National Imaging Registry (NIR)

Guidance for Local DCB 0160 Deployment Assurance

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Document Management

Revision History

Version	Date	Summary of Changes
0.1	15.09.2025	Initial draft document
0.2	11.06.2026	Updated Document

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Andrew Harrison	Principal Safety Engineer, ETHOS Ltd.	04/01/2026	0.1
Kira Pennington	Delivery manager NIR, NHS England		
Savan Shah	Clinical Safety Officer, ETHOS Ltd.	11/06/2026	0.2

Approved by

This document must be approved by the following people:

Name	Title	Date	Version

Glossary of Terms

AFAP	As Far As Possible – The level risk acceptability criteria as per clinical safety standards
Clinical Risk	Combination of the severity (consequence) and likelihood (probability) of harm to a patient and the likelihood of occurrence of that harm.
Clinical Risk Analysis	Systematic use of available information to identify and estimate a clinical risk.
Clinical Risk Control	Process in which decisions are made and measures implemented by which clinical risks are reduced to or maintained within, specified levels.
Clinical Risk Estimation	Process used to assign values to the severity (consequence) of harm to a patient and the likelihood (probability) of occurrence of that harm.
Clinical Risk Evaluation	Process of comparing a clinical risk against given risk criteria to determine the acceptability of the clinical risk.
Clinical Risk Management (CRM)	Systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, and controlling clinical risk.
Clinical Risk Management (CRM) Process	A set of interrelated or interacting activities, defined by NHS England to meet the requirements of this standard with the objective of ensuring clinical safety in respect to the development, deployment and use of NIR.
Clinical Safety	Freedom from unacceptable clinical risk to patients.
Clinical Safety Officer	NHS Digital accredited clinician (contracting to NHS England), responsible for ensuring the safety of NIR through the application of clinical risk management as set-out in the NHS Digital DCB 0129 Standard requirements.
Clinical Safety Case Report (CSCR)	A report that presents the arguments and supporting evidence that provides a compelling, comprehensible, and valid case that a solution is safe for a given application in each environment.
ETHOS Ltd.	Clinical Risk Management Health IT subject Matter Experts (Clinical Safety Engineers and Clinical Safety Officers) contracting to NHS England providing Health IT Clinical Safety assurance in respect of NIR.
Harm	Death, physical injury, psychological trauma and/or damage to the health or well-being of a patient.
Hazard	Potential source of harm to a patient.
Hazard Log	A mechanism for recording and communicating the on-going identification of System hazards associated with a Health IT System.
Health IT System	Product (such as NIR) used to provide electronic information for health or social care purposes. The product may be hardware, software, or a combination.
Residual Clinical Risk	The clinical risk derived during clinical risk estimation for the design.
Intended Use	Use of System in accordance with the specifications, instructions and information provided by the Manufacturer to its clients for its intended use.
Likelihood (probability)	Measure of the occurrence of harm.

Manufacturer	Health Navigator, with responsibility for the design and support of the NIR solution.
Patient Safety	Freedom from harm to the patient.
Residual Clinical Risk	Clinical risk remaining after the application of risk control measures.
Severity (Consequence)	Measure of the possible consequences of a hazard.

Contents

National Imaging Registry (NIR) Guidance for Local DCB 0160 Clinical Safety Assessment

This guidance document is provided to support Healthcare Organisations deploying the National Imaging Registry (NIR), together with suppliers supporting those deployments, in completing local DCB0160 Clinical Safety Assessments. It should be read alongside the NIR DCB0160 Clinical Safety Case Report (CSCR) Template, Core Deployment Hazard Log, and the NIR DCB0129 Clinical Safety Case.

1. Purpose of this Guidance

This document is provided to support Healthcare Organisations deploying the National Imaging Registry (NIR), together with suppliers supporting those deployments, in completing local DCB0160 Clinical Safety Assessments.
The document explains the relationship between NIR DCB0129 assurance, supplier DCB0129 responsibilities and Healthcare Organisation DCB0160 deployment responsibilities, and describes how NIR clinical safety artefacts may be used to support local deployment assurance activities.

2. Why a DCB 0160 Safety Assessment is Required

DCB0160 is a mandatory NHS clinical risk management standard applicable to the deployment and use of Health IT Systems.

