STANDARD OPERATING PROCEDURES (SOP'S) FOR I.V. FLUIDS PROCUREMENT, HANDLING, STORAGE, TESTING, ADVERSE REPORTS.

1. ITEMS COVERED UNDER THESE SOP'S :—

(i) Dextrose 5%
(ii) Dextrose 10%
(iii) D.N.S.
(iv) Normal Saline
(v) Ringer Lactate
(vi) Mannitol
(vii) N/2 Saline
(viii) N/3 Saline
(ix) N/4 Saline
(x) Isolyte P
(xi) Isolyte G
(xii) Isolyte M

It does not cover other medicaments given by IV route.

2. PROCUREMENT OF IV FLUIDS :—

i) These items should be procured as per pattern of past consumption, based upon demands given by store keeper/ pharmacists and approved by officer in charge stores.

ii) In case of annual indents to GMSD for supply of IV fluids, the annual indents must be placed to GMSD at least 3 months in advance and given proper scheduling of supply dates.

iii) In other cases, in case of non-supply of IV fluids from the GMSD, the concerned store keeper/pharmacist should initiate the demand when he/she has a stock of at least 3 months in hand, keeping mind the external and internal lead times, to avoid its stock out.

iv) The Purchase Section will initiate the purchase process and place the supply orders at least two months before the total exhaust of stores of that variety of IV fluid.

v) The procurement of IV fluids should be done from the firms approved by the Ministry of Health & Family Welfare and a comparative statement of the rates may be prepared to facilitate the issue of supply order.

vi) Emergency purchases of IV fluid should also be restricted to IV fluids manufactured by these approved firms only.

3. RECEIPT OF IV FLUIDS :—

i) The pharmacist/store keeper will receive goods against a proper indent/supply order and with the permission of officer I/c stores/store officer only.

ii) The goods should be purchased from manufacturers approved by the Ministry of Health & Family Welfare as mentioned in point Number2 (v).

iii) The goods received from MSD are pre-tested by the GMSD and a proper statement to this effect should be recorded on the body of the delivery challan. Only tested goods and declared of standard quality are to be accepted by the store keeper/pharmacist.

iv) In case of supply received from other sources, the samples for testing of goods are to be sent in all cases to the Government approved testing laboratories before taking them into stock, issue and passing of bills. The samples for testing should invariably be sent immediately but not later than 4 working days, to the labs approved by the hospital for this purpose. The samples should be taken on a random sampling basis. Each batch should be got accordingly tested separately. In case, due to some unforeseen circumstances, emergency procurement of limited supply is resorted to when there is total stock out of particular items, it may not be feasible to get the material pre-tested before issue. In such circumstances, officer in charge (Store) may use his discretion to issue such store without test at the hospital level as the manufacturing

firm before marketing has already tested these materials. However, every effort should be done to avoid such situation.

v) The quantity of stores received should be tallied with the indent/supply order, delivery challan. The batch number, date of manufacturing, date of expiry should be thoroughly checked and recorded in the respective ledgers/inspection registers.

vi) The inspecting officer should also check the quantity, batch number, DOM, DOE, etc., before giving clearance for acceptance of goods. The inspections should be completed immediately but not later than 4 working days after the receipt of goods.

4. STORAGE:

i) All the IV fluids should be stored at a dry, cool place, free from humidity and moisture.

ii) The fluids should be stored in proper shelves, batch wise, and away from direct sunlight and arranged according to the principle of FIFO.

iii) The IV fluids cartons should be placed in upright direction with easily visible batch number, DOM, DOE. The number of cartons should not be more than three over the bottom most layer to avoid development of minor cracks due to pressure.

iv) Proper pesticide control and anti rodent measures should be taken to avoid destruction/damage of IV fluid bottles.

v) IV fluids, which are under test, should be stored separately.

vi) The expired items/IV fluids declared not of standard quality/ items reported to have adverse reaction or having particulate matter, defective and deformed bottles should be kept in a separate enclosure. Labelling them accordingly ensures a proper identification of such material to avoid its use for patients.

vii) An expiry date register of all items should be maintained.

