Procedure

Collaboration Model for MTU-ICT at OUS

1. Purpose and Scope

The purpose of the Regional Collaboration Model for MTU-ICT is to clarify the responsibility for the operation and management of MTU system solutions between Oslo University Hospital (OUS) and Sykehuspartner (SP), as well as to ensure both information and patient safety. Additionally, the process will provide a better opportunity for the reuse of ROS and solution design (LD). This procedure describes how this collaboration model should be implemented at OUS. The collaboration model concerns responsibilities and tasks associated only with the ICT component of the medical-technical equipment.

Expected benefits:

- Reduction in variation of operational and management regimes within the healthcare institution
  - Reduced resource usage for SP and OUS
- Clearly defined and clarified
  - Roles and responsibilities
  - Information channels
- Facilitates the reuse of ROS and LD for MTU system solutions within the healthcare institution and region

2. Responsibilities

Role	Responsibility
Representatives from the HFs in the groups	Specifically responsible for providing advice based on operational experience when selecting solutions; must participate in relevant ROS analyses.
Clinic Manager TIK (Technology and Innovation Clinic)	Responsible for establishing a System Evaluation Group (SEG), as a permanent group with decision-

	making authority, where certain representatives vary depending on the MTU system solution.
OUS Information Security Manager	Must approve the solutions to be implemented.
Project Manager MTA Strategy and Procurement Section (MTA SA)	Responsible for procuring MTU system solutions.
Sykehuspartner (SP)	Provider of operational deliveries within ICT infrastructure (network, security), ICT platform, integrations, and supplier access; must prepare and plan for its future operational tasks and responsibilities based on clarifications conducted in the SEG.
System Owner	Responsible for developing, managing, and operating an information system; may designate a system administrator who is operationally responsible for the tasks assigned to the system owner.

3. Procedure

When procuring an MTU system solution, the Regional Collaboration Model for MTU-ICT shall be utilized.

A System Evaluation Group (SEG) is established. SEG is a multidisciplinary decision-making body responsible for placing the MTU system solution within the service model. Recommendations and justifications for selecting the service model are handled by SEG, which consists of the following roles (one representative may cover multiple roles):

- Representative for medical technology/MTA, HF - manager
- Representative for technology and e-health/ATE, HF
- Representative for information security, HF
- Representative for user department, HF
- Project manager for the procurement, HF (for new procurements)

- Representative for MTU service management, Sykehuspartner
- Representative for information security, Sykehuspartner

An advisory body for SEG is also established, tasked with evaluating and recommending the choice of service model, consisting of:

- Representative(s) for medical technology/MTA, HF
- Representative(s) for technology and e-health/ATE, HF
- Representative for information security, HF
- Representative(s) for user department, HF
- Project manager for the procurement, HF
- MTA Service Leader
- Representative from Sykehuspartner

3.1 Collaboration Model for the Procurement of MTU System Solution

Figure 1: Overall Process. The final box is not covered in this procedure.

