

BSI Audit 359521 1996 July



VIAMED



Attention Selina Bell
BSI QA
P O Box 375
Linford West
MILTON KEYNES
MK14 6LL

Dear Selina

REF: CORRECTIVE ACTION BS AUDIT - 27.3.96.

Further to last BS Audit on 27.3.96. please note the following:

Reference 1. Audits - Now updated, see attached.

Reference 2. Management Review - See attached Agenda update.

Reference 3. Thermacot Test Procedure - Currently being submitted for BS5724. undergoing design changes. Test procedure therefore to be re-written on completion

Reference 4. Suppliers Register updated on regular required basis. Also checked annually on audit.

This completes the corrective action. Please do not hesitate to contact me if you have any further queries in this matter.

Yours sincerely

E. Gillespie (Miss)
Office Manager



Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel: 01535 634542 / 636757 Fax: 01535 635582
Registration No. 1291765 in England



Nonconformity report

Report no. 201673/6

Sheet no. 3

Client's representative

Ms. E. GILLESPIE

BSI QA assessor

M. J. BESANT

Reference	Details of nonconformity	Date
MTR1.	RELATED FROM PREVIOUS VISIT - CORRECTIVE ACTIONS ARE NOT BEING SIGNED OFF BY THE MANAGING DIRECTOR TO CONFIRM EFFECTIVENESS AS REQUIRED BY PROCEDURE VM(COP)13. ISSUE 2	4.17.
MTR2	RECORDS OF MANAGEMENT REVIEW DATES NOT SHOW EVIDENCE THAT ALL TOPICS OF AGENDA (APPENDIX A - VM(COP)13 ISSUE 2) HAVE BEEN DISCUSSED AND ACTIONED	4.1.3
MTR3.	THERE IS NO DOCUMENTED METHOD OF TEST - FOR THERMOCOVS	4.10
MTR4	PROCEDURE VM(COP)04 ISSUE 2 REQUIRES YEARLY REVALIDATION OF SUPPLIER CERTIFICATION STATUS, THIS IS NOT BEING CARRIED OUT.	4.6.

Details of corrective action undertaken during assessment

Receipt of nonconformity report acknowledged
and content understood.

Signed,
for Client

Signed,
for BSI QA

John B. Gillespie

Michael T. Belis

Date 27 Mar 26

COMPANY OPERATING PROCEDURES**System Audits and Review**

VM/COP/13

Issue 2 Rev1

Page 1 of 2

1. AUDITS

- 1.1 Audits will be carried out by the Managing Director or Nominee but the nominee cannot be the department representative.
- 1.2 Relevant sections of the Quality System will be audited according to the Audit programme (Form QC17) as follows:
 - 1.2.1 Check conformance to the statements in the Quality Manual and procedures manual. Audit questionnaires will be used as a guide.
- 1.3 As part of the procedure, samples of documents used will be taken and checked for correct entering and use.
- 1.4 Departures from conformance to procedure will be recorded, and will be examined in order to establish the reason for the non-conformance.
- 1.5 When the reasons for non-conformance have been established, corrective action will be considered, this may include:
 - a) Returning to the original procedure.
 - b) Modifying the original procedure in the light of the reasons for non-conformance.
 - c) Preparing a completely new procedure.
- 1.6 During 1.3 and 1.4 above, the opinions of, and suggestions from those operating the procedure will be sought and corrective action established as necessary.
- 1.7 The results of the Audit will be recorded on the System Audit Record (Form QC18) stating the corrective action and the time scale for its completion.
- 1.8 If it is necessary for the Quality Manual to be revised, the pages in question must be held for approval by the Assessment Body. The approved revised page(s) will be incorporated in the master manual and copies circulated to all holders of Controlled Copies of the Manual.
- 1.9 If the revisions is of a procedure only, it will be revised and circulated in accordance with the amendment control procedure.

