

ISO/TS 22367:2008-05 (E)

Medical laboratories - Reduction of error through risk management and continual improvement

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Management responsibility in preventive and corrective actions, and continual improvement	2
4.1 General	2
4.2 Management responsibility in preventive actions	2
4.3 Management responsibility in corrective actions	2
4.4 Management responsibility in continuous improvement	3
5 Identification of potential and actual laboratory non-conformities, errors and incidents	3
6 Classification of laboratory non-conformities, errors and incidents	3
7 Preventive action and corrective actions	4
8 Assessment of risk arising from actual and potential laboratory non-conformities	5
9 Review of collected laboratory non-conformities, errors and incidents	6
10 Preventive action and corrective action plans	6
11 Preventive action and corrective action plan files	6
12 Continual improvement plan	6
Annex A (informative) Failure modes and effects analysis	7
Annex B (informative) Model for assessing risk of harm	8
Annex C (informative) Ranking of severity levels	9
Bibliography	10