

IQ/OQ/PQ - GramPRO 1

Installation Qualification/Operation Qualification/Performance Qualification

1.0 Purpose

This protocol outlines the steps to performing the IQ/OQ/PQ (installation, operation, and performance qualification) for the GramPRO 1.

2.0 Equipment and Materials

- GramPRO 1
- User's Manual
- Additional Supplies – Stain Kit, Microscope Slides
- Addendum 1: Installation Qualification Record
- Addendum 2: Operation Qualification Record
- Addendum 3: Performance Qualification Record

3.0 Safety and Required Personal Protective Equipment

- None

4.0 Procedure

4.1 Print Addendum 1, 2 and 3 of this IQ/OQ/PQ to record your results.

Note: This protocol is written to meet general requirements for IQ/OQ/PQ.

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Installation Qualification (IQ)

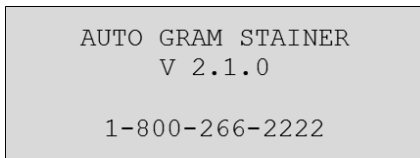


Figure 2: Start Up Page

4.2 Machine Identification and Version

Record the unit's serial number, software version number, and Asset ID (if applicable) on Addendum 1.

Note: The serial number can be found on the machine label located next to the power supply. The software version is displayed on the Start-up Page (see Figure 2 above). The Asset ID will be user generated based on your facility's onboarding for instrumentation.

4.3 Inspection - Receiving

Upon receipt of the instrument, inspect the packaging for any signs of mishandling and/or damage during transportation (e.g. damage to crate, broken pallet). Document results on Addendum 1.

4.4 Inspection – Machine/Components

Unpack the machine/components and inspect for any signs of damage and/or alteration and/or defects, refer to Receiving and Unboxing Section in the User Manual (Section 9.1). Document results on Addendum 1.

4.5 Inspection – Contents

Verify that all contents (e.g. components, ancillary items, etc.) are present, refer to Receiving and Unboxing Section in the User Manual (Section 9.1). Document results on Addendum 1

4.6 Location/Environment

Move the machine to the location of use and verify that it meets requirements for work environment, refer to Specifications and Work Area Requirements Sections in the User Manual (Section 1.0 – Section 2.0). Document results on Addendum 1.

4.7 Installation

Install the machine, refer to First Time instrument Set-Up Section in the User Manual



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(Section 9.0). Document results on Addendum 1.

Note: Ensure all applicable local, state, and national requirements, and safety standards have been met.

4.8 Safety

Verify that Safety Features and Controls have been met. Refer to Introduction Section and Safety Data Sheet in the User Manual (Section 3.0 & Section 17.0). Document results on Addendum 1.

Note: Ensure all applicable local and national requirements, and safety standards have been met.

4.9 Service(s)/Infrastructure

Verify that service(s)/infrastructure necessary for the correct function of the equipment have been setup and function correctly. Refer to Specification Section in the User Manual (Section 1.0). Document results on Addendum 1.

4.10 Maintenance/Cleaning

Verify that maintenance/cleaning instructions including the contact for technical support are documented. Refer to Maintenance Section and Maintenance Log in the User Manual. Verify that required training has been completed. Verify that maintenance/cleaning has been established in the associated processes (e.g. cleaning and contamination control process, preventive maintenance process) to ensure completion. Refer to Maintenance Section and Maintenance Log in the User Manual (Section 15.0 & Section 20.0). Document results on Addendum 1.

4.11 Operating Instructions

Verify that operating instructions are documented and approved. Refer to Operating Instructions Section in the User Manual (Section 10.0 – Section 12.0). Verify that required training has been completed. Document results on Addendum 1.

4.12 Additional Requirements

Verify that any additional requirements not covered by the fore-mentioned sections are in compliance. Document results on Addendum 1.

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Operation Qualification (OQ)

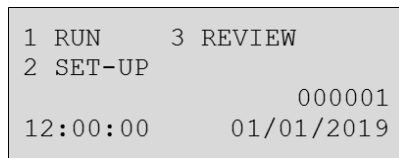
- 4.13 **Start-up Procedure** Perform the start-up steps listed below. Refer to First Time Instrument Set-Up Section in User Manual (Section 9.0). Verify the machine powers on and displays the Start-Up Page (see Figure 2 at the beginning of section 4.0 above). Document results on Addendum 2.

