



QRC-PLN-61

# Quality & Regulatory Annual Plan 2024/25

## Quality & Regulatory annual plan and objectives for 24/25

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<b>Document author:</b>	Paul Evans
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Tŷ GLAN-YR-AFON 21 Heol Ddwyreiniol Y Bont-Faen, Caerdydd CF11 9AD

Tŷ GLAN-YR-AFON 21 Cowbridge Road East, Cardiff CF11 9AD



<b>STRATEGIC OBJECTIVE</b>	Delivering High Quality Digital Services
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<b>WELL-BEING OF FUTURE GENERATIONS ACT</b>	A globally responsible Wales
If more than one standard applies, please list below:	

<b>DHCW QUALITY STANDARDS</b>	ISO 9001
If more than one standard applies, please list below: All standards apply	

<b>DUTY OF QUALITY ENABLER</b>	Choose an item.
<b>DOMAIN OF QUALITY</b>	Choose an item.
If more than one enabler / domain applies, please list below: All Quality standards apply	

<b>EQUALITY IMPACT ASSESSMENT STATEMENT</b>	Date of submission: N/A
No, (detail included below as to reasoning)	Outcome: N/A
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<b>APPROVAL / SCRUTINY ROUTE:</b>		
Person/Committee/Group who have received or considered this paper		
COMMITTEE OR GROUP	DATE	OUTCOME
Claire Osmundsen-Little	25/01/2024	
Audit & Assurance Committee	13/02/2024	
Management Board	15/02/2024	

IMPACT ASSESSMENT	
QUALITY AND SAFETY IMPLICATIONS / IMPACT	Yes, please see detail below
	Duty of Quality implications throughout this plan
LEGAL IMPLICATIONS / IMPACT	Yes, please see detail below
	Legislative requirements around Duty of Quality and Medical Devices Regulations
FINANCIAL IMPLICATIONS / IMPACT	No, there are no specific financial implication related to the activity outlined in this report
WORKFORCE IMPLICATIONS / IMPACT	No, there is no direct impact on resources as a result of the activity outlined in this report.
SOCIO ECONOMIC IMPLICATIONS / IMPACT	No. there are no specific socio-economic implications related to the activity outlined in this report
RESEARCH AND INNOVATION IMPLICATIONS / IMPACT	No, there are no specific research and innovation implications relating to the activity outlined within this report.

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### 1 PURPOSE

The purpose of this document is to present an overview of the Annual Plan 2024/25, for the Quality and Regulatory function within Digital Health and Care Wales (DHCW). The plan defines the

organisations approach to Duty of Quality, the departments achievements in 2023/24, objectives and priorities for 2024/25 including the scheduled audit programme and Medical Devices (MDR). The plan explains the quality governance framework that is in place to ensure report requirements are met, as well as highlighted areas of risk and opportunities for consideration.

## 2 QUALITY ASSURANCE & REGULATORY COMPLIANCE WITHIN DHCW

Welsh Government has placed a greater emphasis on quality through the introduction of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 and the Duty of Quality. The Act sets out the legal duty on NHS bodies including Special Health Authorities to make decisions that improve the quality of services provided and the outcomes of the population of Wales. It defines the legal requirement for all NHS bodies to strive for continuous improvement in all areas, both clinical and non-clinical and to publish a yearly report that shows how DHCW has complied with its requirements. The DHCW clinical team will produce the new candour report, and the Quality & Regulatory Group will support and oversee both duties. All DHCW employees are responsible for quality, and we demonstrate our independently assured compliance by applying relevant International Quality Standards. In addition, the Quality Assurance and Regulatory Compliance Team's aim and objective is to be ahead of regulatory development and compliance, including changes to UK Medical Devices Regulations, and keeping up with regulatory developments. DHCW Quality and Regulatory team employs 15 staff and has an annual budget of £460,000 and is supported through the use of IPassport system.

DHCW has a quality framework that is supported by the Integrated Management System (IMS). The Quality and Regulatory group monitors Quality and Regulatory matters, and the Integrated Management Systems Group and Medical Devices Alerts Group support it. There are also several groups that manage key processes and provide quality assurance, such as the Wales Informatics Assurance Group, Operational Service Board, and Operational Services Group. The Audit and Assurance Committee provides assurance to the Board on the Quality and Regulatory plan and its outcomes. This assurance framework brings a higher transparency and scrutiny of Quality and Regulatory support.

### 2.1 KEY DELIVERABLES IN 2023/24

During 2023/24, several key deliverables have been achieved in line with the 2023/24 annual plan, all objectives from this plan have been achieved, or are on schedule to be achieved during Q4. Notable amongst these is the challenging rollout of iPassport across the organization, replacing SharePoint, MS Teams, and OneDrive. The Quality team facilitated this transition by creating organization units for each team, migrating documentation, streamlining training, and establishing a video training library. iPassport now hosts 950 authorized documents, indicating widespread adoption. Quality Management modules, including Checklists, Standards, Audits, and Non-Compliances, have been successfully implemented, enhancing collaboration and streamlining quality management processes.

The use of SAML for authentication via Azure Active Directory has increased system security and user experience. The Change Control Module within iPassport has gained traction, facilitating the management of organizational changes with a task-driven process.

The Quality Portal serves as a central hub for quality and regulatory activities, providing links to IMS and iPassport and continues to experience large volumes of traffic.

A Risk-Based Internal Audit Programme was established to address ISO certification requirements, resulting in a cadre of trained auditors and a successful shortlisting in the NHS Wales awards.

Quality reporting and metrics, initiated in March 2022, have evolved with the introduction of Power Bi, offering dynamic insights through dashboards presented by Quality Business Partners at Senior Leadership Team meetings. The continual development of these dashboards aims to enhance data presentation.

The team leads the Welsh Informatic Assurance Group (WIAG) meeting for DHCW, which is the gateway to system implementation that provides assurance on a range of defined criteria that the DHCW systems must comply with. During the year the group workshoped the process to understand how best to improve, streamline and speed up its process. This has resulted in a joint development with the M365 Centre of Excellence team to design a more automated process. This will be implemented during the next financial year. There is now a monthly report that is included in the management board.

