Assessment Report.

Viamed Ltd

Report Author **Malcolm Goodall**

Visit Start Date 12/08/2015

Introduction.

This report has been compiled by Malcolm Goodall and relates to the assessment activity detailed below:

Visit ref/Type/Date/Duration	Certificate/Standard	Site address
8229691 Re-certification Audit (RA Opt 2) 12/08/2015 2.5 day(s) No. Employees: 14	CE 01389 Healthcare 93/42/EEC Annex II, Sec 3.2 (2007/47) CE MARKING Richard Tully MD 78787 ISO 13485:2003 ISO 13485: 2003 N/A Richard Tully FM 540797 ISO 13485:2003 CMDCAS CMDCAS Richard Tully FS 28344 ISO 9001:2008 CE 97289 Healthcare 93/42 OBL Annex II, Sect 3.2 (2007/47) CE MARKING Richard Tully CE 540537 Healthcare 93/42 OBL Annex II, Sect 3.2 (2007/47) CE MARKING Richard Tully	Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom

To conduct a recertification assessment to determine the effective implementation of elements of the QMS applicable within the proposed scope of registration are in accordance with the company objectives, applicable requirements of the management standard(s) & BSI Conditions of Contract and to determine whether a re-certification recommendation can be made.

To verify Viamed Ltd continues to effectively implement all requirements of ISO9001:2008.

To verify Viamed Ltd continues to effectively implement all requirements of ISO13485:2003.

To verify Viamed Ltd (Company ID No. 128822) continues to implement all requirements of ISO13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.

To determine if the management system continues to meet the requirements of: 93/42/EEC Annex II 3.2

Management Summary.

Overall Conclusion

The objectives of the assessment were met.

There were no obstacles encountered during the course of the audit. No factors were encountered during the audit that would affect the reliability of this assessment.

All areas were covered per the assessment plan.

The report was finalised and issued on 14th August.

This report is eligible for submission to US FDA under FDA ISO 13485 Voluntary Audit Report Submission Program.

The management system continues to be generally effectively implemented, addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. The result of this assessment enables a recommendation for recertification dependent on submission of a satisfactory action plan.

A corrective action plan is required to define the action to address the non-conformities identified during this assessment and detailed in this report. The corrective action plan must include the correction (containment), root cause, corrective action, timescales & person responsible for implementation.

All Requirements of ISO 9001:2008 continues to effectively implemented.

All Requirements of ISO 13485:2003 [and EN ISO 13485:2012 as applicable] continue to be effectively implemented.

The capacity to systematically meet agreed requirements for products and services supplied within the scope of the certificates is confirmed and the requirements of ISO 13485:2003 and Part 1 of the Canadian Medical Device Regulations are being met.

The management system meets the requirements of MDD 93/42/EEC Annex II 3.2

There were no outstanding nonconformities to review from previous assessments.

5 minor nonconformities requiring attention were identified. These, along with other findings, are contained within subsequent sections of the report.

A minor nonconformity relates to a single identified lapse, which in itself would not indicate a breakdown in the management system's ability to effectively control the processes for which it was intended. It is necessary to investigate the underlying cause of any issue to determine corrective action. The proposed action will be reviewed for effective implementation at the next assessment.

Please submit a plan to BSI detailing the nonconformity, the cause, correction and your proposed corrective action, with responsibilities and timescales allocated. The plan is to be submitted no later than 10/09/2015 by e-mail to msuk.caps@bsigroup.com, referencing the report number.

Mandatory Requirements – Re-Certification.

Review of assessment finding regarding conformity, effectiveness and relevance of the management system:

1 Minor non-conformity has been identified which was effectively closed at the following visit.
The non-conformity are not considered to indicate an underlying weakness in the management system.
A commitment to maintaining and improving the effectiveness of the management system is shown by the client.

Assessment of the Management Review, KPI's, internal audit, corrective and preventive action processes and records confirm the management system to be effectively implemented and maintained.

Management system strategy and objectives:

The client expects to maintain the management system in line with new statutory, international and regulatory requirements.

Review of progress in relation to the organisation's objectives:

Management commitment was seen to be effective in reflecting the requirements of the standard regarding stakeholder focus, management system policy.

Objectives set for the next three years include
- year on year growth.
- diversify into additional markets such as veterinary, oil and gas as well as maintaining medical and automotive business streams.
- staying in business due to new regulatory restraints.

Review of assessment progress and the re-certification plan:

Since the last re- certification in 2012 a total of 5.5 days assessment (including this audit and UAV) have been completed.
This was in line with scheme requirements and the recertification plan (three year plan).
The assessment durations (surveillance and recertification assessments) were in accordance with the IAF MD9 duration guidance.

