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Plasma for fractionation:

South African Plasma Requirements

Dr Jeh-han Omarjee

Head: Microbiological Sciences

NBI is a "not for profit" company committed to providing safe, cost effective, quality medicinal products

NBI Industry Profile

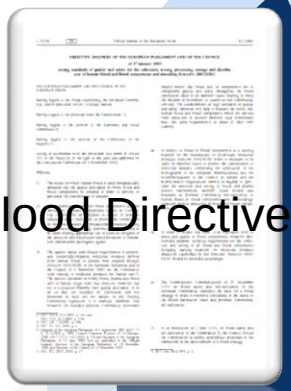
- Not-for-Profit, public benefit organisation
- Registered as a Pharmaceutical Manufacturer
- Schedule 4 medicines (prescription only)
- Registered with the Medicines Control Council (SA)
- Operate in strategic association with BTS in SA
- Largest biotechnology company in SA

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Plasma Quality Requirements



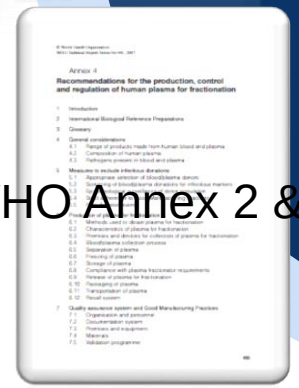
British Pharmacopoeia



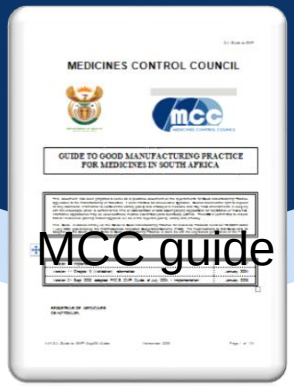
Blood Directive



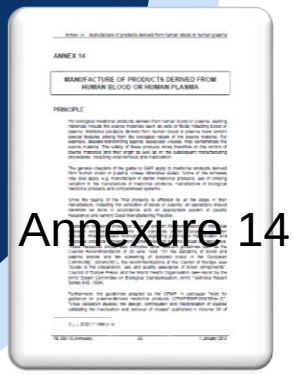
Council of Eu



WHO Annex 2 &4



MCC guide



Annexure 14

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Process towards approving a blood establishment for the supply of plasma for fractionation



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PAPER BASED AUDIT

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Minimum information requested from blood establishment

Regulatory framework of blood transfusion service

National standards for blood transfusion

- Quality Management System


Organisation and personnel
Documentation
Equipment
Validation
Materials
Viral marker testing
Quality Control and monitoring data
Critical Computerized systems
Storage and Transport
Change control Systems
Internals audits
Reporting system
Quality Management System