Whilst the National Imaging Registry (NIR) has been assured under DCB0129 for design and manufacture, deployment of NIR into local healthcare environments introduces additional risks associated with:

- local workflows
- operational procedures
- configuration decisions
- user access controls
- training and adoption
- interoperability between local systems and NIR
- incident management and business continuity arrangements

A local DCB0160 assessment is therefore required to ensure these deployment-related risks are identified, assessed and appropriately controlled within the Healthcare Organisation deploying NIR.

Suppliers may contribute evidence and support deployment assurance activities but do not replace the responsibility of Healthcare Organisations to undertake local DCB0160 assurance.

3. Expected Clinical Safety Governance – Systems and Roles

Healthcare Organisations deploying NIR are expected to operate appropriate governance arrangements to support DCB0160 compliance and appoint a suitably qualified Clinical Safety Officer (CSO).

Suppliers supporting NIR integrations should maintain their own Clinical Safety Management Systems and DCB0129 assurance arrangements where applicable.

The Healthcare Organisation Clinical Safety Officer remains responsible for oversight of deployment safety assessment activities and acceptance of residual deployment risk.

4. Expected Clinical Safety Governance Arrangements for NIR Integrations are as follows:

Supplier Product Safety Responsibilities (DCB0129)

Suppliers of clinical systems already deployed within healthcare organisations (e.g. PACS, RIS, VNA, EPR systems) retain responsibility for the clinical safety of their own products under DCB 0129.

Each supplier maintains:

- A DCB 0129 Clinical Safety Case for their system
- A hazard log covering risks inherent to the design, configuration, and intended use of their product

This responsibility does not transfer when those systems are integrated with NIR.

In other words integration with NIR does not invalidate or replace existing supplier DCB 0129 obligations.

NIR Product Safety Responsibilities (DCB0129)

NIR, as a nationally designed system, has its own DCB 0129 Clinical Safety Case that covers:

- The design, architecture, and intended use of NIR
- Hazards arising from:
    - Central data aggregation
    - Indexing, querying, and image metadata handling
    - National-level workflows and access patterns

Assumptions about how NIR will be:

- Integrated
- Used
- Governed locally

The NIR DCB 0129 does not:

Re-assess the internal safety of PACS/RIS systems

Take ownership of deployment-specific or local integration risks

Local integration and deployment safety (DCB 0160)

Each healthcare organisation integrating local systems with NIR is required to assure safe deployment and use through DCB 0160.

Where suppliers undertake integration activities on behalf of healthcare organisations, they should do so within a clearly defined governance framework.

Key points:

- DCB 0160 applies to the integration to NIR (deployment), not the underlying system designs
- The DCB 0160 safety case must address:
    - Data flows between local systems and NIR
    - Configuration choices
    - Workflow changes
    - User access and operational context

The DCB 0160 safety case remains under local governance of the healthcare organisation, even if authored by a supplier.

Supplier Support Role in Local DCB0160 Activities

Suppliers may support Healthcare Organisations by providing technical documentation, testing evidence, workflow information, training materials, configuration guidance and clinical safety inputs relevant to the NIR integration.

Suppliers may contribute to local DCB0160 activities but responsibility for deployment safety assessment, residual risk acceptance and deployment sign-off remains with the Healthcare Organisation.

However, the healthcare organisation retains accountability for accepting residual risk and approving the DCB 0160 safety case.

This ensures:

- Clinical risk acceptance remains with the organisation delivering care
- Suppliers do not self-accept deployment risk on behalf of the NHS

Hazard ownership and boundaries, i.e. the governance model relies on clear hazard boundaries:

Hazard type	Owned under
Inherent risks of product e.g. PACS / RIS design.	Supplier DCB 0129
Inherent risks of NIR design	NIR DCB 0129
Risks introduced by integration between systems	DCB 0160 (local)

Risks due to local configuration and workflows	DCB 0160 (local)
Changes to supplier system behaviour	Supplier DCB 0129 (updated if required)

The principle being that no single safety case is expected to cover all risks end-to-end. Instead, safety is assured through linked, complementary safety cases.

5. Source of Hazards and Relationship to DCB 0129

The hazards addressed in the local DCB 0160 assessment can be derived from the NIR DCB 0129 Clinical Safety Case. These hazards reflect known safety risks associated with national imaging discovery and retrieval, such as incorrect patient identification, missing images, delayed access, and unauthorised access.

Healthcare Organisations are not expected to re-identify or reassess NIR design hazards. Instead, local deployment assessments should focus on how these hazard themes may manifest within local workflows, operational processes, system configurations and integrations, and what additional controls are required.

