

INFORMATION GOVERNANCE POLICY

NATIONAL SPECIALTY QUALITY IMPROVEMENT PROGRAMMES

IN GI ENDOSCOPY, HISTOPATHOLOGY, RADIOLOGY AND BRONCHOSCOPY

VERSION 3



INSTITUTE OF MEDICINE

ROYAL COLLEGE OF PHYSICIANS OF IRELAND



FACULTY OF PATHOLOGY

ROYAL COLLEGE OF PHYSICIANS OF IRELAND



FACULTY of RADIOLOGISTS and RADIATION ONCOLOGISTS



ROYAL COLLEGE OF PHYSICIANS OF IRELAND



RCSI

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Additional Relevant RCPI Policies

Data Protection Policy
Breach Management Policy and Procedure
Programme Information & Data Management Policy
Records Management Policy
Information Security Policy
Access Control Policy
Vulnerability and Patch Management Policy

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Section 1

1. Overview of the National Specialty Quality Improvement (NSQI) Programmes

There are four National Specialty Quality Improvement (NSQI) Programmes managed by the Royal College of Physicians of Ireland (RCPI) in GI Endoscopy, Histopathology, Radiology, and Bronchoscopy.

1.1 Statement of Purpose for the NSQI Programmes

The primary aim of the NSQI Programmes is to strengthen patient safety efforts in local hospitals and enhance patient care with accurate, timely and complete diagnoses and reports in each of the specialties.

The NSQI Programmes objectives are to

- improve patient care by minimising diagnostic errors in GI endoscopy, histopathology, radiology and bronchoscopy reporting.
- increase public confidence in diagnostic reporting by providing evidence-based assurance on the quality of these diagnostic services.
- continue development of standardised national quality improvement systems for GI endoscopy, histopathology, radiology and bronchoscopy.
- enable individual departments to review their performance against national targets.
- identify and share good practice between participating hospitals.
- recognise and encourage opportunities for quality improvement locally.
- improve communication between participating hospitals.
- actively promote a culture of quality improvement by engaging key hospital stakeholders.

Every year the work of the NSQI Programmes culminates in a national data report for each specialty and is released by RCPI. Each report includes analysis of national data for an agreed set of specialty specific key quality indicators (KQI) measured against key quality targets, in addition to providing key findings and recommendations based on findings.

National Bronchoscopy QI Programme: At the time this policy was revised the National Bronchoscopy QI Programme was in the early stages of development. This policy will be updated to reflect the information governance requirements for that programme before data collection commences.

2. Purpose of this Policy

The Health Information and Quality Authority (HIQA, 2012) defines information governance as follows:

'Information governance provides a means of bringing together all the relevant legislation, guidance and evidence-based practice that apply to the handling of information and offers a consistent way for people working in health and social care to deal with the many different legal provisions, guidance, and professional codes of conduct that apply to handling personal health information'

The objectives of this policy are to:

1. ensure that NSQI Programme data are collected, processed, stored, accessed and reported on in a secure and confidential manner.
2. address the secondary use of data, which refers to the use of data collected by the programmes for a purpose other than the stated primary purpose.
3. outline the process by which requests for the NSQI data can be made and the subsequent processes for review and approval by the working groups and steering committee, ensuring requests are handled appropriately.
4. define the hierarchical levels of access to data.
5. ensure that the NSQI data collected and reported on are compatible with the aim and objectives of the NSQI Programmes.
6. ensure clinicians feel secure with the process and to provide assurance that it will not be used against them in a punitive manner, thus encouraging participation in quality improvement activities.
7. ensure compliance with the legislation to which the NSQI Programmes are subject including the Data Protection Acts 1988 and 2003, the Data Protection Act 2018 (Health Research) Regulations 2018, the General Data Protection Regulation (EU) 2016/679.
8. define the responsibilities associated with the roles assigned locally and nationally in relation to the data collection and reporting.

This policy is not a legal reference document.

3. Scope of this Policy

This policy applies to:

- physicians, surgeons, nurses, allied healthcare professionals, administration staff and management in hospitals participating in the NSQI Programmes.
- the NSQI programme management team who manage the data on a routine basis and receive and manage applications for access to NSQI data.
- working group and steering committee members who approve the national data reports and review and approve applications for access to NSQI data.
- any other individual or organisation that may seek to request access to the programmes data for a specific purpose.

4. Programmes Governance and Accountability for the NSQI Data Collection

The Histopathology, GI Endoscopy and Radiology QI Programmes are funded by the HSE National Quality and Patient Safety (NQPS) Directorate. At the time this policy was released the funding for the National Bronchoscopy QI Programme was being provided by the National Cancer Control Programme (NCCP) and HSE Acute Operations.

The NSQI Programmes are managed by RCPI, which is the service provider as outlined in the service level agreement (SLA) with the National Quality and Patient Safety (NQPS) Directorate, HSE. The governance of the programmes is provided by a steering committee with representation from the Faculty of Radiologists and Radiation Oncologists, Faculty of Pathology, Institute of Medicine, Conjoint Board of RCPI and RCSI, HSE NQPS, HSE eHealth and Disruptive Technologies (formerly OCIO), NCCP, HSE Acute Operations, RCPI senior management team, working group chairs, the Acute Operations National Endoscopy Programme, two patient and public interest representatives, the Private Hospital Association (PHA), the National Office of Clinical Audit (NOCA) and the Health Information and Quality Authority (HIQA) (observer status).

5. Application of GDPR

The vast majority of the QI data analysed by the NSQI Programmes are anonymous, related to the procedure that was carried out and not patient identifiable data. However, analysing of the endoscopist medical council registration number requires that the GDPR does apply and as such the GDPR is the appropriate standard for the NSQI Programmes to apply (see section 5.4 for more detail).

Following a data protection impact assessment (DPIA) of the National Quality Assurance and Improvement System (NQAIS), carried out by eHealth and Disruptive Technologies, HSE and supported by the NSQI programmes management, it was agreed with the HSE Data Protection Office in March 2024, that the appropriate relationship between RCPI and the HSE in respect of the NSQI programmes was that of data processor.

RCPI is now named as a data processor in respect of the NSQI Programmes (see definition on page 21) on behalf of the HSE. A data processing agreement has been signed by RCPI and the HSE to reflect this. RCPI has also completed the HSE IT security questionnaire as part of the DPIA process, this permits the HSE to ascertain that RCPI has implemented the necessary technical and organisational measures (ToM's) in the organisation, and not just the ToMs the supplier has in place around the information systems or services they supply to the HSE.

5.1 Responsibilities of RCPI NSQI Programmes as a Data Processor

1. To collate and analyse data accessed from the national datasets in NQAIS.
2. To store raw and analysed data in secure files on the RCPI SharePoint for the designated 10 years.
3. To share aggregated findings in annual national data reports which are publicly available.
4. To process requests for access to QI data once approved by the relevant working group and / or steering committee.

5.2 Data Controllers

The HSE is an independent data controller in respect of the QI data collected and uploaded into the HSE-owned NQAIS.

Each participating voluntary and private hospital is a data controller for their own QI data, this means that they are responsible for the integrity of QI data and can authorise or deny access to QI data.

5.3 Data Sharing Agreements

At the time this policy was approved, data sharing agreements were being drawn up between the HSE and the voluntary and private hospitals in respect of QI data uploaded / submitted into NQAIS.