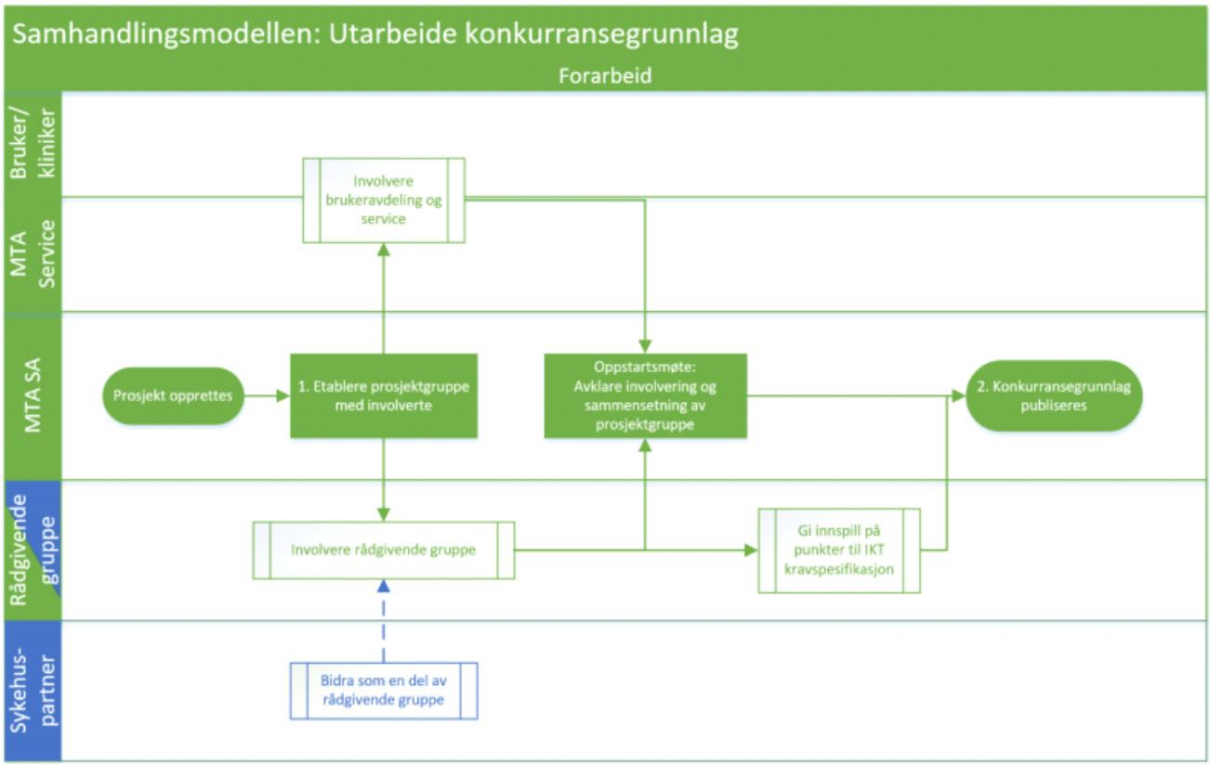

Figure 2: Process Before Publication

1. The Project Manager at MTA SA (Strategy and Procurement Section) is responsible for the procurement. A project group is established, consisting of representatives from the user department, an engineer from MTA Service, and individuals from the Department of Technology and e-Health, EIE, EIE Projects, Hospital Procurement, Sykehuspartner, Infection Control/Hygiene, PNA Coordinator, and/or a physicist for any interfaces with the MTU to be procured. During the initial meeting, the involvement and composition of the project group should be clarified. Similar existing solutions should be identified, and any approved solution designs (LD) with ROS should be mapped.
2. The tender documentation for the procurement is published following input from the project group.

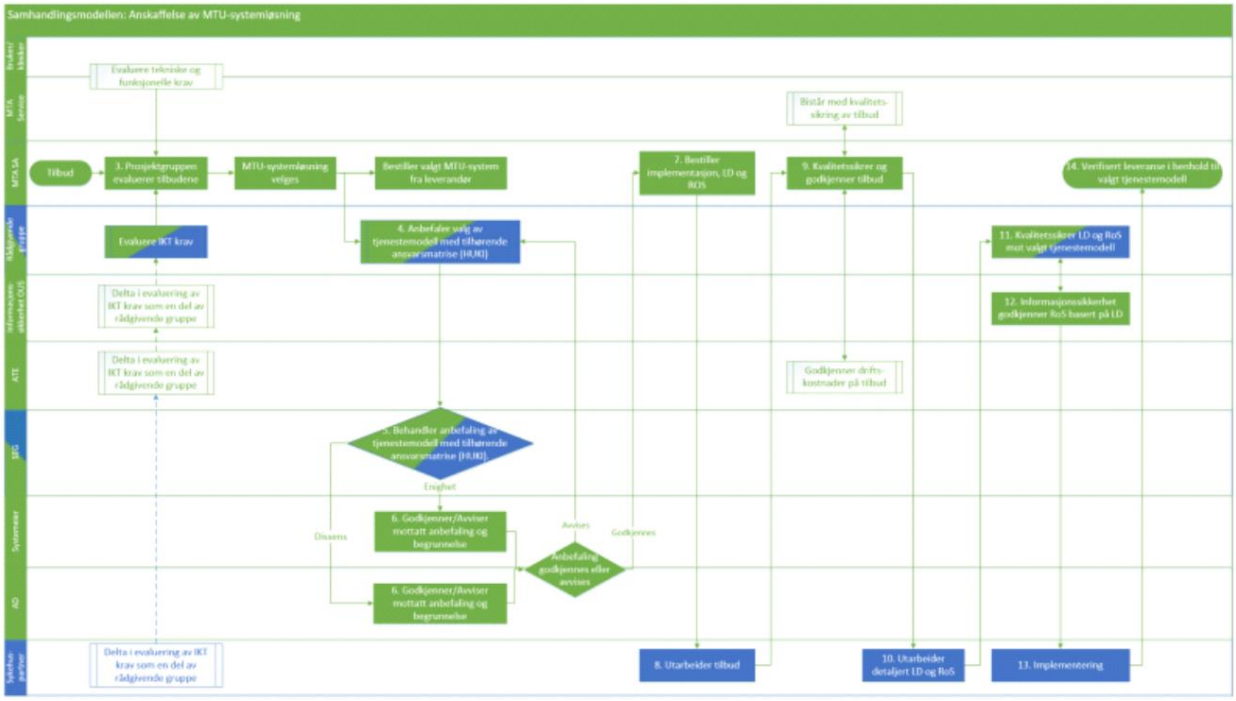

Figure 3: Process for the Procurement of MTU System Solution, also as an Attachment to the Procedure.

