Case for Quality
Company D

Risk Management

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Risk Management

Introduction to *Risk Management procedure* at Company X

Establishes requirements for

Risk Management of Medical Devices

with regards to Safety

Safety – Freedom from unacceptable risk. [ISO 14971]

for patients,
medical device users,
and other persons
(as well as property
and the environment).

People exposed to medical devices after production.

Risk – Combination of the probability of occurrence of harm and the severity of that harm. [ISO 14971]

Risk Management – Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk. [ISO14971].

Scope of Procedure

Applies throughout the entire lifecycle

of medical devices

and medical systems

for which Company X is the manufacturer

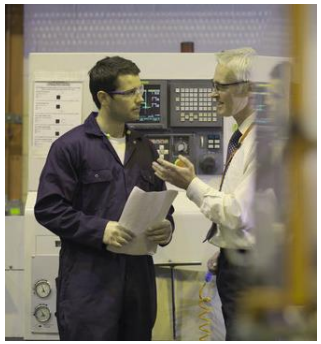
Lifecycle – All phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [ISO 14971]

Medical Device – Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of (1) diagnosis, prevention, monitoring, treatment or alleviation of disease, (2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury, (3) investigation, replacement, modification, or support of the anatomy or of a physiological process, (4) supporting or sustaining life, (5) control of contraception, (6) disinfection of medical devices, (7) providing information for medical purposes by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. [ISO 14971]

Medical system – System containing at least one medical device

Key Terms

Risk Management Team – Team responsible for the review of risk management activities (within a defined scope).



The Risk Management Team is a subset of the Project Team (both pre-launch and post-launch)

Typical roles: Quality Engineer, Design Engineer, Manufacturing Engineer, Marketing Rep, Clinical Affairs Rep, Regulatory Affairs Rep.

Risk Management Board (RMB) – Designated group of subject-matter experts and managers who have responsibility for the supervision of all Risk Management activities at Company X including authorization to balance medical benefits against residual risks to make final decisions regarding the acceptability of Overall Residual Risk (ORR).

Risk Table

Risk Table – Main table for documenting risk analysis, risk evaluation, and risk control activities.

01	02	03	04	05	06	07	08	09	10	11
Risk ID #	Functional Output	Hazard	Hazardous Situation	Harm	Person Affected	Causes	Planned/Existing Risk Control Measures	Severity Level (S_{HARM})	Occurrence Level (O_{HARM})	Risk Region

12	13	14	15	16	17	18
Additional Risk Control Measures	Revised Occurrence Level (O_{HARM})	Revised Risk Region	Risk/Benefit Analysis (required for High/Medium risks)	Verification of Risk Control Measures (Implementation)	Verification of Risk Control Measures (Effectiveness)	Comments/ Rationale (if necessary)