Further details on these deliverables are included below.

## **iPassport**

The rollout and implementation of iPassport across the organisation has been challenging. The transitioning from using SharePoint, MS Teams and OneDrive's etc, as storage locations and management of documentation for teams has been arduous without executive endorsement. However, with the Document Management Strategy this aims to rectify the acceptance and use of the system. (Ref APPENDIX ONE: QUALITY OBJECTIVES).

In preparation the Quality team have created organisation units (OU) for every identified team within the organisation, migrated identified documentation from the Integrated Management System (IMS) onto iPassport, streamlined the training, requirements and created a video training library to aide in learning. All DHCW staff now have iPassport accounts with ease of access to the system provided by SAML, starters and leavers are captured monthly.

The system now houses 950 authorised documents, a quantity much larger than the IMS. This suggests that teams who have embraced the system and identified its advantages are using it more broadly than first anticipated. 688 users have been tasked with the initial basic training for viewer level one within the Controlled Documents module. System wide user traffic has averaged over 9600 logins per month since 1st April 2023, we anticipate this to increase.

## Quality Management Modules

The incorporated Quality Management modules have been successfully implemented and rolled out for all users within the organisation. The QIAL (Quality Improvements Actions List) was made redundant and archived, all open actions from the 6th October 2023 were migrated to the Non-Compliance Module in iPassport, the applicable audit reports were also migrated onto the system. The transition to iPassport from SharePoint has enabled us to centralize our audits and audit management (planning, conducting, and tracking internal and external audits, as well as managing audit findings and recommendations), related documentation, streamline communication, enhance collaboration, and improve our overall quality management processes.

The specific modules which have been implemented include, which can be intuitively interlinked:

- Checklists
- Standards
- Internal Audits
- External Audits
- Non-Compliances

## SAML

SAML is an authentication method that allows access to the system via Azure Active Directory. Provided the user is signed into their NHS Wales account and have an iPassport access is granted via 'Single Sign-On'. By using this method users no longer need to input their iPassport credentials. This increases the security of the system and improves the user experience.

The login strategy was successfully launched in October.

### Change Control Module

The Change Control Module within iPassport allows managing organisational/operational changes and has been piloted by the Quality team since November 2021, ensuring its useability and effectiveness. The module has gained real traction with additional use cases and changes being triaged with the rationale and risks being highlighted, the module also has a risk matrix/analysis aligned to the organisations. The whole process being task driven. Follow-ups and verification steps can also be scheduled.

In line with the module a new Change Control procedure for the management of organisational/operational changes in relation to any quality requests, has been made available for all DHCW staff to use within iPassport. This procedure has helps to control and ensure that any changes within the QMS hasn't negatively impacted on patient safety and quality.

The Quality team have also implemented the use of the Change Control Module to control changes to the Legislation Assurance Register (LAR). Previously the LAR spreadsheet had been updated with little to no control over changes, reviews and updates, making amendments difficult to track and reporting to Audit & Assurance Committee. The intuitive iPassport Change Control form, embedded into the LAR allows the Quality team to analyse and review submitted change requests in the fortnightly Change Control meetings.

Further use cases will be identified for enhanced pilot phase in Q1-2

Amongst other advantages, during an accreditation process it provides an easy path to act upon a non-conformity which causes an operational change.

### **Quality Portal**

The quality portal has enhanced the awareness and visibility of quality across the organisation as it simplifies access to information when performing Internal and External Audits. The portal is the central hub in relation to all Quality and Regulatory related activities and is under continual development to ensure that information is kept up to date and accurate. The portal provides direct access to the IMS and iPassport, information about the Duty of Quality, ISO/BS standards that are held within DHCW and assurance groups such as IMSAG, QRG and WIAG.

Since the portal went Live in March 2021, there has been an overall total of 238,531 visitors to the portal. Last year's annual plan reported that there were 73,646 visitors recorded from the period of March 2021 to July 2022. Over the past 18 months the number of visitors has significantly increased, as from July 2022 to present, there has been 164,885 visitors to the portal.

### **Risk-Based Internal Audit Programme**

The Risk-Based Internal Audit Programme was formulated in response to an external audit during the ISO certificate renewal process. It was identified that the organisation lacked a robust, risk-based approach to internal auditing, a requirement of ISO 9001:2015 Quality Management Systems standard. Recognising the complexity of the organisation, it was deemed essential to establish a cadre of trained internal auditors to successfully implement the internal audit program.

In the absence of existing records for prior internal auditor training, the team revised the previous training materials and developed the Introduction to Internal Auditing Training. This training consists of pre-recorded presentations for a consistent approach, practical exercises, and competency assessments. Attendance is tracked through ESR, and the training is managed via iPassport, with 40 plus individuals having completed the course thus far. Additionally, an ISO 9001:2015 training package was created to provide auditors with an overview of the standard. The Quality team is encouraging other standard leads to develop their respective standard training packages to enhance awareness and understanding, strengthening the internal auditor talent pool.

A framework was established to capture identified risks across the organisation, drawing on feedback from high-level groups, professional judgment from standard leads, and analysis of historical issues. After identifying areas of risk, a cross-clause analysis is conducted to pinpoint the most relevant clauses within each standard, ensuring comprehensive coverage in the programme. The schedule and programme undergo review by the Board Assurance Framework for executive oversight, with the goal of conducting audits twice monthly, utilising the pool of trained auditors.

All audit reports undergo scrutiny by the Head of Quality Assurance and Regulatory Compliance, with findings being added to non-compliance module in iPassport. Progress and findings from the programme are communicated to the Board Assurance Framework through monthly Quality metrics and reports.

The risk-based audit programme was successfully short listed in the NHS Wales awards 2023 due to its successful implementation, engagement with the wider organisation and continual improvement.

### **Quality Reporting & Metrics via Power BI**

The Quality team begun monthly reporting on key Quality related metrics and performance evaluation in March 2022, capturing organisation document position, audit findings, validation and medical device projects, WIAG and iPassport.

With the introduction and use of Power Bi the reporting has evolved and developed into intelligent, dynamic insights providing a host of dashboards for organisational use.