Minimum information requested from blood establishment

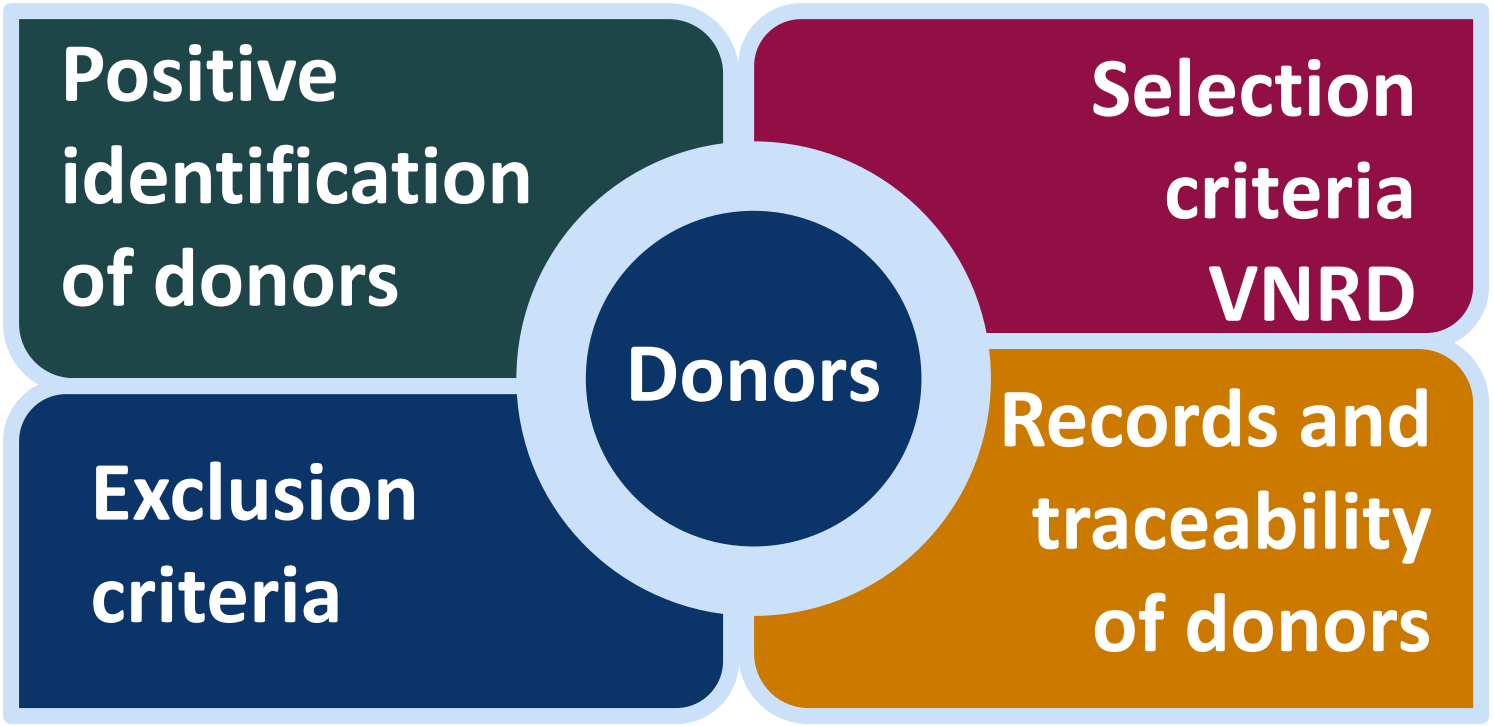
Regulatory framework of blood transfusion service

National standards for blood transfusion

- Quality Management System
- Donor selection

Donor Selection

Measures to exclude infectious donations



Minimum information requested from blood establishment

Regulatory framework of blood transfusion service

National standards for blood transfusion

- Quality Management System
- Donor selection
- Blood collection

Blood collection

Blood/plasma collection process

- Blood bags used and anti-coagulant
- Procedure of collection
- Labelling of units and samples
- Volume of blood /plasma collected
- Mixing
- Reconciliation

