

केन्द्रीय मुहर विभाग-2

संदर्भ -: केम्वी-2/16:8164

09 08 2023

विषय: संशोधित IS 8164:2023 के अनुपालन के दिशा निर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

PNBO/सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

**आदित्य दास
वैज्ञानिक D**

प्रमुख (केम्वी 2)

PNBO/सभी क्षेत्रीय/शाखाकार्यालय/प्रयोगशालाएँ/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:8164

09 08 2023

Subject: Guidelines for implementation of Revised IS 8164:2023

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

PNBO and All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

**(Aditya Das)
Scientist D**

Head (CMD-2)

PNBO/All ROs/BOs/Labs/TXD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 8164

09 08 2023

Subject: Guidelines for implementation of Revised IS 8164:2023 (Specification for Hospital Rubber Sheeting Without Reinforcing Fabric)

1. IS 8164:1976 has been revised as IS 8164:2023 and has been published. The last date for implementation of the revised Standard is **24 Nov 2023** after which the old Standard shall stand withdrawn.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard within a week of issuance of these guidelines.
3. The significant changes in the revised Standard as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard.

Clause	Change
2, Annex A	Cross referred standards have been updated
Table 1	Requirement of hardness, heavy metals, polycyclic aromatic hydrocarbons (PAH) and nitrosamine have been incorporated

4. Consequent upon the issuance of the revised Standard, the existing product manual has been revised which is being circulated separately.
5. The guidelines for implementation of the revised Standard is given below:

A. LICENSEES:

- i. The licensee shall implement the revised Standard by **24 Nov 2023**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest. BOs shall ensure that no Licences are under operation as per the old Standard after **24 Nov 2023**. **The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.**
- ii. The licensee shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports. Verification of implementation of the revised Standard, wherever required, **shall be verified through a surveillance visit within 30 days of confirmation of implementation of the revised standard by licensee.**
- iii. If the Licensee fails to complete all actions by **24 Nov 2023** it shall be dealt with as per the prevailing guidelines.

B. APPLICATIONS FOR GRANT OF LICENCE:

- i. Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed as per the old Standard. However, if the Applicant is desirous of considering the Application as per the revised Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall from such Applicants

also be obtained that if the sample fails while considering the provisions of the revised Standard, Licence will not be granted by BIS as per the old version.

- ii. Applications which are recorded henceforth may be processed as per the old Standard or the revised Standard. Processing of Applications as per the old Standard shall be permitted only up to **23 Nov 2023** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **24 Nov 2023**.
- iii. Beyond **24 Nov 2023** no Licence shall be granted as per the old Standard.

C. CHANGE IN SCOPE OF LICENCE:

- i. For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- ii. However, processing of such applications for change in scope of licence as per the old Standard shall be permitted only upto the date of implementation of the revised Standard or upto **24 Nov 2023** whichever is earlier.

6. The above guidelines come into force with immediate effect.

Aditya Das
Sc. D

Head (CMD-2)
DDG (Certification)