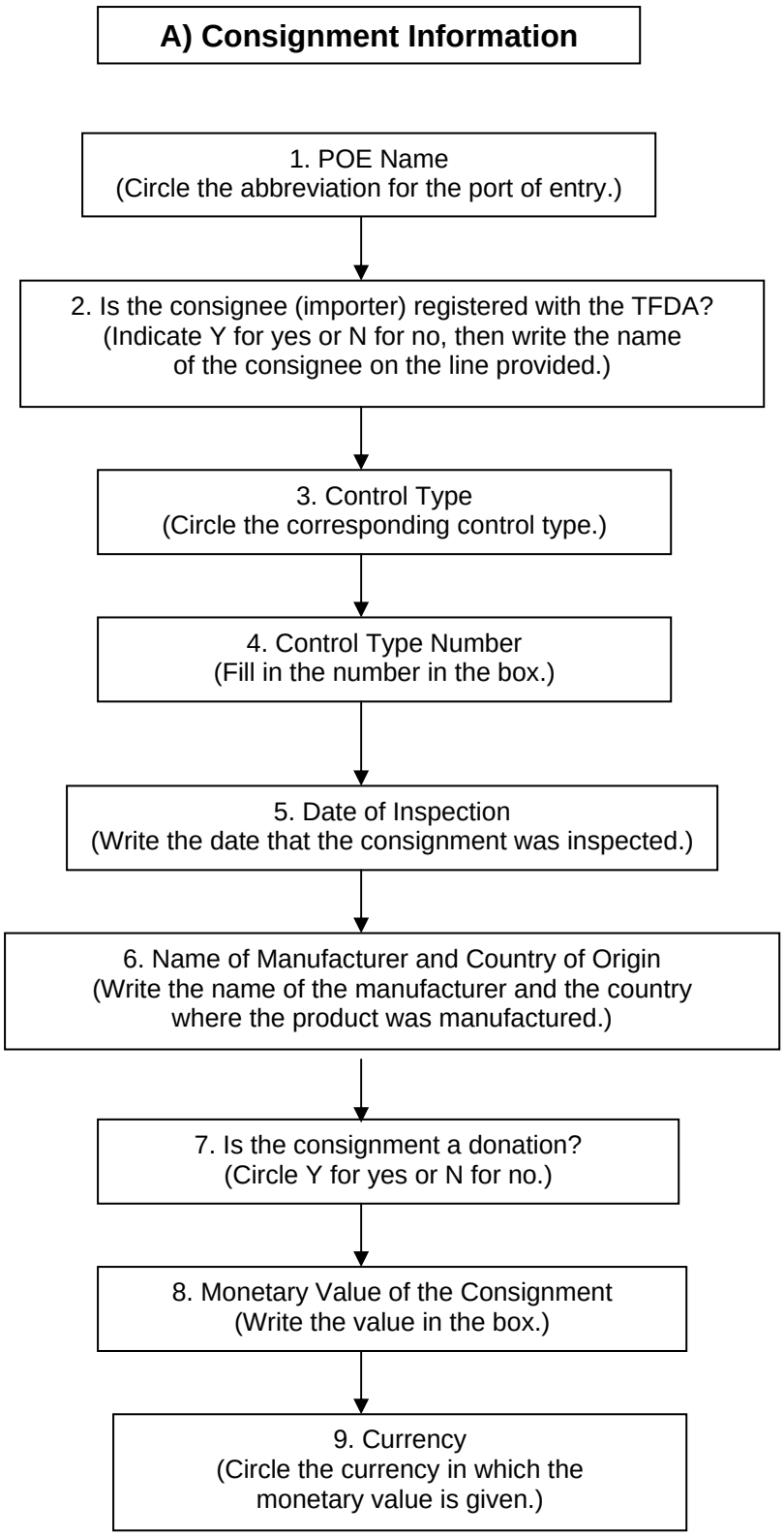
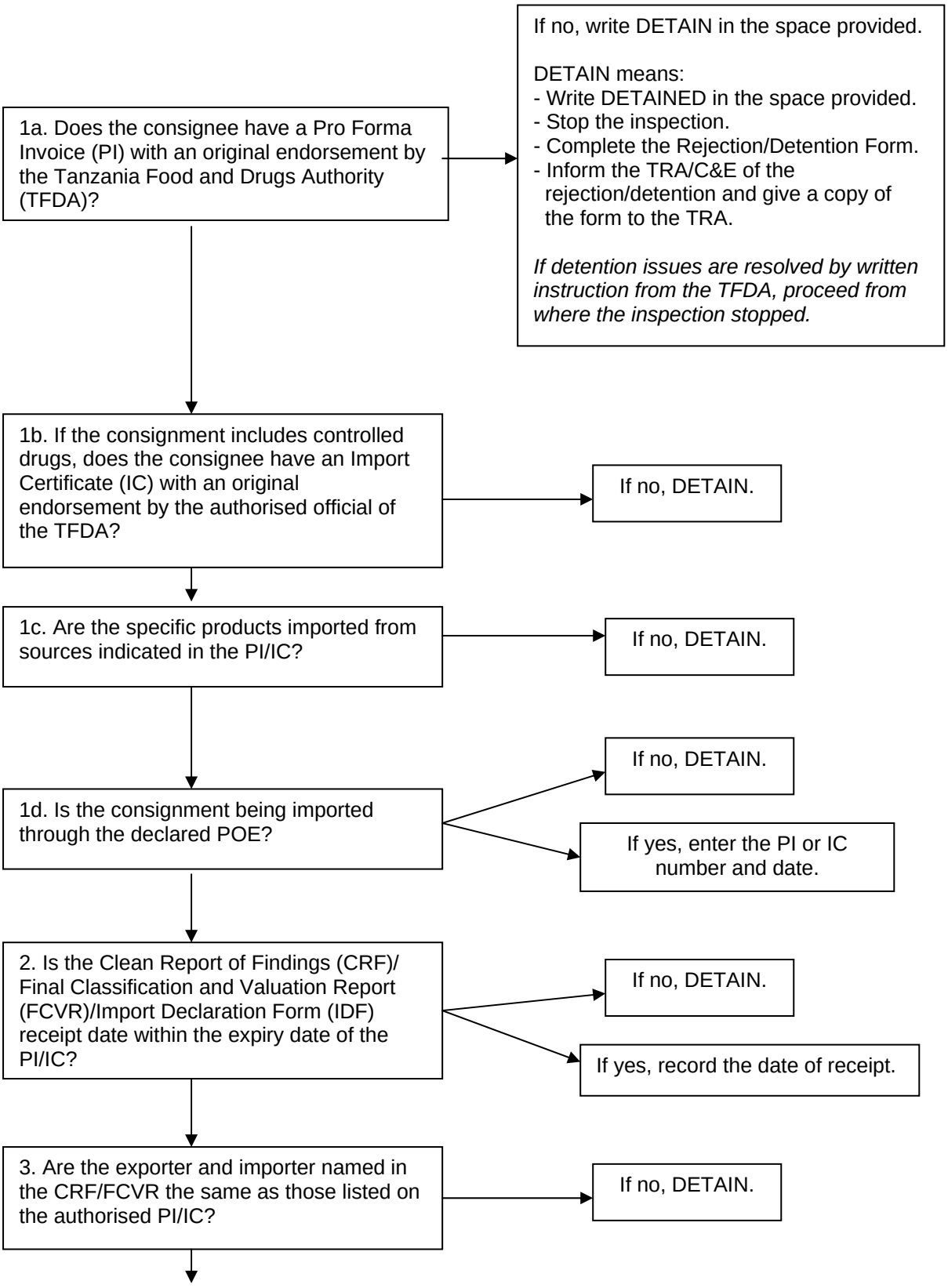
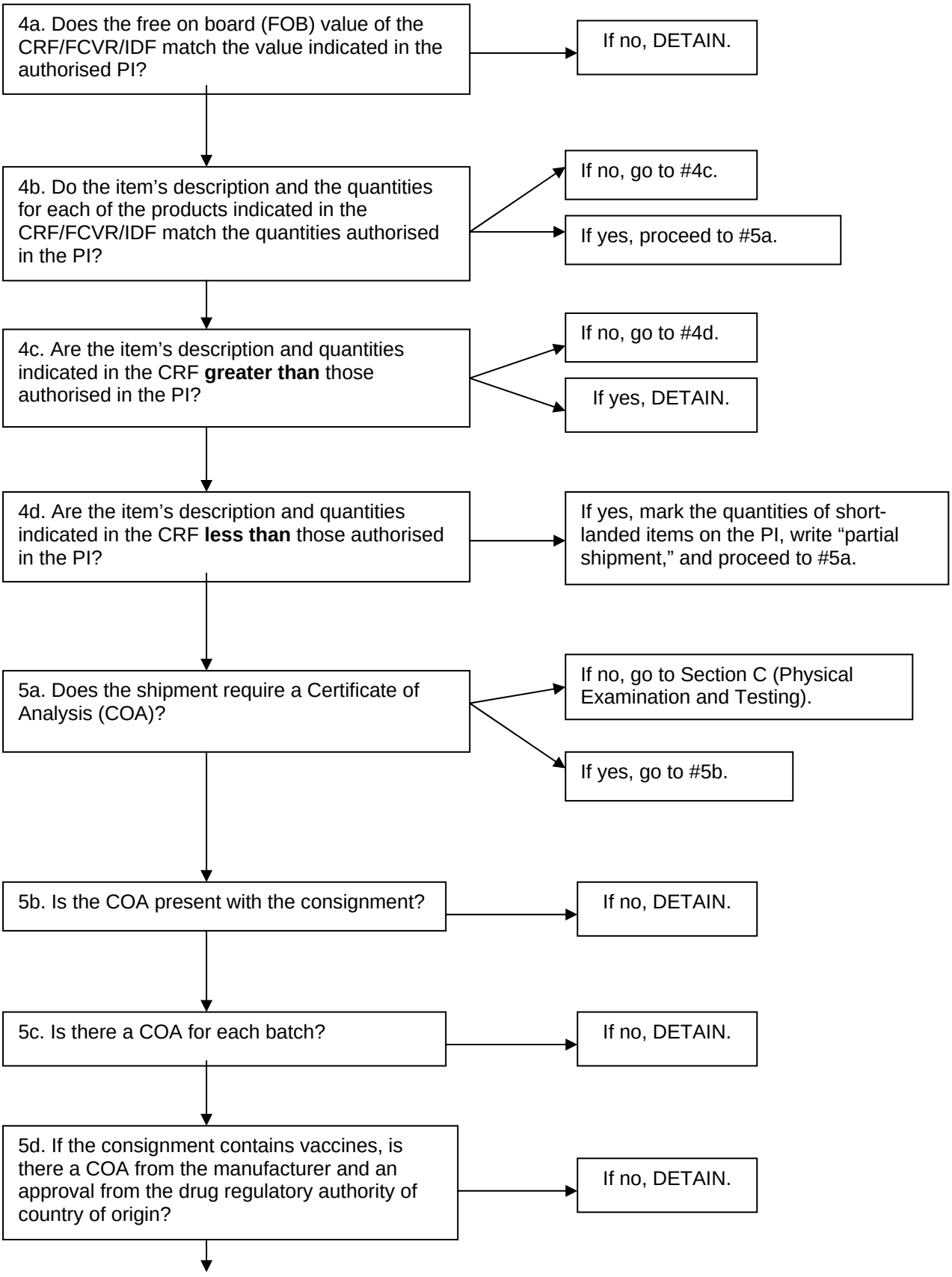
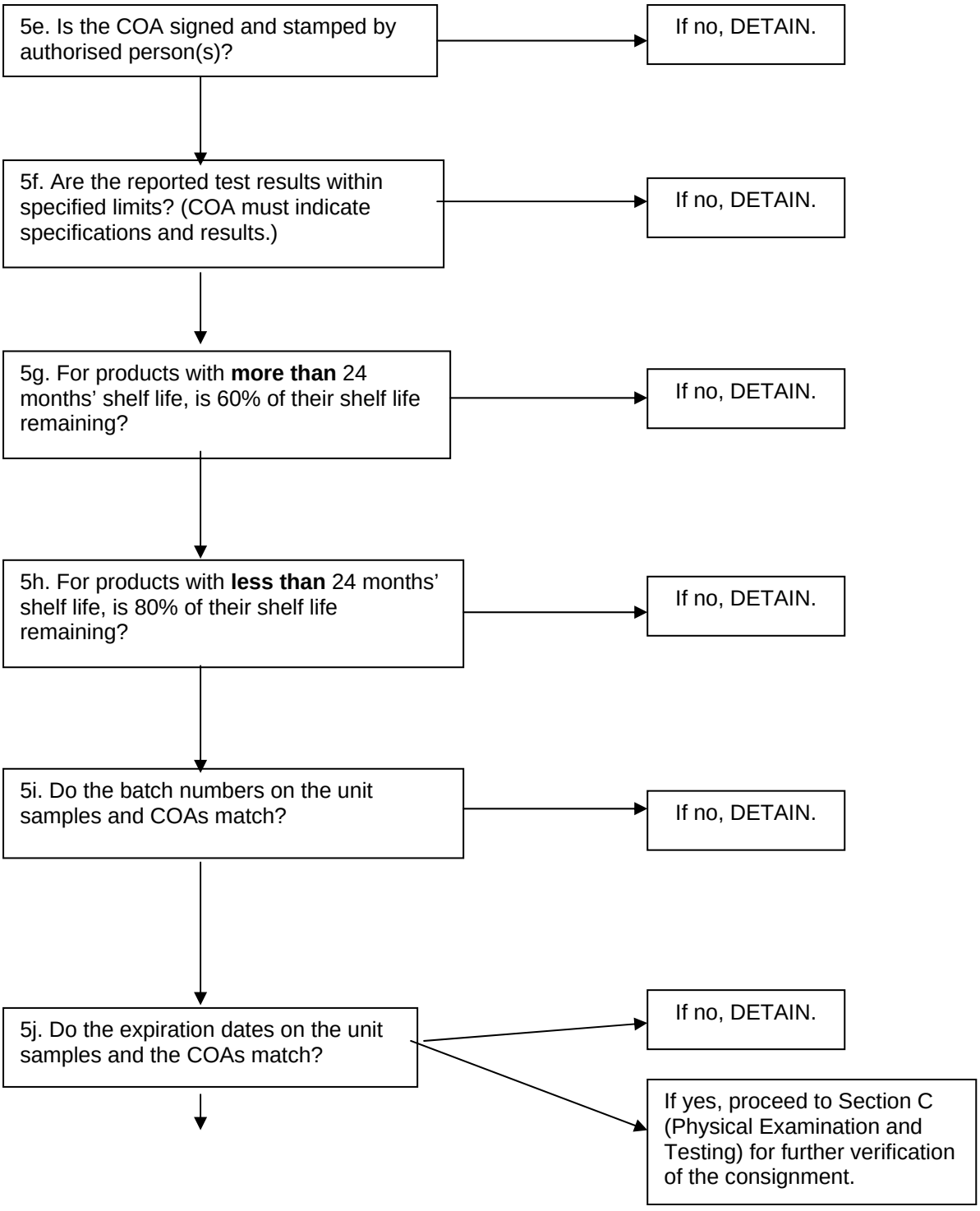
PORTS OF ENTRY CONSIGNMENT INSPECTION FLOWCHART



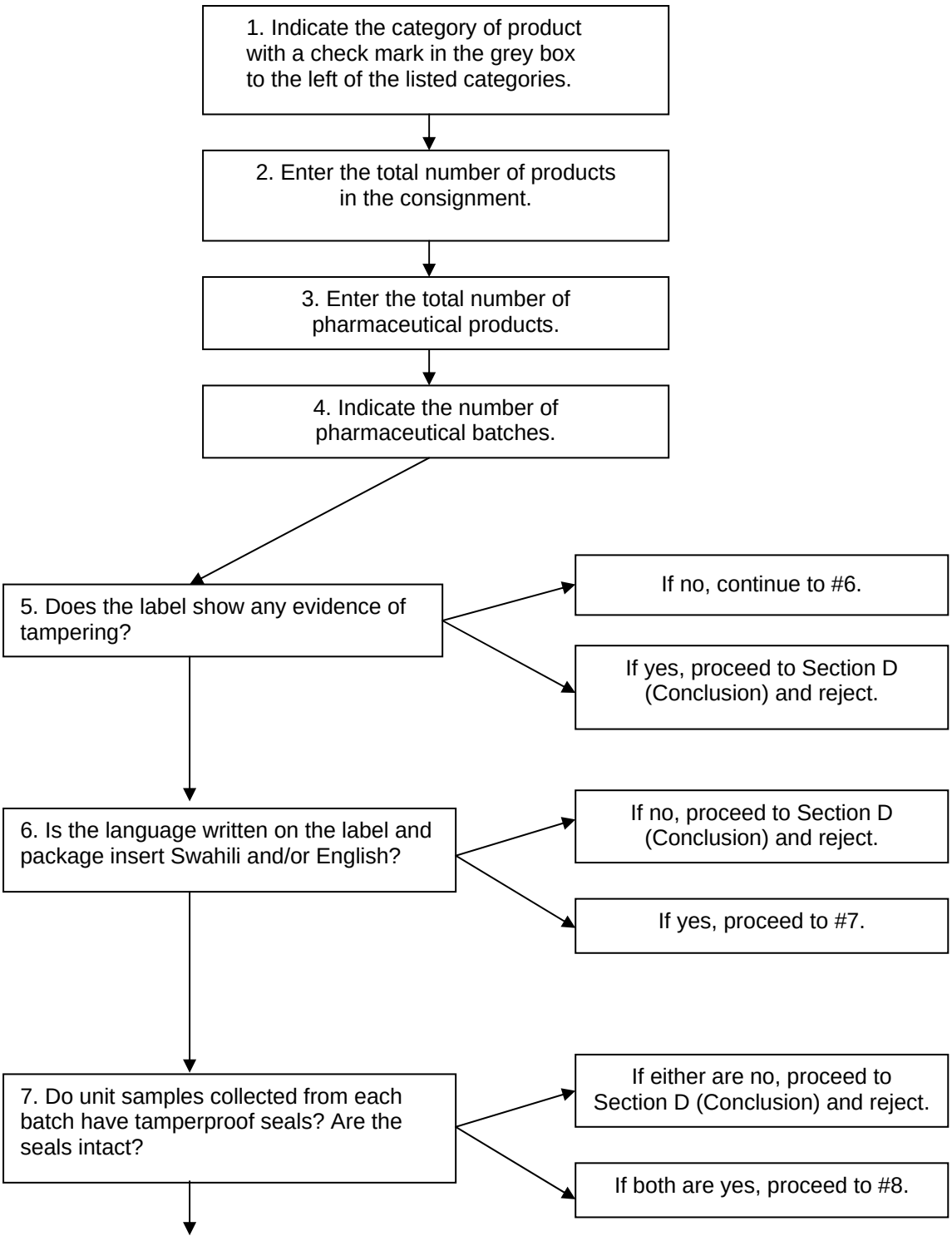
B) Documentation

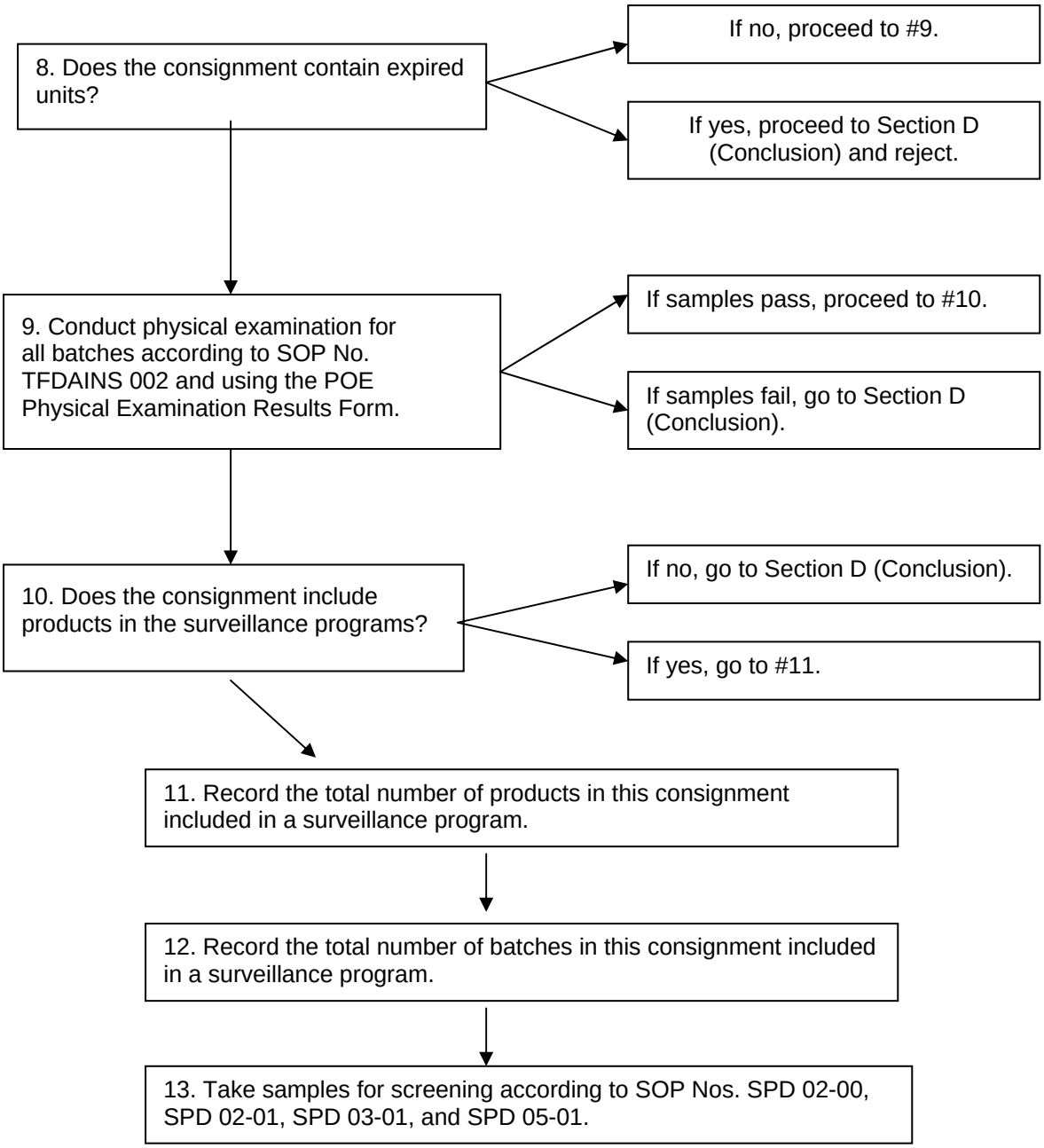



4a. Does the free on board (FOB) value of the CRF/FCVR/IDF match the value indicated in the authorised PI?