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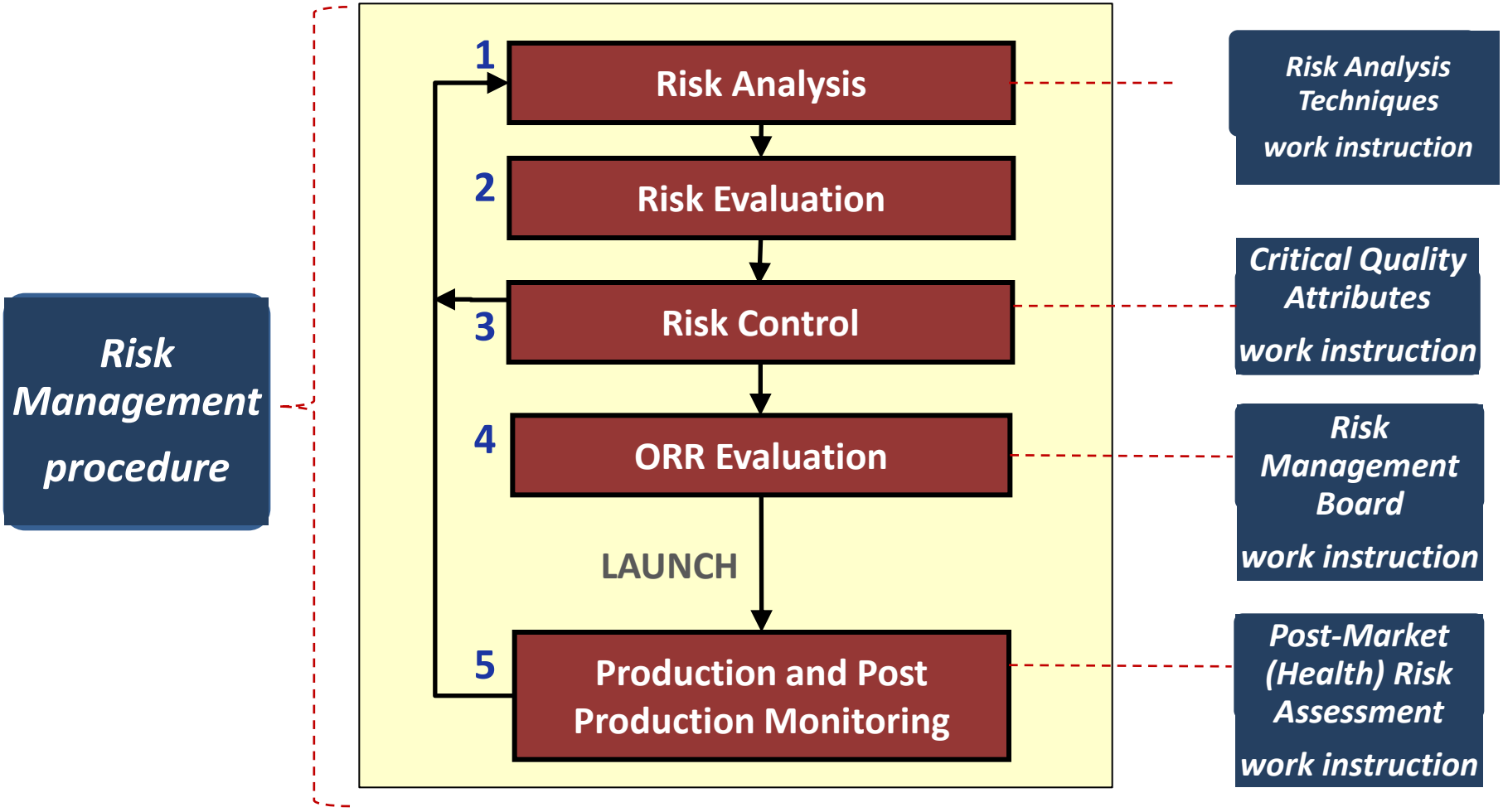
Risk Management Process: 5 Elements



