Assessment Report

Pacific Private (Day) Hospital

Assessment dates	02/11/2018 to 02/11/2018
Assessment Location(s)	Southport (000)
Report Author	Jane McGarry
Assessment Standard(s)	ISO 9001:2015

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Executive Summary

Executive Summary

Recommendation:

Continued Certification to ISO 9001:2015 is recommended

No Non-Conformities were identified during this continuing assessment visit.

The safety and quality framework for Pacific Private Day Hospital is supported by an organisational wide governance and quality improvement system monitored through incident management processes, patient feedback, complaints mechanisms and risk management processes.

Pacific Private Hospital has a dynamic leadership team who are committed to the leadership and accountability of the effectiveness of the quality management system which is achieved through Strategic and Operational review.

It is evident the team is working collaboratively to guide the hospital toward excellence and innovation in compassionate, patient centred care which has been demonstrated through the result of 98% achieved from a recent external staff engagement survey that has shown the hospital is focused on 'delivering exception care' achieving the highest staff engagement award in 2018.

The involvement of staff in the development of the PPDH education Hub which is accessible by all staff on the hospital's intranet includes educational videos on Ophthalmology, Plastics, Endoscopy and recycling. Each video provides critical technical knowledge to broaden the scope of all staff particularly non-clinical staff such as clinical coders and front staff.

The innovative organisational risk management, quality and safety system was found to be well embedded throughout the hospital and is reflected in the Hospital Quality Manual which serves as part of the Pacific Private Day Hospital quality management system and available as a resource for new and existing staff.

The intended results of the Quality Management System are detailed in the quality policy (vision) which includes delivering personalised services achieved by providing patients, visitors and colleagues an environment where safety, clinical excellence and professionalism is paramount.

The scope of the quality management system is structured to meet requirements of ISO 9001:2008 and the National Safety and Quality Health Service Standards (NSQHS) 2012 in a private healthcare setting.

The Quality Management System has shown it is designed to support the Strategic Direction and deliver intended results. This was evidenced through corporate and clinical governance, customer involvement, policy development, identification and implementation of risks and opportunities.

Changes in the organization since last assessment

There is no significant change of the organization structure and key personnel involved in the audited management system.

No change in relation to the audited organization's activities, products or services covered by the scope of certification was identified.

There was no change to the reference or normative documents which is related to the scope of certification.

NCR summary graphs

There have been no NCRs raised.

Your next steps

NCR close out process

There were no outstanding nonconformities to review from previous assessments.
No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Please refer to Assessment Conclusion and Recommendation section for the required submission and the defined timeline.

Assessment objective, scope and criteria

The objective of the assessment was to conduct a surveillance assessment and look for positive evidence to ensure that elements of the scope of certification and the requirements of the management standard are effectively addressed by the organisation's management system and that the system is demonstrating the ability to support the achievement of statutory, regulatory and contractual requirements and the organisation's specified objectives, as applicable with regard to the scope of the management standard, and to confirm the on-going achievement and applicability of the forward strategic plan and where applicable to identify potential areas for improvement of the management system.

The scope of the assessment is the documented management system with relation to the requirements of ISO 9001:2015 and the defined assessment plan provided in terms of locations and areas of the system and organisation to be assessed.

ISO 9001:2015
Pacific Private Day Hospital management system documentation

Assessment Participants

Name	Position	Opening Meeting	Closing Meeting	Interviewed (processes)
Jane McLennan	Director of Nursing	X	X	X
David Harper	General Manager		X	X
Amanda Ginger	National Accreditation Manager Healthscope	X	X	
Serena Mills	Front Office Manager	X	X	X
Deb Clark	CSD/Infection Control L2 RN	X		X
Kelly Mercuri	Quality Coordinator	X	X	X
Judy McCorey	CSD Technician			X
Di Rogers	CSD Technician			X
Tracey Ringa	CSD Technician			X
Jenny Patali	CSD Technician			X
Antionette Gouws	RN PACU			X
Jo Matthews	RN PACU			X
Rikki Griffiths	EN Discharge Lounge			X
Nicole Srom	NUM Theatre	X	X	X

Assessment conclusion

BSI assessment team

Name	Position
Jane McGarry	Team Leader

Assessment conclusion and recommendation

The audit objectives have been achieved and the certificate scope remains appropriate. The audit team concludes based on the results of this audit that the organization does fulfil the standards and audit criteria identified within the audit report and it is deemed that the management system continues to achieve its intended outcomes.

