See Also: SOD Matrix

The **Quality Assurance Manager (QAM)**, calculates the risk priority number (RPN). The QAM uses the Severity, Occurrence, Detection (SOD) matrix and performs the following steps**:**

1. **Determines** the Severity of the condition by assigning a numerical value from column one of the SOD matrix. Assessment of the severity must consider the work products leaving the laboratory and the impact on the customer(s). A higher severity leads to a greater likelihood that customer use of nonconforming laboratory work products will result in corrective management decisions of customers.

    a. Values of 1-2 are generally minimal and do not significantly adversely impact work products leaving the laboratory.

    b. Values of 3-6 are moderate and adversely impact work products leaving the laboratory but have little to no impact on external customers.

    c. Values of 7-9 are significant, adversely impact work products leaving the laboratory and may impact external customers.

    d. A value of 10 would likely require notification of external customers if a nonconformance was identified.

2. **Determines** the Occurrence of failure by assigning a numerical value from column two of the SOD matrix. Assessment of the occurrence must consider the number of failures during a prescribed time frame and whether or not failures are clustered events.

    a. Value of 1 is for scenarios that are not likely, or are theoretical to isolated. Subsequent occurrences would increase the value for this matrix element.

    b. Values of 2-3 are for scenarios that occur rarely or occasionally.

    c. Values of 4-5 are used for repeated, systemic and/or continual failures.

3. **Determines** the probability of Detection of failure by assigning a numerical value from column three of the SOD matrix. Assessment of this criterion must consider who can detect an issue at each stage of use or review.

    a. Value of 1 is for scenarios where detection by most, or all, levels of review provide an opportunity of detection.

    b. Values of 2-3 are for scenarios where detection by some levels of review would be apparent.

    c. Values of 4-5 are not likely to be determined through existing internal management controls.

4. **Adds** the values of Occurrence and Probability of Detection together.

5. **Multiplies** the value obtained by the Severity to determine the Risk Priority Number (RPN).

6. If a nonconformance has not yet occurred, and the RPN is ≥ to 20, **generates** a PAR.

   NOTE: If the RPN is < 20, **actions** by the QAM are discretionary, ranging from taking no action to creating a PAR.

7. If a nonconformance has already occurred, and the RPN is ≥ 20 (but ≤ 50), **generates** a CAR.

End of Document

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