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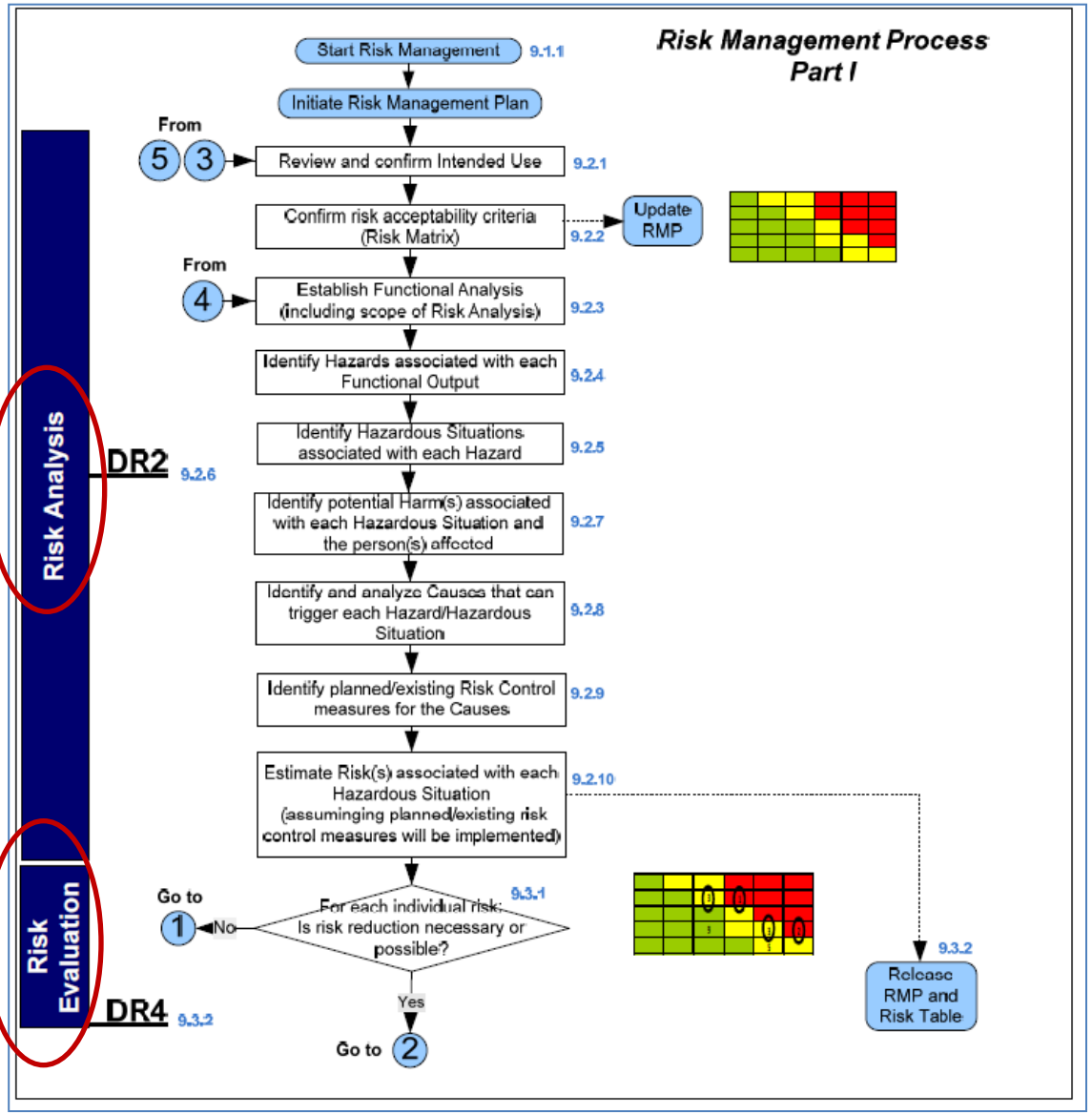