Quality Business Partners (QBP) were introduced in 2023 and attend Senior Leadership Team monthly meetings to present their appointed directorates metrics via the QBP Dashboard. The metrics include the IMS document position, audit findings, and progress on onboarding teams to iPassport. The QBP dashboard will be used to feed into the Directorate Reviews.

The dashboards are in continual development and improvement to enhance the data presented.

### **Validation**

The validation team have continued to work with a number of projects and programmes to ensure compliance with regulatory requirements, achievements include, successful validation of Blood Transfusion module of Welsh Laboratory Information System (WLIMS), electronic Prescription Service (ePS) and Welsh Intensive Care Information System (WICIS).

Work has continued with LIMS 2.0 to establish a wider quality framework for the programme, this will be further developed as part of our objectives for 2024/25.

### **Quality Team Development**

During the year we welcomed new team members that were transferred from the NHS Collaborative quality team, these staff have integrated well across the whole DHCW quality portfolio and continue to add value to these workstreams.

We have invested in the development of the team during the year, including training for several staff in both ISO 9001 and ISO 13485 Lead Auditor requirements, Quality Improvement tools and methodologies, regulatory updates for validation and various leadership and management courses. The team are working collaboratively with other NHS Wales colleagues on a number of workstreams around quality improvement for the benefit of the wider NHS Wales.

Two members of the team were selected for the DHCW talent cohort 2023, and the Head of Quality is participating in the Kings Fund Senior Leadership development course.

We will look to further develop the team during 2024/25 in line with the objective around the quality profession map.

The work of the team was recognised at the DHCW staff awards in April 2023 with the award of the Konrad Kujawinski Quality Award.

## 2.2 DHCW QUALITY STRATEGY

Our Mission 5 - to be the trusted strategic partner and a high quality, inclusive and ambitious organisation - reflects our Quality and Regulatory activities.

Quality is essential throughout DHCW and is achieved by following:

Quality planning - Annual quality and regulatory plan and improvements that are integrated across the Directorates and supported by the internal audit programme.

Quality deliverables - Integrating quality in all processes and ensuring that all teams throughout DHCW understand the Health and Care Quality Standards and what they mean to DHCW and their individual areas.

Quality controls - Through the proactive creation of an internal audit programme that the Quality Standards and Regulatory Group design and oversee, with all progress being reported to the Audit and Assurance Committee regularly.

## 2.3 DEFINING QUALITY THROUGH STANDARDS

Our digital organisation values our workforce skills and its ability. This accreditation shows our dedication to people practices that are ethical, pertinent and growth oriented. BS76000 is a standard that demands clear awareness of the goal of and vision for our business, careful implementation and a commitment to excellence through ongoing learning and development. This standard is about our staff and making the organization the best it can be, through evaluation, recognition, gratitude and enhancement of people practices. Additionally for the organisation, DHCW has the standards certification for ISO 20000 for all its vital IT Service Management Systems and ISO 27001 Information Security Management for all ICT operational services and cyber security. The service desk quality is supported by the work with the Service Desk Institute. All of our standards have been deliberately selected for their relevance to our needs. The IMS is constantly reviewed according to the requirements of ISO 9001 and ISO 14001.

Our internal Quality Framework supports and maintains certification to the following International and British Standards:

- ISO 9001:2015                      Quality Management Systems
- ISO 14001:2015                    Environmental Management Systems

- ISO 20000-1:2018 IT Service Management Systems
- ISO 27001:2013 Information Security Management Systems
- BS 76000:2017 Valuing People
- ISO 30415:2021 Human Resource Management
- BS 10008:2020 Evidential weight and legal admissibility
- Service Desk Institute

DHCW strive to achieve and maintain all the quality standards relevant for a digital organisation, and we shall undertake a benchmark exercise against other NHS digital organisations across the UK nations in 2024/25 to ensure we have all the relevant quality standards.

Regulatory efforts will aim to enhance current processes and create new internal processes, systems and standards that can help meet the requirements of medical devices and other upcoming regulatory changes.

## 2.4 DUTY OF QUALITY

There is a legislative requirement for all NHS organisations to comply with the principles that are outlined in the Health and Social Care (Quality and Engagement) (Wales) Act 2020, which was passed by the Senedd on 17th March 2020, and the Duty of Quality which forms part of the Act.

Publication of an Annual Quality Report is a requirement of the Duty of Quality, which was introduced in April 2023. DHCW has continued to engage with the 'NHS Wales Duty of Quality Reference Group', who meet on a monthly basis, to discuss how to comply with the Act and develop tools such as the Quality Impact Assessment and an e-Learning programme which will be made available in 2024.

DHCW has been producing monthly updates to the Welsh Government Roadmap, of which 2022/23 deliverables have been achieved, with the aim to achieve the final deliverable by the end of 2023.

DHCW approved the first 'Duty of Quality Always on Report', this included data from Quarter 2 and will be published on DHCW's external website in January 2024. Duty of Quality workshops have already been introduced within one Directorate, with the aim of these being widely rolled-out throughout the organisation during 2024/25 to support the embedding of Duty of Quality.

## 3 PRIORITIES AND AREAS FOR IMPROVEMENT

### 3.1 PRIORITIES

DHCW will use its existing skills to help and advice on Regulatory, Quality and Governance arrangements for digital solutions and services across the Health and Care sector in Wales.

It will:

- Support the Quality through planning, continuous improvement, delivery and control, of Digital Health and Care services across Wales.
- Provide advice and support services on how to understand and meet the quality & regulatory compliance requirements for digital services. Assure compliance through validation, audits and standards to the management board.
- Check the processes used within NHS organisations for quality, assurance and governance arrangements for digital solutions, on request from Welsh Government or Health Bodies.

