

National Personal Protective Technology Laboratory

Classification of Defects and Control of Product Quality

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Classification of Defects

- **42 CFR 84.40 requires:**

“ each applicant shall file with the Institute a proposed quality control plan which shall be designed to assure the quality of respiratory protection provided by the respirator ...”

- **42 CFR 84.41 (b) requires:**

“ inspection shall be sufficient to ensure control of product quality ...”

Classification of Defects

- **42 CFR 84.41 (c) requires:**

“ The sampling procedure shall include a list of characteristics to be tested ...”

- **42 CFR 84.41 (d) requires:**

“ The characteristics ... shall be classified according to the potential effect of such defect ...”

Classification of Defects

What do these sections mean and require?

- 1) The Approval Holder (AH) must determine the potential defects (or failure modes) of the respirator**
- 2) The AH must rank (or classify) the defects in order of potential effect on the user**
- 3) The AH must design an effective sampling plan to assure that potential defects are properly addressed**

Classification of Defects

The Approval Holder can determine potential defects by:

- 1) A proper design program & sound engineering judgment (New and existing respirators)**
- 2) Experience from actual field use of the respirator (Existing respirators only)**

Classification of Defects

A design program determines potential defects by

- 1) A classification of defects (C/D) study
(called out by 42 CFR 84)**
- 2) A Failure Mode Effects Analysis (FMEA)
(current practice in many manufacturing areas)**

Classification of Defects

Steps in a classification of defects study.

- 1) Identify potential defects (or failures)**
- 2) Determine the impact of each defect (or failure)**
- 3) Classify each defect into a category**
- 4) List defects by class (critical, major A, etc.)**

Classification of Defects

Steps in a FMEA study.

- 1) **Identify potential failures modes**
- 2) **Determine the impact of each failure mode**
- 3) **Determine the probability of each failure mode**
- 4) **Prioritize the list of failure modes based on numerical scores**
- 5) **Organizing the failure modes into groupings (classification) would be an additional step**

Classification of Defects

A Classification of Defects or a FMEA consists of

- 1) An extensive engineering study or investigation into potential failures and their effect on respirator safety and performance
- 2) A prioritized list of potential failures or defects

Classification of Defects

Typically NPPTL requires that:

- The engineering study portion be available for examination during quality site audits
- The prioritized list should be submitted to NPPTL and reviewed during the approval process
- The prioritized list is used to determine what tests and their frequency are in the sampling plan

Classification of Defects

The prioritized list is used to determine the adequacy and effectiveness of the sampling plan

- **Have all failure modes been examined?**
- **Have sufficient samples been tested for each failure mode?**
- **Where in the manufacturing process were the failure modes examined? (receiving, in-process, final, component, full assembly, etc.)**
- **What testing addresses failure modes and what is “*over and above*” testing**

Classification of Defects

The results of testing, experience and field use should be used to update the C/D or FMEA

- Are there new or unexpected failure modes?
- Is the frequency of failures larger, smaller or the same as projected during the design study?
- Are there potential defects that do not occur in actual use?

Classification of Defects

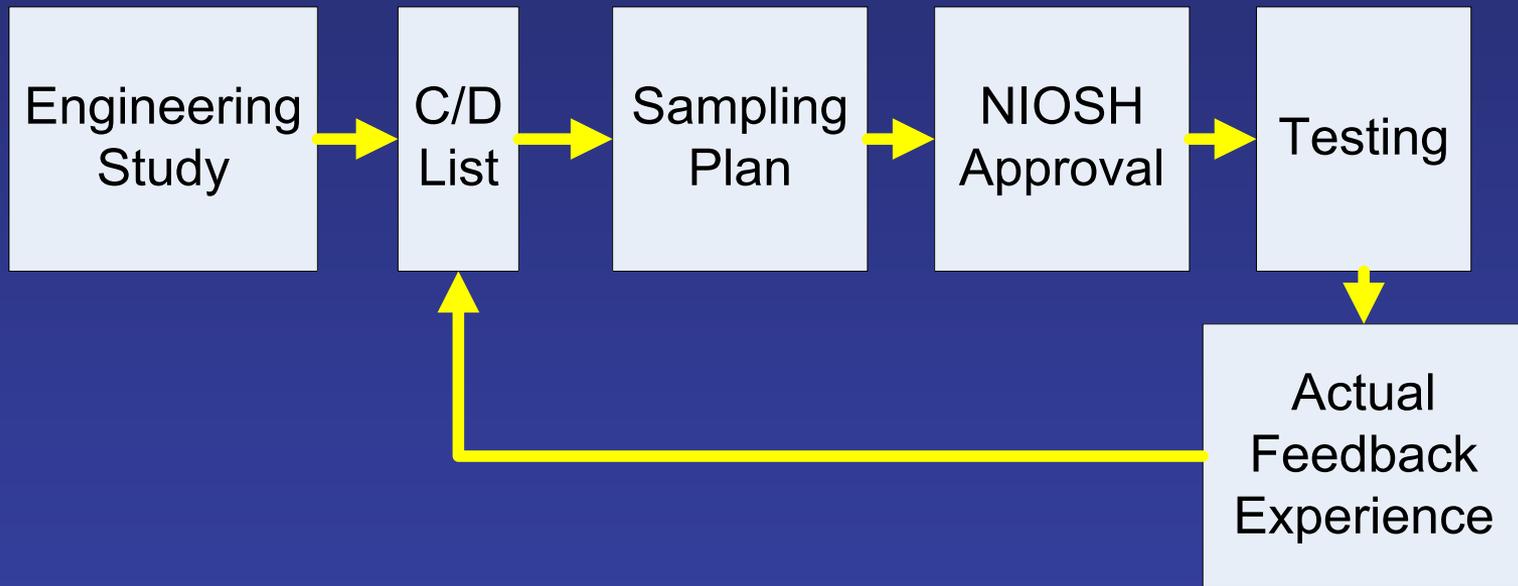
If the actual failure experience is different than projected, the Classification of Defects and the resulting Sampling Plan should be revised.

- The Classification of Defects and Sampling Plan should be “*living documents*” and should be revised on a regular schedule to reflect actual experience
- This keeps sampling and testing targeted on “*real world*” issues and eliminates unnecessary testing and inspection

Classification of Defects

- **The Sampling Plan is part of the NIOSH respirator approval**
- **Any changes must be approved by NIOSH prior to implementing in actual sampling and testing activities**

Classification of Defects



Classification of Defects

Questions?

