

# Workshop – Grading Nonconformities

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# Introduction

- Current Document GHTF/SG3/N19
- Feedback
- Workshop: proposals for revision

# Current Document GHTF/SG3/N19

- *Medical Devices – Nonconformity Grading System for Regulatory Purpose and Information Exchange*
- Published in November 2012
- By Global Harmonization Task Force – Study Group 3 – Quality Systems
- Goals:

# Current Document GHTF/SG3/N19

- Goals:
  - Improve audit information consistency
  - Provide transparency on the grading
  - Facilitate mutual acceptance of results of regulatory audits
  - Provide more progressive grades than the typical binary minor vs. major system
  - Let each regulator make independent decisions according to their jurisdiction

# Grading Concept

- 4 independent parameters:
  - Indirect vs. Indirect QMS Impact
  - Occurrence
  - Absence of a documented process or procedure
  - Release of a Nonconforming Medical Device
- Grading scale from 1 (least critical) to 5 (most critical)

# Indirect vs. Indirect QMS Impact

- Indirect QMS impact:
  - The NC refers to a clause of ISO 13485 considered to have indirect influence on the medical device safety and performance. Those clauses are seen as “enablers” for the QMS processes to operate.
  - ISO 13485 clauses 4.1 to 6.3
  - Sets the starting grade at 1

# Indirect vs. Indirect QMS Impact

- Direct QMS impact:
  - The NC refers to a clause of ISO 13485 considered to have direct influence on design and manufacturing controls, hence on the medical device safety and performance.
  - ISO 13485 clauses 6.4 to 8.5
  - Sets the starting grade at 3

# Indirect vs. Indirect QMS Impact

- Remarks
  - Nonconformities can often be written up against more than one clause. The selected clause must be consistent with the impact of the NC on the safety or performance of the device.



# Occurrence

- Repeat occurrence: the NC refers to the same sub-clause (X.X.X) as another NC identified within either of two previous QMS audits which evaluated the same sub-clause.  
→ Increase the grade by 1
- Occurrence refers to the frequency of a nonconformity cited from one audit to the next performed by the same auditing organization.

# Absence of a Documented Process or Procedure

- The absence of a documented process or procedure affects the consistency and effective implementation of any process.  
→ Increase the grade by 1
- Note: Under MDSAP, it was clarified to the Auditing Organizations that this applies only when ISO 13485 requires a documented process or procedure.

# Release of a Nonconforming Medical Device

- A nonconforming device on the market and outside the control of the manufacturer's QMS is a direct evidence of a QMS failure.  
→ Increase the grade by 1
- The escalation does not apply if the device was released under concession with adequate justification.

# Final Grade

- Sum of the 4 independent parameters
  - Capped at 5

# Feedback

- Most feedback is consistent with the objectives of the GHTF document, with positive comments on:
  - Transparency
  - Consistency
  - Predictability
- Some concerns...

# Feedback

- Reference to an obsolete version of ISO 13485
- Inconsistencies in clauses considered as having direct or indirect QMS impact
- Concerns with criteria for repeat occurrence:
  - Difficulty to identify which past audit covered which subclauses of ISO 13485
  - Some subclauses include multiple requirements so 2 NC relative to the same subclause may have little in common (unrelated cause, impact, etc.)
  - Applicability in case of transfer of certification
  - Applicability across certification schemes
  - Applicability across a multi-facility organization

# Feedback

- Implementation inconsistencies related to the absence of documented process or procedure
  - Absence vs. lack of details
  - Absence vs. Absence of coverage of a specific jurisdiction
- Implementation inconsistencies related to the release of a nonconforming device
  - Demonstrated vs. suspected or potential release of a nonconforming device
- Occasional inconsistency between GHTF (1 to 5) and ISO (minor/major) grading suggesting the subjectivity between the 2 schemes.

# Feedback

- Any additional feedback to be considered



# Workshop

- Form groups with representatives of manufacturers, Auditing Organizations and Regulatory Authorities.
- Answer the following five questions, with specifics whenever possible.
- We will share answers.

Note: Copies of the GHTF document and ISO standard are available. Please leave them in the room after the forum

# Workshop

- **Question 1: Direct vs. Indirect Impact**
  - Should any sub-clause within clauses 4.1 to 6.3 be considered as having direct influence on the device safety and performance?
  - Should any sub-clause within clauses 6.4 to 8.5 be considered as having indirect influence on the device safety and performance?

# Workshop

- **Question 2: Repeat NC**

- What recommendations would you make regarding the escalation for Repeat NC?

*Consider the following:*

- *Nonconformity previously identified under a different certification scheme*
- *Transfer of certification*
- *Multi-facility organizations*
- *Practicality of identifying the subclauses covered by previous audits*
- *“Compound” subclauses*

# Workshop

- **Question 3: Absence of Documented Process or Procedure**

- Are there situations where the grade should be escalated despite the existence of a documented process or procedure?

*Consider the following:*

- *Document not addressing an explicit requirement*
    - *Document not addressing the requirements of a particular jurisdiction*

# Workshop

- **Question 4: Release of nonconforming device**
  - What recommendations would you make to clarify this escalation parameter?  
*Consider the following:*
    - *Situation where conformity cannot be determined after the fact (process subject to validation)*
    - *Deficiencies of design controls*

# Workshop

- **Question 5: Other improvement**
  - Can you make any additional suggestion improve the meaningfulness, reliability and consistency of implementation of the grading system?