Start-Up Steps

- Plug in the power cord from the back side of the machine to a power source.
- Install reagents (Crystal Violet, Decolorizer, Grams Iodine, Advanced Counterstain, DI Water, and Waste) into corresponding tubing.
- Place the “Crystal Violet” cannula into the Crystal Violet bottle.
- Place the “Decolorizer” cannula into the Decolorizer bottle.
- Place the “Grams Iodine” cannula into the Grams Iodine bottle.
- Place the “Safranin” cannula into the Advanced Counterstain bottle.
- Place the “DI Water” cannula into the DI Water bottle.
- Place the “Waste” cannula into the waste bottle.
- Flip power switch to the “On” position.

Main Menu Page

- 4.14 Verify that the Main Menu Page automatically initiates following the startup procedures (see Figure 3). Verify that the following is displayed: Run option; Set-up option; Review option; Seq; Time and Date. Document results on Addendum 2.



```
1 RUN      3 REVIEW
2 SET-UP
                000001
12:00:00    01/01/2019
```

Figure 3: Main Menu

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Run Menu

- 4.15 From the Main Menu, press the #1 key to bring up the Run Menu. Verify the Run Menu appears (see Figure 4). Verify that the following is displayed: Gram Stain option; Clean Cuvette option; Prime Pumps function; Purge function; Exit function. Document results on Addendum 2.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE          * EXIT
```

Figure 4: Run Menu

Run Menu - Gram Stain Sub-Menu

- 4.15.1 From the Run menu, press the #1 key to bring up the Gram Stain Sub-Menu. Verify the Gram Stain Sub-Menu appears (see Figure 5). Verify that the following is displayed: Gram Stain (Short) function; Gram Stain (Long) function; Decolorize Only function; Exit function. Document results on Addendum 2.

Note: Reagent volume and expiration dates are checked at this time to assure staining operation may be completed.

```
1-GRAM STAIN (Short)
2-GRAM STAIN (Long)
3-DECOLORIZE ONLY
          * EXIT
```

Figure 5: Gram Stain Submenu

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Run Menu - Clean Cuvette Sub-Menu

4.15.2 From the run menu, press the #2 key to bring up the Clean Cuvette Sub-Menu. Verify the Clean Cuvette Sub-Menu appears (see Figure 6). Verify that the following is displayed: Wash Cuvette function; Scrub Stain Lines function; Exit function. Document results on Addendum 2.

Note: These functions are not performed as part of the operation qualification. These functions are part of recommended maintenance. Refer to Wash Cycle and Scrub Cycle subsections contained in the User Maintenance Section of the User Manual (Section 15.1 – Section 15.2).

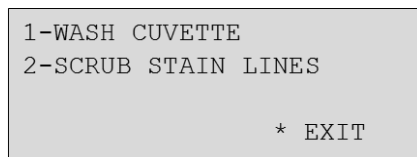


Figure 6: Clean Cuvette Submenu

Run Menu – Purge function

4.15.3 From the run menu, press the #4 key to activate Purge function. Verify that the machine completes the purge function. Document results on Addendum 2.

Run Menu – Prime Pumps function

4.15.4 From the run menu, press the #3 key to activate Prime Pumps function. Verify that the machine completes the prime function. Document results on Addendum 2.

Note: The machine will first run the purge function to clear fluid from the lines and then run the prime function to ensure the correct volume of fluid is in the lines.

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Set-Up Menu

- 4.16 From the Main Menu, press the #2 key to bring up the Set-up Menu. Verify the Set-up Menu appears (see Figure 7). Verify that the following is displayed: Calibration option; Consumables option; Date/Time option; Options option; Exit function. Document results on Addendum 2.

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

Figure 7: Set-Up Menu

Set-Up Menu - Calibration Sub-Menu

- 4.16.1 From the Set-up menu, press the #1 key to bring up the Calibration Sub-Menu. Verify the Calibration Sub-Menu appears see Figure 8. Verify that the following is displayed: Calibrate Detector function; Setup Stain Delays option; Exit function. Document results on Addendum 2.

