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WRITING POLICIES AND PROCEDURES

When things go wrong in a police department or laboratory one does not have to wait long to hear “they were not following procedures”, “there was no defined procedure” or “we need training for that procedure to assure competence.” Laboratories have progressed from no accreditation to compliance with the American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB) formed in 1982 by the American Society of Laboratory Directors (ASCLD) now called the legacy program and presently are transitioning to operate in accordance with the ISO/IEC 17025: 2005 International Standard requirements. At the heart of these programs are written policies and procedures that are thoroughly discussed in our ISO/IEC 17025 chapter. It is also possible to perform a procedure with excellent outcomes and use no written procedure. Although this is not preferred or common there may be several steps of a procedure that have never been put in writing. Many laboratories procedures are a collection of ASCLD/LAB procedures that have been modified to fit the ISO/IEC 17025 standard. Some laboratories have also benchmarked with other laboratories for best practices and modified others procedures to fit the processes in their laboratory. All these methods are acceptable and they work. There is also a distinctive difference between administrative support procedures and scientific procedures which we discuss later in the text. Lastly, well written procedures provide the foundation for the training lesson plan. Training lesson plan learning objectives, curricula materials, assessment and competency measures all develop from the well written procedures.

23 However, when things do go wrong, and they will, an auditor external from the laboratory
24 perhaps from the internal investigative unit from the parent agency or from an external
25 regulatory body will not be concerned with the history of the procedures in question. The auditor
26 will be concerned with *present* conditions and will follow these steps:

- 27 1. The auditor will perform a desk audit of the written procedure in an attempt to identify or
28 not all associated personnel, policies, procedures, controlled documents, data and controls
29 associated with the task.
- 30 2. Next the auditor will develop a Process Flow Chart (PFC) to provide a visual
31 representation of all procedure steps identified in the desk audit.
- 32 3. Lastly, the auditor will interview and observe personnel when they are performing the
33 procedures (surveillance audit) to confirm and verify compliance with all written
34 procedure steps.

35 As an alternative to revising an existing procedure for improvement, it is at times preferable to
36 start with a blank white board approach. The procedure must be aligned with the intent of the
37 ISO clause and describe how *your laboratory* operates in accordance with the specific clause in
38 the standard.

39 Procedures should also clearly identify non-conformances. Non-conformances to customer
40 requirements should not be relied upon for detection on technical review but identified and
41 remedied by the primary scientist performing the work. The definition of non-conformance(s)
42 should also be defined for each step in the procedure. If personnel have difficulty defining a non-
43 conformance to the procedure, then ask “what outcomes would initiate a reanalysis?” The answer
44 is a non-conformance.

45 **Lexicon**

46 The first step in the development of any procedure is the understanding and use of a standardized
47 lexicon or common vocabulary of terms. Policies and procedures for training, operations,
48 communications and all quality management activities are dependent upon the proper and
49 consistent use of terms. The efficiency and effectiveness of communication and the quality
50 management system are greatly improved when staff understand and use the proper terms. Our
51 discussion of procedure development depend upon the following terms defined in ISO 9000 (ISO
52 9000: 2005 Quality Management Systems - Fundamentals and vocabulary, 2013).

53

54 Below are some of the basic terms from this standard we will use in this discussion:

55

56 Audit (3.9.1): systematic, independent and documented process for obtaining audit evidence and
57 evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

58 Corrective Action (3.6.5): action to eliminate the cause of a detected non conformity or other
59 undesirable situation.

60 Effectiveness (3.2.14): extent to which planned activities are realized and planned results
61 achieved.

62 Efficiency (3.2.15): relationship between result achieved and resources used.

63 Information (3.7.1): meaningful data.

64 Non Conformity (3.6.2): non-fulfillment of a requirement.

65

66 Policy (3.2.4): Overall intentions and direction of an organization (3.3.1) with regard to quality
67 (3.1.1) as formally expressed by top management (3.2.7).

68 Preventive Action (3.6.4): action to eliminate the cause of a potential non conformity or other
69 undesirable situation.

70 Procedure (3.4.5): specified way to carry out an activity or a process (3.4.1). Note 1, procedures
71 can be documented or not. Note 2, when a procedure is documented, the term “written
72 procedure” is frequently used. The document (3.7.2) that contains a procedure is called a
73 “procedure document”.

74 Process (3.4.1): set of interrelated or interacting activities which transforms inputs in to outputs.

75 Product (3.4.2): Result of a process (3.4.1). Note 1: There are four generic product categories, as
76 follows: Services, software, hardware, processed materials.

77 Quality Assurance (3.2.11): part of quality management focused on providing confidence that
78 quality requirements will be fulfilled.

79 Quality Control (3.2.10): part of quality management focused on fulfilling quality requirements.

80 Requirement (3.1.2): need or expectation that is stated, generally implied or obligatory.

81

82 National scientific oversight bodies have sounded the alarm and provided guidance to establish
83 and enforce standardization of forensic processes and procedures. In 2005 the U. S. Congress
84 passed the Science, State, Justice, Commerce and Related Agencies Appropriations Act of 2006
85 authorizing the National Academies of Science (NAS) to create an independent body to evaluate
86 forensic sciences (NAS, 2009). The NAS report was the result of many years of advocacy from
87 the forensic professional organizations working with their locally elected representatives. The
88 NAS assembled an esteemed group of professionals who interviewed a diverse group of
89 scientists, legal experts, and leaders from the scientific academic community who interviewed
90 forensic practitioners from local, state, federal agencies and the academic community. The NAS

91 report stated the need to improve the overall quality of forensic services resulting in 13
92 recommendations to improve forensic services.

