

DCB0129 and DCB0160 Clinical Safety: Working Decision and Evidence Worksheet

IG-Smart Governance & Assurance Intelligence — Companion to Asset 07 | Editable template | Edition 25 October 2026

Purpose: Manufacturer/deployer safety evidence and hazard handover.

How to use: Use one worksheet per actual product version and deployment environment; manufacturer and deploying organisation retain distinct clinical risk-management responsibilities.

Professional boundary: This is an original IG-Smart proposed working instrument, not a regulator-issued form, independent audit, legal opinion, clinical sign-off or automatic risk-acceptance system. Use appropriately qualified practitioners and actual applicable requirements. Store restricted client and patient information only in approved secure repositories; record safe evidence references, not secrets or raw data.

Clinical safety competence gate: NHS England's published digital clinical safety guidance describes a Clinical Safety Officer as a suitably qualified and experienced clinician with current registration with an appropriate professional body relevant to their training and experience, and knowledge of clinical risk management. Confirm the applicable manufacturer and deploying-organisation requirements, the nominated person's registration, competence, availability and authority before relying on their assessment. Manufacturer and deploying-organisation responsibilities remain distinct; each organisation retains its management responsibilities. Source: <https://service-manual.nhs.uk/standards-and-technology/service-standard-points/16-make-your-service-clinically-safe>

A. Engagement / decision details

Field	Entry
Product and version	_____
Manufacturer and CSO role	_____
NHS / care deploying body	_____
Care setting and affected patients	_____
Manufacturer hazard log reference	_____
Local hazard record	_____

Field	Entry
Mitigation owner and verification	_____
Open clinical risks	_____
Clinical decision authority	_____
Change/incident trigger	_____

B. Mandatory assurance gates and evidence checklist

For each gate specify an accountable human owner, a secure evidence reference, review outcome, any material exception and next action. **“Mandatory” here marks a proposed IG-Smart screening safeguard, not a universal legal requirement.** Actual mandatory duties must be confirmed separately.

ID	Control / decision question	Screening gate	Evidence ref	Review status	Exception / assumption	Owner	Date
C01	Manufacturer intended use and limitations	Yes	----	Not assessed	----	----	----
C02	Product version and configuration baseline	Yes	----	Not assessed	----	----	----
C03	Manufacturer CSO / safety accountability	Yes	----	Not assessed	----	----	----
C04	Manufacturer hazard log reviewed	Yes	----	Not assessed	----	----	----
C05	Manufacturer clinical safety case information	Yes	----	Not assessed	----	----	----
C06	Deployment care pathway mapped	Yes	----	Not assessed	----	----	----

ID	Control / decision question	Screening gate	Evidence ref	Review status	Exception / assumption	Owner	Date
C07	Deploying organisation CSO / safety accountability	Yes	----	Not assessed	----	----	----
C08	Local clinical hazards assessed	Yes	----	Not assessed	----	----	----
C09	Linked product and local mitigations verified	Yes	----	Not assessed	----	----	----
C10	Training and clinical fallback tested	Yes	----	Not assessed	----	----	----
C11	Unresolved material hazards escalated	Yes	----	Not assessed	----	----	----
C12	Appropriate deployment approval recorded	Yes	----	Not assessed	----	----	----
C13	Interface and data integrity evidence	No	----	Not assessed	----	----	----
C14	AI or device overlay assessed where relevant	No	----	Not assessed	----	----	----
C15	Release/change communication plan	No	----	Not assessed	----	----	----
C16	Incident and near-miss learning plan	No	----	Not assessed	----	----	----

C. Evidence quality and limitations

Evidence source	Relevant legal entity, system and period	Source credibility / independence	Scope limitation	Reviewer conclusion	Action
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-----	-----	-----	-----	-----	-----
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Evidence hierarchy: distinguish (1) assertion, (2) supplied document, (3) independently examined operation, and (4) verified remediation. Evidence confidence is contextual; it should not be combined into a fictional universal compliance percentage.

D. Expert challenge / procurement questions

1. What is the precise intended clinical use?
2. What manufacturer hazard assumptions do not hold locally?
3. Which mitigations must the deploying organisation implement?
4. Which safety risks remain unacceptable?
5. Who is the qualified CSO for each required role?
6. What change would invalidate the safety case?

Record responses and facts that need verification. Avoid accepting promotional, certification or supplier statements without checking entity, scope and relevance.

E. Exceptions, uncertainties and mandatory-stop record

Finding ID	Material uncertainty or gap	Consequence	Decision owner	Interim control	Closure evidence	Deadline	Status
01	-----	-----	-----	-----	-----	-----	OPEN
02	-----	-----	-----	-----	-----	-----	OPEN
03	-----	-----	-----	-----	-----	-----	OPEN

Escalation rule: If an applicable statutory duty, patient-safety requirement, material security safeguard or fundamental assurance boundary is unresolved, do not permit a favourable overall score to override it. Seek qualified review and an appropriately authorised decision.

F. One-page executive decision record

Business need and proposed decision: _____
Affected services and individuals: _____
Verified findings and source scope: _____
Uncertain / missing facts: _____
Legal, regulatory or safety review: _____
Options (including defer / redesign): _____
Controls and outstanding conditions: _____
Decision: PROCEED / CONDITIONAL / DEFER / REJECT (delete as appropriate)
Decision rationale and alternatives: _____
Approver with documented authority: _____
Specialist challenge / dissent: _____
Owner, due date and review triggers: _____

No automated sign-off: the companion Excel workbook contains illustrative review-status flags only. It cannot authorise a regulated, commercial or clinical decision.

G. Material-change and re-review triggers

- New applicable law, regulator interpretation or officially published standard.
- Material change to system, supplier, data, people, configuration or contracted service.
- Serious incident, unexpected test result, breach, safety signal or complaint.
- Evidence expiry, loss of relevant certification scope, or changed assurance limitations.
- Departure of an accountable officer, change in delegation or new risk tolerance.
- Overdue action, untested recovery or new dependency concentration.

Evidence source for this subject: <https://www.england.nhs.uk/long-read/national-review-of-clinical-risk-management-standardsdcb0129-and-dcb0160-supporting-information/>

Safe use and decision control

This is an original IG-Smart working aid, not an official statutory form or automated compliance verdict. Screening gates are prompts: establish their actual legal, clinical, contractual or organisational basis. A conditional decision does not authorise activity while a mandatory prerequisite remains unmet. Keep real evidence in approved access-controlled systems; use references rather than copying personal data or confidential records here.

Read with: [DCB0129 vs DCB0160: Clinical Safety Accountability Guide](#).