6. Using the DCB 0160 CSCR Template

The DCB0160 CSCR template has been structured to support Healthcare Organisations in documenting local deployment assurance activities. Organisations should complete the template using local deployment information, workflow assessments, governance evidence and supplier-provided documentation where appropriate.

The CSCR should clearly explain how hazards are mitigated through architecture, controls, testing, deployment, and ongoing monitoring.

7. Using the Local Deployment Hazard Log

It is recommended that a DCB 0160 compliant Hazard Log is used. Guidance on the format and content of the Hazard Log can be found at:

DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

Also there is a DCB 0129 Hazard Log available for the NIR Design safety assessment which contains guide hazards to consider.

The Hazard Log should be used to document deployment and operational hazards relevant to NIR integration. Hazards should be mapped to the NIR hazard themes provided, where possible, and should reference corresponding DCB 0129 hazards, controls and evidence.

Healthcare Organisations should avoid duplicating DCB0129 design hazards and instead focus on deployment-specific risks arising from local workflows, operational processes, configuration and use of NIR.

8. Conducting the Safety Assessment

Healthcare Organisations should conduct the DCB0160 safety assessment as a structured activity involving clinical, operational and technical stakeholders. Recommended activities include:

- Review of the NIR DCB 0129 safety case and appendices
- Architectural and data flow review for the supplier system and local integration with NIR
- Identification of deployment-specific hazards
- Definition and implementation of controls
- Hazard-based testing and validation

The assessment should be proportionate to the complexity and risk of the integration.

Review and Update of the Safety Assessment

The DCB 0160 safety assessment is not a one-off activity. Healthcare organisations are expected to review and update their CSCR and Hazard Log:

- Prior to initial go-live
- Following significant system or configuration changes
- After safety incidents or near misses
- At agreed periodic intervals (recommended at least annually)

Evidence of review and CSO approval should be retained.

9. Submission and Assurance

The NIR Clinical Safety Guidance Document, together with the NIR DCB0160 CSCR Template and Core Deployment Hazard Log, provides an appropriate and proportionate framework to support DCB0160-compliant deployment clinical safety assurance.

Healthcare Organisations should retain completed DCB0160 documentation, supporting evidence, approval records, and local hazard logs in accordance with local governance requirements.

As part of the NIR onboarding process, Healthcare Organisations may be asked to provide confirmation that local DCB0160 activities have been completed and approved by their appointed Clinical Safety Officer (CSO), and that identified deployment risks have been assessed and managed through local governance arrangements.

Suppliers may be required to provide supporting evidence relevant to the integration, including technical documentation, testing evidence, training materials, interoperability information, and deployment support artefacts. However, responsibility for undertaking DCB0160 activities, accepting residual deployment risk, and approving local deployment remains with the deploying Healthcare Organisation.

NHS England may review onboarding submissions to confirm alignment with NIR deployment requirements and the expectations of DCB0160. Organisations should ensure

that submitted information is complete, internally approved, and consistent with other onboarding and deployment assurance documentation.

Appendices

Appendix A – Risk Matrices and Definitions

Clinical Risk Management Risk Matrix

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Consequence				

Risk Matrix key - Severity

5	Unacceptable level of risk
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Acceptable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required

Hazard likelihood definitions

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases

Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Hazard Consequence definitions

