

 SHAKAMBHARI GROUP #SteelWithin		SHAKAMBHARI ISPAT & POWER LTD. (Formerly known as Ess Dee Aluminium Ltd.)	
STANDARD OPERATING PROCEDURE			
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SOP No.	Version No.	Effective Date	Next review date
SIPL/QAS/009	00	07.07.2026	06.07.2028

1.0 PURPOSE

1.1 To define a procedure for validation of the equipment and product.

2.0 SCOPE

2.1 This SOP applies to any critical manufacturing process or critical manufacturing equipment.

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 ISO 15378:2017, D.2.2

3.2 Attachments

3.2.1 Attachment: Validation of Equipment - SIPL/QAS/009/F01/00

4.0 RESPONSIBILITY

4.1 Production Head / Engineering Department Person:

4.1.1 To carry out the validation process.

4.2 QA Head

4.2.1 To approve all the validation done.

4.2.2 To keep the documents and records.

5.0 DISTRIBUTION

5.1 Quality Control

5.2 Production

5.3 Engineering

6.0 DEFINITION(S) & ABBREVIATION(S)

6.1 Definitions

6.1.1 **Validation:** a process of establishing documentary evidence demonstrating that a procedure, process or activity carried out in production or testing maintains the desired level of compliance at all stages.

6.1.2 **Installation Qualification:** the documentation of the checks made to assure that equipment meets the appropriate design criteria, construction specifications or equipment specifications, and that it is installed properly.

6.1.3 **Operational Qualification:** documented verification that the equipment performs as intended throughout all anticipated critical operating ranges.

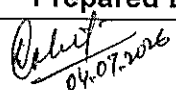
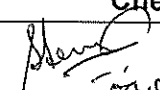
6.1.4 **Performance Qualification:** documented evidence that a process or system (combination of equipment, product and procedure) can reproducibly operate within a pre-defined range.

6.2 Abbreviations

6.2.1 IQ: Installation Qualification

6.2.2 OQ: Operational Qualification

6.2.3 PQ: Performance Qualification

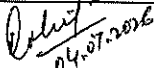
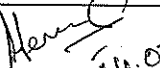
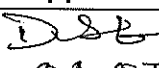
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7.0 PROCEDURE

7.1 Validation of Equipment

- 7.1.1 Installation Qualification:** this is the documented proof that units and systems have been supplied and installed in accordance with the user requirement. This phase shall begin when the equipment reaches the user department. It shall first be verified that all the parts are delivered as per specifications. A list of utilities provided (e.g. electricity, lighting, plumbing, ventilation, etc.) shall be prepared and it shall be verified that they are as per the required specifications / capacity.
- 7.1.2 Operational Qualification:** the OQ includes calibration of instruments attached to the equipment. This phase begins after completion of the installation qualification. An Operational Qualification protocol shall be prepared first. All the results of various tests shall be documented to prove that the equipment functions as per the specifications. The documents should also state the description of the process, the instruments used to carry out the tests and their calibration details. Drafts should be prepared at this stage regarding the calibration wherever applicable.
- 7.1.3 Performance Qualification:** this phase shall see an increased participation from the user department. Actual product runs, though not fully fledged, may be undertaken for various products for which the equipment may be used in future. These runs would help in establishing the limitations of the equipment, if any, with a particular product. As these runs will be carried out on a small scale, the decisions taken at this stage may not be final but would nevertheless act as a sound base during the step of Process Qualification or on-going evaluation.
- 7.1.4 Retrospective Qualification:** in the case of old equipment actually in use, when Retrospective Qualification is being done, the correctness of the installation is checked using the IQ format. Operational Qualification and Performance Qualification become more critical. The Qualification Team determines the units and systems to be qualified in a meeting. Based on this, a qualification plan is drawn which mentions the list of equipment to be qualified along with the order of priority. For each of the equipment to be qualified, a list of the critical unit components, including the ancillary components, systems and utilities, is prepared and recorded. The process parameters of the existing units / systems are determined and protocols are prepared using the annexure as in the case of the Prospective Qualification, approved, and data collection done to assess the installation and operational status. The acceptance criteria are finalized by the qualification team and documented. The installation and operational tests are defined with reference to quality and correctness of operation. The calibration intervals are determined. Ranges of values with the tolerance limits are determined and the acceptance criteria are finalized. Current requirements are deduced and set down in the qualification protocols. If

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any maintenance job needs to be done on a particular machine, it is completed before the qualification begins. During the qualification period, no unplanned alterations to the equipment are performed. A preventive maintenance plan is worked out.

7.1.5 All documents generated so far regarding the Installation, Operation and Performance Qualification, Change Controls and status of the validated drawings should be reviewed periodically by the QA Department to maintain the validated state of the equipment. The Engineering department maintains the qualification status of utilities.

7.1.6 It is possible to have an overlap between the Operational Qualification and Performance Qualification in the case of certain utilities like compressed air and thermic fluid, and in such a case it needs to be stated clearly in the protocol and agreed upon.

7.2 Process Validation of Equipment

7.2.1 Process validation of production equipment shall be carried out for critical processes, i.e. Printing / Lamination / Coating, etc.

7.2.2 Validation shall be done once in two years.

7.2.3 Standard process parameters shall be recorded during process validation.

7.2.4 The validation of any instrument / equipment can also be done.

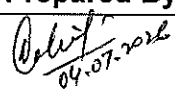
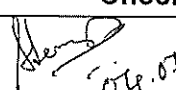
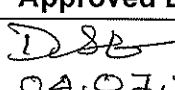
7.3 Validation of Products

7.3.1 Validation of products shall be carried out by the respective customer, as all the products are customer-specific and based on the customer requirement and specification only.

7.3.2 The customer shall conduct a product package compatibility study and stability study at its end and, based on the results, determine the suitability and life of the packaging material.

8.0 REVISION HISTORY

Revision No.	00	Effective Date	07.07.2026	CC No.	NA
Details of revision: New SOP					

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