1998

GM Samaras, PhD, DSc, PE, CPE, CQE george@samaras-assoc.com

Medical Device Risk Management



GM Samaras, PhD, DSc, PE, CPE, CQE george@samaras-assoc.com