

# THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



**10** YEARS OF  
CO-OPERATION

## CHANGING SCOPE OF PRACTICE TOWARD MODEL APPROACHES

*Keeping up with Reality and Quality: A challenge for  
European Blood Establishments*

29 October 2020

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On behalf of the B-QM Working Group

# TOWARDS MODEL APPROACHES

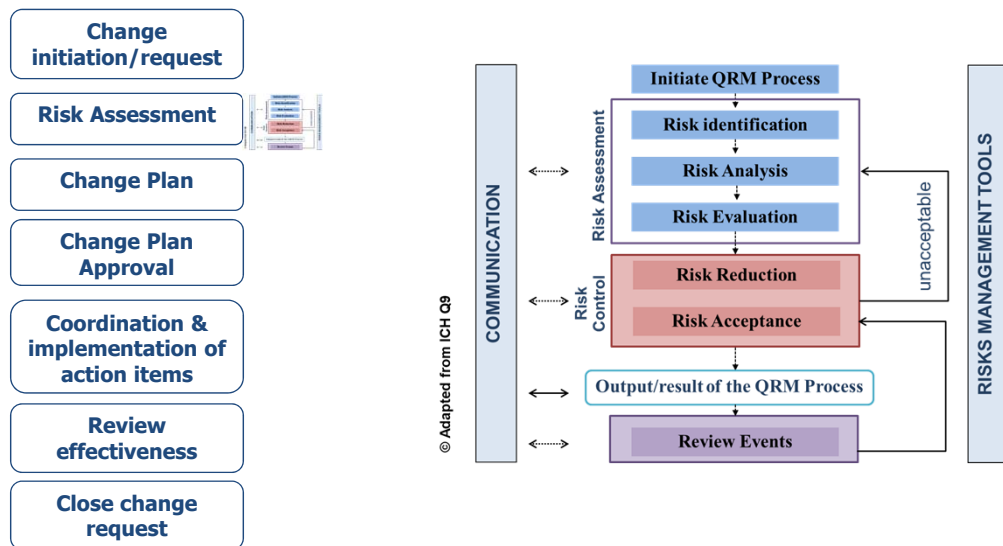
**Prerequisite:** Permissive legislation

If permissive:

**Key in changing the scope:**

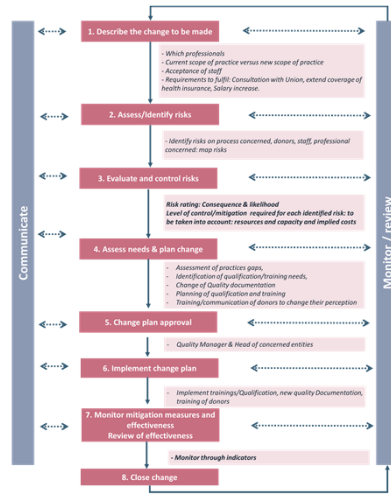
- Rely on your **Quality Management System**
  - 2 Main aspects: **Change Control** and **Risk Management**
- Be able to **identify risks associated with change** of scope of practice and ensure indicators that monitor the effectiveness of the new scope of practice
  - Donor vigilance
  - procedures performed,
  - treatment/care provided,
  - Practice environment,
  - Education, training, certification,

# KEY QM PILLAR: RISK MANAGEMENT & CHANGE CONTROL

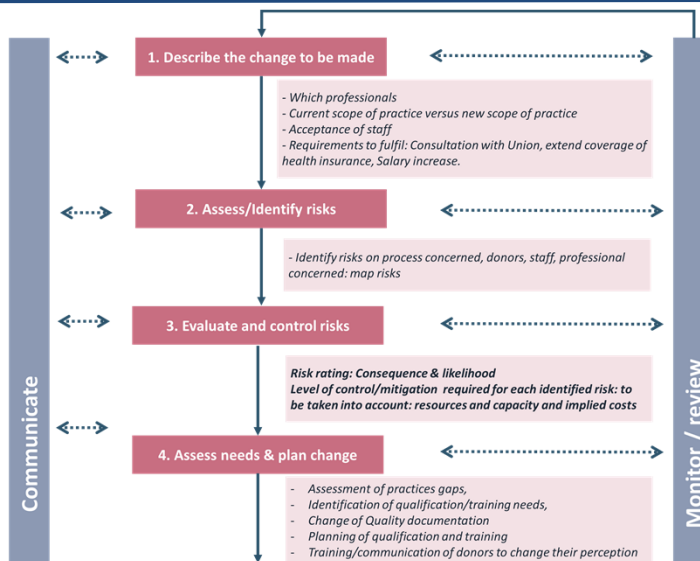


# CHANGE SCOPE OF PRACTICE: A MODEL APPROACH THAT BUILDS ON CC & RM

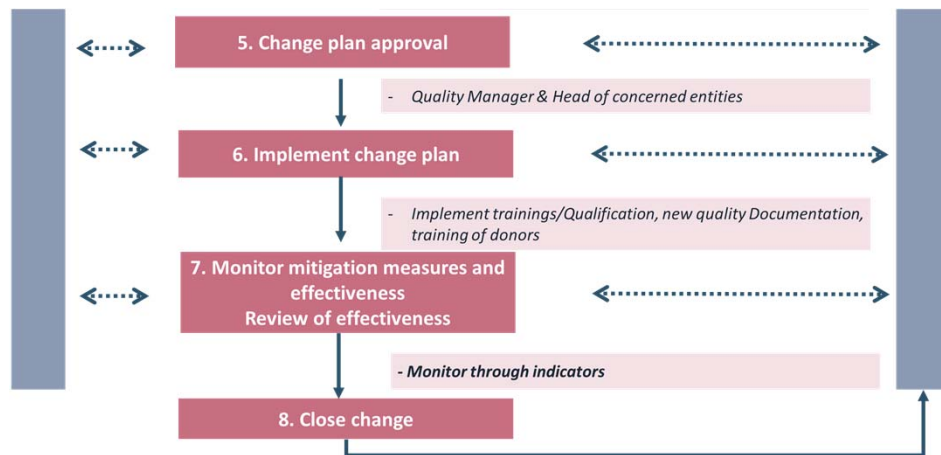
## 8 steps



# CHANGE SCOPE OF PRACTICE: A MODEL APPROACH THAT BUILDS ON CC & RM (2)



## CHANGE SCOPE OF PRACTICE: A MODEL APPROACH THAT BUILDS ON CC & RM (3)



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## FURTHER CONSIDERATIONS

- **Holistic model, suitable for:**
  - Permanent change scope of practice
  - Ad-hoc change scope of practice :
    - When – **crisis** e.g. *COVID19*
      - Physicians/nurses redeployed in intensive care in hospitals
      - Sick personnel
- **Inspection:**
  - Robust change control and risk management to be documented
  - Evidence that the risks to donor and blood components mitigated and remain equal

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# Non Permissive Regulations

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## - **Making the case for regulatory change**

- Demonstrate how your proposed change will promote access to quality healthcare,
- Provide documentation: education, training, evidence demonstrating that quality and safety would remain identical
- Continuity of blood supply
- Cost impact

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# Thank You