

MDIC Complaint Metric

The Medical Device Innovation Consortium, MDIC, on August 1, 2016, published *Medical Device Quality Metrics – Best Practices Document for Metrics Identified Across the Total Product Lifecycle*. The document supports the FDA CDRH Office of Compliance Case for Quality initiative.

It recommends metrics in three broad areas: Pre-production, Production, and Post-production. One metric of common interest is complaints. This falls into the Post-production area.

The report recommends the Complaints Metric as:

Complaints for the product per period / Units sold for the product per period

For the post-production metrics in general, the report says that the selected period should be the same for the numerator and the denominator, such as a rolling 12-month period.

In addition, the report provides some considerations for the Complaints Metric.

- Adjust the numerator if the complaint is classified as not a valid complaint
- Define the period for the metric remembering the recommendation that it be the same for both numerator and denominator
- Replace units sold by units in use in some cases such as capital equipment

The Complaints Metric provides a Complaint Rate. However, the report also suggests a “Compliant Risk Score” based on a severity classification for each complaint and a weighting factor associated with the severity. Appendix B provides an example.

The Appendix B Example

Appendix B provides an example of how to generate a “Complaint Risk Profile Score”. Notice that the terminology changed by adding the word “Profile”.

The Complaint Risk Profile Score classifies each complaint by severity and assigns a weight. The score uses the proportion of received complaints with that severity. Notice that it doesn’t use the number of units shipped, so this is not the Complaint Rate from the Complaint Metric.

The table below is from the example. The manufacturer could use another suitable classification and weights. Consider, for example, the severity classification scale used for ISO 14971:2007 risk management.

Evaluate each complaint for severity and then assign the appropriate weight. For example, each critical complaint would receive a score 30.

Severity Classification	Severity Weighted Value	Severity Definition
Catastrophic	50	Potential for Death
Critical	30	Potential for Serious Injury
Marginal	19	Potential for Non-serious injury
Negligible	1	Minor Patient Annoyance, Cosmetic Issue, No Injury to patient

Consider an example in which the selected period is a calendar quarter. (This uses the 3rd quarter in the report’s Appendix B example.) The data for the quarter is:

- Units shipped: 18,000
- Complaints received: 500
- Catastrophic Complaints: 2
- Critical Complaints: 0
- Marginal Complaints: 4
- Negligible Complaints: 494

The Complaint Rate from the Complaint Metric is $500/18,000 = 0.028$. Expressed as a percentage, this is 2.8% Expressed as parts per million, this is 28,000 ppm.

The Risk Profile Score is the sum of the individual score for each severity.

- Catastrophic Complaints: $2/500 \times 50 = 0.2$
- Critical Complaints: $0/500 \times 30 = 0.0$
- Marginal Complaints: $4/500 \times 19 = 0.152$
- Negligible Complaints: $494/500 \times 1 = 0.988$
- Risk Profile Score: 1.34

The report recommends multiplying the score by 100 to normalize the values giving a Risk Profile Score of 134.

Analysis

The result is a Complaint Rate of 2.8%, meaning that for the devices shipped, 2.8% of them produced a complaint of any severity. Notice that for some devices the received complaint may not be in the same period as the device shipped. However, over many periods, this issue will smooth itself out.

The Risk Profile Score has a less obvious meaning. If all of the complaints were Negligible, then the normalized score would be 100. Any score above 100 is not desirable, and larger scores point to more severe complaints. The Risk Profile Score is most meaningful when viewed in comparison with prior periods.

Both the Complaint Rate and the Risk Profile Score are suitable for quality objectives and reporting at Management Review.