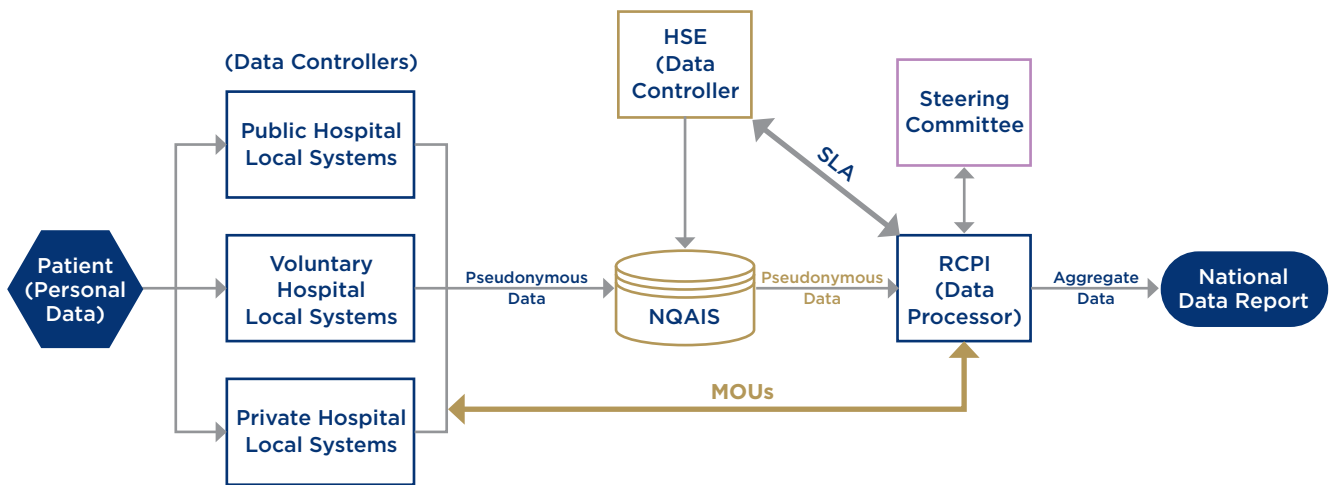


FIGURE 1: MAP OF DATA FLOW FROM LOCAL HOSPITAL SYSTEM, TO NQAIS AND RCPI FOR INCLUSION IN NATIONAL DATA REPORT

5.4 Application of GDPR to QI Data Explained

Patient data are entered into the participating hospitals local information systems as part of local processes. The procedure being carried out is assigned a pseudo-identifier (case ID for histopathology and GI endoscopy, accession number for radiology) by the local system. These data when uploaded from the local systems into NQAIS are pseudonymous. The patient number is not uploaded into NQAIS.

However, the endoscopist medical council registration numbers (MCRN) are uploaded from the local system into NQAIS-Endoscopy to assist individual endoscopists, hospital and group clinical leads to measure performance related to the key quality indicators. These data, accessed by the RCPI programme management, are pseudonimised and used to perform analysis related to the volume of endoscopists achieving certain KQI targets (see section 7.1 for additional details). This dictates that GDPR applies to the NSQI Programmes.

At the time this policy was released, the histopathology and radiology data were classed as anonymous in the RCPI extract. The rationale for this classification is due to the unavailability of the 'key' to re-identify individuals.

RCPI has no access to the 'key' (i.e. the local reporting systems) and therefore cannot re-identify a patient or any data subject.

Many of the members of the NSQI Programmes' working groups and steering committee, as well as those who may request access to the data for secondary purposes are employees of the participating hospitals which, as explained above, theoretically retain potential access to the 'key' to re-identify individuals. Taking account of such links, RCPI has undertaken careful consideration of the risk of re-identification of individuals. While the risk is low, RCPI has implemented the following procedures to mitigate this risk:

- NSQI programme managers will retain all raw data as private and confidential.
- NSQI data will be shared in aggregate form only. This applies to members of the working groups, the steering committee and those whose applications for access to data have been successful.
- All applications for access to programme data will be individually assessed as regards:
 - the risk of "singling out" where it is possible to distinguish the data relating to one hospital or individual from all other information in a dataset.
 - the principle of data minimisation to ensure that the minimum amount of data are processed to achieve the stated purposes.
 - appropriate safeguards which may include binding commitments aimed at preventing re-identification in any agreement for the sharing of pseudonymous or anonymous data.

6. NSQI Programmes Access and Permissions for the National Quality Assurance and Improvement System (NQAIS)

The National Quality Assurance and Improvement System (NQAIS) is a central repository for QI data submitted by participating hospitals. It allows sites to generate local reports and the programmes to generate national reports focused on a set of key quality indicators and associated targets in hospitals for each programme. The HSE National Quality and Patient Safety Directorate are the owners of this system as it pertains to radiology, endoscopy and histopathology.

Access to data in NQAIS locally is restricted to authorised local and national users. New users must be authorised by the QI clinical lead with responsibility for the relevant programme locally.

Once authorised the local operational manager or QI tech lead will grant appropriate access which will be restricted to local or national views of the data on NQAIS as appropriate.

6.1 Local Access to QI Data

It is the responsibility of each participating hospital to assign appropriate access levels for NQAIS to its staff i.e. the local QI clinical lead for each participating department is responsible for authorising a new local user, they must notify the local operation manager to complete user set-up where the appropriate access level will be applied.

The following are links to the programme specific NQAIS user documentation outlining the user roles, associated access rights or responsibilities and the expected users for each programme's NQAIS module. These roles are applicable to the local operational managers and QI clinical leads in the National Histopathology and GI Endoscopy QI Programmes and to the QI tech lead and QI lead radiologist in the National Radiology QI Programme.

This user documentation can only be accessed by first logging into NQAIS

Histopathology: <https://docs.healthatlasireland.ie/docs/nqais-histopathology/nqais-histopathology-user-documentation/view>

GI Endoscopy: <https://docs.healthatlasireland.ie/docs/nqais-endoscopy/>

Radiology: <https://docs.healthatlasireland.ie/docs/nqais-radiology/documents/nqais-radiology-user-guide>

6.2 National Access to QI Data

The local hospitals are responsible for uploading specific data extracts into the national dataset in NQAIS. The NSQI programme managers are national administrators within NQAIS and can access the national dataset however, they do not have access to data within the hospitals local systems (e.g. laboratory information systems, endoscopy reporting systems).

Additional relevant stakeholders including the software vendor with responsibility for NQAIS support, maintenance and development and eHealth and Disruptive Technologies will have appropriate national access rights and permissions.

7. NSQI Programme Data Flow and Upload to NQAIS

The data upload processes vary between the programmes owing to different software in place locally. The following section will outline the information flow and reporting pathway for each programme individually.

7.1 GI Endoscopy

Data required for the National GI Endoscopy QI (NEQI) Programme are entered into the local Endoscopy Reporting System (ERS) as part of a workflow at each participating site. Data are extracted from the ERS at each site by the local operational managers, and securely uploaded to NQAIS-Endoscopy at quarterly intervals throughout the year. Once uploaded the data are signed-off by the local QI clinical lead. The process is outlined in the relevant SOP (available on request) and represented in Figure 2 below.

Each site maintains ownership of its own data at all times.

The endoscopist medical council registration number (MCRN) is uploaded from the local system into NQAIS-Endoscopy to assist individual endoscopists, hospital and group clinical leads to measure performance related to the key quality indicators. No patient identifiable information is uploaded from the local system into NQAIS-Endoscopy. The endoscopist MCRN is publicly available information and therefore subject to a lower threshold for GDPR. A pseudo-identifier for the endoscopist MCRN is created by the programme manager for analysis using the original NQAIS data extract and once complete the original MCRN is securely locked and stored with access restricted to the programme management.

Each site has access to its own data on NQAIS-Endoscopy in order to sign-off the data as being complete and accurate within the agreed time limits and to review it using the reporting functionality provided.

Once uploaded into NQAIS-Endoscopy the data become accessible for the relevant programme manager for analysis and inclusion in national data reports.

