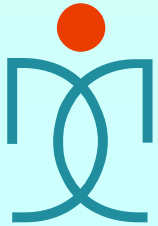
Quest for Automation

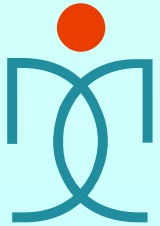
Dr. Parag Dharap

Consultant Pathologist



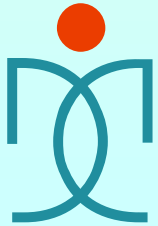
Biochemistry Analyzers

- Semi-automated Analyzers
- Batch Analyzers
- Random Access Automated Analyzers



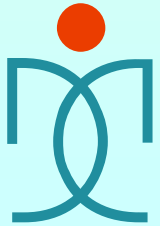
Batch Analyzers

- Single Test Performed On All The Samples In a ‘Batch’
- Sample & Reagent Dispensing Is Automated
- The Measured Results Are Displayed After Appropriate Incubation Period
- Provides Some Degree Of Walk-away Time
- Requires Meticulous Sample Handling as Same Sample is Used for Multiple Tests



Random Access Analyzers

- Multiple Samples with Multiple Reagents
- Ability to Perform Various Tests on Same Sample
- Ability to Analyze Emergency or Stat Samples Out of Turn
- Much Better Throughput Than Batch Analyzer
- On Board Laundry Gives True Walk away Time.

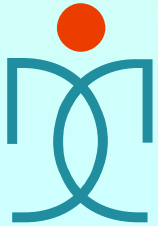


“Selection of an Instrument for Routine Use is a Complex Process, and Pragmatism & Intuition Often Play as Large a Part as Scientific Consideration”

- Broughton

Psychological Factors

- Need for Simplicity, Convenience & Ease of Use
- Faith In Reputation of Manufacturer
- Fashion & the Elegance
- Glamour Associated
- Resistance to Change
- Constant Search for Improvement



ISO 15189 – Technical Requirements Clause 5.3.2

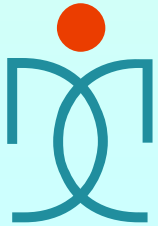
To Comply with the Requirements of the Standard the Laboratory Should Verify the Accuracy & Imprecision Claimed by the Manufacturer for Each Test on a New Instrument or Kit Before Reporting Any Test Results.

