

TERMS OF REFERENCE FOR THE R&D PROJECT

[Veterinary Hospital planning and Surgical Instruments Surgical Instruments Sectional Committee, MHD 13 under Medical Equipment and Hospital Planning Department]

1. Title:

Exploring and Analyzing Safety and Quality Standards for Positioners and Restrainers used during Sample Collection, Surgeries, and Radiological Procedures of both Large and Small Animals.

2. Background:

Positioners and restrainers play a crucial role in the care and medical treatment of both large and small animals. These devices aid in restraining, positioning, and immobilizing animals during medical procedures, diagnostics, and surgeries, ensuring safety for both the animals and the veterinary professionals. Reduced trauma to the animals during these procedures also ensures the faster recovery of the animals. In the Indian context, with its diverse animal population and growing demand for advanced veterinary care, there is a need for comprehensive research and development on the design, efficacy, applicability and safety of such devices.

3. Objective:

To collect and analyse the data from primary and secondary sources on various types of positioners and restrainers for veterinary applications concerning to their, but not limited to, manufacturing, quality and safety.

4. Scope:

4.1 To study and carryout a comparative analysis of different Positioners and Restrainers for Large and Small Animals available in market which are used during sample collection, surgeries and radio examinations.

4.2 The study and comparative analysis shall be based on, but not limited to, the following aspects:

- a) Existing literature which includes international standards, journals, research papers, any SoPs/ guidance/ best practices/ instructions issued by the Ministries/ regulators concerned or any other study

- b)** Collection of scale-wise data on manufacturing base through government sources (websites, reports) or industry associations.
- c)** Analysis of the import and export data and conduct analytical study of the technical regulations on the product in various countries.
- d)** Analytical study on availability of test facilities in the country.
- e)** Existing variety of positioners, immobilizers and restrainers available in the market, nationally and globally.
- f)** Collection of data on the following through visits to two industries – Large scale, total two industries – Medium/Small/Micro scale, and one each of government and NABL accredited private testing facility:
 - i) Material requirements,
 - ii) Design and comfort,
 - iii) Adjustability and versatility,
 - iv) Ease of cleaning and sterilization,
 - v) Durability and longevity,
 - vi) Restraint mechanisms,
 - vii) Portability and storage,
 - viii) Customization options,
 - ix) Sustainability practices [energy consumption, renewable energy sources, sustainable practices, 3Rs (Reuse, Reduce and Recycle), waste management and disposal mechanisms, carbon footprints] and future plans,
 - x) Safety,
 - xi) Performance requirements,
 - xii) Testing & quality control procedures including sampling plans employed by manufacturers.
 - xiii) Any other information relevant to the industry.
- g)** Evaluation of the efficacy and safety of existing positioner, immobilizers and restrainers in veterinary practice for various purposes and different species of animals, domestic and wild. Determination of the applicability and adaptability of these devices to different niche animal species and sizes in the Indian context.

- h) Gap areas in the existing technologies and mechanisms and addressing them in consultation with the stakeholders. Collaboration with manufacturers and R&D bodies to bring forth the design and engineering requirements.

5. Research Methodology:

The study will adopt a multi-faceted research approach, including:

5.1 Literature Review: A comprehensive review of existing research, publications, International Standards and best practices related to animal positioners and restrainers, both in India and globally.

5.2 Field Surveys:

5.2.1 Visits to veterinary clinics, animal hospitals, and research institutions across India to understand the current usage and challenges associated with these devices, through structured questionnaires.

5.2.2 Visiting manufacturing units and laboratories to understand the manufacturing processes, in-process control and associated test methods.

5.3 Design and Engineering Analysis: Collaborations with manufacturers and R&D bodies through structured questionnaires to assess design and engineering aspects of veterinary positioner and restrainers. Collaborate with veterinarians to understand the specific requirements for positioners and restrainers in different veterinary procedures.

5.3.1 Identify the range of animal sizes and species the products need to accommodate.

5.3.2 Take into consideration the ergonomic needs of the product, ensuring that it facilitates efficient and accurate procedures.

5.3.3 Assess mechanical design that provides secure and humane restraint.

5.3.4 Conduct engineering analysis to ensure the mechanisms can withstand the forces exerted by different animals.

5.4 Samples to be tested in-house for functional and safety requirements during the visits to industries.

5.4.1 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.

5.4.2 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.

5.5 Performance Analysis: Conducting performance Analysis and tests in collaboration with veterinary professionals to evaluate the safety and efficacy of different devices **OR** collection of data on clinical trials.

5.6 Stakeholder Interviews: Interviews with veterinarians, animal handlers, academicians/researchers, and other relevant stakeholders to gather insights on the practical requirements and challenges through structured questionnaires.

Data from outcome of the interview shall include, but not limited to,

5.6.1 Product profile and types of each product from manufacturers.

5.6.2 In house Manufacturing capability, if not, from where components are acquired/imported?

5.6.3 Raw materials used and acquisition of materials

6. Expected Deliverables:

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

6.2 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. BIS support or inputs to be provided to the Proposer:

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

8. Delivery Milestones and Review Process:

8.1 The duration of the project shall be five months.

8.2 Interim report covering the review of the literature and existing stipulations thereof within **one month** from the date of award of project.

8.3 Report of site visits and product requirements identified during visits including manufacturing requirements, technologies used for production, quality control procedures

employed and testing facilities for the proposed requirements **by the end of third month** from the date of award of project.

8.4 Final report covering all the aspects of the TOR **by the end of fifth month**, from the date of award of project.

9. Nodal Point:

Member Secretary, MHD 13, may be contacted for more clarification on the R&D project

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