RECOMMENDED - The audited organization can be recommended for certification / recertification / continued certification to the above listed standards and have been found in general compliance with the audit criteria as stated in the above-mentioned audit plan.

Use of certification documents, mark / logo or report

The use of the BSI certification documents and mark / logo is effectively controlled.

Findings from this assessment

Leadership and commitment - ISO 9001:2015 (5.1.1; 5.1.2; 5.2.1; 5.3, 6.1 & 6.2, 9.3):

The General Manager of GCPH and PPDH and Director of Nursing (Top Management) are committed and responsible for providing leadership and direction for quality management systems and processes within the PPDH and are committed to the continual improvement of the hospital to deliver a safe and quality service to meet customer focused vision.

The following process, documents and/or records were reviewed

- The strategic direction is detailed in the organisations Strategic Plan, Safety and Quality Plan and Quality Manual outlines goals required to be met by Executive Team to measure success and meeting patient safety objectives.
- **The goals detailed in the strategic plan are cascaded** from the Hospital Executive Management to the PPDH Heads of department with identifiable and measurable targets that integrate the quality management system (QMS) requirements into the business processes and applying a process and risk based thinking approach.
- The Gold Coast Private Hospital Strategic plan 2017– 2019 v 4 RT.PW1 439
- Strategic Plan 2017-2019 includes Pacific Private Day Hospital and describes the organizations' vision which is based on four pillars of Service Excellence, Teamwork and Integrity, Aspiration and Responsibility. Service Excellence identifies Governance as the strategic initiative 'to improve the safety and clinical outcomes of all PPDH private patients through improved governance'
- All risks associated with governance are linked within the strategic direction for governance and the National Safety Quality Health service standards 2012 – actions are identified with KPI/measures and responsibility and timing for each action.
- Management delegate responsibility and authority to employees who manage, perform and verify work affecting quality.
- **Position descriptions describe roles**, responsibilities and authorities, performance reviews, mandatory education, competency assessment and meetings provide avenues for communication policies and procedures and the quality management system requirements. Customer feedback is extracted from Patient experience surveys, Riskman reports, internal and external audits which provide opportunities for innovation and improvement.
- PPDH Organisational Chart (RT.PW1-006 V 9April 2018)
- PPDH Committee Structure (PO1015 – v 6 Oct 2017)
- The Committee structure is colour coded – blue refers to operational and Green is Clinical which clearly depicts the communications between various clinical and non- clinical committees to the Surgical Excellence and Governance, Medical Advisory Committee, Credentialing all reporting through to the Gold Coast Private Hospital Executive and General Manager for the PPDH site.
- Healthscope Shared learning reports April – June 20178 and signed off by Dr Luke Stradwick as chairperson of the Surgical Excellence committee.
- Minutes for Surgical /excellence committee monthly meeting sighted for 19/6/18; 21/8/18.
- Terms of Reference for the Surgical Excellence Committee & Management Committee are reviewed annually.
- Evaluation of Surgical Excellence committee TOR reviewed 1/10/18 **identified all committee objectives were met, show 95% excellent, 5% Good.**

