सत्यमेव जयते

FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

COMMISSIONER
FOOD AND DRUG ADMINISTRATION, MAHARASHTRA STATE
Survey No. 341, Bandra Kurla Complex, Bandra (East), Mumbai - 400 051

File No.: FDA-13011(11)/14/2026 (DRUG) **Date: 06.08.2026**

COMPLIANCE ORDER

SUBJECT	Operation of Blood Centres/Blood Storage Centres, as per Schedule F, Part XII-B, Drugs and Cosmetics Rules, 1945.

WHEREAS, the human blood and its components are classified as a "Drug" under Section 3(b) of the Drugs and Cosmetics Act, 1940 (herein after referred as "Said Act"), and no person or institution may collect, store, process, or supply blood or blood components without a valid licence in Form 28-C issued under relevant provisions of the Drugs and Cosmetics Rules, 1945;

AND WHEREAS, every Blood Centre/Blood Storage Centre licensed under the aforesaid Rules is required to comply strictly to the requirements laid down in Schedule F, Part XII-B of the Drugs and Cosmetics Rules, 1945, including those relating to premises, accommodation, personnel, donor selection, blood collection, testing, storage, records, and reporting;

AND WHEREAS, it has been observed that certain Blood Centres/Blood Storage Centres operating within the State of Maharashtra are not fully complying with the requirements prescribed under Schedule F, Part XII-B, and non-compliance in this regard attracts action under the provisions of the said Act & Rules.

AND WHEREAS, it is necessary and expedient to issue comprehensive directions in the interest of donor and patient safety and in order to ensure uniform statutory compliance throughout the State by all the blood centres & blood storage centres.

NOW, THEREFORE, In the interest of public health and for safeguarding the safety, quality and efficacy of blood and blood components supplied to recipients, ensuring the safety of blood

donors, and for securing due compliance with the provisions of the Drugs and Cosmetics Act, 1940, the Drugs Rules, 1945, and all applicable notifications, directions, guidelines and standards issued thereunder from time to time by the competent authorities, the Food and Drug Administration, Maharashtra State, hereby directs all Blood Centres and Blood Storage Centres functioning within the State of Maharashtra to strictly comply with the following requirements.

1. Purpose and Applicability

This order is issued for the compliance by all licensees, medical officers-in-charge, and technical staff operating a Blood Centre and/or engaged in the preparation of Blood Components, whether run by a Government, Regional Blood Transfusion Centre, hospital, charitable/voluntary organisation, Indian Red Cross Society unit, or private institutions.

Human blood and its components are classified as a "Drug" under Section 3(b) of the Drugs and Cosmetics Act, 1940. Accordingly, no person or institution may collect, store, process, or supply blood or blood components without a valid licence in Form 28C issued under relevant provisions of the Drugs and Cosmetics Rules, 1945; and every such centre must conform strictly to the requirements laid down in Schedule F, Part XII-B.

All blood centres are advised to review their current practices against the provisions as per Schedule F, Part XII-B and rectify any gaps without delay, as non-compliance attracts penal action under the Act, including suspension or cancellation of licence.

2. Location, Surroundings and Building

2.1 The premises shall be situated away from open sewage, drains, public lavatories, or any other source of unhygienic surroundings.

2.2 The building shall be constructed and maintained under hygienic conditions and shall be designed to prevent the entry of insects, rodents, and flies.

2.3 The premises shall be well lit, adequately ventilated, and screened (wire mesh) wherever necessary.

2.4 Floors, walls, and working surfaces shall be smooth, washable, and maintained free of cracks and open joints to facilitate effective cleaning.

2.5 A reliable water supply of potable quality shall be ensured at all times.

3. Accommodation Requirements

A blood centre must provide clearly demarcated space for each of the following functions, with adequate furniture and fittings:

Area	Requirement
Registration and medical examination	Adequate furniture and facilities for donor registration and selection
Blood collection room	Air-conditioned
Blood component preparation	Air-conditioned; temperature maintained between 20°C and 25°C
Laboratory (testing)	Separate area for serological & TTD testing
Storage	Refrigerators/deep freezers/platelet agitators as applicable, with continuous power backup and temperature-monitoring/alarm systems
Records/administration	Secure area for storage of donor and issue records

Minimum space norms (as per Drug Rules 1945):

1) Minimum 100 sq. m for core Blood Centre operations.
2) With an additional 50 sq. m where component preparation facilities are provided.
3) An air conditioned area of 10 Sq. M shall be provided for Apheresis.

As per the Drugs and Cosmetics (Second Amendment) Rules, 2020 [G.S.R. 166(E) dated 11th March, 2020], the accommodation for a Blood Centre shall additionally include a Store-cum-Records area, a Counselling area with adequate privacy for donors, and an identified Quality Control area (which may be co-located with the component preparation area).