93 NAS recommendations either directly or indirectly refer to the standardization of best practices
94 for the delivery of forensic services:

95 Recommendation #1 calls for a newly created federal agency entitled the National Institute of
96 Forensic Science that will “establish and enforce **best practices** [my emphasis] for forensic
97 science professionals and laboratories.”

98 Recommendation #8 states “Forensic laboratories should establish routine **quality assurance**
99 **and quality control procedures** [my emphasis] to ensure the accuracy of forensic analyses and
100 the work of forensic practitioners.”

101 The NAS report also cited Federal Bureau of Investigation quality assurance standards for DNA
102 laboratories (FBI Quality Assurance, 2013) and the ISO/IEC 17025: 2005 International Standard
103 (section 5.4.4) (ISO/IEC 17025, 2005) specifying the process to be followed for validation of
104 scientific methods. Inherent in these scientific and business procedures are quality controls to
105 assure results are within established customer requirements for approval or rejection of results.

106

107 Scientific Procedure vs. Administrative Procedure

108 We would be remiss by not distinguishing the differences and similarities between a scientific
109 procedure used in laboratory analyses as compared to administrative procedures used for support
110 functions and the total performance of the quality management system designed for continual
111 improvement. The scientific applied research procedures grounded in hypothesis testing,
112 rigorous statistical analyses for type A and type B errors and uncertainty measurement budgets
113 should be clearly understood and used by forensic laboratories if the research method is to be

114 performed in their laboratory by their staff. Most scientific procedures in use by forensic
115 practitioners are methods that have been researched and validated by other researchers and are
116 validated for use by forensic practitioners in their laboratories. Forensic laboratories are now
117 performing more research, publish and validate customized procedures for use in case analyses.
118 Laboratories operating in accordance with ISO/IEC 17025 standards are required to perform
119 procedure validation with their staff, facilities and equipment. The NAS report cites the ISO/IEC
120 17025: 2005 Standard, section 5.4, Test and Calibration Methods and Method Validation and
121 provides a generic guide for the scientific method.

122
123 An effective procedure audit tool can be designed to perform an interrogatory “cross walk”
124 between ISO/IEC 17025 mandatory policies and procedures and scientific or administrative
125 methods. Table 1 is an auditor checklist that correlates requirements for the ISO/IEC 17025 -
126 5.4.4 scientific procedure with the mandatory ISO/IEC 17025 policies and procedures listed in
127 the ISO chapter Table 1 and Table 2. This check list is the minimum and can be expanded upon
128 with additional policies and procedures if management has determined there is unique customer
129 or regulatory requirements. For example, there are several Federal Department of Labor,
130 Occupational, Safety and Health Administration (OSHA) safety regulations directly applicable to
131 forensic laboratories. Hazard Communications and Personal Protective Equipment (29 CFR
132 1910) are examples that apply to all forensic laboratories (Occupation Safety Health
133 Administration, 2013).

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Table 1 ISO/IEC 17025 Clause 5.4.4. Non Standard Method Audit Check List

Table 1

ISO/IEC 17025 5.4.4 Non Standard Methods / Mandatory Policy and Procedures Audit Check List					
ISO/IEC 17025 5.4.4 Non Standard Method Requirement	ISO/IEC 17025 Written Policy Requirement	ISO/IEC 17025 Written Procedure Requirement	Question	Y/N	Comments
Appropriate Identification;	4.3.1 Document Control 4.3.2.2 Document review	4.3.1 Document Control 4.3.2.2 Document Review	Is there a clearly written policy and procedure with controls for: 4.3.1 Document control? 4.3.2.2 Document review?		
Scope;	4.1.5c Protecting customer's information 4.2.2 Quality	4.1.5c Protecting customer's information	Is there a clearly written policy and procedure with controls for: 4.1.5c Protection of customer's information?		
Description of item being tested;	4.4.1 Review of contracts	4.4.1 Review of Contracts	Is there a clearly written procedure with controls for: 4.4.1 Review of contracts?		
Parameters and or quantities or ranges to be determined;	4.4.1 Review of Contracts	4.4.1 Review of Contracts	Is there a clearly written policy and procedure with controls for: 4.4.1 Review of contracts?		
Apparatus and equipment, including technical performance requirements;		5.4.5.2 Validation	Is there a clearly written procedure with controls for: 5.4.5.2 Validation?		
Reference standards and reference materials required;	4.6.1 Purchasing	4.4.1 Review of contracts 4.6.1 Purchasing 5.6.3.1 Calibration of reference standards 5.6.3.4 Handling of reference standards	4.4.1 Is there a clearly written policy for purchasing of standards? Is there a clearly written procedure with controls for: 4.6.1 Purchasing of standards? 5.6.3.1 Calibration of standards? 5.6.3.4 Handling of reference standards?		
Environmental conditions required and any stabilization period needed;		5.3.5 Accommodations and environmental conditions	Is there a clearly written procedure with controls for: 5.3.5 Accommodations and environmental conditions?		
Description of the			Is there a clearly written		