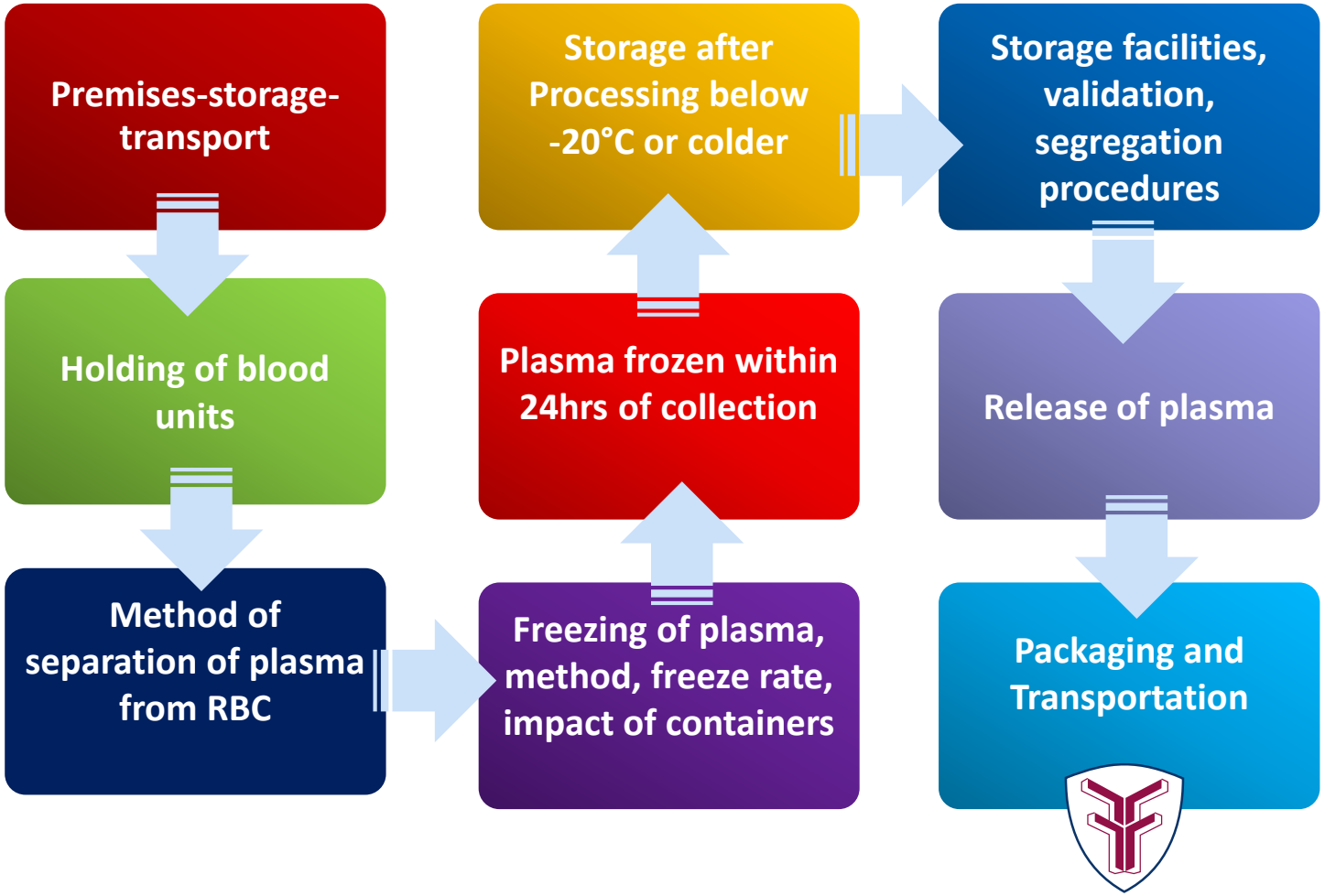
Minimum information requested from blood establishment

Regulatory framework of blood transfusion service

National standards for blood transfusion

- Quality Management System
- Donor selection
- Blood collection