- Make sure that digital services that are developed and deployed by DHCW meet the minimum standards for strategic, architectural and technical fit, as set by the Chief Digital officer (CDO).
- Assure regulatory compliance and informatics assurance (including patient safety) of hosted digital health and care services, deployed and developed by DHCW by working with regulators, the CDO and their relevant officials.
- Show our commitment to quality by following recognised standards and legislation. A consistent approach to quality management and regulatory compliance across DHCW will make sure that the required standards are kept centrally. The main areas of attention for the department are:
  - Health and Social Care (Quality and Engagement) (Wales) Act 2020 compliance, including matching all business activities to the Health and Care Quality Standards 2023.
  - Focus on new UK Medical Devices Regulations and activities to support the full software lifecycle.
  - Making quality more visible and integrated into the organisation.
  - More support for external audit and more resource for internal audit.
  - Increasing and formalising monitoring and analysis with the aim of improvements.
  - Optimising the use of iPassport modules.
  - Create and publish a Quality Annual Report and 'Always On' reports in line with the Duty of Quality requirements.
  - Producing regular reports on Quality metrics and Quality Improvement plans.
  - Provide training/education on QMS for Board members based on the institute for Healthcare Improvement (IHI) framework to support the implementation of the Duty of Quality.
  - Continue with the Risk-based Internal Audit Programme.
  - Continue with the development and maintenance of the Quality SharePoint Portal.

The plan will be supervised by the Head of Quality Assurance & Regulatory Compliance and the Executive Director of Finance & Business Assurance. Progress will be reported to Management Board through the Quality section and quarterly to Audit & Assurance Committee.

### 3.2 AREAS FOR IMPROVEMENT

The following are areas identified during the development of the plan which are potential improvement areas:

- Strengthen our risk-based internal audit programme with a more focused cross standard inputs by encouraging standard leads to further contribute areas of risk within their areas of expertise continuing to target two audits per month, and targeting areas highlighted in the data capture framework.
- Revise the internal auditor training programme by dividing the training package into focused lead auditors, with commitment and dedication to contribute. Secondly, deliver an audit awareness training for broader organisational delivery.
- Assist ISO/BS standard leads in readying for external audits by utilizing the 'Inspection Prep' module within iPassport. It is crucial to build the OU iPassport portfolios to fully leverage this tool. The creation of documentation for module use is necessary for usage purposes.
- Further development and roll out of additional iPassport modules.
- Conduct a series of workshops across all teams within DHCW to map team operations and activities against the requirements of the Duty of Quality.

- Gap analysis to be completed for ISO 13485:2016 to enable DHCW to seek certification to this standard in readiness for the updated UK Medical Devices Regulations.
- Streamline the WIAG process for both project managers and assurance leads through the introduction of a WIAG PowerApp.

## 4 OBJECTIVES FOR QUALITY & REGULATORY WITHIN DHCW FOR 2024/25

The Quality Team has four main objectives for 2024/25, aligned with the DHCW strategic priorities and the Welsh Government Roadmap. These objectives are to:

- Ensure compliance with the Duty of Quality and other regulatory requirements, by developing and implementing robust quality assurance frameworks and systems, conducting internal audits and inspections, and preparing for external reviews and assessments.
- Support and enable the continuous improvement and innovation of the quality of services and functions across DHCW, by providing expert advice and guidance, facilitating and delivering training and development programmes, and leading and supporting quality improvement projects and initiatives.
- Promote and embed a culture of quality within DHCW, by engaging and empowering staff, partners and stakeholders, communicating and sharing good practice and learning, and embedding the DHCW values and behaviours.
- Develop and enhance the capability and capacity of the Quality Team, by ensuring staff have the appropriate skills, knowledge, tools and resources, providing opportunities for personal and professional development, and fostering a supportive and collaborative team environment.

In the appendix, we provide a detailed table of the summary activities required to deliver these objectives, as well as the estimated quarter of delivery for each activity.

The expected benefits and outcomes from the objectives in this plan are aligned with the DHCW vision of providing high-quality, accessible, and integrated digital health and care services for Wales. By conducting workshops and developing team-based quality plans aimed at meeting the requirements of the Duty of Quality and the new Health and Care Quality Standards 2023, we aim to:

- Enhance the safety, efficiency, and effectiveness of our digital solutions and processes.
- Improve the satisfaction and experience of our customers, stakeholders, and staff.
- Support the delivery of person-centred and integrated care across primary and secondary sectors.
- Promote innovation, learning, and continuous improvement in our digital products and services.
- Demonstrate compliance with the relevant legislation, regulations, and best practices.

In addition, we recognise the importance of digital inclusion and disability needs in a digital context, and through the delivery of Duty of Quality workshops and resulting team-based quality plans, we will strive to:

- Ensure that our digital solutions and processes are accessible, inclusive, and responsive to the diverse needs and preferences of our users.
- Provide training, guidance, and support for our staff and customers to use our digital solutions and processes effectively and confidently.
- Engage with our users and stakeholders to understand their needs, expectations, and feedback, and to co-design and co-produce our digital solutions and processes.

Monitor and evaluate the impact and outcomes of our digital solutions and processes on digital inclusion and disability needs and identify areas for improvement.

## 5 EXTERNAL AND INTERNAL AUDIT REQUIREMENTS

During the year, an external audit will check how well we follow the quality standard on planned dates, and a representative for the standard will guide and help with this. The external audit covers both the standards that DHCW is trying to achieve and the ones that need to be renewed. Below is a summary of the external audit plan for the coming year (Ref APPENDIX TWO for clauses covered) :

### 5.1 EXTERNAL AUDIT SCHEDULE TO SUPPORT STANDARDS

Standard	Current Position
Quality (ISO 9001)	Q4 24/25 Surveillance Visit 2
Service Management (ISO 20000)	Q2 24/25 Surveillance Visit 1
Information Security (ISO 27001)	Q1 24 (Surveillance Visit 1)
Valuing People, Diversity & Inclusion (BS 76000)	Q3 24/25 Surveillance Visit 1

Standard	Current Position
Environmental Management (ISO14001)	Q4 24/25 Surveillance Visit 2
Software Development (DHCW standards)	TBD
Service Desk Institute Certificate	Q3 24/25
GAMP 5 v2	Working in compliance with
Digital Economy Act / Trusted Third Party	Internal Audit has confirmed compliance with the DEA.
Medical Device Quality Management Systems (ISO13485)	Working towards
Information Management (BS 10008)	Q3 24/25
Business Continuity (ISO 22301)	Working towards

## 5.2 INTERNAL AUDIT SCHEDULE TO SUPPORT STANDARDS

The Quality and Regulatory group oversees and plays a crucial role in ensuring internal audit compliance within the organisation. Recognising the need for an enhanced approach, the audit programme has transitioned from a clause-based audit schedule to the implementation of a

dynamic and agile risk-based internal audit programme. This shift has demonstrated increased effectiveness in evaluating audit requirements, providing a more adaptive and responsive framework for assessing organisational risks. The programme targets two audits per month, adapting its schedule in line with highlighted risks to the organisation and standards.