- **The documented quality policy is incorporated** in the Quality manual and developed in consultation with Hospital Executive (Top Management).
- **Quality policy reviewed** on an annual basis at the Hospital Executive meetings meeting minutes reviewed by management committee on 21/8/18.l
- The reviewed quality policy is **communicated** within the organisation and relevant interested parties via contractor induction.
- **The quality policy** is displayed in the Reception area of the hospital and is located in the Hospital Quality Manual.
- **Management Review- Inputs and Outputs** – The management committee meets quarterly minutes for 21/8/18 show standard agenda items that are consistent with other committee meeting agendas.
- Staff meetings held monthly minutes for 21/5/18 & 21/6/18 – action sheet reviewed from May meeting item 6.4 show this item actioned and closed at the following monthly meeting held on 21/6/18 sighted and also displayed in communications books in Endoscopy, communication board in CSD and Communication board OT NUMs office well as posted on the intranet.
- Surgical Excellence meetings held monthly for 19/6/17; 21/8/18.
- **Agenda items reflect the Star Values** listed in the Strategic plan namely: Service Excellence; Teamwork and Integrity; Aspiration; and Responsibility.
- Risk Register is a standing agenda item 5.6 on the management meeting on 15/8/17 to discuss shared learnings and their outcomes.
- Sampled Terms of reference for all management committees are reviewed annually and the objectives contained in the Terms of reference are evaluated.
- Results of evaluation show 95% as excellent for surgical excellence committee

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

The Context and Scope of Management System - ISO 9001:2015 (4, 4.3, 4.4 & 7.5):

The following process, documents and/or records were reviewed:

- **Internal issues** specific to Pacific Private Day Hospital (PPDH) are identified in the Hospital Strategic Plan 2017 – 2019; Safety and Quality Plan and the PPDH Quality Manual; Infection Control; Riskman Register and monthly departmental meetings.
- **External Issues** detailed in the PPDH Quality manual and are through a variety of stakeholders which include regulatory and peak bodies, state Health department, public and Private healthcare sectors, suppliers, tenants, consumers, Australian Commission on Safety and Quality in Healthcare, accredited healthcare professionals.
- **Monitoring and review** of internal and external issues is described in the framework provided in the safety and quality plan, quality manual and strategic plan that details the review process for enhancement of safety, clinical risk management, identification of issues and opportunities for improvement to achieve intended results of the PPDH QMS.
- **Interested parties** are identified in the strategic plan as consumers, families and carers, staff, accredited healthcare professionals, contractors and suppliers, service providers such as pathology medical imaging and pharmacy.
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- The QMS of PPDH applied all requirements contained in the ISO 9001:2015 standard, National Safety and Quality Health Services (NSQHS) standards 2012, and the Healthscope and Pacific Private Day Hospital Safety and Quality Plan, whilst meeting compliance with statutory and regulatory requirements to maintain the hospital licence.
- The QMS applied to all operations carried out at PPDH. **The scope of certification** is "For the provision of elective admissions for ophthalmic surgery, plastic surgery, gastroenterology, dental, orthopaedics and general surgery in private day surgery unit".
- **The sequence and interaction of the** processes required for the QMS are described in the 'Interaction of Processes' map in the PPDH Manual RT.PWI-428 V3 Oct 2018 and include interaction of processes for planning, Management, customer related process, support process, assessment processes, resource management, operations, customer survey, customer complaints, audits, corrective action and system review.
- **PPDH Document Control** is described in the Pacific Private Hospital Manual RT.PW1-428 V3 Oct 2018.
- All documents are controlled according to the Control of Documents PPDH Policy, reviewed in October 2018 v 5, 08.024 due for review Oct 2019 and Control of records 08-027 v 6 reviewed May 2018, due for review April 2018.
- Only documents and forms that have been approved by the General Manager and / or Director of Nursing are able to be used within Pacific Private Hospital.
- Document register of approved internal documents and forms as well as approved external documents and forms.
- PPDH document controller ensures that the registers of documents and forms are kept up to date at all times. No Healthscope policies are kept in hard copy – Healthscope IT has set up access to policies on the L Drive.
- Hard copy the HICMR policies located near NUMS office. CSD and Endoscopy have HICMR relevant policies.

