TECHNIKON LLC

CRITICAL

PROCEDURES

MANUAL

Technikon # 1410-622

(revised for public distribution)

TECHNIKON LLC

MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1000
DOCUMENT TITLE				ISSUE DATE
TITLE PAGE				
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CRITICAL PROCEDURES MANUAL				CPM-1001
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	C. R. Glowacki	1	1	NEW

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MANUAL CONTROL

THIS IS A CONTROLLED DOCUMENT

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	C. R. Glowacki	2	4	NEW

DISTRIBUTION

Master Copy	No. 1	Technikon ISO Library	ISO-9001 Coordinator or designate
	No. 2		
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	No. 8		
	No. 9		

This manual outlines Technikon LLC critical procedures and is intended to guide Technikon's continuous improvement process.

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C. R. Glowacki
ISO-9001 Coordinator

First Published -

MANUAL REVIEW AND REVISION

The ISO Coordinator or his designate has the authority to issue and approve revisions of this manual. The manual will be reviewed at least annually in a manner selected by the ISO Coordinator. The requirements outlined in Section 5 of the Quality Manual govern the format and change/modification procedure for this manual.

Changes made to individual pages do not require reissue of the entire section. Each page will note the latest revision date. Changes will be identified by an (*) in the left hand margin. Hand written changes or updates are not permitted except in emergencies and only with the authorization of the ISO Coordinator. Dates and initials are required adjacent to those changes. Any suggestions for changes or modifications should be sent to the ISO coordinator.

The ISO Coordinator sends out proposed changes for review to the ISO Implementation Committee, and they will assess the effect, if any, these changes may have on their quality systems. Any change to this manual that affects the Quality System will be communicated back to the ISO Coordinator for resolution.

The ISO Coordinator directs the disposition of obsolete copies of the manual, sections, or pages being revised. Copying of the manual is permitted; all such copies are readily identifiable as non-controlled copies. Controlled copies of this manual are printed on paper with a colored “Technikon” logo. The distribution of controlled copies is shown in Document CPM-1002, of this Manual.

TECHNIKON LLC

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REVISION AND REVIEW HISTORY

See Critical Procedures Document CPM-1005, Section 4.4.4.

TECHNIKON LLC

MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1003
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INTRODUCTION				
APPROVED BY	PREPARED BY:	PAGE	OF	SUPERCEDES
	C. R. Glowacki	1	1	NEW

This manual defines Technikon's critical procedures with regard to the application of quality systems in all areas and activities having an influence on quality of services and customer satisfaction.

This manual is set out as a reference document outlining both the critical procedures of Technikon and references to Technikon's controlled documents that comply with the ISO 9001 - 2000 standard.

Individual document reference numbers are quoted within the body of this manual and references will be made to locations where these documents or records may be found. (Also, refer to the Index located in Appendix I of the Quality Manual). This permits the revision of procedures in various work departments of Technikon independent of the Critical Procedures Manual.

The Critical Procedures Manual and procedures of various work departments may contain specific procedures and references that are proprietary and, therefore, considered **Confidential**. Access to these documents will be granted only when authorized by the Technikon President or designate(s).

The "Scope of Registration" encompasses provision of a service of emission testing and process improvement including contract design of processes for casting related industries.

The functions of the manual are to

1. Define Technikon's critical procedures regarding quality in a form directly related to ISO-9001 and equivalent standards.

2. Identify and reference the critical procedures and records that affect quality. (Refer to Index of Department Manuals located in Appendix I of the Quality Manual for specific procedures by Technikon department.)

3. Act as the reference document for purposes of audit, management review and external assessment of Technikon's quality program.

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MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1004
DOCUMENT TITLE				ISSUE DATE
DEFINITIONS				
APPROVED BY	PREPARED BY:	PAGE	OF	SUPERCEDES
	C. R. Glowacki	1	1	NEW

CPM	Critical Procedures Manual
AD	Administration Department
OPS	Operations Department
MT	Measurement Technology Department
EHS	Environmental Health and Safety Department

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MANUAL TITLE			Document #
CRITICAL PROCEDURES MANUAL			CPM-1005
DOCUMENT TITLE			ISSUE DATE
DOCUMENT CONTROL			
APPROVED BY	PREPARED BY: C. R. Glowacki	PAGE 1 OF 9	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

To define the methods used to control the issuance, correction, revision, and distribution of quality documents that are essential to the integrity of the Technikon Quality System.

2. SCOPE

Document control shall be addressed by the following applicable systems:

2.1 Issuance and approval of original documents.
2.2 Distribution of documents.
2.3 Identification of controlled and uncontrolled/obsolete documents.
2.4 Correction and/or revision of documents.
2.5 Document status.
2.6 Electronic documents.

3. DEFINITIONS

AD = Administration
MT = Measurement Technology
OPS. = Operations
ISO Coordinator = ISO Coordinator or designate
Technikon Quality System Manuals:
(1st tier) Quality Manual
(2nd tier) Critical Procedures Manual
(3rd tier) Department Policy & Proc. Manuals
(4th tier) Forms Manual
Internal Audit Binder
Management Review Binder
Vendor Deficiency Binder

ISO-9001 REFERENCE

4. PROCEDURE - DOCUMENT CONTROL

4.1 Approval and Issuance of Original Documents.

4.1.1 Quality Manual. The ISO Coordinator has responsibility for the approval and issuance of Quality Documents contained in the Quality Manual.

4.1.1a These documents shall be reviewed for accuracy and applicability to the Technikon Quality System by the ISO Coordinator. Approval for issuance shall be by signature of the ISO Coordinator on a cover page containing the document issue and revision number on the line labeled "Approved by:". Upon approval, a copy of the document will be issued to each party specified on the distribution list.

4.1.2 Critical Procedures Manual. The ISO Coordinator has responsibility for the approval and issuance of Quality Documents contained in the Critical Procedures Manual.