3. The project group evaluates received bids.
4. A recommendation and justification for the chosen service model with an associated responsibility matrix (HUKI) are developed by an advisory group following a review of the attached checklist, which reflects the responsibility matrix. This group serves as an advisory body to SEG. The starting point for assessment should be at the far left of the model (SaaS-1). The person responsible for presenting the recommendation to SEG, in the case of new procurements, is the project manager. The responsible person may delegate the task to another representative.
5. SEG is a multidisciplinary decision-making body for placing the MTU system solution within the service model. Recommendations and justifications for the choice of the service model are handled by SEG.
6. If there is agreement, the recommendation and justification are sent to the system owner for approval via P360. In case of dissent within SEG, SEG escalates the matter to the AD (Administrative Director).
7. Upon approval of the service model by the system owner or AD, the project manager orders the implementation, LD, and ROS.

8. Sykehuspartner prepares an offer for the agreed service model.
9. The project manager ensures the quality and approval of the offer from SP.
10. Sykehuspartner prepares a detailed LD with ROS.
11. The advisory group ensures the quality of LD and ROS against the chosen service model.
12. ROS based on LD is approved by OUS Information Security.
13. Sykehuspartner implements according to the LD.
14. The delivery is verified according to the chosen service model.

Operational and management responsibilities must be established in connection with the commissioning of the MTU system solution. When operations and management are taken over by OUS and/or Sykehuspartner, the user department, system owner, Sykehuspartner, and MTA Service must be informed about the service description, HUKI, response times, where to report faults, etc. A clear division of responsibilities and tasks in the form of a responsibility matrix (HUKI) with any changes tailored to the specific solution and a service description must be developed. The service description must include HUKI, which defines roles and responsibilities for each service model, detailed task descriptions, and describes the handling of service and maintenance agreements with the supplier. Necessary rights to manage and operate the solution must be granted based on the chosen service model and approved ROS.

3.2 Collaboration Model for Modifying Existing MTU System Solutions

For changes (including expansions) in existing MTU system solutions, the process flow is as shown in Figure 4 and as an attachment to the procedure.

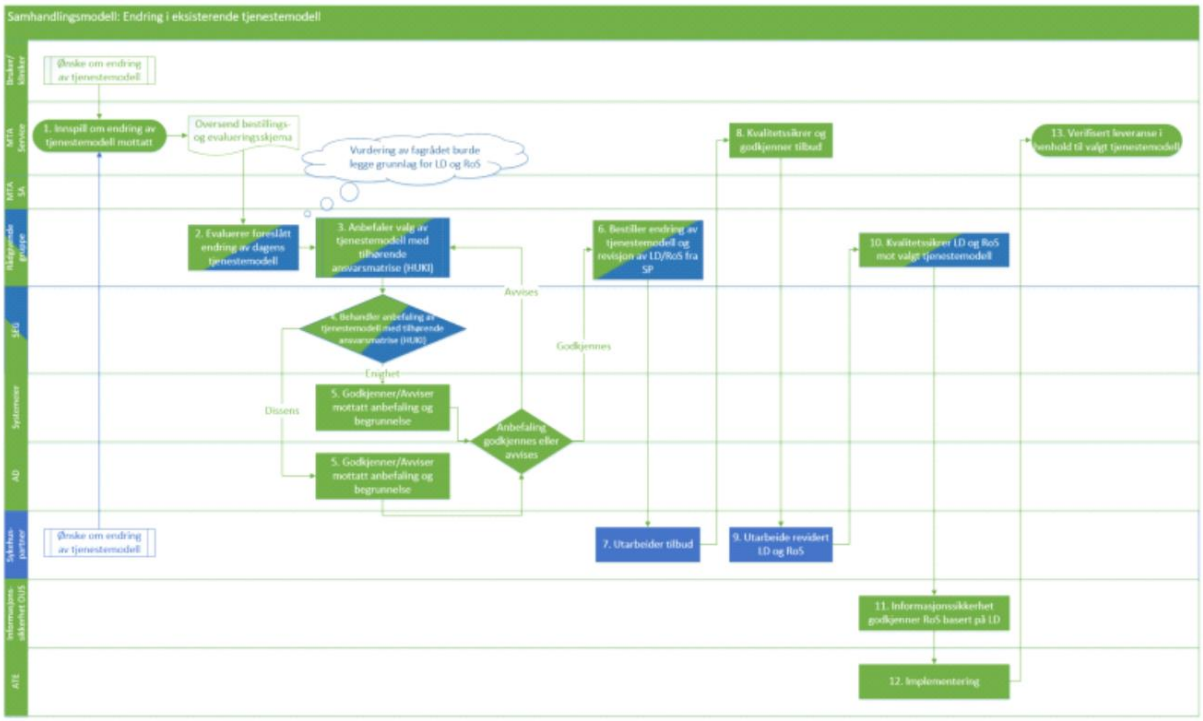

Figure 4: Process for Modifying (Including Expanding) Existing MTU System Solutions

1. MTA Service receives input about changes in the existing service model from the user/clinic and/or MTA Service and/or Sykehuspartner.
2. Advisory Group evaluates the proposed service model.
3. A recommendation and justification for the selection of the service model, along with an associated responsibility matrix (HUKI), are prepared after reviewing the attached checklist that reflects the responsibility matrix. The starting point for assessment should be at the far left of the model (SaaS-1). For changes (including expansions) in the existing MTU system solution, the MTA Service Leader is responsible for the presentation. The responsible party may delegate the presentation to another representative.
4. The recommendation and justification for the choice of the service model are handled by SEG.
5. If there is agreement, the recommendation and justification are sent to the system owner for approval via P360. case of dissent within SEG, SEG escalates the matter to the AD (Administrative Director).
6. Upon approval of the service model by the system owner or AD, the project manager orders the implementation, LD, and ROS.

7. Sykehuspartner prepares an offer for the agreed service model.
8. The project manager ensures the quality and approval of the offer from SP.
9. Sykehuspartner prepares a detailed LD with ROS.
10. The advisory group ensures the quality of LD and ROS against the chosen service model.
11. ROS based on LD is approved by OUS Information Security.
12. Sykehuspartner implements according to the LD.
13. The delivery is verified according to the chosen service model.

The service description must be updated based on the new service model. The service description should include HUKI, which defines roles and responsibilities for each service model, detailed task descriptions, and the handling of service and maintenance agreements with the supplier. The user department, system owner, Sykehuspartner, and MTA Service must be informed about the updated service description. Necessary rights to manage and operate the solution must be granted based on the chosen service model and approved ROS.

4. Definitions

Abbreviation	**Explanation**
Project group	Consists of the project manager, users from the user department, an engineer from MTA Service, and individuals from the Department of Technology and e-Health, Property Department (EIE), EIE Projects, Hospital Procurement, Infection Control/Hygiene, PNA Coordinator, and/or a physicist for any interfaces with the MTU to be procured.
Operations	Practical tasks and routines necessary to ensure that the MTU system solution meets clinical and technical requirements for functionality and patient safety throughout the MTU system solution's lifespan.

EIE	Property Department, Oslo Hospital Services.
Management	Ensures the governance and administration of the MTU system solution throughout its entire lifespan.
HUKI	Responsibility matrix; H = Main responsible, U = Executing, K = Control, I = Information.
ATE	Department of Technology and e-Health, Technology and Innovation Clinic.
LD	Solution Design; a technical description of the MTU system solution and its associated integration.
MTA	Medical Technology Department, Technology and Innovation Clinic.
MTU	MTU with an ICT component.
ROS	Risk and Vulnerability Analysis.
SEG	System Evaluation Group.
SP	Sykehuspartner; provider of operational deliveries within ICT infrastructure.
Service Description	System-specific description of a service, clarifying responsibilities.

5. References

- Regulations on the handling of medical equipment - Legal data
- Regulation on medical equipment
- Medical Device Regulation (MDR)
- HSØ Interaction tool for MTU ICT

Attachments

- AGREE method report v9 for Interaction model for MTU ICT in OUS.docx

- Process for acquiring the MTU system solution.pdf
- Process for changing the service model.pdf
- Checklist interaction model MTU-IKT.xls
- Responsibility matrix (HUKI).xls

Other eHandbook documents

Requirements specification for procurement of MTU solutions with ICT interface and connection to network