  The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Performance Evaluation
Monitoring, Measurement, Analysis & Evaluation (Measurement, Analysis & Improvement) ISO 9001:2015 cl 9.1.2. 9.1.3, 10.2, 10.3

The following documents, records and processes were reviewed

- **Customer Satisfaction** - Patient surveys and carer surveys with results displayed on the notice board in patient waiting area.
- Patient satisfaction survey October 2018 identified that satisfaction with Pre-admission clinic as 100%.
- Policies and procedures for Corrective No: 08-025 identifies the process for determining and implementing effective immediate corrective actions and proactive and preventive actions.
- Staff engagement for Pacific Private Day Hospital is above Healthscope Corporate KPI for the facility.
- Staff engagement from Pacific Private Hospital survey acknowledged by Healthscope Corporate show 93% - survey conducted by external group Willis Towers Watson 2018
- Pacific Private Hospital awarded the highest staff engagement award in 2018

- Results show 98% of the organization is focused on delivering exceptional patient care.
- Complaints and compliments are entered into Riskman report sighted for 8 complaints entered from Jan 1 to 30 Sept 2018 show 8 complaints and 17 compliments.
- Tabled and discussed at staff meeting minutes sampled 17/10/18.
- Benchmarking through Healthscope's KPI's are reported quarterly and include governance, risk management, credentialing, customer satisfaction, infection control, medication safety, patient identification handover, blood and pressure injuries, clinical deterioration and falls.
- Analysis of data and results are tabled at meetings. Trend analysis is via Management Committee meetings.
- Incident / analysis report in power point presentation presented to Surgical Excellence committee meeting. Trend analysis report for July sighted for WHS (2) cancellations (4), patient care,(1) product issues (3), errors,(1) administration (2), CSSD (1) and transfers (1).
- Management committee meeting minutes for 21/8/18.
- Monthly responses to all questions displayed on staff room notice board.
- My Hospital web page/Pacific Private Day Hospital websites presents the results of their clinical performance and safety measures as community information in providing safe, quality care.
- Qualtrics data added to My Hospital website

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Internal Audit (Internal Audit) ISO 9001:2015 cl 9.2

The following documents and processes were reviewed

- Internal audit policy no 08-023 sighted and accessible to staff on the intranet
- Auditor selection for the facility – 3 trained auditors and recently expand the auditing responsibility for staff.
- Internal audit plan for last financial year has all scheduled audits completed with one outstanding highlighted in red (the coding audit) that is conducted by the state manager.
- Internal audit schedule for July – Oct 2018 completed and highlighted in green remainder of audits scheduled for Nov 2017 – June 2018 highlighted in red and up to date.
- Audit tools with instructions for conducting the audit and examples of how to complete the audit form.
- Internal audit report identifies findings – referenced documents process / item audited and outcome with quality action plan box ticked.
- Each audit report is identified by tracking number e.g. 46.18 identified the number and year for monthly environmental audit conducted on 13/7/18.
- Presentation to the staff meeting 17/10/18 – minutes and verification for the audit results at item 5.4.2.
- Surgical excellence committee on 21/8/18 – minutes and verification for audit results at item 5.4.2.
- Quality action plan 2017/2018 - 44 entries completed with identified responsible person, by when, progress and outcomes and completion date. Three (3) Quality improvements identified and highlighted in yellow for completion with actions to finalise the outcomes.

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Resources, Competence and Awareness (Resources, Competence, Awareness & Training) ISO 9001:2015 cl 7.1-7.4:

The following documents, records and processes were reviewed

- Mandatory Training 4.10 reviewed September 2018 – Corporate policy detailing the mandatory training requirements. Policy was updated in line with the new NSQHS standards.
- Competency and training requirements for PPDH are based on the mandatory training list detailed in the Healthscope policy 4.10.
- Resources in general were found to be effective for the needs of the organisation. This includes people, infrastructure and work environment. Resource review is undertaken during management review and elements of this were noted within the meeting minutes sampled.
- Staffing levels are discussed in Surgical Excellence committee meetings.
- Competence expectations are set by the jurisdiction, Healthscope corporate and the organisation itself.
- Expectations of staff competence are expressed in position descriptions and assessed at performance review, as noted in the position descriptions and performance appraisals sampled.
- Awareness of the quality policy, objectives and their contribution and the implications for not conforming to the system are expressed to staff during the orientation period, as outlined in the Orientation - Employee Competency policy 4.16.
- This was also confirmed with staff interviewed. Policy and objectives are available in the PPHD Manual and this is available on the intranet to all staff.
- Sighted staff intranet – contains education Resource HUB – staff can access video's relating to Ophthalmology; Plastics; PVC Recycling and Endoscopy.