In pursuit of excellence, the Quality Assurance and Regulatory Compliance team has taken proactive measures to establish a comprehensive internal auditor training programme. This initiative extends its reach to standard leads and representatives from various departments across the organisation. The programme aims not only to equip individuals with the necessary skills and knowledge for effective internal auditing but also to foster a collaborative and standardised approach to quality management throughout the organisation.

Through a carefully crafted training curriculum, participants are exposed to the latest industry standards, methodologies, and best practices. The training programme goes beyond theoretical concepts, incorporating practical exercises and case studies to enhance the application of auditing principles in real-world scenarios. The emphasis is on developing a pool of well-trained internal auditors who can contribute to the continuous improvement of quality processes and regulatory compliance within the organisation.

By extending training to standard leads and representatives from different departments, the Quality Assurance and Regulatory Compliance team ensures a holistic understanding of internal audit processes across the organisation. This approach promotes a culture of accountability and collaboration, where individuals from diverse areas can actively contribute to maintaining and enhancing the quality standards set by the organisation.

In summary, the Quality Assurance and Regulatory Compliance team's commitment to a dynamic risk-based internal audit programme, continuing with its target of two audits per month, coupled with the comprehensive internal auditor training initiative, reflects a strategic and proactive approach to quality management and regulatory compliance. These initiatives position the organisation to navigate the evolving landscape of standards and regulations while fostering a culture of quality, continuous improvement and excellence.

## 6 THE QUALITY AND REGULATORY GOVERNANCE FRAMEWORK

In continuing to increase the support to form part of the governance framework, as well as to meet the requirements for reporting, the Quality Department will conduct the following meeting:

- Quality & Regulatory Group
- IMS Assurance Group
- Medical Devices and Alerts Group (MDAG)
- Wales Informatics Assurance Group (WIAG)

Terms of Reference for all the above groups are currently under review and updated versions will be published in Q1.

The Duty of Quality requires a defined Internal and External Governance Framework, this has been agreed by DHCW Management Board as follows:

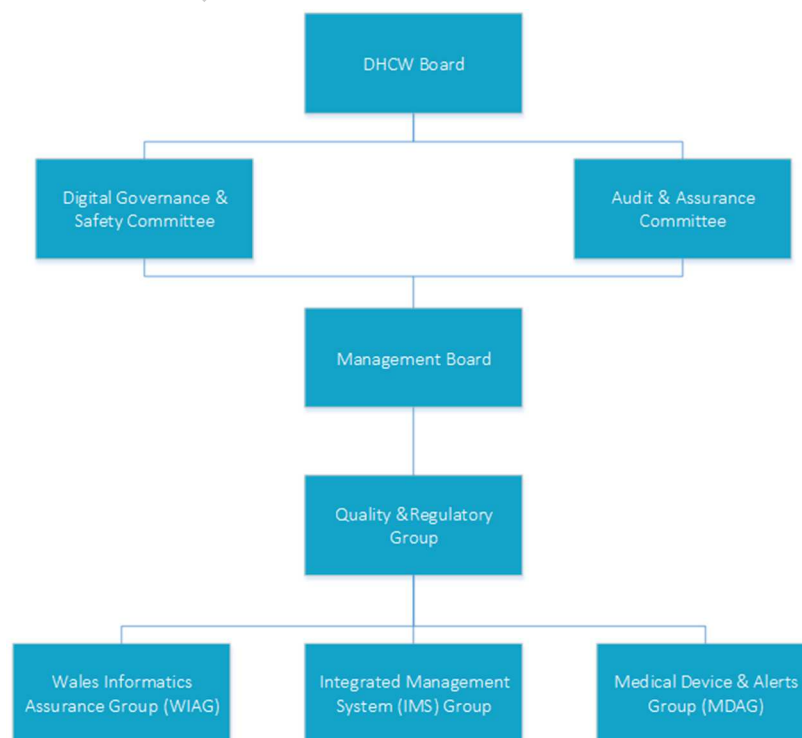
- i) Internal – Report generated by Quality & Regulatory Team with input from identified leads (membership of Quality & Regulatory group), review and approval as per Table 1.

**Table 1**

Item	Group	Purpose
Annual Quality Report (drafted by Quality & Regulatory Team)	Quality & Regulatory Group	Review
	Incident Review & Learning Group	Review
	Management Board	Approval
	Audit & Assurance Committee	Approval
	DHCW Board	Approval

- ii) External – Reviews from NWSSP Internal Audit Team, Audit Wales, and Peer Review by another NHS Body Quality Team prior to submission to Management Board and alongside internal reviews from Quality & Regulatory Group and Incident Review & Learning Group.

Annual plans and monthly progress reports are produced to support the visibility of Quality and Regulatory across the organisation. To ensure operational oversight by Management Board and scrutiny by Committees the report feeds into the Management Board for operational performance, and both the Audit and Assurance Committee and Digital Governance & Safety Committee for governance. These then feed into the DHCW Board.



## 7 SUMMARY

DHCW will continue to be a source of quality management and regulatory compliance guidance, to ensure that all digital solutions and services that are used across the Health and Care Sector in Wales are of the appropriate regulatory quality.

The introduction of the Duty of Quality in April 2023 will be beneficial in embedding quality throughout DHCW and will increase the quality team's engagement with all Directorates within DHCW. The Duty of Quality has introduced a new legislative requirement to publish regular 'Always On' reports and an annual report setting out how DHCW has complied with the Act. The annual report replaces the current Annual Quality statements. The Duty applies to all health service functions, both clinical and non-clinical functions. The implementation of the Duty of Quality will be managed by the Quality Assurance & Regulatory Compliance Team, and the Duty of Candour will be managed by the Associate Director of Information Governance and Patient Safety, as the Operational Lead for Candour. The annual report will provide information from the Duty of Quality alongside the Duty of Candour implementation within a joint annual report to the Welsh Government.

