Step 1: Assess unmanaged risk

Rate each factor from 1 to 4.

Factor	1 — Low	2 — Moderate	3 — Significant	4 — Critical
Consequence	Minor inconvenience or easily corrected error	Limited injury, disruption, financial loss, or compliance concern	Serious injury, substantial loss, legal exposure, or major operational disruption	Death, catastrophic injury, major institutional loss, criminal exposure, or sustained mission failure
Exposure	Rare activity affecting very few people	Occasional or limited activity	Recurring activity or many affected people	Frequent, widespread, decentralized, or difficult-to-supervise activity
Reversibility	Effects are quickly and fully correctable	Correctable with moderate effort or cost	Difficult, costly, or time-sensitive to correct	Irreversible or likely to cause lasting harm
Existing control gap	Strong existing institutional controls	Controls exist but need local clarification	Controls are inconsistent, informal, or difficult to verify	No reliable controls or oversight currently exist

Step 2: Match the regulation to the risk

Risk profile	Appropriate regulatory approach
Level 1 — Guidance	Recommended practices, examples, local discretion, minimal documentation
Level 2 — Standardized Practice	Written procedure, defined roles, basic records, periodic review
Level 3 — Mandatory Control	“Must” requirements, assigned accountability, training, approval thresholds, documentation, compliance verification
Level 4 — Restricted or Escalated Activity	Specialized authorization, central review, competency requirements, monitoring, auditability, suspension criteria, or prohibition

Use the least burdensome control that reasonably addresses the risk. Higher risk may justify stronger controls, but additional procedural complexity should not be added unless it meaningfully reduces risk.