Risk Management Process Flow

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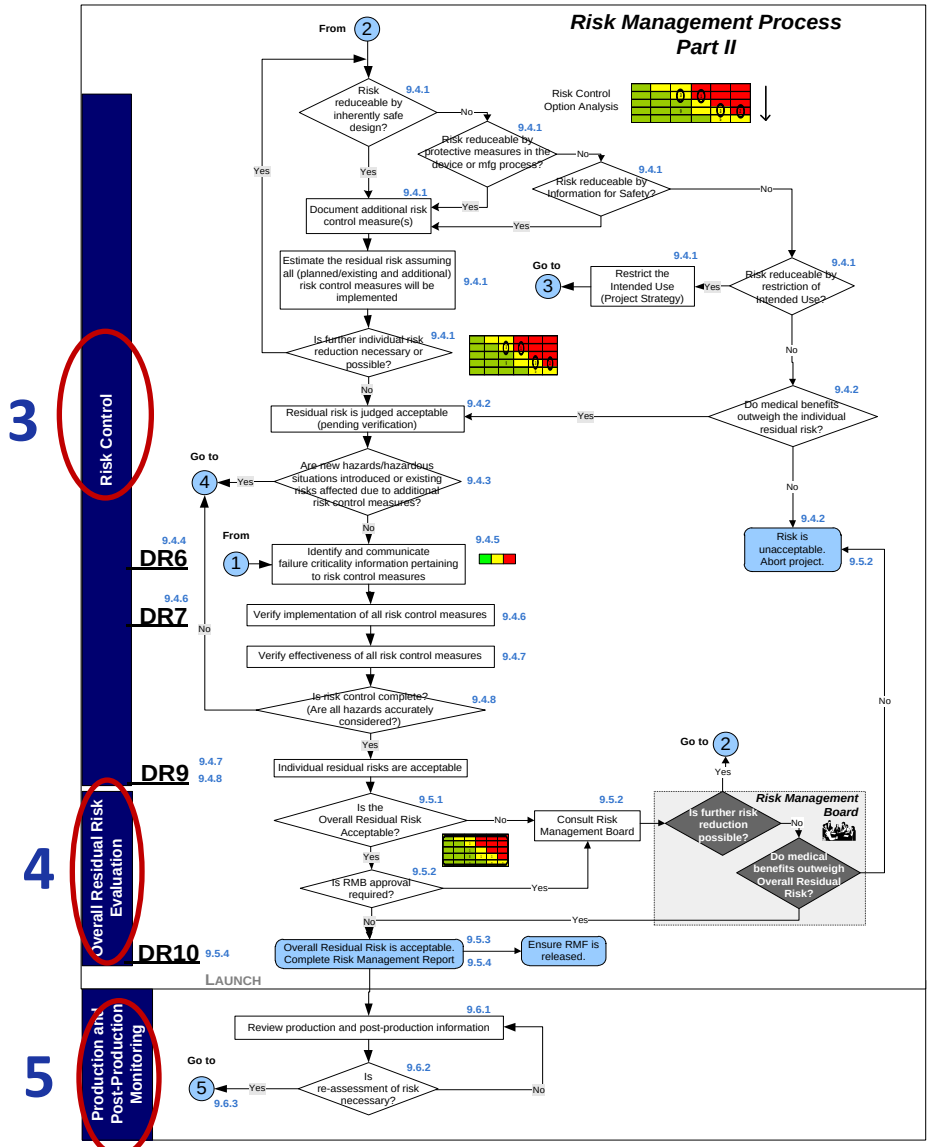
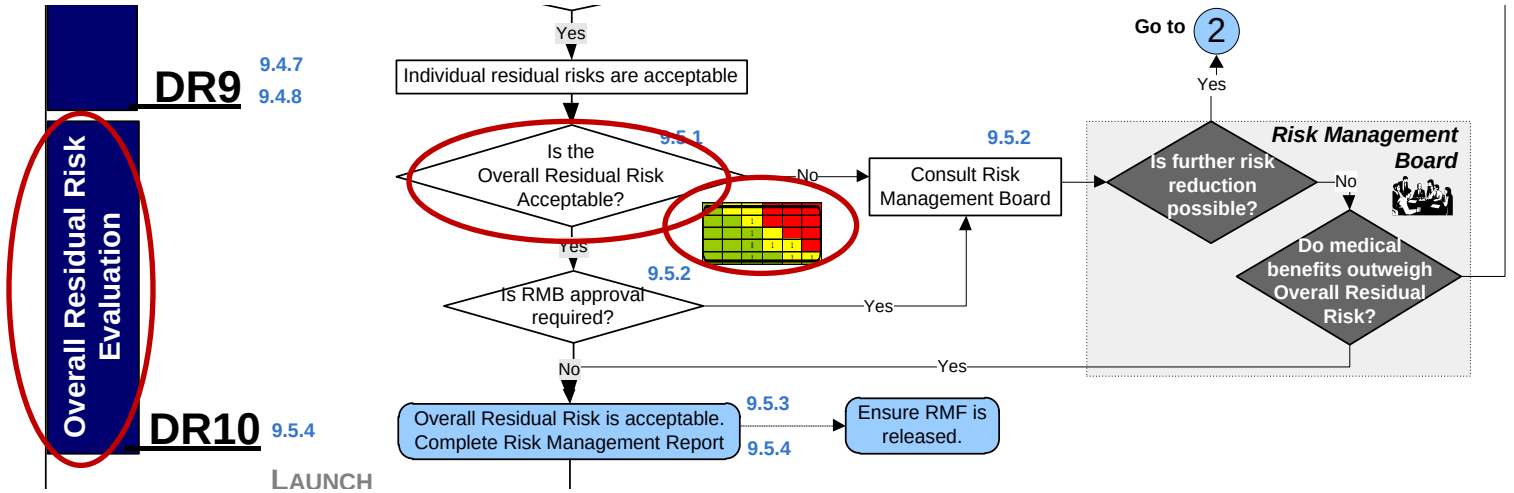


Risk Management Process Flow (contd.)