4.1.2a These documents shall be reviewed for accuracy and applicability to the Technikon Quality System by the ISO Coordinator. Approval for issuance shall be by signature of the ISO Coordinator on a cover page containing the document issue and revision number on the line labeled "Approved by:". Upon approval, a copy of the document will be issued to each party specified on the distribution list.

4.1.2b These documents shall be issued with a unique number assigned by the ISO Coordinator. This number shall start with the prefix CPM and be allowed the numeric range of 1000 to 1999.

4.1.3 Department Policy and Procedures Manual. The ISO Coordinator has responsibility for the final approval and issuance of

ISO-9001 REFERENCE

Quality Documents contained in each Department Policy and Procedures Manual.

4.1.3a These documents shall be reviewed for accuracy by the responsible Department Head. Initial approval is necessary before submittal to the ISO Coordinator. Initial approval shall be by signature of the specific Department Head on the Manual Control page near the beginning of the manual. Approval of revisions shall be by signature of the respective Department Head in the appropriate box on Technikon Form #007 accompanying the revision.

4.1.3b After approval by the respective Department Head, these documents shall be reviewed for accuracy and applicability to the Technikon Quality System by the ISO Coordinator. Final approval for issuance shall be by signature of the ISO Coordinator in the box labeled "Approved by :"of the cover page header. Upon approval, a copy of the document will be issued to each party specified on the distribution list.

4.1.3c These documents shall be issued with a unique number assigned by the ISO Coordinator and according to the following parameters:

- Administration Department Policy and Procedures Manual - Each document number shall start with the prefix "AD" to be followed by a unique numeric designation in the range of 2000 to 3999.

- Operations Department Policy and Procedures Manual - Each document number shall start with the prefix "OPS" to be followed by a unique numeric designation in the range of 4000 to 5999.

ISO-9001 REFERENCE

- Measurement Technology Department Policy and Procedures Manual - Each document number shall start with the prefix "MT" to be followed by a unique numeric designation in the range of 6000 to 7999.
- Environmental Health and Safety Department Policy and Procedures Manual - Each document number shall start with the prefix "EHS" to be followed by a unique numeric designation in the range of 8000 to 9999.

4.1.4 Forms Manual. The ISO Coordinator has responsibility for the final approval and issuance of Quality Documents contained in the Forms Manual. Only those forms unique to the Technikon Quality System and under its direct control shall be included in the Forms Manual.

4.1.4a These documents shall be reviewed for accuracy and applicability to the Technikon d will be added to the Forms Manual and the template in *MyNetworkPlaces/Entire Network/Microsoft Windows Network/Technikon/techserver/ISO 9001*will be updated

4.1.5 Any member of the Technikon Quality System may initiate a quality document.

4.2 Distribution of Documents.

4.2.1 The ISO Coordinator shall be responsible for the distribution of controlled Quality System documents.

4.2.2 Master Distribution List. A distribution list of all controlled quality documents shall be maintained in a separate binder labeled "Master List" in a section entitled "Controlled Document Distribution List" and kept in the Technikon ISO library.

ISO-9001 REFERENCE

4.2.2a The Master Distribution List will be maintained by the ISO Coordinator and be comprised of each individual Quality System Manual Distribution List located in separate sections.

4.2.2b The Quality System "Master Distribution List" shall be reviewed at least annually for completeness and accuracy.

4.2.2c Upon review and approval of the Master Distribution List and Controlled Document Distribution List, a copy of each Quality Manual Distribution List shall be signed by the ISO coordinator and issued, with the revision number and date, to the appropriate responsible party specified on the Master Distribution List.

4.2.3 Each Quality System Manual shall contain a section entitled "Distribution" to be found in the "Manual Control" document and will be listed in a table of contents.

4.2.3a This section shall contain the following:

- Copy Numbers
- Copy Holders
- Approval signature of ISO Coordinator
- Issue and Supersede Date

4.3 Identification of Controlled and Uncontrolled/Obsolete Documents.

4.3.1 All documents, paper and electronic, which are contained in Technikon Quality System Manuals shall be controlled. A master list of all controlled documents shall be found in a section entitled "Controlled Document List" in the "Master List" binder located in the Technikon ISO Library and will be maintained by the ISO Coordinator.

ISO-9001 REFERENCE

4.3.1a Controlled paper documents shall be identified by the colored "Technikon" logo in the top left-hand corner of the document in compliance with Form #XXX of the Forms Manual. Any variation or incompleteness of this description will invalidate the document's controlled status and subsequently shall be subject to the conditions set forth in section 4.3.3 of this document.

4.3.1b Electronic controlled documents shall be located solely in the *MyNetworkPlaces/Entire Network/Microsoft Windows Network/Technikon/techserver/ISO 9001* directory and be made accessible only to the ISO Coordinator or designate by a security password.

4.3.2 All Technikon Quality System Manuals shall contain original documents. No photocopies or facsimiles of any kind will be permitted.

4.3.3 Uncontrolled copies of controlled documents shall not be used within the Technikon Quality System except for training, distribution to customers, and draft revisions.

4.3.4 A document shall be considered "obsolete" when replaced by a new or revised version to the Technikon Quality System. The document will be taken out of the Technikon Quality System as outlined in section 4.4.1c of this document.

4.4 Document Review, Correction, and/or Revision

4.4.1 Document correction or revision may be initiated by any member of the Technikon Quality System.

4.4.1a Approval of corrected or revised documents will follow the guidelines set forth in Section 4.1 of this document.

ISO-9001 REFERENCE

4.4.1b Only uncontrolled copies may be used as draft materials for document correction or revision.