4. Health, Clothing and Sanitation of Staff

4.1 All staff engaged in blood collection, processing, and testing shall wear clean overalls, head-gear, and foot-wear, and gloves wherever required.

4.2 Personnel shall be medically fit, free of infection, and shall undergo periodic health check-ups.

4.3 Personnel handling blood/blood components shall be vaccinated against Hepatitis B and other relevant infections, with records maintained.

5. Personnel Requirements

The blood centre shall have following categories of whole time Competent Technical staff & shall possess required qualification as per G.S.R. 166 (E) dated 11-03-2020.

5.1 Medical Officer (Blood Transfusion Officer) — possessing qualifications specified in condition (i) of Rule 122-G as amended in G.S.R. 166 (E) dated 11-03-2020.

5.2 Technical Supervisor — possessing qualifications specified in G.S.R. 166 (E) dated 11-03-2020.

5.3 Blood Centre Technician(s) — possessing qualifications specified in G.S.R. 166 (E) dated 11-03-2020.

5.4 Registered Nurse(s) — for necessary Medical Assistance & care.

5.5 Medical Social Worker – Blood Centre organizing blood donation camps shall have whole time or part time counseling staff (Counselor or Medical Social Worker) possessing qualifications specified in G.S.R. 166 (E) dated 11-03-2020.

Any change in technical staff must be reported forthwith, in writing, to the Licensing Authority and Central Licence Approving Authority (CLAA).

6. Donor Selection and Blood Collection

6.1 Only **voluntary, non-remunerated donors** shall be allowed; no professional or paid donor shall be accepted, blood & blood component shall be processed from blood collected from voluntary donation.

6.2 Privacy and thorough medical examination shall be ensured to determine donor suitability.

6.3 Written, informed consent of the donor shall be obtained; donors shall be counselled on the procedure and, in the case of apheresis, on the specific hazards involved.

6.4 Blood collection shall be conducted with minimal risk of contamination and shall be segregated from activities/equipment unrelated to collection.

6.5 For apheresis procedures (plasmapheresis/plateletpheresis/leucapheresis), the Medical Officer must certify donor fitness; haemoglobin/haematocrit and, where warranted, platelet/WBC/differential counts shall be assessed; the procedure shall be carried out by trained personnel under supervision, as per validated Standard Operating Procedures.

6.6 **Detailed Donor Selection Criteria — updated as per G.S.R. 166(E) dated 11th March, 2020**

In addition to the general criteria in Section 6 above, Blood Centres shall apply the donor selection criteria for whole blood and apheresis donation, prescribed under Schedule F, Part XII-B, Section I-H ("Criteria for Blood Donation"), as substituted by the Drugs and Cosmetics (Second Amendment) Rules, 2020 [G.S.R. 166(E) dated 11.03.2020]:

Parameter	Criteria
General well-being	Donor shall be in good health, mentally alert and physically fit, and shall not be an inmate of a jail or other confinement. “Differently abled” donors, or those with communication or sight difficulties, may donate provided clear, confidential communication is established and valid, informed consent is obtained.
Age	Minimum 18 years; maximum 65 years. A first-time donor shall not be over 60 years of age; for a repeat donor the upper limit is 65 years. For apheresis donors: 18–60 years.
Body weight and volume collected	350 ml – donor weight of at least 45 kg; 450 ml – donor weight of more than 55 kg; Apheresis – donor weight of at least 50 kg.
Donation interval	Whole blood: once in 3 months (90 days) for male donors and 4 months (120 days) for female donors. Apheresis: minimum 48 hours between procedures, not more than twice a week.
Blood pressure	Systolic 100–140 mm Hg; diastolic 60–90 mm Hg, with or without medication, with no findings suggestive of end-organ damage.
Pulse	60–100 per minute; regular.
Temperature	Afebrile; 37°C / 98.4°F.
Haemoglobin	≥ 12.5 g/dL (thalassemia trait may be accepted, provided haemoglobin is acceptable).
Meal and alcohol	Donor shall not be fasting; the last meal should have been taken at least 4 hours prior to donation; donor shall not have consumed alcohol or show signs of intoxication before donation.

6.6.1 Permanent deferral conditions include:

- Known or “at-risk” HIV, Hepatitis B or Hepatitis C infection (including transgender persons, men who have sex with men, female sex workers, injecting drug users, persons with multiple sexual partners, or other high-risk behaviour as assessed by the Medical Officer);
- Malignancy, chronic liver disease/liver failure, or chronic kidney disease/renal failure;
- Diabetes requiring insulin, or diabetes with multi-organ complications;
- Cardiac disease, including myocardial infarction, coronary artery disease, hypertensive heart disease, angina pectoris, or open-heart/bypass surgery;
- Epilepsy/convulsions and schizophrenia;
- Bleeding disorders and unexplained bleeding tendency;
- Autoimmune disorders such as systemic lupus erythematosus, scleroderma, dermatomyositis, ankylosing spondylitis, or severe rheumatoid arthritis;
- History of organ, stem cell or tissue transplant; and recipients with two consecutive fainting episodes following blood donation.
- In addition, all other deferral conditions as specified in G.S.R. 166(E) dated 11.03.2020.

6.6.2 Temporary deferral periods include:

- Pregnancy/delivery – 12 months after delivery; abortion – 6 months; breastfeeding – for the entire period of lactation;
- Major surgery – 12 months after recovery; minor surgery – 6 months; tooth extraction/dental surgery – 6 months after recovery;
- Blood transfusion received – 12 months;
- Malaria – 3 months after full recovery; Typhoid – 12 months; Dengue/Chikungunya – 6 months after recovery;
- Tattooing, acupuncture, body piercing or other invasive cosmetic procedures – 12 months;
- Vaccination – 14 days for non-live vaccines/toxoids; 28 days for live attenuated vaccines.
- In addition, all other deferral conditions as specified in G.S.R. 166(E) dated 11.03.2020.

Schedule F, Part XII-B, Section I-H (as substituted by G.S.R. 166(E) dated 11.03.2020) sets out the complete criteria — including physiological deferral for women, infectious and non-infectious disease conditions, medication-related deferrals, occupation-related restrictions, and travel/residence-related deferrals — all of which must be incorporated into each Blood Centre's donor questionnaire and donor-screening SOPs.

7. Mandatory Testing of Blood Units

Every unit of blood collected shall be tested, before issue/use, for freedom from:

- HIV-1 and HIV-2 antibodies (tested in the centre's own laboratory or a Government-approved laboratory)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis C Virus (HCV) antibody
- Syphilis (VDRL)
- Malarial parasite

The results of each test shall be recorded on the label affixed to the blood container. Units returning reactive/questionable results shall be quarantined in a designated storage location pending confirmatory/repeat testing, and shall never be issued for transfusion.

In line with National Blood Transfusion Council (NBTC) recommendations for enhanced blood safety, Blood Centres are encouraged to adopt Nucleic Acid Testing (NAT) for HIV, Hepatitis B and Hepatitis C wherever feasible, in addition to the mandatory serological

tests above, and to participate in the External Quality Assurance Scheme (EQAS) for immunohaematology and Transfusion-Transmitted Infection (TTI) testing coordinated under the NBTC.

8. Storage of Blood and Blood Components

8.1 Provision shall be made for storage of blood/components pending completion of mandatory tests, separate from tested and released stock.

8.2 A designated quarantine area, preferably with biohazard labelling, shall be maintained for units with questionable, pending, or reactive serological results; such units shall be segregated immediately and never issued for transfusion.

8.3 Cold-chain integrity shall be continuously monitored, with backup power and audible alarm systems. Indicative storage parameters:

- **Whole blood/Red Cell Concentrate:** 4°C ± 2°C
- **Platelet Concentrate:** 22°C ± 2°C, under continuous gentle agitation
- **Fresh Frozen Plasma/Cryoprecipitate:** −30°C or below

8.4 Refrigerators/deep freezers used for blood storage shall not be used to store any other item (reagents, food, specimens, etc.).

8.5 Blood shall never be frozen at any stage unless intended as a frozen component, and containers shall never be placed in direct contact with ice.

9. Labelling Requirements

Every blood/blood component bag shall bear a label with:

- The proper name of the product, prominently displayed in bold letters
- Name and address of the Blood Centre
- Licence number
- Serial/unit number
- Date of collection and date of expiry (as prescribed in Schedule P)
- Blood group and colour-coded label: **O – Blue, A – Yellow, B – Pink, AB – White**
- Rh group
- Results of mandatory tests (HIV 1&2, HBsAg, HCV antibody, VDRL, malarial parasite)
- Total volume, nature and percentage of anticoagulant used
- Donor category — the words "Voluntary Donor" or "Replacement Donor" shall appear with no less prominence than the product's proper name

The cross-matching report shall invariably be issued to the recipient/hospital together with the blood unit.

