



EP22 – Presentation of Manufacturer’s Risk Information

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EP 22 Presentation of Manufacturer's Risk Mitigation Information

Project proposal submitted in October 2004

2 subcommittee drafts were proposed and rejected

Third draft was approved to move to the EP Area Committee for consideration

- Subcommittee
- Area Committee
- Delegate Review and Comment
 - Special Reviewers
 - Paired Review
- Board Review

Focus is on information to be provided to user by the manufacturer; no mention of QC frequency



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Originally intended to provide statistical and scientific guidance to allow manufacturers to make QC frequency recommendations in their labeling

- No peer-reviewed science in clinical diagnostics currently exists that links risk assessment or reliability to frequency
- Product labeling must have language that defers to regulatory requirements



EP 22 Presentation of Manufacturer's Risk Mitigation Information: Scope

Guidance to manufacturers

Focuses on information to provide to users of in vitro diagnostic devices

- Scope and effectiveness of design features intended to mitigate risk of device failure
 - Focus is on failure modes
 - How a failure manifests itself
 - How the risk mitigation feature works to prevent failure
 - Studies done to verify effectiveness of the design feature



Means to Communicate Information

Risk mitigation information can be supplied by manufacturers:

- In the product insert
- In the device manual
- As a separate sheet
- Via the internet

Format of information

- EP22 suggests a table with the following headers and information.



Table Headers

Targeted Failure Mode

Device Feature or Recommended Action

Description of How Feature or Recommended Action Performs Its Intended Function

Known Limitations of Feature or Recommended Action

Actions Required to Address Known Limitations

Studies Performed to Verify

Feature/Recommendation Achieves Intended Purpose



Studies Performed

Proposed that manufacturer provide the following study information to demonstrate the robustness of the design feature or recommended action.

- Description
- Sample matrix tested
- Number of samples tested
- Reagents and calibrator lots tested
- Number of replicates
- Number and types of devices tested
- Location of testing
- Conditions of stress
- Statistical methods used
- Study results
- References



Summary

Provides a framework for sharing information with users

Suggests key information to be shared with users to support local laboratory decisions about character and frequency of QC

Should reduce or eliminate unsubstantiated QC recommendations