Area's covered during the last visit cycle are manufacture, repair, management system maintenance, design, control of external manufacture and sub-contract manufacture. This is in line with certification scopes.

A review the the visit durations has been completed with the recommendation for continuation of the current visit duration at 1/1/2 days per annum. This does not include OBL requirements.

BSI Client Management Impartiality and Surveillance Strategy:

3 auditors have been involved since the last re-certification in 2012
Assessor qualifications have been reviewed and found to be appropriate.
Assessor impartiality has been reviewed and it is confirmed there is no conflict of interest.

Do you want the current Total assessment days / Cycle to continue ?

Yes

Areas Assessed & Findings.

Opening meeting :

The opening meeting was conducted with the presence of the MD.

The assessment plan, objectives and scope of the assessment were confirmed.

The opening meeting and full assessment was performed in English.

Audit Scope:
This visit will cover the location activities for the management system processes at the 15/17 Station Road, (adjacent premises) Cross Hills, Keighley, BD20 7DT address being audited in the UK.

Scope of Certification:
The registration certificates and scope of the registration were confirmed as follows:

FS 28344 The design and manufacture of supramaximal nerve stimulators.

CE 01389 - The design and manufacture of microstim nerve stimulators, oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

(Certificate amended - removal of reference to Pulse Oximeter Probes)

MD 78787 - The design, outsource manufacture, manufacture and service (including that carried out on customer premises of nerve stimulators and nerve locators, resuscitators, monitoring devices for physiological parameters including accessories) of the following: Apgar timer; Gas Exchange monitors; Oxygen monitors; Oxygen Sensors; Pulse Oximeters; Pulse Oximetry sensors and cables; Temperature monitors; Temperature probes and cables including Temperature probes in catheters ; Cot lids; Gas respiratory adaptors; Gas respiratory valves; Heat shields; Nerve locators; Nerve stimulators; Oxygen hoods and tents ; Phototherapy light shields; Resusitators; Ventilation tube holders; Simulation, Test and Calibration Equipment for monitoring devices.

FM 540797- The design and manufacture of supramaximal nerve stimulators.

(Certificate amended - removal of reference to Infant Resuscitators in line with MDALL listing)

CE 97289 - Design and manufacture of Electrochemical Oxygen Sensors.

CE 540537 - The design and manufacture of Sp02 modules and monitors and sensors, gas flow sensors, breathing gas exchange monitors and sensors, gas sampling lines and temperature probes

(Certifcate amended - addition of gas sampling lines and identification of Sp02 modules in line with change to OEM CE certificate)

Quality Manual version:
Electronic, document number 14445/2014

Exclusions and Non-Applications of Requirements in the QMS:
No exclusions are claimed. Requirements for active implantable and sterility are not applicable due to the nature of the products.

Significant Changes:
There have not been any major or significant changes to the QMS, structure, or device since the last visit.

Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been no adverse incidents, recalls, or requirement for field safety corrective actions or (vigilance/mandatory problem reports) since the last report.

Corporate Identity of the Manufacturer:
Viamed is a family business designing, manufacturing and distributing a range of medical devices. VST also operates from the same premises as a separate company utilising common resources. For commercial reasons VST has its own ISO 9001 certificate.

Description of the manufacturer:
Viamed distribute a range of medical devices in a world market. Some devices are sold under OBL agreements. The manufacture of some devices is outsourced. Some small scale manufacture takes place of legacy products. Processes include QA, design, manufacture, purchasing, sales, warehousing and distribution.

Critical Subcontractors:
Blue Point Medical GmbH & Co. KG, An der Trave 15, 23923 Selmsdorf, Germany for the manufacture of instrumentation Instrumentation Industries (Manufacture).

Senior Management of the Assessment Location(s).
Mr Derek Lamb – MD/CEO

Dates of the Audit:
12th and 13th August 2015

Quality System maintenance : 5.6, 8.2.2, 8.5.2, 8.5.3

The client has created and implemented a system called Intrastat. All documents, planning, processes, files, issues (actions) and records are maintained through this system.

Quality Policy - is witnessed to meet the standard requirements establishing a framework for objectives. The policy was issued in 2011 however the system does not entirely meet the standard in that no evidence is available to show the policy is reviewed for continued suitability. See NCR 1226815N1

Quality Objectives were reviewed which are aligned for monitors against purchase orders, invoicing, back orders, sales order quantities and number of returns. Data is analysed for trends and is currently available upto July 2015

Management review: A rolling 3 monthly review covers all aspects of the management system within a 12 month period. The last review in July by the MD shows a multi point agenda from the electronic management system covering the requirements of 5.6 including regulatory changes and post market surveillance.