COMPANY OPERATING PROCEDURES

AMENDMENT CONTROL

VM/COP/01
Issue 2
Page 3 of 3

Amendment

<u>Cop Nos</u>	<u>Issue</u>	<u>Date</u>	<u>Rev</u>	<u>Paragraph/Page</u>
VM/COP/05	1	01/04/93	1	Page 1, para 1.3 Amended to include initialling copy Purchase Order
VM/COP/09	1	01/04/93	1	Page 2, para 4.1.2 amended to include SRN No. in Repairs Book
VM/COP/06	1	27/04/93	1	Page 1, section 2.2 amended Records kept in Supplier File
VM/COP/09	1	27/04/93	2	Page 4, Paras 4.3.1 and 4.3.2 amended on Recording Checks
VM/COP/11	1	24/05/93	1	Page 1, para numbering changed; para 2.2 includes Accept Criteria: para 3 includes colour coding status.
VM/COP/09	1	01/08/93	1	QC09 Form upgraded Page 5 Para 6.3 amended.
VM/COP/08	1	02/11/93	1	Page 2 Para 3.1 Pink copy should be filed
VM/COP/03	1	05/05/94	1	Addition of Para 4.1.2 . Page 3 Para 3.2 removed
VM/COP/07	1	05/05/94	1	Page 2 addition of Para 3.6/3.7/3.8
VM/COP/05	1	05/05/94	2	Page 2 addition of para 4
VM/COP/06	1	05/05/94	2	Page 1 addition of para 2.3/2.4
VM/COP/14	1	05/05/94	1	Page 1 addition of Para 4 Para 3 amended para 5 amended
VM/COP/14	1	05/05/94	1	Page 5 para 3 amended
VM/COP/09	1	05/05/94	3	Form QC10b added
VM/COP/09	1	05/05/94	3	Page 5 Para 6.3 extended
VM/COP/12	1	05/05/94	1	Para 7 amended
VM/COP/02	1	05/05/94	1	Page 2 para 2.3 amended
VM/COP/04	1	05/05/94	1	Page 1 para 1.5 added
VM/COP/13	1	01/11/94	1	Sect. 11 & 12 added
VM/COP/09	1	01/11/94	2	Computer printout QC10b
VM/COP/05	1	01/11/94	3	Rewritten to match procedure
MANUAL	2	01/11/95		Updated to BS EN ISO 9001/EN46001
VMCOP/13	2	01/07/96	1	1.10 removed MD signing off audit



VIAMED



MANAGEMENT MEETING 28.10.95 - AGENDA UPDATE.

Further to BS Audit on 27.3.96. it was noted that several points on Appendix A of VM/COP/13 were not reflected in the meeting. As the points omitted are continually being discussed and updated. it was not thought valuable at the time to log as 'points raised' as concentration was placed on matters of importance. It has now been noted that all points however trivial. must be minuted on the meeting agenda.

1. Contract review. Picking. Packing & Despatch.

Noted on item 4 of meeting.

2. Purchasing Controls - Omitted from Minutes.

This is continually revised and updated on a weekly basis.

3. Supp/Sub-contractor Performance - Omitted from Minutes.

The point was raised at the meeting and agreed to be in order. Not noted on minutes.

4. Storage and Stock Control - Noted on item 5 of meeting.

5. Customer Complaints - Noted on item 8 of meeting.

6. Calibration - Noted on item 6 of meeting.

7. Documentation & Records - Omitted from Minutes

The point was raised at the meeting and agreed to be in order. Not noted on minutes.

8. Training - Omitted from Minutes

Training records updated in Oct 95 - not required to be updated until Nov 96. Not discussed in depth as of no relevance. Omitted from minutes.

9. Audits - Noted on item 7 of meeting.

10. Review of Responsibilities

Responsibilities of all relevant Departments noted on Viamed Official Health & Safety Policy which is checked/updated annually for insurance purposes.