```
1-CALIBRATE DETECTOR
2-SET STAIN DELAYS

* EXIT
```

Figure 8: Calibration Submenu

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Set-up Menu - Calibration Sub-Menu - Calibrate Detector function

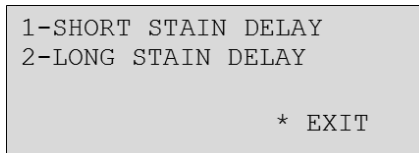
4.16.1.1 From the Calibration Sub-Menu, press the #1 key to activate the Calibrate Detector function. Verify that the calibration is successfully completed. Document results on Addendum 2.

Note: If the calibration is not successfully completed, a Detector Calibration Error will be displayed. Refer to Self-Calibration Errors subsection contained in the Quality Control Section of the User Manual.

Set-up Menu - Calibration Sub-Menu - Set Stain Delays Sub-Menu

4.16.1.2 From the Calibration Sub-Menu, press the #2 key to bring up the Set Stain Delays Sub-Menu. Verify the Stain Delays Sub-Menu appears (see Figure 9). Verify that the following is displayed: Short Stain Delay option; Long Stain Delay option; Exit function. Document results on Addendum 2.

Note: These functions are not performed as part of the qualification. These functions are used to customize the parameters for the Short Stain and Long Stain function. We recommend contacting Hardy's technical support for assistance prior to altering these settings.



```
1-SHORT STAIN DELAY
2-LONG STAIN DELAY

* EXIT
```

Figure 9: Set Stain Delays Submenu

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Set-up Menu - Consumables Sub-Menu

4.16.2 From the Set-up menu, press the #2 key to bring up the Consumables Sub-Menu. Verify the Consumables Sub-Menu appears (see Figure 10). Verify that the following is displayed: Review Reagents option; Review Tubing option; Exit option. Document results on Addendum 2.

```
1-REVIEW REAGENTS
2-REVIEW TUBING

* EXIT
```

Figure 10: Consumables Sub-Menu

Set-up Menu - Consumables Sub-Menu - Review Reagents Sub-Menu

4.16.2.1 From the Consumables Sub-Menu, press the #1 key and verify the Review Reagent Sub-Menu is displayed (see Figure 11). Verify the following is accurately displayed: # of Cycles Remaining; Exp Date of Reagents; Change Kit option; Exit function. Document results on Addendum 2.

Note: For entering in the current Reagent Kit being used refer to the Reagent Kit Registration subsection contained in the Consumables Section of the User Manual.

```
REAGENT STATUS
CYCLES REMAINING 110
EXP DATE 01/01/2020
1-CHANGE KIT *EXIT
```

Figure 11: Review Reagents Sub-Menu

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Set-Up Menu - Consumables Sub-Menu - Review Tubing Sub-Menu

4.16.2.2 From the Consumables Sub-Menu, press the #2 key and verify the Review Tubing Sub-Menu is displayed (see Figure 12). Verify the following is accurately displayed: # of Cycles Remaining; Change Kit option; Exit function. Document results on Addendum 2.

Note: For entering in the current Tubing being used refer to the Pump Tube Replacement Procedure subsection contained in the Consumables Section of the User Manual.

```

TUBING STATUS
CYCLES REMAIN      1100
1-CHANGE KIT      *EXIT
```

Figure 12: Review Tubing Sub-Menu

Set-Up Menu - Date / Time Sub-Menu

4.16.3 From the Set-up menu, press the #3 key to bring up the Date / Time Sub-Menu. Verify that the Date /Time Sub-Menu is displayed (see Figure 13). Verify the following is accurately displayed: Time; Date; Date option; Time option; Exit option; From the Date / Time menu, press # 1 and verify the Date Sub-Menu is displayed. Verify the date can be changed. From the Date / Time menu, Press # 2 and verify the Time Sub-Menu is displayed. Verify the time can be changed. Set Date and Time to current Date and Time. Document results on Addendum 2.

```

SYSTEM DATE / TIME
TIME 12:00:00
DATE 01/01/2019
1-DATE 2-TIME *EXIT
```

Figure 13: Date/Time Submenu

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Set-Up Menu - Options Sub-Menu

4.16.4 From the Set-up menu, press the #4 key to bring up the Options Sub-Menu. Verify that the Options Sub-Menu is displayed (see Figure 14). Verify that the Audio Alert, Idle Delays, and Exit option are displayed. Document results on Addendum 2.

```

1-AUDIO ALERT
2-IDLE DELAYS

* EXIT
```

Figure 14 Options Sub-Menu

Set-Up Menu - Options Sub-Menu - Audio Alert Sub-Menu

4.16.4.1 From the Options Sub-Menu, press the #1 key and verify the Audio Alert Sub-Menu is displayed (see Figure 15). Verify the following is accurately displayed: Status of the Alert (e.g. ON, OFF); Audio Alert OFF function; Audio Alert On function; Test function; Exit function. Document results on Addendum 2.

From the Audio Alert Sub-Menu, press the #1 button and verify that the status is correctly displayed as OFF. Press the #3 button and verify that the test is initiated and the audio alarm is not triggered. Press the #2 button and verify that the status is correctly displayed as ON. Press the #3 button and verify that the test is initiated and the audio alarm is triggered. Document results on Addendum 2.