Internal audits: The audit plan is up to date with the schedule with no overdue actions. Two auditors are used to ensure objectivity. Procedure VM3/COP/13 Issue 3 covers the process. Review of audits for Design and Despatch Audit 03 and 01 respectively show a check list approach however for the audit against design it is unclear to the objective evidence reviewed as part of the audit. See NCR1226815N2

Complaints, capa and vigilance: Procedure VM3/COP/10 Complaints and CAPA, VM3/COP/10/02 for Vigilance. Samples from the complaints and capa log were seen for entries since the previous visit. 2 complaints have been received since the last visit not related to Medical devices. Complaint 147 issue 58920 was reviewed with investigation completed and supplier issue raised and completed. No vigilance issues have been received.

The capa/ncr log showed only minor issues with appropriate investigation to cause.

Core QA processes were seen to be generally effective and to follow documented .

Regulatory requirements are generally met in the management system however review of CMDR requirements show not all requirements have been met. See NCR 1226815N3

Top Management Discussion : 5

The managing director and Chairman were available to present the top management aspects of the management system.
Commitment to maintenance of the effectiveness of the management system was demonstrated.
The quality policy and objectives were assessed for its suitability in communicating the ongoing business strategy.
Processes for review of management system effectiveness were explained.
Communications processes were presented and considered consistent with the approach observed during assessment of other areas of the organisation.

Resource needs (Personnel, infrastructure and environment) have been determined and are considered appropriate in relation to management system performance.

Purchasing and supplier control : 7.4.1, 7.4.2

Procedure VM3/COP/04 Purchasing and Suppliers and VM3/COP/05 Receipt of Goods describe the purchasing process. The Intrastat system is used to idnetify products and parts within a 2 to 3 month stock usage against sales orders. The system colour codes items short or nearing shortage of stock to allow orders to be raised. Orders are raised through the MRP system and include description and supplier codes enabling specification to be identified. The process was reviewed for orders 10327, 10303, 10241, 102143 and 10313. With detail includes and authorisation by the MD for each order as required by internal procedures.

Control of suppliers is witnessed through supplier Teledyne, Bunzl healthcare, Inspiration Healthcare, Maxtec, Sunnycare medical. All required documentation is witnessed through the system with the system identifying certification expiry.

The overlall process for purchasing and supplier control is seen to be effective.

Document and Record Control : 4.2.3, 4.2.4, 6.3

Procedure VM3/COP/14 Documentation details document control, storage and authorisation. Again the Instrastat system is used to control version history and issue with documents ID's allocated to individual documents with only current documents viewable to all users accept the MD. Amendments are raised through the issue log with an amendment log maintained. Obsolete documents are archived. Documents of external origin are also maintained and controlled in the same way.

Page level security is witnessed for viewing e.g all use or internal use only.

Control of Records are seen through the Intrastat system with all records maintained indefinitely including notified body and competent authority records.

Review of the back up system was performed with the main server backing up to a back up server nightly with the back up server located in another building. Zip files are maintained and kept off site.

The system for record and document management is considered to be effective.

Competence, training and awareness : 6.2.2, 4.2.4

A review of hte competency and training process was performed. Matrix is maintained through the Intrastat system with hard copy records maintained in personnel files.

Records for Emily Hanson (Sales), Catherine Spence (Picking) and Emma Clark (Inspection) were reviewed and although records are maintained the Intrastat system did not match the hard copy records in all cases. See NCR 1226815N4

Sales, order processing, stores and dispatch : 4.1, 4.2, 6.3, 6.4, 7.1, 7.5, 8.2.4

Helen provided an overview of the process where orders are received and processed on the Intrastat and Opera systems. This included the independent check on orders before processing, the bar code order identification system and the stores processes for both receiving and despatch.
The same process is used for all products, including oxygen sensors sold under the VST name and certificate FM 607767.
Samples from recent orders were seen to follow the process as stated and as documented in the Sales Order Processing procedure VM3-COP-20.5 issue 3. The independent check, input to output was demonstrated on the software system traceable by the log in process. Process interaction includes links to purchasing to ensure appropriate stocking levels and the grading of orders, such as urgent requests to ensure processing in a timely manner. For convenience orders are printed
The warehouse was visited where the same information used to pick and dispatch orders, both on screen and in printed orders was seen. All product in the warehouse had clear status using unique bar codes for each product and was appropriately stored. No product requires special storage conditions or has limited shelf life. The software system ensures rotation, last in, first out.
Packing is generally of boxed oem equipment and low risk being described in VOP-22-01.1 issue 1. Some items require special packaging instructions, such as hoods and light shields. Packaging instructions for these items was seen to be detailed in VM3-COP-52.02
The 100% goods receiving process was demonstrated for pulse oximeters (OBL product) and nerve stimulation product. The inspection is in two parts, pre QA on receipt and QA before becoming available stock. Identification is in the bar code and also in segregated areas of stock.
Product is read from the bar code and on screen instructions provide inspection instructions such as function tests and checks on the ifu issue status.
The nerve stimulator receives a go, no go test. This was audit trailed back to technical files where the test was seen to be appropriate.
The environmental conditions were seen to be appropriate for product sold socially clean.
The sales order processing, stores and dispatch processes were seen to be effective.