5. ISSUE:

i) Only items declared of standard quality on testing should be issued except in case of emergency and with the approval of officer In charge store (Reference point Number3 (iv).

ii) Each and every bottle should be checked against light with white and black background, for any particulate matter present in the bottle before issue. No bottle, having such matter should be issued in any circumstances. This should be properly recorded on the issue vouchers by the storekeepers/ pharmacists.

iii) All the issue of material should be made against a proper indent from the concerned department with relevant entries of batch number, DOM, DOE, quantity issued, made in each indent.

6. TRANSPORTATION OF BOTTLES :

i.) The indentor will ensure that cartons of IV fluids are transported in proper position and carefully to avoid any breakage/cracks due to fall/overpressure.

7. STORAGE IN WARDS/OTHER USER AREAS :

i) The user department should stock the optimum quantity of stores only at a time and in any case not more than the estimated consumption in 2 weeks.

ii) The storage should be done in racks in upright position, in a cool and dark place, away from sunlight and having minimum moisture/humidity. The cartons should not have more than three layers on top of the bottom most layers to avoid development of pressure cracks.

iii) Before using IV fluid on patients, each and every bottle of IV fluid should be re-checked against light by the user and no bottles should be used for patients if it contains any particulate matter/fungus/the shape of bottle is deformed.

iv) The sister in charges of the ward should keep a record of all the IV fluids received in their wards with details of batch Number, DOM, DOE, Name of manufacturer, etc.

8. REPORTING AND FOLLOW UP ACTIONS ON REPORTS OF POOR QUALITY OF IV FLUIDS, IF ANY.

i) Any user, if finds any particulate matter in a bottle while rechecking it before infusion, the use of that batch of bottles should be stopped immediately and a written complaint, in the

prescribed proforma, along with the unused bottles having particulate matter, should be sent to the officer in charge store, immediately, without any delay.

ii) The store in charge will get a circular issued for return of the IV fluid of that batch number from all the users for exchange of fluids of other batch.

iii) All the bottles received back should be got rechecked physically against light for any particulate matter. The number of bottles found defective should be noted down.

iv) The officer in charge store will inform the Drug Controller authorities to draw the samples out of defective batch to test for suitability of use. The information will also be sent to the manufacturing firm and DGHS for information and necessary action at their end.

v) The further use/disposal of this material will be based upon the advise of the Drug Controller Authorities.

vi) In case of replacement from supplier, the fresh batch should be taken.

9. FOLLOW UP ACTION ON REPORTS OF ADVERSE REACTION/ POOR QUALITY OF I.V. FLUIDS.

The following procedure is to be adopted by all concerned when an adverse reaction is reported due to administration of I.V. Fluids/other drugs in the wards/other areas of the hospital.

(i) The use of I.V. Fluid (or any drug) which has caused adverse reaction in a patent should be stopped forthwith and the Doctor In charge should be informed immediately.

(ii) Immediate steps should be taken to mange the patient against the observed drug reaction.

(iii) After noting the label details of I.V. Fluid/ drug which has/ have caused adverse reaction, empty/unused bottle and used vial/ampoule, etc.) should be sealed and kept in safe custody.

(iv) A proforma attached should be filled by the reporting physician and sent to the Head of the Department of the ward. This should be sent immediately to the A.M.S. Office Cyclostyled proforma can be obtained from his office.

1481 DGHS/2002—12

(v) The Medical Superintendent/Store In charge should issue immediate instruction to various wards so as to recall the unused stock of drugs if any lying with the ward and order immediate stoppage of the drug from circulation in the hospital.

(vi) Immediate steps should be taken to report the matter to the State Drug Control Authorities along with the information in the Proforma for further investigations by them.

