

Accreditation of Testing (qualification) in Clean Rooms

INTRODUCTION

According to the ABNT NBR ISO 14644-3 Clean room and clean zone are spaces where the air particle concentration is controlled and classified, and which are constructed and operated in a manner to control the introduction and retention of contaminants inside the space. Those spaces are essential for manufacturing or packing processes where any kind of dust and particles in the air can contaminate the final product, for example, in the electronics and pharmaceutical industries.

The development of this accreditation process emerged from Trescal Brazil's "perception" of its main customer's needs, mainly in the pharmaceutical area. The company started the service non-accredited in "governmental" companies that produce medicines, vaccines, and perform virus studies.

Ensaios
ABNT NBR
ISO/IEC 17025



CRL 0646

METHODS & RESULTS

Preparation for testing:

01

Check that cleaning and decontamination of the clean area has been performed according to the manufacturer's/user's specifications;

02

Cleaning and decontamination should preferably be performed by the user;

03

The cleaning and decontamination must be performed according to the procedure of the area;

04

The person carrying out the tests must be properly uniformed, in accordance with the requirements and following the GMP and GLP standards.



The main testing that have been accredited:

1

Supplied air flow test

2

Outlet air flow test

3

Air flow Velocity test

4

Air Exchange rate test

5

Temperature / Humidity test

6

Air pressure difference test

7

Airborne particle count test

8

Filter leakage test

9

Recovery test

10

Airflow Direction test

11

Illuminance test

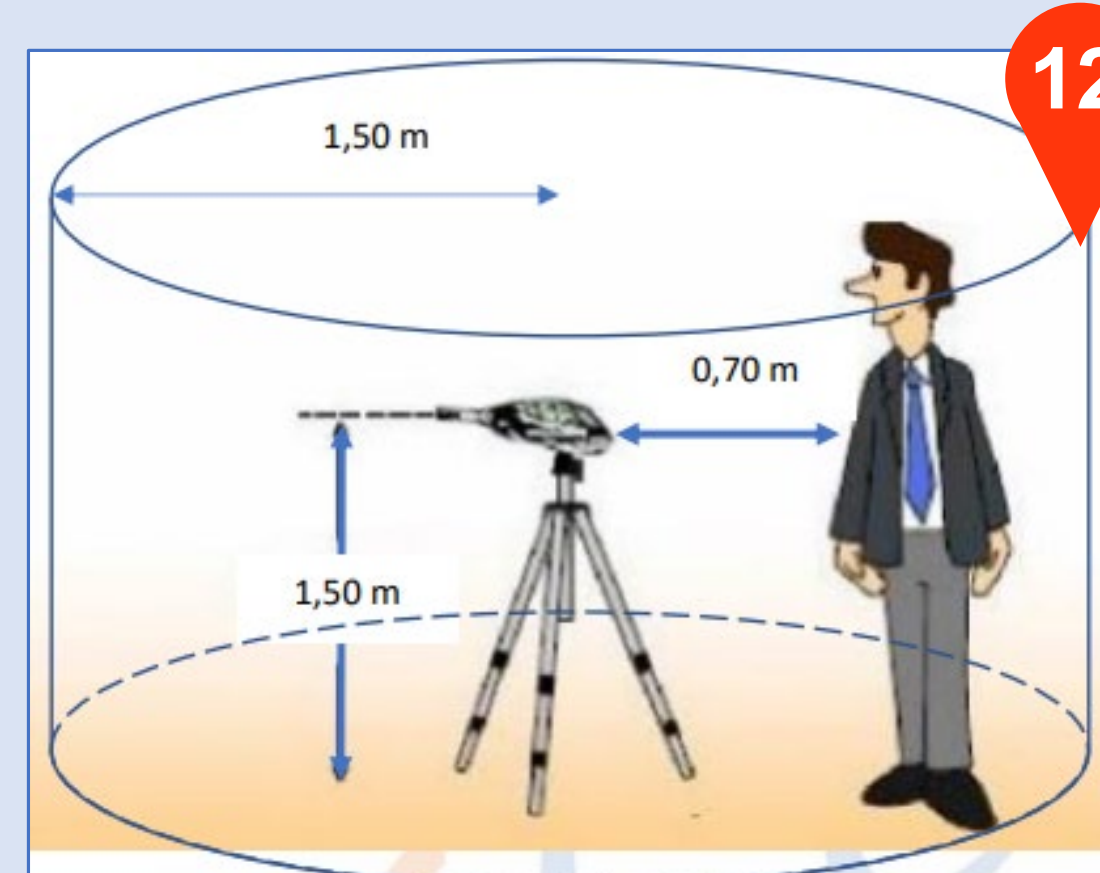
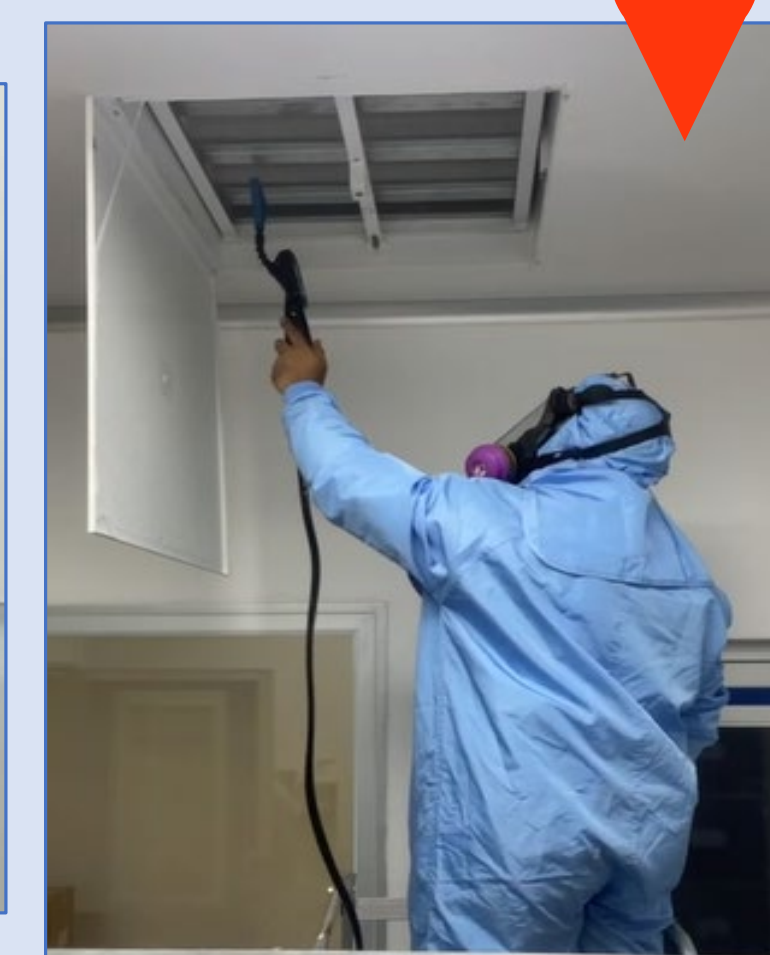
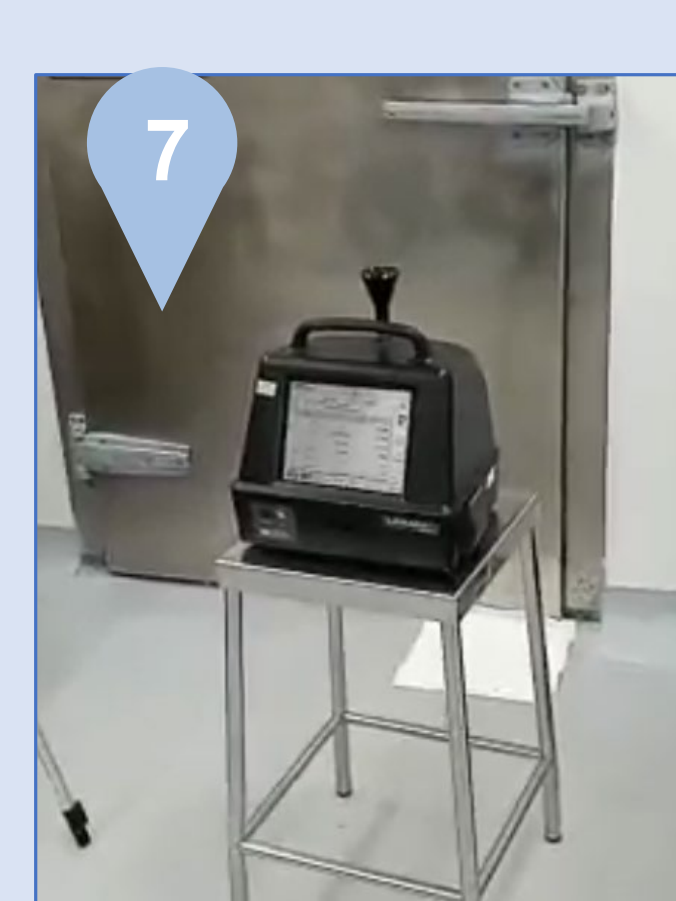
12

Sound pressure level



$$N = \frac{Q_T (m^3/h)}{V (m^3)}$$

$$n = -2,3 \times \frac{1}{t_1} \log_{10} \left(\frac{C_1}{C_0} \right)$$



CONCLUSION

In 2019, Trescal Brazil engineering team received training from Trescal Barcelona (ASSI) experts, and in Brazil by an ISO 14644 committee member; after that, the team started the development of the method for carrying out the accredited testing and the preparation of the accreditation process to be submitted to Cgcre / Inmetro.

The process of preparation for accreditation involved the creation of test procedures, according to ABNT-NBR-ISO 14644-3, acquisition of reference standards with accredited calibration, qualification of the team, in addition to all other requirements necessary to be accredited.

5 months after going through the evaluation process with INMETRO, in November 2021, the accredited scope linked to number CRL 0646 was released.



LUAN ARJONAS DE CAMARGO

DEVELOPMENT AND IT MANAGER
BRAZIL

LUAN.CAMARGO@TRESICAL.COM

+55 11 98191-8753

REFERENCES

NBR ISO 14644-3_Rev2009 Cleanrooms and Associated Controlled Environments Part 3: Test Methods
M-363_Rev01 - Calibration Method for Clean Room Tests