TERMS OF REFERENCE FOR THE R&D PROJECT

[Neurosurgery Instruments, Implants & Accessories Sectional Committee, MHD 07 under Medical Equipment and Hospital Planning Department]

1. Title:

Study of the general and functional requirements of High Tech – Repetitive Transcranial Magnetic Stimulator (RTMS).

2. Background:

- RTMS is a non-invasive neurostimulation technique that uses magnetic fields to stimulate specific areas of the brain.
- It is used to treat:
    - Obsessive compulsive disorder (OCD)
    - Migraines
    - Depression
    - Cravings in substance dependence
    - Bipolar disorder
    - Schizophrenia
    - Anxiety disorders
    - Neuropsychiatric disorders
    - Generalized anxiety disorder (GAD)
- The global TMS system market was estimated at USD 1.29 billion in 2023 and is expected to hit around USD 2.46 billion by 2030, growing at a CAGR of 9.69% from 2022 to 2030. RTMS led the market and accounted for more than 38.5% share of the global revenue in 2021.
- Considering the exponential market needs due to increasing prevalence of Neurological diseases such as Parkinson's Disease, Alzheimer's Disease, and other neurological problems, along with the increasing technological advancements recent technological advancements in the industry and concerns raised by consumer organization on the durability of the product, a detailed study of the performance characteristics of RTMS is required to address the limitations of the existing Indian Standard.

3. Objective:

To collect and analyze the relevant data and information from both primary and secondary sources in regard to performance characteristics of RTMS.

4. Scope:

4.1 Comprehensive study of existing literature which includes international standards, journals, research papers, any SoPs/ guidance/ instructions issued by the Ministries/ regulators concerned and any other study.

4.2 Collection of scale-wise data on manufacturing base through government sources

(websites, reports) or industry associations.

4.3 Analysis of the import and export data and conduct analytical study of the technical regulations on the product in various countries.

4.4 Analytical study on availability of test facilities in the country.

4.5 Collection of data on the following through visits to two industries – Large scale, total two industries – Medium/Small/Micro/Start-ups, and one each of government and NABL accredited private testing facility:

a) Type of raw materials
b) Varieties manufactured
c) Manufacturing processes
d) In process quality controls
e) Manufacturing facilities (Automation, Industry 4.0)
f) Quality parameters
g) In-house test facilities
h) Parameters tested
i) Marking and labelling
j) Packaging
k) Finished materials quality parameters
l) Sampling plans
m) Sustainability practices [energy consumption, renewable energy sources, sustainable practices, 3Rs (Reuse, Reduce and Recycle), waste management and disposal mechanisms, carbon footprints], future plans.
n) Any other information relevant to the industry.

4.6 Collection of user feedbacks (which will include but not limited to performance of the RTMS)

4.7 Generation of data after testing the product for important characteristics and establishing parameters for RTMS such as:

4.7.1 Coil configuration (Round coil, Figure-eight coil, Four-leaf coil, Double-cone coil, etc)
4.7.2 Coil type (Material)
4.7.3 Intensity of Stimulation
4.7.4 Frequency of Stimulation
4.7.5 Duration of Stimulation
4.7.6 Power supply to coil

5. Research Methodology:

The project will involve the following research methodologies:

a) Study the literature and analyse it in respect to the scope
b) Survey the market through structured questionnaires for collecting information in respect to the scope

c) Contact the relevant organizations and associations (Industry/ user associations) for gathering the data
d) Visits to the manufacturing units to observe:
    - manufacturing processes,
    - in-process controls,
e) Discussion with focused groups (Quality control personnel and person responsible for manufacturing) through structured questionnaires
f) Samples to be tested in-house for functional and safety requirements during the visits to industries. Samples shall be tested in such a manner that there is sufficient data to compare the performance and the range of varieties being manufactured by any particular manufacturer. For this purpose, samples from the lowest, middle, highest range shall be preferably considered for testing. In case of non-availability of samples during the visit or tests are time consuming in nature, the test results of the samples already tested and documented by the manufacturer may be collected for the purpose of analysis.
g) Comprehensive reporting on all aspects.

6. Expected Deliverables:

A comprehensive report consisting outcomes of the study covering all aspects of the scope both shall be submitted in both paper and digital formats.

Along with the final report the survey formats and responses, questionnaires, results of testing, reports of visits, other relevant documents/ information to be appended.

7. Delivery Milestones and Review Process:

7.1 The duration of the project shall be five months.
7.2 An interim report indicating the review of the literature, desktop research and sampling plan shall be submitted in **one month** from award of the project.
7.3 Draft report shall be submitted **by the end of third month** from award of the project.
7.4 Final report shall be submitted **by the end of fifth month** from award of project.

8. Support from BIS:

BIS will provide access to latest available editions of Indian standards and/ or international standards relevant to the project, on request.

9. Nodal Point:

Member Secretary, MHD 07 may be contacted for more clarification on the R&D project (Email address: mhd7@bis.gov.in)