10. Records to be maintained

Blood centres shall maintain, and preserve for a minimum period of **five years**, the following records:

- Blood donor records
- Master records for blood and blood components
- Issue register
- Records of components supplied
- Register of diagnostic kits/reagents used (name, batch number, expiry, date of use)
- Transfusion adverse-reaction records
- Records of purchase, use, and stock of disposable needles, syringes, and blood bags
- Inspection Book in Form 35, for entries by visiting Inspectors.

11. Processing of Blood Components:

11.1 Component separation from whole blood shall be carried out under the requirements specified under Schedule F, Part XII-B, Section III, using validated equipment and SOPs.

11.2 It then lays down component-specific processing and storage standards under Categories of Blood Components:

11.2.1 **Packed Red Blood Cells** — separated within 21 days (ACD) or 35 days (CPDA-1) of collection, stored at 2–6°C, with donor suitability, testing, and pilot-sample requirements specified.

11.2.2 **Platelet Concentrates** — separated within 6 hours of collection, stored 20–24°C with continuous gentle agitation for up to 5 days, with minimum yield, pH, and sterility testing criteria.

11.2.3 **Granulocyte Concentrates** — stored 20–24°C for a maximum of 24 hours.

11.2.4 **Fresh Frozen Plasma** — frozen within 6 hours of collection, stored below −30°C, valid for up to one year.

11.2.5 **Cryoprecipitate** — prepared from FFP, stored below −30°C for up to one year, with a minimum anti-haemophilic factor activity of 80 IU/bag.

12. Conditions of Licence — General Compliance

12.1 The licence and any renewal certificate currently in force shall be displayed at the approved premises and produced on demand to an Inspector appointed under the Act.

12.2 No blood or component shall be collected from, or prepared using, professional or paid donors.

12.3 Any change in technical staff shall be reported forthwith to the Licensing Authority/CLAA.

12.4 Any change in the constitution of the firm operating the licence shall be intimated in writing; the existing licence remains valid for a maximum of three months from the date of change unless a fresh licence is obtained in the name of the reconstituted firm.

12.5 Adequate space, plant, and equipment shall be provided and maintained as specified in Schedule F, Part XII-B/XII-C.

12.6 Adequate arrangements shall be maintained for storage of Whole Human Blood, Blood Components, and blood products, with stability data furnished to the Licensing Authority as & when required.

13. Action Required by Blood Centres

All blood centres are required to:

13.1 Conduct an internal self-audit against prescribed checklist within 30 days and document findings.

13.2 Rectify any deficiencies in infrastructure, staffing, testing, labelling, or record-keeping without delay.

13.3 Ensure all technical staff hold valid qualifications as prescribed under Rule 122-G and Schedule F, Part XII-B.

13.4 Ensure SOPs for donor selection, collection, testing, component preparation, storage, and issue are current, validated, and available for inspection.

13.5 Report any change in technical staff or constitution of the licensee entity to the Licensing Authority/CLAA without delay.

13.6 Be prepared to produce the licence, records, and SOPs to an Inspector at any time.

14. Disposal of Reactive and Expired Blood Units

Blood Centres shall follow a documented Standard Operating Procedure, consistent with Schedule F, Part XII-B and NBTC/DGHS guidance, for identifying, segregating and disposing of blood units that are unfit for transfusion:

14.1 **Immediate segregation and quarantine:** A unit found reactive on any screening test must be segregated immediately and kept in a separate quarantine area, preferably with biohazard labelling, until sent for disposal.

14.2 **Personnel protection:** Disposable gloves must be worn during handling; hands washed immediately after contact; open wounds covered. Any bag breakage, splash, or needle-stick injury must be reported to the concerned authority at once.

14.3 **Statutory compliance:** The disposal method must comply with the Bio-Medical Waste Management Rules and directions of the local State Pollution Control Board.

14.4 **Sterilisation (method of choice):** Autoclaving at 121°C and 15 p.s.i. for 30 minutes, validated at least monthly with a biological indicator (*B. stearothermophilus*). Incineration of blood bags is not recommended due to their PVC content.

14.5 **Chemical disinfection (alternative):** 0.5–1.0% hypochlorite-detergent solution with a minimum contact time of 30 minutes.

14.6 **Disposal of sharps and glassware:** Needles destroyed via electric needle destroyer or soaked in hypochlorite and placed in a puncture-proof, non-chlorinated plastic container for deep burial/incineration; reusable glassware disinfected with hypochlorite-detergent before being autoclaved or oven-treated at 160°C for 1 hour.

14.7 **Spill management:** Cover the affected area with filter paper/cloth, treat with 1% hypochlorite solution for at least 30 minutes, and then wipe clean.

14.8 **Final disposal:** Post-treatment waste is handed over to an authorised Common Bio-Medical Waste Treatment Facility (CBMWTF) via dedicated, bio-hazard labelled transport; on-site storage should not exceed 48 hours.