4.4.1c Document revision distribution will include a copy of Technikon Form #XXX to be completed and returned to the ISO Coordinator by the responsible party upon insertion of the new or revised document into the Technikon Quality System Manual and destruction of the obsolete document. The responsible party must comply within 30 days.

4.4.2 All 1st & 2nd tier Technikon Quality System Documents shall be reviewed at least annually by the ISO Coordinator for completeness and accuracy.

4.4.2a Approval of corrected or revised documents will follow the guidelines set forth in Section 4.1 of this document.

4.4.3 Each 3rd tier Department Policy and Procedures Manual document shall be reviewed at least annually by the respective Department Head for completeness and accuracy.

4.4.3a Approval of corrected or revised documents will follow the guidelines set forth in Section 4.1.3 of this document.

4.4.4 All revisions to Technikon Quality System Manuals will be followed up by an entry in the "Review and Revision" section of the respective Quality Manual Master Copy as stated in Section 4.5.2 of this document.

4.5 Document Status

4.5.1 The Master Copy of each Quality System Manual shall contain a

ISO-9001 REFERENCE

section entitled "Review and Revision", which will contain a review history using Technikon Form #XXX of the Forms Manual. The "Review and Revision" section will be designed in such a way that each Quality System document will have its own unique tabbed area that is categorized in a table of contents at the beginning of the section.

4.5.1a Technikon Form #XXX of the Forms Manual shall be sectioned to contain lists of document revisions where each entry will include:

- Revision Number
- Revision Date
- Space for revision explanation and results
- Initial box for each responsible party on distribution list.
- Initial box entitled "Electronic Backup"

4.5.2 The replacement of a controlled (paper) document, outlined in section 4.4.1c of this document, shall be verified by the ISO Coordinator's entry on the line corresponding to the responsible party in the appropriate Quality System Manual Master Copy "Review and Revision" entry for that document.

4.5.3 The replacement of a controlled (electronic) document, which constitutes revision of that document located in the *MyNetworkPlaces/Entire Network/Microsoft Windows Network/Technikon/techserver/ISO 9001* directory and its backup, shall be verified by the ISO Coordinator's entry on the line marked "Electronic Backup" in the appropriate Quality System Manual Master Copy "Review and Revision" entry for that document.

4.6 Electronic Documents

4.6.1 The ISO Coordinator shall be responsible for electronic backup

ISO-9001 REFERENCE

of controlled documents.

4.6.1a Electronic controlled documents shall be located solely on the *MyNetworkPlaces/Entire Network/Microsoft Windows Network/Technikon/techserver/ISO 9001* directory and be made accessible only to the ISO Coordinator, Asst. ISO Coordinator, and designate(s).

4.6.2 Electronic controlled documents shall be backed up on CD and stored in a binder named "Technikon Quality System Electronic Backup" and kept in the Technikon ISO library.

4.6.2a Electronic backup shall be performed after each document revision is issued.

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CRITICAL PROCEDURES MANUAL			CPM-1006
DOCUMENT TITLE			ISSUE DATE
CUSTOMER INTERFACE			
APPROVED BY	PREPARED BY:	PAGE 1 OF 1	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

To define the manner in which the Technikon receives requests for testing from its customers, tracks the progress of a test, and distributes the report to the customer.

2. SCOPE

3. DEFINITIONS

4. PROCEDURE – Emissions Test

5. PROCEDURE – Process Development

6. REPORT STORAGE AND RETENTION

6.1 Scope 2.1 and Scope 2.2

6.1.1.

TECHNIKON LLC

MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1007
DOCUMENT TITLE				ISSUE DATE
PERSONNEL TRAINING				
APPROVED BY	PREPARED BY:	PAGE	OF	SUPERCEDES
	C. R. Glowacki	1	3	NEW

ISO-9001 REFERENCE

1. PURPOSE

To ensure that members of the Technikon Quality System are provided with the necessary training to perform all activities affecting quality.

2. SCOPE

2.1 **Technikon Quality System** training shall be addressed through the following applicable systems:

2.1.1 Training to the ISO 9001 Standards
2.1.2 Tier I & II training
2.1.3 Tier III training

3. DEFINITIONS

Tier I = Quality Manual policies
Tier II = Critical Procedures Manual policies
Tier III = Each Department's Policy and Procedures Manual
ISO Coordinator = ISO Coordinator or his designate

4. PROCEDURE - Training to ISO 9001 Standards

4.1 **The ISO Coordinator** has responsibility for training all Technikon members to the ISO 9001 Standards.

4.2 **All Members** of the Technikon Quality System will be required to complete training to the ISO 9001 Standards. Training shall consist of:

4.2.1 Understanding each ISO 9001 standard as it is stated by the ISO Coordinator.

4.2.2 Completing Technikon Form #XXX upon understanding the ISO 9001 Standards.

ISO-9001 REFERENCE

4.2.3 Return Technikon Form #XXX to the ISO Coordinator.

4.3 All ISO 9001 training records shall be maintained by the ISO Coordinator. These records shall consist of the completed Technikon Form #XXX for each member of the Technikon Quality System and shall be located in a binder labeled "Technikon Training Records".

5. PROCEDURE - Tier I & II Training

5.1 **The ISO Coordinator** has responsibility for Tier I & Tier II training of all Technikon employees.

5.2 **All members** of the Technikon Quality System will be required to complete Tier I & II training. Training shall consist of:

5.2.1 Reading and understanding each policy as it is stated in The Quality Manual and The Critical Procedures Manual.

5.2.2 Completing Technikon Form #XXX upon reading and understanding The Quality Manual and The Critical Procedures Manual.

5.2.3 Return Technikon Form #XXX to the ISO Coordinator.

5.3 **All Tier I & Tier II** training records shall be maintained by the ISO Coordinator. These records shall consist of the completed Technikon Form #XXX for each member of the Technikon Quality System and shall be located in a binder labeled "Technikon Training Records".

6. PROCEDURE - Tier III Training

6.1 **Each Department Head** has responsibility for the appropriate Tier III training of each member of their respective departments.

6.2 **Each Department Policy and Procedures Manual** shall contain a policy to address Tier III training as it applies to that department and shall consist of at least the following:

ISO-9001 REFERENCE

6.2.1 Procedure for the appropriate Tier III training of department members.

6.2.3 A method to verify and record that proficiency training was accomplished by each member in their respective areas where the activity of that member may affect quality.

6.2.4 Location of training records must be in a similar location as the respective Tier III Manual and that location must be identified in the procedure.

7. NEWLY HIRED PERSONNEL

7.1 **All Temporary Employees Having 720 Hours** or more of accumulated time in Technikon and all newly hired regular employees shall comply with Sections 4.2, 5.2, and 6.2 of this document before performing any quality related activities.

7.2 **Temporary Employees With Less Than 720 Hours** of accumulated time in Technikon shall be under the direct supervision of qualified personnel and shall not have any quality related activities. They shall receive, as a minimum, Tier III training as appropriate to their duties as determined by the respective Department Head.

8. PROCEDURE FOR JOB GROWTH

8.1 **Continuous Improvement** and job growth is addressed through the yearly appraisal process.

8.2 **Appraisals are Conducted** by a department head with an employee to set goals for additional training and job improvements. The goals are documented in the appraisal form.

8.3 **Appraisal Forms for Employees** are retained in the Technikon Management area.

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CRITICAL PROCEDURES MANUAL				CPM-1008
DOCUMENT TITLE				ISSUE DATE
INTERNAL AUDITING				
APPROVED BY	PREPARED BY:	PAGE	OF	SUPERCEDES
	C. R. Glowacki	1	7	NEW

ISO-9001 REFERENCE

1. PURPOSE

To provide an internal quality auditing system that verifies Technikon compliance with ISO-9001 standards and Technikon's policies and procedures to promote Technikon's continuous improvement.

2. SCOPE

This procedure applies to all Departments within Technikon

3. DEFINITIONS

ISO-9001 Coordinator = ISO-9001 Coordinator or his/her designate
IAFF = Internal Audit Finding Form, Form #XXX (Form located in Technikon Forms Manual)

4. RESPONSIBILITY

4.1 **The ISO-9001 Coordinator** is responsible for assuring that this procedure is followed.

4.2 **The Quality System** is audited internally by people who are independent of the Department under audit and have been certified as internal auditors.

5. PROCEDURE

5.1 **The ISO-9001 Coordinator** establishes a schedule for internal audits at the beginning of each calendar year. This schedule assures that each of the departments is audited against the ISO-9001 standards at least once during the calendar year. The department's areas will be spot-checked for compliance to all the ISO-9001 standards.

ISO-9001 REFERENCE

5.2 **The ISO-9001 Coordinator** establishes the audit schedule, assigns the Lead Auditor and audit team members, if needed, and notifies them of the audit month and department.

5.3 **Prior to the Audit**, the Lead Auditor shall do the following:

5.3.1 Contact the appropriate Department Head to identify a date to perform the audit during the month established by the ISO Coordinator as indicated on the schedule.

5.3.2 Review the previous Non-Conformance Report(s), if applicable.

5.3.3 Review the previous Internal Audit Checklists, if applicable.

5.3.4 Determine what area(s) to audit.

5.3.5 Prepare audit checklist.

NOTE: Areas will be spot checked since every procedure and method cannot be reviewed annually.

5.4 **The Lead Auditor** shall meet with the audit team members prior to the audit to discuss the following:

5.4.1 Review of the Internal Audit Checklist and confirmation that the audit team members understand the objectives and the steps in the audit.

5.4.2 If necessary, modification of the Internal Audit Checklist based on discussion with the audit team members.

5.4.3 Assignment of audit responsibilities to all team members.

ISO-9001 REFERENCE

5.4.4 Review of the importance of note taking on the Internal Audit Checklist and proper completion of Internal Audit Finding Form (IAFF).

5.5 **The Audit Team** conducts an opening meeting with the Head of the Department to be audited and/or designee. The team explains the audit process and what specific areas will be reviewed.

5.6 **The Audit Team** shall interview department personnel and review the appropriate department manuals and records to verify compliance with the ISO-9001 standards and Technikon department policies and procedures. Any failures to comply with the ISO-9001 standards or policies and procedures shall be documented on an individual IAFF. The IAFF will indicate a Non Conformance Rating Scale as follows:

5.6.1 Major No documented procedure/lack of consistency, major non-conformance with standard.

5.6.2 Middle Consistence of practice, but no/vague written procedures; many procedural deviations.

5.6.3 Minor Written procedure, but poor document control; minor procedural deviations.

5.7 **The Audit Team** shall meet to review all IAFF's and discuss the audit. Once the audit team is satisfied that they have identified all issues, a close-out meeting shall be held with the Head of the audited Department and/or designee.

ISO-9001 REFERENCE

5.8 **During the Close-Out Meeting**, all audit findings and comments shall be discussed to insure that all issues have been properly identified. The Department Head or designee will sign each IAFF indicating agreement with the finding. If the Head of the audited Department and/or designee feels a finding is incorrect, the lead auditor and Department Head will discuss the finding and review the applicable standard, policy or procedure.

NOTE: The action plan, person responsible, and projected completion date will be agreed upon within a week of the audit.

5.9 **After the Close-Out Meeting**, the Lead Auditor shall submit the Internal Audit Checklist(s) and IAFF(s) to the ISO-9001 coordinator. Where appropriate, the ISO-9001 Coordinator may recommend voiding an IAFF after review of the applicable procedure, policy and standard, and confirmation of the observation. This review will be conducted for any non-conformances with which the Department Head does not agree. This recommendation must be approved by the Technikon President.

5.10 **The ISO-9001 Coordinator** shall present the IAFF(s) to the Technikon President with a cover letter summarizing the audit. This report is due within 30 days after the audit is conducted.

5.11 **The Technikon President** shall review the audit and approve the recommendations. If the Technikon President does not approve the recommendations, the ISO-9001 Coordinator and appropriate Department Head will revise the recommendations until they are approved.

5.12 **The ISO-9001 Coordinator** shall retain all audit records.

ISO-9001 REFERENCE

5.13 **The ISO-9001 Coordinator** shall maintain contact with the persons responsible for completing the recommendations. If corrective action has not been completed within one month after the target date for completion, the ISO-9001 Coordinator shall send written notification to the Technikon President and, where applicable, the Supervisor of the person responsible for completing the corrective action. The Technikon President will set a modified target date.

5.14 **The Next Internal Audit Team** shall verify the implementation and effectiveness of corrective action as part of the successive audit conducted on each department.

5.15 **The ISO-9001 Coordinator** or designate shall present a summary of the status of the internal audits and the findings at each Management Review Meeting. An Audit Finding Matrix chart will be kept current for the meetings to indicate problem areas.

INTERNAL AUDIT SCHEDULE

DEPARTMENT	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Administration		**X**										
Measurement Technology						**X**						
Operations										**X**		

NOTE: Internal audits will mainly be checking for compliance and system continuity. SOP's will only be spot checked.

INTERNAL AUDIT CHECKLIST

DEPARTMENT AUDITED: _____

DATE OF AUDIT _____ **AUDITORS:** _____

_____

_____

APPLICABLE ISO-9001 STANDARD	LOOK AT	LOOK FOR	COMMENTS

MANUAL TITLE			Document #
CRITICAL PROCEDURES MANUAL			CPM-1009
DOCUMENT TITLE			ISSUE DATE
CORRECTIVE AND PREVENTIVE ACTION			
APPROVED BY	PREPARED BY: C. R. Glowacki	PAGE 1 OF 5	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

To ensure that all departures from planned quality standards, including customer complaints, shall be investigated and recorded with a view toward analysis, cause identification, preventive action, and changes to procedures as required.

2. SCOPE

2.1 **Corrective Action** and any other problem areas will be addressed through the following applicable systems:

2.1.1 Equipment Corrective Action
2.1.2 Complaint/Request for Action (CRA) Form #XXX
2.1.3 Suspected Bad Data
2.1.4 Internal Quality Audit
2.1.5 Quality System/Process

2.2 **Preventive Action** will be addressed through the following application systems

2.2.1 Annual Standard Operating Procedure Review
2.2.2 Prescribed interval equipment calibration/verification
2.2.3 Document equipment maintenance and repair
2.2.4 Employee Training
2.2.5 Management Review Meetings

3. DEFINITIONS

SOP = Standard Operating Procedure

ISO-9001 REFERENCE

4. PROCEDURE - CORRECTIVE ACTION

4.1 Equipment Corrective Action System

When quality related equipment is found to be outside its calibration specifications, it will be immediately recalibrated or placed out of service to await recalibration. Applicable calibrations are documented in the equipment calibration/verification log or as specified in Department SOP's. The Department Head, or designate, initiates notification to customers whose data may have been affected by the "out of calibration" equipment if the data has been released. The Critical Procedure entitled "Test Equipment Calibration/Verification & Maintenance", Document # CPM-1010 explains in detail the procedure to be used for "out of calibration" equipment, including the documentation required.

4.2 Complaint/Request for Action System (CRA)

4.2.1 When a customer wishes to register a complaint or initiate a request for some type of action, a CRA form will be filled out (See Forms Manual for Form). The form is filled out by a member of the Technikon Department involved.

4.2.2 The ISO-9001 Coordinator, or his/her designate will check the form for completeness to insure the reason for the complaint is clearly identified and documented, a recommendation for corrective action is shown and a responsible person assigned.

4.2.3 Corrective Action to eliminate the cause of the complaint will be initiated. This will be shown in the "action taken" step of the form.

4.2.4 After the CRA has been verified or disclaimed, the form will be completed, the customer will be notified of the findings, if pertinent, and the form will be signed and dated by the responsible person.

ISO-9001 REFERENCE

4.2.5 Once the CRA has been resolved, the ISO 9001 Coordinator or his designate will review the CRA, sign it, and date it. The record will be kept in the Technikon CRA file permanently.

4.3 Suspected Bad Data System

4.3.1 When data has been generated that are suspect for any reason, the data will be rechecked for confirmation. If data are confirmed, but still suspect, the test equipment calibration will be verified, if possible, and then the data will be rechecked again. If the equipment is out of calibration, refer to Section 4.1.

4.3.2 If nonconforming data or reports are discovered after distribution, a "Complaint/Request for Action" Form is initiated to resolve the issue. Follow procedure in Section 4.2 of CPM-1009.

4.4 Internal Quality Audit

4.4.1 The ISO 9001 Coordinator is responsible to track corrective actions in this system. The IAFF's will be tracked, and the status of corrective actions will be reported to the Technikon President, as part of the quality management system. Refer to "Internal Audit Policy", Document No. CPM-1008 for operation of the internal audit system.

4.5 Quality System/Process

4.5.1 The Quality System and Process for Technikon will be reviewed at the Management Review Meeting, which is held at least annually. At this time, any changes needed to improve the System or process will be discussed and initiated within Technikon.

ISO-9001 REFERENCE

5. PROCEDURE - PREVENTIVE ACTION

5.1 Annual Standard Operating Procedure review

5.1.1 Standard Operating Procedures including Calibration Procedures will be reviewed on an annual basis. Records of those reviews will be maintained within each department. A system to track the review process and to note when the review is due will be maintained by each Technikon Department. By this process, errors in methodology, SOP's and procedures can be corrected.