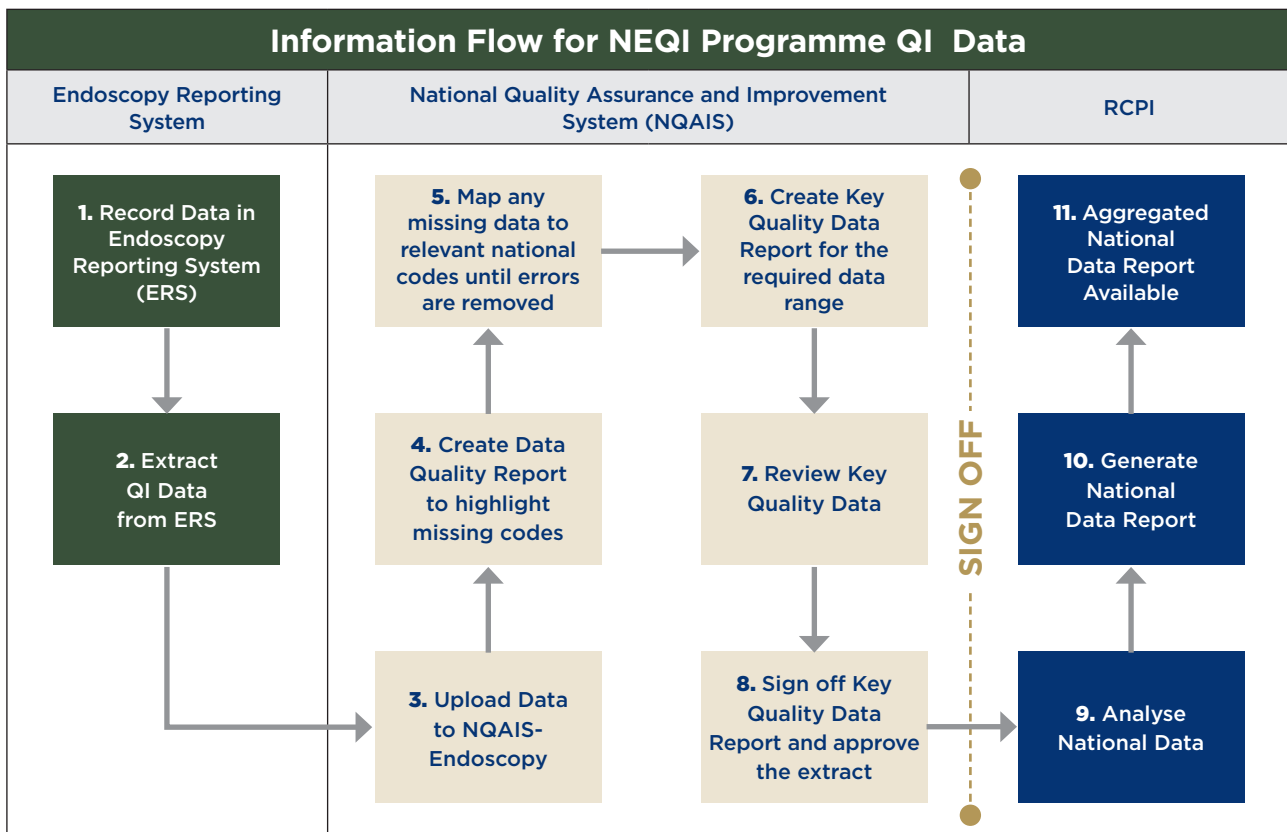


FIGURE 2: INFORMATION FLOW FOR NEQI PROGRAMME QI DATA

All hospitals participating in the NEQI Programme upload data on a retrospective quarterly basis, complying with an upload schedule ([Upload Schedule](#) and [Lapsed Participation Process](#)) approved by the programme's working group and must have their data from the previous year uploaded by March of the following year for inclusion in the annual national data report.

7.2 Histopathology

Data required for the National Histopathology QI (NHQI) Programme are entered into the local Laboratory Information System (LIS) as part of workflow at each participating laboratory by both the local operation managers and the QI clinical leads. Once signed-off, data are extracted from the LIS at each site, encrypted and securely uploaded to NQAIS-Histopathology on a retrospective monthly basis throughout the year.

Each participating hospital maintains ownership of its own data. No patient or histopathologist identifiable information are uploaded from the local system into NQAIS-Histopathology.

Each site has access to its own data on NQAIS-Histopathology to review it using the reporting functionality provided and to sign-off the data as being complete and accurate within the agreed time limits.

Once uploaded into NQAIS-Histopathology the data become accessible for the programme manager for analysis and inclusion in national data reports.

The full process is outlined in the relevant SOP (available on request) and represented in Figure 3 below.

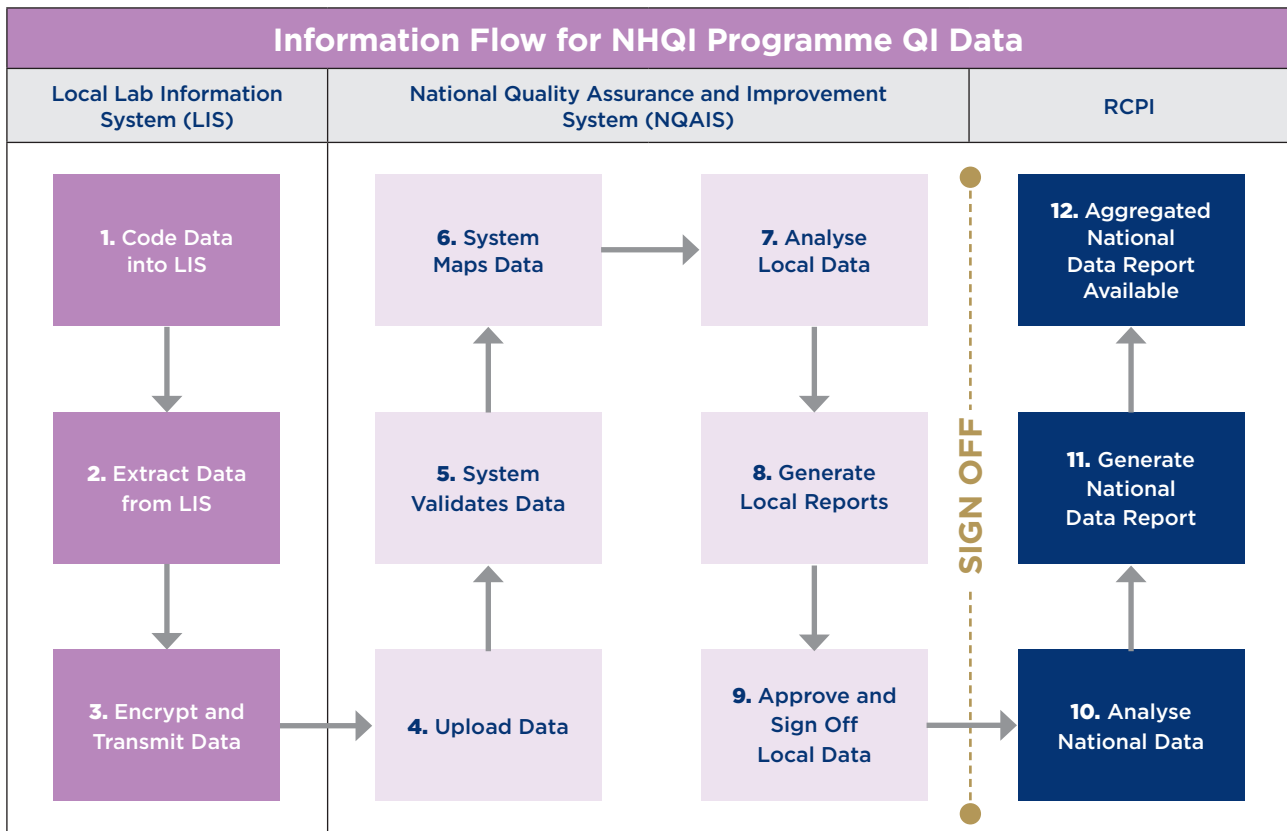


FIGURE 3: INFORMATION FLOW FOR NHQI PROGRAMME QI DATA

All hospitals participating in the NHQI Programme upload data on a 12-month retrospective monthly basis, complying with an upload schedule ([Upload Schedule](#)) and [Lapsed Participation Process](#) approved by the programme’s working group and must have their data from the previous year uploaded by March of the following year for inclusion in the annual national data report.

