The University of Iowa Dezii Translational Vision Research Group

TITLE: DTVR Qualification, Calibration and Preventive Maintenance Policy

SOP Number: D-GLO-PRO-010 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to outline the qualification, calibration, and preventive maintenance policy for systems and individual pieces of equipment used in the manufacturing and laboratory for testing of products processed by The University of Iowa Dezii Translational Vision Research Group (DTVR).

B. APPLICABILITY

This procedure shall be performed by The University of Iowa DTVR personnel at the Carver College of Medicine (CCM) under the supervision of Quality Assurance.

C. REFERENCES

D-GLO-PRO-006 Equipment, Room Use, Maintenance & Cleaning Logs
D-GLO-PRO-009 Laboratory Documentation in the LabGuru System

D. EQUIPMENT

Equipment as outlined in each specific SOP

E. PROCEDURE

1. All equipment to be used in the manufacturing process or in product analysis by The University of Iowa DTVR shall have the following requirements performed prior to use.

   1.1 For critical equipment preparation, execution, and approval of IQ, OQ, and PQ Protocols according to SOP D-GLO-PQV-001 with detailed description of the equipment qualifications for installation (IQ), operation (OQ), and performance qualifications (PQ).

   1.2 For all equipment fill-out New Equipment form F-D-GLO-PRO-004 and submit to QA for entry into LabGuru.

   1.3 A Standard Operating Procedure (SOP) for Equipment Operation (EQP), Calibration, and Preventive Maintenance shall be written. A separate SOP for the Equipment Calibration (ECL) or Equipment Preventive Maintenance (EPM) of the piece of equipment may be written.

      1.3.1 Each SOP will contain sufficient detail/reference to:

1.3.2 Appropriate manuals to allow the procedure for calibration / preventive maintenance of the equipment.

1.3.3 Specific limits the equipment must meet for calibration and preventive maintenance (voltage, pressure differentials, etc.).

1.3.4 Frequency for Calibration / Preventive Maintenance for the given piece of equipment. The frequency of Calibration/ Preventive Maintenance will be based on the current industry standards, the manufacturer's recommendation and the equipment frequency of use.

1.4 Initial Calibration / Preventive Maintenance of the equipment prior to being used, documented and turn-in of the respective performance form to QA office.

2. Calibration shall be performed using recognized industry standards or materials that have been calibrated against recognized industry standards, e.g. ASTM, NIST or NIST traceable standards, where available.

3. Calibration/Preventive Maintenance shall be performed within two months of the due date. Due date intervals (60 days) will be tracked by QA using Calibration Manager LabGuru. Equipment cannot be used after the due date.

4. Equipment will be tagged as to status when performing Calibration/Preventive Maintenance so that it cannot be used.

5. Calibration/Preventive Maintenance shall be documented in the respective equipment log according to: D-GLO-PRO-006, D-GLO-PRO-009.

5.1 The individual performing the Calibration/Preventive Maintenance will initial and date the logbook upon completion.

5.2 All Calibration/Preventive Maintenance is reviewed by a second individual. Proof of review may be either by signing the log book, signing the paperwork from an outside contractor or by approval electronically in LabGuru.

6. Results of the Calibration/Preventive Maintenance shall also be documented on the respective forms. The forms or certificates of Calibration/Preventive Maintenance will be turned into QA for review, signed by QA, entered in LabGuru, and stored in the QA office.

6.1 Any repairs must be noted in the Equipment log book and on the form turned into QA.

6.2 Any time repairs are made to equipment, the change control form F-D-GLO-PRO-016 must be filled out to determine if any requalification is necessary, even if Like-for-Like changes are made.

7. Any failing calibration results will be investigated following SOP D-GLO-PRO-013 for impact to products made or tested. Critical equipment that fails calibration and cannot be repaired shall be retired or inactivated using form F-D-GLO-PRO-005.

8. If a piece of equipment fails calibration and repairing it does not solve the problem, it will be taken out of service and tagged as "Out of Calibration". The functional group Director and QA will be notified and will determine the necessary actions to correct the situation.

F. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document