procedure;			procedure with controls for: 5.4.5.2 Validation?		
Affixing of identification marks, handling, transporting, storing and preparation of items;		5.7.1 Sampling 5.7.3 Recording sampling data 5.8.1 Receipt of test items 5.8.4 Avoiding loss of test items	Is there a clearly written procedure with controls for: 5.7.1 Sampling? 5.7.3 Recording of sampling data? 5.8.1 Receipt of test items? 5.8.4 Avoiding loss of test items?		
Checks to be made before the work is started;	5.2.2 Training	5.2.2 Training 5.4.5.2 Validation	Is there a clearly written policy and procedure with controls for: 5.2.2 Training? Is there a clearly written procedure with controls for: 5.4.5.2 Validation?		
Checks that the equipment is working properly and, where required;		5.5.5 Use of equipment; 5.6.1 Calibration of equipment; 5.6.3.3 Intermediate checks and reference standards	Is there a clearly written procedure with controls for: 5.5.5 Use of equipment? 5.6.1 Calibration of equipment? 5.6.3.3 Intermediate checks and reference standards?		
Calibration and adjustment of the equipment before each use;		5.6.1 Calibration of equipment	Is there a clearly written procedure with controls for: 5.6.1 Calibration of equipment?		
Method of recording the observations and results;		4.3.1 Document control; 4.3.2.2 Document review; 4.3.3 Amending documents by hand; 4.3.3.4 Changes to documents in electronic systems; 5.7.3 Recording sampling data.	Is there a clearly written procedure with controls for: 4.3.1 Document control? 4.3.2.2 Document review? 4.3.3 Amending documents by hand? 4.3.3.4 Changes to documents in electronic systems? 5.7.3 Recording sampling data?		
Safety measures to be observed;	Federal Occupation	Federal Occupation	Is there a clearly written policy and procedure with		

	Safety and Health Administration regulations State and local safety regulations (HazCom, PPE)	Safety and Health Administration regulations State and local safety regulations	controls for: Federal Occupation Safety and Health Administration regulations State and local safety regulations?		
Criteria and/or requirements for approval/rejection;	4.2.2 Quality 4.8 Resolving complaints 4.91 Handling non conformances 4.11.1 Corrective action	5.9.1 QC monitoring	Is there a clearly written policy with controls for: 4.2.2 Quality? 4.8 Resolving complaints? 4.91 Handling non conformances? 4.11.1 Corrective action? Is there a clearly written procedure with controls for: 5.9.1 QC monitoring?		
Uncertainty or the procedure for estimating uncertainty.		5.4.6.1 Estimate of uncertainty (calibration) 5.4.6.2 Estimate of uncertainty (testing)	Is there a clearly written procedure with controls for: 5.4.6.1 Estimate of uncertainty (calibration)? 5.4.6.2 Estimate of uncertainty (testing)?		

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145 **Instructions on How to Develop Procedures**

146 Readers are also encouraged to seek additional instruction on how to prepare effective
 147 procedures and their use for the development of training programs for new personnel and audit
 148 teams. Specific training for the development of procedures for procedural writing teams often

149 leads to the formation of 1st party auditing team training lesson plans and specific procedure
150 training for bench personnel to competency.

151 The development of written procedures incorporates eight main steps.

152 **1. Desk audit**

153 The desk audit is most commonly performed off site and is an exercise to identify and
154 understand documents for Policy (Why), Procedure (Who does What, When, Where and How)
155 and any supporting controlled documents, records, and data. The main operative word is “Who.”
156 Procedures are performed by people that are empowered by top management with
157 responsibilities and authority to perform a specific task.

158 The desk audit will collect all existing policies, procedures, controlled documents, records and
159 data related to the procedure in question. The desk audit should provide the audit or procedure
160 writing team a foundation for understanding the purpose of the procedure and how it is
161 performed.

162

163 **2. Observe procedure and being used**

164 The observation of the procedure or a surveillance audit provides the auditor or procedure
165 writing team the opportunity to observe the procedure being performed first hand.

166 Observations are compared to existing policies and procedures to confirm the procedure
167 is being followed as written. It is often the case that changes have been made to improve
168 the procedure but may not have been incorporated in writing.

