dFMEA Instructions for Use (IFU)

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The design (or device) Failure Modes Effects Analysis (dFMEA) is an inductive (bottom-up) risk analysis method that relies upon subjective, experiential judgment of an experienced medical device risk analyst. The key to success is having a qualified analyst and team of domain experts, since this is a subjective, experiential estimate of risk. I routinely use this tool with my medical device clients. This tool is distributed without charge; use it at your own "risk" ☺.

There are two worksheets in the MS Excel workbook.

The first worksheet is the set of Risk Assessment tables that underlie the dFMEA tool. It is your responsibility to establish the specific definitions of the severity levels and frequency of occurrence levels (both of which are merely ordinal scales in this tool) for your specific medical device. Please recall that if you estimate your individual product will fail only once every million uses (10^{-6}; "improbable" per ISO 14971), but you plan on selling at least 1000 units, then your probability estimate has to be somewhere close to once every thousand uses (10^{-3}; "frequent" per ISO 14971, assuming independence, same epochs, etc.) The risk you are attempting to determine is not for a single product sold by you to a single user, but for the aggregate to which the public will be exposed. That is the risk your company is undertaking with its decision to sell its product.

The second worksheet is the actual dFMEA template that you will use to identify hazards, estimate their pre-mitigation risk, identify possible risk controls, implement the risk controls, conduct both ISO 14971:2007§6.3 verification tests, estimate the post mitigation risk, and if necessary either (a) redesign, if intolerable or (b) justify, if "As Low As Reasonably Possible" (ALARP).

CAUTION: It is important to be skilled in the use of a MS Excel worksheet, so as not to inadvertently either delete formulae within existing line items or, when adding new line items, corrupting the many formulae in the spreadsheet.

There are twelve (12) hazard sections (A-L) to the template: energy, biological, environmental, incorrect output, use of device, user interface, function failure, maintenance, & aging, security, software, manufacturing, and IVD-specific hazards. Each hazard section has a number of hazard categories that are numbered. They are generic, they are not comprehensive, they do not necessarily all apply to your particular medical device, and the clear expectation is that you critically will think through what is and is not relevant to the safety and effectiveness of your device and all its users.

If a hazard line item does NOT apply to your device, go to Column C, select the cell corresponding to that hazard category, and select the "NA" value from the dropdown menu. Then move over to Column D and enter the reason for the "NA". You are finished with that hazard line item!

If your medical device has more than one example of a relevant hazard in any hazard line item, insert (carefully) one or more new row(s) beneath that specific hazard category and fill in the new dFMEA information just as you are doing with the existing, already identified, hazard categories. Make sure you copy the formulae from the original line item prior to filling in the new information. Also you make sure to change the corresponding line item number in column A (e.g., E4.02, E4.03, etc.); the new line items number will propagate automatically across the spreadsheet.

For each relevant hazard category, do the following:

- In Column D, identify the failure mode (e.g., electrocution, overdose, etc.);
- In Column F, select the pre-mitigation severity level from the dropdown menu;
- In Column G, identify the failure cause (e.g., exposed wire, containment failure, etc.) (*You must enter this or there will be no risk computation*);
- In Column H, select the pre-mitigation probability of occurrence level from the dropdown menu;

The initial Risk Index (iRI) will compute and the initial risk class will be displayed. If the initial risk class is green (acceptable), fill in the justification of both the chosen severity and probability in Column K and then NO additional action is required.

- Otherwise, in Column K, enter the recommended action or the document identification number describing the recommended risk control measure(s);
- In Column L, select the type of control from the dropdown menu;
- In Column N, identify the actual action taken (be sure to identify the two ISO 14971 risk verifications – verification that the proposed risk control was properly applied AND verification that the properly applied risk control actually reduced the targeted risk frequency of occurrence) or the document identification number describing the actions taken and the results of the two verifications;
- Skip Column O, since post-mitigation severity level does NOT change;
- In Column P, select the post-mitigation probability of occurrence level from the dropdown menu;

The final Risk Index (fRI) will compute and the final risk class will be displayed.

- If the final risk class is intolerable (red), the device design needs to be changed;
- If the final risk class is ALARP (yellow), a detailed justification (or reference to the document identification number describing the detailed justification) must be provided in Column T.

That is all there is to it!

This tool is easy to use, is intended to be used iteratively throughout the development process, and should first be used before you begin your basic design, while you are still formulating your initial Design Inputs (Product Requirements & Constraints) per 21 CFR 820.30(c)

Call me (719-485-3751) or email me (george@samaras-assoc.com), if you need help.