10 PROFORMA FOR I.V. FLUID ADVERSE REACTION REPORT.

Date :

Place of reaction (Ward/O.T./Emergency)

Name of Officer reporting :

Designation :

Details of IV Fluid, which caused adverse reaction :

Name of IV Fluid	Batch Number	DOM	DOE	Manufacturer

Date of adverse reaction : Name of Patient :

Reg. Number

Type of reaction noticed :

How the adverse reaction was managed :

State of the patient now :

Further details of the IV Fluid under reporting :

Name of IV Fluid	Qty. indented	Date of Indent	Qty. Consumed	Balance Qty. in hand

I certify that use of the above batch of IV Fluid has been stopped in my department and quantity left has been kept separately under safe custody.

Signature of Head of Department Signature of Complainant

STANDARD OPERATING PROCEDURES (SOP'S) FOR MATERIALS MANAGEMENT

1. ITEMS COVERED UNDER THESE SOP'S.

(i) Disposable & Rubber goods, Instruments, Equipments, Furniture.

(ii) Injections

(iii) Tablets & Capsules

(iv) Surgical Stores

(v) Syrups & Ointments

(vi) Linen, Liveries & Contingency Store

(vii) Stationary Items

(viii) X-ray films & Chemicals

(ix) There is a Separate SOP for IV Fluid Store (Appendix II).

2. DEMAND FORECASTING

(i) The demand should be placed as per pattern of past consumption and based upon demands given by user department /store keeper/pharmacists duly approved by the officer in charge stores. All the demands of the user department should be routed through concerned store keeper/pharmacists and officer in charge stores. Annual demand should be prepared by each store keeper and put up to officer in charge stores at least four months before the start of new financial year so that the annual indents may be placed to GMSD at least three months in advance by the purchase section and given proper scheduling of supply dates.

(ii) In rest of the cases demand should be put up at least 3 months in advance, keeping in mind the time taken for placement of purchase order and supply of goods, to avoid its stock out.

(iii) The purchase section should initiate the purchase process well in time and place the supply orders at least two months before the total exhaust of stores.

(iv) The store keeper will give urgent reminder to the purchase section when he is left with stock of one month consumption

and also bring it to the knowledge of CMO Stores for follow up with the Officer in charge purchase.

(v) Each storekeeper will maintain a list of essential and critical items stocked by them and will make every effort to make it available without interruption by keeping constant liaison with the purchase section, user department and suppliers.

3. RECEIPT OF STORES

(i) A copy of supply order placed by purchase section should invariably be endorsed to the CMO Store who would mark it to the individual store keeper/pharmacist.

(ii) The store keepers/pharmacists will receive goods against a proper indent/supply orders and with the authorization of CMO stores.

(iii) The quantity of stores received should be tallied with the indent/supply orders and delivery challans. The batch number, date of manufacturing, date of expiry should be thoroughly checked and recorded in the respective ledgers/inspection registers.

(iv) The inspecting officer detailed for each store, should be informed in writing about the receipt of goods at the earliest but not later than two working days.

(v) The inspecting officer should verify the goods in the stores only. They should check the Quantity, Quality, Batch number, DOM, DOE, comparison with approved sample, if available, before giving clearance for acceptance of goods. The inspection should be completed immediately but not later than two working days after the receipt of intimation.

(vi) A copy of delivery challans would be sent to the purchase section by store keepers/pharmacists through CMO stores, duly recorded by LDC posted in stores, who would maintain a master register for all such records.

4. TESTING OF GOODS

(i) The goods received from GMSD are got pre-tested by the GMSD before supply to hospitals and a proper statement to this effect should be recorded on the body of delivery challan

of GMSD. Only tested goods and declared of standard quality are to be accepted by the store keepers/pharmacists.

(ii) In case of all drugs supply received from other sources, the samples for testing of goods are to be sent in all cases to be Government approved testing labs, before taking them into stock, issue and passing the bills. The samples for testing should invariably be sent immediately but not later than four working days, to the labs approved by the hospital for this purpose. The samples should be taken on a random sampling basis. Each batch should be got accordingly tested separately.

