

5 Whys Root Cause Analysis

Problem Statement

Bonding failure rate increased significantly on Catheter Assembly Line A.

5 Whys Analysis

Why 1: Why is the bond failing?

Answer: Adhesive not holding securely

Why 2: Why is adhesive not holding?

Answer: Curing process is inconsistent

Why 3: Why is curing inconsistent?

Answer: Operators cure with varying time/distance

Why 4: Why are curing techniques varying?

Answer: No clear SOP or visual standard

Why 5: Why is there no clear SOP?

Answer: Documentation is outdated and incomplete

Identified Root Cause

Lack of a standardized, updated curing process in the SOP, leading to inconsistent bonding performance and increased failures.