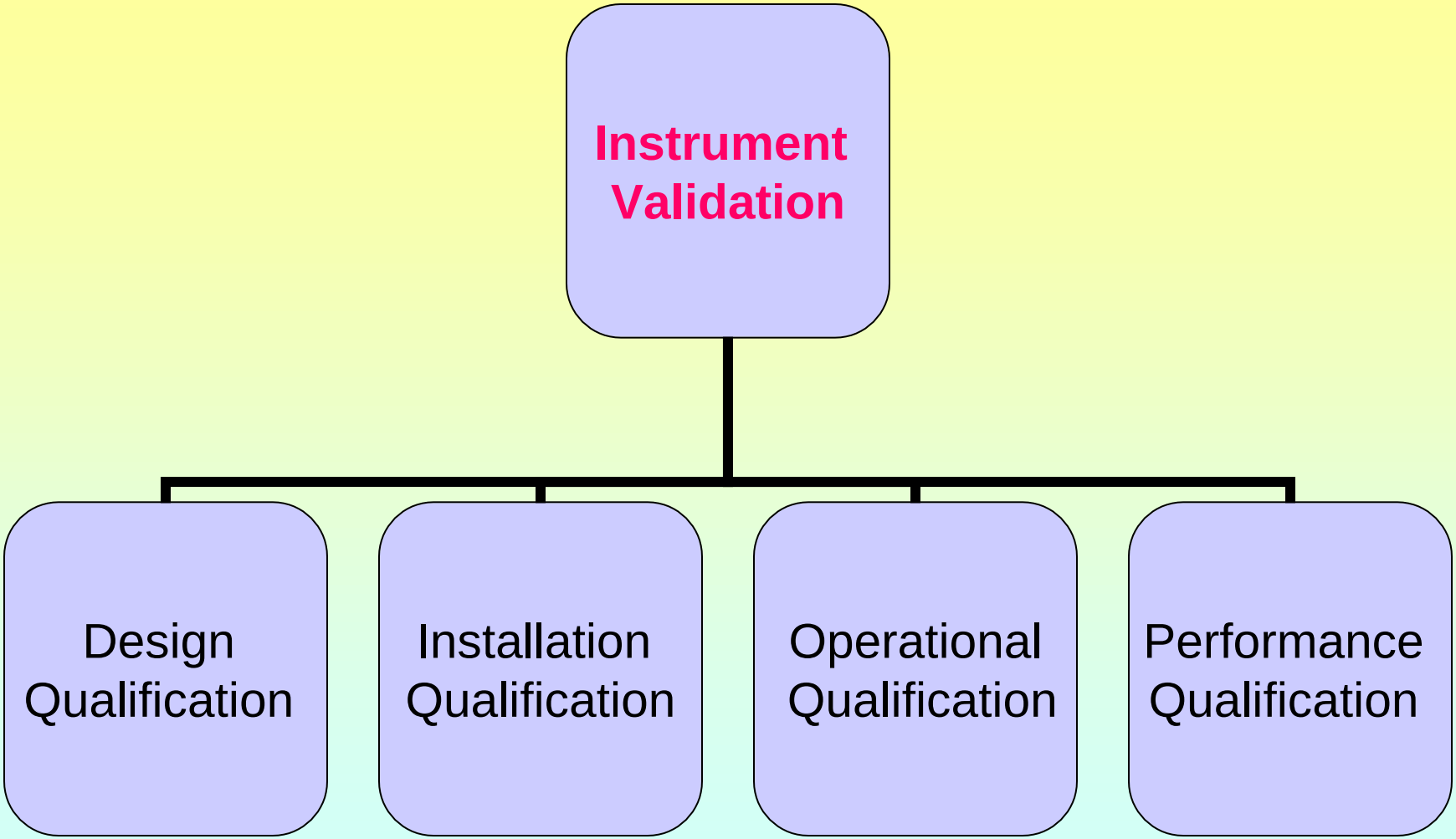
Selection Itinerary (White, Fraser JAC – Sept 1984)

- Pre Evaluation Assessment
- Familiarization
- Evaluation
- Specific Studies
- Assessment of Performance
- Introduction to Routine Services

Steps in the Selection Process

- Determine Need
- Define Service Requirements
  - Application
  - Methodological
  - Performance Characteristics
- Define Resources – Staffing, Finances

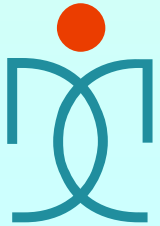



Instrument Validation
Design Qualification
Installation Qualification
Operational Qualification
Performance Qualification

Design Qualification (DQ)

Ensures that Manufacturers and Vendors are Equipped Adequately to Support Installation, Service, and Training

An assessment of Instruments suitability for its intended use



Installation Qualification (IQ)

- Site Inspection
- Installation Requirements
- Installation of All Component Parts
- Electrical Installation
- Alarms And Visual Displays
- Serial And Model Numbers
- Calibration Certificates
- Environmental Conditions
- Maintenance Documents
- Software Compliance

IQ is Performed by Vendor in Co-operation with the User

Operational Qualification (OQ)

OQ Review encompasses SOPs for-

- Start-up
- Operation
- Maintenance
- Safety
- Cleaning

Performance Qualification (PQ)

- Performance Check
- Preventive Maintenance and Repairs
- SOP for Operation, Calibration and Maintenance
- Carryover Effects – For Each Auto-pipetting Device/Instrument.

Verification of Analytical Performance

- Perform Precision/ Accuracy Checks at Medical Decision Levels for Repeatability (20 replicates) - Compare with Manufacturer's claims – Use of Chi square Test

  Use of **F test** to compare between two equipments

- Linearity Studies

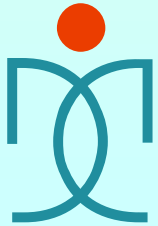
- Carryover Studies – Processing High & Low Level Samples (H-L-H-H-L-L-H-L)

- Discuss with Users – Check User IQC for Calib. frequency, random errors & biases

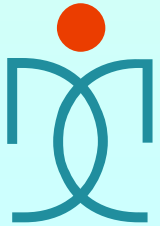

CHOICES
STRATEGY
RIGHT WAY

Information Check-list From Manufacturer

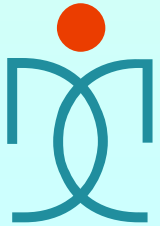
- Open / Closed System
- Throughput or Number of Test per Hour which Differs from Chemistry to Chemistry
- Analytical Performance Characteristics such as Precision of Syringes, Carryover Studies, Traceability
- Other Technical Information Like
  - Absorbance Range
  - Type of Lamp Used & Its Expected Life & Cost
  - Type Of Filters



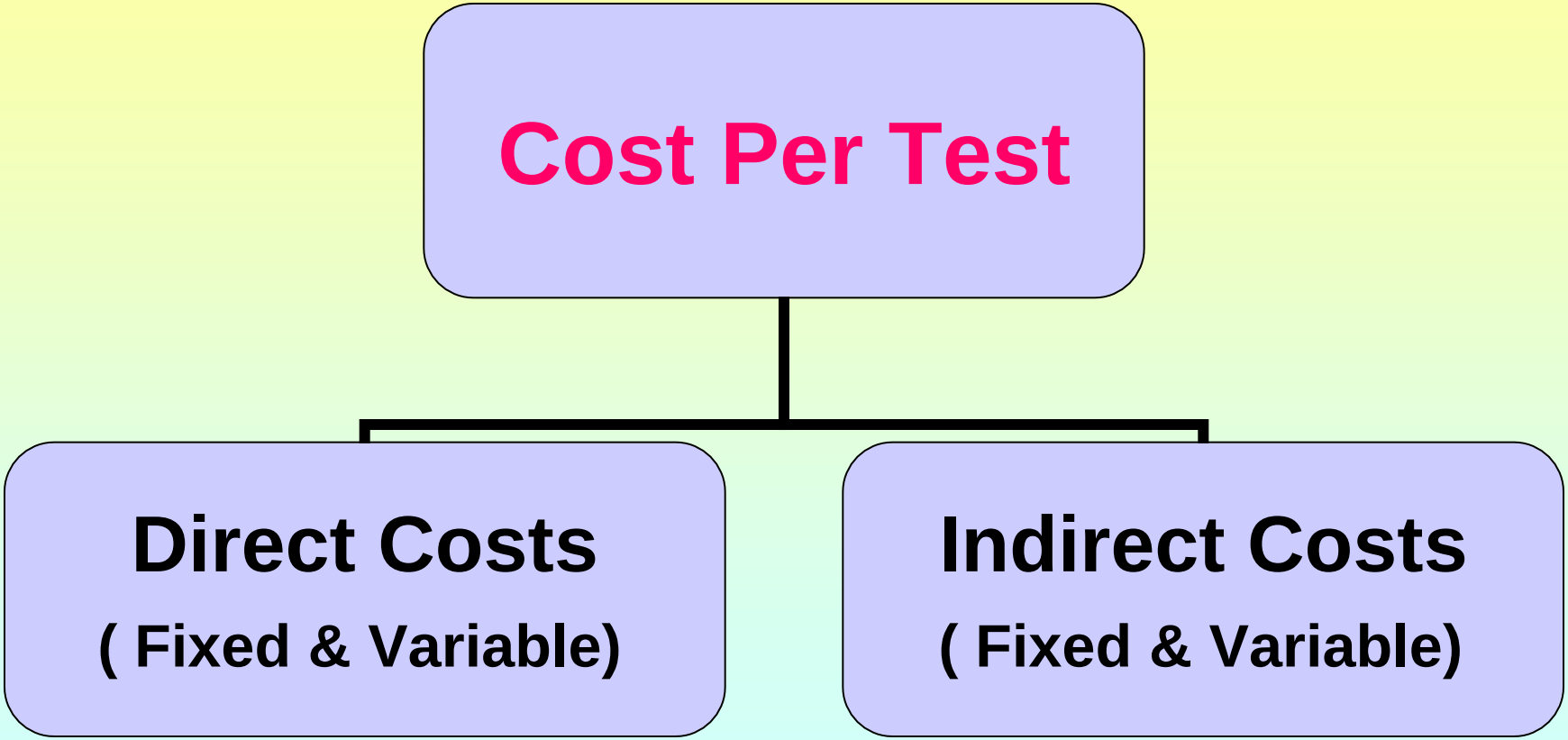
- Number of Sample Positions
- Positions for Blanks, Standard & Controls
- Average Reagent Volume (incl. Dead vol.)
- Availability of Stat / Emergency Processing
- On-line Quality Control Review, Calibration Tracking
- Self Diagnostics
- On Board Refrigeration/ Cooling
- Onboard Inventory Management
- Reaction Mixture Mixing Rates



- Cuvette Optical Checks
- Computer Capabilities - User Friendliness, Maintenance, Reference Ranges, Patient Demographics
- Interfacing – Uni or Bi Directional
- Availability of Service Engineers with ‘T.A.T’
- Maintenance Cost - Supplies Required To Be Replaced At A Regular Interval- Bulbs, Tubings, Washers, Electrodes Etc. Cost & Availability Of Supplies
- Bar Code Reader Availability
- User Base



Financial Aspect

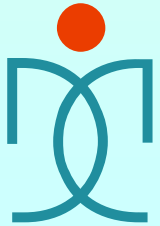


Direct Costs

- ✓Initial Capital Investment
- ✓Depreciation
- ✓Reagents
- ✓Labour
- ✓Service Costs
- ✓Collection Supplies
- ✓Additional/ Accessory Requirement Costs
- ✓Testing Supplies
- ✓Quality Control Material
- ✓Wastage

Indirect Costs

- ✓ Electricity
- ✓ Lab Overheads
- ✓ Accounting Expenses
- ✓ Space
- ✓ Laboratory Information System



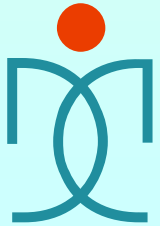
Instrument Cost for 5 Yrs

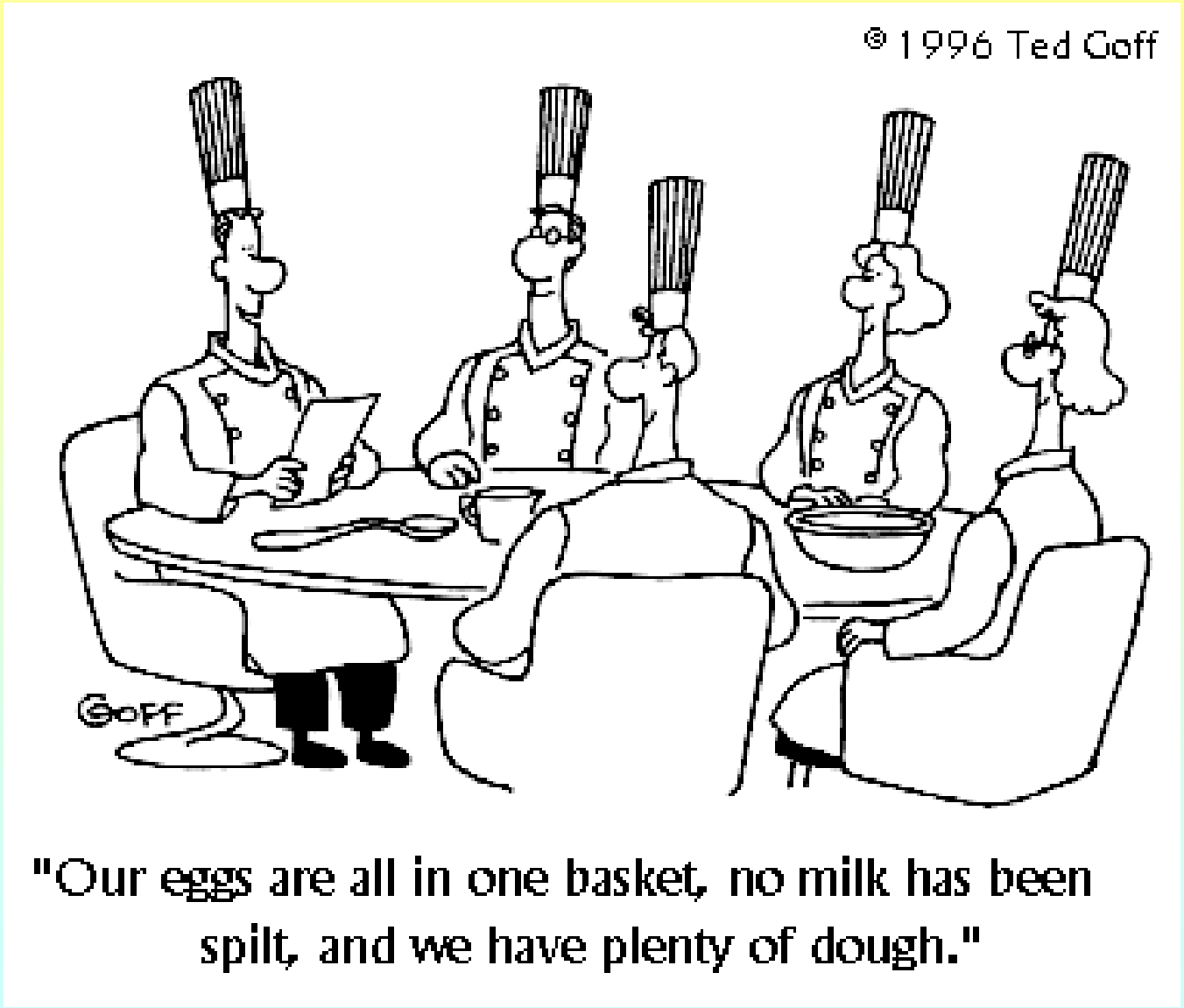
- Instrument Price
- Loss of Interest on Money for 5 Yrs / Int. Cost if Funding Thru Loan
- Service Contract For 4 Yrs.

- Notional Maintenance Cost – Expected Cost of Part Replacements as per Manufacturers' Guidelines

- Reagent Cost / Test * Test Volume (Load)/ Year * 5 Yrs.

(Load is Inclusive of Samples, QC, Repeats, Dilutions, Troubleshooting, Wastages)

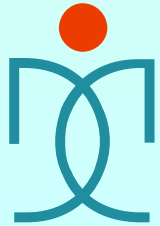




"Our eggs are all in one basket, no milk has been spilt, and we have plenty of dough."

Question Yourself

- Is Your Sample Load Enough to Justify the Costs Involved?
- Need - Will it Really Improve My Lab Services?
- Is The Instrument Suitable For Your Climate & Other Environmental Conditions?
- Resources - Do We Have Enough Resources To Purchase & Maintain The Instrument?

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Photometer Performance

- To be tested at 405 nm with p. Nitrophenol 2.15 mmol/L in NaOH 10 mmol/L, in duplicate.

- CVs to be checked for Linear concentration between absorbance 0.0 – 2.5 A & 2.5 – 4.0 A

Accuracy of Sample Pipetting

To be Tested at 405 Nm with P. Nitrophenol 2.15 Mmol/L in NaOH 10 Mmol/L, Various Volumes of 5 – 100 Microlt with Distilled Water Diluent 50 to 200 Microlt. for 10 Measurements Each

Linearity Range Check

To be Done with Different Dilutions with 9G/L Saline