

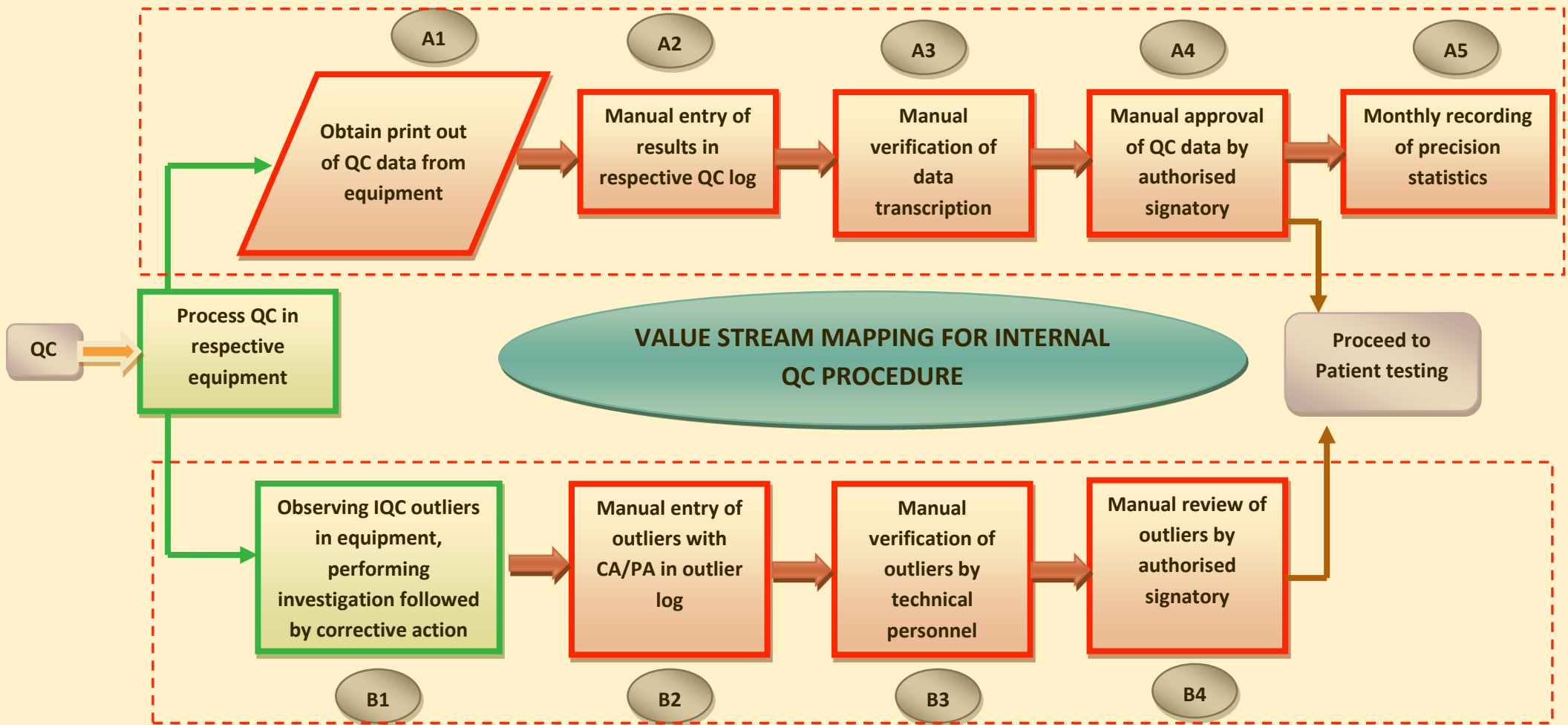
## **DIVISION OF CLINICAL BIOCHEMISTRY**

### **PROCESS IMPROVEMENT STUDY OF QC PROCEDURE**

**OBJECTIVE OF THE STUDY:** To implement the process of optimising and leaning the management of resources(material and manpower) and also to create a comparable platform for processing and reporting patient samples and quality control samples as per CAP(CHM 14300, CHM 14500, CHM 14600, CHM 13900, CHM 14900) and ISO 15189:2012(4.13, Note:1 and 5.6.2.2). As per international and national standards, **QC material shall be treated as patient sample;** hence we have attempted to lean the QC procedure across all phases of total testing process.

**VALUE STREAM MAPPING:** The main aim of value stream mapping is to treat the quality control testing process itself and not the QC sample alone as patient sample which needs standardisation of QC procedures.

## PROCEDURE FOR RECORDING ACCEPTABLE RESULTS



## PROCEDURE FOR RECORDING AND HANDLING OUTLIERS

Lean (existing)

Bottle necks

Step No	Process	Current procedure of recording IQC results		Proposed procedure for recording of IQC results	
		Manual Entry		Electronic format	
A1	Obtaining printout of QC results from the instrument	Wastage of resources(paper,printer,manpower) and time		Minimal wastage of resources and around 99% of results are enabled with auto transfer.	
A2 and B2	Manual entry of results in respective QC log and outliers in outlier log	<p><b>Wastage of resources:</b> Number of QC sheets printed, approx. 170 data points entered manually for around 90 measurands tested per day.</p> <p><b>Man-hours:</b> approx 45-60 minutes per run for manual recording of QC in respective QC logs</p> <p><b>Defects:</b> Legibility of data entry, amendments (overwriting due to errors in transcription, decimal entry errors, accuracy of data transcription and methodology of individual measurand cannot be entered), space constraint and outlier recording and monitoring has to be done manually in separate log.</p>		<p><b>Resources:</b> Minimal wastage of resources</p> <p>Reduction in transcription errors through automated interfacing of data. Real time monitoring of data is available, user friendly and is oriented towards patient safety. Approx. 160 out of 170 data points are auto transferred and there is only minimal need for manual entry online.</p> <p><b>Man-hours:</b> Approx. 40 min per run is saved per technical personnel and the credibility of data is ensured as it is electronically transferred.</p> <p>Outlier recording is also done in software and hence a separate log for the same need not be maintained.</p> <p>Validation of electronic QC procedure during installation is done followed by verification (once in six months). (validation document is attached along with.)</p>	

Step No	Process	Current procedure of recording IQC results		Proposed procedure for recording of IQC results	
		Manual Entry		Electronic format	
<b>A3 and B3</b>	Manual verification of data transcription by technical staff	<b>Man-hours:</b> Time taken for manual verification of data -approx 30 min per run. Traceability of analysts entering the data(difficulty to identify the short signature) and space constraint observed due to complexity in design of QC sheet in registering the signature		No need of manual verification as automated transfer is enabled and traceability to personnel handling the data is established through specific login. <b>Bench review</b> is done by the technical personnel using his/her login so that the traceability of the analyst to the QC is established	
<b>A4 and B4</b>	Manual approval of qc data by authorised signatory	<b>Wastage:</b> Man-hours involved- 20 minutes		<b>Supervisor review</b> is done using his/her login by authorized personnel  (Laboratory Director/Division Head or his/her designee) and hence there is reduction of time taken for review per run	
<b>A5</b>	Manual recording of precision statistics(periodic)	High probability of transcription error due to manual recording of precision statistics onto QC log, difficulty in comparison of current mean to previous month mean		Reduction in transcription errors with an enabled option of electronic updation of mean and SD. User friendly Comparison of previous month precision statistics, monitoring of LJ charts, trend analysis of all analytes(in a common platform)	