7.3 Radiology

Data required for the National Radiology QI (NRQI) Programme are entered by a QI lead radiologist and a QI tech lead into the local information system integrated with the RIS/PACS as part of a normal workflow at each participating site.

Encrypted QI data relating to predefined KQIs, collected in the local information systems are automatically exported via a secure VPN connection to a HSE server nightly and then submitted to NQAIS-Radiology.

A portion of QI activity related to those KQIs listed under 'Summary Data' require manual input into NQAIS-Radiology by a QI lead radiologist.

Each participating hospital maintains ownership of its own data at all times.

No patient or radiologist identifiable information are uploaded from the local system into NQAIS-Radiology.

Each site has access to reports on its data in NQAIS-Radiology to review them online and generate local reports. Graphs available in NQAIS allow for visual comparison of local QI data records against the national aggregate, however local users do not have direct access to the national aggregate data. Once uploaded into NQAIS-Radiology the data become accessible for analysis and inclusion in national data reports.

The steps involved are represented visually in Figure 4 below.

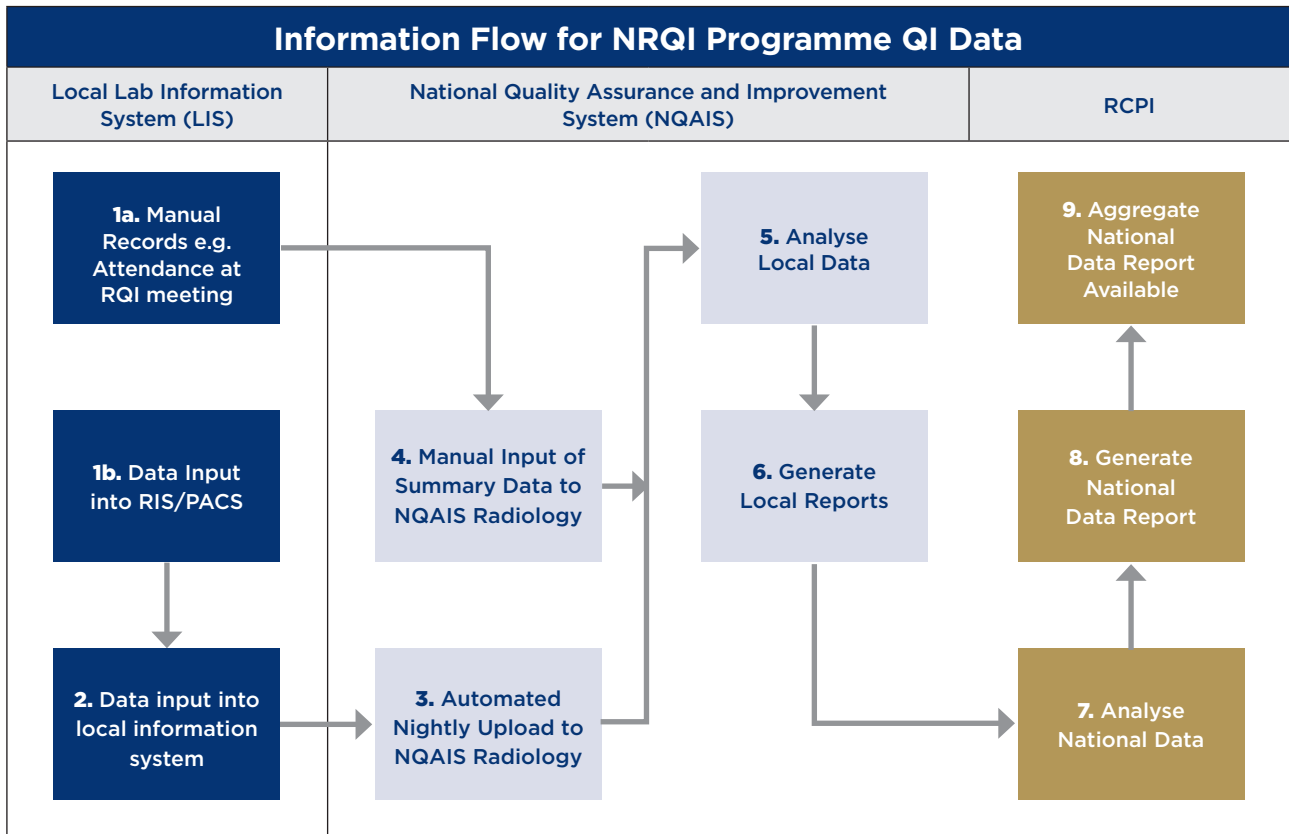


FIGURE 4: INFORMATION FLOW FOR NRQI PROGRAMME QI DATA

8. Reporting on NSQI Programmes Data

8.1 National Data Report

The annual national data report is the primary output for each of the NSQI programmes. The programme management team acquire a data extract from the relevant NQAIS module containing information from individual hospitals regarding procedures or cases. These data are transformed and combined into hospital level and national aggregate data before being analysed against pre-determined targets and recommended standards.

The national data report for each programme is created annually and covers data collected within the previous calendar year, 1 January to 31 December.

QI data necessary for this report are obtained from NQAIS and supported by a software provider, who provide NQAIS support to participating sites and to the NSQI programmes management team. The information in this report is disseminated nationally to the relevant stakeholders including hospital and HSE management, it is also made available on the RCPI website.

8.1.1 Hospital Identification

At the time this policy was released the National Histopathology and Radiology QI Programmes were not publishing the names of the hospitals in the annual data reports. The hospitals are represented in the findings using an identifier, known only to each hospital and the relevant programme manager.

In 2020, after significant discussion with stakeholders, the National GI Endoscopy QI Programme published its first report identifying the hospitals names against findings.

8.2 Ad Hoc Reporting

The programmes' working groups, steering committee, programmes sponsors, RCPI Faculties and Institutes and the Conjoint Board of Ireland may request the programme manager to prepare ad hoc reports using aggregate data from the national dataset. This can facilitate more in-depth study of specific KQIs, associated targets or recommendations, the development of new KQIs, to assess existing services or to evaluate potentially beneficial QA or QI activities as indicated by the NSQI Programmes annual national data report findings among other activities. Requests for access to QI data may be received from other individuals or organisations for a specific purpose. All requests are managed through the request process detailed in section 2 of this policy.

As is the case with the national data report, the programme manager will provide aggregate data only.

9. NSQI Programmes Data Retention

9.1 Extracts for Completion of National Data Reports

As agreed with both the HSE DPO and the RCPI DPO as part of a data protection impact assessment carried out on NQAIS, the QI data extracts analysed for the national data reports by the programme management will be retained for 10 years. This will permit adequate retrospective analysis of trends in the data and to aid improvements and amendments related to KQIs and targets. The retention period will be reviewed annually in line with any changing operational requirements. The first extracts date from 2015.

9.2 Extracts for Additional Data Requests

Data extracts created for any additional data requests will be retained for 12 months after the publication or intended use of the outputs.

10. Data Quality

At the time this policy was released the NSQI programme management team were in the preliminary stages of developing a data quality strategy. This will outline the necessary processes that must be in place to manage data quality, to ensure the team are adequately trained in this area, to audit internal practices, ensure necessary improvements are put in place and standards are monitored.

10.1 HIQA Data Quality Framework

It is important that those collecting and using the QI data can have confidence in the quality of the data. The data collected must be reliable, accurate, relevant and timely, to facilitate decision-making and associated quality improvements to provide safe and high-quality care for patients. HIQA recommends the use of a data quality framework, which will enable the programmes to assess the current data quality and necessary improvements using the following four tools: 1) a data quality strategy 2) a data quality assessment 3) reporting on data quality and 4) a data quality improvement cycle. This framework is applied by the programmes and included in the annual national data reports.

10.2 Data and Information Cycle

The data and information cycle are clearly outlined in each programme's annual data report and are detailed in section 7 of this policy.

10.3 Data Quality Statement

A data quality statement is revised annually for each of the programmes and published in the national data report.

10.4 Data Assessment Tool

Each programme uses the HIQA data assessment tool to measure data quality against the following five criteria 1) relevance, 2) accuracy and reliability, 3) timeliness and punctuality, 4) coherence and comparability and 5) accessibility and clarity.

Data quality checks take place at the time of analysis by the programme management and at source, within the hospitals local information systems and as such the programmes can report high levels of data record completeness. This is an important measure as it directly relates to the robust nature of the dataset and subsequent findings.

10.5 Data Dictionary

The programme management maintain an up-to-date data dictionary for each data collection.

11. Risk Management

The NSQI programme management team maintain a risk register in the form of a RAID log, detailing risks, assumptions, issues and dependencies for each programme. This ensures that the team can routinely appraise any possible impacts to the data collection that may affect data quality and the programmes operationally. Any impact is detailed, along with the owner who assigns a priority, response or escalation required and any necessary actions and the resolution stage.

High priority risks that have the potential to negatively impact the data quality or any other operational elements of the programmes are escalated to the working groups and steering committee. Actions and appropriate responses are then discussed and owners assigned to complete these in order to mitigate or resolve the risk.

RCPI maintains a corporate risk register where risks related to the programmes may be detailed where they have the potential to impact the delivery of the corporate plan.

12. Roles and Responsibilities

The roles and responsibilities of those directly responsible for running the programmes in the participating hospitals, the Faculties and Institutes, working groups, steering committee and the RCPI are detailed in the memorandum of understanding (See Appendix 1 for a list of these roles and responsibilities).

These representatives are those likely to access QI data, analyses or reports, and are asked to read, agree and observe the responsibilities associated with their roles set out in the memoranda of understanding issued to each participating site.

In addition, hospitals must ensure that these individuals agree to and comply with this information governance policy.

NQAIS has been developed and validated as a central database by the HSE eHealth and Disruptive Technologies (formerly OCIO) for storage, analysis and report generation. The appropriate, effective, and efficient access to information within NQAIS requires a clear understanding of the roles and responsibilities of the parties involved in the programmes.

Listed below are the responsibilities associated with the HSE eHealth and Disruptive Technologies Office.

12.1 eHealth and Disruptive Technologies, HSE

HSE eHealth and Disruptive Technologies has overall responsibility for the successful delivery of the necessary ICT solution(s) to support the needs of the NSQI programmes, in connection with public and voluntary hospitals, and is accountable for the approved ICT capital budget.

Responsibilities of HSE eHealth and Disruptive Technologies:

1. Identify a designated ICT project manager to assume overall responsibility for the delivery of the necessary ICT solution(s), and for the approved ICT capital funding.
2. Procure software development services (as necessary) to facilitate the development of NQAIS-Endoscopy, -Histopathology, -Radiology and -Bronchoscopy interfaces, and QI web interface applications to meet the needs of these programmes, and to facilitate the ongoing maintenance, support and development of these systems to meet ongoing and evolving needs.
3. Assist with the detailed design, development, testing and implementation of the central reporting system on an ongoing basis.
4. Lead the detailed design, development, testing and implementation of all necessary local information system extracts and interfaces in collaboration with the NSQI programme management and participating histopathology / endoscopy / bronchoscopy departments **[endoscopy, histopathology and bronchoscopy specific]**.
5. Procure software development services (as necessary) to facilitate the development of NQAIS-Radiology and RIS/PACS extracts and interfaces, local QI data collection system and QI web interface applications to meet the needs of this programme, and to facilitate the ongoing maintenance, support and development of these systems to meet ongoing and evolving needs **[radiology specific]**.
6. Manage the ongoing relationships and contracts with the web-interfaces vendors for the provision of essential ICT services to public and voluntary hospitals (e.g. software development, maintenance & support, database/systems administration) **[endoscopy, histopathology and bronchoscopy specific]**.
7. Manage the ongoing relationships and contracts with RIS/PACS, the local QI data collection system and the web-interfaces vendors for the provision of essential ICT services to public and voluntary hospitals (e.g. software development, maintenance & support, database/systems administration) **[radiology specific]**.
8. Advise the Data Controller and QI programme manager on appropriate technical & organisational security measures to safeguard against unauthorised access, alteration, disclosure and destruction of data.
9. Identify a designated person with responsibility for liaison with the programme management on an ongoing basis.
10. Process data only on and subject to the instructions and agreement of the Data Controller (i.e. potential data processor role).

13. Communication Data: How your data are managed

Communication data refers to personal data that is held for the purposes of informing stakeholders involved in the running of the programmes, locally or nationally on programme related content.

13.1 Who is collecting the data?

The NSQI programme management team process relevant stakeholders' personal data which is used for the purposes of communication.

13.2 Why are the data being collected?

These data are maintained on mailing lists which are used to inform you on programme related updates, any issues or requirements regarding data uploads and compliance, to forward documentation including the national data reports and to inform on events taking place. The programme management team may also use this mailing list to send out surveys, where appropriate. The data collected through surveys is done in line with the information governance principles contained in this policy.

13.3 Categories of personal data concerned

This data refers to basic personal information including individuals' full names and place of work, and contact information including email addresses and phone numbers.

13.4 Who else might receive it?

Personal data are not shared with third parties. No information is shared without seeking prior written consent first.

13.5 Data Retention Policy

These data will be retained until a request is received to remove an individual from a mailing list. It is possible to opt out of the mailing list by emailing the relevant programme manager to request this.

13.6 Your Rights Concerning your Personal Information and the Way in Which We Process It

You have the right to

1. get access to your personal information
2. request us to correct inaccurate information or update incomplete information (Right of Rectification)
3. request that we restrict the processing of your information in certain circumstances
4. request the deletion of personal information excluding medical records (Right of Erasure / Right to be Forgotten)
5. receive the electronic personal information you provided to us in a portable electronic format
6. object to us processing your personal information in certain circumstances; and
7. lodge a complaint with the data protection commissioner

(A copy of the RCPI Data Protection Policy can be made available for further detailed information.)

Section 2

14. Applications for Access to QI Data

14.1 Applying for Access to QI Data

Applications for access to QI data must be made via email to the relevant programme manager or department manager who will then send the appropriate Request for Access to Data Application link via email. The same process will apply whether the application is made externally from individuals, participating sites, the HSE or related organisations or internally via the associated Faculties or Institutes.

Before submitting the application, it is important to clarify the purpose for which the data will be used. The [NOCA GDPR Assessment Table](#) is a useful resource that will assist in making a distinction between research, service evaluation, clinical audit, healthcare record review or clinical registers. Requests for the purpose of research must be sent to the appropriate Research Ethics Committee for approval before a request for access can be progressed by the working groups or steering committee.

Where deemed appropriate by the working group, they can refer the application to the steering committee for further discussion before making a decision on the application.

The hospitals are the data controllers in respect of their own data as such any requests for individual hospitals data must be made to the individual hospital via their internal processes.

Data that have been published in the annual national data reports for previous years may be shared with applicants, however stipulations will be made not to release findings from any work undertaken as a result of analysing data that have yet to be published by the NSQI Programmes (see section 14.1.1 below).

14.1.1 Access to Data that have not been Published

If a request for data is made to the programmes for data that have not been published in the relevant annual data report, the data will first be verified and approved by the relevant programme's working group(s) and once approved sent to the steering committee to approve the request. Where the request is to share these data publicly before they have been published by the relevant programme the request must also be approved by the Office of the Chief Clinical Officer.

