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IV CALIBRATION

NOTE – ALL QUESTIONS ARE PRIORITY “A” EXCEPT #24B.

1. Does the supplier have a written description of the calibration system? (ISO 4.11.1) Sat Unsat

2. Is the calibration system coordinated with the quality program/ inspection system? (ISO 4.2.3) Sat Unsat

3. Is a listing of all standards maintained which includes nomenclature, identification number, calibration interval and source of calibration? Sat Unsat

4. Are calibration intervals for measuring and test equipment and measurement standards established based on stability, purpose and degree of usage? (ISO 4.11.1) Sat Unsat

- 5a. Does the system provide for the mandatory recall of all items? Sat Unsat

- 5b. Are items returned for calibration as scheduled? (ISO 4.11.1) Sat Unsat

6. Are calibration/recall procedures readily available to the calibrating personnel? Sat Unsat

7. Does this procedure provide for: (ISO 4.11.1) Sat Unsat
 - a. Adjustment of calibration frequency? Yes No

 - b. Determining the adequacy of measuring/test equipment and procedures? Yes No

 - c. Identification and prevention of use of any equipment which does not perform satisfactorily Yes No

 - d. Definition of significant out-of-tolerance conditions? Yes No

 - e. Written notification by calibration activity to user or Yes No

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a designated organization of significant out-of-tolerance conditions?

- f. Corrective action by supplier on affected product?** Yes No

- g. Is an adequate checkout and accountability system in effect for locating equipment for recall purposes? (ISO 4.11.1)** Yes No

- 8. Are tools, gauges and test equipment traceable to the National Institute of Standards Technology? (NIST) (ISO 4.11.1)** Sat Unsat

- 9. Do calibration/inspection records reflect: (ISO 4.11.1)** Sat Unsat

 - a. Item identity number and name?** Yes No

 - b. Frequency of calibration?** Yes No

 - c. Procedure for calibration/inspection?** Yes No

 - d. Date calibrated/inspected and due date for calibration/inspection?** Yes No

 - e. Personnel performing calibration/inspection?** Yes No

 - f. Deviation from standard values?** Yes No

 - g. Actual measurement/value documented?** Yes No

 - h. Standard used (traceable to NIST)?** Yes No

- 10. Are tools, gauges and test equipment identified in a manner to reflect: (ISO 4.11.1)** Sat Unsat

 - a. Date calibrated/inspected and/or date due for calibration/inspection?** Yes No

 - b. Personnel responsible for calibration/inspection?** Yes No

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- c. Item identity or serial number? Yes No
11. Are inactive standards identified as “inactive” or “calibration not required”?
 Sat Unsat
12. Are adequate facilities used for transportation, storage and calibration of all tools, gauges and test equipment?
 Sat Unsat
13. Does the described system require evaluation of the adequacy of the calibration system based on out-of-tolerance calibration data? (ISO 4.11.2.c)
 Sat Unsat
14. Does the supplier maintain cleanliness and provide for protection of test equipment? (ISO 4.11.2.h)
 Sat Unsat
15. Does the supplier have the necessary gauges and measuring devices to permit reliable inspections to meet the procedural acceptance criteria? (ISO 4.11.2.a)
 Sat Unsat
16. Are new or reworked tools “proven” prior to usage? (ISO 4.11.2.b)
 Sat Unsat
17. Are customer-furnished tools, gauges and test equipment adequately controlled? (ISO 4.11.2)
 Sat Unsat N/A
18. Are employee-owned tools and gauges used for product acceptance subject to the same controls as company-owned equipment? (4.11.2)
 Sat Unsat N/A
19. Is calibration performed utilizing standards that have a higher accuracy level than the accuracy requirements of the equipment being calibrated?
 Sat Unsat
20. Is calibration performed in a controlled environment (as determined necessary to assure the continued accuracy of the equipment and standards)? NOTE: The supplier’s procedure must specify environmental considerations to be applied.
 Sat Unsat
21. Are tamper-proof seals used to protect from access to adjustment features which could affect calibration?
 Sat Unsat N/A
22. Are items which are not calibrated to their full capability or
 Sat Unsat N/A

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which require functional check only labeled to indicate the applicable condition?

23. Are acceptance certificates of calibration provided for all equipment? Sat Unsat N/A

24a. Does each piece of inspection, measuring and test equipment, that can affect quality, have a different and unique identification number assigned? Sat Unsat

24b. Review and record a sample of measuring and test equipment serial/traceability numbers:

Sample Size: _____
Serial/Traceability Numbers:

25. Does the supplier use outside calibration laboratories? (ISO 4.11.2.a) Sat Unsat N/A

26. Are outside laboratories evaluated for acceptability? (ISO 4.6. Sat Unsat

27. Are these laboratories on an approved subcontractor list? (ISO 4.6.2) Sat Unsat

Additional concerns/comments: