Registration No. 2000/026390/08

1. Definitions and abbreviations:

1.1 **Analyte:** the component of the sample that is quantified and reported often referred to as a parameter.
1.2 **Subcontractor:** organisation or individual engaged by the proficiency testing provider to perform activities specified in ISO/IEC17043:2010 and the quality of a proficiency testing scheme.
1.3 **Coordinator:** one or more individuals responsible for organizing and managing all the activities involved in the operation of a proficiency testing scheme.
1.4 **Customer**: organisation or individual for which a proficiency testing scheme is provided through a contractual arrangement.
1.5 **Cycle:** a number of surveys.
1.6 **Design Value:** this is the sample concentration that the collaborator laboratory is aiming for in production of the PT sample. Due to the large volumes involved, losses during production and the use of natural materials, these values are not used as the assigned value**.**
1.7 **Inter-laboratory comparison:** organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
1.8 **Outlier:** observation in a set of data that appears to be inconsistent with the remainder of that set i.e. incorrect recording or other gross error.
1.9 **Participant:** a laboratory, instrument, organisation or individual, which receives proficiency test items and submits results for review by the proficiency testing provider.
1.10 **Proficiency testing:** evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.
1.11 **PT Provider:** the organisation that takes responsibility for all tasks in the planning, development and operation of a proficiency testing scheme.
1.12 **PT Scheme:** proficiency testing designed and operated in one or more rounds or a specified area of testing, measurement, calibration or inspection.
1.13 **PT Item (sample):** a sample, product, artifact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing.
1.14 **Reference Laboratory**: a laboratory that is subcontracted to provide analytical test items, and the evaluation and set or other information used for proficiency testing.
1.15 **Robust statistical method**: statistical method insensitive to small departures from underlying assumptions surrounding an underlying probabilistic model
1.16 **Measurand:** an object being measured or quantity intended to be measured.
1.17 **Sample Matrix:** Blood products for proficiency productions are from human origin, including but not limited to whole blood, packed red cells.
1.18 EQA – External Quality Assessment.
1.19 ID – Identification.
1.20 ISO – International Standards Organization.
1.21 PT – Proficiency Testing.
1.22 QA – Quality Assurance.
1.23 Lab – Laboratory.

2. Technical Requirements

2.1 **General**

2.1.1 The South African National Blood Service-Proficiency Testing Scheme (SANBS-PTS) strives to provide its customers (internal /external) with Proficiency Testing Scheme (PTS) of the highest international standards that are technically relevant and comply with the applicable ISO: 17043 requirements.
2.1.2 The delivery of trial materials and reports to participants is subcontracted; however, this is monitored by using customer feedback to ensure efficiency and competency of the subcontractors.
2.1.3 All participants' details and performance are kept confidential. The scope of the SANBS – PTS excludes the monitoring of corrective and/or preventative actions of

external participants. It is the participant's responsibility to implement own corrective action following poor performance and to supply those results to the relevant managers.

2.1.4 Advisory group for the SANBS-PTS has been performed and is available to make recommendations and assist with any relevant matters that may arise, *Role and functions of the Proficiency Advisory Committee (PAC)* (FRM-QCL-089).

2.2 **Personnel**
(Refer to *Quality Policy* Manual (PM-QMD-001).

2.2.1 SANBS-PTS has the necessary authority, resources and technical competencies required to perform duties.

2.2.1.1 *Executive Management Structure* (INF-QMD-005) and *Medical, SLS and SHEQ divisional organogram* (INf-QMD-006) and *Quality Control Organogram* (INF-QCL-022).

2.2.2 All personnel involved with the PTS are permanent employees of SANBS and have signed a contract of employment. Members of the Advisory Committees comprises of staff employed by SANBS, letters of appointment have been signed by the committee members.

2.2.3 The Medical Director, Manager Quality Control (QC), Head of QC and QC Specialist (Immunohematology) with the assistance of the QC laboratory administrative assistant are vested with the authority by the Chief Executive Officer (CEO) of SANBS to plan and organise the proficiency testing schemes; perform particular types of sampling; conduct statistical analysis; evaluate the performance of the participants; give opinions; interpretations and authorise the report.

2.2.4 The scheme coordinators are authorised to operate equipment; prepare; handle and distribute test items; operate the database and distribute the reports.

2.2.5 The Manager ICT who is based at the SANBS ICT department has the authority to operate and maintain the database as per the requirement of the department.

2.2.6 All SANBS-PTS staff has personal files where all training and competency records are filed and maintained.

2.2.7 Training in SANBS-PTS is an ongoing activity and the effectiveness of training activities is evaluated using the various competency methods. Refer to policy PM-QMD-001.

2.3 **Equipment, accommodation and environment**
(Refer to PM-QMD-001).

All equipment used for the preparation of the PT items are serviced, calibrated and maintained as recommended by the supplier. A *Maintenance, Verification and Calibration Schedule for Equipment* (FRM-QMD-006) is compiled and maintained for equipment in the work area.

All equipment is maintained and operated by trained personnel. All maintenance records are kept on file in the respective areas.
Universal safety precautions are followed when preparing samples for the program. Safety requirements and waste disposal is documented in each procedure.

All activities regarding the PTS are carried out in access controlled facilities. The temperatures are monitored and recorded daily.

2.3.1 All the PTS activities are carried out in the SANBS Quality Control laboratory in Constantia Kloof.

2.3.2 SANBS QC laboratory is access controlled.

2.3.3 Environmental conditions are monitored and recorded daily, i.e. temperature of room, fridges, freezers, incubators. There is a centralized air conditioning system which is maintained by an external company. There is a back-up generator for instances when there is power failure. The Maintenance department is responsible for ensuring adequate lighting as per maintenance schedule. Environmental conditions during transportation are monitored by reviewing participant's response.

2.3.4 To prevent cross contamination, all activities are carried out at different times, e.g. complete the dispensing of patient cells, and change tubing prior to dispensing donor cells.

2.3.5 All methods and equipment used in SANBS-PTS shall be validated /verified as extensively as necessary and approved as fit for the intended purpose.

2.4 **Design of Proficiency testing schemes**
(Refer to *Proficiency Testing Program for Technical Division* (SOP-QCL-002).
Survey Identification:
SANBS PTS allocates a unique identification for each program. It is a combination of the program name, the issuing month and the set number, e.g. BPT04-13.

2.4.1 **Planning**

Requirement from clause 4.4.1.3 of ISO/IEC 147043	SANBS PT **Fulfillment of requirement**
a) Provider	South African National Blood Service (SANBS) Quality Control Department Proficiency Testing Scheme – (SANBS-PTS) Practice Number: 2000/026390/08.
b) Coordinators	The Head of QC and QC Specialist shall be responsible for all aspects of the proficiency testing scheme. The Manager: Quality Control (Scheme Manager) shall be responsible for the overall management and coordination of the relevant schemes. The QC Specialist (Immunohematology) in SANBS-PTS shall be responsible for preparing sample, finalizing accompanying documentation, data entry of responses, compiling and checking of reports. Reports shall be checked by the head/Manager QC of SANBS-PTS. Packaging and posting of survey material and result forms shall be done by the staff of SANBS-PTS. Reports accessed via online PT Program.
c) Subcontracted Activities	SANBS-PTS shall use approved subcontractors for the shipping of PTS samples and the postage of laboratory evaluation reports. Vendors are approved as per procurement documents
d) Participation	All results are evaluated online and Reports issued online.
e) Participation Level	The typical participation levels range from one challenge to the full survey.
f) Selection of Measurand	Measurand will be selected as per production standard operating procedure (SOP) for each Program.
g) Concentration ranges	This shall be a combined decision between the Proficiency Advisory Committee (PAC) and QC staff.
h) Potential major sources of errors	During the preparation, distribution and data entry of the PT schemes results errors can arise with: 1. Sample preparation – contamination or swapping of samples to be used are all clearly labeled. Decoding of samples is checked by a second person prior to dispensing. 2. Labeling and packing of prepared samples for shipping - A checklist is completed to cover all steps prior to shipping
i) Sample production characterization and Distribution	Procedures shall be established and implemented for each program.
j) Procedures for preventing collusion and falsification	Production procedures include procedures to prevent collusion and falsification e.g. decoding of samples, random sampling from supplied material.
k) Information provided to participants	The information provided to participants shall include but is not limited to the PTS Information Booklet, covering letter, instruction sheet, response sheet and reports. Each instruction sheet shall provide the participants with instructions on selection of sample, sample reception, storage conditions, sample preparation, sample analysis, sample reporting, where applicable statistical data and summaries, safety instructions, special handling requirements and, where necessary, limitations on methods that can be used and contact details of the scheme-coordinators and any additional

	notes.
l) Dates for Shipments and reporting deadlines	Dates for shipments and reporting deadlines shall be communicated to the participants prior to the first shipment. The deadline for change of participants details shall be 2 weeks prior to shipping, and the deadline for submission of results shall be determined by the QC staff. These dates shall be agreed upon by the PTS provider and PAC when the program of work is established. An email shall be sent to all participants when the schedule is posted and a notification of shipment shall be sent to the participants by the scheme co-coordinators.
m) Instructions to participants on methods to use	Participating laboratories are free to perform routine procedures according to their standard operation procedures. Each SANBS- PTS shall have a specific instruction sheet associated with it which shall be a document controlled on SAP.
n) PT sample homogeneity and stability	The uncertainty associated with PTS sample shall be determined by testing for homogeneity and stability. Internal quality control including homogeneity and stability shall be detailed in different scheme production procedures.
o) Participant reporting	All results evaluated online and Reports issued online.
p) Statistical analysis	This shall be described in the respective PTS production SOP and instruction sheets where applicable.
q) Metrological traceability and uncertainty of the assigned value	This shall be described in the respective PTS production SOP and instruction sheets where applicable.
r) Evaluation of participant performance	Explanation of the scoring used for the PTS scheme shall be described in the respective PTS Production SOP and instruction sheets where applicable.
s) Preliminary reports, confidential reports and generic reports	Coordinators shall complete *Hemocue Proficiency Batch Checklist* (FRM-QCL-128, *Checklist for the Virology PT Program* (FRM-QCL-107) and *Crossmatch* and *Antibody Identification Proficiency Check list* (FRM-QCL-110) report and *DAT Proficiency /Checklist* (FRM-QCL-149 for each trial and program (this includes reports even when there were no results to evaluate online). Reports provided to participants shall be detailed in the respective PTS Production SOP and instruction sheets.
t) Lost or damaged samples	When notified by participants of lost or damaged samples, replacement samples can be provided. This is dependent on availability (within 5 working days after receipt of samples).

2.4.2 SANBS-PTS together with input from the PAC plan and review all schemes annually or as required (Refer to SOP-QCL-002).

2.4.3 The planning is carried out by the QC specialist (Immunohematology), the Head of QC, the QC manager together with inputs or advice from the PAC.

2.4.4 PTS Plan – the current PTS was implemented prior to adding ISO: 17043 requirements. Should additional programs be required in future, the plan tabled above shall apply.

2.4.5 SANBS-PTS has established advisory groups which consist of but is not limited to QC staff, QS staff, Statistician and technical experts for each of the programs.

2.4.6 The Roles and Functions of a PAC are described in FRM-QCL-089.

2.4.7 Preparation of Proficiency test items.

- The PT items chosen are of the same matrix as the items used in routine testing.
- The preparation of the Proficiency test items is described in the relevant procedures. The quantity of sample provided to the participant for each sample is sufficient for analysis. Each PT item shall be labeled with the relevant PTS; sample number; survey; batch number, and the storage temperatures.
- Crossmatch, Antibody ID and titre performed monthly. HLA, Virology and DAT programs quarterly.

2.4.8 Homogeneity and stability

- Homogeneity and stability testing are detailed in the respective procedures.
- All testing materials are tested and guaranteed for homogeneity and stability in the initial stage as part of the QC Process. The procedure for homogeneity and stability is defined in the respective PTS procedure.
- Testing includes raw material testing, in-process testing, and testing at the due date after storage at different temperatures.

2.4.9 Statistical Design

- All statistical matters are dealt with by the Manager QC and a Manager ICT: Business support. If required, expert statistical advice will be outsourced from the PAC.
- The accuracy and measurement of uncertainty of each measurand is taken into consideration as the possible sources of error which is stated in the individual PTS procedures.
- The minimum number of participants for any scheme is 1.
- The number of PT item to be tested / measured depends on the participants' scope of testing.
- Outliers are not included for qualitative results SANBS-PTS.
- All incorrect results will still be evaluated.
- The objective of statistical design is defined in the individual PTS SOP.

2.4.10 Assigned values:

- The procedure for determining assigned values is described in the relevant PTS SOP.
- The uncertainty is taken into consideration at the initial stages of preparation.
- All information regarding the study's specific design and assigned values (where applicable) will not be released until the PT study has been closed and the official PT report has been issued.

2.5 **Choice of method or procedure**

All participants are required to use the test method of their choice.
When results are obtained using different test methods the performance evaluation is not affected because of the nature of the schemes.

2.6 **Operation of proficiency testing schemes**

All storage areas available for the PT items are access controlled.
The Manager QC/Head of QC authorizes the release of PT items from the storage area for packaging and dispatch, evidence of authorization of release is recorded.
The condition of PT items and materials are assessed during storage to detect deterioration by means of visual inspection. Results are recorded on the worksheets.

2.6.1 **Instructions for Participants**

Instructions to Participants are sent with every shipment. Each PTS may have its own **instructions for Participants** which are document controlled.
The following is the minimum requirement for Instructions for Participants which is detailed in the individual PTS Information Booklet:

- The samples must be treated as 'routine sample' (i.e. defined as the work flow and level of effort followed for the majority of customer samples analyzed using the registered method).
- Factors that could influence the testing i.e. Nature of the PT items' conditions of storage, whether the PTS is limited to selected methods and timing of the PT items.
- Sample preparation if required.
- Special handling instructions and safety requirements.
- Specific environmental conditions that the test must be performed at.
- Recording and reporting of PTS results.
- Closing date for submission of results and consequence of late submission or no returns.
- Contact details of PTS coordinator/s.
- Instructions on returning of proficiency test items.
- Selection of sample.
- Survey requirements.
- Sample dispatch notification and actions to be taken if sample were not received.

- Sample reception.
- Evaluation of submitted results.
- Corrective action.
- Disputes and appeals.

2.6.2 **Proficiency test items handling and storage**

- All PT items are prepared at different times and labeled accordingly to avoid cross contamination between analytes. All PT items are identified and segregated from the time of preparation to distribution as per the respective SOP.
- All labeled PT items are stored in the QC laboratory which is access controlled until packaging and distribution. The condition of the PT items is checked visually during the packaging process to detect possible deterioration prior to distribution.
- All PT items are potentially hazardous and are thus clearly marked to ensure their safe handling, decontamination and disposal as per each laboratories safety protocols.

2.6.3 **Packaging, labeling and distribution of Proficiency test items**

- Samples are labeled and packed as per relevant QC procedures.
- Packaging is done as per all IATA requirements.
- PT samples shall be sent by courier to external participants and SANBS drivers for participants in the Egoli region. All samples are sent at ambient conditions. If this is not the case, then the respective packages are clearly marked with the required temperature requirements.
- All participants are notified once the PT item has been dispatched and are instructed to contact SANBS- PTS if the PT items are not received as per the schedule or the dispatch notification.
- Preparation of Donation testing Proficiency samples for the KZN area are performed in QC laboratory KZN, which is accredited to ISO 17025 and Transfusion medicine.

2.7 **Data Analysis and evaluation of proficiency testing schemes results**

2.7.1 Data Analysis and Records

- Maintenance of the Database is performed by the ICT Department. Procedures for Data entry and statistical analyses are included in the respective SOP.
- Methods of evaluating PTS performance is described in relevant PTS SOP.
- Outliers are not applicable to the SANBS-PTS; all results submitted within the stipulated timeframe are assessed.
- Results that are inappropriate for statistical evaluation such as miscalculations, transpositions and other gross errors are included in the evaluations.
- PT items that were distributed but found to be unsuitable for performance evaluation e.g. because of non-homogeneity, instability, damage or contamination are cancelled for evaluation.

2.7.2 Evaluation of performance.

Methods of evaluating PTS performance is described in the respective PTS SOP and is performed by the PTS coordinator.

- SANB-PTS issues a commentary on the performance of its participants which forms part of the report issued. The relevant PAC may have input in the commentary prepared by SANBS-PTS.

  The commentary may include at least the following:

  a) Overall performance against prior expectations, taking measurement uncertainties into account where applicable. Uncertainty is not applied to qualitative methods. HeamoCue is consensus based; therefore, uncertainty does not apply as HeamoCue controls are done at time of product only.
  b) Variation between methods or procedures;
  c) Situations where unusual factors make evaluation of a result and commentary on performance impossible.
  d) Conclusions.

The scope of the SANBS-PTS excludes the monitoring of corrective action and/or preventative action; this is the responsibility of the participants. However, the PTS staff will assist should the need arise.

2.8 **Reports**

2.8.1 SANBS-PTS does not subcontract the authorization of reports; however, the relevant PAC is given the opportunity to give their expert opinion into the final analysis and evaluation of the participants' results. All reports are approved by the Manager QC or Head of QC. All SANBS-PTS reports are available online prior to shipment of the PT material for the next survey, and all reports are available online.

2.8.2 SANBS-PTS issues a final individual report – all participants shall receive individual reports which include both individual results as well as an aggregate performance for all laboratories nationally online.

2.8.3 All reports are available online.

2.8.4 Reports issued by SANBS-PTS are standardized and simple. The reports shall include the following; if these are not included on the report the information shall be in the Information booklet or instruction to participant as well as online

- Name of PTS provider SANBS indicating the PTS provider is indicated at the top of the page.
- Contact details of the PTS provider include the telephone number, fax, email and physical address.
- Name and contact details of the PT coordinator is indicated at the end of the report
- Name and function of the person authorizing the report is indicated at the end of the report.
- Activities that are subcontracted are included at the end of the report.
- Dates and status of report positioned at the top right hand corner of the report.
  - Date of issue of report.
  - Shipment Date.
  - Receipt Date of PT Items.
  - Receipt Date of Response.
  - Process Date of PT Items.
- Page number i.e. Page X/Y which will indicate the end of report positioned at the bottom left hand corner of the page.
- A statement of confidentiality will appear on the last page.
- The PTS batch number identifies the PTS and will be used as the report number.
- A clear indication of what test items were used, the preparation, homogeneity and stability is stated in the instructions to the participants.
- A clear indication of the participation's results, 'Your Result'.
- Statistical data and summaries, including assigned values, range of acceptable results and graphical displays.
- Procedure used to establish assigned values is stated in the instruction to the participants.
- Procedure used for evaluation is stated in the instruction to the participants.
- Assigned values and summary statistics for test methods/procedures.
- Scoring is done on the participant performance.
- Information about the design and implementation of the PTS is stated in the Instructions to the participants.
- Procedures used to statically analyze the data are stated in the instructions to the participants.
- Advise on the interpretation of the statistical analysis (Memorandum).
- Comments or recommendations based on the outcomes of the PT batch are in the form of commentary.

2.8.5 The turnaround times (TAT) of the reports are defined in the PTS procedure which is determined by the relevant advisory group and is also stated in the Instructions to the Participants. If the reports cannot be issued as per the TAT then this information shall be communicated to the participant via email.

2.8.6 Laboratories may, provide copies of SANBS- PTS reports if required, in response to a request for a proposal or bid, marketing and advertising purposes. When this occurs, the participant must include all of the report pages. SANBS- PTS Reports may be used for teaching purposes. SANBS – PTS recommends that the reported results should not

be used as the any measure for judging the performance of any individual clinical laboratory.

2.8.7 When new or amended reports are issued as the following shall be included and documented:

- A reference to the original report it replaces or amends i.e. the issue date.
- A statement concerning the reason for the amendment or re-issue.

2.9 **Communication with participants**

Refer to procedures, instruction to participants and the information booklet).

2.9.1 All SANBS participants have access to the *Transfusion Service Proficiency Program: Information Booklet* (INF-QCL-005) on SAP which contains all the relevant information pertaining to SANBS PTS. The handbook is issued to all external participations on registration or as it is updated.

- The scope of the SANBS- PTS is described in PM-QMD-001.
- All SANBS Laboratories are not charged for their participation, whereas external laboratories are charged a nominal fee.
- The participation of all SANBS Laboratories is governed by the SOP-QCL-002.
- Criteria for participation in the PTS:
  - ✓ All SANBS Laboratories that perform the relevant testing are automatically registered for the relevant PTS by their managers and can update orders quarterly or monthly, 2 weeks prior to production.
  - ✓ External laboratories apply online. On receipt of a new application relevant information is stored online.
- A confidentiality statement is stated in INF-QCL-005 and on the participants' report.
- The application process is described in INF-QCL-005.
  All changes in the design and operation of the PTS are communicated to the participants via email and/or on the participant's instructions.

2.9.2 Laboratories may return the specimens to SANBS-PTS for checking should there be a discrepancy with their results and the PT provider.

- Within 5 working days of receiving any PTS report, the participant may dispute the decision to SANBS-PTS in writing for external participants or via notification system for SANBS participants.
- Disputes, queries, complaints, compliments including subcontracted work will be managed as notifications.
- The dispute shall be investigated by SANBS-PTS staff and shall be limited to investigating whether or not SANBS-PTS procedures were followed, the QC manager shall give written feedback to external disputant. Should a participant disagree with the decision taken by SANBS-PTS, the matter will be forwarded to the PAC who will make the final decision.
- Requests for disputes/appeals/complaints shall be made in writing, clearly stating what the participant is disputing /appealing/complaining about, and shall provide adequate information to support the dispute/appeal/complaint.
- All disputes or/and appeals will be managed according to the notification process.
- All communications with participants are done electronically via email.

2.9.3 SANBS-PTS issues certificates of participation/performance and a certificate of enrolment to external participants are available online.

2.10 **Confidentiality**

2.10.1 Participant numbers are used to identify participants.

2.10.2 All SANBS-PTS staff and members of the advisory committees have signed a confidentiality statement and are made aware of the importance of confidentiality. Only authorised personnel have access to the data entry facilities.

2.10.3 All performance data is treated as confidential and is disclosed to a restricted list of individuals their regional QA managers and QA coordinators. *Waiver of Confidentiality* (FRM-QCL-090) and document is available.

2.10.4 Should a regulatory authority or any other 3rd party require PTS results, then the affected participant shall be required to submit written consent to the Manager QC.

3. Management requirements

3.1 **Organization**

(Refer PM-QMD-001).

3.1.1 The SANBS - QC Department, Registration Number: 2000/026390/08 is a not for profit organization and operates the Proficiency Testing Schemes on a cost-recovery basis.

3.1.2 SANBS conforms to requirements for proficiency testing. *Proficiency Scheme Manual* (INF-QCL-006) describes the general overview of the SANBS PTS. Detailed procedures for the undertaking of a PTS can be found in INF-QCL-005.

3.1.3 The Quality Management System ISO/IEC: 17043 has been established and implemented to cover all tasks carried out at the SANBS-PTS and any related tasks carried out at other departments such as distribution.

3.1.4 For Organizational Organogram refer to INF-QMD-005.
Organogram of QC Department PT Schemes: INF-QCL-022.
Due to the fact that the members of the PAC and proficiency testing staff are employed by SANBS, potential conflict of interest exists. Some members of the PAC are part of management of the participants and have access and input into the design of the Programme of different surveys. QC has identified access to this information as being potential conflict of interest. The potential conflict of interest is that there is a working relationship between participants and scheme personnel. All members of the PAC and proficiency testing staff are therefore required to sign a confidentiality agreement and a declaration of any conflict of interest. Lists of all members are kept on file.

3.1.5 Confidentiality:

- All SANBS-PTS staff has been given the authority and resources by the CEO of SANBS to carry out the duties as stated in their role profiles which have been signed by the individual and management, all role profiles are filed in the personnel files.
- All SANBS-PTS staff and members of the PAC are required to sign an acknowledgement of confidentiality of information when signing employment contracts, an undertaking to protect the confidentiality of clients and other propriety, signed copies are kept in their Personnel files.
- The policies *Disciplinary Process* (CP-HCM-001) is applicable for avoiding involvement in activities that might diminish confidence in tasks associated with the PTS, such as disclosure of the design of the PTS to their laboratories.
- INF-QMD-005 indicates the relationship between quality management, technical operations and support services.
- The responsibilities, authority, interrelations and required competence of all SANBS-PTS staff are stated in their job description.
- All SANBS-PTS staff is made aware of their relevance, importance and contributions of their activities towards achieving the SANBS-PTS activities by signing their job descriptions and communications during regular staff meetings and training sessions.
- It is the responsibility of the Head of QC and the Manager QC to ensure that all staff is adequately supervised.
- The Head of QC and the Manager QC has the overall responsibility for all the technical operations and the provisions of the resources needed.
- The SANBS Quality Systems management is stated in PM-QMD-001.
- See List of Deputies in SANBS-PTS by referring to *Deputisation* in INF-QMD-006.

3.1.6 Staff meetings and online communications are used as means of communicating effectively the quality management system.

3.2 **Management System**

(Refer to PM-QMD-001).

3.2.1 SANBS-PTS strives to provide its participant customers with PTS that are technically relevant for Transfusion Medicine, Hemocue instruments, Donation Testing, Virology, DAT and HLA antibodies in accordance to ISO/IEC17043:2010 and ISO 17025:2005, Standards of Practice for Blood Transfusion in South Africa and SANAS requirements.

3.2.2 SANBS-PTS has established its own policies as defined in this document, which is referenced to the relevant procedures and or other SANBS policies. All SANBS-PTS staff has access to all documentation and shall read, understand and sign all relevant documentation. SANBS-PTS also provides the following documentation to its user as a means of communication to their participants and customers, INF-QCL-005; application forms, instructions to the users, and reports.

3.2.3 Quality Policy Statement of SANBS-PTS.

3.2.3.1 The following Quality Policy Statement is issued under the authority of the CEO of SANBS. PM-QMD-001.

3.2.4 The management of SANBS-PTS shows their commitment to the development, implementation and continuous improvement of the management system by attending SANBS Management Review Meetings, performing Internal Audits; identify opportunities for improvement and by striving to obtain accreditation status to ISO/IEC: 17043 and ISO/IEC: 17025, Standards of Practice for Blood Transfusion in South Africa and to maintain continuous accreditation status.

3.2.5 The management of SANBS–PTS monitors customers' complaints. A quarterly Quality systems report which covers all complaints received are distributed and it is discussed at the management review meeting.

3.2.6 SANBS documentation is defined in *National and Area Document Codes* (INF-QMD-002), and all related proficiency documents start with the prefix QCL.

3.2.7 The roles and responsibilities of technical management and the Manager QC are stated in PM-QMD-001 and in their role profiles.

3.2.8 The Manager Quality Systems together with the Technical managers of SANBS is responsible for maintaining the quality management system. All changes to the system are communicated at the Quality Management Review (QMR) meetings and to all staff during departmental meetings. All minutes of QMR meetings are on the server which is available to all staff.

3.3 **Document control**

(Refer to PM-QMD-001)

All documents are controlled as detailed in PM-QMD-001.

3.4 **Review of requests, tenders and contracts**

(Refer to PM-QMD-001).

3.4.1 Review of Requests: The review of request, tenders and contracts are done as per application process, this include subcontracted work.

3.4.2 All SANBS Laboratories are automatically enrolled by the managers as per PM-QMD-001.

External Applicants complete an application form which is available from SAP. The INF-QCL-005 fully describes the PTS which is available online on SAP for all SANBS Laboratories and a hard copy is issued to all external participants on enrollment and annually or whenever it is updated. QC department handles all applications and updates the participants list as participants enroll or when they no longer participate.

3.4.3 On receipt of enrolment forms quotations are obtained for transportation of samples.

3.4.4 Quotations are issued to applicants, who will be enrolled as soon as signed quotation is received.

3.4.5 Closing date for Virology Proficiency enrolment is end of November for the following year.

3.4.6 The coordinator updates the participants list.

3.4.7 Contracts: PTS contracts are reviewed annually or on registration.

3.5 **Pilot Studies**

3.5.1 The request for a new analyte to be added to a scheme or for a new scheme will be discussed at the advisory meeting.

3.5.2 The number of surveys that are to be piloted will be decided at the meeting, the participating labs and the time frame for completion of the pilot study.

3.5.3 Before a pilot study is conducted, if it is an existing PTS then the relevant protocol must be reviewed to include the new analyte or a protocol must be written with all the relevant details as per ISO/IEC17043.

3.5.4 A pilot study protocol for the analyte or PTS will be developed stating the acceptance criteria. If a new analyte is added to an existing PTS then this must be stated on all the PTS documentation or if it is a new PTSP then all documentation must be labeled as 'PILOT STUDY'.

3.5.5 At the end of the Pilot study, the PAC will be consulted with all relevant information, if the acceptance criteria were met then it will be approved and signed off by the Manager QC as fit for use.

3.5.6 Packaging and transportation of PT items is subcontracted and this is stated on the report and instructions to the users.

3.5.7 Any changes to the contract shall be communicated to the customers and records of this communication are available in the relevant survey file.

3.5.8 All amendments made to participants' applications throughout the year are communicated to all staff via email.

3.6 **Subcontracting Services Packaging**

(Refer to PM-QMD-001).

SANBS-PTS subcontracts the packaging, transportation and delivery of PTS material and reports.

3.6.1 Certificates and audits are used as means of assessing competency of subcontractors, where this is not possible, SANBS-PTS used customer feedback with regards to lost samples as a means of verifying their competence to provide a courier service. Where audits have been done or certificates are available then these are filed with the procurement office.

3.6.2 Various aspects of the PTS can be subcontracted; however, the planning, evaluation of performance or the authorization of the final report shall not be subcontracted.

3.6.3 All activities that are subcontracted are stated on the report.

3.6.4 When subcontracting occurs, SANBS-PTS ensures that it is placed with a competent subcontractor and takes responsibility for this work. A notification is send out prior to the shipment informing participants of the date of shipment and should the participant not receive their material/report within 5 working days, then the participant is instructed to contact the relevant coordinator who will carry out an investigation regarding the delivery of the material/report.

3.7 **Purchasing service and supplies**

(Refer to PM-QMD-001).

3.7.1 The policies and procedures for the selection of services and materials that can affect the quality of the PTS are as per procurement documents.
All materials and equipment used during production must be recorded on *Consumables and Equipment Used for Validation* (FRM-QCL-117).
All critical materials are listed in *Approved Critical Materials, and Vendor List* (SOP-QCL-027).

3.7.2 All purchased supplies, equipment and materials are checked prior to use by performing QC, checking expiry dates, validation/verification is done as required. Records of the inspection/verification are available on QC logs, Validation/Verification records.

3.7.3 All purchase order information is available in a file and on the electronic SAP system.

3.7.4 All suppliers that are accredited or certified to ISO9001 will not be assessed by SANBS. Suppliers not accredited or certified will be assessed by SANBS. A list of the SANBS approved suppliers and those that have been assessed are available from SANBS Procurement Division and on the SAP System.

3.8 **Service to the customer**

Worksheets include a comments field where participants can provide ongoing feedback. A questionnaire is sent out annually to all participants requesting their feedback regarding the overall service that was offered by SANBS-PTS. The feedback is used as a tool to monitor SANBS-PTS performance and as an improvement tool to better the service provided by SANBS-PTS. Action will be taken where less than 90% of the responses are satisfactory.
The feedback from participants is discussed at management review meetings and at staff meetings. Participants' identity is not revealed on the report.
Action will be taken where less than 90% of responses are satisfactory.

3.9 **Complaints/Appeals:**

Any response of 'unsatisfactory' will be investigated and records maintained. All complaints received by SANBS-PTS are resolved as per *Management of Non-Conformances, Customer Complaints and SHE Incidents* (CP-QMD-025).

3.10 **Control of nonconforming work**

Management of non-conforming work is included in the procedures for preparation, issuing and reporting of each test.

3.11 **Continuous Improvement**

(Refer to PM-QMD-01).
SANBS-PTS always strives to identify Opportunities for Improvement (OFI) by using audit results, analyzing data, corrective and preventative actions and management review as a tool to improve the quality management systems. Improvements are documented and monitored using the business plan.

3.12 **Corrective Actions**

(Refer to CP-QMD-025).

3.13 **Preventative Actions**

(Refer to CP-QMD-025 and PM-QMD-001).
(Preventative action will be taken when potential sources of non-conforming activities within the PTS are identified. This action is defined, implemented, communicated to the relevant people. Preventative maintenance is performed on equipment and documented.

3.14 **Control of Records**

(Refer to PM-QMD-001).
The SANBS-PTS policy is that all quality records (including but not restricted to records listed below) shall be retained for a minimum period of one year on site and five years off site.
Records may include but are not limited to:

- Request forms.
- Examination results and reports.
- Instrument printouts.
- Examination procedures.
- Laboratory work-books or sheets.
- Accession records.
- Calibration functions and conversion factors.
- Quality control record.
- Complaints and actions taken.
- Records of internal and external audits.
- External quality assessment records.
- Inter-laboratory comparisons.
- Quality improvement records.
- Instrument and maintenance/ calibration records.
- Lot documentation, certificates of supplies.
- Incident/ accident records and actions taken.
- Staff training and competence records.
- Management review reports.
- Corrective and preventative actions.
- Customer Feedback.

PTS Technical Records
All technical data records relating to each proficiency testing survey shall be maintained for a period of 5 years which includes:

a) Result of homogeneity and stability testing.
b) Instructions to participations.
c) Participants' original responses.
d) Collated data for statistical analysis.
e) Information required for reports.
f) Final report.

3.15 **Internal Audits**

(Refer to *Internal Audit Management Programme* (CP-QMD-026).
Internal Audits are performed according to schedule.

3.16 **MANAGEMENT Review Meeting**

Refer to PM-QMD-001 and *Management Review Meeting* (CP-QMD-027).

Revision Summary

VERSION NUMBER	REVISION DETAILS
6	• Removed *Quality Corporate Procedures* (CP-QMD-015). • Included *Management Review Meeting* (CP-QMD-027). • Included *Internal Audit Management Programme* (CP-QMD-026). • Included *Management Of Non-Conformances, Customer Complaints And SHE Incidents* (CP-QMD-025). • Included *Quality Control Organogram* (INF-QCL-022). • Included *National and Area Document Codes* (INF-QMD-002). • Added last point on 2.4.7: Crossmatch, Antibody ID and titre performed monthly. HLA, Virology and DAT programs quarterly.