14.1.2 Access to Data that are not Routinely Published in the NDR

Figure 5 below maps the process to be followed from when a request for data is made, through to the decision by the working group and /or steering committee to approve or deny the application.

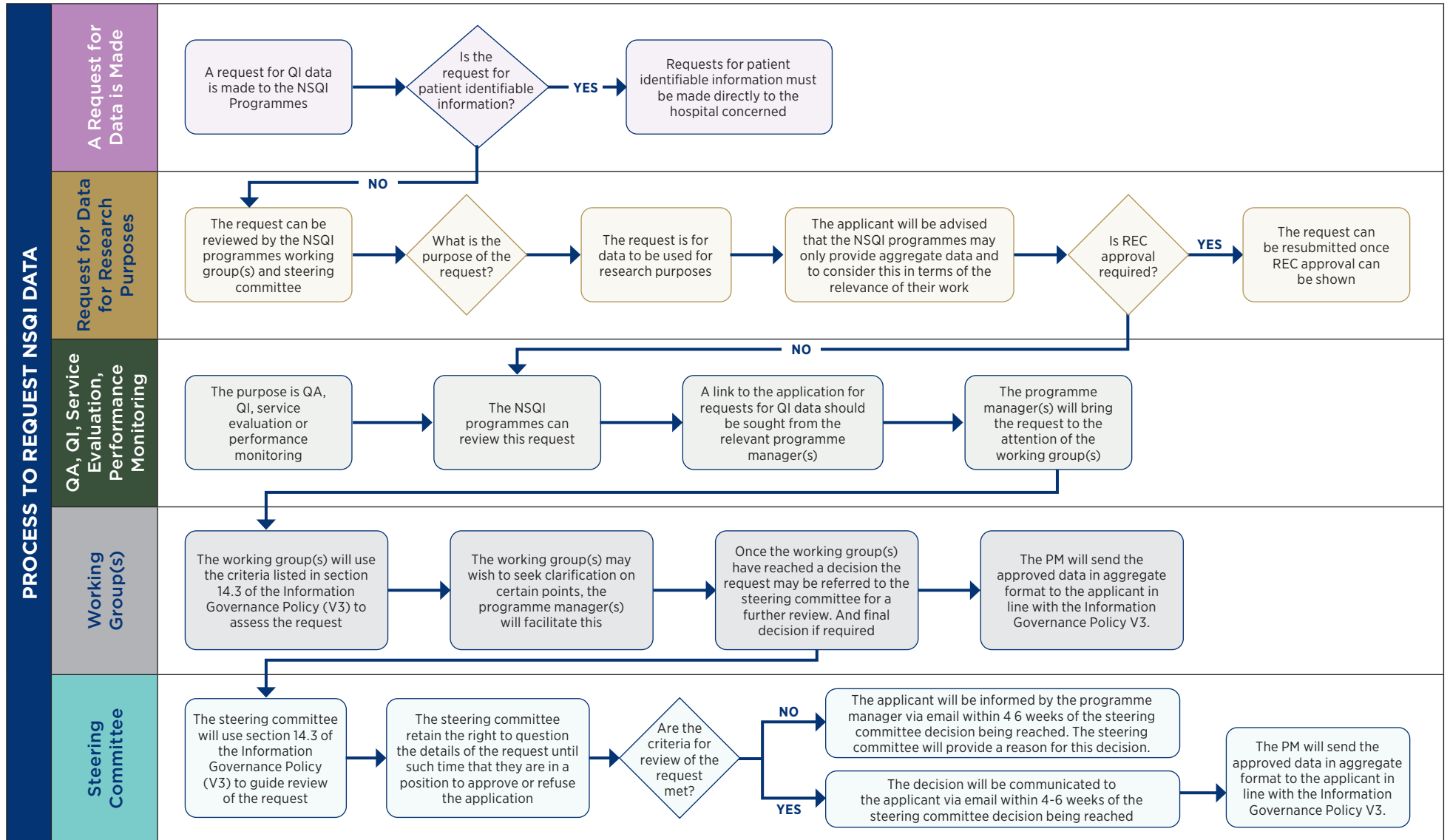


FIGURE 5: PROCESS MAP - REQUEST FOR ACCESS TO NSQI DATA

14.2 Application Form for Access to QI Data

The application form will seek information on the parties making the request, the programme(s) from which they are requesting data, the time period, the purpose for the data request, any approval required from a research ethics committee (REC), expected output from the proposed work, proposed publications, data security, access and sharing and the right of the working group and /or steering committee to question the output of the work, should it not align with the aims of the NSQI programme(s) impacted. Lastly, applicants will be asked to confirm a number of declarations and acknowledgements before submitting the form.

Only aggregate data will be shared by the NSQI Programmes. Aggregate data are anonymous and provide an overall summary of the findings from individual sites in relation to the different KQIs and targets.

14.3 Assessment of QI Data Requests by the Working Groups and Steering Committee

The following criteria will be used to inform the decision-making process.

14.3.1 Ethical Approval

-
1. If required, ethical approval must have been obtained from the relevant REC by the applicant prior to the submission of an application for access to QI data.
-

14.3.2 Data Completeness

-
2. Only QI data that have been validated may be shared with an applicant. Data validation refers to the checks that take place at both a local level prior to upload and subsequent sign-off, enabling local sites to check for the accuracy and quality of the data. The programme manager can provide the working group and / or steering committee with a report on data completeness prior to their approval of any data request.
-

14.3.3 Individual / Organisation

-
3. The applicant must work within a reputable institution of some standing (e.g. third level institution, health service organisation).
 4. The individual / organisation must be able to prove their ability to maintain the confidentiality and integrity of the QI data.
 5. The extent to which the individual / organisation for which the individual works has a track record in the field of research or experience in the analysis of large data files will be considered during the assessment process.
-

14.3.4 Outputs

-
6. The proposed usage of the outputs from analysis of the data requested (e.g. publication and any other proposed dissemination).
 7. The extent to which the proposed outputs align with the programmes aims and objectives.
 8. The extent to which the outputs will serve the public good.
 9. In the view of the working group and /or steering committee the benefits to accrue from the data use outweigh any potential risks.
-

14.3.5 Data Security, Access and Sharing

10. All individuals who will have access to the data must be named. In general, access will only be granted to:
 - a) Individuals who, either in their own right or as employees of a reputable organisation / institution, have a proven track record in data analysis or research, or are to be supervised by a clinician with such a track record or
 - b) Individuals working in organisations / institutions that can give a clear rationale, acceptable to the working group and / or steering committee for access being granted.
 11. Access to data will not be granted to individuals or individuals working in organisations that have a vested interest in conducting the work (i.e. have a material or personal interest in the activities or business performance of a particular enterprise or set of enterprises).
 12. The purposes for which the data are to be used must be clearly set out. The data are not to be used for any other purpose.
 - a) The programme manager will record the details of the data given to the data applicant for the programme records.
 - b) The data supplied, and all paper and electronic copies, will be destroyed on an agreed date, the applicant must confirm this has taken place via email to the programme manager.
 13. Users of the data must ensure that, in complying with these conditions, they also observe the relevant provisions of the Data Protection Acts and the GDPR.
 - a) Responsibility for ensuring the confidentiality of all outputs (reports, publications, presentations, articles etc.) based on the work carried out on the NQAIS data (or using any element of the NQAIS modules) rests with the applicant.
 - b) The applicant must comply with the following conditions regarding storing and sharing the data.
 - i) The following media of storage are considered unacceptable, USB stick (unless encrypted) / email / shared access PC with generic password (e.g. in a shared clinical area)
 - ii) We strongly recommend that QI data be stored on a personal laptop which must be secure and password protected.
 - c) The relevant NQAIS module must be acknowledged as the data source in all outputs.
 - d) On completion of the proposed work, or by the agreed timeframe, all versions of the data from NQAIS modules (or subsets thereof) must be deleted/destroyed by the researcher and a confirmation email sent to the relevant programme manager.
-

14.3.6 Rights and Responsibilities

14. All outputs (reports, publications, presentations, articles etc.) must be submitted to the relevant working group and / or steering committee for consultation and approval, prior to being circulated into the public domain so that adherence to the Information Governance Policy V3 can be assured.
 15. The working groups and steering committee reserve the right to question data or conclusions that appear to deviate from the original stated purpose until the matter is resolved.
 16. Ultimately investigators take academic responsibility for their data analysis and conclusions.
-

14.4 Approval Process

The applicant will be notified by the programme management regarding the approval via email within four to six weeks of the working group or steering committee decision being reached. In the event an application is not approved, the working group or steering committee will provide a reason for this decision, which will be notified to the applicant by the programme manager via email within four to six weeks of the steering committee final decision being reached.