11. Resources - Noted on items 3 & 8 of meeting.

12. Quality Planning - Noted on item 8 of meeting.



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BSI QA representative(s)	<u>M. J. BURG</u>	Client reference number	<u>937274</u>
Client	<u>VIAMED LTD</u>		
Date of visit	<u>27 Mar 96</u>		
Reference documents:			
Management Standard	<u>BS25180 9002:1994.</u>		
Certificate number	<u>BS 28343/BS 28344</u>		
Product standard	<u>—</u>		
Scheme requirements	<u>REG. 204. LEVEL 9/3.</u>		

1. Coverage of assessment. See Assessment Summary.

2. Scope of client's operations

2.1 Are there any significant changes to the system?
(detail changes on continuation sheet). Yes/No

2.2 Client's manual issue status: Issue 2. Aug 1995

2.3 Number of employees: 12

3. Nonconformity reports

3.1 Nonconformities raised on visit report 188913 cleared? MJMB raised all MTB1. Yes/No

3.2 Nonconformity reference numbers raised this visit: MTB1-5

3.3 Client is required to forward letter by 17 April 95 (dd/mm/yy) to SCINT B22.
detailing each nonconformity, the proposed corrective action and a programme for implementation covering each nonconformity.

Where it is found on a subsequent visit that corrective actions have not been implemented, in accordance with the agreed programme, then BSI QA may take steps to withdraw certification.

4. Complaints Summary

2 visit since last visit

5. Visit duration:

1 day

Signed
for client, acknowledging receipt

Signed
for BSI QA

M. J. Burg

Medical J. Burg

Where the client wishes to distribute copies of this report all pages must be included.

ISO 9000	Clause no.	Previous visits*	This visit*	Specify areas assessed. Indicate with tick										Nonconformity Summary
		Clauses Covered	Clauses Covered											Quantity of major NCR's
4.1		/ / / /	/	/										1
4.2		/ / / /	/	/										
4.3		/ / / /	/	/										
4.4			N/A											
4.5		/ / / /	/	/										
4.6		/ / / /	/	/										2
4.7		/ / / /	/	/										
4.8		/ / / /	/	/										
4.9		/ / / /	/	/										
4.10		/ / / /	/	/										1
4.11		/ / / /	/	/										
4.12		/ / / /	/	/										
4.13		/ / / /	/	/										
4.14		/ / / /	/	/										
4.15		/ / / /	/	/										
4.16		/ / / /	/	/	/	/	/	/	/	/	/			
4.17		/ / / /	/	/	/									1
4.18		/ / / /	/	/	/									
4.19		/ / / /	N/A											
4.20		/ / / /	N/A											

Scheme requirements

* Indicate either: ✓ = Assessed or: - =not applicable to this scheme



Nonconformity report

Report no. 201675/6

Sheet no. 4

Client's representative

Ms. L. Gillette

BSI QA assessor

M. G. Bresler

Details of corrective action undertaken during assessment

Receipt of nonconformity report acknowledged and content understood.

Signed,
for Client

Signed,
for BSI Q

El Gillespie
Michael F. Breig

Date 27 Nov 96.

Our ref: 9370214/SJB

Date: 4 July 1996



Miss E Gillespie
Office Manager
Viamed Limited
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT



BSI Quality Assurance
PO Box 375
Milton Keynes MK14 6LL
United Kingdom
Telephone: +44 (0)1908 220908
Fax: +44 (0)1908 220671

Dear Miss Gillespie

CONTINUING ASSESSMENT REPORT NUMBER 201675/201676

Date of visit - 27 March 1996

Thank you for your recent letter in which you provide details of the action to be taken to address the nonconformities raised during your last assessment.

Your reply has been forwarded to your Client Manager Mike Bishop, who will verify implementation of the corrective action at the next continuing assessment. If there are any problems, your Client Manager will contact you within 28 days from the date of this letter to discuss any specific concerns.

Yours sincerely

A handwritten signature in blue ink that reads 'Selina Bell'.

SELINA BELL (MRS)
Client Administrator to Mike Bishop, Client Manager
Northern Region
Operations



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This mark indicates accreditation for those activities in the schedule to certificate number 003, issued to BSI Quality Assurance.

