

WHO Quality risk Management-2003 VERSUS QRM 2026

1. QRM Governance and Organizational Responsibility

2026 places greater emphasis on governance, competency assessment, management oversight, multidisciplinary participation, and accountability throughout the risk management lifecycle.

2003 focused primarily on assigning qualified personnel and documenting responsibilities.

Action: Update QRM procedures to define governance structures, management responsibilities, competency assessment criteria, and cross-functional team involvement in risk activities.



2. Product and Process Knowledge Management

2026 strengthens the requirement for lifecycle-based knowledge management, use of process flow diagrams, and management of subjectivity in risk evaluations.

2003 emphasized process understanding but provided limited guidance on subjectivity reduction and structured knowledge utilization.

Action: Establish formal knowledge management practices, maintain updated process maps, and implement controls to minimize evaluator bias during risk assessments.