INTERPLANT STANDARD - STEEL INDUSTRY		
IPSS	**SPECIFICATION & GUIDE FOR CALIBRATION SYSTEM OF INSTRUMENTATION**	**IPSS: 2-07-098-14**
	No Corresponding IS	

0. FOREWARD

0.1. Interplant standardization: Standardization activity in steel industry is being pursued under the aegis of Steel Authority of India Limited (SAIL). This Interplant Standard has been prepared by the Standards Committee on Instrumentation and Automation IPSS 2:7, with the active participation of representatives from the steel plants, other concerned organizations and established manufacturer in the field, and was adopted on April, 2014.

0.2. Interplant standards on design parameters primarily aim at achieving rationalization and unification of parts and assemblies of process and auxiliary equipment used in steel plants and these are intended to provide guidance to the steel plant engineers, consultants and manufacturers in their design activities.

0.3. Objective of this standard is to give specification and guide to the design of a calibration system & its management for the instrumentation laboratory. A description of such system is given below..

1. SCOPE:

1.1. This standard covers the details of requirement of instrumentation equipment test & measurement system to enable the users for proper monitoring by various measurement system & its components. The functionality of the test, calibration & measurement system also may be extended testing of parameters in line process condition.

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2. GENERAL

2.1. Egyptians had anticipated the spirit of the present day system of legal metrology, standards, traceability and calibration recall. With this standardization and uniformity of length, the Egyptians achieved surprising accuracy. Thousands of workers were engaged in building the Great Pyramid of Giza. Through the use of cubit sticks, they achieved an

accuracy of 0.05%. In roughly 756 feet or 230.36276 meters, they were within 11.43 centimeters.

2.2. The need for calibration has been around for at least 5000 years. In today's calibration environment, there are basically two types of requirements: ISO standards and regulatory requirements. The biggest difference between the two is simple – ISO standards are voluntary, and regulatory requirements are mandatory. If an organization volunteers to meet ISO 9000 standards, they pay a company to audit them to that standard to ensure they are following their quality manual and are within compliance. On the other hand, if a company is manufacturing a drug that must meet regulatory requirements, they are inspected by government inspectors for compliance to federal regulations. In the case of ISO standards, a set of guidelines are used to write their quality manual and other standard operating procedures (SOPs) and they show how they comply with the standard. However, the federal regulations specify in greater detail what a company must do to meet the requirements set forth in the Code of Federal Regulations (CFRs).

2.3. The part covering calibration is 21CFR Part 820.72. It is very specific about the requirements as seen in the following paragraphs: Sec. 820.72 Inspection, measuring, and test equipment.

2.4. Control of inspection, measuring, and test equipment. Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or

2.4.1. Electronic inspection and test equipment, are suitable for their intended purposes and capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

2.4.2. Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to re-establish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented

2.4.2.1. <u>Calibration standards.</u> Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

2.4.2.2. Calibration records. The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment. Please note that each paragraph (a, b, 1 and 2) all have requirements for documenting everything. In the industry environment, if there is no documentation for an action, then the action did not occur. Documented evidence is critical in showing something happened, when it happened, what occurred using each piece of equipment, and who did the action on what date. There cannot be enough stress placed on documenting everything in an FDA regulated company. This includes training, updating of SOPs and calibration procedures, and the repair and replacement of parts in test equipment. All aspects of a quality calibration program must be documented for several reasons, the least of which is not having to reinvent the wheel every time a process is improved or updated.

3. The following are the requirements for cGMP (current Good Manufacturing Practice) under the controlling authority:.

3.1. Equipment
(Automatic, mechanical, and electronic equipment).

Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a finished product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper Performance. Written records of those calibration checks and inspections shall be maintained.

3.2. Laboratory Controls
(General requirements)

- The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

- Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans,and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:
  The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. struments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.4

3.3. Electronic records; electronic signatures
(General Provisions Scope)

- The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures ,and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

- This part applies to records in electronic form that are created ,modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in statutory agency regulations. This part also applies to electronic records submitted to the statutory agency under requirements of the Factories inspectorate, and the Public Health Service Act, even if such records are not specifically identified in statutory agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

- Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997.

- Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with Sec. 11.2, unless paper records are specifically required.