14.9 **Documentation:** All discarded blood units must be recorded, and the daily stock register must reflect units discarded with the reason for discarding.

15. Blood Donation Camps

Where blood donation camps are organised (e.g., by Regional Blood Transfusion Centres, Government Blood Centres, Indian Red Cross Society, Charitable Trusts or licensed private Blood Centres), the following requirements shall be fulfilled:

- Camps must be conducted in accordance with the requirements prescribed under Schedule F, Part XII-B, Section II.
- The organising centre shall intimate the venue and group-wise details of blood units collected to the Licensing Authority and the CLAA within **seven days** of the camp.

15.1Premises

15.1.1 The camp premises shall have sufficient area and a hygienic location that permits proper operation, maintenance, and cleaning.

15.1.2 The site shall have continuous, uninterrupted electrical supply for all equipment used.

15.1.3 Adequate lighting shall be provided for all activities carried out at the camp.

15.1.4 Hand-washing facilities shall be available for staff.

15.1.5 A reliable communication system to the parent Blood Centre / camp organiser's office shall be maintained.

15.1.6 Furniture and equipment shall be arranged suitably within the available space.

15.1.7 Refreshment facilities shall be provided for donors and staff.

15.1.8 Facilities for medical examination of donors shall be available.

15.1.9 Arrangements for proper disposal of biomedical waste shall be in place.

15.1.10 All information regarding personnel deployed, equipment used, and facilities available at the camp shall be documented and kept available for inspection.

15.2 Personnel Requirement for Outdoor Blood Donation Camps

To collect blood from 50–70 donors in about 3 hours, or from 100–120 donors in about 5 hours, the following minimum staffing shall be deployed:

Personnel	**Requirement**
Medical Officer	One, for overall medical supervision of the camp; responsible for donor fitness assessment, addressing adverse reactions, and certifying suitability of each donor before collection
Nurses / Phlebotomists	Two, together with the Medical Officer, to manage 6–8 donor collection tables/couches
Blood Centre Technicians	Three, whole-time technical staff for donor screening (Hb estimation, blood grouping) and handling of collected units
Medico-social Workers	Two, for donor registration, counselling, and post-donation care
Attendants	Two, for general assistance and donor comfort
Transport	A vehicle with seating capacity for 8–10 persons, with provision for carriage of collection equipment/materials and camp logistics

The Medical Officer & other staff deployed at the camp must meet the same qualification criteria prescribed under Rule 122-G of Drugs & Cosmetics Rules 1945.

15.3 Equipment required for the Camp

- BP apparatus and stethoscope

- Blood collection bags (single/double/triple/quadruple, as required)
- Donor questionnaire/registration forms
- Weighing device for donors and for blood bags
- Artery forceps and scissors; stripper for blood tubing
- Bedsheets, blankets/mattresses for donor couches
- Lancets and swab sticks
- Glass slides; portable Hb meter or copper sulphate method kit
- Test tubes (large and small, 12×100 mm) with stands
- Anti-A, Anti-B, Anti-AB and Anti-D antisera
- Test tube sealer film; dielectric/portable bag sealer
- Medicated adhesive tape
- Insulated blood bag containers/cold boxes capable of maintaining 2°C–10°C during transit
- Needle destroyer, where applicable
- Plastic waste receptacles for biomedical waste
- Donor cards and refreshments for donors

15.4 Emergency Kit at the Camp

Every camp shall carry an emergency medical kit, including:

- Oxygen cylinder with mask, gauge, and pressure regulator
- 5% Glucose or Normal Saline (IV fluids)
- Disposable sterile syringes, needles, and IV infusion sets of assorted sizes
- Injections: Adrenaline, Noradrenaline, an antihistamine (e.g. Mephentine), a corticosteroid (Betamethasone/Dexamethasone), and an anti-emetic (Metoclopramide)
- Aspirin

15.5 Post-Camp Compliance

15.5.1 The organising Blood Centre/organisation shall intimate the venue and group-wise details of units collected to the Licensing Authority and the Central Licence Approving Authority (CLAA) within seven days of the camp.

15.5.2 All collected units shall be transported to the parent Blood Centre under validated cold-chain conditions and subjected to the full panel of mandatory testing (Section 7 above) before release; no unit collected at a camp may be issued directly from the camp site.

15.5.3 Donor deferral criteria (per Schedule F, Part XII-B, Section I-H) shall be applied at the camp itself during donor screening — e.g. deferral for recent surgery,

tattooing, pregnancy/breastfeeding, malaria history, recent immunisation, or listed medical conditions (cancer, heart disease, uncontrolled diabetes, hepatitis, TB, epilepsy, etc.), and any person with these conditions shall not be permitted to donate.

