hazardous events Hazardous situation Hazard Exposure (P1) Sequence or combination of events Hazardous event Non-hazardous event (leads directly to No event (near miss) harm) hazardous situation circumstance in which people, Hazardous situation property or the environment are Probability of ISO 14971 does not This is what currently exposed to one or more hazards Should ISO 14971 (and should not) ISO 14971 means event that require the analysis require analysis of with P2 of near misses? can cause these harm (P2) hazardous event event that can cause harm Hazardous event No probability between hazardous event and harm because Harm hazardous event leads directly to harm

Risk

Probability of

occurrence of harm

P1 x P2

Severity of harm

Hazardous situation (exposure) can lead to no event, hazardous events and non-

