

Manage complaints M1

type	Management process - § 7.7
purpose	record each complaint, handle it impartially, provide a prompt response, and implement corrective actions to prevent recurrence
process owner	Quality Manager, medical biologist, technician
risks	• failing to provide users with simple ways to lodge a complaint • failing to record every complaint (especially verbal or telephone ones) • failing to assess the validity of the complaint • failing to review the complaint • failing to ensure fairness ("No one can be both judge and party") • failing to determine at which stage the error occurred • failing to identify root causes • failing to make and record an appropriate decision • failing to monitor the effectiveness of actions taken • failing to formalize a written, courteous response to the complainant
upstream process	• manage patient rights • address risks
downstream process	• conduct internal quality control • manage nonconformities • implement corrective actions • conduct management review • improve
inputs	• internal quality control log • nonconforming results
Activities (sub-processes)	• provide users with simple ways to file complaints (website form, reception-area suggestion box, dedicated email address, paper complaint form) • record all complaints (including verbal or telephone ones) • assess the validity of the complaint • review the complaint • ensure fairness (the person investigating and validating the complaint must not be the one directly involved) • determine the stage where the error occurred • identify root causes • make and record an appropriate decision • monitor the effectiveness of actions taken • formalize a courteous written response to the complainant (investigation findings and actions taken)
outputs	• complaints log • risks and opportunities
resources	personnel, dedicated software
indicators	• average time to acknowledge receipt of complaint • average processing and final response time • rate of recurring complaints (same cause) • total number of complaints relative to activity volume
procedures / documents	risk and opportunity management, complaint management, data control, corrective actions, management review / complaints log, risks and opportunities, document list

customers	laboratory, patients, users, referring physicians, care facilities (clinics, hospitals), payers (social security, health insurance providers)
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