15.6 Objective for Organising a Blood Donation Camp

Blood donation camps shall be organised for the sole and bona fide purpose of augmenting the pool of regular, voluntary, non-remunerated blood donors and the blood stock of the parent Blood Centre, consistent with the National AIDS Control Organisation (NACO) "Standards for Blood Banks and Blood Transfusion Services", which provide that blood donation camps should be organised to augment blood stocks by approaching offices, institutions, industries, and educational, social and Non-Govt. Organisations (NGOs) for need-based collection from a targeted donor group at a fixed venue.

15.6.1 No camp shall be organised, directly or indirectly, for a commercial motive, for publicity/promotional gain unconnected with blood safety and voluntary donation, or as a vehicle for coerced or incentivised "one unit in, one unit out" replacement donation tied to a specific patient/beneficiary. In line with the National Blood Transfusion Council (NBTC) policy to phase out replacement donation in favour of 100% voluntary non-remunerated donation, camps must be structured, publicised and conducted so as to solicit purely voluntary donations.

15.6.2 Every blood donation camp shall be organised only by, or in formal collaboration with, a licensed Blood Centre holding a valid licence in Form 28-C; no unlicensed individual, entity or organisation may independently collect blood at a camp.

15.6.3 The camp plan — including its objective, target donor numbers, target donor group/institution, and publicity material to be used for donor mobilisation — shall be documented and approved by the Medical Officer-in-charge of the parent Blood Centre before the camp is conducted.

15.7 Utilisation of Blood Units Collected at the Camp

Blood collected at a camp are, from the moment of collection, the property and responsibility of the parent licensed Blood Centre and shall be utilised strictly in accordance with the following:

15.7.1 No unit collected at a camp shall be issued, transfused, or otherwise utilised directly from the camp site under any circumstance. Every unit shall first reach the parent Blood Centre, undergo the complete mandatory testing panel prescribed in Section 7 above, and be released only after it qualifies as safe for issue.

15.7.2 Camp-collected units shall thereafter be utilised through the parent Blood Centre's routine, blood-group-wise inventory and issue system — issued to hospitals/patients strictly on the basis of cross-matching, compatibility, and clinical need (with priority to emergency/therapeutic requirement) — and not diverted, reserved, or preferentially allocated to any donor, camp organiser, or their nominee.

15.7.3 No unit collected at a camp shall be pre-committed or exchanged on a "one unit in, one unit out" basis for a specific patient in return for a donor arranged by that patient's relative/friend; such practice amounts to disguised replacement donation and is inconsistent with the NBTC's voluntary, non-remunerated donation policy.

15.7.4 Transfer of blood collected at a camp to another licensed Blood Centre (including inter-institutional transfer by private hospital blood banks) shall be undertaken only in accordance with the applicable MoHFW/CLAA guidelines governing transfer of blood and blood components between Blood Banks and from blood donation camps, and shall be duly documented in the issue and transfer registers maintained under Section 10.

15.7.5 Camp-collected units shall be distinctly tagged/traceable to the camp venue and date in the centre's records and on the e-RaktKosh portal (Section 16), to preserve donor-to-recipient traceability and to support look-back investigations if required.

15.8 Transport of Blood from the Camp Site to the Blood Centre

In addition to the general cold-chain requirement at Section 15.5 above, the following minimum directives shall govern transport of blood collected at a camp:

15.8.1 Units shall be transported in validated insulated blood-bag containers/cold boxes capable of maintaining 2°C–8°C throughout transit, using conditioned/frozen gel packs; blood bags shall never be placed in direct contact with ice or dry ice, and the cold box shall not be opened unnecessarily during transit.

15.8.2 Wherever practicable, units intended for platelet-rich component preparation shall be maintained at 20–24°C (room temperature, without agitation) rather than refrigerated, and shall be clearly segregated and labelled at the time of collection so that transport conditions match the intended component, consistent with DGHS Transfusion Medicine Technical Manual guidance on component-specific handling.

15.8.3 Transport shall be completed within the shortest feasible time and, in any case, within the time-limit fixed in the Blood Centre's validated Standard Operating Procedure so as not to compromise the yield or quality of blood components (whole

blood intended for platelet separation is time-critical and should ordinarily reach the processing laboratory within a 6 hours of collection).

15.8.4 A dedicated vehicle/transport arrangement shall be used for carriage of blood units (as provided for under Section 15.2 above); blood units shall not be transported together with reagents, specimens, food, or other unrelated material.

15.8.5 A trained member of the camp technical team shall physically accompany the consignment from the camp site to the parent Blood Centre and shall be responsible for the integrity of the cold chain in transit.