- Computer systems (including hardware and software), controls,and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

- This part does not apply to records required to be established or maintained by Sec. 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

3.4. Implementation.

- For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.

- For records submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met and the document or parts of a document to be submitted have been identified in public docket No. 92S-0251 as being the type of submission the agency accepts in electronic form. This docket will identify specifically what types of documents or parts of documents are acceptable for submission in electronic form without paper records and the agency receiving unit(s) (e.g., specific center, office, division, branch) to which such submissions may be made. Documents to agency receiving unit(s) not specified in the public docket will not be considered as official if they are submitted in electronic form, paper forms of such documents will be considered as official and must accompany any electronic records. Persons are expected to consult with the intended agency receiving unit for details on how (e.g., method of transmission, media, file formats,and technical protocols) and whether to proceed with the electronic submission.

- Developed by the Calibration Management Special Interest Group (SIG) of ISPE’s GAMP Forum in conjunction with representatives from the pharmaceutical industry and regulators, the Guide describes the principles of calibration and presents guidance in setting up a calibration management system, providing the structured approach required to establish formal criticality assessment, management, documentation, and corrective actions vital to regulatory compliance.

- Featured Topics – The Guide is structured to follow the life cycle of validation and is intended to cover initial calibration in addition to periodic inspection, testing, and calibration.
    1. laboratory instrumentation
    2. quality
    3. safety
    4. environmental issues
    5. Regulatory requirements

3.4.1. ISO 9001:2008
Basically, this is what is required according to ISO 9001:2008

3.4.2. CONTROL MONITORING AND MEASURING EQUIPMENT

3.4.3. Identify your organization's monitoring and measuring needs and requirements (if your test instrument makes a quantitative measurement, it requires periodic calibration); and select test equipment that can meet those monitoring and measuring needs and requirements.

3.4.4. Establish monitoring and measuring processes (calibration procedures and calibration record templates for recording your Calibration results).

3.4.5. Calibrate your monitoring and measuring equipment using a period schedule to ensure that results are valid (you should also perform a yearly evaluation of your calibration results to see if there is a need to increase or decrease your calibration intervals on calibrated test equipment). All calibrations must be traceable to a national or International standard or artefact.

3.4.6. Protect your monitoring and measuring equipment (this includes during handling, preservation, storage, transportation, and shipping of all test instruments – to include your customer's items, and your calibration standards).

3.4.7. Confirm that monitoring and measuring software is capable of doing the job you want it to do (your software needs to be validated before being used, and when required, your test instruments may need to be qualified prior to use).

3.4.8. Evaluate the validity of previous measurements whenever you discover that your measuring or monitoring equipment is out-of calibration (as stated in the FDA regulations, "When accuracy and precision limits are not met, there shall be provisions for remedial action to re establish the limits and to evaluate whether there was any adverse effect on the device's

quality"; this is just as applicable when dealing with ISO as with any other standard or regulation; especially when the out of tolerance item is a calibration standard, and may have affected numerous items of test equipment over a period of time).

3.4.9. ISO 17025

3.4.9.1. ISO 17025 – General requirements for the competence of testing and calibration laboratories. According to ISO 17025, this standard is applicable to all organizations performing tests and/or calibrations. These include first-,second-, and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certifications .ease keep in mind that if your calibration function and/or metrology department fall under the requirements of your company, rather it be for compliance to an ISO standard (ISO 9001:2000 or ISO 13485) or an FDA requirement (cGMP, QSR, etc.), then you do not have any obligation to meet the ISO 17025 standard. You already fall under a quality system that takes care of your calibration requirements.

3.4.10. ANSI/NCSL Z540.3-2006

3.4.10.1. ANSI/NCSL Z540.3-2006 – American National Standard for Calibration-Requirements for the Calibration of Measuring and Test Equipment.

3.4.11. The objective of this National Standard is to establish the technical requirements for the calibration of measuring and test equipment. This is done through the use of a system of functional components. Collectively, these components are used to manage and as

3.5. Interfaces

3.6. Power supply: 90---260 V AC, 47---60 Hz. Or 24 V DC.

3.7. Ambient Conditions: Temperature upto 50 deg.C.,Enclosure class IP 65.

Amendment issued (by user dept.)
No: date of issue:
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