# Document Metadata

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## **Purpose**

To establish the intended domain, context, and application boundaries for AI and GenAI systems within hospital environments, ensuring use-case alignment with risk tolerance and ethical expectations.

## **Scope**

Applies to all AI/GenAI applications used in clinical, operational, and administrative contexts across the hospital system.

## **Policy Statement**

All AI system implementations must be contextually mapped to their operational environments. Use cases must be pre-approved based on risk profiles, patient safety, and adherence to regulatory requirements.

## **Roles and Responsibilities**

• AI Product Managers: Define and document use case boundaries.

• Clinical Leadership: Validate clinical appropriateness of GenAI deployment.

• Risk Officers: Approve or escalate high-risk use case scenarios.

## **Implementation Phases**

### **Must Do**

• Conduct formal context definition and use case classification (AI RMF MAP-1.1).

• Prohibit dual-use deployment without revalidation (AI 600-1 §2.1).

• Map each GenAI system to a patient impact level (MAP-1.2).

### **Should Do**

• Review use case intent against FDA SaMD classification guidance.

• Document task substitution vs. augmentation role of GenAI.

• Include stakeholder input in use case validation (MAP-2.1).

### **Recommended**

• Apply scenario modeling or simulation-based evaluation before deployment.

• Re-map use cases annually or upon major version update.

## **References**

• NIST AI RMF: MAP-1, MAP-2

• NIST AI 600-1: §2.1.1, §2.5.1

• FDA: PCCP Guidance 2024

• HIPAA Security Rule: §164.308(a)(1)(ii)(A)

## **Review Cycle**

Reviewed annually or when a new use case is introduced.