15.8.6 A Transport/Dispatch Register shall be maintained recording: number and group-wise break-up of units dispatched, time of departure from the camp, cold-box temperature at departure, time of arrival and temperature at the Blood Centre, condition of each unit on receipt, and the signatures of the dispatching and receiving staff.

15.8.7 Any unit found to have suffered a temperature excursion, physical damage, leakage, or undue transit delay shall be flagged, kept separately identified, and referred to the Medical Officer-in-charge for assessment before any further processing, testing, or issue.

15.9 Camp-Specific Standard Operating Procedure (SOP)

Every licensed Blood Centre that organises, or participates in organising, outdoor blood donation camps shall prepare, document, and maintain a separate, validated Standard Operating Procedure exclusively for Blood Donation Camps, distinct from its in-house/static collection SOPs, and covering at minimum:

15.9.1 Pre-camp planning and approval — site survey/suitability assessment, obtaining the Licensing Authority's NOC/camp permission, donor mobilisation and IEC (information, education, communication) material, and confirmation of personnel and equipment deployment (Sections 15.1–15.4 above);

15.9.2 Camp-day procedures — donor registration, pre-donation counselling, medical examination and application of donor selection/deferral criteria (Section 6.1), informed consent, phlebotomy technique, and management of donor adverse reactions;

15.9.3 Packing, cold-chain maintenance and transport of collected units to the parent Blood Centre (Section 11.8 above);

15.9.4 Receipt, verification, and hand-over of units at the parent Blood Centre, including reconciliation of the number of units dispatched against units received, and initiation of mandatory testing (Section 7);

15.9.5 Utilisation/issue of camp-collected units strictly through the Blood Centre's routine inventory system (Section 15.7 above);

15.9.6 Post-camp reporting, including intimation to the Licensing Authority/CLAA, MIS/e-RaktKosh data updation (Section 16), and donor acknowledgement/certification;

15.9.7 Defined roles and responsibilities for each category of personnel deployed at the camp (Medical Officer, Nurses/Phlebotomists, Blood Centre Technicians, Medico-social Workers, Attendants, and transport staff).

15.9.8 The camp SOP shall be approved and signed by the Medical Officer-in-charge, reviewed and updated at least once every year (or sooner, if practice or guidance changes), version-controlled, and kept available for production to an Inspector.

15.9.9 All personnel deployed on camp duty shall be trained on the camp SOP before deployment, and training records shall be maintained and preserved along with other records under Section 10.

Blood Centres are required to align this camp-specific SOP with the relevant guidance in the DGHS Transfusion Medicine Technical Manual, the NACO/NBTC Standards for Blood Banks and Blood Transfusion Services, and the NBTC's Guidelines for Organising Voluntary Blood Donation Camps, Checklist for Camp Permission, and NOC Guideline, in addition to the statutory requirements of Schedule F, Part XII-B.

16. Daily Data Updation on the e-RaktKosh Portal

All Blood Centres shall comply with the following reporting requirements on e-RaktKosh (Centralised Blood Bank Management System, eraktkosh.mohfw.gov.in), maintained by the Blood Cell, National Health Mission, Ministry of Health & Family Welfare, Government of India, in coordination with the State Blood Transfusion Council (Maha-SBTC):

16.1 Every Blood Centre shall be registered on the e-RaktKosh portal and shall keep its blood stock and related data updated on a daily basis — in real time to the extent feasible — so that the current stock position is accurately reflected for hospitals, patients and the public.

16.2 Data to be updated shall include, without limitation: daily blood collection (voluntary/replacement), component preparation, group-wise and component-wise stock in hand, issues to hospitals/patients, blood donation camp schedules and outcomes, and donor registration details, as per the fields prescribed on the portal.

16.3 A designated staff member (e.g. the Blood Centre Technician or Technical Supervisor) shall be responsible for daily data entry, and the Medical Officer-in-charge shall periodically verify the accuracy of the data uploaded.

16.4 Lapses in daily updation, or discrepancies between physical stock and the stock reflected on e-RaktKosh, will be treated as a compliance deficiency liable for action by the Licensing Authority/State Blood Transfusion Council; Blood Centres have been specifically directed to correct gaps in inventory reporting and strictly adhere to daily stock-update protocols.

16.5 Login credentials shall be kept secure; any technical difficulty preventing timely updation shall be promptly reported to the SBTC/e-RaktKosh helpdesk; and data on e-RaktKosh shall be reconciled with the internal registers maintained under Section 10 above during the periodic self-audit.