5.2 Prescribed Internal Equipment Calibration/Verification

5.2.1 Calibration/Verifications of Equipment will be established within each department according to written calibration procedures, and SOPs. These methods will insure systems are working correctly. The frequency will be dictated by the procedures in each department, and records of these data will be maintained within each department.

5.3 Document Equipment Maintenance and Repair

5.3.1 All quality related maintenance and repair work performed on equipment will be documented and a record maintained. This will provide a history on that piece of equipment. Refer to Department Policy & Procedure Manuals for location of documentation.

5.4 Employee Training

5.4.1 All training in methodology will be documented to show employees' proficiency and capability to perform all quality related activities. For additional information on training, See Critical Procedures CPM-1007 entitled Personnel Training.

ISO-9001 REFERENCE

5.5 Management Review Meetings

5.5.1 "Complaint/Request for Action" forms will be discussed at Management Review Meetings to look for common, long term, or repeated problems occurring in the Quality System so they can be addressed and corrected. Any other problems with the Quality System will be resolved at the Management Review Meeting.

6. DOCUMENTATION

6.1 **All Complaint/Request for Action** forms will be reviewed and signed by the ISO Coordinator or his designate. The section entitled "Action Taken and Status" will provide closure of the problem, and any follow-up needed will be documented with a date for the follow-up.

6.2 **All Complaint/Request for Action forms and Their Outcome** will be reviewed at the annual Management Review Meeting as per Section 1.3 of the Quality Manual. Records of the meeting will be maintained in the ISO-9001 Library.

6.3 **In Addition**, whenever a specific incidence of quality system or service non-conformance is encountered, investigative protocol shall include an assessment of whether or not the specific failure is indicative of a more general failure having the potential to affect similar services or systems. If so, the corrective action in the specific instance shall be broadly applied in a preventive sense.

TECHNIKON LLC

MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1010
DOCUMENT TITLE				ISSUE DATE
TEST EQUIPMENT CALIBRATION/VERIFICATION & MAINTENANCE				
APPROVED BY	PREPARED BY: C. R. Glowacki	PAGE 1	OF 4	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

To assure accurate quantitative test results through the regular maintenance and calibration or verification of test equipment. Also to handle data generated from equipment that has been found to be out of calibration.

2. SCOPE

This procedure applies to all Technikon test equipment.

2.1 **Equipment** that may be calibrated/verified by the user.

2.2 **Equipment** that must be calibrated/verified by an approved contractor.

2.3 **Equipment** that is verified to be outside of specified tolerances.

2.4 **Standards** or Equipment used to Calibrate or Verify Equipment.

3. CONDITIONS

If specific conditions are required, they will be listed in the Department's SOPs and Calibration Procedures.

4. DEFINITIONS

NIST = National Institute of Standards and Testing

5. PROCEDURE

5.1 Equipment Calibrated/Verified by User

5.1.1 All test equipment must be inspected and calibrated or verified by a proficient employee before being put into service, and at regular intervals as

stated in the Calibration Procedure or SOPs for that department. The procedures and SOPs are found in each Department's Policy and Procedures Manual. These procedures and SOP's will address accuracy, frequency, and where the data are stored.

5.1.2 The Calibration Procedure shall conform to the procedure recommended by the Manufacturer or as specified in "Standard Test Methods" or SOPs. When possible, standards will be NIST traceable, or manufacturer's equivalent, and shall be stored in an area so they can be used only for calibration or verification.

5.1.3 A calibration and maintenance record must be kept for every piece of equipment that affects quality, and shall be maintained within each department. The record may be hard copy or electronic. Each record shall contain or reference at least the following information.

- 5.1.3.1 The identity of the equipment. (Vendor, Serial Number, Model, or any other identification)
- 5.1.3.2 The date of calibration/verification or maintenance.
- 5.1.3.3 The results of calibration/verification or maintenance.
- 5.1.3.4 The date of the standard's last calibration, if required.
- 5.1.3.5 The initials or signature of the person performing the calibration/verification or maintenance.

5.1.4 If applicable, the unit that has been calibrated/verified or maintained will be tagged with a tag identifying the equipment, the calibration date, tester, and the next calibration date.

5.2 Equipment Calibrated/Verification by Qualified Contractor

5.2.1 All equipment, which due to their complexity or need for highly trained personnel, must be cleaned and calibrated by an approved

contractor as stated in the equipment manuals.

5.2.2 If applicable, the unit that has been verified or calibrated, will be tagged with a tag indicating the equipment, its serial number, the calibration date, tester, and the next calibration date if applicable.

5.2.3 Records of work done by Contractors will be maintained by each department, either hard copy or electronic.

5.3 Equipment Out of Specified Tolerances

5.3.1 When a piece of equipment is found to be outside the normal tolerances allowed by the Calibration Procedure or SOP, the unit will be adjusted to within the normal tolerance, if possible. The before and after calibration data is to be recorded if adjustments are made. Each department's Policy and Procedures Manual will address what must be done with a unit out of specification.

5.3.2 If the calibration to the specified tolerance is not possible, the instrument will be removed from service.

5.3.3 The Department Head or designated representative will attempt to determine the actual time the unit was out of tolerance by reviewing available data from the time period between the last and present calibration dates. Customers will be notified their data may be in error.

NOTE: Some protocols or SOP's require that standards or known spikes be run periodically during analyses. If out of specification data is determined, one need only go back to the time that standards gave good data.

5.3.4 When the actual date the unit began reporting inaccurate results has been determined, all tests subsequent to that date will be reevaluated and the corrected data reported.

ISO-9001 REFERENCE

5.3.5 Customers will be notified of the corrected data.

5.4 Standards or Equipment used to Calibrate or Verify Instruments

5.4.1 Standards or equipment used to calibrate or verify instruments will be addressed in each Department's Policy and Procedures Manual or the Department's SOP's or Calibration Procedures.