169 **3. Interview staff using procedure**

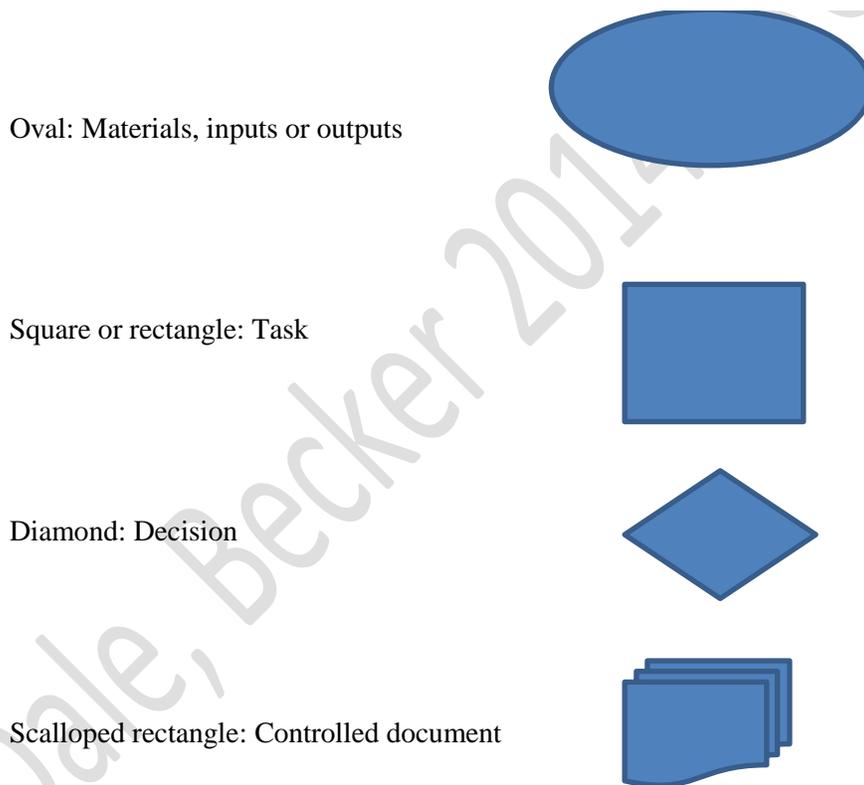
170 Staff is queried as to their ability to articulate their knowledge, understanding and
171 application of the procedure. Are the staff aware why they are performing the procedure
172 and do they have the big picture for who does what, when, where and how?

173 **4. Develop Process Flow Chart**

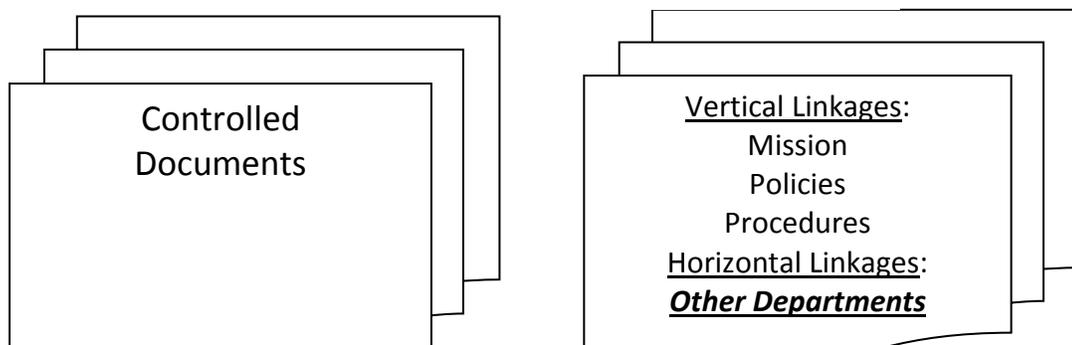
174 The flow chart uses standardized symbols that identify sequential tasks, materials, documents and
175 decisions needed to provide a visual of a specific procedure. More complex flow charts can show
176 linkages to other processes, time and resources needed for each task and selected LMPM metrics.
177 Information to begin the flowchart is gathered from existing documents and interviews with staff
178 and supervisors. The most important step is to observe the procedure from start to finish followed
179 by a comparison of your observations to staff interviews and documents. Do your best to keep
180 this process simple and concise. The flow chart process should identify at a minimum all
181 controlled documents, data collection points, time, costs, non-conformances, rework (go with
182 remediation or no-go with corrective action decisions) and horizontal linkages to other processes,
183 procedures and regulations. Personnel, by job title, are identified by the step in the process that
184 they perform. Horizontal linkages to other procedures (multi-section cases or support services)
185 and vertical linkages to upper level policies and the laboratories mission statement and customer
186 requirements assure the procedure is on target with quality management system goals. A useful
187 adaptation of the flow chart includes scaling of symbol sizes for time or costs which identify
188 which steps in the process are most costly and timely. For example, the symbol for a specific task
189 is sized at 1" corresponding to 1 hour. A 2" square would represent 2 hours. Operational
190 management line leveling procedures indicate no item will cycle through the total process sooner
191 than the timeliest step. Therefore, resources should be applied to the timeliest step in the process
192 to reduce cycle time. Flow charts also provide excellent training aids for new employees learning
193 the process. The flow chart is the foundation of your procedure. The procedure outline and then
194 final descriptive narrative will depend on accuracy and completeness of the flow chart.

195 Ultimately, an internal or external accrediting body auditor will develop their own procedure flow
196 chart for your written procedures mandated by regulations, agency, accrediting body standard or
197 customer requirements. Remember to keep the flow chart simple and concise. If it becomes
198 visually very complex and confusing, then this could be an indication your procedure is too
199 complex and may cause unwarranted remediation, non-conformances and resulting corrective
200 actions.