- Blood processing into components (plasma)

Plasma Processing



Minimum information requested from blood establishment

Regulatory framework of blood transfusion service

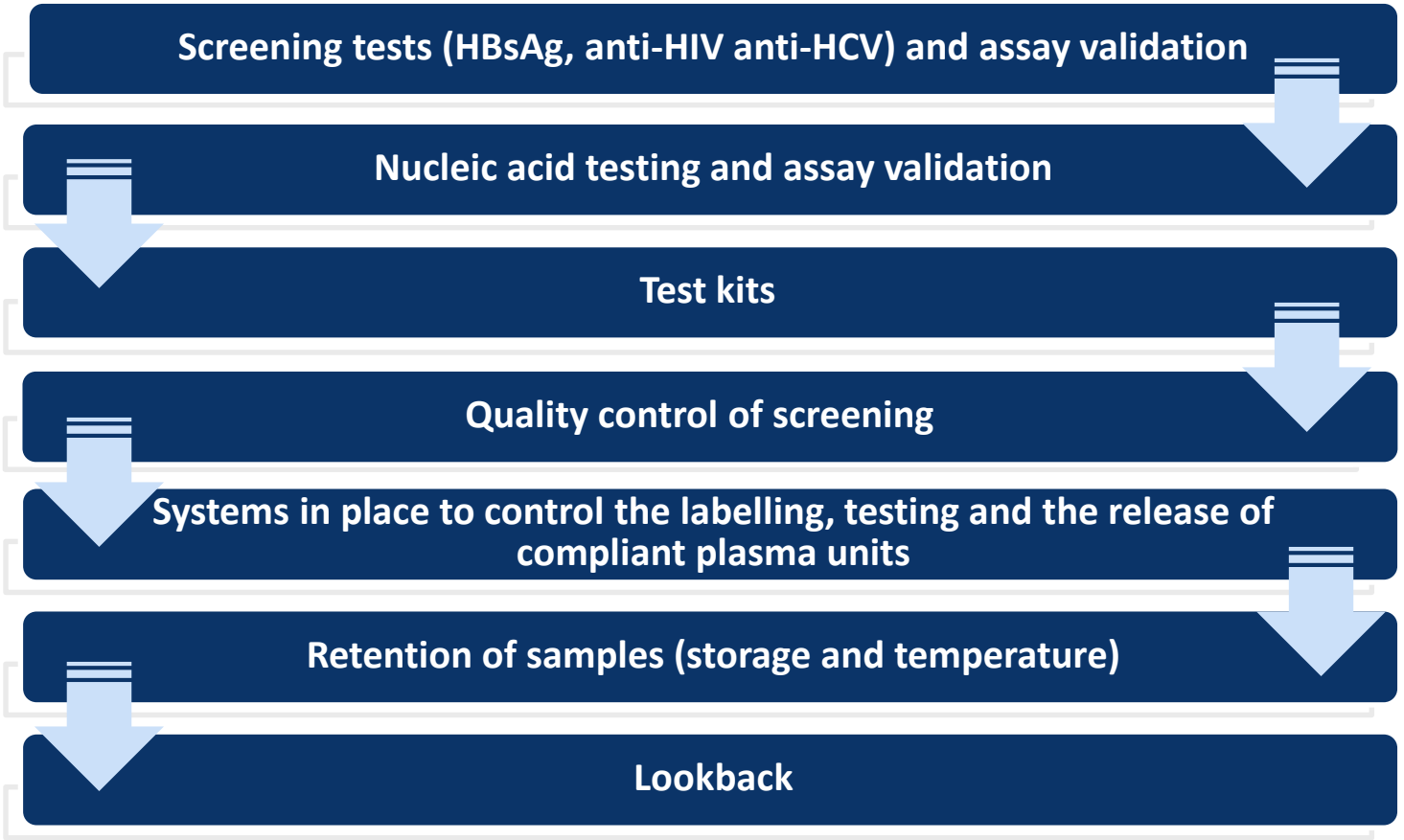
National standards for blood transfusion