14.5 Formal Data Sharing Arrangements for each Programme

Only aggregate data will be shared by the NSQI Programmes. Aggregate data are anonymous and provide an overall summary of the findings from individual sites in relation to the different KQIs and targets.

Figure 5 above outlines a detailed process whereby internal stakeholders, individuals, participating sites or organisations can make a request for specific data relating to the NSQI Programmes. These requests can be once off or form part of a more formal and routine data sharing arrangement.

National GI Endoscopy QI Programme: The National GI Endoscopy QI Programme has a formal data sharing arrangement in place with the HSE Acute Operations National Endoscopy Programme. This agreement came into force in 2022 following a detailed request submitted by the aforementioned programme which was subsequently reviewed and approved by the National GI Endoscopy QI working group and the steering committee.

National Histopathology QI Programme: At the time of the approval of this policy there are no data sharing arrangements in place.

National Radiology QI Programme: At the time of the approval of this policy there are no data sharing arrangements in place

15. Key Definitions

The following key definitions are provided to assist the reader in navigating the content within this policy.

Data	“Data can be defined as raw facts and statistics before they have been organised or put into context” (HIQA, 2012).
Anonymised Data	is defined in the GDPR as <i>information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.</i>
Data Controller	Defined by the GDPR (Article 4(5)) as <i>the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law.</i>
Data Processor	as defined by the Data Protection Act 2018 <i>is an individual who, or a legal person, public authority, agency or other body that, processes personal data on behalf of a controller, but does not include an employee of a controller who processes such data in the course of his or her employment.</i>
Personal Data	is defined by the Data Protection Act 2018 as <i>information relating to— (a) an identified living individual, or (b) a living individual who can be identified from the data, directly or indirectly, in particular by reference to— (i) an identifier such as a name, an identification number, location data or an online identifier, or (ii) one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.</i>
Pseudonymisation	is defined in the GDPR (Article 4 (5)) as <i>the means of processing personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.</i>

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Appendix 1: Roles and Responsibilities (Memorandum of Understanding)

HOSPITAL CEO / GENERAL MANAGER AND SENIOR MANAGEMENT:

1. Identify a clinical lead locally from within the histopathology laboratory / endoscopy unit in collaboration with the histopathology department head to have overall responsibility for the NHQI / NEQI programme. [histopathology and endoscopy]
2. Ensure QI data reports are reviewed by the Quality and Patient Safety Committee or appropriate local structure within each department, linking with relevant hospital governance and programme structures as set out in the programme guidelines and taking action as required.
3. Ensure necessary resources are available for the programme to function effectively.
4. Develop local policies and procedures for complying with the monthly upload and reporting requirements of the programme.
5. Ensure the local QI data reports (generated in NQAIS) are reviewed at appropriate senior management levels.
6. Ensure that the senior management review process for local QI data is formalised.
7. Ensure that all users of NQAIS-Histopathology / Endoscopy / Radiology have access to the Information Governance Policy V3.
8. Ensure that all local NQAIS users have access to appropriate training and information prior to using the system.
9. Ensure that where radiology work is outsourced that the company to whom the work is outsourced is able to identify who is responsible for the QI elements of that work and is in a position to cooperate and collaborate with the local radiology department where necessary. [radiology]

RADIOLOGY CLINICAL DIRECTOR / CONSULTANT RADIOLOGIST IN ADMINISTRATIVE CHARGE / HEAD OF DEPARTMENT / APPROPRIATE EQUIVALENT INDIVIDUAL

1. Nominate a QI lead radiologist locally from within the radiology department in conjunction with radiology colleagues and inform the CEO /GM of this nomination. The NRQI Programme recommends that this role is rotated at intervals as agreed locally.
2. Establish, develop and implement the NRQI Programme function within the Directorate and within the framework of overall clinical governance provisions of the organisation.
3. Report and manage the QI data within the radiology department and ensure the necessary actions to improve quality are initiated and / or referred to the appropriate person.
4. Review local QI data reports on a quarterly basis.
5. Support the QI lead radiologist and QI tech lead in their roles within the NRQI Programme.

QI CLINICAL LEAD (CONSULTANT HISTOPATHOLOGIST / ENDOSCOPIST / RADIOLOGIST):
Overall responsibility locally for the NHQI / NEQI / NRQI Programme rests with the local QI Lead

1. Ensure local QI data are uploaded to NQAIS-Histopathology and signed off on a monthly basis in line with the Outline of Programme Requirements with Data Upload Schedule. [\[histopathology\]](#)
2. Ensure local QI data are uploaded to NQAIS-Endoscopy and signed off at appropriate intervals in line with the Lapsed Participation Process (see section 6 of NEQI MoU).
[Each unit's QI data should be uploaded to NQAIS-Endoscopy quarterly and should be signed off within 2 weeks after the end of each quarter e.g. Jan – Mar should be uploaded and signed off by the end of the 2nd week in April.] [\[endoscopy\]](#)
3. Ensure local summary data as outlined in the Key Quality Indicators (see QI Guidelines, section 5) are accurately recorded and submitted to NQAIS-Radiology in line with the Lapsed Participation Process (section 5 of MoU).
Please note non-summary data is automatically uploaded from the local information system to NQAIS-Radiology on a nightly basis. [Summary QI data requires a manual input to NQAIS and should be completed 2 weeks after the end of each quarter e.g. Jan – Mar should be uploaded by the end of the 2nd week in April.] [\[radiology\]](#)
4. Review reports in NQAIS-Endoscopy / Radiology on a quarterly basis at a minimum.
5. Review reports in NQAIS-Histopathology on a monthly basis at a minimum.
6. Ensure communication of local data reports to senior hospital management and Clinical Governance / Quality and Patient Safety Committees, including Clinical Director / consultant in administrative charge ([radiology only](#)).
7. Report and manage the QI data within the laboratory / endoscopy unit / radiology department and ensure the necessary actions to improve quality are initiated and / or referred to the appropriate person.
8. Identify a local operations manager (LOM) in collaboration with the laboratory manger locally from within the histopathology laboratory who will assist in achieving Programme goals. [\[histopathology\]](#)
Identify a local operations manager (LOM) locally from within the endoscopy unit who will assist in achieving Programme goals. [\[endoscopy\]](#)
Identify a QI tech lead locally in collaboration with the radiography services manager from within the radiology department who will assist in achieving Programme goals. [\[radiology\]](#)
9. Collaborate with the QI tech lead for all practical purposes related to NRQI Programme. [\[radiology\]](#)
10. Authorise local user access rights and access levels to the QI Data Collection System and NQAIS-Radiology (central repository) for this Programme in accordance with local policies. [\[radiology\]](#)
11. Ensure all new users of NQAIS-Histopathology / Endoscopy / Radiology have access to relevant training materials.
12. Maintain users and mapping tables on the NQAIS-Histopathology / Endoscopy system.
13. Maintain the integrity and validity of the data locally, ensuring that the QI programme's coding structures are adhered to. [\[histopathology and endoscopy\]](#)
Maintain the integrity and validity of the QI data locally, ensuring that data relating to the QI programme's key quality indicators are recorded routinely and accurately on PACS/RIS and local information system. [\[radiology\]](#)
14. Collaborate with the local operations manager on site to maintain local code mapping tables in NQAIS-Histopathology / Endoscopy.
15. Attend (or nominate deputy) the annual conference organised by the programme management and the working group.
16. Ensure familiarity with the programme's Issue Resolution Pathway and Lapsed Participation Process.
17. Inform CEO / Clinical Director / Consultant in Administrative Charge if participation in this role is no longer possible to enable them to appoint a replacement, you may recommend a successor. NHQI / NEQI / NRQI programme management should also be informed.
18. Inform colleagues of the purpose of the QI programme, any updates and relevant changes and ensure awareness of programme goals is maintained.