201
202 **Figure 1 Basic Flow Chart Symbols**



216
217 **Figure 2 Basic Procedure Process Flow Chart**



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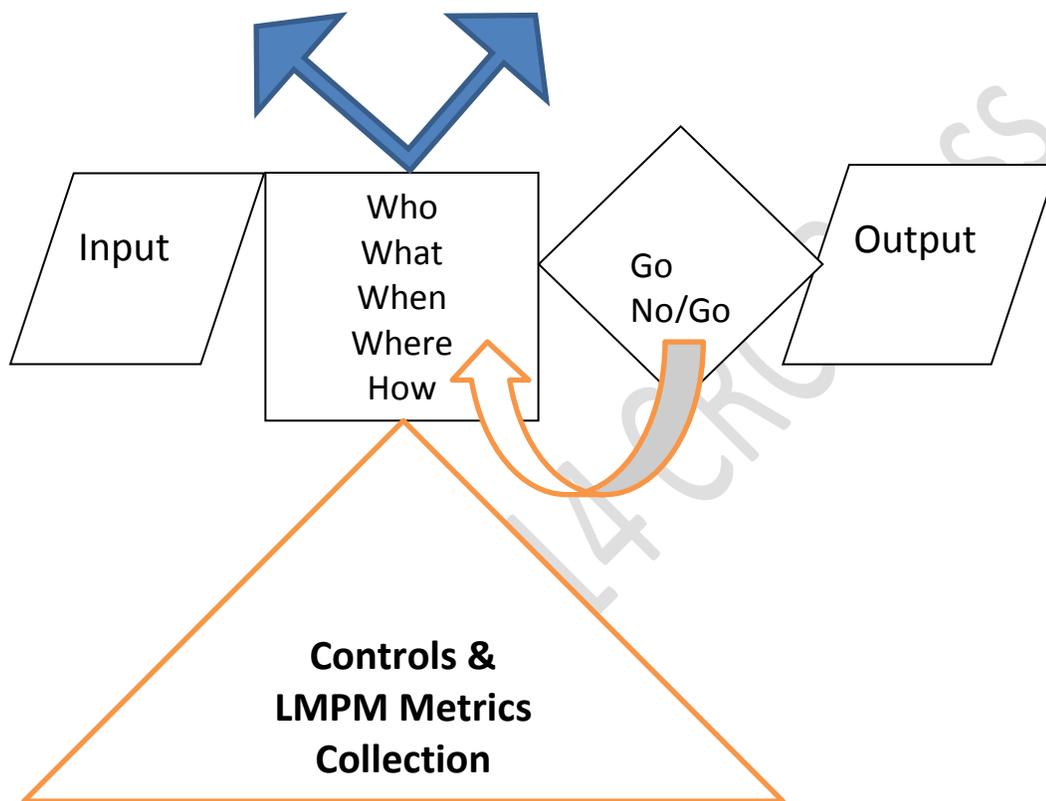
5. Verbally articulate Process Flow Chart

234

Perhaps the most challenging and most important task in procedure writing is the concise and articulate written description of the procedure following the PFC. A simple and very effective approach to this critical task is to have one member of the writing team verbally articulate the PFC to the staff that actually performs the task. Any errors in the PFC or misunderstanding on how the procedure is performed will be identified in this step.

239

6. Transcribe verbal articulation to text



239

240 The verbal articulation of the procedure will now be written by a scribe on the procedure writing
241 team. The narrative description of the procedure, using active voice, is written after the
242 completion of the PFC (Table 2). One effective way to do this is to verbally articulate a
243 description of the PFC from the beginning to the end. This does two things: 1. any redundancies,
244 missing steps or tasks that don't make sense will be readily apparent. 2 If you cannot "talk" your
245 way through the PFC, then the procedure is not clear and will not be understood by personnel.
246 Do this by yourself, with others on the procedure team and stakeholders until all steps are
247 concise and clearly described and written. The PFC will be very accurate after several
248 reiterations of this process.

249 A critical component of procedure writing process is identification of individuals with writing
250 skills, teaming with subject matter experts and supervisors, who will be responsible for the
251 writing of all procedures in a clear and consistent manner. This is not an easy task and must be
252 done properly as a team made up of the writers, bench scientists and supervisors. All will be held
253 accountable to these procedures in future audits, so now is the time to do it right.

254
255 It is also very effective for the procedure writing team to be trained as the first audit team. The
256 procedure writing team is best positioned to perform the first audits as they developed the
257 procedures. Writing guidelines for scientists and business are thoroughly discussed in separate
258 works by Hogan (Hogan, 2005) for business writing and Pechenik (Pechenik, 2007) for scientific
259 writing. Hogan provides detailed guidance on how to explicitly write clear memoranda, letters,
260 email and procedures. He emphasized the major mistake that writer's make is not including all
261 steps needed in a procedure and or not providing these detailed instructions *when needed* by the
262 readers. Pechenik provides a treasure trove of practical instructions designed for graduate

263 students and research scientists documenting laboratory experiments, writing research papers or
264 posters and general guidelines for proper scientific writing. The challenge is to combine business
265 and scientific writing skills to provide effective, concise and practical procedures for the bench
266 scientists, supervisors, support staff and management.

267 There are many guidelines for grammar and writing style texts available. Strunk and White, *The*
268 *Elements of Style* (Strunk Jr. & White, 2000), is one text that should be in everyone's reference
269 library. A consistent format and style are essential for efficient use by all staff. Time is well
270 spent studying basic and advanced protocols for proper grammar, style, sentence structure and
271 format for business technical writing and scientific publications. We are seeking a unique mix of
272 business technical and scientific writing that will produce a clear, concise and understood
273 procedures that will be *understood and used* for daily analyses and provide the framework for
274 continual improvements. The uniform theme from all writing guides is clarity and conciseness
275 developed from active voice sentence structure *clearly identifying who does what when*.