Consequence Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single

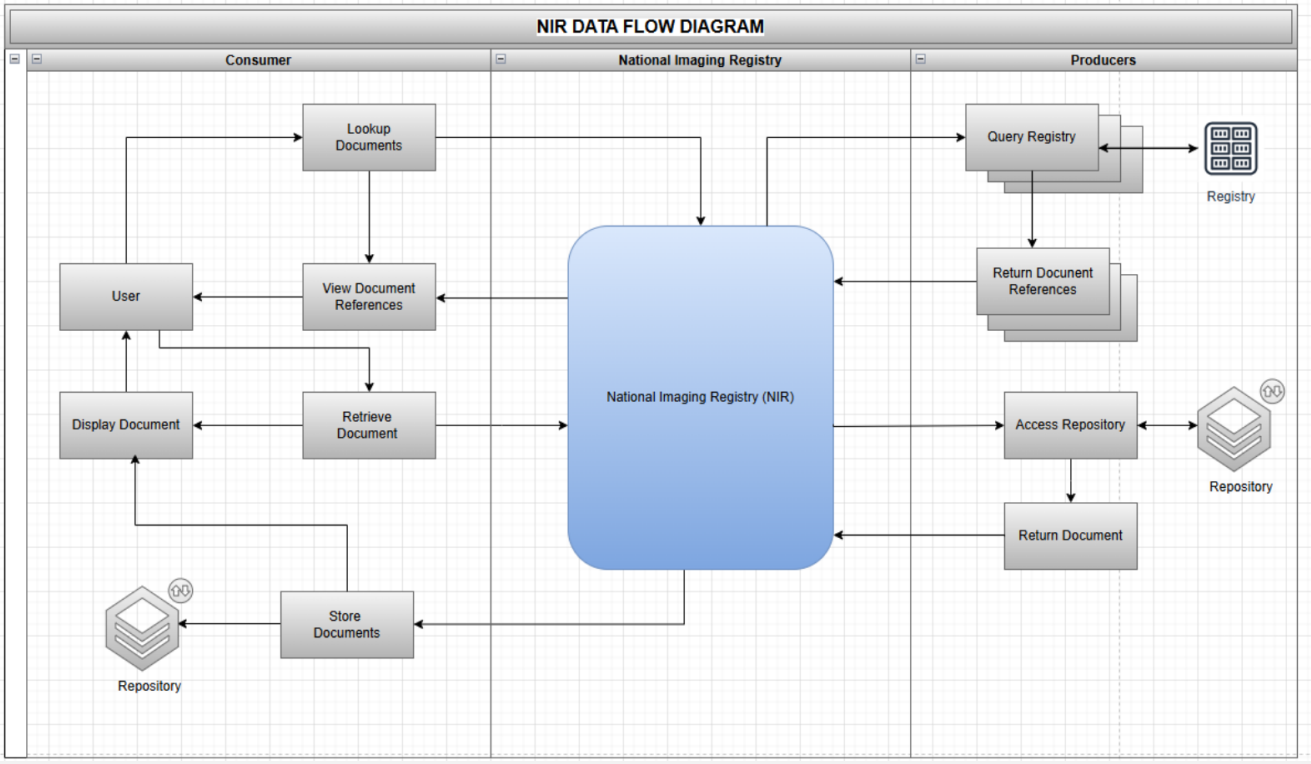
Appendix B – NIR Deployment Controls and Safety Recommendations (DCB 0160)

The Deployment Controls and Safety Recommendations outlined in this DCB 0160 Clinical Safety Case Report for the NIR solution represent risk controls and safety considerations identified during the clinical risk assessment.

Hazard Group	Individual Hazard IDs	Hazard Sub-Group	Operational Requirements to be Maintained and Recommendations
Availability & Retrieval Failures	HAZ 001, HAZ 002	Network & Infrastructure Availability	Organisations must maintain high network uptime and monitor PACS/VNA gateway performance continuously. Network redundancy, load balancing, and failover configurations must be validated and documented. Automated alerts should notify support teams of connectivity issues, and escalation procedures should be triggered for sustained outages.
Availability & Retrieval Failures	HAZ 001, HAZ 003, HAZ 004	Image Retrieval Workflow	System behaviour must ensure complete retrieval of images and related metadata across federated networks. Partial query results must generate explicit user notifications. Retry logic must be implemented, and timeouts configured to prevent misleading outputs. Testing should include simulated retrieval failures.
Availability & Retrieval Failures	HAZ 001, HAZ 004, HAZ 002	Operational Response & Escalation	Local SOPs must define fallback options when image retrieval fails. Clinical and technical users must be trained on escalation routes and how to differentiate between local and remote issues. Tabletop exercises should verify readiness and escalation effectiveness.
Data Quality & Patient Identification Errors	HAZ 003, HAZ 005	Metadata Conformance & Validation	All connected systems must perform schema validation before publishing data to the NIR. Incomplete or malformed metadata must be rejected automatically. Supplier conformance tests during onboarding must validate compliance with IHE XDS and XCA profiles.
Data Quality & Patient Identification Errors	HAZ 005	Patient Identity Management	Patient identifiers must be validated against authoritative sources, and merge/unmerge processes logged. Systems must prevent accidental overwrites or duplicate creation. Regular audits of patient demographic consistency across federated systems are required.
Data Quality & Patient Identification Errors	HAZ 003, HAZ 005	Data Provenance & Traceability	The NIR must maintain the 'single source of truth' principle. Audit logs must document the origin of each dataset and timestamp of registration. Provenance records should be reviewed periodically to ensure traceability and prevent data drift.
Security, Privacy & Access Control Failures	HAZ 006	Identity Federation & Authentication	All NIR users must authenticate via NHS Identity or federated access controls. Access tokens must be time-bound and traceable. Failed authentication attempts should be logged and reviewed for anomalies.
Security, Privacy & Access Control Failures	HAZ 006	Role-Based Access & Least Privilege	Access permissions must be role-based and reviewed quarterly to ensure alignment with job functions. Clinical data should only be accessible to authorised staff, and audit trails must capture all image access events.
Security, Privacy & Access Control Failures	HAZ 006	Encryption & Data Transmission Security	All communication between NIR components and connected systems must use TLS 1.2+ encryption. Certificate management must follow NHS Cyber Security guidelines, with regular rotation and validation. Breach response procedures must be rehearsed annually.
Governance & Operational Risks	HAZ 007, HAZ 008	Governance & Accountability Structures	Each trust must define governance roles for NIR-related incidents and maintain documented accountability structures. Governance meetings should include periodic review of clinical safety reports and escalation trends.
Governance & Operational Risks	HAZ 002, HAZ 006	Incident Escalation & Safety Oversight	Incident management must align with NHS England’s national escalation framework. Clinical Safety Officers must be informed of all incidents with potential patient impact. Incident reporting metrics should be reviewed monthly.