LOCAL OPERATIONS MANAGER (HISTOPATHOLOGY / ENDOSCOPY):

1. Upload encrypted QI data to NQAIS-Endoscopy [endoscopy]
2. Collaborate with the QI clinical lead to ensure local data are uploaded to NQAIS-Histopathology once signed off on a monthly basis in line with the Outline of Programme Requirements with Data Upload Schedule [histopathology]
3. Review and verify the completeness of local QI data before they are sent to the QI clinical lead for sign off.
4. Collaborate with the QI clinical lead to ensure local QI data are uploaded to NQAIS-Endoscopy and signed off. [Each unit's QI data should be uploaded to NQAIS-Endoscopy quarterly and should be signed off within 2 weeks after the end of each quarter e.g. Jan – Mar should be uploaded and signed off by the end of the 2nd week in April.] [endoscopy]
5. Collaborate with the QI clinical lead to maintain local code mapping tables in NQAIS-Histopathology / Endoscopy.
6. Give local user access rights and access levels to NQAIS-Histopathology / Endoscopy as approved by the clinical lead.
7. Ensure familiarity with the programme's Issue Resolution Pathway and Lapsed Participation Procedure.
8. Attend (or nominate deputy) the annual conference organised by the programme management and the working group.
9. Inform the QI clinical lead if participation in this role is no longer possible to enable them to appoint a replacement, you may recommend a successor. NHQI / NEQI programme management should also be informed as appropriate.
10. Inform colleagues of the purpose of the QI Programme, any updates and relevant changes and ensure awareness of programme goals is maintained.

QI TECH LEAD:

1. Collaborate with the QI lead radiologist for all practical purposes related to NRQI Programme.
2. Support the Clinical Director and QI lead radiologist in managing the technical requirements of the NRQI Programme, and in validating the data completeness in the local information system and NQAIS-Radiology, where authorised by QI lead radiologist.
3. Give local user access rights and access levels to NQAIS-Radiology as approved by the QI clinical lead.
4. Ensure familiarity with the programme's Issue Resolution Pathway and Lapsed Participation Process.
5. Ensure all QI activity is accurately recorded on PACS/RIS and the local information system.
6. Attend (or nominate deputy) the annual conference organised by the programme management and the working group.
7. Inform the QI lead radiologist if participation in this role is no longer possible to enable them to appoint a replacement. NRQI programme management should also be informed.
8. Inform colleagues of the purpose of the NRQI Programme, any updates and relevant changes and ensure awareness of programme goals is maintained.

The following are the responsibilities assigned to the RCPI programme management, the working group and steering committee which form the supporting governance structure.

FACULTY OF PATHOLOGY, RCPI

Faculty of Pathology's responsibilities include:

1. Develop and maintain standards of practice and safety in the NHQI Programme.
2. Develop and continuously review the national benchmarks using the data provided.
3. Provide professional and educational support to the participating hospitals in achieving the proposed targets.
4. Provide the specialist clinical support and advice to the programme through appointed members of the working group and the steering committee.
5. Appoint and support members to the working group as required.

CONJOINT BOARD OF RCSI AND RCPI

The responsibilities of the Conjoint Board in Ireland of the Royal College of Physicians of Ireland (RCPI) and Royal College of Surgeons in Ireland (RCSI) have been delegated to the NEQI Programme working group.

THE FACULTY OF RADIOLOGISTS AND RADIATION ONCOLOGISTS, RCSI

1. Develop and maintain standards of practice and safety in the NRQI Programme.
2. Develop and continuously review the national targets using the data provided.
3. Provide professional and educational support to the participating hospitals in achieving the proposed targets.
4. Provide the specialist clinical advice and support to the programme through an appointed working group and members on the steering committee.
5. Appoint and support members on the working group as required.

RCPI PROGRAMME MANAGEMENT TEAM:

1. To ensure all responsibilities as data processors are met.

2. Review the status of data uploads across all sites on a regular basis and to email reminders to the QI clinical lead and local operations manager in line with the Data Upload Schedule and Lapsed Participation Process. [\[endoscopy & histopathology\]](#)
Review the status of data uploads across all sites on a regular basis and email reminders to the QI lead radiologist and QI tech lead in line with the Lapsed Participation Process. [\[radiology\]](#)

3. Provide local assistance and support when required.

4. Visit sites in accordance with this agreement to provide local assistance and support when required. [\[endoscopy\]](#)

5. Provide administrative programme support of NQAIS-Histopathology / Endoscopy / Radiology to include but not limited to trouble shooting, non-technical support and triage of technical issues in conjunction with OpenApp / HSE eHealth.

6. Manage the roll out & embedding of the QI programme to all participating hospitals.

7. Liaise between the working group and the programme funder.

8. Analyse, interpret and manage data to produce national data report annually.

9. Provide NQAIS training on a scheduled basis.

10. Manage the development of standard operating procedures (SOP) where appropriate and oversee their implementation within the scope of the programme.

11. Organise regular meetings of the working group and assist in the dissemination of valuable and relevant communication to programme participants nationally.

12. Produce quarterly reports for the steering committee on overall progress including completeness of data uploaded / active participation in programme.

STEERING COMMITTEE

1. Determine, review and approve the programme's strategy and ensure activity is aligned with this strategy.
2. Review and approve the programmes' governance structures in conjunction with the NHQI / NEQI / NRQI Programme working groups and participating hospitals.
3. Assist with resolving strategic level issues and risks e.g. support concerns/reviews.
4. Maintain focus on the project scope in the light of emerging issues. Reconcile differences in opinion and approach between stakeholders.
5. Review and approve programme documentation such as policies, guidelines documents or reports produced by the four NSQI Programmes.
6. Communicate the work of the programmes out to relevant represented organisations in membership.
7. Support the embedding of a quality improvement culture.

WORKING GROUP

1. Provide clinical professional expertise to the Programme and provide guidance to the NHQI / NEQI / NRQI programme management team.
2. Take a genuine interest in the programme outcomes and take responsibility for the overall success of the programme.
3. Actively participate in meetings through attendance, discussion and review, completing corresponding tasks as and when required.
4. Become familiar with national and international standards of best practice.
5. Research and generate specialist programme documentation as required.
6. Provide key clinical input into the design and implementation of the NHQI / NEQI / NRQI Programme.
7. Provide specialist clinical support in the development of national KQI targets.
8. Develop and release programme materials and documentation with NHQI / NEQI / NRQI programme management team.
9. Work closely with the NHQI / NEQI / NRQI Programme, the Faculty of Pathology / the Conjoint Board / The Faculty of Radiologists and Radiation Oncologists and steering committee on the implementation, roll out and embedding of the programme and on the approval of any key programme decisions.
10. Provide insight into practical implications of project decisions.
11. Provide specialist clinical support in the appraisal of participant input and the resolution of participant queries and issues.

<https://www.rcpi.ie/Healthcare-Leadership/National-Specialty-Quality-Improvement-Programmes/National-Radiology-Quality-Improvement-Programme>
SQIProgrammes@rcpi.ie