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Requirements for products and services – ISO 9001:2015 8.2:

The following documents, records and processes were reviewed:

- Communication of the requirements for service provision, including determining the needs and expectations, review and changes are achieved through:
- providing information via the PPDH intranet,
- patient information brochure, notice board in patient waiting area,
- My Healthscope Website contains patient journey information that describes expectations and outcomes of particular surgical procedures.
- Change management process RT.PWI-422 flow chart details the steps required to implement and manage the change management within a department.
- Change Plan for distribution of S8 drugs for each list in theatres. PACU nurse and OT NUM sign S8 drugs from main DD room for each specific list. Drugs removed from DD treatment room

storage and delivered to each theatre anaesthetic nurse sign in OT drug book upon receipt of specific drug. Double signage evident in each theatre drug register.

- Swipe visitor entry implemented to the DD room; form sighted with clear methods for recording entry/exit details.
- Pharmaceutical waste contained attached to wall in DD treatment room used for disposal of pharmacy drugs is sealed and disposed through Daniels.

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Externally Provided Processes, Products and Services ISO 9001:2015 8.4.1 – 8.4.3:

The following documents, records and processes were reviewed

Service agreements are in place for all externally provided processes and services. These are reviewed on a 12 monthly basis and the Contractor Evaluation completed and reported.

- Contractor Evaluation 2018-2019 sighted – results discussed at Management committee - 16 contractor evaluations with management approval.
- Agency orientation checklist and qualification review
- SESS Contract annually – 1/10/18
- TIMG – Medical records – 23/10/18
- ALCON – Phaeco machines – 3 year agreement until 2021
- OSZDOC – Scancare network – June 2018
- Maintenance SESS – PreVac Steriliser – August 2021
- Temperature report – August 2021
- If suppliers are found to be underperforming between review periods, this is entered into Riskman incident management system and handled according to local management guidelines. Remediation is sought with the supplier but can be escalated to corporate or legal action taken as required.
- Who's On Location is the contractor management software used to manage and maintain requirements for contractors, including licensing, service agreements, qualifications and induction. It automatically informs PPDH and the contractor when any requirement is within 1 month of expiry. This system was sampled with contractors Caretech and Veolia.

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Management of Patients – Day Operating Theatre ISO 9001:2015 – 7.5.1, 8.1, 8.2.1, 8.2.3.1 (d), 8.5.2, 8.5.3, 8.6.

Sampling of patient management processes (8.2.3.2)

The following documents, records and processes were reviewed

- Patient Process Map in Pacific Private Day Hospital (PPDH) Manual – RT.PWI-428 version 3 Oct 2018 (details the Patient Process Map and policies, procedures, guidelines relating to each episode of care from pre admission, to post-discharge follow up.
- Day Theatre Patient Journey processes sampled from Pre Admission, admission process, Pre-operative Waiting Room, Theatre, Recovery Room and Discharge for patient #108485; #108500; #103826. Clinical handover observed from theatre to recovery.
- Management of patients admitted to PPDH - reviewed patient pre-admission process, interviewed administration officer to verify the patient admission criteria prior to operative procedures.
- Admission scheduling and bookings process – interview Front Office Manager for facility,
- Operating theatre lists sent to PPDH office administration from doctors' rooms – patient's complete pre admission documentation on line or if preferred via pre admission booklet.
- Admission process on presentation to PPDH sighted. Front office manual sighted for Webpas manual version if electronic system off line. All front office staff received training for manual version of Webpas.
- Patient admission and identification process observed with admission nurse, checking patient health information and consent for procedure signed. Patient admission Criteria – 01-00 1version 7 next review Oct 2019 – policy includes guidelines for patient selection and exclusions.
- Patient interview - #103826 pre-op waiting area who confirmed consent for procedure, explanation of procedure and rights and responsibilities discussed.
- Patient property management and documentation management pre-operatively, intra operatively, post operatively and discharge.
- Patient's advised prior to admission not to bring valuables into hospital. Patient property is placed into a carry basket on admission and follows the patient through their journey in the Pacific Private facilitated.
- Legislative compliance – PPDH is a member of the Australian Day Hospital Association which has access to Law compliance.
- Sighted Law Compliance Report – October 2018 details legislative changes and compliance required for each site. The report provides legislative changes per state including Commonwealth.
- Clinical Incident management report for period 1 January – 30 Sept 2018 - 231 incidents noted with report by incident class, no adverse outcomes recorded for the 231 incidents ; 22 incidents related to equipment fault; 31 clinical complications, 17 hazards; 10 manual tasks – no treatment required.
- Patient feedback processes – 100% of patients receive a follow up phone call within 24 hours post op 99 – 99.8% response received.
- Pathology interface - Pathology register sighted and tracks the patient, specimen, number, pathology company – signed in by theatre staff and signed out as taken by pathology contractor.