Medical Device Regulation overall compliance project plan is currently 75% complete. Assessment work on the existing service portfolio has been completed and is now 100% complete with changes or new systems being captured as BAU via NSR and WIAG. Focus continues with the cross analysis of Annex II to ensure all necessary outputs of all stages are described and fit for purpose. Medical device file SOP completion due Q4. Any new work for any service will be recorded as MD as part of the New Service Request form process also through the current assurance process, via the MD assessment form.

## 8 CONCLUSION

The plan above demonstrates how DHCW is dedicated and striving to enhance quality and regulatory compliance, especially the compliance related to fulfilling the Duties of Quality and Candour in the Health and Social Care (Quality and Engagement) (Wales) Act 2020 and the UK Medical Devices Regulations. The Quality and Regulatory Team will supervise this work, and the Management Board will receive formal reports on progress.

The plan aligns with the strategic objectives and vision of DHCW, but in particular Mission 5 which highlights the importance of the strategic trusted partner linked to the provision of safe, effective, and innovative digital health and care services for the people of Wales.

It highlights priorities and area of improvement for 2024/25 together with actions to deliver them. Key themes include compliance with the Duty of Quality, defining and integrating quality within each directorate, implementation of the document management strategy and iPassport.

The plan addresses the main challenges and risks associated with the implementation of the new Medical Device Regulations, such as ensuring the readiness of the service portfolio, the adequacy of the medical device file Standard Operating Procedure (SOP), and the compliance of the new service requests process.

The plan defines the key milestones and deliverables for each stage of the project, as well as the indicators and measures to monitor and evaluate the progress and outcomes.

It details the plans and the governance framework to deliver on quality objectives.

The plan reflects the commitment and engagement of DHCW to enhance quality and regulatory compliance, not only as a legal obligation, but also as a moral duty and a value proposition NHS Wales and the public.

## 9 DEFINITIONS

TERM	DEFINITION
DHCW	Digital Health and Care Wales
SOP	Standard Operating Procedure
WIAG	Wales Informatics Assurance Group
IMS	Integrated Management System
QMS	Quality Management System
MDR	Medical Devices Regulations
CDO	Chief Digital Officer
MDAG	Medical Devices and Alerts Group
QIAL	Quality Improvement Action List
SAML	Security Assertion Markup Language
IMSAG	Integrated Management System Assurance Group
QRG	Quality & Regulatory Group
ISO	International Standards Organisation
BS	British Standard

## 10 ATTACHMENTS / APPENDIX

### APPENDIX ONE - QUALITY OBJECTIVES

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
<b>Duty of Quality</b> Publication of 1 <sup>st</sup> Annual Quality Report	<ul style="list-style-type: none"> <li>Include information from the 'Duty of Quality Always On Reports'.</li> </ul>	Q1	Monitor - Completion of Always On reports and annual quality report via QRG.
<b>Duty of Quality</b> Duty of Quality Workshops	<ul style="list-style-type: none"> <li>To embed the Duty of Quality throughout DHCW, workshops are to be rolled-out throughout the Directorates.</li> <li>Workshops will focus on the 12 Health and Care Quality Standards, tailoring them to each department/team.</li> <li>Workshops will identify relevant information that can be captured and shared, as well the production of the Always On Reports.</li> </ul>	Q1-2	Monitor - Scheduled plan of workshops to be agreed in January SLTs and monitored via QRG and quality team meetings. Progress against schedule will be reviewed and issues escalated via QRG Chair.
<b>Medical Devices</b> Preparation for ISO 13485 Certification	<ul style="list-style-type: none"> <li>Work towards gaining certification for ISO 13485:2016 Medical Devices – Quality Management Systems.</li> <li>Develop and produce a Gap Analysis to establish the amount of work that is required to gain certification.</li> </ul>	Q2	Regular review of gap analysis through MDAG and Quality Team meetings, where progress against agreed timelines for remediation of issues identified in the gap analysis will be reviewed, culminating in an external audit to seek certification to ISO 13485:2016 by the end of Q2



Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
Quality Assurance Profession Map	<ul style="list-style-type: none"> <li>• Develop a Power App for the CQI Quality Profession Map that allows the Quality and Regulatory staff to access the map, view their current level and plan their development goals.</li> <li>• Conduct a Gap Analysis of the current skills, competencies and behaviours of the Quality and Regulatory staff against the CQI Quality Profession Map and identify areas of improvement or development.</li> <li>• Design and deliver a training programme for the Quality and Regulatory staff based on the CQI Quality Profession Map, covering the core technical competencies, governance and assurance and contextual awareness domains.</li> <li>• Implement a self-assessment tool for Quality and Regulatory staff to measure their progress and performance against CQI Quality Profession Map and provide feedback and support for their career development.</li> <li>• Communicate and promote the benefits and value of the CQI Quality Profession Map to the wider DHCW organisation and stakeholders, highlighting the alignment with the organisation vision and values, the duty of quality and the regulatory requirements.</li> <li>• Evaluate the impact and effectiveness of the CQI Quality Profession Map implementation on the Quality and Regulatory function and the organisation, using data-driven metrics and feedback mechanisms.</li> </ul>	<p>Q1</p> <p>Q2</p> <p>Q3</p> <p>Q3</p> <p>Q4</p> <p>Q4</p>	<p>Monitor – progress will be reviewed at fortnightly Quality objectives update meeting.</p> <p>Specific KPI’s will be developed within the Objectives spreadsheet to define target dates for completion of each element of this objective, this will allow for clear and robust update reports to be presented to Quality &amp; Regulatory group, and Audit &amp; Assurance committee</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
<p>Improve efficiency by streamlining documents and processes by using the WIAG PowerApp</p>	<ul style="list-style-type: none"> <li>Ensuring the PowerApp replaces the current process of using AQPs for signatures before moving onto the SCRR stage.</li> <li>Roll-out of the PowerApp to Assurance Leads and Project Managers, to enable them to receive automated notifications of the status of the project assurance requirements and the projects that are requesting assurance.</li> </ul>	<p>Q1</p>	<p>Monitor – Progress of PowerApp to be added as recurring agenda item at WIAG meetings following fortnightly meetings with Centre of Excellence. End to end walkthrough video to be made available in January for review before testing begins. Progress discussed at quality team meetings. Issues to be reviewed by WIAG and if required escalated to Head of Quality Assurance and Regulatory Compliance.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
iPassport Next Steps	<ul style="list-style-type: none"> <li>• Build the Organisational Units iPassport Portfolios.</li> <li>• Ensure all document types outlined in the Document Management Strategy are migrated, approved and managed on iPassport.</li> <li>• Identify documentation which is managed outside of the IMS and migrate where required.</li> <li>• Aide with building intelligent OU SharePoint portals to access latest documents versions.</li> <li>• Link relevant documentation to clauses within the Standards module to support internal, external audits and compliance.</li> <li>• Capture all Internal &amp; External Audits including findings.</li> <li>• Explore additional modules for organisational use – Equipment, Incident Reports, Inspection Prep, Companies etc.</li> <li>• Explore additional use cases for pilot of change control module</li> </ul>	<p>Q4</p> <p>Q2</p> <p>Q3</p> <p>Q4</p> <p>Q4</p> <p>Q1-4</p> <p>Q1-4</p> <p>Q1-2</p>	<p>Monitor via various Quality meetings. Current and further development of Power Bi dashboards, monthly, quarterly and annual/bi-annual reporting. Making quality specific dashboards available organisation wide. All DHCW staff to have completed basic viewer level one Controlled Document module. All IMS migrated documentation to be managed and approved. 100% uptake across the organisation, in line with document management strategy.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
<p><b>Validation</b> Development of a Strategy for an Agile approach to 'Computerised System Validation'.</p>	<ul style="list-style-type: none"> <li>Explore Agile working and how the methodology can be applied to Computerised System Validation.</li> <li>Perform a gap analysis against Agile requirements to identify any changes to current procedures.</li> <li>Develop strategy for implementation of an agile approach to Computerised System Validation.</li> </ul>	<p>Q1</p> <p>Q2</p> <p>Q4</p>	<p>Monitor – Progress will be reviewed monthly during the Validation Team Monthly Meeting (recurring agenda item) and bi-monthly at the Quality Team Objectives and Planner Review Meetings.</p>
<p><b>Programme/ Project Quality</b> Build on work undertaken with LIMS 2.0 programme to develop a framework for Quality within a Programme/Project</p>	<ul style="list-style-type: none"> <li>Map out Quality requirements within a programme.</li> <li>Map programme activities against the Health and Care Quality Standards 2023.</li> <li>Develop a framework for Quality within a programme/project.</li> </ul>	<p>Q4</p>	<p>Monitor – Progress will be reviewed on a weekly basis via programme checkpoint reports. Validation &amp; Quality objectives are captured within a Gantt chart alongside timescales for delivery. All key activities have defined exit criteria.</p>
<p><b>Validation</b> DHCW Validation is going to scope the potential of offering Validation as a service to Health Boards within Wales.</p>	<ul style="list-style-type: none"> <li>Evaluate the feasibility and effectiveness of this service the Validation team will assess the current position in regard to documentation and processes, to perform a cross analysis against GAMP5. This will ensure full coverage of the service can be measured and applied in varying situations.</li> <li>The team will calculate the capacity needed to run the service on one system to determine the maximum workload that can be offered within current staffing levels.</li> <li>Data from the scoping exercise will be inputted into the 2025/2026 annual plan if deemed applicable.</li> </ul>	<p>Q4</p>	<p>Monitor – Progress will be tracked via regular review against a cross analysis of GAMP5 through Quality Team meetings, and Validation Monthly Meeting where progress against agreed timelines for deciding the feasibility of providing this service will be tracked.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
<p><b>Improvements:</b> Increase the visibility of Quality Assurance &amp; Regulatory Compliance at a departmental level and integrate it across the Organisation by developing processes. Team members to source and attend quality training and learning course to development knowledge and skills.</p>	<ul style="list-style-type: none"> <li>• Insider articles to raise awareness of Quality within the Organisation</li> <li>• 10 talks on (Quality, Medical Devices, iPassport, all improvements)</li> <li>• Integrating Quality at a departmental level by working with leads to focus on Quality Management activities in their areas, including the workshops required for Duty of Quality, this will be led by Directorate Quality Business partners.</li> <li>• Development and roll out of further Quality Improvement tools, including,               <ul style="list-style-type: none"> <li>○ RCA Training</li> <li>○ PDCA Training</li> <li>○ Pareto</li> <li>○ Kaizen</li> </ul> </li> <li>• Develop quality learning and training materials in iPassport.</li> <li>• Implement and maintain a capacity plan for the team.</li> <li>• Develop and maintain an Organisation Site Master file, that all employees will be able to access and view.</li> <li>• Implement a Director led, Quality supported GEMBA process across DHCW.</li> </ul>	<ul style="list-style-type: none"> <li>• One Insider articles to be scheduled in each quarter.</li> <li>• One Ten talk to be scheduled in each quarter.</li> <li>• Quality to attend every directorate SLT monthly meeting. Duty of Quality workshops to be scheduled across DHCW during Q1-Q4</li> <li>• Quality Improvement tools to be developed according to schedule in Quality Objectives planner. All tools to be developed by the end of Q4.</li> <li>• Site Master file to be implemented by end of Q1. Implement a GEMBA process to be implemented by end of Q2.</li> </ul>	<p>Monitor – regular reports on progress to be received by Quality and Regulatory Group.</p> <p>Individual KPI's for each workstream to be developed and hosted within Quality objectives planner and reviewed at each fortnightly meeting.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
<p>Implement the Controlled Document Management Strategy</p>	<ul style="list-style-type: none"> <li>• Provide regular updates to Directorates regarding the roll-out of the Strategy within DHCW.</li> <li>• Implement and complete the roll-out of the strategy to Directorates throughout DHCW.</li> </ul>	<p>Q1</p> <p>Q4</p>	<p>Monitor – Policy and Implementation Plan produced following Executive approval of Strategy (Q4 2023/24).</p> <p>Task and Finish Group with representatives from all directorates to start in Q1 to agree process and timelines for migration of controlled documents.</p> <p>Quality Business Partners to provide monthly updates to SLTs of document migration progress as per agreed timelines and escalate any concerns to Quality Manager (Regulatory Compliance).</p> <p>Monthly updates to QRG and at quality team meetings on the progress of the strategy, escalating any areas of concern to QRG.</p> <p>Monitor – All directorates to have migrated documents in line with the strategy and reported to QRG by the end of Q4.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
Improvement of the Audit Programme	<ul style="list-style-type: none"> <li>Quality team to work with all Standard Leads to identify what training is available and produce a schedule of standard specific training programmes. The aim is to train auditors across several standards by using a cross-clause analysis, which will minimise the number of audits and the time that Auditors and Auditees have to take outside of the delivery of their daily roles.</li> <li>Review the use of AI to conduct a cross clause analysis to streamline the number of internal audits conducted within DHCW. AI will support the analysis as to the number of standards DHCW is currently certified to, or aims to be certified to, as they are growing and therefore increasing the complexity of the analysis.</li> <li>Standard specific training for all Standards will be produced and made available via iPassport.</li> </ul>	<p>Q1</p> <p>Q2</p> <p>Q4</p>	<p>Monitor – Quality team to meet with all assurance leads to discuss training programme. Quality team and assurance leads to agree schedule which approved and reviewed monthly at IMSAG and noted at QRG.</p> <p>Monitor – Team to review findings of AI cross clause analysis and discuss at quality team meeting and IMSAG. Any suggested changes to audit programme to be escalated to QRG. To be added to IMSAG agenda for Q1 for information and Q2 for sharing of information and potential escalation.</p> <p>Monitor – standard specific training progress to be reviewed at IMSAG and noted at QRG. Where there are concerns about progress against agreed timelines, escalation is via QRG.</p>

