DECEMBER 11-12,2025
۲۱ و ۲۰ آذر ماه ۱۴۰۴
دومین کنگره پلاسما پزشکی ایران
The 2 nd Congress on Plasma Medicine
دبیرخانه دائمی کنگره پلاسما پزشکی ایران
www.plasmamedsym.ir

Safety, Standards, and Policy Requirements for the Regulation of Plasma Medicine

Farzaneh Moradi

Iran Advanced Technologies Company, Atomic Energy Organization of Iran, Tehran, Iran
National Center for Atomic Quality and Standardization of Iran (INS), Atomic Energy Organization of Iran, Tehran, Iran

OPEN ACCESS

Citation:
Moradi F. Safety, Standards, and Policy Requirements for the Regulation of Plasma Medicine. *Iran Biomed J*. Supplementary (2-2026): 8.

ABSTRACT

Introduction: Plasma medicine, an emerging field at the intersection of plasma physics, chemistry, and life sciences, offers novel therapeutic pathways for wound healing, sterilization, cancer treatment, and tissue regeneration. Despite promising outcomes in preclinical studies, its clinical translation remains constrained by limited safety validation and the lack of harmonized international standards and policy frameworks. This study aimed to analyze current safety and regulatory challenges within plasma medicine, identify deficiencies in existing standards, and propose foundational requirements for developing evidence-based policies.

Materials and Methods: We conducted a comprehensive review of regulatory and technical documents (ISO, IEC, FDA, and EMA). We also analyzed peer-reviewed studies on plasma-tissue interactions, device characterization, and risk assessment. A Comparative evaluation of plasma source parameters, reactive species dynamics, and biocompatibility data was performed to highlight key safety domains and inform policy recommendations.

Results and Discussion: Our findings reveal a fragmented regulatory landscape characterized by inconsistent terminology, absence of standardized dosimetry models, and insufficient long-term cytogenetic safety data. Major risk areas include uncontrolled exposure to reactive species, thermal and electrical effects, and variability in biological responses. We recommend the establishment of validated reference devices, standardized testing protocols, and harmonized safety thresholds as prerequisites for coherent policymaking.

Conclusion: The safe integration of plasma-based technologies into healthcare systems requires interdisciplinary coordination among researchers, clinicians, manufacturers, and regulatory bodies. Development of internationally recognized standards, grounded in reproducible safety metrics and transparent evaluation procedures, is essential for advancing plasma medicine from experimental research to regulated clinical practice.

Keywords: Health policy, Medical device safety, Plasma medicine, Regulatory standards plasma-tissue interaction, Risk management

Corresponding Author: Farzaneh Moradi
Iran advanced technologies company, Atomic energy organization of Iran, Tehran, Iran; National Center for Atomic Quality and Standardization of Iran (INS), Atomic energy organization of Iran, Tehran, Iran; E-mail: farzanemoradi91@gmail.com