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Monitoring & Measuring Resources (Control of monitoring and measuring equipment) ISO 9001:2015 cl 7.1.5

The following documents, records and processes were reviewed

Biomedical equipment is serviced in line with requirements and service arrangements. Records of calibration are maintained. The following documents, records and processes were reviewed.

- Endoscope Processing System - Service agreements 31/12/18 Reliance processing machine Steris System 30/6/18
- Defibrillator October 2018 – Nova
- Equipment is tagged for easy visual verification of calibration as per equipment sighted in CSD department.
- AssetPlus is the electronic register of equipment maintenance and was sampled.
- Calibration Certification conducted by HK Calibrations technologies – sighted calibration certification Nova Biomedical. Reference calibration standards used: HKCT'S precision instrument traceable to Australian National Standards via our NATA Certified Calibration Certificate.

The audited processes were found to be effective and compliant with the ISO9001 2015, planned arrangements were met and process results achieved

Next visit objectives, scope and criteria

The objective of the assessment is to conduct a surveillance assessment and look for positive evidence to ensure the elements of the scope of certification and the requirements of the management standard are effectively addressed by the organisation's management system and that the system is demonstrating the ability to support the achievement of statutory, regulatory and contractual requirements and the organisations specified objectives, as applicable with regard to the scope of the management standard, and to confirm the on-going achievement and applicability of the forward strategic plan.

The scope of the assessment is the documented management system with relation to the requirements of ISO 9001:2015 and the defined assessment plan provided in terms of locations and areas of the system and organisation to be assessed.

ISO 9001:2015
Pacific Private Day Hospital management system documentation

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organisation within 30 days of an agreed visit date.

Next Visit Plan

Date	Auditor	Time	Area/Process	Clause
01/11/2019			Leadership/Management Responsibility- Leadership and Commitment, Policy, customer focus, scope, objectives and targets, planning, responsibility, authority, accountability and communication, management review	
01/11/2019			Context and Scope of Management System - external and internal issues, needs and expectations of interested parties, boundaries and applicability of the management system	
01/11/2019			Planning, Risks and Opportunities	
01/11/2019			Internal audits and Inspections -	
01/11/2019			Customer related processes - Patient Management	
01/11/2019			Operational Planning - Requirements for products and services - Central Sterile Department	
01/11/2019			Monitoring, Measurement, Analysis, Evaluation and Improvement - customer satisfaction, system performance, non- conformity, corrective action and continual improvement	
01/11/2019			Monitoring and measuring resources	
01/11/2019			Communication	
01/12/2019			Externally provided processes, products and services - Procurement, Subcontractor Management	

Appendix: Your certification structure & ongoing assessment programme

Scope of Certification

FS 614825 (ISO 9001:2015)
For the provision of elective admissions for ophthalmic surgery, plastic surgery, gastroenterology, dental, orthopaedics and general surgery in private day surgery unit.

Assessed location(s)

The audit has been performed at Central Office.