(iii) In case, due to some unforeseen circumstances, emergency procurement of limited supply is resorted to or local purchases when there is total stock out of a particular items, it may not be feasible to get the material pre-tested before issue. In such circumstances, CMO stores may use his discretion to allow issue of such store without getting tested at the hospital level as these materials are already got tested once by the manufacturing firm before marketing. However, every effort should be made to avoid such situations.

5. VERIFICATION OF BILLS

(i) The bills of the goods received, shall be received directly by the LDC of stores, who would enter them in a register & will put up to the Officer in charge stores, who would then forward these to the store keepers/pharmacists for verification.

(ii) The store keeper/pharmacist would verify the bills and put up to the CMO in charge stores for signatures as early as possible but not later than seven working days from the date of receipt of bills/receipt of test reports, which ever the case may be, would then be entered in the master register and sent to the account section by the LDC.

(iii) Those bills for which formal sanction have not been issued, should be sent to purchase section for sanctions/re-validation.

6. ISSUE

(i) Only items declared of standard quality on testing should be issued except in case of emergency and with the approval of CMO stores [also refer to 4(ii), 4(iii)].

(ii) All the issue of material should be made against a proper indent from the concerned department duly signed by and officer working in the stores. The relevant entries of batch number, DOM, DOE, quantity issued should be made in each indent by the store keepers/pharmacists.

7. REPORTING AND FOLLOW UP ACTIONS ON REPORTS OF POOR QUALITY GOODS.

(i) In case of any complaint from the user regarding adverse reactions by any of the drug items, CMO stores will inform the Drug Controller Authorities to draw the samples out of the reported defective batch to test for suitability of use. The information will also be sent to the manufacturing firm. The use of the above said batch of drug will be stopped immediately and all issued stocks withdrawn. The further use/disposal of this material will be based upon the advise of the Drug Controller Authorities. In case of replacement from supplier, the fresh batch should be taken against the defective lot.

(ii) In case of non-drug items the reported poor quality items should be got re-checked by inspecting officer/any other authority for taking appropriate and relevant decision in the case, in consultation with Officer in charge purchase section.

8. RECORD KEEPING

Expiry Date Register

(i) An expiry date register should be maintained and periodically reviewed by all store keeper/pharmacists for all items having a life. The format should be as follows, month wise.

MONTH OF EXPIRY.....YEAR.....

Date of expiry	Name of Items	Quantity Received	Supplier's name P. S. O. Number

Stock Ledger Register

(ii) The stock ledgers should be maintained by all store keepers/pharmacist. All pages should be numbered and certified from the officer in charge of stores in the beginning of the register.

(iii) All the entries in this ledger should be initialed by store keeper/pharmacist and same should be checked and verified by gazetted officer working in store. All cutting should be similarly got initialed and attested.

(iv) All the bills verified should be entered in the stock ledger register after making due entries in the relevant pages, preferably with red ink.

(v) No new stock ledger should be opened without prior permission and approval of officer working in store. In case a new register is opened, all entries should be carried forward to the new register and should be certified by store keeper/pharmacist and countersigned by officer in charge stores.

9 MISCELLANEOUS

(i) All the individual stores have to be sealed by the individual seal of store keeper/pharmacists and the main gates to be sealed by the hospital seal in custody of the CMO Stores/Officer working in stores at the closure time.

(ii) Duplicate keys of all the stores are to be kept (in sealed envelope) in custody of the Additional Medical Superintendent stores, to be used in exigencies of services. Such events are to be entered in an Events Register to be maintained by CMO Store/Officer working in store. In such case, stores should be opened in the presence of at least two gazzetted officers

(iii) All the administrative matters pertaining to stores will be decided by the CMO Stores, who in turn will keep informed the Additional Medical Superintendent stores about any important matters.

(iv) All leaves will be sanctioned by the CMO stores or Additional Medical Superintendent (stores & purchase). The record of leave to be maintained by the LDC (stores).

(v) All correspondence outside the stores should be through the office of CMO stores only.