```

AUDIO ALERT IS ON
1 - AUDIO ALERT OFF
2 - AUDIO ALERT ON
3 - TEST * EXIT
```

Figure 15: Audio Alert Sub-Menu

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Set-Up Menu - Options Sub-Menu - Idle Delays Sub-Menu

4.16.4.2 From the Options Sub-Menu, press the #2 key and verify the Idle Delay Sub-Menu is displayed (see Figure 16). Verify the following is accurately displayed: Sleep Delay, Stir Delay; Auto Prime; Exit option. Document results on Addendum 2.
Note: These functions are not performed as part of the operation qualification. These functions are used to customize the parameters for machine functions. We recommend contacting Hardy's technical support for assistance prior to altering these settings.

SLEEP DELAY	5 MIN
STIR DELAY	187 MIN
AUTO PRIME	24 HR
# ACCEPT	* EXIT

Figure 16: Idle Delay Submenu

Review Menu

4.17 From the Main Menu, press the #3 key to bring up the Review Menu. Verify that the Review Menu is displayed (see Figure 17). Verify the following is accurately displayed: Stain option; Cal Wet option; Cal Dry option; Exit function. Document results on Addendum 2.

RESULTS REVIEW	
1 STAIN	3 CAL DRY
2 CAL WET	
	* EXIT

Figure 17: Review Menu

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Review Menu - Stain Sub-Menu

4.17.1 From the Review menu, press the #1 key to bring up the Stain Sub-Menu. Verify the Stain Sub-Menu is displayed (see Figure 18). Verify the following is accurately displayed: Date, Time; Seq value; t value; min value; max value; Prev function; Next function; Xfr function. Document results on Addendum 2.

Note: This menu contains the Staining history performed on the machine. The prev and next function allows you to scroll through the history. The xfr function is an obsolete function that is no longer utilized.

```
01/01/19      12:00:00
Seq=000001    t = 04900
  min =00450max =01200
  1-Prev 2-Next 3-Xfr
```

Figure 18: Stain Submenu

Review Menu - Cal Wet Sub-Menu

4.17.2 From the Review menu, press the #2 key to bring up the Cal Wet Sub-Menu. Verify the Cal Wet Sub-Menu is displayed (see Figure 19). Verify the following is accurately displayed: Date, Time; Seq; Avg; Prev function; Next function; Xfr function. Document results on Addendum 2.

Note: This menu contains the Cal Wet history performed on the machine. The prev and next function allows you to scroll through the history. The xfr function is an obsolete function that is no longer utilized.

```
01/01/19      12:00:00
Seq=000001avg= 1000
  1-Prev 2-Next 3-Xfr
```

Figure 19: Cal Wet Submenu

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Review Menu - Cal Dry Sub-Menu

4.17.3 From the Review menu, press the #3 key to bring up Cal Dry Sub-Menu. Verify the Cal Dry Sub-Menu is displayed (see Figure 20). Verify the following is accurately displayed: Date, Time; Seq; Avg; Prev function; Next function; Xfr function. Document results on Addendum 2.

Note: This menu contains the Cal Dry history performed on the machine. The prev and next function allows you to scroll through the history. The xfr function is an obsolete function that is no longer utilized.