5.4.2 The standards or equipment used will be listed, the location of the documentation showing authenticity will be indicated, and the frequency of renewing the standard or recalibrating the equipment will be indicated.

6. REFERENCES

6.1 SOP's and Calibration Procedures in Department Policy and Procedures Manual.

7. DOCUMENTATION

7.1 Any Documentation will be defined and maintained as stated in the SOP's or Calibration Procedures for the Technikon Departments.

TECHNIKON LLC

MANUAL TITLE				Document #
CRITICAL PROCEDURES MANUAL				CPM-1011
DOCUMENT TITLE				ISSUE DATE
PURCHASING				
APPROVED BY	PREPARED BY:	PAGE	OF	SUPERCEDES
	C. R. Glowacki	1	11	NEW

ISO-9001 REFERENCE

1. PURPOSE:

To assure the quality of goods and services purchased by Technikon.

2. SCOPE:

This procedure applies to the procurement of capital equipment, operating supplies and services.

2.1 Purchasing Procedures

2.2 Procurement of Capital Equipment

2.3 Procurement of Operating Supplies

2.4 Procurement of Services

2.5 Verification of Received Product Quality

3. REFERENCE:

3.1

3.2

4. DEFINITIONS:

5. PROCEDURE:

5.1 Purchasing Procedures - Scope 2.1

5.1.1 .

ISO-9001 REFERENCE

5.1.2 .

5.1.3 Vendor Deficiencies

5.1.3.1 "Written" Purchase Orders Any vendor problems involving a "written" purchase order will be handled by the respective Technikon employee. Any unresolved vendor problem and actions taken will be documented on the Vendor Deficiency Form, Form #XXX, and kept in the Vendor Deficiency Records binder located in the ISO library. A copy of this record will be forwarded to the purchase order originator.

5.1.3.2 "Verbal" Purchase Orders Verbal purchase orders are not allowed within the Technikon Quality System.

5.2 Procurement of Capital Equipment - Scope 2.2

5.2.1 Vendors of capital equipment may supply Technikon by completing a qualification program prior to approval. The qualification program may include one (1) or more of the following criteria

5.2.1.1 ISO certification

5.2.1.2 A history (>3 years) of supplying products acceptable to Technikon.

5.2.1.3 Traceability to a national or consensus standard such as NIST.

5.2.1.4 Passing a performance and/or process audit conducted by a Technikon staff member.

NOTE: A waiver from qualification will be granted with a signed

declaration stating the reason for the waiver.

5.2.2 A list of approved Capital equipment vendors is attached. These vendors may also be used for additional equipment, services, and/or supplies.

5.2.3 There will be times where capital equipment will be purchased for the purpose of evaluating new and/or experimental analytical techniques, instruments and vendors. It will not be necessary to purchase this equipment from an approved capital equipment vendor. If the results of an analysis using this equipment are provided to customers, then the experimental/evaluative nature of the analyses will be so indicated as part of the report.

5.3 Procurement of Operating Supplies - Scope 2.3

5.3.1 Vendors of operating supplies may supply Technikon by completing a qualification program prior to approval. The qualification program may include one (1) or more of the following criteria

5.3.1.1 ISO certification

5.3.1.2 A history (>3 years) of supplying products acceptable to Technikon.

5.3.1.3 Traceability to a national or consensus standard such as NIST.

5.3.1.4 Passing a performance and/or process audit conducted by a Technikon staff member.

NOTE: A waiver from qualification will be granted with a signed declaration stating the reason for the waiver.

5.3.2 A list of approved operating supplies vendors is attached. These

ISO-9001 REFERENCE

vendors may also be used for additional equipment, services, and/or supplies.

There will be times where operating supplies will be purchased for the purpose of evaluating new suppliers and vendors. It will not be necessary to purchase these supplies from an approved operating supplies vendor.

Publishers of reference books, encyclopedia, etc., are not required to be on the list of approved operating supplies vendors.

5.4 Procurement of Services

5.4.1 Vendors of services may supply Technikon by completing a qualification program prior to approval. The qualification program may include one (1) or more of the following criteria

5.4.1.1 ISO certification

5.4.1.2 A history (>3 years) of supplying services acceptable to Technikon.

5.4.1.3 Traceability to a national or consensus standard such as NIST.

5.4.1.4 Passing a performance and/or process audit conducted by a Technikon staff member.

NOTE: A waiver from qualification will be granted with a signed declaration stating the reason for the waiver.

5.4.2 A list of approved service vendors is attached. These vendors may also be used for additional equipment, services, and/or supplies. There will be times where services will be purchased for the purpose of evaluating new service providers. It will not be necessary to purchase these services from an approved service vendor.

ISO-9001 REFERENCE

5.5 Verification of Received Product Quality - Scope 2.5

5.5.1 Verification of the receipt of capital equipment, operating supplies and services is the responsibility of the person initiating the purchase requisition. Verification can also be conducted by a co-worker who is familiar with the use of the purchased product. The receipt of material or services is documented by one or more of the following:

5.5.1.1 Completion of a "receipt of materials".

5.5.1.2 Completion of the Department Purchasing log (either electronically or hard copy) Refer to 5.1.2 this procedure.

5.5.2 Verification of the quality of capital equipment, operating supplies, and services is the responsibility of the person initiating the purchase requisition. Verification can also be conducted by a co-worker who is familiar with the use of the purchased product. Verification criteria may include:

5.5.2.1 Equipment or services meet or exceed published Vendor specifications.

5.5.2.2 Certificate of analysis.

5.5.2.3 Label purity certification i.e. Analytical Reagent Grade, USP, etc.

5.5.2.4 Other criteria acceptable to the responsible person.

5.5.3 The acceptance of materials or services is documented by one or more of the following:

5.5.3.1 Coding and approving the vendor's invoice for payment.

ISO-9001 REFERENCE

5.5.3.2 Allowing payment of invoices for materials with a "receipt of materials".

5.5.3.3 Indicating "yes" in the Department Purchasing Log under "Acceptable".

6. DOCUMENTATION:

6.1 Each Department within Technikon maintains a hard copy or electronic copy of all initiated orders.

6.2 Invoices coded and approved by Technikon are maintained in the Technikon Management area.

APPROVED VENDOR LIST - CAPITAL EQUIPMENT

VENDOR	EQUIPMENT
Agilent	Chromatograph Accessories
Agilent	Chromatographic Equipment
Agilent	Electronic
Alltech	Chromatograph Accessories
Balston	Chromatograph Accessories
CDS	Chromatograph Accessories
ChromTech	Chromatograph Accessories
Environics	Chromatograph Accessories
Fisher Scientific	Chromatographic Equipment
hNU	Chromatograph Accessories
ISCO	Chromatograph Accessories
ISCO	Chromatographic Equipment
JM Science	Columns
Leap Technologies	Chromatograph Accessories
Mettler	Balances
Millipore	Water Purification Systems
National Instruments	Computer/Network Equipment
Sartorious	Balances
Varian	Vacuum Leak Detector
Varian Instruments	Chromatograph Accessories
Varian Instruments	Chromatographic Equipment
Whatman	Chromatograph Accessories

APPROVED VENDOR LIST - OPERATING SUPPLIES

VENDOR	EQUIPMENT
3M	Laboratory Supplies
Ace Glass	Laboratory Supplies
Adward	Laboratory Supplies
Aeltec	Laboratory Supplies
Air Product	Laboratory Supplies
Aldrich Chemical	Laboratory Supplies
Aldrich Chemical Company	NMR Solvents
Allied Electronics	Electronics Supplies
All-Pack, Inc.	Laboratory Supplies
Alltech	Chromatographic Supplies
Altex	Chromatographic Supplies
American Air Gases	Laboratory Supplies
Chemical Research Supplies	Chromatographic Supplies
Chrom Tech	Chromatographic Supplies
Chrompack	Chromatographic Supplies
Cole Parmer	Laboratory Supplies
Denver Instruments	Calibration Standards
Fisher Scientific	Laboratory Supplies
Fluka Chemical Corp.	Specialty Chemicals
Gelman Sciences	Filtration Equipment
Hamilton	Chromatographic Supplies
IOTECH	Electronics Supplies
ISCO	Chromatographic Supplies

APPROVED VENDOR LIST - OPERATING SUPPLIES

VENDOR	EQUIPMENT
J&W Scientific	GC Columns
Jones Chromatography	Laboratory Supplies
Lancaster Chemicals	Specialty Chemicals
Mallinckrodt Baker	Laboratory Supplies
Matheson	Laboratory Supplies
Millipore	Laboratory Supplies
MVAK Technologies Inc.	Laboratory Supplies
National Instruments	Computer/Network Supplies or Software
Newark Electronic	Electronics Supplies
NIST	Laboratory Supplies
Omega Engineering	Laboratory Supplies
Pfaltz & Bauer	Laboratory Supplies
Phenomenex	Chromatographic Supplies
Pierce	Laboratory Supplies
Praxair, Inc.	Compressed Gases
Restek Corp.	Columns, Standards
Scott Specialty Gases	Laboratory Supplies
See Capital Equipment list	Operating supplies for Capital Equipment
SGE, Inc.	Syringes
SGE, Incorporated.	Chromatographic Supplies
Sigma Chemical	Chromatographic Supplies
SKC	Laboratory Supplies
Supelco	Chromatographic Supplies
Technical Heaters	Laboratory Supplies

APPROVED VENDOR LIST - OPERATING SUPPLIES

VENDOR	EQUIPMENT
Thermo Environmental	Instrument Supplies
VWR Scientific	Laboratory Supplies

APPROVED VENDOR LIST - SERVICES

VENDOR	SERVICE
Clayton Environmental Consultants, Novi, MI division	Laboratories
See Capital Equipment list	Instrument Repair
See Operating Supply List	

TECHNIKON LLC

MANUAL TITLE			Document #
CRITICAL PROCEDURES MANUAL			CPM-1012
DOCUMENT TITLE			ISSUE DATE
LOCAL AREA NETWORK - OPERATION			
APPROVED BY	PREPARED BY:	PAGE 1 OF 1	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

2. SCOPE

3. APPARATUS:

1.
2.
3.

4. BACKUP PROCEDURE

5. RESTORATION PROCEDURE:

6. REFERENCE: (Located in)

MANUAL TITLE			Document #
CRITICAL PROCEDURES MANUAL			CPM-1013
DOCUMENT TITLE			ISSUE DATE
REPORTS			
APPROVED BY	PREPARED BY:	PAGE 1 OF 2	SUPERCEDES NEW

ISO-9001 REFERENCE

1. PURPOSE

To define the manner in which Technikon transmits written information and data to the customer.

2. SCOPE

This procedure applies to reports being issued by Technikon.

2.1

2.2

2.3

2.4

2.5

3. DEFINITIONS

SOP = Standard Operating Procedures

4. PROCEDURE

4.1

4.2

4.3

4.4

ISO-9001 REFERENCE

4.5 Secrecy Agreements and Confidentiality - Scope 2.5

4.5.1

4.5.2

4.5.3

ISO-9001 REFERENCE

1. PURPOSE

To define the procedures used by Technikon when implementing, documenting, verifying, and controlling design functions.

2. SCOPE:

Applicable to the following Design Functions.

2.1

3. DEFINITIONS:

4. PROCEDURE

4.1

4.2

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