Virtual manufacture and OBL products : 4.1, 4.2, 6.2, 6.3, 6.4, 7.1, 7.5, 7.6, 8.2.3, 8.2.4, 8.3

Steven provided an overview of the arrangements in place to control outsourced product, some of which is sold under OBL certificates.
The arrangements for the nerve stimulator product and the 100% incoming testing seen in the warehouse were confirmed for this product covered under CE 01389.
Contracts for suppliers of OBL product such as pulse oximeters under CE 540537 and oxygen sensors under CE 97289 were seen to have the same basic contact and layout. The contract for oxygen sensors is currently under review to add further products.
The detail of the contracts was examined against the requirements of 2013/473/EU. The contract implies most of the requirements but does not specifically state that all requirements by both parties will be met and relevant information exchanged and this was raised as an issue for corrective action.
The client operates a common quality system for all products and services and no distinction, other than in technical files is made regarding how product is purchased, handled or tested.
The communication between OEM and OBL was demonstrated in respect of labelling and marking for pulse oximeter product where information used by the OEM in English is mirrored with changes in only the name and address.
Virtual manufacture and OBL control was seen to be generally effective.

Design : 4.2, 7.3

There has been no design or design change activity for some time. Only legacy product having been through the clients own design process, products which are now several years old. Current product sales are either bought in and sold on, outsourced or OBL product.
The design process is documented in VM3/COP/16 issue 3 which specifies design requirements for design input, risk management and input review, design reviews and validation that includes clinical data.
Technical files were seen for the Nerve stimulator products which were seen to be constructed in line with meddev guidance.
The client has recently received both routine technical file and OBL visits where technical files were examined by a technical expert.
Design input is seen to include requirements of the Canadian MDR
Documented procedures were seen to be inclusive however there has been no recent activity to sample.

During the course of the visit logos were found to be used correctly.

Minor Nonconformities Arising from this Assessment.

Ref	Area/Process	Clause
1226815N1	Quality System maintenance	5.3
Scope	MD 78787	
Statement of non conformance:	Review of the quality policy for continued suitability is not fully effective.	
Requirements:	Quality policy Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	
Objective Evidence:	The policy reviewed is dated 2011, however there is no evidence that the policy has been reviewed since for its continued suitability.	

Ref	Area/Process	Clause
1226815N2	Quality System maintenance	8.2.2
Scope	MD 78787	
Statement of non conformance:	The internal audit records are not fully effective.	
Requirements:	Internal audit	

	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). NOTE See ISO 19011 for guidance related to quality auditing.
Objective Evidence:	On review of the internal audit performed 15/7/2015 AUD-03, there is not indication as to what was reviewed to obtain the audit conclusion

Ref	Area/Process	Clause
1226815N3	Quality System maintenance	4.1
Scope	FM 540797	
Statement of non conformance:	Description of responsibilities for international regulations is not fully effective.	
Requirements:	The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.	

	These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1). NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.
Objective Evidence:	On review of the top level management system in line with CMDCAS requirements the management system does not fully define responsibilities for - person responsible for meeting CMDR requirements - requirements to submit certificate within 30 days. - to submit licence product list annually Although procedure VM3/COP/01 for Amendments goes some of the way to satisfy these requirements.

Ref	Area/Process	Clause
1226815N4	Competence, training and awareness	6.2.2
Scope	MD 78787	
Statement of non conformance:	Training records are not fully effective	
Requirements:	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4). NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.	
Objective Evidence:	On review of training records for Emma Clark and Catherine Spence the electronic records did not always match the hard copy records.	

Ref	Area/Process	Clause
1226815N5	Virtual manufacture and OBL products	
Scope	CE 540537	
Statement of non	The technical agreement lacks some detail	

conformance:	
Requirements:	2013/473/EU
Objective Evidence:	The technical agreement with Bluepoint dated Oct 2009 does not specify: That the oem will accept unanounced visits by the Notified Body (currently by prior agreement) Specify products covered by generic description and not specific models or types e.g. SpO2 sensors rather than any unique description such as model/type. Specify that the oem will maintain CE certification and communicate and update with new copies of the certification when and if it changes. Does not specifically detail arrangements to exchange information regarding any recall activity Does not specify any document retention period for the oem. Is not specific regarding the communication between obl and oem of relevant feedback (post market surveillance) information.