- Quality Management System
- Donor selection
- Blood collection
- Blood processing into components (plasma)
- Testing of blood products

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Testing of blood products

Screening of blood/plasma for infectious markers



Minimum information requested from blood establishment

Regulatory framework of blood transfusion service

National standards for blood transfusion

- Quality Management System
- Donor selection
- Blood collection
- Blood processing into components (plasma)
- Testing of blood products

Epidemiology data (HIV, HBV and HCV) and emerging diseases

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Epidemiology data of donor population

- Request epidemiology data for the previous 2-3 years
- Analyse and review data based on screening tests
- Determine incidence and prevalence rates
- Residual risk

PHYSICAL AUDIT

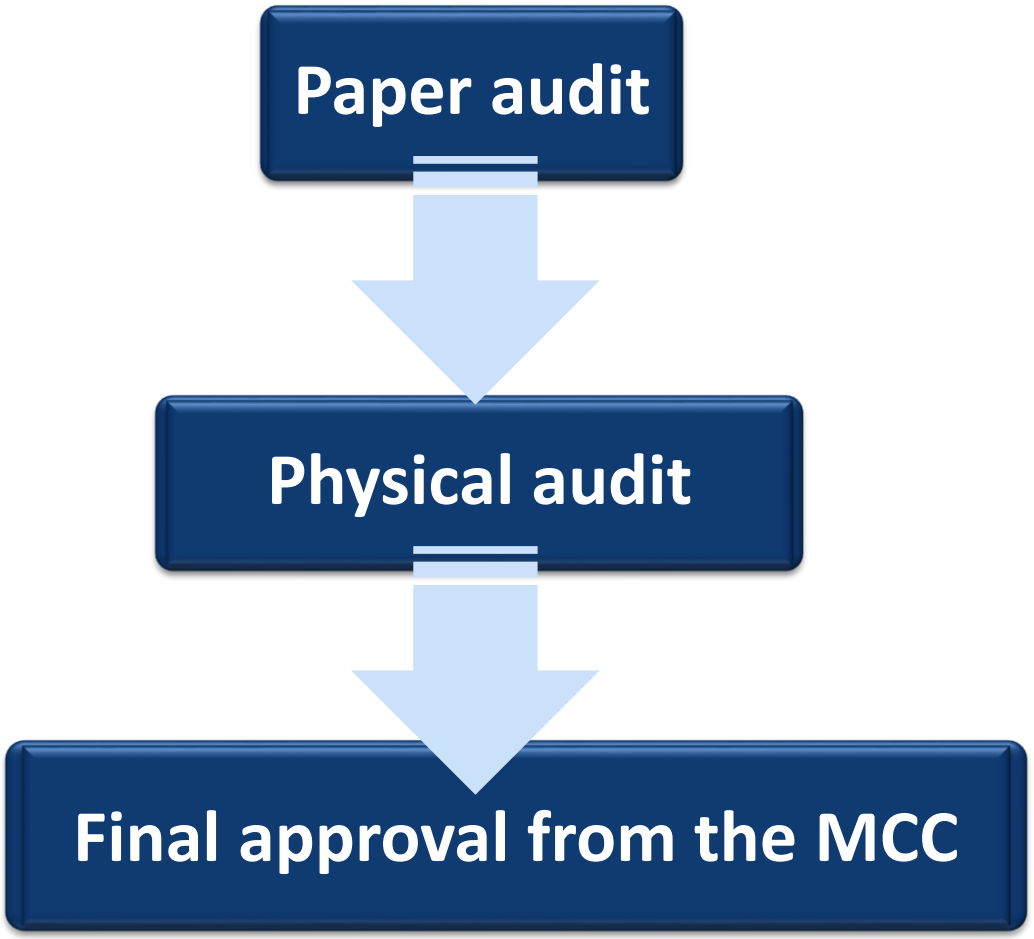


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Key criteria that will be assessed

- Compliance with the principles of GMP
- QMS system is established
- Compliance with standards
- A system that is operational for the issue of good quality and safe plasma

Road Map to approval



NBI's Other Plasma Quality requirements Once supplier is approved



Artificial mini-pool testing

- Hepatitis A and Hepatitis E virus (non-lipid enveloped virus)
- Parvovirus B19 (<log4 IU/ml)
- Major GMP breakthroughs

Plasma Consignment



Plasma Reconciliation









LIMS as the sentinel



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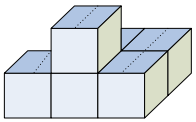
Q-ARM Artificial Pool testing (APT/mini-pool testing)



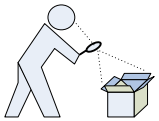




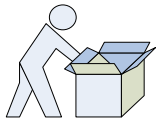
Artificial mini pool testing



40 Plasma boxes

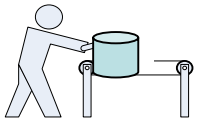


Verification and reconciliation of donations

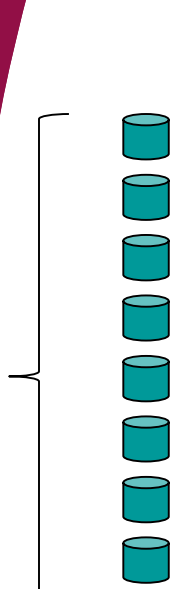


Removal of donation segments

X 36 donations



Pooling of donation segments for each box creating BOX POOLS

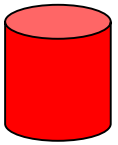


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Row A	B-00124365	B-00122926	B-00124368	B-00124503	B-00124506
Row B	B-00124358	B-00124367	B-00122934	B-00124495	B-00122930
Row C	B-00122933	B-00124497	B-00124369	B-00124498	B-00124359
Row D	~~B-00124361~~	~~B-00124502~~	~~B-00124499~~	~~B-00124504~~	~~B-00122929~~
Row E	B-00124357	B-00124363	B-00124370	B-00124507	B-00122931
Row F	B-00124360	B-00124505	B-00124501	B-00124509	B-00122925
Row G	B-00122928	B-00124364	B-00124496	B-00122935	B-00124362
Row H	B-00124366	B-00124508	B-00122936	B-00122927	B-00122932

HAV RNA and HEV RNA

\+

NAT and Serology



Positive

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NBI's Other Plasma Quality requirements

- An electronic system to issue plasma to fractionator
- Plasma Master File

Plasma Master File (PMF)

- **PMF is a compilation of all scientific data on quality and safety of plasma**
- **Request information to compile the PMF**
  - Plasma Origin
  - Plasma Quality and Safety
  - Epidemiology data
- **The data is requested and reviewed annually**



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Thank You



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