276 The most common cause of unclear procedures and related corrective actions are the lack of
277 active voice sentence structure (inappropriate use of passive voice sentence structure) resulting in
278 no staff designated responsible for performance of key tasks and decisions (Table 2). It is not
279 clear who is responsible for the task or has the authority and responsibility to make decisions.

280 Who being a job title or position (e.g. DNA Section Supervisor or DNA Technical Leader).
281 Consistent use of present tense in the active voice will provide the clearest procedure that will be
282 understood and used. The active voice construction consists of Subject – Verb – Object. In
283 passive voice sentence structure the subject is acted upon and the subject is usually unclear or not
284 included. At times the passive structure may be used intentionally not assigning responsibility

285 and authority for a particular outcome. Passive sentence structure has no place in laboratory
 286 procedures as tasks, responsibilities, authorities and outcome measures must be crystal clear.

287 **Table 2 Passive vs. Active Voice**

PASSIVE	ACTIVE with Responsibility Assigned
Ensure data from the quantitation step are recorded on form 19b.	The Forensic Scientist III responsible for performing step #3 records all instrumental data generated from instrument ABC123 on form 19b.
A determination is made as to whether the results are acceptable.	The Chemistry Case Review Technical Leader decides if the analytical results from extraction step #6 are within limits of acceptability.
Unacceptable results, as defined in Procedure #12654 Step #21 are monitored for continual improvement.	The DNA Team Leader is responsible for monitoring all non-conformances as defined in Procedure #12654 Step #21, correcting the non-conformance with remediation, or initiating a Corrective Action as per QM Procedure #1299.
Requests for service contracts are accompanied by proper documents.	All Section Chiefs are responsible for including with a Request for Contracted Services (Form Fiscal 103b) three independent quotes for all services over \$5,000.
Additional resources can be identified through decreases in non-essential items.	Top management will identify additional resources through the reduction in non-essential services.
Successful completion of the competency will allow her to start work.	If the Forensic Scientist I meets established performance standards, then the Technical Leader for Training recommends to the Unit Chief assignment to supervised casework activities.
Administrative and Technical reviews are continually monitored.	All technical personnel are responsible for the initial administrative and technical review for all of their work following Procedure QA1012.
Laboratory wide preventive actions are designed to prevent high risk procedures.	All Unit Chiefs are responsible for identifying and monitoring high risk procedures for non-conformances as per Procedure QA1099
All Corrective Action Reports need to be completed in a timely manner.	The Quality Assurance Manager is responsible for initiating, monitoring and completion all Corrective Reports within 60 days of the Unit Chief verifying a recurring non-conformance as per Procedure QA963.
All emails related to case analyses will be retained.	The Forensic Scientist in charge of a case retains all email and hard copy documents verifying communications that affect the case analyses as per Procedure IM#2256

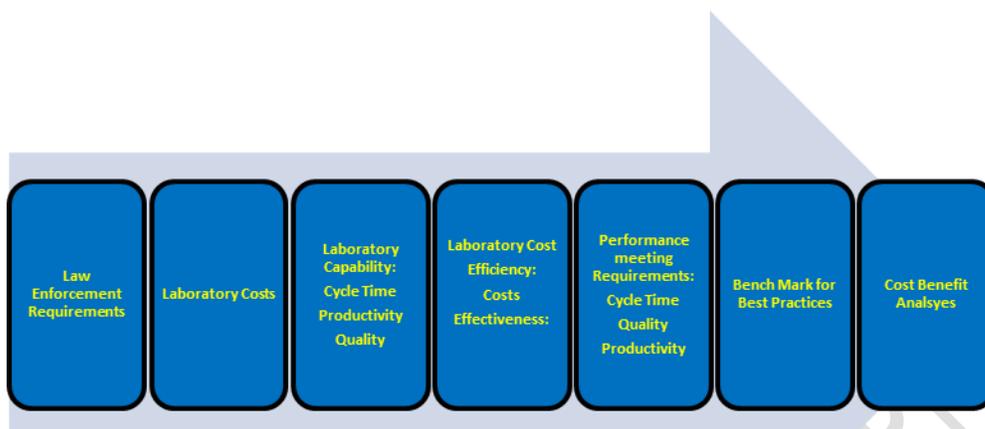
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289 **7. Add Laboratory Management Model Performance (LMPM) metrics**

290 Ideally, procedures should link to the key Laboratory Performance Metrics for Customer
291 Requirements, Costs, Capability, Cost Efficiency, Cost Effectiveness, Performance and
292 Bench Marking (Figure 1 LMPM metrics) for best practice. A collective sum of metrics
293 from all procedures equals the total metrics for the forensic unit (e.g. DNA unit). Staff
294 and supervisors should confirm the procedure is associated with customer requirements.
295 If not, then the procedure may not be needed and resources can be applied elsewhere
296 more appropriately. The cost of the procedure with personnel time, consumables,
297 contracts, support personnel and facilities can be measured per unit output and monitored
298 for continual improvement in efficiency and effectiveness. Performance can be measured
299 to determine if capabilities are meeting customer requirements. Lastly, the procedure,
300 using these metrics can be bench marked with similar procedures and laboratories
301 (private or public). Perhaps the most practical use of the LMPM metrics is to choose one
302 metric of interest to top management and law enforcement customer(s). For example,
303 timeliness or cycle time is a component of the capabilities metrics. Information
304 technology support can establish data collection points for time integrated with the
305 laboratory information management system at the end of key tasks in the procedure.
306 Similarly, data collection points can be developed for remediation, non-conformances
307 and reanalysis to gather Good and Bad quality data metrics.