17. Roles and Responsibilities of FDA Officers for Implementation of this Order

17.1 Joint Commissioner (Drugs) — Licensing Authority, Blood Centres/Blood Storage Centres

The Joint Commissioner (Drugs), being the Licensing Authority for Blood Centres/Blood Storage Centres under the Drugs and Cosmetics Rules, 1945, shall be responsible for:

I. Overall supervision and enforcement of this Order within the jurisdiction, including ensuring that all Blood Centres/Blood Storage Centres holding licence comply with the requirements of Schedule F, Part XII-B & other applicable guidelines.

II. Reviewing and approving inspection reports and compliance recommendations submitted by the Assistant Commissioner (Drugs) & drugs Inspectors and directing further action, including re-inspection, wherever necessary;

III. Ensuring that inspections of all licensed Blood Centres/Blood Storage Centres within the jurisdiction are conducted as per prescribed periodicity.

IV. Initiating the administrative action in case of non-complaince of mandatory requirements arising out of inspection.

V. Periodically reporting the status of compliance, enforcement action taken, and pendency, if any, to the office of the Commissioner, Food and Drug Administration, Maharashtra State.

17.2 Assistant Commissioner (Drugs) & Drugs Inspector

I. Conducting periodic and, surprise inspections of Blood Centres/Blood Storage Centres within the assigned jurisdiction, to verify compliance with the requirements set out in this Order, including premises and accommodation, personnel, donor selection and blood collection, mandatory testing, storage, labelling, records, and processing of blood components;

II. Verifying compliance with the conditions of licence, including staffing, equipment, cold-chain arrangements, and biomedical waste management.

III. Verifying, during inspection, that daily data updation on the e-RaktKosh portal is being carried out by the Blood Centre as required under this Order;

IV. In the case of outdoor blood donation camps, verifying compliance with the personnel, equipment, emergency kit, and camp-specific SOP requirements prescribed under this Order;

V. Preparing and submitting a detailed inspection report to the Licencing Authority clearly recording deficiencies observed and recommending appropriate action;

VI. Bringing instances of serious or repeated non-compliance — including operation without a valid licence, unsafe donor selection practices, improper storage of blood & blood components, non-testing of units, or improper disposal of reactive/expired units — to the immediate notice of the Licensing Authority for necessary action under the Act;

VII. Maintaining jurisdiction-wise inspection records and ensuring timely follow-up inspection to confirm rectification of deficiencies previously pointed out.

18. Action for Non-Compliance

Without prejudice to the administrative directions contained in this Order, any Blood Centre/Blood Storage Centre found to be in contravention of the provisions of this Order, shall be liable for action as per the relevant provisions of Drugs & Cosmetics Rules 1940, as follows,

18.1 Issuance of a show cause notice calling upon the licensee to explain the reasons of deficiencies/violations noticed during inspection within the specified time period.

18.2 Suspension or Cancellation of the licence granted, in whole or in part, in respect of a Blood Centre/Blood Storage Centre found to be operating in contravention of the conditions of licence or the requirements prescribed under Schedule F, Part XII-B, of the Drugs and Cosmetics Rules, 1945;

18.3 Prosecution under Section 27 of the Said Act for the manufacture, storage, distribution, or supply of blood/blood components in contravention of the provisions of Chapter IV of the Act.

18.4 Any other administrative or legal action as may be warranted under the Act and the Rules made thereunder, or as may be directed by the Licensing Authority or the Commissioner, Food and Drug Administration, Maharashtra State, from time to time.

Note: *This order is a summary compiled for guidance and ready reference. It does not substitute the statutory text of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (including all subsequent amendments), which shall prevail in case of any discrepancy. Blood centres should refer to the official Gazette notifications and the current consolidated Rules, and can consult the Food and Drug Administration, Maharashtra State (as the State Licensing Authority) or Central Drugs Standard Control Organisation the Central Licence Approving Authority (CLAA), as applicable & as and when required in case of doubts, disputes or any queries.*

To,

All Licensees of Blood Centres / Blood Storage Centres operating within the State of Maharashtra under the Drugs and Cosmetics Act, 1940 and Rules, 1945.

Digitally signed by
TUKARAM H MUNDHE
Date: 06-08-2026
17:28:50

(Tukaram Mundhe, I.A.S.)
Commissioner
Food and Drug Administration,
Maharashtra State, Mumbai.

Copy to:

The Additional Chief Secretary, Food and Drug Administration, Government of Maharashtra, Mantralaya, Mumbai.

Copy forwarded for necessary action:

1. All Joint Commissioners (Drug), FDA Maharashtra.
2. All Assistant Commissioners (Drug), FDA Maharashtra.
3. All Drugs Inspectors, FDA Maharashtra.
4. Director, SBTC, Maharashtra State.