

Putting WGS Methods on Scope Where to Start?





2018 Genome Trackr Meeting

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- Considering lab resources, how much work will it be to add this method to the ISO scope?
- Which scope?
Microbiology or Chemistry?





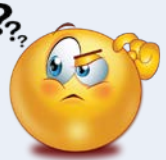

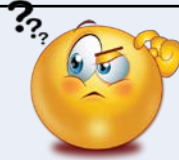







Personnel (6.2)

Standard Clause	What is Needed	Action Taken
Job Description	Analysts doing work will need to have it added	 Add WGS to job descriptions
Document Competence	Training checklists and competence samples performed	Attend trainings   Pass certificates Passed Proficiency Testing 

Equipment (6.4)

Standard Clause	What is Needed	Action Taken
Maintenance Schedule	Every instrument and piece of equipment will need a maintenance schedule	 Equipment annual PM needs to be recorded Add information to a SOP
Identity of equipment and location	Manufacturer's name, type of identification and serial number	All have serial numbers, all manuals will need to be added to inventory  
	Records of calibration	 Paperwork will need to be kept and filed
	Records of equipment issues and repairs	Keep log book to record equipment issues 
Equipment SOP	Procedures and work instructions	 Create necessary documentation

Standard Clause	What is Needed	Action Taken
Traceability (6.5)		
Standards	Sequencing control Equipment checks	Identify controls to use and check if additional ones are needed 
Supplies	Supplies to use	 Create inventory 
Worksheets and Tables	Forms and worksheets	Create worksheets, validate calculations, control document
Validation or Verification (7.2)	Validate and verify procedures and equipment	Use validated method and verify equipment when needed 
Technical Records (7.5)	Document procedures, who did it and when	 All worksheets and templates should have to be controlled.
Measurement Uncertainty (7.6)		

Ensuring Validity of Results (7.7)		
Monitoring Validity of Results	Reference materials or quality control materials, control charts, intermediate checks and reviews	Write procedure on data review and refer to quality metrics that are in place.
Proficiency Testing	Participate in PT when available	 Document PT status
Reporting Results (7.8)		
Result Release	Review and authorize prior to release	
Customer?	Identify customer and how do they want the report	Need discussion with NYSDAM division that use WGS data 
Non-conforming work (7.10)		
Recording	Establishment of non-conforming work and how to proceed once found	Write SOP to describe when non-conforming work was performed. 

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