Assessment Participants.

On behalf of the organisation:

Name	Position
Mr Derek Lamb	Managing Director
John Lamb	Chairman
Helen Lamb	Director and Company Secretary
Steven Nixon	Director - Product Developmner

The assessment was conducted on behalf of BSI by:

Name	Position
Malcolm Goodall	Team Leader
Edward Collins	Team Member

Continuing Assessment.

The programme of continuing assessment is detailed below.

Site Address	Certificate Reference/Visit Cycle	
Viamed Ltd 15/17 Station Road Cross Hills Keighley BD20 7DT United Kingdom	Contract 200483566	
	Visit interval:	12 months
	Visit duration:	1.5 Days
	Next re-certification:	01/09/2018

Re-certification will be conducted on completion of the cycle, or sooner as required. An entire system re-assessment visit will be required.

Certification Assessment Plan.

VIAMED-0009370214-000|Contract 200483566

		Visit1	Visit2	Visit3
Business area/Location	**Date (mm/yy):**	09/16	09/17	09/18
	Duration (days):	1.0	1.0	2.0
Core QA processes - Including: The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes, and complaints.		X	X	X
General objectives for quality and improvement		X	X	X
Scheme requirements for vigilance and feedback		X	X	X
Design				X
Manufacture and test:		X	X	X
Head boxes and phototherapy shields			X	X
Nerve stimulators		X		X
Tom Thumb resuscitator			X	X
Purchasing and supplier controls		X		X
Sales and order processing			X	X
Reassessment visit				X
Discussion with Top Management				X

Next Visit Plan.

Visit objectives:

To conduct a surveillance assessment to determine the continued effective implementation of the company's management system, in accordance with the company objectives, the management standard & BSI Conditions of Contract and to determine whether a recommendation for continuing certification can be made.

To verify Viamed Ltd continues to effectively implement all requirements of ISO9001:2008.

o verify Viamed Ltd continues to effectively implement all requirements of ISO13495:2003.

To verify Viamed Ltd (Company ID 128822) continues to implement all requirements of ISO13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.

To determine if the management system continues to meet the requirements of 93/42/EEC Annex II 3.2

Date	Assessor	Time	Area/Process	Clause
06/09/2016	Ed Collins	0900	Opening Meeting	
		0930	Review of findings from previous visit	8.5.3
		1000	Core QA processes - Including: The use of BSI and UKAS logos, internal audits, management review, customer satisfaction, preventive action, corrective action processes, and complaints.	4, 5, 8
			General objectives for quality and improvement	4, 5
			Scheme requirements for vigilance and feedback	8.5.1, 8.2
		1100	Purchasing and supplier controls	7.4.1, 7.4.2, 7.4.3
		1230	Lunch	
		1300	Manufacture and test: Nerve stimulators	7.5.1, 4.1, 7.4.3, 8.3, 7.6, 7.5.3, 7.5.5
		1515	Summary Report Preparation	
		1600	Closing Meeting	
			Full report to follow	
07/09/2016		0900	OBL requirements for OBL products	
		1230	Closing Meeting	7.4.1, 4.1

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. It is a condition of Registration that a deputy management representative be nominated. It is expected that the deputy would stand in should the management representative find themselves unavailable to attend an agreed visit within 30 days of its conduct.

Notes.

The assessment was based on sampling and therefore nonconformities may exist which have not been identified.

If you wish to distribute copies of this report external to your organisation, then all pages must be included.

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Davy Avenue, Knowlhill
Milton Keynes
MK5 8PP

Tel: +44 (0)845 080 9000

Email: MK.Customerservices@bsigroup.com

Regulatory Compliance.

BSI conditions of contract for this visit require that BSI 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 the BSI client manager as soon as practical after the event.

Expected Outcomes for Accredited Certification.

What accredited certification means:

The accredited certification process provides confidence that the organization has a management system that conforms to the applicable requirements of the certified standards covered within this assessment and scope of certification.

What accredited certification does not mean:

It is important to recognize that certification defines the requirements for an organization's management system, not for its products or services. It does not imply that the organization is providing a superior product or service, or that the product, service or performance itself is certified as meeting the requirements of an ISO standard or specification or that the organisation can guarantee 100% product, service or performance conformity, though this should of course be a permanent goal.