```
01/01/19      12:00:00
Seq=000001avg= 0400

1-Prev 2-Next 3-Xfr
```

Figure 20: Cal Dry Submenu

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Performance Qualification (PQ)

- 4.18 Process at least five control slides with known sample material using the procedure for normal processing of specimen slides. Refer to Specimen Slide Preparation and Methanol Fixation Procedure subsections contained in the Operations Instructions section of the User Manual (Section 8.1 – Section 8.2).
Note: Hardy Diagnostics Quality Control slides (Cat. No. [QS0700](#)) which contain a known sample material are recommended. See the Quality Control Checks subsection contained in the Quality Control section of the User Manual (Section 13.1).
- 4.19 Inspect the processed slides to confirm proper staining and results. Document results on Addendum 3.

Report

- 4.20 Generate a validation summary.
Note: The validation summary should contain the following: Identification of Machine (e.g. Asset ID#, Serial #); the outcome of the qualification (e.g. successful, unsuccessful); List of Major Issues and Resolutions as applicable; Signature Sign-Off.
- 4.21 Assemble validation report together as indicated below:
- Validation Summary
 - Validation Protocol
 - Addendum 1: Installation Qualification Record
 - Addendum 2: Operation Qualification Record
 - Addendum 3: Performance Qualification Record

Acceptance Criteria

- 4.22 Successful completion of IQ.
- 4.23 Successful completion of OQ.
- 4.24 Successful completion of PQ.
Note: Issues that are not related to improper operation by the machine will not constitute a failure of the qualification of the machine. Issues of this nature will be noted and considered a failure of that specific application (e.g. supplies and material issues).



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Approval

5.0 Review the protocol to ensure qualification method and requirements are understood by personnel performing and approving the qualification.

Note: Add supplemental documents as needed to document any additional internal requirements not covered by this standard qualification protocol.

Role	Title	Signature	Date
Performed By			
Approved By			



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Addendum 1: Installation Qualification Form

Serial #	Software Version		Asset ID
Description	Complies	Initials/Date	Objective Evidence / Deviations / Comments
Inspection – Receiving	<input type="checkbox"/> Y <input type="checkbox"/> N		
Inspection – Machine/Components	<input type="checkbox"/> Y <input type="checkbox"/> N		
Inspection – Contents	<input type="checkbox"/> Y <input type="checkbox"/> N		
Location/Environment	<input type="checkbox"/> Y <input type="checkbox"/> N		
Installation	<input type="checkbox"/> Y <input type="checkbox"/> N		
Safety	<input type="checkbox"/> Y <input type="checkbox"/> N		
Service(s)/Infrastructure	<input type="checkbox"/> Y <input type="checkbox"/> N		
Maintenance/Cleaning	<input type="checkbox"/> Y <input type="checkbox"/> N		
Operating Instructions	<input type="checkbox"/> Y <input type="checkbox"/> N		
Additional Requirements <i>(list below as needed or write "None")</i>	Complies	Initials/Date	Objective Evidence / Deviations / Comments
	<input type="checkbox"/> Y <input type="checkbox"/> N		
Additional Comments:			

Note: If a specific question does not apply, fill out the question marking "Yes" for complies and document that it does not apply in the Objective Evidence.

Role	Title	Signature	Date
Reviewed By			
Approved By			

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Addendum 2: Operation Qualification Form

Serial #	Software Version			Asset ID
Section	Complies	Initials	Date	Objective Evidence / Deviations / Comments
Start-Up Procedure	<input type="checkbox"/> Y <input type="checkbox"/> N			
Main Menu Page	<input type="checkbox"/> Y <input type="checkbox"/> N			
Run Menu – General	<input type="checkbox"/> Y <input type="checkbox"/> N			
Run Menu - Gram Stain Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Run Menu - Clean Cuvette Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Run Menu – Prime Pump function	<input type="checkbox"/> Y <input type="checkbox"/> N			
Run Menu – Purge function	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – General	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Calibration Sub-Menu - General	<input type="checkbox"/> Y <input type="checkbox"/> N			

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Set-up Menu – Calibration Menu – Calibrate Detector function	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Calibration Menu – Set Stain Delays Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Consumables Sub-Menu - General	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Consumables Sub-Menu - Review Reagents Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Consumables Sub-Menu - Review Tubing Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Date / time Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Options Sub-Menu – General	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Options Sub-Menu – Audio Alert Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Set-up Menu – Options Sub-Menu – Idle Delays Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Review Menu – General	<input type="checkbox"/> Y <input type="checkbox"/> N			
Review Menu – Stain Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Review Menu – Cal Wet Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			



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Review Menu – Cal Dry Sub-Menu	<input type="checkbox"/> Y <input type="checkbox"/> N			
Additional Comments:				

Role	Title	Signature	Date
Reviewed By			
Approved By			



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Addendum 3: Performance Qualification Form

Results	
Testing Date	
Testing Time	
Control Slide ID (e.g. product code, lot number)	
Control Slide Description	
# of Control Slides Processed	
# of Passing Control Slides	
# of Machine Interventions	
# of Warnings and/or Alarms	
Additional Testing	<input type="checkbox"/> N/A <input type="checkbox"/> Y Describe methods and Results :
Passed (Circle)	Yes No

Note: Provide details on staining issues, machine interventions, and warnings and/or alarms in the comment section below.

Comments:

Role	Title	Signature	Date
Performed By			
Approved By			