If no, DETAIN.
4b. Do the item's description and the quantities for each of the products indicated in the CRF/FCVR/IDF match the quantities authorised in the PI?
If no, go to #4c.
If yes, proceed to #5a.
4c. Are the item's description and quantities indicated in the CRF **greater than** those authorised in the PI?
If no, go to #4d.
If yes, DETAIN.
4d. Are the item's description and quantities indicated in the CRF **less than** those authorised in the PI?
If yes, mark the quantities of short-landed items on the PI, write "partial shipment," and proceed to #5a.
5a. Does the shipment require a Certificate of Analysis (COA)?
If no, go to Section C (Physical Examination and Testing).
If yes, go to #5b.
5b. Is the COA present with the consignment?
If no, DETAIN.
5c. Is there a COA for each batch?
If no, DETAIN.
5d. If the consignment contains vaccines, is there a COA from the manufacturer and an approval from the drug regulatory authority of country of origin?
If no, DETAIN.


5e. Is the COA signed and stamped by authorised person(s)?
If no, DETAIN.
5f. Are the reported test results within specified limits? (COA must indicate specifications and results.)
If no, DETAIN.
5g. For products with **more than** 24 months' shelf life, is 60% of their shelf life remaining?
If no, DETAIN.
5h. For products with **less than** 24 months' shelf life, is 80% of their shelf life remaining?
If no, DETAIN.
5i. Do the batch numbers on the unit samples and COAs match?
If no, DETAIN.
5j. Do the expiration dates on the unit samples and the COAs match?
If no, DETAIN.
If yes, proceed to Section C (Physical Examination and Testing) for further verification of the consignment.

C) Physical Examination





D) Conclusion

Conclude the inspection by releasing, rejecting, or detaining the consignment and writing the reasons for any shipments rejected or detained. The inspector(s) should print his/her name and sign and date the form.