Objective	Key Activity to Meet Objective	Deliverable	Monitor/KPIs
Benchmark against other NHS digital organisations across the UK nations	<ul style="list-style-type: none"> <li>Identify NHS digital organisations across the UK nations to include in benchmark exercise.</li> <li>Request information regarding business processes, performance metrics, quality standards, and other relevant certifications.</li> <li>Critically evaluate information provided and report findings and recommendations.</li> </ul>	<p>Q1</p> <p>Q1</p> <p>Q2</p>	<p>Monitor – Progress will be reviewed during the fortnightly Quality Team Objectives and Planner Review Meetings.</p>

## APPENDIX TWO - STANDARDS SCOPE

	Summary of Clauses Covered
Quality (ISO 9001)	Context of the Organisation : Leadership : Planning : Support : Operation : Performance Evaluation : Continual Improvement
Service Management (ISO 20000)	SM Policy and Plan : Document Management and Control : Resource Management : Service Improvement (PDCA) : Service Transition : Service Reporting and Service Level Management : Capacity Management : Information Security Management : Service Continuity : Availability : Incident Management : Service Request Management : Problem Management : Configuration Management : Change Management : Release & Deployment Management : Budgeting & Accounting Management : Relationship Management : Supplier Management
Information Security (ISO 27001)	ISMS Policy and Plan : Organisation of Information Security : Human resource security : Asset Management : Access Control : Cryptography : Physical and environmental security : Operations Security : Communications Security : System acquisition, development and maintenance : Supplier relationships : Information security incident management : Information security aspects of business continuity management : Compliance
Valuing People, Diversity & Inclusion (BS 76000)	Context of the Organisation : Leadership : Planning : Support : Support mechanisms : Staying in/continuing the relationship : Getting in/starting the relationship : Operation : Performance Evaluation : Improvement
Environmental Management (ISO14001)	Environmental Strategy : IMS Policy (Inc Environmental Statement) : Environmental Management SOP : Environmental Aspects Register : Legislation Register : Environmental Objectives and Targets : Training : Awareness (Control of Contractors) : Communication : Monitoring and Measuring : Documented Information : Emergency Preparedness and Response : Internal Audit (SHE Inspections) : Management Review : Non-Conformity and Corrective Action (SHE Action Plans)

	Summary of Clauses Covered
Software Development (DHCW standards)	Requirements gathering, analysis and specifications : Planning, estimation and work item tracking : Source control : Software design and maintainability : Coding standards : Code reuse : Observing the 'Definition of Done' : Deployment : Governance of Technologies
Service Desk Institute Certificate	Leadership : Policy and Strategy : People Management : Resources : Processes and Procedures : Managing Employee Satisfaction : Managing the Customer Experience : Management Information and Performance Results : Social Responsibility
GAMP 5 v2	DHCW follow a risk-based approach to Computerised System Validation based on Good Automated Manufacturing Practice (GAMP5 v2) guidelines; this approach allows activities to be scaled according to the scope, complexity, and categorisation of the system, to meet the expectations of the end user and governing regulatory bodies.  Validation is key to ensuring that the systems we supply and/or host are fit for their intended purpose throughout the life cycle of the system. The Validation Team support Projects and Operational Services to adopt a life-cycle approach to Validation from the initial concept phase through to retirement of the system.
Digital Economy Act / Trusted Third Party	DEA Research Code of Practice : DEA Research Code of Practice policies : Information security policies : Organisation of information security : Human resource security : Asset management : Access control : Cryptography : Physical and environmental security : Operations security : Communications security : System acquisition, development and maintenance : Supplier relationships : Information security incident management : Information security aspects of business continuity management : Compliance : Research Governance : Human resource skills and competencies
Medical Device Quality Management Systems (ISO13485)	Quality Management System : Management Responsibility : Resource Management : Product Realisation: Measurement, analysis and improvement

	<b>Summary of Clauses Covered</b>
Information Management (BS 10008)	Information Capture : Information in Structured Databases : Version Control : Storage Systems : Information Transfer : Indexing and Other Metadata : Authenticated Output Procedures : Identity : Information Retention and Disposition : System Maintenance : Information Management Testing : Information Stewardship
Business Continuity (ISO 22301)	Context of the organisation : Leadership : Planning : Support : Operation : Performance Evaluation : Improvement

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