Governance & Operational Risks	HAZ 001, HAZ 003, HAZ 004, HAZ 005	Training & Readiness Testing	Clinical and technical teams must undergo induction training on NIR use, safety principles, and failure procedures. Tabletop and live exercises should validate understanding and readiness at least annually.
Interoperability & Protocol Translation Risks	HAZ 003, HAZ 004, HAZ 009	IHE Profile Conformance (XDS, XCA)	Suppliers must prove conformance with IHE XDS and XCA standards through onboarding testing. Non-conformant implementations must be risk assessed and formally accepted by NHS England.
Interoperability & Protocol Translation Risks	HAZ 009	API & Future Standards Alignment	Future development phases must ensure APIs align with evolving interoperability frameworks. Backward compatibility testing must confirm safe transition between standards.
Interoperability & Protocol Translation Risks	HAZ 003, HAZ 004, HAZ 010	Cross-Vendor Translation & Gateway Behaviour	Gateway components must handle message translation consistently across vendor systems. Monitoring must detect translation errors and latency. Vendors must participate in interoperability testing during each major release.

Appendix C – Detailed Data Flow



Appendix D – Standards Compliance

Referenced Standards and Frameworks within NIR Documentation

Category	Standard / Framework	Description / Use within NIR
Document Exchange	IHE XDS.b (Cross-Enterprise Document Sharing)	Core profile for registering and discovering clinical documents.
Cross-Community Access	IHE XCA (ITI-38 / ITI-39)	Enables discovery and retrieval of imaging and report data across organisations. Referenced in *NIR Error Handling-v33* and *Trust Model-v24*.
FHIR Document Sharing	IHE MHDS (Mobile Health Document Sharing)	FHIR-based standard for federated document access. Supported in parallel with XCA (*NIR Product Brief*).
Imaging Retrieval	DICOM WADO-RS / WADO-WS	Imaging retrieval protocols for RESTful and SOAP-based access to diagnostic images. Mentioned in *Trust Model-v24*.
Security & Identity	WS-Security (OASIS Standard)	SOAP message signing and encryption (for XCA / XDS exchanges).
	SAML 2.0 / XUA (Cross-Enterprise User Assertion)	Provides user identity and authorisation in SOAP exchanges.
	OAuth 2.0 / IUA (Internet User Assertion)	RESTful (FHIR/MHDS) authentication and authorisation mechanism.
	Mutual TLS (mTLS) via NHS Private CA	Enforced at transport layer for system authentication (*Trust Model-v24*, *Security and Compliance Strategy-v5*).
Data Representation	HL7® FHIR® R4	Used for MHDS document queries and retrievals.
Metadata & Governance	NHS England DDC Interoperability Standards Catalogue	NHS reference for national-level interoperability alignment.
Error Handling & Compliance	IHE IT Infrastructure Technical Framework Vol. 3 (ITI TF-3)	Referenced for error response patterns in *NIR Error Handling Framework-v33*.