ORR Evaluation

After all risk control measures have been verified, the Overall Residual Risk (ORR) posed by the medical device (i.e., all residual risks documented in the Risk Table and displayed on the Risk Matrix) is evaluated to decide if the ORR is acceptable.

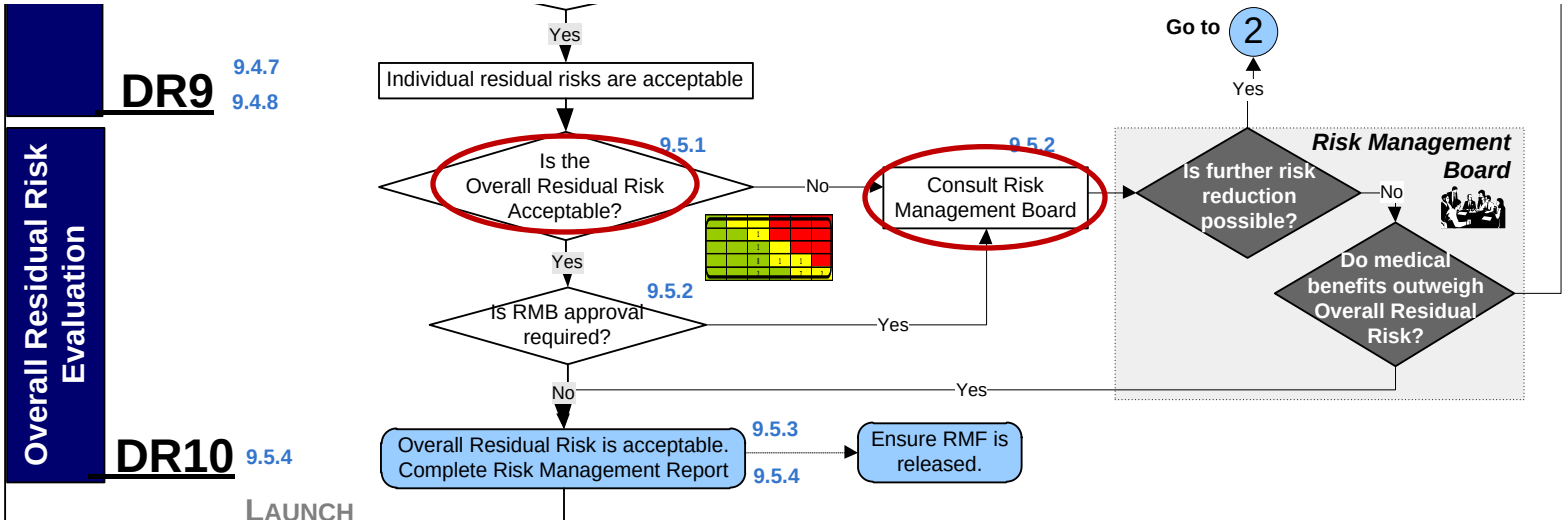


Note: It is possible that the ORR can be considered unacceptable even though the individual residual risks are acceptable. This is particularly true for complex medical devices/systems with a large number of individual risks.

ORR Evaluation – Risk Management Board

The Risk Management Board (RMB) must be consulted and must decide about the acceptability of the ORR if any of the following conditions is true:

- Any residual risk is in the High Risk (Red) region,
- Any residual risk in the Medium Risk (Yellow) region has severity S3 or higher, or
- The Risk Management Team requests RMB consultation.



RMB Members

The Risk Management Board must include, at a minimum, the following five functions (roles):

1. Head of RA/QA (or authorized designate*)
2. Head of R&D (or authorized designate*)
3. Risk Management Expert
4. Medical Expert (Clinical Expert)
5. Post-Production Monitoring Expert

Note 1: Where a safety representative or comparable function is required by national law, this person or authorized designate must be a member of the Risk Management Board.

Note 2: *Authorized designates must have equivalent or similar organizational responsibility and/or authority.

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– **Additional** functions (roles) may be added to the Risk Management Board as needed, for example:

- **Project Leader**
- **Technical specialist(s)**
- **Manufacturing representative(s)**
- **Marketing representative (for perspective on product use)**
- **Legal representative (typically only for higher risk products)**