308

Figure 3 LMPM Metric Categories



309

310 **8. Training program if competency affects reported results or opinions**

311 Lastly, the procedure and PFC can be used as a foundation to develop training plans that will
 312 assure competency of personnel. Training plans should develop learning objectives, curricula
 313 materials, assessments and competency tests that confirm personnel perform at the proper
 314 standards. Causative factors for all know non-conformances should be identified, measured and
 315 monitored for continual improvement and assurance that the work force is competent.

316

317 Below is an example of a Purchasing department procedure that was developed using the above
 318 steps starting with the blank white board approach. The resulting PFC (Figure 5) and the
 319 resulting procedure were much clearer and concise than the existing procedure in use that was
 320 revised several times over the last several years.

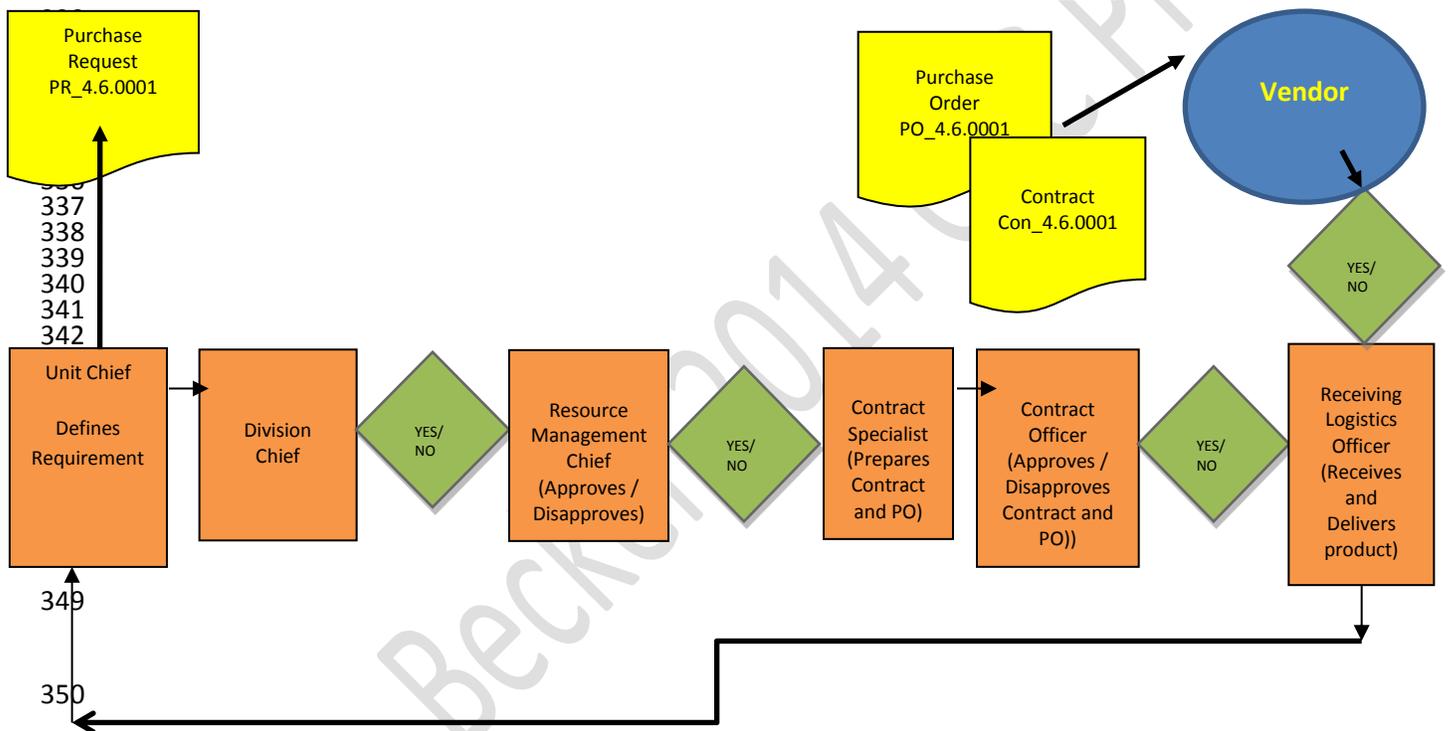
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Figure 4 Example of Purchasing Procedure PFC



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Metro Laboratory

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Procedure

361

4.6.0001 Purchasing

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363 Control Document Number: 4.6.0001-10142012

364 Approval Date: November 1, 2012

365 Authority: Chief, Resource Management

366

367 1. References

368 a. Internal Procedures

369 i. 4.6.0002 Competitive and Sole Source Vendor Selection

370 ii. 4.6.0003 Receipt of Products

371 iii. 4.6.0004 Development and approval of Annual Budget

372 b. External Regulations

373 i. ISO/IEC 17025: 2005 International Standard

374 ii. Metro City Financial Policy for Vendor Selection

375 iii. Metro City Annual Budget Policies and Procedures

376 2. Laboratory Mission Statement

377

378 Metro Laboratory shall strive to meet our customer requirements through the application
379 of the best science to the best evidence in an efficient, effective and ethical manner with
380 the highest quality.

381

382 3. Policy

383 Metro Laboratory shall be diligent in keeping current with state of the art technologies having potential to
384 increase efficiency and effectiveness of services provided to our customers. New technologies may
385 provide greater productivity, higher quality (less non-conformance), increased efficiency (less cost), and
386 decreased cycle times with associated decreased resulting backlogs. *All staff* will continually advise their
387 *Branch Chief* of potential new products for evaluation to increase quality of services provided to our
388 customers.

389 4. Procedure

390 a. All Staff

391 i. All staff shall keep current with latest technologies and services that may
392 increase the efficiency, effectiveness, and contribute to the continual
393 improvement of operations in their respective units. Staff shall forward, with
394 detailed descriptions of benefits and a *CD_PR_4.6 (Purchase Request)* to their
395 respective *Unit Chief by 1June* to be assessed for submission to budget approval
396 and subsequent purchase and evaluation.

397 b. Unit Chief

398 i. *Unit Chief(s)* shall discuss with staff merits of recommended products and
399 services. *Unit Chief* will assess potential for increasing effectiveness, efficiency,
400 timeliness and quality of services *shall approve or not*, sign, date form Purchase
401 Request (CD_PR_4.6) and if approved submit to the *Chief, Resource*
402 *Management* by *1July*.

403 **c. Chief, Resource Management**

404 i. **Chief, Resource Management**, shall review the CD_PR_4.6 for accuracy,
405 completeness and Unit Chief approval. Upon verification of availability of
406 budgeted funds; **approve or not**, sign and date and forward to the **Contract**
407 **Specialist** as appropriate.

408 **d. Contract Specialist**

409 i. **The Contract Specialist** shall review the CD_PR_4.6 for appropriate
410 completeness and appropriate Unit Chief and Resource Management Chief
411 approvals. Upon verification of appropriate approvals, the Contract Specialist
412 will follow appropriate internal / external fiscal policies, procedures and
413 regulations and decide if the purchase of this product requires a sole source
414 justification or shall be a competitive bid process.

415 ii. If a sole source purchase is justified, the Contract Specialist will follow sole
416 source procedures, develop a contract and **forward to the Contract Officer** for
417 approval and execution.

418 iii. If a competitive bid is required, the necessary procedures will be followed to
419 allow competitive bidding by appropriate vendors. Upon completion of the
420 competitive bid process, a contract will be **forwarded to the Contract Officer** for
421 approval and execution.

422 **e. Contract Officer**

423 i. The **Contract Officer** shall review, **approve or not**, sign and date all sole source
424 purchases and contracts (Con_4.6.0001) for accuracy and completeness as per all
425 fiscal policies, procedures and regulations.

426 1. Approved Sole source purchase requests and competitive bid contracts
427 shall result in a Purchase Order (PO4.6.0001) approved, dated, signed

428 and forwarded to successful vendors for purchase of products by August

429 1.

430 ***f. Logistics Officer***

431 i. The Logistics Officer, upon receipt and before 1 October of the associated
432 funded fiscal year, ***will confirm the inventory of the product received is***
433 ***accurate or not*** and concurs with associated PO_4.6.0001. Upon verification, the
434 Logistics Officer shall make entry in the Log Book (LB_4.6.0001) the
435 description of the product, invoice number, date and initials. Any discrepancies
436 or damage will result in the product being returned to the vendor.

437 ii. Upon proper receipt, the Logistics Officer, affix Property Tag (ID_4.6.0001) for
438 products valued over \$500 and shall deliver the product to the associated Unit
439 Chief. Upon delivery, the Unit Chief shall sign and date the Receipt of Product
440 form RE_4.6.0001. The Logistics Officer will maintain completed RE_4.6.0001
441 forms.

442 ***g. Potential Non-Conformances***

- 443 i. Purchase not strategically aligned with Mission priorities
- 444 ii. Purchase not strategically aligned with customer requirements
- 445 iii. Purchase does not increase capabilities or performance LMPM metrics
- 446 1. Increase productivity
- 447 2. Increase quality
- 448 3. Decrease cycle time
- 449 iv. Purchase not funded
- 450 v. Incorrect entries or no signatures, dates, approvals on controlled documents
- 451 vi. Controlled documents missing for property valued over \$100
- 452 vii. Untimely completion of process steps
- 453 1. CD_PR_4.6 Purchase Request

- 454 a. June 1, Unit Chief
- 455 b. July 1, Division Chief
- 456 c. August 1, Resource Management Chief
- 457 2. Con_4.6.0001 Contract
- 458 3. PO_4.6.0001 Purchase Order
- 459 4. Log Book
- 460 a. October 1, Logistics Officer
- 461 5. RE_4.6.0001 Receipt
- 462 viii. Sole Source should be Competitive Bid
- 463 ix. Competitive Bid should be Sole Source
- 464 x. Damaged products received
- 465 xi. Incorrect products received
- 466 xii. No ID number affixed for property valued over \$500
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