Related Documents

These documents provide additional information and are specifically referenced within this document. Links to documentation have been provided where available and were accurate at the time of issue of this report.

Ref	Title (NIR Confluence Link)	Version
1	NHS Standard: DCB 0129 – Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification	V3.2
2	NHS Standard: DCB 0160 – Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Specification	V4.2
3	DCB 0129 Hazard Log	D0.1
4	MHRA Software Classification Guidance: *Medical Device Stand-alone Software Including Apps (including IVDMDs)*, *MEDDEV 2.1/6*	*2.1/6*
5	NHS England Developer Portal (2025): *Digital Onboarding Process* – https://digital.nhs.uk/developer/guides-and-documentation/digital-onboarding	-
6	NIR Solution Design Specification (Derived from NIR Product Brief v3 (28 Jun 2025)	v1.5
7	NIR Interoperability and Standards Compliance https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1128204655/NIR+Interoperability	Appx E
8	NIR Observability and Logging Strategy https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1121401300/NIR+Observability+and+Logging+Strategy	Version 14 (12 September 2025)
9	NIR Error Handling Framework: https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1161766556/NIR+Error+Handling	Version 33 (12 September 2025)
10	NIR Supplier Onboarding Pack and Supplier Conformance Criteria (SCC)	DOSM
11	NIR Quality Assurance and Test Strategy https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1098875238/UAT-+Test+Pack	v3.0
12	NIR Programme Communications Plan - *Governed by NHS England Diagnostics Programme Communications and Engagement Strategy (DDC, 2025) see also - https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1111209985/NIR+-+References*	NHS DDC Programme Document, 2025

Ref	Title (NIR Confluence Link)	Version
13	Clinical Safety Management System (CSMS) – NHS England Clinical Safety Team **-** *published NHS document governing all DCB 0129/0160 processes and responsibilities.* *https://www.england.nhs.uk/long-read/digital-clinical-safety-assurance/*	Version 1.2, 03 March 2025
14	NIR Clinical Risk Management Plan (CRMP)	v2.0
15	NIR Operational Support Model	v2.0
16	Incident Management Procedure (IMP) https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1132940087/NIR+Incident+Management+Priority+Level	-
17	NIR Change Management Process https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1154670369/NIR+-+New+Feature+Requirements+Process also: - https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1187350949/NIR+Key+Operating+Procedures	-
18	NIR Service Review Reports **-** Derived from *NHS England Service Review and KPI Reporting Framework (DDC, 2025)* and *NIR Reporting Dashboard v164*.	Aligned to NHS DDC Reporting Framework (2025)
19	NIR Service Desk Process Flow - *Based on NHS England DDC Service Operations Handbook (2025) and ITIL v4 Incident and Request Fulfilment workflows.*	Aligned to NHS DDC Service Desk Framework (2025)
20	NIR Monitoring and Alerting Platform **-** *NIR Observability and Logging Strategy v14 (12 Sep 2025)*; built on *AWS CloudWatch*, *Splunk*, and *NHS CSOC integration standards (2024)*.	Derived from NIR Observability v14 (12 Sep 2025)
21	NIR Interoperability Testing Procedure https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1098875238/UAT-+Test+Pack	-
22	NIR Confluence Workspace	NIR

Ref	Title (NIR Confluence Link)	Version
23	NIR Governance Model – Derived from https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1161775785/API+Catalogue+Website+Requirements	-
24	NIR Clinical Risk Management File (CRMF) https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1195113158/NIR+-+Clinical+Safety+DCB+0129+and+DCB+0160	-
25	Clinical Safety Workshop Records https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1208353642/NIR+-+Hazard+Assessment+Workshop+1+30+09+2025 also: https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1208353679/NIR+-+Hazard+Assessment+Workshop+2+10+10+2025	-
26	Change and Release Safety Assessments – Derived from: https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1195113171/Governance+R+R+Safety+Plan	-
27	Medical Device Classification Assessment Form	TBA See Section Medical Device Regulations
28	NIR Data Protection Impact Assessment (DPIA)	Version 0.5 (8 August 2025)
29	NIR Reporting and Governance Dashboard https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1149081087/NIR+Reporting+Management+Dashboard%C2%A0-+Requirements+Specification	-
30	NIR Security Architecture and Controls Framework https://nhsd-confluence.digital.nhs.uk/spaces/CLP/pages/1121401325/NIR+Security+and+Compliance+Strategy	-

END OF SECTION