Southport / FS 614825 (ISO 9001:2015)

Location reference	0047520130-000
Address	Pacific Private (Day) Hospital 123 Nerang Street Southport Queensland 4215 Australia
Visit type	Continuing assessment (surveillance)
Assessment reference	8834181
Assessment dates	02/11/2018
Audit Plan (Revision Date)	02/11/2018
Deviation from Audit Plan	No
Total number of Employees	83
Effective number of Employees	35.7
Scope of activities at the site	Main Certificate Scope applies.
Assessment duration	1 day(s)

Certification assessment program

Certificate Number - FS 614825
Location reference - 0047520130-000

		Audit1	Audit2	Audit3	Audit4
Business area/Location	**Date (mm/yy):**	11/2017	11/2018	11/2019	11/2020
	Duration (days):	3	1	1	2.5
Leadership/Management Responsibility- Leadership and Commitment, Policy, customer focus, scope, objectives and targets, planning, responsibility, authority, accountability and communication, management review		X	X	X	X
Context and Scope of Management System - external and internal issues, needs and expectations of interested parties, boundaries and applicability of the management system		X	X	X	X
Planning, Risks and Opportunities		X	X	X	X
Internal audits and Inspections -		X	X	X	X
Customer related processes - Patient Management Operation Central Sterile Department		X	X	X	X
Monitoring, Measurement, Analysis, Evaluation and Improvement - customer satisfaction, system performance, non-conformity, corrective action and continual improvement		X	X	X	X
Review of previous BSI report findings		X			X
Management System/Process Requirements /Documented Information		X	X	X	X
Resources - people, infrastructure, environment, organisational knowledge		X	X		X
Monitoring and measuring resources		X	X		X
Communication		X	X	X	X
Design and Development		X			X
Externally provided processes, products and services - Procurement, Subcontractor Management		X		X	X
Operation - Patient Management, Operation - Central Sterile Department		X	X		X
Transition to ISO 9001:2015 (Additional 1 Day).					

Expected outcomes for accredited certification.

What accredited certification to ISO 9001 means

ISO 9001:2015 specifies requirements for a quality management system when an organization: needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; and aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

What accredited certification to ISO 9001 does not mean

1) It is important to recognize that ISO 9001 defines the requirements for an organization's quality management system, not for its products and services. Accredited certification to ISO 9001 should provide confidence in the organization's ability to "consistently provide product that meets customer and applicable statutory and regulatory requirements". It does not necessarily ensure that the organization will always achieve 100% product conformity, though this should of course be a permanent goal.
2) ISO 9001 accredited certification does not imply that the organization is providing a superior Product or service, or that the product or service itself is certified as meeting the requirements of an ISO (or any other) standard or specification.

Definitions of findings:

Non-conformity:

Non-fulfilment of a requirement.

Major nonconformity:

Nonconformity that affects the capability of the management system to achieve the intended results. Nonconformities could be classified as major in the following circumstances:

- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity:

Nonconformity that does not affect the capability of the management system to achieve the intended results.

Opportunity for improvement:

It is a statement of fact made by an assessor during an assessment, and substantiated by objective evidence, referring to a weakness or potential deficiency in a management system which if not improved may lead to nonconformity in the future. We may provide generic information about industrial best practices, but no specific solution shall be provided as a part of an opportunity for improvement.

Observation:

It is ONLY applicable for those schemes which prohibit the certification body to issue an opportunity for improvement.
It is a statement of fact made by the assessor referring to a weakness or potential deficiency in a management system which, if not improved, may lead to a nonconformity in the future.

How to contact BSI

Should you wish to speak with BSI in relation to your registration, please contact your customer service officer.

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E-mail (for corrective action plans): Please e-mail your corrective action plan to clientservices.au@bsigroup.com

Notes

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This audit was conducted on-site through document reviews, interviews and observation of activities. The audit method used was based on sampling the organization's activities and it was aimed to evaluate the fulfilment of the audited requirements of the relevant management system standard or other normative document and confirm the conformity and effectiveness of the management system and its continued relevance and applicability for the scope of certification.

As this audit was based on a sample of the organization's activities, the findings reported do not imply to include all issues within the system.

Regulatory compliance

BSI requires to be informed of all relevant regulatory non-compliance or incidents that require notification to any regulatory authority. Acceptance of this report by the client signifies that all such issues have been disclosed as part of the assessment process and agreement that any such non-compliance or incidents occurring after this visit will be notified to BSI as soon as practical after the event.